health technology
directions

PATH Program for Appropriate Technology in Health

Immunization: A Key to Primary Health Care

It is estimated that, in the developing world, six infectious diseases kill some five million children annually. These diseases are preventable through immunization, which is a much more efficient use of scarce medical resources than attempting to treat these diseases after they occur. Immunization, the stimulation of the body's immune system to make protective antibodies against infectious diseases, is a key component of primary health care programs.

The essential components of an immunization program include the availability of safe, effective vaccines, the maintenance of the potency of the vaccines during distribution throughout the country, their correct administration, and the efficient management of program resources to achieve maximum immunization coverage. Great advances have been made in this century in developing and improving vaccines against the major infectious diseases. Their widespread use in the industrialized world for the past two or three decades has drastically reduced the deaths and illness formerly associated with these diseases. However, as developing countries build up their health care systems and extend immunization services to a larger proportion of their populations, they encounter problems different from those experienced by the industrialized nations—problems such as tropical temperatures, lack of electricity, inadequate transportation, shortages of trained personnel and equipment, and low levels of literacy among their populations. As a result of these special challenges, some innovative and creative solutions are emerging.

In recognition of the seriousness of the problem of infectious childhood diseases and the great benefits of giving preventive immunization, the World Health Organization instituted the Expanded Programme on Immunization (EPI) in 1974. EPI's goal is to make basic immunizations available to all children of the world by 1990, with special priority given to those in developing countries.

The EPI covers six major killers of children in the developing world: diphtheria, whooping cough (or pertussis), tetanus, measles, polio, and tuberculosis. Since many cases of these diseases and, often, the most serious complications occur in the first year of life, EPI has focussed its efforts on reaching infants under one year of age and pregnant women (the latter for immunizing the mothers and their newborn babies against tetanus). EPI helps national programs by providing training, vaccines, equipment, and technical cooperation. It also supports the development and field-testing of improved equipment and methodologies related to immunization.

This issue of **DIRECTIONS** takes a look at some of the problems encountered by national immunization programs and at the technology that is available now or that will be in the near future to help solve these problems. Four basic aspects of immunization services are examined:

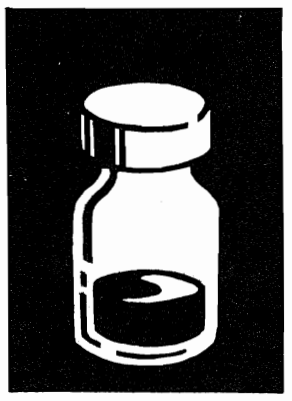
1. Vaccines—their safety, effectiveness, and stability.

2. Cold chain—the transportation, storage, and handling of heat-sensitive vaccines from manufacturer to health worker in the field.

3. Vaccination equipment and sterilization—for correct administration of immunizations.

4. Program management—schedules, records, training, resource allocation.

Vaccines



This section focuses on immunization against six of the major killers of children in developing countries: BCG, DPT (diphtheria-pertussis-tetanus), measles and polio vaccines, and tetanus toxoid. We review the latest information about the safety, effectiveness, and stability of these vaccines.

An understanding of how immunization works can provide insight into the technical problems involved in delivering effective immunization services. Immunity can be of two basic types, active and passive. In active immunity, the body develops its own antibodies in response to the presence of a disease agent or other foreign antigen. Passive immunity results when a person receives antibodies developed in another host.

Both types of immunity can develop naturally, for example, when someone becomes infected with a disease agent (active) or when a baby receives its mother's antibodies across the placenta or in breast milk (passive). Medical immunization mimics these natural processes. By giving a person modified disease agents or their active antigenic fractions, active immunity can be induced without the person actually developing the disease. Similarly, antibodies produced in a separate animal or human host can be isolated from the blood serum and given to a person to establish passive immunity when immediate or short-term protection is needed or when effective vaccines are not available.

Active immunizations can be of three types: live vaccines, killed vaccines, and toxoids. Technically, a vaccine is any material used to produce immunity to a disease. It frequently consists of a suspension of microorganisms that are alive but weakened by chemical treatment (attenuated) or killed (inactivated). Measles

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PATH is pleased to announce a grant from the Rockefeller Foundation to support the continued publication of Health Technology **DIRECTIONS.** With our new funding, we are resuming our schedule of quarterly issues (last issue March 1982).

PATH identifies, develops, and adapts health technologies and products for use in developing countries. It mobilizes the financial and technical resources required for their development. PATH provides a link between primary health care providers in developing countries and manufacturers and developers of health products and related technology. New technologies are introduced into health programs through PATH's field offices in Geneva, Jakarta, Manila, and Mexico City, and affiliated organizations in Bangladesh, Egypt, Nepal, Sri Lanka, and Thailand. Technical and administrative services are located in Seattle, Washington.

and Sabin oral polio are examples of live viral vaccines, while the Salk polio vaccine is a killed viral vaccine. BCG is an example of a live bacterial vaccine, while pertussis is a killed one. A toxoid is a product of bacterial toxins or poisons that has been rendered nontoxic (so it does not cause the serious symptoms associated with the disease), but it does retain the ability to stimulate immunity to the toxin. Diphtheria and tetanus are examples of toxoids.

Each vaccine has its own characteristics with respect to safety, effectiveness, and stability. These are determined in part by the nature of the disease organism itself, in part by the type of vaccine (live, killed, or toxoid), and in part by the manufacturing practice used. Some organisms have several different strains or types—polio for example, has types *1*, *2*, and *3*—which must all be identified and included in the vaccine in an appropriate balance. Live vaccines are usually more susceptible to damage by heat and sunlight. Some vaccines are more difficult to purify (like pertussis) and, therefore, cause more secondary reactions among recipients. The potency of some vaccines can be enhanced by adding mineral salts (like aluminum hydroxide or phosphate) or by mixing them with other vaccines. Pertussis, for example, acts as an adjuvant or enhancer for diphtheria and tetanus. Advances in vaccine production in recent years include better culturing techniques, freeze-drying processes, and the updating and clarification of national and international vaccine standards.

BCG

The bacillus of Calmette and Guerin (known as BCG) was derived from bacteria (Mycobacteria bovis), which are closely related to the bacteria (M. tuberculosis) that cause tuberculosis (TB). BCG is a live, attenuated vaccine that has been in use since the 1920s. BCG is believed to produce an active immunity which, because of the close similarity between the organisms, protects the individual against the tubercle bacillis. There have been two important recent developments related to BCG: the availability of a freeze-dried form and the publication of data from India raising serious questions about the value of BCG in protecting against tuberculosis.

As with other live vaccines, BCG is sensitive to sunlight and warm temperatures. The new freeze-dried vaccine represents a great improvement over the old liquid form which, though it is still being produced by some companies, is generally not recommended for use. When kept at or below 8°C, freeze-dried BCG can be stored safely for 1 to 2 years. BCG can also be kept frozen. If it is not kept refrigerated, it will gradually lose its potency. The higher the temperature, the more rapidly potency decreases. The reconstituted vaccine is very unstable and should be used during one working session.

Overall, BCG is considered a very safe vaccine. Mild ulcers are occasionally reported at the site of the intradermal injection. More rarely, inflamed lymph glands are observed, particularly among infants. Fatal complications may occur at a rate of one per ten million vaccinations. Studies have led to the recommendation that, to reduce complications, the infant dose should be cut to ¼ or ½ that given to adults or older children. Where the risk of tuberculosis infection is not high, some programs delay giving BCG until after the first year of life, when the risk of complications is lower. In most developing countries, the risks of TB infection, and especially of the acute forms of miliary TB and tuberculous meningitis, are much higher for infants than the risks of vaccine complications.

UN Photo

Questions about the effectiveness of BCG in preventing tuberculosis have been raised throughout its sixty-year history. Different studies have produced conflicting results, some showing BCG to be highly effective and others showing no protective effect. Interpretation of these results has been difficult for several reasons. First, the BCG used in the various studies was produced by many different laboratories and may not be comparable. Second, there is no proven laboratory method for measuring the potency of the vaccine. The number of culturable particles (or clumps of bacteria) per milliliter is a commonly used measure but has never been directly related to BCG's potency in the human. Therefore, it is difficult to compare vaccines from different manufacturers or batches, to evaluate changes in potency after passage through the cold chain, or to establish a minimum dose level. The BCG scar at the injection site and a vaccinated person's sensitivity to tuberculin are used as field measures of potency, but they have also not been proven to relate directly to the vaccine's ability to protect against TB. Third, the various studies have examined different age groups over dissimilar periods of time. Individuals were given their BCG at diverse ages and were exposed to unequal risks of infection. Case definition and methods for finding cases of TB also varied widely.

The Tuberculosis Prevention Trial, conducted in southern India with assistance from WHO, was intended to resolve some of the questions raised by earlier studies, but its surprising findings have raised many new questions. The 1979 report describes the results of seven and a half years of follow-up in a community study where 260,000 people were randomly assigned to receive either BCG or a placebo; new cases of TB were identified by surveys using sputum samples and chest X rays. The study found no difference in the number of new cases between the BCG and placebo groups. The report concluded that, in that particular population, BCG did not have any protective effect.

WHO, however, continues to recommend development of BCG vaccination programs, because the relevance of the Indian findings to other geographic areas or to childhood immunization programs is not clear. The presence of other mycobacteria, very common in this part of India, may be interacting with BCG in some special way that is not yet understood. In addition, the way that new cases were detected meant that only chronic pulmonary TB was identified; the acute forms that affect infants were not recorded (and seem to be less common in this area than elsewhere). In fact, fewer than 5,000 infants were included in the study, making it even more difficult to detect any significant effect among that age group. Follow-up is continuing as those who entered the study as young children begin to reach the adolescent years when pulmonary TB is most likely to develop. Since studies from other areas do show BCG to be effective in protecting children from tuberculosis, most countries continue to use it. Meanwhile, further research is under way to look at the interaction between other mycobacteria and BCG and at the relationship of BCG to the acute forms of tuberculosis that afflict young children especially.

DIPHTHERIA TOXOID

Diphtheria toxoid is usually given in combination with tetanus toxoid (DT) or in a triple vaccine (DPT) with pertussis and tetanus. The toxoid is made by growing *Corynebacterium diphtheriae* germs in a liquid mixture of salts, harvesting the toxin that is released into the liquid, and weakening it (making it into a toxoid) by adding formaldehyde. The concentration of the toxoid is measured by limit flocculation (Lf) units. These units indicate the amount of toxoid needed to cause flocculation (clumping into visible particles) when mixed with a standard amount of antitoxin.

Diphtheria toxoid is a very safe and relatively stable vaccine. Few reactions to the vaccine occur among infants and young children. For children six years and older and for adults, a lower dose is recommended (less than 2 Lf units rather than the 10 Lf units or more given to infants), to reduce the likelihood of side effects. Death or permanent disability has not been reported in association with diphtheria immunization. The toxoid can be stored safely for several years at 4° to 8°C, but it must not be allowed to freeze.

The toxoid is very effective in protecting against the development of diphtheria. Immunized people do occasionally get the disease, but the infections are much milder and hence less likely to be fatal. Purification of the toxoid during production reduces the possibility of reactions, but it also reduces the toxoid's potency. For *primary immunization*, then, an adjuvant of pertussis vaccine (as in DPT) or aluminum salts should be added. Diphtheria is not much of a problem in many tropical areas now. In those regions, mild diphtheric skin infections commonly occur while the baby still has protection from its maternally derived antitoxin, thus stimulating natural immunity to more serious forms of the disease. As living standards rise, though, delaying babies' exposure to a later age, diphtheria could become a much more serious problem. Most countries have therefore chosen to incorporate diphtheria prevention into their regular childhood immunization program, especially since a safe, effective, inexpensive, and convenient vaccine is available.

MEASLES

Live attenuated measles virus vaccine is a safe, highly effective vaccine, but it requires careful handling and storage to prevent damage due to excessive heat or light exposure. Measles is one of the leading causes of death among children under one year of age in developing countries. Since 1967, when the live vaccine replaced a much less effective, killed vaccine in the U.S.A., the deaths and disability associated with measles have been greatly reduced. One dose given between 12 and 15 months of age causes the development of antibodies in 95% of those vaccinated and is known to protect against measles for at least 15 years, perhaps even for life. Infants in developing countries are often vaccinated at younger ages—as soon after 9 months as possible—to provide earlier protection (see Program Management, p. 5). Fears about measles vaccine not being effective for malnourished children have not been supported in field studies, since these children also develop immunity after vaccination.

Aside from occasional fever and skin rash, the only other side effect reported with use of measles vaccine is a rare condition called subacute sclerosing panencephalitis (a "slow virus" infection of the central nervous system), which occurs much more frequently with natural measles infection. The further attenuated strain, an improved vaccine which causes fewer reactions, was developed in the late 1960s. Immune serum globulin (ISG), which

was given with earlier measles vaccines to reduce adverse reactions, is no longer needed and should not be used with present-day, safer vaccines.

Active research efforts continue to improve the stability of the freeze-dried measles vaccine. Vaccines introduced in 1976 are much more stable than earlier ones. Potency of the vaccine can be measured in the laboratory in two ways. The number of virus particles in a given volume can be *estimated* by determining the median tissue culture infective dose ($TCID_{50}$ or TCD_{50}), or the concentration of virus needed to ensure that at least 50 of 100 tissue culture plates that are inoculated with the virus will become infected. A more exact measure using plaque-forming units (PFU), which refers to *counting* the plaques or patches of virus that grow when the vaccine is cultured, has been proposed as the new basis for international standards. Tests have shown that, for measles vaccine, one $TCID_{50}$ corresponds to about 1.4 PFU. The new stability standard proposed by WHO in 1981 is for the vaccine to retain at least 1000 PFU per dose after incubation at 37°C for seven days. Additionally, any drop in potency during incubation should be by less than a factor of ten; for example, 20,000 PFU dropping to 1500 PFU would not be acceptable, while 9,000 PFU dropping to 1000 PFU would be. It is known from testing that, if the vaccine remains potent when exposed to a high temperature of 37°C, it will be sufficiently stable when kept at the much lower temperatures that are recommended for storage (either frozen at −20°C or refrigerated at +4° to 8°C).

PERTUSSIS

Pertussis (whooping cough) is a highly contagious respiratory disease. It has been estimated that, in an unvaccinated population, at least 80% of children will get the disease. In developing countries, 1-3% of these children will die from it, even if they receive medical care, and many more will suffer serious illness or permanent disability.

The vaccine used for pertussis is a saline suspension of killed *Bordetella pertussis* bacteria. Researchers have not been able to isolate the active protective antigen yet, so the whole killed organism, which contains many different proteins and toxins, must be used. These impurities are believed to be the cause of the adverse reactions sometimes associated with the vaccine. Since pertussis serotypes can vary over time and in different places, it is important to include all the prevailing serotypes. The vaccine is usually administered as part of the triple DPT vaccine. Concerns about its safety, though, have led to greatly reduced levels of use in some European countries in recent years.

To understand the issue of the safety of the pertussis vaccine, one must compare the size and nature of the risks of vaccine reactions to the risks of getting whooping cough and its complications. Relatively mild, temporary reactions reported include local pain and swelling at the injection site, fever, irritability, vomiting, and loss of appetite. Prolonged, uncontrollable crying, excessive sleepiness, and, even more rarely, convulsions, a shocklike state, and encephalitis are among the more serious conditions reported in association with pertussis vaccination. Estimating the risk of these various reactions has been difficult, because studies use different definitions, and few examine the occurrence of similar events among control children who were not recently vaccinated with pertussis. In a recent large study in the U.K., it was estimated that severe neurological illness occurred in 1 per 110,000 DPT immunizations, with lasting damage in 1 per 310,000 immunizations. Convulsions, the most frequent immunological reaction following DPT injection, occurred 100 to 3000 times more often during whooping cough than following DPT immunization. It appears, then, that the risks of vaccine complications do not outweigh the risks associated with getting the disease. Meanwhile, research continues on improved vaccines, such as the new cell-free toxoid being tested in Japan that appears to be less toxic.

The effectiveness of pertussis vaccine has also been questioned. Declines in rates of whooping cough cases and deaths in Europe even before the vaccine was widely introduced in the 1950s have been cited as proof that an improved standard of living is more important for disease prevention than the vaccine.

However, the recent epidemics of pertussis in the United Kingdom since 1977 (when vaccine acceptance dropped off sharply) show that the vaccine did, in fact, play a significant role in controlling the disease. Several studies have shown that those who are immunized get the disease less than one-fourth as often as the unvaccinated and usually get a milder form of it.

In weighing the risks of the vaccine against its benefits, most authorities would agree that pertussis immunization is worthwhile, particularly in developing countries where the incidence of and mortality from whooping cough is so high. Even babies under six months, who experience a significant rate of disease but are too young to have completed a full course of vaccination, do benefit from it indirectly through "herd immunity"; that is, less infection will circulate if most older infants in the community are fully vaccinated. In the DPT form, pertussis is convenient and reasonably stable as long as it is refrigerated at 4° to 8°C (it *must not* be frozen), and has the additional advantage of acting as an adjuvant for diphtheria and tetanus toxoids.

POLIO

Two types of polio vaccine are available: a live, attenuated vaccine given orally (Sabin) and a killed or inactivated vaccine injected intramuscularly (Salk). Both vaccines are trivalent, that is, they contain all three major strains of polio virus. The main advantages and disadvantages of each are summarized in Table 1.

Both types of vaccine are quite safe. There is some risk of the live virus mutating in a vaccinated person and causing that person or someone in contact with that person to develop a case of paralytic polio. A WHO study, however, showed this risk to be less than one per ten million doses of vaccine. One way to reduce this risk is to vaccinate all members of family groups or communities at the same time.

Effectiveness of the vaccines seems to vary in different places. Potency is usually measured in terms of seroconversion, that is, in terms of those who did not have antibodies to polio in their blood stream before vaccination but do afterwards. There is some evidence that newer versions of the killed vaccine produce high rates of seroconversion (90-100%) after one or two doses and require less frequent boosters to maintain protection.

The live vaccine also produces high rates of seroconversion in most populations, but studies in several tropical countries have uncovered cases where oral polio vaccine has not stimulated antibodies, even after extra doses were given. Live vaccine also induces immunity in the cells lining the digestive tract, however. Such immunity may not be reflected in studies of antibody levels in the blood. The live vaccine appears to offer good protection against polio, even in those areas of the world where it has failed to induce satisfactory seriological responses. Children with diarrhea may need extra doses of the live vaccine. Unlike people who only have humoral immunity, those with intestinal immunity may also be protected against harboring or spreading wild, more virulent polio viruses through the feces.

As with any live vaccine, oral polio is sensitive to excessive heat and light. It should be stored frozen at −20°C or kept refrigerated at 4° to 8°C. The killed vaccine is more stable and needs only careful refrigeration at +4° to 8°C.

Because of the high cost of killed polio vaccine and the incompleteness of the data showing killed vaccine to be more effective than the live vaccine, WHO/EPI currently recommends oral polio vaccine for routine use in developing countries. In those places where oral polio does not seem to be effective, use of killed vaccine either alone or in combination with live vaccine is being studied.

TETANUS

Tetanus toxoid is safe and relatively stable. The toxoid is made by weakening the natural toxin with formaldehyde. The few side effects reported are usually due to impurities or allergy and can be avoided by using highly purified toxoid and not giving boosters too frequently. As with the diphtheria toxoids, an adjuvant like pertussis or aluminum salts should be added when the purified toxoid is used for *primary* immunization. Fatal allergic reactions have been recorded on very rare occasions. The three doses of DPT given to infants provide long-lasting protection against tetanus. The two doses of tetanus toxoid given to pregnant women during the second half of pregnancy protect both the mother during childbirth and the baby, since the mother's antibodies pass through the placenta. Since newborn tetanus has a fatality rate of 80% and is very common in many developing countries, the health benefits to be gained from widespread tetanus immunization of pregnant women are significant.

TABLE 1

Polio: Live vs. Killed Vaccines

Live

Advantages:

1. Humoral and intestinal immunity.
2. May be lifelong. Does not need boosters (reinforcing doses).
3. Induces antibody quickly.
4. Oral administration easier and more acceptable.
5. In epidemics, not only produces antibody quickly but blocks spread via alimentary tract.
6. Relatively inexpensive.
7. May spread a mild infection to others not yet vaccinated, giving them immunity as well.

Disadvantages:

1. Can mutate into more virulent strain causing recipient or a contact to get the disease.
2. In some tropical countries, it does not induce antibodies in as high a proportion of recipients, even after repeated doses.
3. Cannot be given to those who are immunodeficient or immunosuppressed.
4. Is very heat-sensitive, especially when not stabilized.

Killed

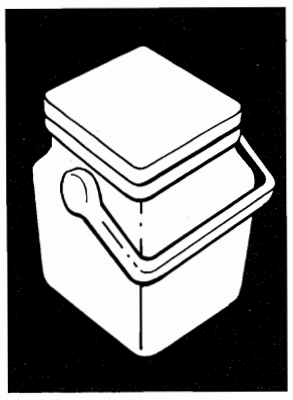
Advantages:

1. Humoral immunity in high proportion of recipients.
2. Two doses may be sufficient for primary immunization.
3. Can be combined with DPT.
4. Since virus is killed, it can't mutate or infect others.
5. Can be given to immunodeficient or immunosuppressed people.
6. Works in tropical countries even where live vaccine has failed to "take".

Disadvantages:

1. Requires repeated boosters later.
2. Much more expensive.
3. Does not induce intestinal immunity.
4. Use of virulent strains to produce vaccine could cause disease if inactivated improperly.

Cold Chain Equipment



The cold chain refers to the distribution of heat-sensitive vaccines from the manufacturer to the national vaccine store and eventually out to the health workers who do the vaccinations. The chain includes the people who handle the vaccine, according to established procedures, and the equipment to keep the vaccine cold. There are many challenges in maintaining an effective cold chain under the special circumstances often found in developing countries: the lack of reliable electrical power, high ambient temperatures, the variety of transport used to carry vaccines and the time needed to reach remote areas, the shortage of trained equipment maintenance personnel, the difficulties of communication and transportation when repairs or spare parts are needed, and the very limited funds available.

In recent years WHO/EPI has played a major role in aiding the development, adaptation, and field testing of equipment to meet these conditions, and in disseminating practical information about the results of these activities. (See box on EPI/UNICEF Product Information Sheets.) For areas where some electricity is available but the supply is not continuous, possible solutions include voltage regulators, well-insulated freezer chests (which hold a cold temperature better than front-opening freezers), and refrigerators with ice-tube linings that freeze when the power is on and keep the chest cold when the power cycles off. Where a reliable supply of electricity is not available, other fuels, such as kerosene and liquid gas, are being used to power refrigerators.

One of the most exciting innovations is the development of solar-powered refrigerators for vaccine storage and ice-making. Solar-powered refrigerators offer the potential for high performance, lower running costs, better reliability, and a longer working life than conventional refrigerators. Five alternative methods of solar cooling are being developed; several are already available for field testing. EPI has three reports available in English or French (EPI/CCIS/81.5, EPI/CCIS/82.3, and EPI/CCIS/82.8) reviewing solar refrigeration.

EPI/UNICEF Product Information Sheets

Product Information Sheets, published by EPI and UNICEF in English, French, and Spanish, contain technical and purchasing data for the following:

1. Cold rooms for bulk storage of vaccine.
2. Refrigerated vehicles/systems for bulk transport of vaccine.
3. Refrigerators and freezers for the storage of vaccines.
4. Cold boxes, carriers and vaccine packaging.
5. Ice packs and cold packs for cooling insulated containers.
6. Thermometers and thermorecorders for monitoring vaccine storage.
7. Accessories, including alarm systems.

The sheets can be obtained from national WHO/EPI or UNICEF representatives or by writing to WHO/EPI, 1211 Geneva 27, Switzerland.

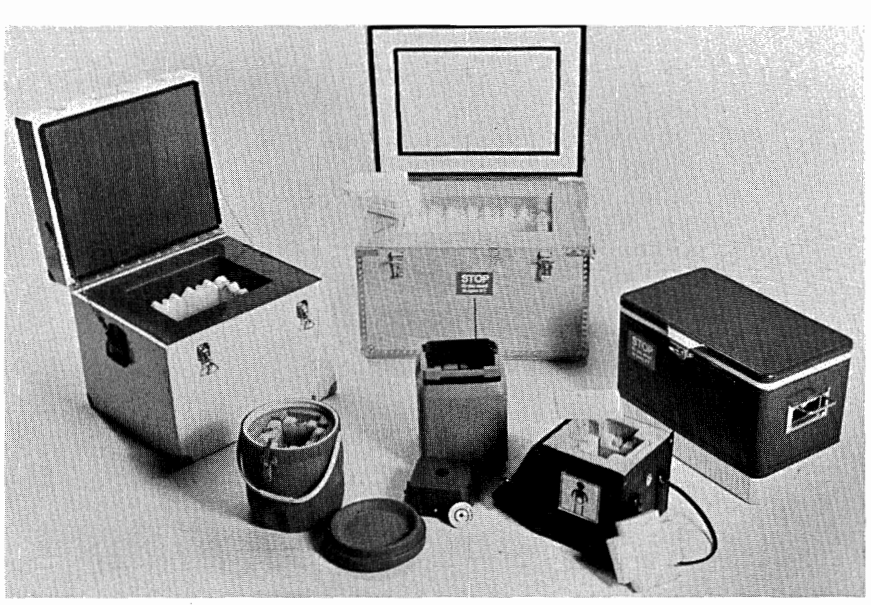
In choosing a refrigerator or freezer, the program manager should determine the following information:

1. Vaccine storage capacity needed:
   —how much at +4°C?
   —how much at −20°C?
2. Icemaking performance needed:
   —how many icepacks to be frozen per 24 hours?
3. What external temperatures are reached:
   —not more than +32°C?
   —high daytime and low nighttime temperatures?
   —continuous temperatures between +32°C and +43°C?
4. What power sources are available?
5. What cold life is needed if power source fails?
6. Are repair facilities and spare parts available, and for which types?
7. Which refrigerators meet needs at lowest running cost?

Cold boxes for transporting vaccine between stores and vaccine carriers for use in the field are an important part of the cold chain. The EPI/UNICEF Product Information Sheets and special reports (see EPI/CCIS/81.3) provide practical technical and purchasing information on more than 25 types of boxes and carriers that are available. A program manager should determine the amount of vaccine to be carried (storage capacity), how long the vaccine must be stored (cold life) with extra safety margins added if the box must be opened often, how the box will be carried (how heavy it can be), and how durable it must be. Using these criteria and the EPI data, the manager can identify the best box at the best price for his or her program. Several developing countries (India, Indonesia, Pakistan, the Philippines, Senegal, and Thailand) are now producing their own cold boxes and carriers.

Temperature monitoring systems are an essential safeguard for heat-sensitive vaccines. The system can be as simple as daily manual reading and recording of the temperature where vaccines are stored or as elaborate as automated monitoring systems with alarms and standby alternative cooling systems. The liquid crystal thermometer is an easy-to-read, inexpensive, reversible thermometer (0°C to +20°C) for use in refrigerators. For accurate readings, it should be mounted with its adhesive backing on a small wood or plastic block and placed in the middle of the refrigerator, away from the walls or the light bulb.

Since vaccine potency declines at a rate determined by both time and temperature exposure, it is important to know the temperature history of each vial of vaccine. The PATHmark time-temperature indicator for measles vaccine, one of a series of cold chain indicators now being tested, is the only monitor available for *individual* vaccine vials (see box on PATHmark field trials update). The indicator is a small disc of chemically treated paper with an adhesive backing (so it can be attached to the lid or label of each vial) and a clear, protective coating. The PATHmark changes color from light red to dark red to black as it accumulates heat exposure sufficient to reduce measles vaccine potency below acceptable levels. It is nonreversible. It is also available as a management indicator for vaccine shipments. Another chemical indicator is the 3M Monitor Mark, a larger-sized, nonreversible time-temperature indicator, which is being tested in 50 countries for use with boxes of vaccine being shipped or stored throughout the cold chain. Results from both sets of field trials are expected in 1983. The freezewatch alarm, a nonreversible chemical indicator that changes color when exposed to temperatures below −4°C for more than one hour, is designed to warn if DPT or tetanus vaccines have been frozen.



WHO/EPI

PATHmark FIELD TRIALS

The PATHmark time-temperature indicator for measles vaccine is currently undergoing field trails in nine countries: Argentina, China, Kenya, Mexico, Nepal, Pakistan, the Philippines, Yemen Arab Republic, and Zimbabwe. The indicators are attached to individual vials of measles vaccines and distributed through the cold chain. Data are collected by cold-chain personnel and health workers who handle the vials. This limited introduction of PATHmark is designed to provide information on the indicator's acceptability to those who will use it, to test the training materials, and to familiarize peripheral health workers with the concept of quality control at the end of the cold chain. The development of the time-temperature indicator and the accompanying field trials are supported by the Edna McConnell Clark Foundation, IDRC (International Development Reseach Centre, Canada), OXFAM in U.K., UNICEF, and WHO/EPI. The trials began in May, 1982; early results are expected in the spring of 1983, with the remainder by the end of 1983.

The ultimate goal is to have vaccine manufacturers place an indicator on each vial at the time of production, so that the complete time-temperature history of each vial is monitored. Until then, programs can order PATHmarks directly and attach them as soon as vaccines arrive in the country. For more information about PATHmarks for measles vaccine, please write:
PATH
Canal Place
130 Nickerson Street
Seattle, WA 98109 USA

Vaccination Equipment

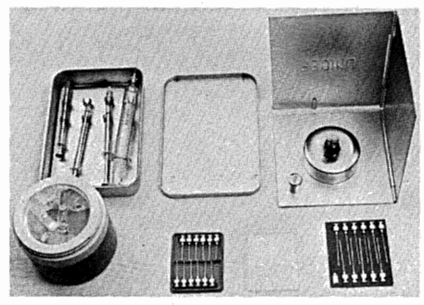
For injectable vaccines, supplies of needles and syringes and a method of sterilizing them are needed. Although disposable, presterilized needles and syringes seem convenient, they often pose considerable storage and distribution problems. Reusable glass or nylon syringes work well and, with correct sterilization techniques, are quite safe.

For measles, DPT, and tetanus toxoid, a 1 ml, 2 ml, or 5 ml syringe is used with a 22 gauge, 1¼ inch (30.7 mm) needle. Each injection is given with a sterile needle and syringe which is not reused until it has been completely sterilized again. Because BCG is given intradermally, a special 1 ml tuberculin syringe is used with a very short 25 or 26 gauge, 10 mm (approximately ⅜ inch) needle. It has been accepted practice to use the same BCG syringe for several injections, sterilizing the needle between each use by passing it through a flame. However, many health workers have found that flaming the needles makes the steel lose its hardness and become dull. Using a separate syringe and needle for each BCG injection avoids this problem. Work is currently under way to develop a one-dose BCG syringe.

Sterilizing needles and syringes is a time-consuming task and requires adequate fuel for heating water. Syringe barrels and plungers must be separated, washed, and individually wrapped in gauze, and needles must be pushed into gauze rolls to protect the tips. Recently, a metal rack has been designed to hold needles and syringes with no need for gauze wrapping. It holds enough equipment for an immunization session of about 35 infants and fits into a small home pressure cooker. It is currently being field tested along with a clockwork timer that automatically releases steam pressure after it has been maintained for 15 minutes. Steam pressure in a domestic pressure cooker or a pressure sterilizer at 15 psi (pounds per square inch) for 15 minutes is preferred over open boiling for 20 minutes. It provides higher temperatures for more thorough sterlization and uses less fuel.

Alternative means of administering vaccines, other than standard needles and syringes, have also been investigated. For example, a bifurcated (two-tined) needle, originally developed for use in smallpox vaccination campaigns, has been used to administer BCG. It is simpler to use than a standard intradermal needle and syringe, but it seems to produce less effective immunity than intradermal injection and requires a more concentrated and costly form of BCG. Delivery of vaccines in an aerosol form, to be inhaled individually or in a group treatment, is also being investigated using measles vaccine.

Jet injectors, which force vaccines through the skin in a pressurized spray without the use of a needle, have been tried with BCG, DPT, and measles with varying degrees of success. These injectors can be powered by springs, hydraulics, gas cylinders, or electricity. The advantages are their speed, relative painlessness, ease of administration with minimal training, and safety from infection due to unsterile needles. Concerns about their ability to deliver uniform doses have led some to recommend against their use, especially with BCG vaccine. The other disadvantages are their need for regular maintenance and repair and their high initial cost; they are cost-effective only when used in mass campaigns immunizing several hundred children each day. Because most immunization programs are based on reaching mothers and children through the routine health care services, (supplemented with occasional campaigns), there are few situations where jet injectors would be especially advantageous.



WHO/EPI

Program Management

To combine the components of vaccine and equipment into an effective immunization service, a program manager must consider several issues. First, after a survey of the existing situation, he or she should set program goals and develop an appropriate and feasible immunization schedule. Systems for keeping records and for training health and cold chain personnel are essential elements. In choosing between different strategy options, a program manager will need to do an analysis of the costs of each option. Finally, a method of evaluation must be developed to measure program success in meeting the stated goals and to identify needed changes and improvements.

GOALS

The setting of program goals is a policy matter and depends in large part on what immunization services are already being provided and on what resources are available. The goals might consist of expanding existing immunization services at health centers, extending service to new geographic areas, designing special programs to reach high-risk subgroups, or developing educational programs about the importance of immunization. In any case, specific numerical goals for each area should be set to provide the program with a clear direction and to allow for concrete evaluation along the way.

SCHEDULES

Immunization schedules are determined by considering the health needs of the population, the requirements and costs of the particular vaccines chosen, the resources available, and the way services are structured. It is seldom possible to achieve the ideal schedule because of conflicting needs, so some compromises are necessary.

The health needs of the people to be served are considered epidemiologically: which diseases are public health problems *and* have an effective vaccine available, which age groups are at greatest risk of the disease, and which groups are at low risk of exposure or are already immune. If most children in the community have developed natural immunity to measles by age two, for example, it will not make sense to offer measles vaccine to unvaccinated children over two years of age.

The immunological requirements of the vaccines must also be taken into account. Because maternal antibodies can pass through the placenta and the breast milk, they may interfere with an infant's ability to respond to a vaccine and to produce his or her own antibodies. DPT and polio vaccines, for example, should not be given before the age of 2 to 3 months and measles not until 9 months of age. A delicate balance is involved, since the goal of completing the series of doses in time to protect the child at high risk may conflict with the goal of delaying vaccination until maternal antibodies subside so the vaccine will "take" well. There has been much controversy over the best age to give measles vaccine. In developed countries, where measles usually occurs after 18 months of age, the vaccination is given around age 15 months. In many developing countries, though, where the incidence of and mortality from measles are high in the first year of life, the age for immunization recommended by the EPI is as soon as possible after 9 months of age. Programs that have tried vaccinating for measles at 6 months have found that a reinforcing dose after the age of one year is often needed to obtain long-lasting immunity. The EPI recommendation is based on a balance of factors such as maternal antibodies, the pattern of weaning, the rates of measles occurrence, and the effectiveness of the vaccine at different ages. For multiple-dose vaccines, the interval between doses presents a similar dilemma. The longer the interval, the better the "take", but completion of the schedule is delayed. For DPT, oral polio, and tetanus toxoid, the minimum interval between sequential doses is one month.

The resources available (including the existing health care system) determine the type of schedule that is workable. Since each visit is costly in terms of personnel and transport, the goal is to limit the number of times a child must return for immunizations. Several types of vaccinations can be given at the same time, but the minimum interval between doses must still be observed. The number of people needing immunization in a community, the amount of travel time for outreach or mobile teams, and the availability of refrigeration or vaccine carriers, will all influence the schedule in different ways. A minimum of three visits is needed if the third visit is delayed to the age of 9 months (to administer measles). An illustrative three-visit schedule might be:

age of child	immunization
3-5 months	BCG, 1st DPT, 1st polio
6-8 months	2nd DPT, 2nd polio
9-10 months	measles, 3rd DPT, 3rd polio

When services are organized around mobile teams or special campaigns, six-month intervals are the longest that can be used without leaving too many infants unprotected during the first year of life. Schedules should also take into account seasonal conditions that affect work patterns (such as harvest time) or transportation (rainy season) and cultural beliefs and practices that may affect acceptance of immunization.

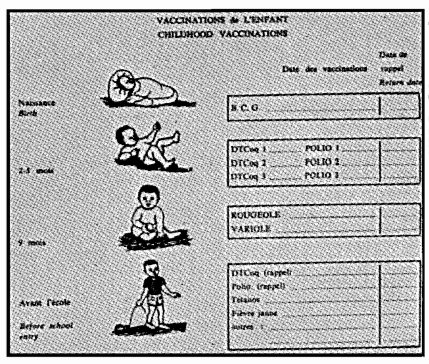
RECORDS

A record-keeping system is essential in order to know which vaccinations have been given and when. Some programs have used BCG, which produces a scar, as a marker indicating that the first DPT and polio doses were all given at the same time, but it is usually better to give BCG at birth

if possible. Many programs have developed immunization cards which are retained by the parents (often in a plastic envelope) and contain a record of the child's vaccinations and the date of return visits needed. Parent-retained cards allow the parent to take the child to whatever facility is most convenient and avoid the problem of clinic files and multiple patient names. In addition to information needed for individual care, each program should collect data for evaluation, for inventory control, and for planning future services. The data needed include the number of doses administered, the number of vials of vaccine used per session, the number of first, second, and third doses, the age of the person vaccinated, and records of cold chain monitoring systems. Surveillance data or case-reporting of the diseases for which vaccinations are given would enable staff to recognize epidemics quickly and to measure program success.

TRAINING

Because there are a variety of skills needed to provide effective immunization services, several types of personnel training programs have been developed, which can be integrated with other primary health care training or carried out separately in smaller units. WHO/EPI offers courses on planning and management, on mid-level management, on the cold chain, and on cold chain equipment repair. These courses are given several times each year in various re-



WHO Chronicle

gions of the world, and focus on self-instruction and learning through doing. Training manuals (which can be adapted to local conditions), Users' Handbooks explaining various types of refrigerators, a Repair Technician's Handbook for compression refrigerators, and various posters, folders, and slides are available from EPI (by contacting the local or regional WHO representative). New EPI materials being developed include a child growth record, a training course for peripheral health workers, a booklet on prevention of neonatal tetanus, and material on the logistics of handling vaccines, essential drugs, ORS, and other primary health care supplies.

RESOURCE ALLOCATION

Once the goal has been set, how does the program manager determine the best strategy for allocating available resources to the various components identified earlier (such as vaccines, personnel, facilities, and cold-chain equipment)? The cost of a course of the basic six vaccines themselves is relatively low, less than US$0.50 per child. The costs associated with the other components, however, can vary widely. A good way to begin is to identify several possible strategies that could fit the goal and the local situation—for example, extending the range of existing facilities by increasing the hours when vaccinations are available, developing specialized mobile teams to serve remote areas, or training nonmedical people, such as teachers, to give oral polio. Then, after identifying all the costs of each strategy, the program manager can calculate a cost per person immunized. (EPI has a paper, "Costing Guidelines," on how to determine cost-effectiveness—EPI/GEN/79/5.) A related approach is to compare how many of the targeted population (usually children under one year and pregnant women) can be reached with each strategy. In general, where the existing health care system already offers some maternal and child health (MCH) care, immunization services are delivered most efficiently if they are integrated into MCH services. They share the same target group, and the facilities and personnel requirements are similar. When a special immunization program is needed, it will be most successful and stable if it can eventually serve as the basis for broader health services.

After a strategy has been chosen, it is important to develop a method for evaluating its success. Otherwise, scarce resources may be wasted on a program that is ineffective or that is good but could be improved. Evaluation can be continuous (temperature monitoring of vaccines or daily/weekly/monthly service reports, for example) or periodic (vaccination coverage surveys). Most countries do not routinely collect data on the number of children or mothers needing vaccination in each area. In order to determine the percentage of people covered by services, special surveys are needed. EPI has developed a model cluster-sampling survey technique which provides basic data on vaccination coverage and uses evaluation resources efficiently. Well-designed evaluations feed information back to program managers so that they can improve their programs; these evaluations also serve as evidence that resources have been used effectively to achieve agreed-upon goals.

From this review, it is clear that immunization services, an essential component of primary health care, involve a complex array of medical, logistical, and management concerns. Choosing vaccines on the basis of priority public health needs, developing and maintaining an effective cold chain, and selecting program strategies that make the best use of limited resources will result in a marked improvement in the health of mothers and children.

This issue of DIRECTIONS was prepared by Vivien Davis Tsu, M.P.H. We wish to thank all those who provided information and assistance, especially the staff of WHO's Expanded Programme on Immunization in Geneva and Washington, D.C. Special thanks also go to those who reviewed the manuscript: Dr. Hjordis Foy, Professor of Epidemiology and International Health, School of Public Health, University of Washington, Seattle; Dr. Alex D. Kanarek, Assistant Director, Technology Transfer, Connaught Laboratories, Ltd., Ontario; Dr. Kenneth Warren, Director, Health Sciences, Rockefeller Foundation; and the staff of EPI in Geneva.

INTERCHANGE

We encourage readers to send in ideas and questions related to their experiences with health technology. Contact:

PATH
Canal Place
130 Nickerson Street
Seattle, WA 98109 USA
CABLE: PATH Telex: 4740019

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A reader in Nigeria has inquired whether the cellophane from cigarette packets could be used as the cover slip in the Kato smear test for intestinal schistosomiasis. According to our experts, this cellophane is too thin; it would corrugate, thereby distorting the fecal smear. Glass or plastic cover slips can be used, but the wettable cellophane described in the Schisto issue of **DIRECTIONS** (March 1982) offers the additional advantage of retaining moisture so that the slide remains readable for up to one year. (See below for ordering information.)

■

Through the courtesy of the Du Pont Company, PATH has obtained a limited supply of *wettable cellophane*. We will supply it to health programs in rolls of 2" (5.08 cm) width, to be cut into ⅞" (2.22 cm) strips for standard microscope slides. There will be a small handling and shipping charge. Send inquiries to PATH in Seattle.

■

The Institute of Child Health in London provides a variety of *Teaching Aids at Low Cost* (TALC). These include slide sets with accompanying script, "Road to Health" weight charts and flannelgraphs, measuring spoons for preparing oral rehydration solution, and low-cost books appropriate to primary health care providers. The slide sets are particularly valuable instructional tools and cover a wide range of topics, including tropical diseases like guinea worm and leprosy, nutrition, diarrhea, child development, and obstetrical problems. Sets of 24 slides are available for less than US$10. For information, write: *Teaching Aids at Low Cost*, P.O. Box 49, St. Albans, Herts. AL1 4AX, U.K.

■

The Appropriate Health Resources and Technologies Action Group, Ltd. (AHRTAG) is preparing an illustrated guide to storekeeping in health centers and rural hospitals in developing countries. Practical ideas on storage, stock control, and dispensing of drugs and other medical supplies would be welcome. They also want to hear about the day-to-day problems related to storage and supplies. Please write: AHRTAG, 85 Marylebone High Street, London W1, U.K.

PATH's New Schisto Kit

The PATH Urinary Schisto Diagnostic Kit, announced in the March 1982 issue of **DIRECTIONS**, has been improved and is now available. By special arrangement with Nuclepore Corporation, PATH is able to supply kits with *precut* filter membranes at low cost to public sector health programs. Based on advice from experts in the field, the membrane is a 12-14 micron pore size instead of 8 micron (to reduce problems of clogging). In addition, the kit can be ordered with either screwtop or pop-top filter holders. Kits (including filters, filter holders, and forceps) can be ordered in quantities sufficient for 100, 1000, or 5000 tests. Discounts are available on larger quantities and customized orders of any combination of the components can be arranged.

PATH has also developed a set of 42 slides that show the step-by-step procedure of the urine filtration diagnostic method. The slides are available in English, French, or Arabic.

For further information on the PATH Schisto Kit or the instructional slide sets, please write:
PATH
Canal Place
130 Nickerson Street
Seattle, WA 98109 USA

Other Publications On Immunizations

A reference list for this issue is available from PATH for those interested in reading more about immunization.

An excellent monograph entitled *Immunizations* is available from the American Public Health Association. The 43-page paper, prepared by the International Health Programs section of APHA, discusses vaccines and the cold chain, immunization delivery strategies, community participation, and management and evaluation. It also includes a brief annotated bibliography. The issue is Series I, Number 2 (October 1981) of the Primary Health Care Issues and can be obtained by writing APHA/IHP, 1015 Fifteenth Street, N.W., Washington, D.C. 20005, USA. The cost is approximately US$5.00.

health technology
directions

PATH Program for Appropriate Technology in Health

Assessing Nutritional Status

Practical Measures for Primary Health Care

Malnutrition is still directly or indirectly responsible for much of the morbidity and mortality in developing countries, particularly among children. Because of their greater nutritional requirements, children (who experience rapid growth between the ages of six months and five years), as well as pregnant and lactating women, are especially vulnerable to malnutrition. Many of the classical methods of assessing nutritional status—dietary surveys, biochemical tests, and clinical examinations—require resources that are often not available in rural areas or urban slums. Technologies appropriate for routine field use are needed to strengthen primary health care programs in developing countries.

Such technologies must be:

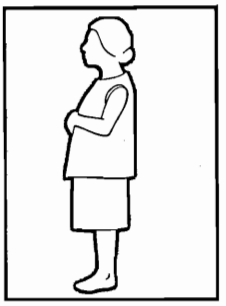
- Accurate, reliable, and able to be standardized;
- Easy to learn, use, and interpret;
- Low cost, both in terms of equipment and personnel;
- Portable and durable; and
- Culturally relevant.

The main purpose of nutritional status assessment in primary health care programs is to enable health workers to screen for high risk factors and identify those individuals most in need of referral and/or intervention. Measurement of individual status can also be used to evaluate the impact of an intervention and to monitor the progress of individuals over time. These methods can also provide information for planning and evaluating nutrition programs. The technologies used should be matched as closely as possible to the needs of the program and to the outcome desired.

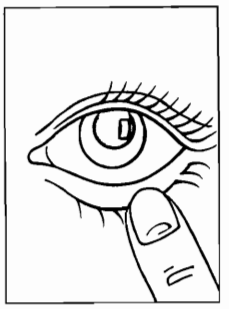
This issue of **DIRECTIONS** looks at nutritional status assessment technologies for use in primary health care programs and points out the needs for improved assessment methods. It also discusses aspects of program management, focusing on the selection of technologies.

Specific technologies for assessing the following are reviewed:

1. Growth in children under five



2. Maternal nutritional status and fetal growth



3. Anemia and vitamin A deficiency

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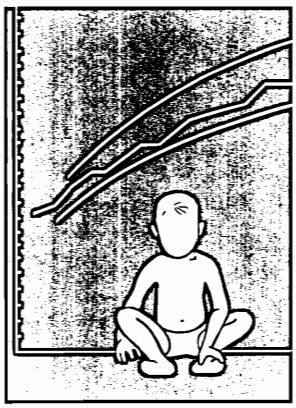
The Malnutrition Syndrome

Malnutrition has many causes; a particularly important one in developing countries is the interaction between common infectious diseases and nutrient deficiencies. Because of the many types of malnutrition (see Table 1) and their differing degrees of severity, the number of people affected worldwide is difficult to determine. Easily recognizable clinical cases of severe malnutrition are only a small portion of the total. Mild to moderate malnutrition, sometimes called "marginal malnutrition," is up to ten times more prevalent than severe malnutrition. Estimates are that about one-fourth of the population of developing countries (that is, half a billion people) have energy-deficient diets. More than 100 million children under the age of four have protein-energy malnutrition. Every year, half a million people go blind from vitamin A deficiency. While the **proportion** of undernourished people is decreasing, the **total number** is increasing because of the overall growth in population.

Using Growth Indicators in Children under Five



Growth is the best overall indicator of health and nutritional status in children under five. Measurements of body size and composition, known as anthropometric measurements, are the most widely used indicators for young children. There are two approaches to the assessment of the nutritional status of children—**monitoring** growth, by taking the same measurement at regular intervals, and **screening**, by taking a measurement on a single occasion. Monitoring allows health workers to observe the pattern of growth and to detect early signs of growth failure. Screening does not provide information on the progress of growth, but is useful for rapid detection of cases of severe malnutrition.

Each of the commonly used indicators (shown in Table 2) reflects a different aspect of growth. Some are used primarily for monitoring, such as weight-for-age, and others, such as arm circumference, are particularly suitable for screening. However, some primary health care programs have found it more practical to use the less-complicated screening methods for monitoring.

Growth monitoring most frequently measures weight-for-age, which is recorded on a chart that graphically demonstrates the growth process. Most growth charts are similar to the Road-to-Health chart.

The reference curves represent either percentages of the median of the reference population (for example, 75% of the **middle** weight for a given age) or percentiles (for example, the third percentile or point at which 97% of **all** weights for a given age are higher). Health workers record the child's weight on the chart at each visit, and determine adequacy of growth by comparing the child's growth curve to the reference curves. In some programs, only one curve is used. In others, multiple curves form channels that represent degrees or classifications of malnutrition. The channels are often colored to correspond with the classification. A few programs also observe absolute weight gain to evaluate growth.

Growth tables are a recent modification of growth charts. Field

TABLE 1
FORMS OF MALNUTRITION IN DEVELOPING COUNTRIES

Deficiency Disease	Nutrient
Protein-Energy Malnutrition Severe forms: Marasmus and Kwashiorkor	protein and calories
Anemia	usually iron
Xerophthalmia	vitamin A
Endemic Goiter	iodine
Pellagra	niacin
Beriberi	thiamin
Rickets	vitamin D
Scurvy	vitamin C

tests in the Philippines found that this kind of growth table was easier to interpret than the charts using growth curves. A growth monitoring program in Africa plans to adopt a modification of this system, believing that mothers can most easily understand and remember the growth progress of their children when it is translated into a numerical score.

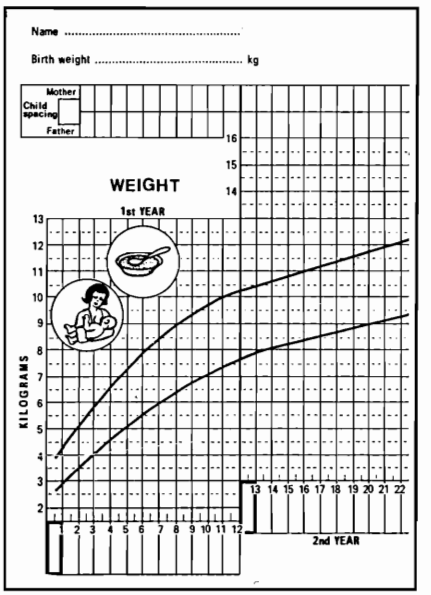
A variety of scales are available. Table- or floor-model beam scales are the most accurate, but they are the most expensive and difficult to transport. There are also many reasonably accurate, portable, and relatively inexpensive scales that can be made by local artisans or commercial manufacturers. With all these scales, the child is suspended in a sling, seat, or pants, which can make it difficult to obtain accurate readings, and may lead mothers to object to the procedure.

Health workers must also know or be able to estimate accurately the child's age. Construction of a local events calendar can help parents associate a birth with an event such as a festival, harvest, planting, or disaster. Parents can be asked which local children of known age were born at the same time as their child. Health workers can also count the number of teeth the child has and note other developmental characteristics to estimate age.

Height-for-age is a useful supplement to weight-for-age. It allows health workers to determine to what degree low weight-for-age is due to stunting (retarded skeletal growth) or wasting (extreme thinness). Accurate measurement of height requires a measuring board and two people to take the measurement. Children younger than two are measured lying down. A separate board may be needed to measure the standing height of older children. Or, they can be measured standing against a wall to which a non-stretching tape is attached.

Growth charts usually include space for additional information, such as immunization history and clinic appointments. Other factors that affect nutritional risk can be recorded as well. Educational messages can also be printed on the card. Usually the mother keeps the chart, which then serves both an educational and motivational purpose. Sometimes the clinic or health center keeps a duplicate copy. If height is measured, it is usually recorded only on the clinic copy. Charts that are not crowded enable parents to see the direction of the growth line more easily. It is important to provide a durable plastic envelope and/or make the chart of sturdy paper so that it will survive a lot of handling.

Which reference population to use is a matter of controversy. One side of the debate holds that most children, regardless of ethnic origin, have approximately the same potential for growth given adequate nutrition, and so recommends using international standards. Existing local data can be used as a basis for deciding which channels or cut-off points best represent the normal range for that country or region, keeping in mind that international standards should not be interpreted as targets but rather as a reference for comparison.



Road to Health

The opposing view is that studies indicate that genetic background and environmental factors (diet, infections, altitude, for example) do make a difference; therefore, a definition of nutritional status should be made on the basis of comparisons to a local standard. However, it is not always possible for developing countries to collect the data necessary to establish local reference population values. One solution is the development of standards that can be used by several countries within a region. When local standards are not used, the Harvard Standard is frequently employed. Recently, the reference population of the National Center for Health Statistics of the United States is finding wider usage.

TABLE 2
ANTHROPOMETRIC INDICATORS FOR CHILDREN

Indicator	What Does It Measure?
Weight-for-age	wasting and stunting* combined
Height-for-age	stunting
Weight-for-height	wasting
Arm circumference	wasting

*Wasting, which is extreme thinness, reflects acute, current malnutrition; **stunting,** which is retarded skeletal growth, reflects chronic, long-term malnutrition.

The measurement of arm circumference is a useful screening tool. Because arm circumference changes only about 1 cm in children between the ages of one and four, it has been used as an age-independent measure in children of that general age range. To measure arm circumference, a tape or arm band made of durable and non-stretching material is placed around the mid point of the child's relaxed, left upper arm. Arm circumference tapes can be made from used X-ray film or from other durable materials, but they must be checked periodically against a ruler. Workers also need practice taking this measurement to ensure accuracy.

Simplified measurements of arm circumference have been developed and used in some programs. For example, a bangle or bracelet with a circumference of 13 cm that fits beyond a child's elbow indicates severe malnutrition. Many problems have been reported with this method, especially where workers have difficulty sliding the bracelet over the elbow of even a very thin child. Another method estimates the thickness of a child's upper arm by noting the distance between the health worker's index finger and the ball of the thumb. Sticks of wood or bamboo and/or pipes or tubes of various circumferences are needed to train health workers in this method and to serve as references for measurement.

The Echeverri Tape for measuring arm circumference is a method that has been recently introduced in Latin America. In contrast to other arm circumference bands, this measure is age-specific and can be used on infants under one year. The first six years of growth are divided into seven stages on this tape.

Another screening alternative involves measuring maximum thigh circumference. Because the thigh is larger than the upper arm, measurement error is less likely than with arm circumference. Thigh circumference can be used as an age-independent measure in infants as young as six months. One color-coded tape has cut-off points for detecting severe malnutrition at 17.5 cm, moderate at 21.5 cm, and borderline at 24.5 cm.

The advantages of these circumference measures are their simplicity and low cost. Mothers and health workers with little or no formal education can learn to use and interpret them, even carrying out assessment at home. In some projects, schoolchildren have been trained to measure the arm circumference of their siblings and neighbors. While these methods are usually employed as screening devices, some programs have used them as monitoring tools, recording regular measurements on charts designed for people who do not read. In areas where the level of illiteracy is very high, these methods might be a practical substitute for weight monitoring.

Name _____
Date of Birth _____

PHILIPPINE NUTRITION PROGRAM
NUTRITION HEALTH CHART FOR BABIES

PROVINCE: _____
MUNICIPALITY: _____
BARANGAY: _____

	MONTH	Birth-month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
	WEIGHT (Kg)																			
	NUTRITION LEVEL	*(PLOT MONTHLY WEIGHT IN CORRECT BLOCK TO DETERMINE NUTRITION LEVEL)*																		
	1 HEALTHY	3.1	3.8	4.5	5.1	5.7	6.2	6.7	7.1	7.6	8.0	8.3	8.6	8.9	9.1	9.3	9.5	9.7	9.9	10.1
	2 MILDLY MALNOURISHED	2.9	3.6	4.2	4.8	5.4	5.9	6.3	6.7	7.1	7.6	7.8	8.2	8.4	8.6	8.8	9.0	9.2	9.4	9.5
	3 MILDLY MALNOURISHED	2.7	3.4	4.0	4.6	5.0	5.5	5.9	6.3	6.7	7.1	7.4	7.7	7.9	8.1	8.2	8.5	8.6	8.8	9.0
	4 MILDLY MALNOURISHED	2.6	3.2	3.8	4.3	4.7	5.2	5.6	5.9	6.3	6.7	6.9	7.2	7.4	7.6	7.7	8.0	8.1	8.2	8.4
	5 MODERATELY MALNOURISHED	2.4	2.9	3.5	4.0	4.4	4.8	5.2	5.5	5.9	6.2	6.4	6.7	6.9	7.1	7.2	7.4	7.6	7.7	7.8
	6 MODERATELY MALNOURISHED	2.2	2.7	3.2	3.7	4.1	4.5	4.8	5.1	5.5	5.8	6.0	6.2	6.4	6.6	6.7	6.9	7.0	7.2	7.3
	7 MODERATELY MALNOURISHED	2.0	2.5	3.0	3.4	3.8	4.1	4.4	4.7	5.0	5.3	5.5	5.8	5.9	6.1	6.2	6.4	6.5	6.6	6.7
	8 SEVERLY MALNOURISHED	1.9	2.3	2.8	3.1	3.5	3.8	4.1	4.3	4.6	4.9	5.1	5.3	5.4	5.6	5.7	5.8	5.9	6.1	6.2
	9 SEVERLY MALNOURISHED	1.7	2.1	2.2	2.8	3.2	3.4	3.7	4.0	4.2	4.6	4.6	4.8	5.0	5.1	5.2	5.3	5.4	5.5	5.6
	10 SEVERLY MALNOURISHED																			

Philippine Growth Table

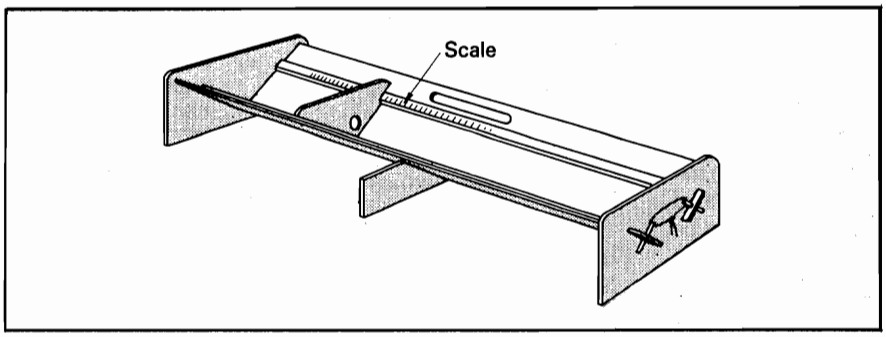
USAID Mission

Recent research has found that measuring the mid-upper-arm circumference of newborns is a good screening technique for low birth weight. A circumference less than or equal to 9.0 cm at birth and through the first fourteen days of life is the cut-off point. As with other arm circumference measures, health workers need training and supervision in its use.

Another screening tool measures arm circumference and relates it to height. The QUAC (Quaker arm circumference) stick is age-independent and can also be used to detect severe malnutrition in school-age children five to ten years old as well as in preschool children.

Other screening methods rely on weight and height. The weight-for-height or Thinness Chart can be used to identify wasted children, regardless of their ages. This chart consists of columns marked with a weight, with three colored sections corresponding to nutritional status categories at the top of each column. A child is weighed and placed standing against the column that has his or her weight. The health worker notes the color of the column at the top of the child's head. This chart can be used as a monitoring tool for recording periodic measurements on a card. A length board for using the Thinness Chart in children under two years is being developed.

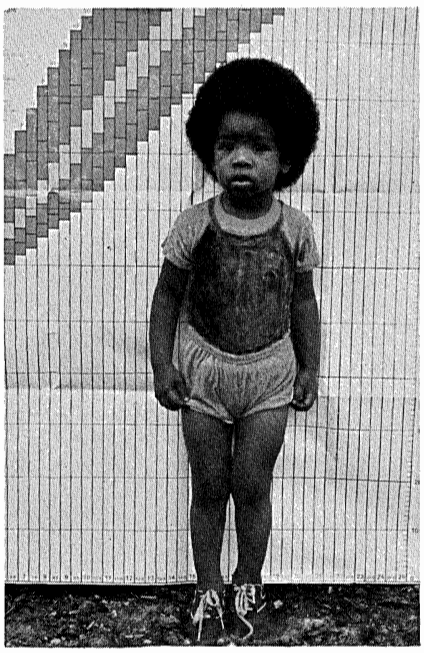
The Wasting-Stunting-Classifying Scale is a new method for quick assessment that combines weight-for-height and height-for-age to enable health workers to determine if a child is wasted, stunted, or both. Weight-for-age taken on a single occasion is widely used as a method of defining nutritional status; however, this measure alone cannot distinguish a wasted child from a stunted child.



WHO 82132

This lightweight (2.5 kilo) and portable infant measuring board can be made locally.

Taking a health history and looking for clinical signs of malnutrition provide valuable information for deciding whether or not a child needs nutritional or other health interventions. For example, the clinical signs of marasmus are wasting of both muscle and fat, whereas the signs of kwashiorkor include edema; apathy; weak, wasted muscles, with presence of fat; light, sparse hair that is easily plucked; flaky-paint rash; and enlarged liver. Similarly, other nutrient deficiency signs should be noted (see section on anemia and vitamin A beginning on page 8). It is especially important to take a history and look for clinical signs when an anthropometric measure is taken only once.



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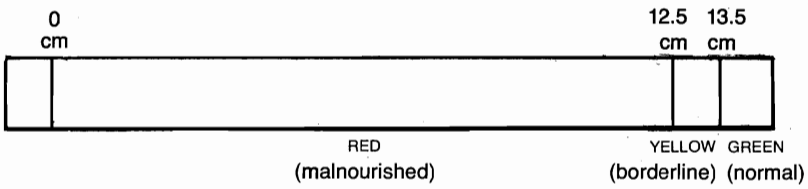
Thinness Chart

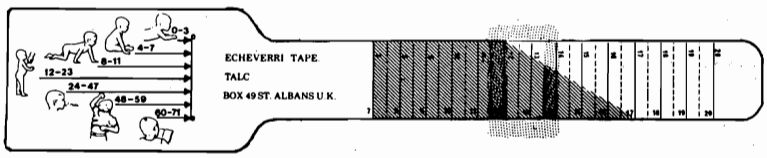


TALC

Simple, easy-to-make, color-coded tapes allow nonliterate people to use and interpret this measure.

Dr. Alfred Zerfas

Zerfas insertion tape with a slot at the zero end prevents reading errors.



Echeverri Tape

Measuring Maternal Nutritional Status and Fetal Growth

Low birth weight (less than 2,500 g) is an important cause of perinatal and infant mortality and morbidity, as well as subsequent retarded growth and development in school age children. Primary health care workers need simple, accurate, and inexpensive methods to permit detection of women who are at risk of delivering low birth weight babies. Maternal nutritional status is only one of the many factors that influence fetal growth. Therefore, combinations of several indicators thought to be associated with low birth weight are used.

Health workers with little training can easily detect the risk factors listed below. The presence of one or more of these factors usually indicates that the woman should be referred to higher levels of care.

These factors include:

1. Age: over 35, or over 30 and primiparous; under 15 (some countries use age 18).
2. Obstetrical history: fifth or later child; history of abortion, stillbirth, or Caesarean delivery; interval of less than one year between pregnancies; previous low birth weight baby; previous death of an infant; hemorrhage or a history of bleeding during pregnancy.
3. Appearance: severe pallor (a sign of anemia—see following section); general thinness or wasting; loose folds of skin.
4. Other: smoking; alcohol consumption; occupation (heavy manual labor during pregnancy appears to reduce birth weight); socioeconomic status (care must be taken to develop objective, quantifiable measures of the latter).

A number of anthropometric measures have also been used to identify women at risk. Measures that reflect the woman's nutritional status during her childhood and **prior to** pregnancy are weight before pregnancy, height, and head circumference.

Those that are considered to reflect her nutritional status or dietary intake **during** pregnancy are weight gain during pregnancy and arm circumference.

While there is agreement that both past and present malnutrition of pregnant women influence fetal growth, more basic research and field testing are needed to determine the true significance of the anthropometric measures of nutritional status during pregnancy. Further, taking anthropometric measurements of adults presents certain problems. For example, an accurate, easily transportable, and inexpensive scale for adults is not yet available. Measuring height, head, and arm circumference may be more feasible, since the tools are low cost and durable, but they require training and standardization. Establishing standards and determining meaningful cut-off points for defining nutritional status are also difficult. International standards may be used for detecting malnutrition in children because these standards represent potential for growth; but for adults, definitions of normal ranges will vary by region and country. For instance, a project in India considered women less than 145 cm tall to be at risk, while the corresponding figure in a Guatemalan project was 152 cm.

The normal standard for a woman's prepregnancy weight depends on height. A weight-for-height by week of pregnancy reference table has been developed, but its usefulness depends on accurate weighings and reasonable estimates of gestational age. This table relies on standards for women from the United States, and considers any woman whose measurements are less than 100% of the reference value to be at risk. Although this table is new and requires further field testing, it may be possible to adapt it for use in other countries. Generally, programs that have scales for monitoring weight gain during pregnancy consider a woman who gains less than 5 or 6 kilos by the 24th week to be at risk.

Simple technologies for monitoring fetal growth also exist. Measuring uterine height is one method. A tape measure of nonelastic material is color coded with the upper and lower limits of uterine height for the beginning of the sixth, seventh, and eighth months of pregnancy. To take the measurement, the zero end is held at the upper edge of the pubis. Pressing lightly, the health worker extends the tape to the

UN photo 152 054 John Isaac

Examining for uterine size.

center point of the uterine fundus, and notes the color of the tape. The measurement can be done in a woman's home.

Some projects use measurements of uterine height, but without a color coded tape, to monitor fetal growth. A less-precise method of measuring fetal growth, which women can be taught to do themselves, involves measuring the height of the uterus in relation to a woman's umbilicus using the index and middle fingers. At five months of pregnancy, the uterus is at the height of the umbilicus. Each month, the uterus moves up a distance equivalent to two fingers width. More or less than this is a danger signal. A project in China teaches fathers to record fetal movements and heart rate four times a day and to measure uterine height. This paternal involvement is thought to contribute to "intrauterine bonding."

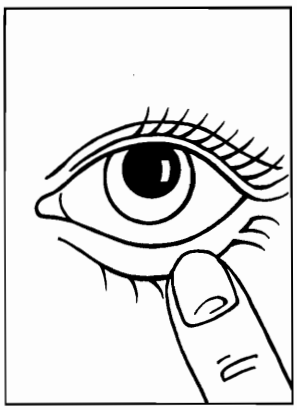
Assessment of the following group of risk indicators may require more highly trained health workers and/or more resources. These are:

1. A twin pregnancy
2. Ankle edema or a history of edema during previous pregnancy
3. Jaundice
4. High blood pressure
5. Presence of infectious disease such as malaria or tuberculosis
6. Protein or glucose in urine.

Women's cards, similar to a child's growth chart, can be used to record the information obtained by assessing and scoring risk. These cards can be retained by the mothers (even kept in the same plastic envelope or bag as the child's growth card), and health workers or the health center can retain a duplicate. In addition to basic biographical information and a checklist of "at-risk" indicators, some cards record pregnancy history, menstrual history, tetanus immunization status, family planning methods, expected date of delivery, and breastfeeding status. Indicators are often assigned scores; the total score of "overall risk" then determines which appropriate actions can be taken (e.g., referral, education). A graph for plotting weight gain during pregnancy is often included. Ideally, all married women or women of childbearing age (depending on what is culturally appropriate) should be provided with these cards, so that risk can be determined before conception or early in pregnancy.

Which indicators to use depends not only on the level of training and resources available, but also on the health problems of the population of the area and the characteristics of individuals and the environment. It is not necessary to use complex cards with a great many indicators. As women are often seen only one time during pregnancy, there is a need to use indicators that can quickly identify women at risk. A project in Guatemala used only three indicators—maternal height, head circumference, and "house score" (a composite index based on a description of the materials used in building the walls and ceiling and on the quality of the rooms). A low "house score" was consistently associated with low birth weight. These were found to be very cost-effective and simple measures for detecting women at risk.

Detecting Anemia and Vitamin A Deficiency



Anemia

Anemia, the reduction in the concentration of hemoglobin (or red pigment) in the blood, causes varying degrees of debility, which interferes with an individual's ability to carry out daily tasks. Severe anemia during pregnancy is associated with increased rates of maternal morbidity and mortality, as well as higher risk to the fetus. Anemia usually results when the body lacks sufficient stores of iron or folic acid, needed to produce red blood cells. Shortages of these key building blocks can be caused by dietary deficiency and/or by parasitic infections such as malaria or hookworm that involve red blood cell loss. Bacterial infections and hemoglobin disorders (like sickle cell disease) also contribute to the development of anemia.

Infants, and women in their reproductive years, are especially vulnerable to anemia. During the last trimester of pregnancy, iron is transferred to the fetus across the placenta. A child born to an iron-deficient mother will probably have insufficient stores of iron. The rapid rate of growth of children increases their iron requirements. Iron stores may be quickly depleted, even in a child born with adequate iron levels.

In spite of the high prevalence and negative health impact of anemia in developing countries, a simple, reliable, and inexpensive method to detect anemia is not yet available. Although there have been many advances in the development of sophisticated instruments to detect anemia, the cost of these technologies does not permit their widespread use in primary health care programs. In the absence of an affordable detection instrument, health workers must rely on older, less reliable methods.

One way to screen for anemia is to examine the patient for signs of pallor. The inner surface of the lips and the inner side of the lower eyelids are pale, light pink, or white in anemic individuals. If it is difficult to judge degrees of pallor, a person suspected of being anemic can be compared to a healthy person whose normal skin color is as dark or light as that of the person being checked. Also, standard color photographs showing the lips and tongues of healthy and anemic people can be used for direct comparison. The "anemiometer," a strip of paper with three bands of different shades of red, is used to measure mild, moderate, and severe anemia. The health worker holds it up to a person's inner eyelid and matches the color. It should be emphasized that these tests are not very reliable, except in cases of severe anemia.

The other common technologies for detecting anemia—hemoglobin concentration and hematocrit—require laboratory facilities, which may not be available, and a blood sample, which some people may object to giving.

To measure hemoglobin concentration, a measured sample of blood is taken from a finger prick and mixed with a known volume of diluting fluid. The depth of color of the diluted blood is determined in a spectrophotometer or colorimeter. Some photometers run either on electricity or on current from a car battery. The colorimeter must be calibrated, and a graph and table prepared for the hemoglobin values. Alternately, a comparator can be used. This is a visual method where the test solution is compared with a series of colored glass standards that show the concentration of hemoglobin. Another approach is the Sahli method, in which blood is diluted in an acid solution, converting hemoglobin to acid hematin. The test solution is then matched against a colored glass reference. This method is often used because it does not require expensive instruments, but it is not an accurate way of estimating hemoglobin.

The traditional unit for expressing hemaglobin concentrations is grams per 100 ml, with the following values considered as cut-off points for defining marginal deficiency states: non-pregnant women, 12.0 g/100 ml; pregnant women, 11.0; men, 13.0; children at birth, 13.5; children at one year, 11.5; and children 10-12 years, 11.5. The problem with such standards is that there is no clear-cut dividing line between normal and iron-deficient people. What is normal value for one person may not be for another.

The hematocrit, or the packed cell volume, measures the volume of red blood cells in a volume of blood. In the microhematocrit method, a blood sample is taken from a finger prick, allowed to flow into a capillary tube, and centrifuged to separate the cells and the plasma. The centrifuge must be driven from a source of electric power. The packed cell volume is found by measuring the length of the column of red blood cells and expressing this as a percentage of the total length of the whole sample.

Neither laboratory tests nor clinical examination can give a precise determination of the cause of anemia—whether it is due to an iron deficiency, other nutrient deficiencies, infection, hemorrhage, or a combination of these. Further blood tests may be needed.

Vitamin A Deficiency

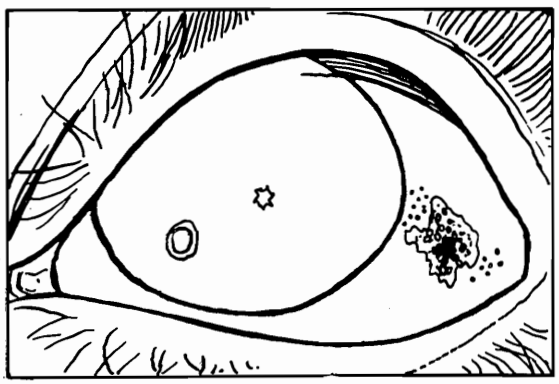
Xerophthalmia is an eye disease that results from vitamin A deficiency and is the primary cause of blindness among children in the developing world. Inadequate vitamin A status can vary from marginal deficiencies without clinical signs, to the presence of early and reversible clinical signs (night blindness, Bitot's spots, and conjunctival xerosis), to severe depletion with advanced and irreversible corneal changes and a high probability of blindness. Children with protein-energy malnutrition, respiratory infections, measles, and/or diarrhea are at especially high risk of developing vitamin A deficiency. Recent research has found that even children with mild xerophthalmia may have a much higher mortality rate than children without apparent deficiency.

Simple techniques for assessing vitamin A status and xerophthalmia should be part of primary health care programs, especially in areas where vitamin A deficiency is endemic. Because biochemical tests, although accurate, are not always practical, primary health care workers need to be trained to recognize the clinical signs of vitamin A deficiency.

Night blindness is frequently the earliest symptom of vitamin A deficiency and can even occur when biochemical tests indicate that vitamin A status is adequate. Until recently, an objective measure of scotopic vision (ability to see in the dark) in preschool age children was very difficult to obtain, because it required the child's cooperation. A study in Indonesia demonstrated that a **history** of night blindness, elicited from a child's parent or guardian, can be valid evidence of vitamin A deficiency. The key to obtaining this history is the existence of local term(s) for the condition, such as "chicken blindness." Reports from other countries indicate that, in areas where vitamin A deficiency is chronic, local terms usually do exist. However, this technique of history taking may not be valid for cultures without such terms. These findings merit further research, as this is a technique which requires little training and no clinical experience. Even school children could be taught to screen their younger siblings.

The other eye signs associated with vitamin A deficiency can only be recognized by clinical examination. Color photographs and line drawings depicting the changes in the eye, accompanied by brief texts describing the photographs, are the simplest and most commonly used tools. These can be used to train workers, who can carry these photographs and drawings with them, referring to them as they examine a child's eyes (see drawing below left). Film strips, slide shows, and manuals are also available for training and reference.

Another finding of the study in Indonesia that is potentially useful for identifying individuals and groups of people at risk of xerophthalmia is the neighborhood clustering of vitamin A deficiency. This also needs further research in other countries.



Helen Keller Int'l., NY

Example of diagnostic eye drawing showing foamy Bitot's spot.

Selecting a Technology

Program planners and managers need to select the technologies that are most appropriate for their regions or countries. Choice of a technology should be based on the following considerations:

1. Prevalence and severity of malnutrition at the local level
2. Goals of the program
3. Available resources
4. Cultural factors that may influence the usefulness and acceptability of the technology.

With these in mind the actual measurement tools, the reference population and cut-off points, and the recording system can be determined. In addition, a program manager must decide which individuals or groups to assess, the frequency of assessment, and how the results of assessment will be used. It is often valuable to combine two or more assessment techniques. For example, various anthropometric indices measure different aspects of growth and development—low weight-for-height (wasted) versus low height-for-age (stunted).

Once the appropriate techniques have been selected, it is essential that their use be properly managed in order to ensure cost-effective programs. This requires thorough planning and organization, training of personnel, and practical recordkeeping systems, as well as rigorous supervision throughout.

Local Nutrition Profile

In order to determine the prevalence, severity, and causal factors of malnutrition, it is useful to establish a community nutrition profile and to quantify nutritional risk. The profile should include the severity and types of malnutrition, the numbers, ages, and other characteristics of the people affected, and any apparent seasonal patterns. Cultural factors (such as weaning practices or food taboos) and socioeconomic factors affect food availability and should be noted. Similarly, the presence of diseases known to cause or interact with malnutrition should be included. Community nutrition profiles are established in order to provide baseline data, to highlight special problems, to identify high-risk or vulnerable groups, and to evaluate the impact of a particular intervention.

It may be necessary to use two or more anthropometric parameters, dietary surveys, and medical/biochemical tests. A well-designed and implemented dietary survey, using 24-hour recall or dietary intake records, may yield useful information, particularly with regard to individual consumption, but it is relatively difficult to carry out. If such survey data are not available, a preliminary assessment of a community's nutritional status can be carried out by primary health care workers using anthropometric measures, observation of gross clinical signs of malnutrition, and interviews about eating practices. Even a limited survey, if focussed on vulnerable groups like children under five and pregnant women, can reveal general problems or identify special local problems, such as beriberi, rickets, or goiter. For example, higher rates of endemic goiter and cretinism are associated with use of cassava as a staple food in some areas.

The decision on whether or not to undertake a comprehensive dietary survey should depend on the specific objectives of the program, adequate personnel and other resources, as well as proper supervision of the study.

Program Goals

The purpose or objective of nutritional status assessment is generally to identify those individuals or groups who are at risk of nutritional or health problems. Once these people have been identified, different intervention strategies can be initiated, depending on the goal of the program and the resources available to it.

Techniques that identify people in need of assistance can also be used to evaluate the effectiveness of an intervention. These methods must be sensitive enough so that changes may be detected over a short period of time. Another purpose of nutritional status assessment technologies is to motivate and educate families. Methods used for education must be designed for easy understanding and interpretation. Collection of aggregate data on a whole community, not just individuals, can also be done. This requires care in the design of records, so that health workers, parents, and statisticians can easily use them.

Available Resources

Resources include existing health infrastructure, personnel, training, and the costs and logistics of utilizing a technology. A technology for nutritional assessment should not identify more people in need of intervention than can be cared for, whether by medical treatment, a supplement program, or nutritional education. It is important to keep this in mind when selecting a cut-off point. If resources are scarce, a conservative cut-off point should

be selected to ensure that those people identified really are the most severely malnourished or can benefit significantly from the intervention.

Program planners need also to consider the degree of training necessary to carry out assessment. The more risk factors to be looked at and the more complicated the technology, the more training health workers will need. It is essential to develop plans for in-service training and supervision of health workers. Several manuals and training courses in nutrition for primary health care workers exist.

Cultural Factors

The availability of age data, the degree of literacy of the population, and the significance attached to various colors used to code degrees of malnutrition are examples of some of the cultural factors that could influence the decision on which technology to select. The local attitude towards taking blood samples and the prestige associated with a certain technique can also affect the acceptability of given technologies within a community.

Technologies for nutritional status assessment are important components of primary health care and can be easily incorporated into ongoing programs. By identifying those individuals and groups at highest risk of malnutrition, program planners as well as health workers can make decisions about the best allocation of scarce resources. There are many interventions that can be carried out at the primary health care level to reduce the health threats of malnutrition. These range from food and vitamin supplements, such as vitamin A capsules, to health education. In fact, the best assessment techniques also offer an educational component. At the same time that high risk individuals are identified, patients, parents, and/or the community can learn about the causes and consequences of malnutrition and the steps that they can take to prevent it. Although additional appropriate assessment methods are needed, and many of the existing technologies require further field testing, the available assessment techniques are a first step to improving nutrition in developing countries.

Materials Available

A reference list and more information on any of the technologies discussed in this issue are available from PATH for those interested in reading more about nutritional status assessment.

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Arm circumference tapes, growth charts, and other nutritional status assessment technologies can be obtained from TALC. Contact: Teaching Aids at Low Cost, Institute of Child Health, P.O. Box 49, St. Albans, Herts. AL1 4AX, U.K.

□

The World Health Organization has published a manual for trainers of community health care workers in nutrition. **Guidelines for Training Community Health Workers in Nutrition** (WHO Offset Publication No. 59) outlines the basic nutrition tasks of community health workers, including the assessment of nutritional status. Learning objectives, training content, and exercises for each group of tasks are specified. To order this publication, contact the WHO Regional Office or write to WHO, Distribution & Sales Service, 1211 Geneva 27, Switzerland.

□

The International Vitamin A Consultative Group (IVACG) and the International Nutritional Anemic Consultative Group (INACG) were formed to guide international activities aimed at reducing vitamin A deficiency blindness and nutritional anemia. Several reports offering guidelines and recommendations and reviewing current knowledge on these deficiency diseases can be obtained from the Nutrition Foundation, 888 Seventeenth Street, N. W., Washington, D.C. 20006. Single copies are free.

□

A series of training materials on the recognition, treatment, and prevention of vitamin A deficiency has been prepared by Helen Keller International in cooperation with the Nutrition Foundation. Filmstrips, flipcharts, manuals, and color slides are designed for health workers at all levels. They are available in English, French, Spanish, Bengali, and Creole. For more information, contact: Helen Keller International, Inc., 22 W. 17th St., New York, NY 10011.

INTERCHANGE

We encourage readers to send in ideas and questions related to their experiences with health technology.

■

World Neighbors has developed teaching materials on the subject of medicinal plants. Six filmstrips, four posters, and a newsletter provide information on identification and use of selected medicinal plants, based mainly on experiences of practitioners of traditional medicine in the Philippines. The entire set of filmstrips, **Understanding Medicinal Plants,** and the user's guide, are available for US $50.00. For information write: World Neighbors, Development Communications, 5116 North Portland Avenue, Oklahoma City, OK 73112 U.S.A.

OXFAM and LEPRA (The British Leprosy Relief Association) have produced a packet of 25 documents for teaching and training on leprosy. The English language material includes textbooks, color slide self-teaching sets, and other publications and reprints. Inquiries on the current cost of the packet should be sent to: Medical Care Unit, OXFAM, 274 Banbury Road, Oxford, OX2 7DZ, U.K.

■

The next issue of **DIRECTIONS** will look at technologies for perinatal health care, including home delivery and midwifery kits, simplified birth and prenatal care records, and support materials. If you have any comments or suggestions on these topics, we would like to hear them.

Update on Gonorrhea Treatment. New guidelines on gonorrhea treatment have been announced in a recent Report of a WHO Consultative Group. The tetracycline regimen reported in the last issue of **DIRECTIONS** has now been modified to extend for 7 days instead of 4½ (500 mg by mouth 4 times daily). The report, "Current Treatments in the Control of Sexually Transmitted Diseases" (WHO/VDT/83.433), includes treatment recommendations for *Chlamydia trachomatis*, syphilis, chancroid, and a variety of other STDs. It also discusses antimicrobial resistance in *N. gonorrhea* and the management of PPNG. To obtain a copy of the report, write: WHO, Bacterial and Venereal Infections Unit, Division of Communicable Diseases, CH 1211 Geneva 27, Switzerland.

Time to Evaluate

DIRECTIONS has been published for more than a year now, and it is time for us to evaluate whether or not we are achieving our goals and how we might improve. Our new, more compact size (starting with this issue) is one effort on our part to develop a more convenient format for our readers. Enclosed in this issue (for a randomly selected sample of our readers) will be a brief questionnaire designed to help us assess our publication. If you have not received a questionnaire, we would still welcome your comments and suggestions. However, we particularly urge those of you who receive questionnaires to fill them in and return them to us as soon as possible.

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PATH (Program for Appropriate Technology in Health) is a nonprofit, nongovernmental organization devoted exclusively to the development and application of appropriate health technologies for primary health care (PHC) programs in developing countries.

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Technologies for Pregnancy Care

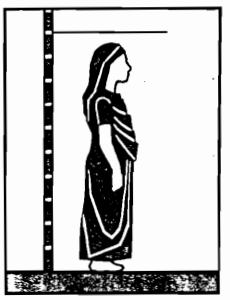
Although the majority of births in the world occur in developing countries, the rates of maternal and perinatal mortality and morbidity are disproportionately high in many of those countries. Maternal mortality (death from pregnancy-related complications) is the main cause of death among women of reproductive age, and in some areas represents as much as 10 percent of overall mortality. Further, it is estimated that, if current rates do not decrease, 40 million perinatal deaths will occur in the developing world before the year 2000. Even when perinatal problems do not lead to immediate death of the fetus or infant, they often compromise the infant's subsequent chance for survival and healthy development. Much of this mortality and morbidity could be prevented through antenatal care.

Recognizing and managing the high-risk pregnancy is an important concept in primary health care. The application of this concept to the organization of antenatal health services requires that basic care be provided to all pregnant women and that special attention be given to those women who need it more. By identifying women who are at higher risk of a poor pregnancy outcome, health workers can focus effectively on the interventions needed to improve the chances of favorable outcomes.

Technologies that can help prevent or minimize the complications of pregnancy are a key aspect of antenatal care. Some of these technologies are **hard;** that is, they involve equipment and drugs needed to provide care. Hard technologies include both diagnostic tools and medications used for treatment. **Soft** technologies—to promote and facilitate the use of hard technologies—are also needed. Examples of soft technologies include checklists or scoring systems for risk assessment, records on individual care and the health problems of the population, and support materials to promote healthy practices during pregnancy and to train health workers.

This issue of **DIRECTIONS** looks at available technologies for antenatal care and points out where new and improved ones are needed. The following categories of risk and actions and their associated technologies are reviewed:

1. Basic Care for All Women



2. Risk Assessment: Potential Danger

3. Immediate Danger: Immediate Action

The last section discusses aspects of program management, including goals, intervention strategies, record keeping, and training and supervision.

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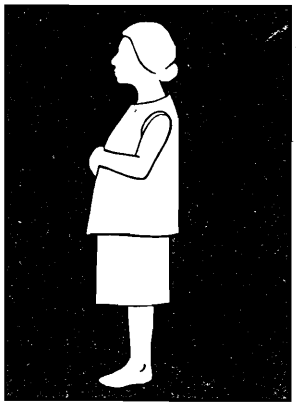
Basic Care for All Women



All pregnant women should have access to basic antenatal health care. The availability of such care allows high-risk groups and individuals to be detected.

One of the most important aspects of basic antenatal health care is advice on how the pregnant woman can keep healthy. The importance of a good diet (with foods rich in iron, folate, and calcium), of personal and domestic hygiene, and of rest and sleep should be emphasized. Pregnant women should also be taught ways to prevent or relieve the minor discomforts of pregnancy. Women should be told which conditions are normal during pregnancy and which ones are signs of danger. For example, vomiting during the first three months of pregnancy is common and is not a cause for concern; persistent vomiting after this time, however, requires immediate attention. Similarly, although edema (swelling due to fluid retention) is common in pregnancy, women should be informed that severe swelling is a sign of danger to both the mother and the fetus and requires medical care. Health workers should also discuss the importance of avoiding contact with others known to have infections such as tuberculosis. During antenatal visits, preventive health education on related topics (like birth spacing) to improve future pregnancy outcomes can be initiated as well. Even a woman with a normally progressing pregnancy should be encouraged to visit a health center for at least one routine check by another, more highly trained health worker.

Because neonatal tetanus is a leading cause of neonatal mortality in many developing countries, an essential component of antenatal care in those countries is tetanus immunization. With tetanus immunization, maternal antibodies pass across the placenta, providing passive protection to the newborn. Studies in developing countries have demonstrated that maternal immunization is a very effective way to reduce or eliminate deaths from neonatal tetanus. (Clean delivery techniques, to be discussed in the next issue of **DIRECTIONS**, can also prevent tetanus.)

In most areas where the incidence of neonatal tetanus is high, few women have received immunization prior to pregnancy. Unless adequate documentation of previous immunization is available, all women should be given two injections of adsorbed tetanus toxoid during their first pregnancy. The ideal schedule for un-immunized women is to provide the first dose in the fifth month of pregnancy and the second at least six weeks later but not later than four weeks before the expected date of delivery. However, because women often do not seek prenatal care until late in pregnancy, it may be difficult to follow this schedule. Shorter intervals between doses and between the last dose and the date of delivery will lead to lower levels of protection but should be used if necessary. Satisfactory protection can be achieved with two doses four weeks apart, with the second at least two weeks before delivery. Additional (booster) doses can be given with each pregnancy or up to five years after the primary series. A fourth dose within ten years may be enough for lifelong protection.

Another approach to the prevention of neonatal tetanus through immunization programs is to immunize all women of childbearing age. As above, two doses at least one month apart should be given. When mass immunization programs are carried out, women should be given a record that indicates the number and dates of doses given.

The existence of a vaccine that would provide immunity after a single dose would greatly facilitate the provision of antenatal care in developing countries. Although experiments with single-dose tetanus toxoid preparations have been carried out, further research is needed to confirm the safety and effectiveness of these preparations.

Indo-Dutch Project for Child Welfare

Risk Assessment: Potential Danger

At the same time that pregnant women are receiving basic antenatal health care, they should also be assessed for factors that can indicate potential danger or complications at the time of delivery. Actions (including referral) can be taken at the primary care level to minimize the complications to which these factors may often lead. Long-range programs or social interventions beyond the usual boundaries of health care, such as multisectoral programs to increase food production and improve food storage and distribution, may be what is needed to reduce or eliminate these factors.

Most risk factors are related to a woman's reproductive history or her personal characteristics. Table 1 lists examples of such risk factors, some of which can be detected through history-taking at any point during pregnancy and even prior to pregnancy.

Other risk factors require physical assessment, including abnormal presentation of the fetus (breech or transverse lie) late in pregnancy and the possibility of twins. All health workers should be trained to conduct an external examination of the abdominal area using touch (palpation) and be taught that it is the size and position of the fetus that is important, not the size of the uterus. If twins, a large baby in relation to the pelvis, malpresentation, or any abnormality are suspected, the woman should, wherever possible, be referred to a midwife or physician for delivery.

Abnormal presentation is more common in premature deliveries and multiple gestations. Because fetuses in the breech position often turn to the normal vertex position by the thirty-fourth week of pregnancy, referral to a health center for delivery should be made only if the malpresentation is still present after that time. Rates of twin delivery are much higher in African countries (32/1,000 live births in Ghana as opposed to 10 to 13/1,000 in India, for example). This is of practical importance, since health workers in those parts of the world where twins are more common will need more skills to identify, manage, and deliver twin pregnancies.

Risk factors are often arranged as checklists or indices for determining overall risk. Some indices have scoring systems, where different weights or scores, representing the different degrees of risk involved, are assigned to each fac-

TABLE I
SAMPLE RISK FACTORS*

Age	Usually over 35, or over 30 and primiparous Under 19
Obstetrical history	Usually five or more children First child Less than 24 months since last delivery Previous obstetrical complications, especially Caesarean section, perinatal deaths, low-birth weight baby, etc.
Medical history	Diabetes, heart disease, renal disease, psychoses, etc.
Maternal characteristics	Possibility of twins Deformities of the legs and pelvis Short stature Smoking Alcohol consumption Illiteracy Performs heavy manual labor

*The cut-off points or norms for each factor must reflect local conditions and available resources.

tor. An epidemiologic assessment of a given population should be conducted to identify the degree to which factors are actually associated with an increased risk of pregnancy-related problems (see page 10 for a discussion of the Population Attributable Risk approach to setting program priorities). Health workers add the weighted factors to get an overall score. Cut-off points for the total score are set to determine those women needing immediate referral to a midwife or physician or those to be booked at a hospital or health center for eventual delivery. Because most indices were developed for use in a specific population, they invariably require modification to reflect local conditions and available resources.

An alternative to a scoring system is a checklist of risk factors, which is more feasible in a primary care setting. Village health workers and traditional birth attendants can use checklists to carry out a preliminary selection of women at risk. A simple checklist should include questions about age and reproductive history as well as indicators of potential cephalopelvic disproportion at term (height, and deformities of the legs and pelvis). As with scoring systems, the significance of particular factors will depend on local conditions.

Another approach to deciding how to allocate resources on the basis of risk is to identify high-risk groups or communities rather than individual women at risk. Particularly in urban and periurban areas, where inadequate water and sanitary facilities and crowded housing are frequently found, there may be certain neighborhoods that are priority areas for intervention.

When modifying an existing scoring system or checklist or when developing a new one, there are several points to consider. First, the end-point or undesirable outcomes for each factor or group of factors must be specified (i.e., low birth weight, perinatal mortality, and/or maternal complications). The specified outcome should be one that is possible to treat and prevent, as well as important to society. Further, the checklist or scoring system should not be so complex that it is difficult or time-consuming for a health worker to administer or understand. When indicating the kind of action to take in cases of high risk, it is important to specify the ideal timing. It is not helpful to identify a woman at high risk when it is too late to provide care for her. In addition, the kinds of resources available for management of women at risk should be evaluated. If existing referral resources and personnel are sufficient to serve only 20 percent of all pregnant women, for example, the list or total score indicating risk should be adjusted to identify the 20 percent most in need of referral services. If treatment is not possible or appropriate referral facilities are not available, there may be little benefit in classifying a woman as high-risk.

In order to make decisions about which factors to include in a checklist or scoring system and the weight to assign to each, local epidemiological data on the frequency of health problems and their associated factors is needed. It may be feasible to design a checklist or scoring system based on discussions with health workers and local leaders. However, such measures of risk are often arbitrary, and when tested prospectively do poorly at distinguishing those women with a negative pregnancy outcome from the rest of the population.

Once an index or a checklist has been developed, it is important to evaluate its usefulness, or its validity. That is, how well does the index measure high risk among those who are truly at risk (sensitivity) and how well does the index define risk only where it exists (specificity)? Most indices are conservative (that is, the cut-off point is set low) and tend to misclassify women who are not at risk as high risk (false positive). This may mean an unnecessary use of scarce resources. On the other hand, if the cut-off points were raised to reduce the number of false positives, women needing special care might not be identified (false negatives), which could result in increased morbidity and mortality. There is always a compromise between the sensitivity and the specificity of any diagnostic tool, which must be taken into account when determining cut-off points.

This step, of evaluating the usefulness of an index, is often overlooked. When it has been done with existing sophisticated scoring systems, it has been found that as much as 50 percent of all women were identified as high-risk patients, and that among this 50 percent, as many as 90 percent are false positives (not truly at risk). Such inaccurate scoring systems can greatly increase the

UN/UNICEF 147,428

A health worker in Colombia measures fundal height.

costs of providing antenatal care without any significant reduction in morbidity or mortality.

Finally, it should also be kept in mind that many poor pregnancy outcomes are unpredictable. Some researchers have suggested that it is very difficult to predict which infants are really endangered until labor has begun. Including intrapartum indicators (factors which can be determined after labor has begun) greatly improves the predictive values of a scoring system. Unfortunately, unless a woman is already at or near a health center or hospital for delivery, or emergency transportation is available, there may not be sufficient time to initiate the proper actions. Several countries, including Zimbabwe, have established low-risk maternity facilities close to hospitals to facilitate emergency transfer.

In spite of the shortcomings of these indices, checklists and scoring systems of at-risk factors can improve antenatal care by serving as a screening mechanism and by standardizing referral patterns, thereby enabling a higher proportion of the pregnant women "at-risk" to receive special care during their pregnancies.

Immediate Danger: Immediate Action

Pregnant women, especially those in the last three months of pregnancy, should always be checked for signs of immediate danger so that early or emergency treatment can be provided.

Eclampsia and Preeclampsia

Toxemia, also known as preeclampsia, is one of the most dangerous conditions of pregnancy. During the last trimester of pregnancy, preeclampsia can progress rapidly to eclampsia (convulsions and coma), threatening the life of both the mother and child. While the causes of this condition are not known, primiparous women, women carrying twins, young adolescent women, and overweight women all have a greater risk of developing it.

The warning signs of toxemia are not difficult to detect and should not be ignored. Edema (fluid retention) in the ankles and especially in the hands or face is often the earliest and most obvious sign. Health workers should check to see if the ankle edema persists after a woman has been lying down on her left side for some time. Another way to check edema severity is to press a finger into the area and observe for an indentation or "pit" that remains.

Additional symptoms of toxemia that can be detected at the primary care level are severe headaches, upper abdominal pain, vomiting (late in pregnancy), dizziness, blurred vision, or any indication of fits (convulsions). A pregnant woman with any of these symptoms should be referred immediately to the midwife or health center.

Two other signs of toxemia, which require special equipment and additional training, are the presence of protein in the urine (proteinuria) and a rise in blood pressure. Specially prepared and easy-to-use dipsticks are available to check for proteinuria; alternately, a laboratory test can be carried out (see box). A protein level greater than 0.5 g/liter is a sign of severe preeclampsia. Limited resources may require that these tests be conducted only on those pregnant women who have been referred to a health center or hospital because one or more of the physical signs of preeclampsia was found. A sphygmomanometer and a stethoscope are needed to measure blood pressure; electronic devices for measuring blood pressure that do not require a stethoscope have been developed, but their accuracy is questionable. Diastolic blood pressure that remains above 90 mm of mercury even after the woman has had a rest period indicates the need for referral and treatment.

In the case of preeclampsia, rest, reduced salt intake, decreased work load, and careful observation by a health care worker are recommended. In more severe cases, treatment may include sedation, intravenous solutions, medication to reduce blood pressure, and referral for Caesarean section if necessary.

Anemia

In some developing countries, as many as 80 percent of pregnant women have been reported to have anemia (a reduced concen-

TESTING FOR PROTEIN IN URINE

PATH is currently developing a dipstick to detect the presence of protein in urine. The goal is to make an inexpensive dipstick available and, perhaps, to transfer the technology for local production. Those interested in further information should write to PATH.

Old Techniques Can Still Be Useful

Using a pipette or pouring very carefully, put 5 ml of urine in a clean test tube (where the 5 ml level has been marked). If the urine is cloudy, it must be filtered or centrifuged first. Using a dropping pipette or an eye dropper, add two drops of sulfosalicylic acid solution (300 g acid/liter water) to the urine. If there is protein in the urine, it will form a white precipitate when the acid is added, thus turning the urine cloudy. (Source: WHO, Manual of Basic Techniques for a Health Laboratory, Geneva: WHO, 1980.)

tration of hemoglobin or red pigment in the blood). An essential component of antenatal care, therefore, is the prevention, detection, and treatment of anemia. Severe anemia during pregnancy is associated with growth retardation (low birth weight), increased rates of late fetal death or stillbirth, and maternal complications, such as congestive heart failure, stroke, and infection. Even mild to moderate hemorrhage in an anemic woman can have severe consequences.

Anemia during pregnancy is often due to a combination of factors, but nutritional deficiencies (usually iron) and malarial infection are the most important. Other causes are parasitic infections such as hookworm, bacterial infections such as tuberculosis, and inherited red blood cell disorders such as sickle cell disease or the various thalassemic syndromes.

A simple, inexpensive and reliable technique for detecting anemia under field conditions is not yet available. A simplified hemoglobinometer has been developed at the Caribbean Food and Nutrition Institute but must still undergo field testing. Anemia is usually detected through laboratory tests of hemoglobin concentration or by measuring the hematocrit or packed cell volume. (See **DIRECTIONS,** Third Quarter 1983, for more details on techniques for detecting anemia.) The WHO suggested lower limit of normal hemoglobin concentrations for pregnant women is 11 g/dl (dl = 100ml); the lower limit for the hematocrit is 33 percent. Recent studies have suggested that an old method using copper sulphate to determine hemoglobin concentration merits renewed attention. The test is quick and easy to perform (see box).

Where the technologies to conduct these tests are not available, health workers should suspect anemia and refer the patient to a health center for further diagnosis and/or treatment when the following signs are present: extreme pallor, especially of the lips, tongue, fingernails and inner eyelids; weakness; fatigue; or difficulty breathing after exertion. None of these diagnostic tests can establish the actual cause of anemia. In primary care settings where individual diagnosis may not be feasible, it is probably better to establish the major causes of anemia through small, well-designed population surveys and then treat individuals on the basis of the local group information.

The first step in the prevention and treatment of nutritional anemia is to encourage all pregnant women to eat a diet rich in iron-containing foods. However, when iron reserves are depleted by closely-spaced pregnancies and poor general diet, it is difficult to replenish iron stores with diet alone. Additional supplementation can be provided by administration of oral iron preparations, such as ferrous sulfate or ferrous glutamate. Many months of oral treatment are required to replenish iron reserves—generally 120 mg ferrous sulfate tablets taken once a day for 10 to 15 weeks is sufficient, although the dose needed may vary.

COPPER SULFATE TEST FOR ANEMIA

In Jamaica and rural India, health workers screen the hemoglobin concentration of pregnant women using the copper sulfate method. Two cut-off points, 10 g/dl and 8 g/dl are used. To perform this test, a drop of blood from the finger tip is dropped into a copper sulfate solution.* Within 10 to 15 seconds, the health worker observes the position of the drop in the solution.

INTERPRETATION OF COPPER SULFATE TEST RESULTS

Position of drop	Hemoglobin concentration g/dl	Action to be taken
Solution I	**Specific Gravity 1.0477***	
Drop sinks	more than 10 g/dl	One 200 mg tablet ferrous sulfate per day
Drop is suspended	equal to 10 g/dl	One 200 mg tablet ferrous sulfate per day
Drop floats on surface	less than 10 g/dl	Repeat screening in Solution II
Solution II	**Specific Gravity 1.0435***	
Drop sinks	more than 8 g/dl and less than 10 g/dl	Three 200 mg tablets ferrous sulfate per day
Drop is suspended or drop floats on surface	less than or equal to 8 g/dl	Three 324 mg tablets ferrous fumarate and 5 mg folate per day

The solutions are reusable; drops of blood remaining at the bottom of the containers will not affect subsequent testing.

*A laboratory technician should prepare these solutions.

For women who are not seen by health workers until late in their pregnancy, iron stores can be replaced with less delay by administering the iron parenterally. The intravenous route is recommended over the intramuscular when possible. Both methods are, however, occasionally associated with serious side effects, including anaphylactic reactions. Injected preparations are also more expensive, but they do eliminate the need for multiple visits to a health center. Because of the risk of side effects, though, their use in primary care programs is only rarely justifiable.

Research is being conducted on the use of slow-release types of oral iron preparations that have fewer side effects and require less frequent administration. At present, however, the cost is much higher than that of conventional iron compounds.

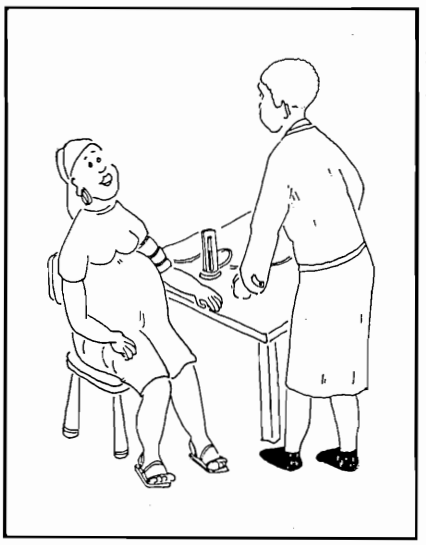
In areas where the prevalence of nutritional anemia is high, it is often the policy to provide all pregnant women with iron and folate supplements. If an iron supplement is to be used routinely in a prenatal program, a pilot study carried out in a representative sample of women can be helpful in determining the optimum dosage.

Women should always be told of possible side effects of iron supplementation, particularly nausea, vomiting, diarrhea, and constipation. These complaints are dose-related; taking the iron together with a meal can decrease their frequency. This will, however, reduce the ability of the body to absorb the iron. High consumption of tea also reduces the body's absorption of iron. The patient's stools will become black, and this discoloration may be disturbing to some women. Finally, it may be difficult to ensure that women take the medication daily, especially if side effects occur.

When causes other than nutritional deficiency contribute to anemia, treatment must be directed to the condition itself to alleviate the anemia. Appropriate medication for malaria (see below), hookworm, and bacterial infections are usually available at health centers. There is no specific treatment for anemia caused by the inherited blood disorders, except transfusion of packed red blood cells. In the case of thalassemia major, providing women with iron supplements may lead to toxic iron overload.

Malaria

Malaria is common in many parts of the world. Not only does it contribute to anemia, but mothers with malaria are more likely to deliver low-birth-weight babies. The effects of malaria on partially immune women and nonimmune women and their babies differ, however. Among partially immune women (from endemic malarial areas), the most serious consequence of malarial infection is anemia. Among nonimmune women (who previously resided in nonmalarious areas or who live in areas of nonstable malaria), untreated malaria can lead to death. In areas where malaria is endemic, routine malaria prophylaxis for nonimmune women should be initiated.



Maendeleo ya Wanawake, Kenya

In most cases, a single dose of 600 mg of chloroquine will eliminate fever and reduce the parasite load. In areas where the malaria is chloroquine-resistant (see **DIRECTIONS**, Second Quarter 1983, on Drug Resistance), the options for prophylaxis and treatment are less clear-cut. The effects of the malaria must be weighed against the effects of the drugs (Fansidar, quinine), whose safety in pregnancy have not been established.

Other Dangers

Aside from the fact that blood loss can contribute to anemia, vaginal bleeding during the last part of pregnancy may be a critical warning sign of **placenta previa**, where the placenta occupies the lower part of the uterus, or **abruptio placentae**, where the placenta partially separates from the uterine wall before delivery. Vaginal bleeding early in pregnancy may be a warning of impending abortion. Any pregnant woman reporting such bleeding should be referred immediately to a health center or hospital.

Some dangerous pregnancy-related conditions, such as female circumcision, are limited to certain regions of the world. Female circumcision can cause obstructed labor and lead to uterine rupture, endangering both the mother and the fetus. It is very important that antenatal care include steps to detect, refer and/or treat, as indicated, such culture-specific conditions.

Sexually transmitted diseases (STDs), especially syphilis, gonorrhea, and Hepatitis B, are other examples of dangerous conditions that may not be problems in all parts of the world.

Gonorrhea and syphilis can have serious consequences for the developing fetus or newborn child. When facilities are available, screening tests can be carried out and antibiotic therapy initiated. At the primary care level, as with anemia, the population or epidemiologic approach is probably the most effective. A small study to determine the prevalence of STDs among a population and to define any characteristics that identify a high-risk group can be used as the basis for general treatment recommendations. Hepatitis B has been suggested as the most common cause of maternal deaths in developing countries. While expensive and sophisticated technologies are needed for a definitive diagnosis, all pregnant women with jaundice (yellowness of the skin and conjunctiva) require referral. A new vaccine for Hepatitis B is currently undergoing field trials.

Dangers to the Growing Fetus

Other danger signs during pregnancy include decreases in fetal movements and fetal heart sounds. Fetal movements can usually be felt by the fourth month of pregnancy. Most healthy fetuses will move at least 10 times in 12 hours. Mothers can be encouraged to monitor fetal movements by counting the first 10 kicks of the fetus during a day and noting the time of the last kick. If the tenth comes later and later each day, the fetus may be in danger. Fetal heart sounds can usually be heard beginning with the fifth month of pregnancy. Fetoscopes, or hollow tubes that are narrower at one end where the ear is placed, can be used to detect the heartbeat. These tools can be made locally from wood, fired clay, plastic cones and other materials. Fetal heart beats can also be heard by placing one's ear directly against the woman's abdomen over the fetal shoulder.

Indo-Dutch Project for Child Welfare

TAKE IRON AND FOLIC ACID TABLETS

Husbands or other family members can be taught to monitor fetal heart rates as well. The normal fetal heart rate is 120-160 beats per minute; anything less, and the health of the fetus may be in danger. During the last month of pregnancy, a fetal heart sound heard above the woman's umbilicus may mean a breech presentation. Also, if no heartbeat is heard after repeated attempts, the woman should be referred.

Monitoring fetal growth to detect growth retardation is another important element of antenatal care. Measuring fundal height is one simple method. This can be done using a nonelastic tape, marked in centimeters, or with appropriately colored segments indicating the upper and lower limits of uterine height for the last three months of pregnancy. Health workers will need to estimate the duration of pregnancy to assess fetal growth. If a woman does not know the date of her last menstrual period, other methods of estimating gestational age can be used. About the twenty-fifth week of pregnancy, fetal parts can be felt through the abdominal wall. From the twentieth to the thirty-fourth weeks of pregnancy, the gestational age in weeks is approximately the same as the fundal height in centimeters, if growth is progressing normally. Any time that fetal growth retardation is suspected, especially when it occurs in combination with other signs of fetal danger, the woman should be referred for assessment and treatment.

Maternal malnutrition presents another danger to the developing fetus as well as to the mother. It is difficult to assess the nutritional status of a woman with a single measurement (see **DIRECTIONS**, Third Quarter 1983, on Assessing Nutritional Status). Some programs have used arm circumference to detect maternal malnutrition, but its predictive value with regard to pregnancy outcome is a subject of controversy. Monitoring weight gain during pregnancy is another method, but prepregnancy weight and an accurate scale are needed to do this.

Women who have had many children at closely spaced intervals, women with diseases such as tuberculosis, malaria, diarrhea, and parasitic infections, and women from cultures that have beliefs that prevent them from eating nutritious foods during pregnancy are at a high risk of malnutrition. Heavy work loads and other energy-using activities also increase the nutritional needs of pregnant women and may reduce fetal weight gain. Women who are extremely thin, with loose folds of skin, are probably very malnourished. Providing such women with food supplements during pregnancy and lactation may improve the birth weight and chances of survival of the child. The kind of supplement (whether mainly protein or energy) and the amount should be determined after taking into account the nature of the most common nutritional problems of the local population as well as the resources required for carrying out a supplementation program. The value of supplementation during pregnancy is still not well-documented; more research is greatly needed.

Program Management

Although the major emphases of antenatal care are similar throughout the developing world, each country needs to develop its own strategy for implementation and to determine what the content of care will be. It may also be necessary to develop individual approaches for different regions within a country. Planning and establishing an antenatal care program (or the antenatal component of an overall maternal and child health program) that makes the best use of available technologies and resources while meeting local needs requires a clear statement of program goals. Goals can be determined by an assessment of local health problems and the selection of priorities. Once the goals of a program have been set, decisions about the best intervention strategy can be made, after considering the costs and benefits of different actions. Information on health problems, service utilization, and the availability of resources is a basic need for the development, as well as the ongoing monitoring and evaluation, of local strategies.

Selecting Priorities for Intervention

Most of the undesirable outcomes of pregnancy (perinatal and maternal mortality and morbidity) and their associated causes and risk factors (low birth weight, anemia, or birth trauma, for example) are widespread occurrences. The selection of priority health problems is based on several criteria, including prevalence, seriousness, manageability, and level of community concern. For each health problem, each criterion needs to be assigned a weight, which is then added or multiplied to give a rank order. Most frequently, weights are assigned on an intuitive basis. Where adequate statistical data exist, though, it may be possible to do this using the concept of Population Attributable Risk. Population Attributable Risk percent (PAR%) refers to the proportion of all cases of a disease (or of a particular outcome such as neonatal death) in a given population that are attributable to a particular factor. It reflects both the relative risk associated with the factor and the frequency with which the factor occurs in the given population. Using this concept, a particular factor that is both dangerous (for example, neonatal tetanus), and accounts for much death would rank as a high priority for intervention efforts. PAR% is calculated as

$$\frac{\text{Incidence of disease (or outcome) among those exposed to factor}}{\text{Overall incidence of disease (or outcome) from all causes}} \times 100$$

Finally, the selected priorities need to be examined in relation to overall national health policies and priorities.

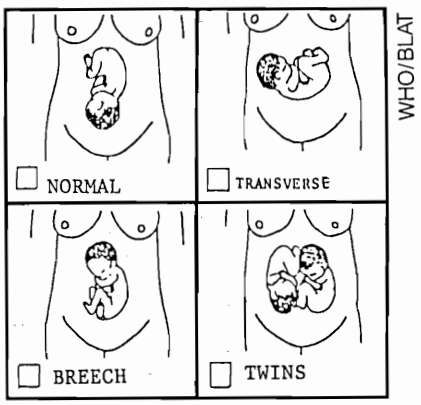
In addition to ranking the biologically definable outcomes (perinatal mortality, for example), program planners and managers may want to look at "service outcomes" for defining priorities for intervention. Service outcomes are measures of the utilization and coverage of health services, such as the number of antenatal visits made or the number of women receiving two doses of tetanus toxoid. Although such numbers are not strictly related to health status, it is usually assumed that an increase in the use of health services will result in improvements in the health of the population.

This process of selecting priority health problems for intervention provides the information necessary to set program goals. Each goal should identify the outcomes or risk factors that are to be improved by the intervention. Specific objectives that reflect program goals should be expressed numerically to allow for program evaluation, to assess whether changes in practices or reallocation of resources are needed.

Developing Local Strategies

After goals have been set, the best strategy for intervention can be determined. This will depend on the available resources, including personnel, facilities, and equipment, and on the organization of services, particularly the ability to supervise, maintain supplies, and facilitate referral. In areas where primary care is provided by health workers with little training, such as traditional birth attendants (TBAs) and village health workers, a basic component of antenatal care is the early recognition of danger signs and risk factors on the basis of history and clinical observation. The provision of information on the importance of tetanus immunization and healthy practices during pregnancy should be the other major emphasis. Where more highly trained personnel are available, such as nurse-auxiliaries or nurse-midwives, the content of antenatal care can be expanded and referral patterns

modified. Outlining the overall strategy requires a definition of the tasks to be performed at each level of care, as well as a specification of how and when they will be performed and by whom. Such detailed outlines of program operations can serve as a basis for training and supervision. These explicit statements, along with the numerically defined objectives, also provide the criteria for monitoring and evaluating the program.



Example of part of pictorial antenatal care record.

Maintaining Records and Providing Support Materials

A record-keeping system is an essential component of an antenatal intervention strategy. Carefully designed records enable program managers to identify the health problems of the population, monitor the use of health services, and evaluate the outcome of an intervention. They also serve as action guides for health workers, indicating the important questions to ask, the risk factors to detect, and the actions to take for the care of individual women. Records can also be used as educational tools for mothers by printing on them messages and symbols that reinforce advice about proper care during pregnancy. A separate record of antenatal care is not necessary. It is most practical to include the events of the antenatal period in an overall "mother's card" that covers care through pregnancy, delivery, and the first month postpartum. A new WHO "home-based" mother's card has space for several pregnancies and intervening contraceptive use. These simple mother-retained cards are now being tested in Fiji, India, Mexico, Panama, and the Philippines. Such cards facilitate continuity of care as well as the evaluation of the results of an intervention.

Information for women on care during pregnancy is an important component of antenatal intervention strategies. To increase the effectiveness of such educational programs, printed materials (flip charts, booklets, posters) are often used to communicate ideas about healthy practices during pregnancy. These materials need to be carefully prepared, field tested, and revised to ensure that they are understood. The messages to be communicated should be clearly identified and the number of messages limited. Above all, local customs and resources should be kept in mind during the design phase. The next issue of **DIRECTIONS** will include a discussion of the development and use of records and support materials for nonreaders.

Training and Supervising Health Workers

An antenatal intervention strategy may require the training of more health workers. Currently, the emphasis is on using and training locally available people for the provision of primary health care. In the area of antenatal health care, this is usually the traditional birth attendant. Training programs for TBAs do not focus exclusively on the antenatal period, but it is important to include elements of such care in training. The exact content of training will depend on the overall local strategy and the kind of services the TBAs are currently providing. In addition to an initial training course or program, there is always a need for in-service training and rigorous supervision of personnel.

Even in areas where resources are extremely limited, a few simple antenatal care measures can have a significant impact on maternal and perinatal mortality. Although there is a need for new and improved technologies (a simple and accurate method for detecting iron-deficiency anemia, for example) and for further field-testing and refinement of existing ones (analysis of the validity of high risk indices, for another), antenatal services can be improved without waiting for these developments. Often the problem is bringing these technologies to the women who can benefit from them. In many areas of the world, less than one-fourth of all pregnant women receive antenatal care.

Well-designed support materials that take into consideration the local cultural conditions as well as the health needs of pregnant women can greatly facilitate the introduction of new technologies and expand the coverage of antenatal health services. Village health workers, TBAs, and community leaders also have a key role in informing communities of the importance of antenatal care and encouraging all women to seek it.

Materials Available

For those interested in reading more about antenatal care, a reference list and more information on any of the technologies discussed in this issue are available from PATH.

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Several previous issues of **DIRECTIONS** have had detailed discussions of topics related to antenatal care. These include: "Assessing Nutritional Status: Practical Measures for Primary Health Care" (Volume 3, Number 3) on maternal nutrition; "Drug Resistance: An Urgent Problem" (Volume 3, Number 2) on treatment of malaria and gonorrhea; and "Immunization: A Key to Primary Health Care" (Volume 3, Number 1) on tetanus immunization. Single copies of these back issues are available free from PATH.

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The BLAT (British Life Assurance Trust) Centre for Health and Medical Education has recently published the package, **A Traditional Birth Attendants' Trainer's Kit,** on behalf of the World Health Organization. The kit has three parts: Part one deals with TBA training; Part two has suggestions for lesson planning; and Part three is a collection of learning resources. BLAT Centre is actively seeking the comments of as many TBA trainers as possible regarding the usefulness of the kit. For more information, please contact: BLAT, Centre for Health and Medical Education, BMA House, Tavistock Square, London WC1H 9JP, U.K.

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A revised edition of the World Health Organization's document, **Risk Approach for Maternal and Child Health Care** (WHO Offset Publication No. 39, Geneva: WHO, 1978) will be published soon. A new workbook of detailed methods for risk assessment (Public Health Paper No. 76) is now available in Spanish and Portuguese. A French language version should be available in late January, 1984, and an English language version at the end of February, 1984. To order these publications, contact the WHO Regional Office or write to WHO, Distribution and Sales Service, 1211 Geneva 27, Switzerland.

INTERCHANGE

The next issue of **DIRECTIONS** will look at technologies for labor and delivery, newborn care, and postpartum care. If you have any comments or suggestions on these topics, we would like to hear them.

■

Evaluations

Enclosed in our last issue (for a randomly selected sample of readers) were brief questionnaires designed to help us to assess **DIRECTIONS.** If you have not completed and returned your questionnaire yet, we would like to remind you to do so. This kind of feedback is very helpful. We also welcome comments from those who did not receive questionnaires.

■

The last issue of **DIRECTIONS** contained an illustration of a lightweight and portable baby length measurer that can be made locally. This measurer was designed by the Appropriate Health Resources and Technology Action Group (AHRTAG) on behalf of the World Health Organization. Copies of the working drawings to make the measurer are available free from AHRTAG, 85 Marylebone High Street, London W1M 3DE, England.

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DIRECTIONS is published four times a year. Single copies are distributed at no cost to health program managers in developing countries and others interested in primary health care programs. References to commercial products do not constitute endorsement by PATH.

We encourage nonprofit organizations to quote, excerpt, or translate the information in **DIRECTIONS.** Please acknowledge the source as "Health Technology **DIRECTIONS**" (issue date), Program for Appropriate Technology in Health (PATH), and send us a copy for our files.

PATH (Program for Appropriate Technology in Health) is a nonprofit, nongovernmental organization devoted exclusively to the development and application of appropriate health technologies for primary health care (PHC) programs in developing countries.

health technology
directions

PATH Program for Appropriate Technology in Health

Primary Eye Care

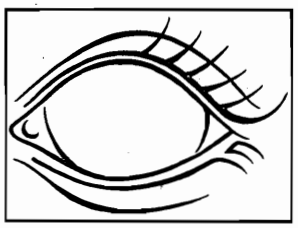
Blindness affects more than 40 million people in the world today. At least 75 percent of the blind live in developing countries, where blindness prevalence rates run from 10 to 40 times higher than those of the industrialized countries.

Some of the causes of blindness are universal, particularly those associated with the aging process (cataracts), metabolic disorders (glaucoma), and trauma (accidents). The other major causes of blindness—nutritional blindness (xerophthalmia), river blindness (onchocerciasis), and trachoma—are found almost exclusively in the developing countries. These causes have been almost eradicated from developed nations as a result of improved standards of living and access to health care.

Blindness has a tremendous impact, not only on the quality of individual lives but also on the economies of developing nations. The cost of blindness in Third World countries has been estimated to be a minimum of $1.1 billion a year. In addition to the costs of providing care and rehabilitation, when available, blindness often means the end to a person's economically productive life.

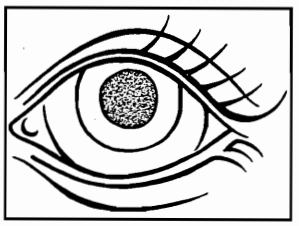
Yet four out of five cases of blindness could be prevented or cured. Technologies are a key aspect of any strategy to reduce the rates of blindness. Diagnostic tools, medications, and surgical equipment are, however, only part of a blindness-control technology package. Equally important are the delivery systems, which can ensure that available technologies reach those people most in need in a culturally appropriate and cost-effective manner.

This issue of **DIRECTIONS** deals with the leading causes of blindness in the developing world, giving special emphasis to technologies for the control of xerophthalmia and cataract. The last section discusses program management, focusing on the integration of eye care into primary health care and personnel training. A future edition of **DIRECTIONS** will provide a detailed review of onchocerciasis and trachoma and their related technologies.



1. Leading Causes of Blindness

2. Xerophthalmia



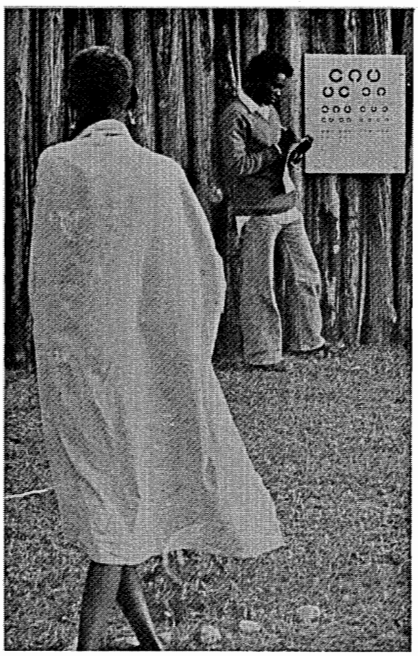
3. Cataract

Volume 5, Number 1 ISSN: 0730-8620 First Quarter 1985

HOW TO MEASURE VISION LOSS

Blindness is defined as a visual handicap that does not allow the individual to function effectively in the community without special assistance. Visual acuity (the ability to see objects clearly at a distance) is the most readily tested indicator of visual function.

Levels of visual acuity can be expressed according to three different notations: the decimal, the 6-meter scale, and the 20-foot scale. In the 6-meter and the 20-foot scale notations, the numerator is the distance at which the test is performed (the 6 in 6/60 or the 20 in 20/200); the denominator is the number assigned to the smallest line of figures the patient can read correctly (the 60 in 6/60 or the 200 in 20/200). Normal vision is considered to be 1, 6/6, or 20/20. To say a person has a visual acuity of 1/10 (expressed as 0.1), 6/60, or 20/200 means that this person must be at 1 meter, 6 meters, or 20 feet, to see what a person with normal vision can see at 10 meters, 60 meters, or 200 feet, respectively.



International Eye Foundation

To test visual acuity, test letters or figures (optotypes) of different sizes are needed. In industrialized countries, alphabet letters are often used. In areas where the level of illiteracy is high, a single letter or symbol which can be understood by the person being examined is more appropriate. In Kenya, the Landolt "C" is described to the patient as a corral with a door, and the patient is asked to point the way out. For the tumbling "E," the patient indicates by imitation with his or her fingers the direction the "E" is pointing. Another African country has used optotypes of village huts.

Single optotypes of different sizes can be used or multiple optotypes can be arranged in lines on a chart, with the largest figure on the top line. Each line corresponds to a level of visual acuity.

The relative size or scale of the optotypes on each line used depends on the testing distance (the distance between the chart and the patient). If it is not convenient or practical to place a chart at six meters, testing can be done at three meters, or half the standard distance. The optotypes of standard charts will then be twice their normal size. To compensate for this change, they should be assigned a denominator twice that designated. For example, the standard 6/60 optotype would have a value of 6/120 (or 3/60) at three meters.

The number of lines on a chart can also be modified according to the purpose of the testing and health care level at which it is carried out. For surveys to measure the prevalence of blindness, at least four lines which define categories 1 through 4 of visual impairment are useful (6/18, 6/60, 3/60, and 1/60 or their equivalents). In a primary health care setting, where the objective is to identify individuals in need of referral to more specialized eye care, the lines 6/6, 6/9, 6/18, and 6/60 may be sufficient. Any patient with a visual acuity worse than 6/18 can be referred to a secondary level.

Charts can be made locally. In the Philippines, optotypes are silk-screened onto a piece of cloth which is lightweight and easily transportable. Other countries use sturdy cardboard or light boards with varnish to protect them. A red line is often drawn under the line of optotypes equivalent to normal or near normal visual acuity. It is important to make the optotype the appropriate size for the testing distance, to define each line on the chart and, if possible, to print instructions for testing and recording visual acuity.

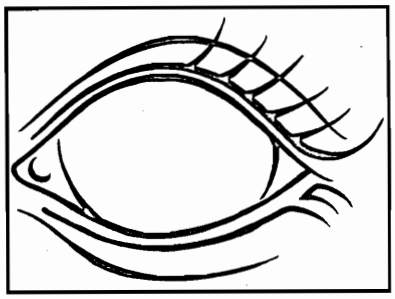
Additional equipment needed to conduct a test of visual acuity includes an occluder to cover one eye and a string to measure the testing distance. A flashlight can be used to test for light perception, although this is a very qualitative measure and may be difficult to interpret. The chart should be hung at the patient's eye level on a wall in a well-lit area with no glare.

For those who cannot be tested satisfactorily because they do not understand the test or are unwilling to cooperate, the ability to count clearly separated, extended fingers at a distance of three meters can be considered the equivalent to a visual acuity of 3/60, and at one

meter, to 1/60. This measure can be used as a screening indicator to determine whether or not more definitive surveys of ocular status are needed. The ability of the eye to fix on and follow a target may also be tested. This may confirm the **presence** of vision, but it cannot determine a **level** of visual acuity.

Untestability should be recorded, as it can influence the data analyses in surveys or lead to unnecessary referrals. If the patient is wearing eyeglasses during the test, this also should be noted.

Leading Causes of Blindness



In the developing world, the impact of four eye diseases on blindness prevalence rates is so great that control of these alone could reduce the level of blindness almost to the rate now found in the United States (0.2 percent). The pathology and epidemiology of these four diseases are described below.

Xerophthalmia

Xerophthalmia, or nutritional blindness, was first recognized thousands of years ago. Today, it is the leading cause of child blindness in the developing world. It is estimated that up to ten million children develop this disease every year and that more than a half million lose their sight. In the larger countries of Asia (Indonesia, India, Bangladesh, and the Philippines), five million children are affected. It is also known to exist in Africa, Latin America, the Caribbean, and the Eastern Mediterranean.

Xerophthalmia results from an insufficient supply of vitamin A to the tissues of the eye. In the absence of vitamin A, the epithelial tissues of the eye and other organs become thickened (keratinized) and necrotic.

The effects of vitamin A deficiency on the eye range from reversible alterations in the retina and conjunctiva to severe and irreversible changes in the cornea, with a high probability of partial or total blindness. Keratinized epithelium in the lungs and intestines may also contribute to the respiratory and gastrointestinal infections that occur more frequently in xerophthalmic children. In addition, research has found that even children with mild vitamin A deficiency may have a mortality rate four to eight times higher than children without an apparent deficiency. New data suggest that mild deficiencies may also increase the risk of morbidity due to upper respiratory disease and diarrhea.

Other factors contribute to or precipitate xerophthalmia. The cause and importance of each factor varies from one community to another. In addition to diets deficient in vitamin A, known risk factors include absence or early termination of breastfeeding, generalized malnutrition, diarrhea, respiratory tract infection, worm infestation, measles, and tuberculosis. Any one or a combination of these factors can affect the availability and utilization of vitamin A reserves. For example, diarrhea will decrease the absorption of vitamin A at the same time that dietary intake may be reduced because appetite is depressed and/or foods containing vitamin A are withheld. Although vitamin A deficiency can occur at any age, these risk factors are most often found in populations of children under five.

Cataract

Cataract, a cloudiness or opacity of the lens in the eye, is the leading cause of blindness in the world. Approximately 17 million people (16 million of them in developing countries) throughout the world are blind from cataracts. Every year over 1 million new cases develop. It is estimated that in India alone, 25 million people are affected, 5 million of whom are blind. Prevalence surveys have found that the age of onset is earlier and that rates of cataract and cataract blindness are higher in developing countries than in developed countries.

In the normal eye, the lens is transparent, and serves to focus light onto the retina. Cataracts are opacities that obstruct the passage of light and may impair vision. One or both eyes may be affected. Opacities vary in size, number, and location. The effect on vision depends on the size,

density, and location of the cataract. Small cataracts on the periphery of the lens may have no effect; more extensive ones, or ones in the center of the lens, may result in severe visual impairment and blindness. There is no known means of preventing cataract formation, but sight can be restored by surgical removal of the lens.

Senile, or aging-related cataract, is by far the most common kind, although there are several other types. Despite its high prevalence, little is known about its natural history or its risk factors. Epidemiologic research has confirmed the association of cataracts with several factors that may play a role in their development. These factors are diabetes mellitus; exposure to ultraviolet light and to ionizing, infrared, and microwave radiation; poor nutritional status; exposure to toxic drugs and chemicals; and biochemical variables. Although an association exists, none of these can be said to be the cause of senile cataracts. Important causes are probably multifactorial and synergistic. Further research on possible risk factors is needed so that measures to prevent or delay the development of cataracts can be identified.

In addition to the higher rates of cataract found in developing countries, premature cataract development has been reported in India, Nepal, and Africa. In these areas, cataract begins to appear as a cause of blindness in the fourth and fifth decades of life, whereas it more commonly occurs in the sixth or seventh decades in the United States. This finding, together with a rise in life expectancy in the developing world and the corresponding increase in the number of elderly people in these countries, means that unless control measures are implemented, the magnitude of cataract blindness will increase five times by 2025.

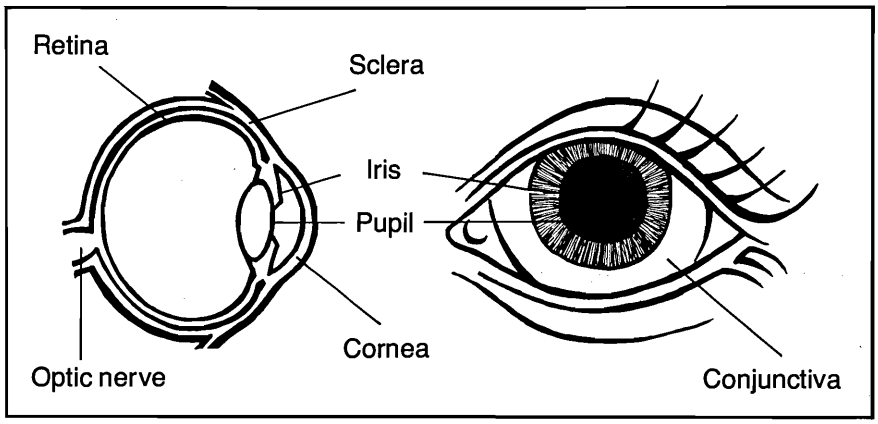
A major problem in understanding the etiology and epidemiology of cataracts, and consequently in determining appropriate intervention strategies, is the lack of a uniformly accepted method of measurement and classification. A standardized photographic system used for classifying human cataracts for laboratory study is not suitable for use under field conditions because it requires complex equipment. The development of a classification system for field use would also facilitate research efforts.

Onchocerciasis

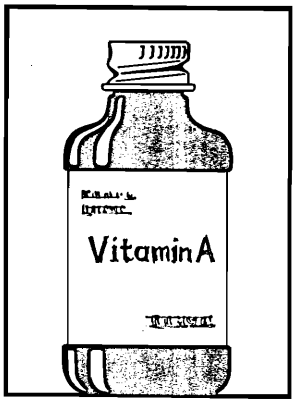
Onchocerciasis, or river blindness, is a parasitic disease that infects as many as 50 million people. One million people are blind as a result of the eye lesions caused by this disease. In villages where the disease is widespread, as much as 50 percent of the adult population may be blind. Onchocerciasis occurs throughout the area of Africa south of the Sahara, in Yemen, and in parts of Central and South America. It is caused by the filarial worm, **Onchocerca volvulus,** which has a complex life cycle involving humans and blackflies of the **Simulium** species, the vector of this disease. The blackfly requires fast-moving water for breeding. Some of the most fertile, arable valleys of Africa are infested by the vector; as a consequence, these areas have been abandoned by the people previously living there. The current strategy for prevention is to control and eventually eradicate the blackfly population by the application of insecticides over a period of 20 years. Several drugs are available for treatment, but they are so toxic they cannot be used on a large scale.

Trachoma

Trachoma, the world's leading cause of preventable blindness, affects an estimated 400 to 500 million people. Approximately 6 million people have been blinded by it. Trachoma is widespread in rural communities of the developing world. The highest prevalence rates occur in parts of Africa, the Middle East, and the drier regions of southeast Asia, but the disease is also found in Latin America and the Pacific. Trachoma is a chronic, contagious, inflammatory disease that can lead to scarring of the conjunctiva, deformities of the eyelids, corneal opacity, and blindness. The infectious agent is **Chlamydia trachomatis,** which is transmitted person to person by close contact and by flies common to the areas where it occurs. The severity of the disease is often related to environmental factors, such as lack of water and poor sanitation. Current preventive and control measures include treatment with antibiotics, surgical intervention to correct eyelid deformities, health education, and improved sanitation.



Xerophthalmia



Diagnosis

Xerophthalmia is diagnosed by the presence of one or more of its clinical signs (see box).

A clinical examination is not required to detect night blindness, which is often the earliest symptom of vitamin A deficiency. A history of night blindness, elicited from a child's parent, is a valid indicator of vitamin A deficiency. Reports indicate that in areas where vitamin A deficiency is known to exist, there are usually local terms, such as "chicken blindness" (because chickens cannot see in the dark), to describe this condition. Even where no local term exists, the symptoms, such as stumbling, are generally familiar to mothers. Relatively untrained field workers and even school children may be taught to identify this sign, especially if a local term for the condition exists.

A clinical examination is required to recognize other signs of xerophthalmia. Color photographs and line drawings depicting the clinical signs of vitamin A deficiency (xerophthalmia recognition cards) can be used as diagnostic tools and training aids.

Conjunctival xerosis and Bitot's spots are easily recognized by the trained health worker and represent the earlier, milder manifestations of xerophthalmia. They are more prevalent than corneal disease, and their presence identifies children at increased risk of developing destructive corneal lesions.

Corneal xerosis and ulceration and keratomalacia are the most severe manifestations of vitamin A deficiency. Although they are easily diagnosed, they are relatively rare. Sometimes corneal lesions caused by vitamin A deficiency are secondarily infected by bacteria, making it difficult to recognize xerophthalmia. In such cases, evidence of conjunctival xerosis and other factors associated with xerophthalmia can aid in diagnosis. Measles and other illnesses can bring on a rapid and sudden deterioration in vitamin A status, and corneal lesions may appear before the typical conjunctival changes. Corneal scars require a detailed history and interpretation by a highly trained health worker to determine the cause.

Biochemical tests can be used to detect vitamin A deficiency, but they are not sufficient to estimate the level of clinical disease. Determination of serum retinol (vitamin A) levels requires the availability of laboratory facilities and a trained technician.

Recent research has found that the relative dose response (a comparison of the fasting serum retinol level with the level after administration of a small dose of vitamin A) is a useful test for detecting children with critically depleted liver stores. Although such children show no clinical signs, they are at very high risk of developing xerophthalmia, especially the blinding corneal lesions that measles and other infections can precipitate.

Dietary histories can provide an understanding of the causes of vitamin A deficiency. Family-based qualitative histories to determine family food patterns, individual child histories with questions on breastfeeding and

SIGNS OF XEROPHTHALMIA

Night blindness (XN): The inability to see in the dark.

Conjunctival xerosis (XIA): A dryness and roughness of the conjunctiva.

Bitot's spots (XIB): Patches of xerosis covered by a fine foamy or cheesy material.

Corneal xerosis (X2): A dry, rough, hazy, pebbly appearance of the cornea.

Corneal ulceration (X3A): A disintegration of the corneal tissue. May be superficial or deep and perforating.

Keratomalacia (X3B): Melting or necrosis of the cornea. May be localized or involve entire cornea.

Corneal scars (XS): Results from healed disease.

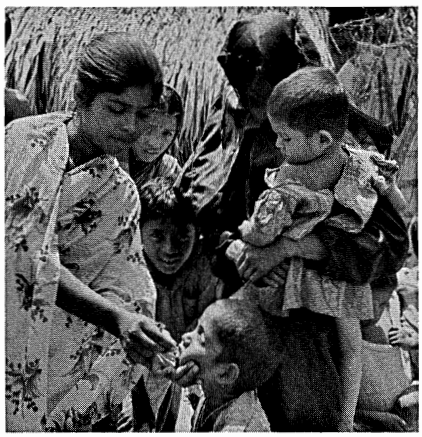
Xerophthalmia fundus (XF): Small, white lesions on the retina.

weaning, and 24-hour quantitative histories to try to determine the exact quantities of food a child has eaten are methods that can be used. A well-trained health worker is needed to take and evaluate a quantitative history, but most health workers can qualitatively determine if the child's diet is likely to be inadequate in vitamin A.

Treatment

All children with any of the signs of active xerophthalmia and all severely ill or malnourished children in areas where xerophthalmia occurs, whether or not they show evidence of clinical disease, should receive vitamin A therapy. The schedule is shown in Figure 1. With this therapy schedule, night blindness will disappear within 24 hours; conjunctival and corneal xerosis, corneal ulceration and localized corneal destruction will begin to respond within two to three days. But if necrosis is already complete, the eye cannot be saved.

Vitamin A ester is available for periodic dosing in individual 100,000 IU and 200,000 IU dose gelatin capsules. (The use of International Units for pharmaceuticals was officially discontinued 20 years ago, but their use for Vitamin A still persists. The equivalents in milligrams [mg] are 55 mg and 110 mg, respectively.) In India, multiple-dose bottles of vitamin A are used. The concentrated dosage noted above can be given by standardized spoons or droppers at a cost of less than US $.05 per single dose. For newborns, 50,000 IU capsules are needed for periodic dosing, but are less readily available. Where unavailable, appropriate portions of high-potency capsules can be used. The high-dosage capsules are to be used for prophylaxis on a 4- to 6-month periodic dosing schedule, not daily. For pregnant women, single doses above 10,000 IU should not be given, but this level is safely taken daily.



Helen Keller International, Inc.

Vitamin A distribution in Bangladesh

Only **water-based** vitamin A should be used for injections. Oil-based preparations are liberated too slowly from the injection site. If water-based vitamin A is unavailable, oil-based vitamin A should be administered orally, even if it is in injectable form. Studies have demonstrated that oral megadoses of vitamin A are as effective as intramuscular injection for the treatment of xerophthalmia.

Extremely large doses of vitamin A or overfrequent administration (for example, daily doses of 200,000 IU capsules) may be toxic. High doses are particularly inappropriate for women in early pregnancy, since animal studies have shown that certain fetal abnormalities can occur.

When eyes with active keratomalacia and/or corneal ulcers are identified, they should be covered with a shield to protect the eyeball from pressure. Eye shields can be made locally from used X-ray film, heavy paper, or cardboard.

Prevention

Three different forms of intervention are employed in the prevention of xerophthalmia: periodic distribution of high-dose vitamin A, fortification of food products, and nutritional education programs.

While hospital-based studies have demonstrated that providing children with 200,000 IU of vitamin A every six months can prevent the development of mild xerophthalmia and keratomalacia, the effectiveness of large-scale distribution programs in reducing the prevalence of xerophthalmia and preventing blindness in the community is not well proven. This is not because the vitamin is ineffective but because such programs often miss as much as 40 percent of the target population, especially the children, who are usually at the highest risk of developing xerophthalmia. Because research has shown that vitamin A deficiency and xerophthalmia cluster within families and neighborhoods, targeted distribution schemes that focus on high-risk communities have been employed as an alternative to population-based distribution. A disadvantage of targeted distribution is the failure to reach individual cases dispersed throughout the larger population. The delivery costs of massive-dose distribution programs can be quite high, unless such efforts are incorporated into existing health programs. Massive-dose distribution programs are best considered as short-term emergency measures in areas where xerophthalmia is an identified public health problem. Further research and evaluation are needed to determine the most cost-effective and efficient distribution strategy.

The long-range solution to preventing xerophthalmia is to

increase the consumption of dietary vitamin A and carotene. Vitamin A, or retinol, is a fat-soluble substance found in liver and other meat, poultry, and dairy products. Carotenes, found in dark green leafy vegetables, yellow fruits, and red palm oil, for example, are usually converted into retinol in the intestines. The carotenes are biologically less active than retinol, and their dietary sources are less efficiently processed and absorbed than retinol sources. It is now known that even among malnourished children, however, carotene is readily absorbed.

Fortification (the addition of vitamin A to a staple food) is one approach to increasing dietary intake. An appropriate, low-cost vehicle for such fortification must be identified. This food should be widely consumed by children; its intake should be relatively uniform so that the selected concentration delivers sufficient vitamin A without overdosing the highest consumers; and it should be centrally processed for convenient addition of vitamin A to the staple. In Guatemala, fortification of sugar with vitamin A has resulted in a generalized improvement of the vitamin A status of the population. A pilot program to assess the feasibility and appropriateness of fortification of MSG is about to begin in Indonesia. Salt has been identified as a potential vehicle in Malawi, and further investigations as to its value are being pursued.

Health and nutrition education programs that promote increased consumption of vitamin A- and carotene-rich foods, along with measures taken to reduce other risk factors associated with xerophthalmia, are other long-range approaches. It has often been assumed that in areas where xerophthalmia is prevalent, carotene-rich foods are not available or are culturally unacceptable. A study in Indonesia found that, although such foods are already in the family cooking pot, children with xerophthalmia were found not to be eating them. In this case, teaching mothers the importance of vitamin A in the diet and demonstrating how to specially prepare these already existing foods for young children is an appropriate solution. If carotene-rich foods are absent from the community, families may be encouraged to grow them in home or community gardens.

Promotion of general good eating and health practices can contribute to the prevention of xerophthalmia. Children who are breastfed are eight times less likely to develop xerophthalmia than children who are not. In addition, pregnant and lactating women should be particularly encouraged to eat foods rich in vitamin A and carotenes. Preparation of weaning foods rich in vitamin A or carotene, such as mashed papaya, should be taught, since children of this age frequently experience concurrent diarrhea and other infections that increase the need for vitamin A.

Prevention and treatment of diarrhea with oral rehydration therapy should be included in educational programs. Children with diarrhea are at 13 times greater risk of corneal xerophthalmia than children without diarrhea.

Designing appropriate educational strategies requires a clear understanding of existing dietary patterns and other health-related practices. Data from surveys can provide information on the kinds and quantities of food children consume, but in-depth, qualitative research may be needed to determine **why** children do not consume adequate amounts of foods with vitamin A.

Measles immunization is another important component of a xerophthalmia- and measles-associated blindness reduction strategy. Although the relationship between measles, nutritional status (including vitamin A status), and blindness is not yet thoroughly determined, preventing measles through immunization can eliminate one of the most significant risk factors for the development of childhood blindness.

Xerophthalmia Treatment and Prevention Schedule

1. **Children* with xerophthalmia or general illness or malnutrition**
   Immediately — 200,000 IU vitamin A orally or
   100,000 IU vitamin A intramuscularly
   Following day — 200,000 IU vitamin A orally
   1-2 weeks later — 200,000 IU vitamin A orally
   Note: Water miscible vitamin A must be used for the intramuscular injection

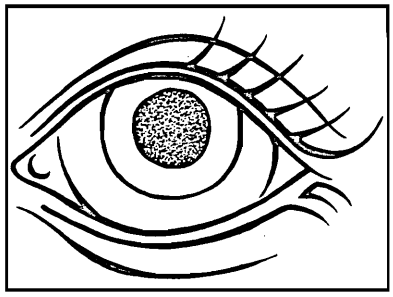
2. **All children***
   Every 4-6 mos. — 200,000 IU vitamin A orally

3. **Mothers at birth of child or within one month after delivery**
   — 200,000 IU vitamin A orally

*For children less than 1 year of age reduce all doses by one-half

Helen Keller International, Inc.

Cataract



Diagnosis

Blinding cataract can be diagnosed by screening for visual acuity and identifying those individuals whose acuities are equal to or less than 3/60 or 6/60. A subsequent clinical examination will detect lens opacities. Health care workers with minimal training can carry out these activities. Careful selection of patients for surgery is important; because of the need to make efficient use of personnel and equipment, most programs limit surgery to those individuals who are bilaterally blind (cannot count fingers at three meters with either eye).

Treatment

Treatment consists of surgical removal of the opaque lens and provision of corrective eyeglasses. Operating on only one eye and providing eyeglasses restores sight sufficiently to allow the person to return to a productive life.

In cataract surgery, the clouded lens is removed from the eye through an incision in the sclera just above the cornea. Intracapsular extraction removes the entire lens and its capsule. Extracapsular extraction leaves the posterior capsule in the eye while removing the anterior capsule, the cortex, and the lens nucleus. Sutures close the external surgical incision.

Because cataract surgery is a delicate operation requiring special training and experience, it is not an appropriate technique for the primary health care level. Cataract extraction should be performed as close as possible to the patient's community; a trained surgeon, an adequate secondary care facility (local or district hospital), or the use of mobile eye services are needed.

Phacoemulsification, a newer technique that uses high frequency sound vibrations (ultrasound) to soften and liquify the lens, which is then aspirated through a hollow needle, is used by some surgeons in some industrialized countries. The high costs of purchasing and maintaining this equipment and the fact that it is not easily transportable make it an inappropriate technique for most developing countries.

Many programs rely on mobile eye services to provide cataract removal surgery. A four-wheel drive vehicle that serves as a self-contained unit is useful. A mobile eye unit should carry the necessary diagnostic and surgical supplies and instruments, sterilization equipment, water, a portable operating room light that can be powered by the vehicle battery, and educational materials for training other health care workers.

Cataract extraction methods that are older and simpler, but no less effective than those used in industrialized nations, are recommended for the secondary level of health services. Cryoextraction using a small, portable, handheld cryoextractor is one technique that has been successfully used in many developing countries. This method uses a very cold probe, with a refrigerant reservoir, to freeze the lens. The frozen lens adheres to the probe and it is lifted out of the eye. Cryoextractors with replaceable canisters containing sufficient refrigerant to perform 30 to 40 operations are commercially available. These instruments may also be manufactured locally. Some cryoextractors require electricity or gas as a source of power.

Alternatives to cryoextraction are the traditional and inexpensive surgical techniques employing either capsule forceps, lens spoons, or suction/aspiration methods (erysiphakes). More time may be needed to perform cataract extraction with these instruments, but some surgeons select these methods because of personal preference, experience, cost, availability, and training.

Studies have demonstrated that an 80 to 90 percent success rate (similar to that of cataract operations in the U.S.) can be achieved using these older and simpler methods, as long as standards of asepsis are maintained. Sterilization of some instruments may be done by boiling. Delicate instruments can be disinfected in methyl alcohol, acetone, and certain other commercially available solutions. Cryoprobes can be placed in a sealed box with paraformaldehyde tablets.

For postoperative care, an eye

shield is necessary to protect the eye. Patients should be encouraged to use the eye shield while sleeping to prevent them from rubbing their eyes before the wound has healed.

After the lens has been removed, the eye will need a substitute lens to compensate for the loss of the natural lens. In the developing world, eyeglasses are the most practical and least expensive alternative. Contact lenses and intraocular lens implants are often used in industrialized countries, but the need for careful follow-up and the higher costs of these devices are disadvantages. Ideally, refraction (determining the power needed in the corrective lenses) is performed on postoperative patients. Because many programs do not have the resources to carry out this test, plain spherical eyeglasses with a power of + 10, + 12, or + 14 diopters (a unit of measurement of the power needed to see objects in focus) are issued to patients.

Bifocal lenses with an insert with an additional power of 2.5 to 3.5 diopters are useful, particularly for individuals whose work requires an ability to see close-by objects. Where the capacity for follow-up exists, patients can be provided a pair of temporary eyeglasses which they can wear until the cornea is no longer changing. At a return visit, approximately six months later, a permanent pair of eyeglasses is issued. An ample supply of low-cost eyeglasses is essential for an effective cataract treatment program.

Diagnosis and treatment are the essential components of a cataract care program; there is as yet no known means of prevention.

Public education about the benefits and availability of cataract surgery is necessary. In many areas of the world, fear of eye operations and eye health care is widespread. Often, an individual whose sight has been restored through cataract surgery is the best community educator on the advantages of this operation.

EXAMINATION OF THE EYE

Both primary eye care and surveys to assess ocular status should include an examination of the front visible part (anterior segment) of the eye in addition to tests of visual acuity. An examination can reveal eye lesions that cause visual impairment, and the patient can be treated or referred, if needed.

A primary examination of the eye does not require complex equipment or supplies. Clean hands, a source of light, and, in areas where trachoma is prevalent or suspected, a pencil or cotton-tipped stick to roll back the upper lid are sufficient for examination by the primary or auxiliary health care worker. The best means of illuminating the eye is natural lighting, but in open shade rather than direct sun. A hand-held, battery-operated flashlight may help to detect cataract and lesions of the cornea and conjunctiva, but it is not necessary. Likewise, a hand-held magnifying lens and binocular head-band magnifying lens (or loupe) can reveal small irregularities not seen by the naked eye, but they are not essential. The thumb and forefinger can be used to keep the lids apart to allow a better view of the eye. Desmarres retractors, lid speculums, and bent paper-clips as lid retractors should be used only by a person specially trained in ophthalmology.

A history is another important part of a primary eye exam. Information on duration of the condition, possible injury, illness at or near the time the eye problem first occurred, medications currently used, dietary history, water supply, or eye disorders in other family members can be obtained. The specific questions asked depend on the purpose of the exam (primary health care or survey) and the prevalent eye diseases in the region.

More complex examinations of the eye can be carried out at the secondary or referral level of care, particularly on those individuals identified during a survey as having significant visual impairment. For this purpose, the use of a slit-lamp biomicroscope permits a more detailed examination of the cornea and lens. Electricity is required. A hand-held, battery-operated ophthalmoscope is used to examine the ocular fundus (preferably after the pupil is dilated). A Schiotz tonometer can be used to measure intraocular pressure (to rule out or evaluate for the presence of glaucoma).

Program Management

The lack of eye health services in many developing countries contributes to much blindness. Primary health care (PHC) workers can be trained to recognize and treat infectious and nutritional eye diseases, thus preventing vision loss. Keys to effective integration of eye care into health services at all levels are flexibility, recognition of available resources, selection of technologies which are appropriate and culturally acceptable for the country, and regular training and supervision of health care workers.

Planning

Blindness prevention measures can be added to existing program activities or be included when new primary health care services are begun. An important first step is to establish a national committee or similar body which guides policymakers and planners and coordinates the diverse sectors involved in blindness prevention activities. To date, 54 countries have formed such national committees.

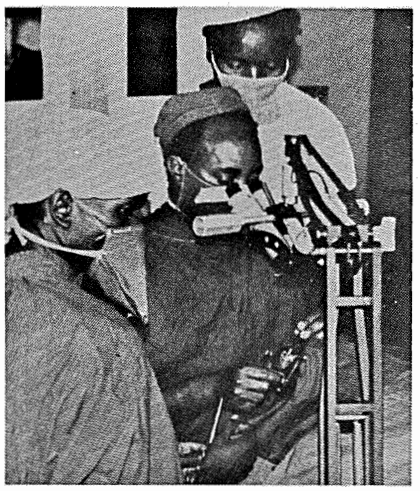
An effective program requires an assessment of the distribution, magnitude, and causes of blindness within a country. Communities with a high prevalence of avoidable blindness should be identified and given priority for intervention activities. Data from hospital and clinic records can indicate the existence of significant eye diseases but usually do not cover the population with the highest risk of blindness.

Prevalence surveys provide more accurate estimates of the problem. Field survey teams should collect and analyze data on blindness prior to initiating activities and also while programs are ongoing. These teams can use existing local health personnel. An additional assessment of resources, including facilities, personnel, transportation, communication, water and environmental sanitation, and other factors affecting the design and implementation of blindness prevention programs, is required. This information serves as a basis for the formulation of a plan of action and the development of specific intervention strategies.

Primary Eye Care

To reduce avoidable blindness, priority should be given to the delivery of essential eye care. Primary eye care includes promotional and preventive measures as well as clinical activities.

The PHC worker should make the local community aware of the fact that the majority of blinding diseases are either preventable or curable. This awareness is necessary for active community participation in blindness prevention. Promotional efforts should focus on village authorities and other local leaders, such as school teachers, as well as on individuals. Much of the content of preventive eye care messages is information a PHC worker already knows. Education about healthy diets, personal hygiene (such as daily face washing), environmental sanitation measures (such as the construction of latrines), and accident prevention is a basic component of both primary health care and primary eye care.



International Eye Foundation

Ophthalmic clinical officer performing cataract extraction

Clinical primary eye care activities begin with the recognition of eye problems. Following recognition of a problem, a distinction should be made between those conditions that can be treated by the PHC worker, those that require referral after treatment has been initiated, and those requiring immediate or emergency referral for treatment. Eye problems that can be recognized and treated by PHC workers are conjunctivitis and lid infections, including ophthalmia neonatorum (conjunctivitis in the newborn usually caused by untreated gonorrhea in the mother and transmitted during birth); trachoma; trauma in the absence of visual problems; and mild xerophthalmia. Conditions requiring treatment and immediate referral are corneal ulcers, injuries to the eyeball, large eyelid lacerations, burns, and deformities of the eyelids due to trachoma. Referral is required for cataracts, vision loss, and painful red eye (conjunctivitis).

An adequate referral system is essential to primary eye care. Secondary and tertiary health facilities may need to be strengthened. Secondary eye care activities which are usually carried out in district hospitals include management of cataract, ocular trauma, corneal and intraocular infections, and surgery for correction of lid deformities due to trachoma. More highly trained health workers, such as ophthalmic assistants, general practitioners trained in eye care, or ophthalmologists (depending on the country's personnel policies) perform these activities. Less common blinding conditions which may require complex

equipment and specialized staff are treated at a tertiary eye care facility, often a university hospital.

In areas where primary and secondary eye care services are lacking, mobile eye units can fulfill similar functions. They can also provide valuable support to existing eye care activities. It is extremely important to establish mechanisms that ensure the continuity and follow-up of mobile eye team services and collaboration with local health personnel. Eventually, mobile eye services should be replaced by a permanent eye care infrastructure.

Staff at the secondary level, whether a fixed facility or a mobile unit, should be actively involved in the training, continuing education, supervision, and evaluation of primary eye care personnel. In addition, this level should provide the logistical support needed for the regular stocking of drugs, equipment, and supplies.

Training

Basic elements of PHC worker training are: methods of examination, including patient history and assessment of visual acuity; distinction between conditions to be treated and those needing referral; methods of prevention and treatment; and educational techniques. Training should be practical and task-oriented.

A successful blindness prevention program in Kenya teaches health workers four basic rules about the normal eye: 1) the cornea should be clear; 2) the pupil should be black; 3) the white part/conjunctiva should be white; 4) the eyelids should open and close properly. By going through these rules, students learn to recognize which part of the eye has a problem, which problems can be treated, and which ones need referral.

EYEGLASSES FOR DEVELOPING COUNTRIES

There is an urgent need for ample supplies of low-cost eyeglasses in the developing world. In addition to cataract patients, school children and the working population with refractive errors (defects in which light beams are not focused exactly on the retina, such as nearsightedness) can greatly benefit from improvements in vision offered by corrective lenses.

Low-cost eyeglasses can be produced locally. Production involves four processes: frame manufacture, surfacing of optical blanks to produce a lens which has a power, edging of the lens to fit the frame, and assembly of the lens into the frame. Edging and assembly processes can be easily established on a small scale, using imported lenses and frames. (Frames are often second-hand donations.) Frame manufacture and lens surfacing can also be done locally, but they require more expensive equipment. The publication **Reading Glasses for Africa** describes how to establish a workshop to assemble eyeglasses (see Materials Available).

The lack of more highly trained eye care workers (including nurses and ophthalmic assistants) at the secondary and tertiary levels of care is a major constraint to full implementation of blindness prevention programs in developing countries. This is particularly evident when looking at the situation with respect to cataract. In Tanzania, where there are 15 practicing eye specialists, and approximately 100,000 people waiting for operations, it would take 20 years to treat these cases. In India, where there are many more ophthalmologists, it has been estimated that the number of cataract operations performed annually must be increased by a factor of four to reduce the backlog of untreated cases and handle the new ones.

Two solutions have been proposed to resolve this problem: increasing the number of cases performed by eye surgeons (through increased supplies of equipment and hospital eye beds, reduced hospital stay, and mobile "cataract camps") and increasing the number of eye surgeons (by training more ophthalmologists or by training general practitioners or ophthalmic paramedical officers to do cataract surgery). The costs of training and supporting an ophthalmic paramedical officer are less than one-half those of training an ophthalmologist, and experience has shown that when surgery is performed by an ophthalmic paramedical officer under the supervision of an ophthalmologist, the results are comparable to the results achieved by ophthalmologists. Despite these facts, paramedical ophthalmic officers are not widely used to perform cataract surgery, except in a few African countries.

The leading causes of blindness in the developing world are largely preventable through the use of appropriate technologies such as simple screening and diagnostic tools, community education, and medical and surgical therapies. Although certain specific functions, such as cataract surgery, require specially trained personnel, most eye care activities can and should be an integral part of the primary health care system. Xerophthalmia is a good example of the need for an integrated approach, since its con-

trol depends on nutrition education, medical screening, and vitamin supplements, all of which can best be provided through the PHC system. Similarly, cataract treatment depends not only on surgical skills but also on community screening, patient education, and appropriate postoperative care. Although further research is still needed to clarify the causes of the earlier onset of cataracts in developing countries, there are useful tools available for treating or preventing the blindness associated with cataracts and xerophthalmia. Programs which use these tools effectively can greatly reduce the staggering burden blindness now places on individuals and society as a whole in the developing world.

Materials Available

More information on the technologies discussed in this issue and on additional materials and organizations dealing with blindness is available from PATH.

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The **Primary Eye Care Manual** describes the practical skills needed for primary eye care activities. Write the International Eye Foundation at: 7801 Norfolk Avenue, Bethesda, MD 20014, U.S.A.

□

Strategies for the Prevention of Blindness in National Programmes: A Primary Health Care Approach (Geneva: WHO, 1984) is particularly valuable. To order this and other related documents, contact the WHO Regional Office or write to WHO, Distribution and Sales Service, 1211 Geneva 27, Switzerland.

□

The **Red Eye Chart,** a poster illustrating eye care at the primary level, is available in seven languages and can be printed in any language if an appropriate translation is provided. Contact the Program for the Prevention of Blindness, WHO, or the International Eye Foundation.

□

Sets containing the instruments needed for cataract extraction and other eye operations are available from Dixey Instruments Limited, 19 Wigmore Street, London, W1A 4DU, U.K., and from ECHO, 4 West Street, Ewen Surrey KT17 1UL, U.K.

□

The International Agency for the Prevention of Blindness (IAPB) publishes **IAPB News.** Write to: IAPB, National Institutes of Health, National Eye Institute, Building 31, Room 6A03, Bethesda, MD 20205, U.S.A.

□

The Local Production of Eyedrops provides details on how hospital pharmacies can produce eyedrops from basic powders. Other available publications include **Reading Glasses for Africa** and **Focus on Blindness,** the proceedings of a seminar. To order, contact: Africa Region Medical Office, Christian Blind Mission International, P.O. Box 1363, Moshi, Tanzania.

□

Research Priorities for the Prevention of Blindness in Developing Countries and a series of training materials can be ordered from: Helen Keller International, Inc., 15 West 16th Street, New York, NY 10011, U.S.A.

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The **Xerophthalmia Club Bulletin** is available free. Write Xerophthalmia Club Secretary, Mrs. A. Pirie, 31 Observatory Street, Oxford, U.K.

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health technology
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Essential Drugs

It is estimated that there are between 100,000 and 200,000 drug products available today on the world market. The World Health Organization (WHO) has determined that fewer than 250 of these drugs are essential to treat most of the illnesses experienced by a majority of the world's population. The provision of these essential drugs is the focus of this issue of **DIRECTIONS**.

Drugs can be loosely defined as medicinal substances used in the treatment and prevention of disease. They include locally prepared herbal remedies as well as the highly purified pharmaceuticals synthesized in modern factories. Whatever their form, drugs play an important role in primary health care (PHC).

With the encouragement of international organizations such as WHO and UNICEF, many countries have turned their attention to the development and use of essential drug lists. This important work needs to be matched by community and individual strategies to improve the availability and use of these drugs.

The problems involved in providing essential drugs present an almost overwhelming challenge to all countries. Drug selection is difficult mainly because of the variety of drugs from which to choose. Drug procurement problems include the number of possible drug sources, the complexity of estimating needs, and the difficulties of arranging payment for the drugs that are needed. Drug distribution requires the carefully planned interaction of transportation, storage, and management systems. Appropriate drug use relies on training and public education. These problems are magnified in developing countries where infrastructure and resources are often scarce.

The policy decisions related to essential drugs are made at several levels. This issue of **DIRECTIONS** focuses on national, community, and individual strategies. The section on national strategies discusses drug selection, supplies, costs, distribution systems, and regulation. The section on community strategies covers needs assessment, storage, stock control, and training. And finally, consumer education and patient information are discussed under individual strategies.

1. National Strategies

2. Community Strategies

3. Individual Strategies

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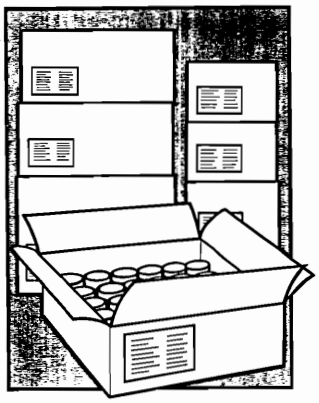
National Strategies



Many of the policy decisions about the provision of essential drugs are made at the national level. These decisions are often influenced by international agencies and programs as well. The effects of these policies, however, are felt at the community level and eventually by the consumer. For this reason, national policy makers need to consider the concerns of the local systems and individual consumers when choosing strategies.

Drug Selection

The drug selection process is made difficult by the vast number of available prescription and nonprescription items. All of these medicines are created from approximately 250 active substances, which are the chemicals in drugs responsible for the therapeutic effect. Many medicines are either duplicates of other drugs, combination drugs, preparations such as vitamins, or tonics and potency drugs that have little or no proven therapeutic value. Duplicate drugs are those that have the same active substance as other drugs but are marketed in a slightly different form or dosage, often with a different brand name. It has been estimated that there are, on the average, 70 different brand names for each drug marketed today.

Combination drugs contain two or more active ingredients in a fixed ratio. Combination drugs may be more convenient for consumers, and combining ingredients allows the use of lower dosages of each active substance. The disadvantages of combination drugs are that the fixed ratio of active ingredients does not allow the prescriber to vary the dosage of one ingredient without affecting the other and that people taking several medications may face an increased risk of adverse drug interaction. WHO supports the use of combination drugs only where the combination has a proven advantage over single compounds given separately.

Preparations with no known therapeutic value include many vitamin tonics and cough preparations which are available without prescription. In many cases, there are food sources available that provide the same nutrients as vitamin preparations at a fraction of the cost.

In 1977, WHO asked a panel of experts to compile a list of drugs necessary to treat almost all health problems. The panel provided a list of about 200 drugs and vaccines, most of which are no longer protected by patents and can be produced at low cost. The most recent revision of this list (1982) includes about 230 drugs and a model list of 22 drugs for use in primary health care (see box).

More than 80 countries have developed national formularies or drug lists based on the WHO Model List of Essential Drugs. These limited lists are usually compiled by a national committee made up of practitioners, planners, pharmacists, procurement officers, pharmacologists, and representatives of the national pharmaceutical association. They take into consideration country- or region-specific health problems and projects, as well as dosage forms, efficacy, side effects, and costs.

International nonproprietary (generic) names for drugs are used, and combination drugs are avoided unless they meet an important specific therapeutic need. Committees meet regularly to revise their lists in light of new treatments and changing needs. In addition, formulary committees often draw up standardized treatment schedules that outline courses of treatment to be used with the listed drugs.

Some practitioners have complained that these limited lists of drugs restrict their "clinical freedom" to choose prescriptions from all available drugs. The counterargument is that it is almost impossible for practitioners to be fully informed about even the few hundred drugs they regularly prescribe, let alone the thousands that are available. In reality, most practitioners prescribe a very limited number of drugs with which they are familiar. Seen in this light, an essential drug list facilitates choices from the huge number of available products.

One way to reduce practitioner resistance to a national formulary would be to make sure that practitioners are well represented in the

drug selection process. In Haiti, for example, after surveying physicians, the panel subsequently modified its list based on their suggestions. Another approach is to set up a system permitting exceptions to the limited list, as was done in Norway and Barbados. In Barbados, requests for permission to prescribe nonlisted drugs have decreased as practitioners have become more familiar and comfortable with the recommended formulary drugs.

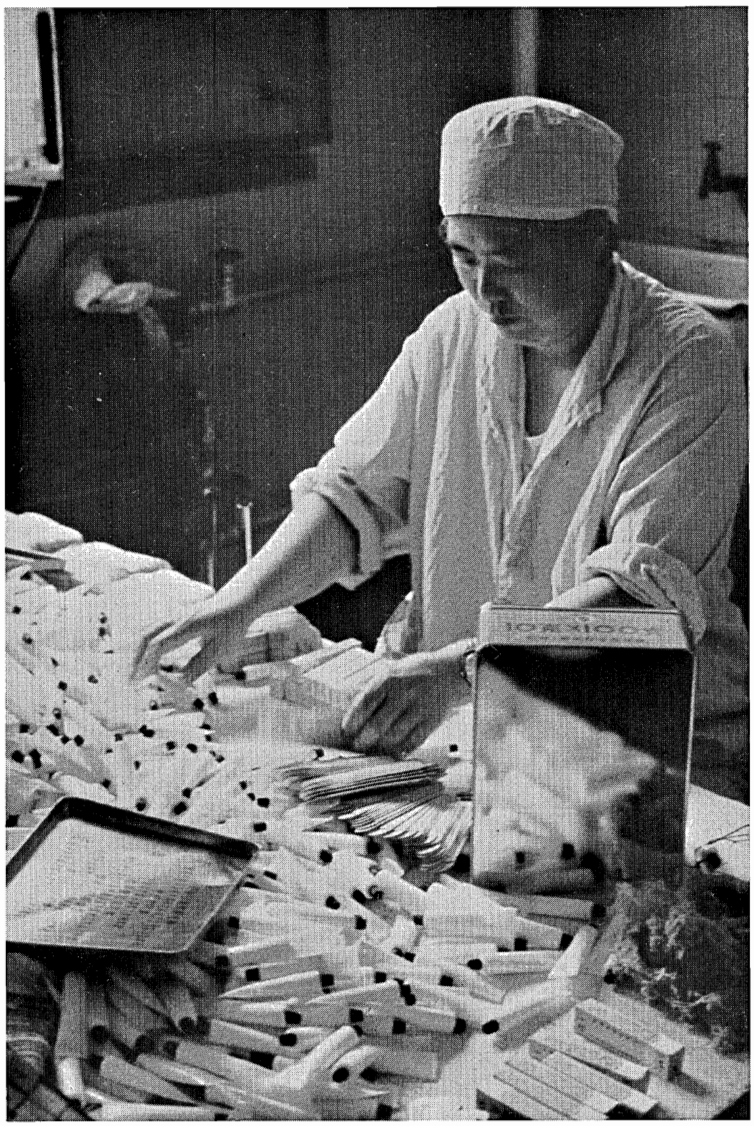
Drug Supplies

The drug supply problem in developing countries is not just one of shortage or poor distribution, it is also a problem of misuse. In developing as well as developed countries, there is an increasing tendency to use drugs as the treatment of choice for all kinds of disease. As a result, treatments other than drugs are too often overlooked. Dietary changes, rest, exercise, and other traditional cures are often better treatments and frequently less expensive than the tonics and elixirs sold in village shops. Steam inhalation is a good substitute for decongestants, and home remedies for coughs are often as effective as manufactured cough suppressants. Some drugs, such as antidiarrheals, can actually prolong illness. One often-overlooked, partial solution to drug scarcity is more appropriate use of available medicines. Although some illnesses require the prompt use of proper medication (as in pneumonia or dehydration from diarrhea), drugs should not be routinely provided as the first treatment for all conditions.

WORLD HEALTH ORGANIZATION MODEL LIST OF DRUGS FOR PRIMARY HEALTH CARE

The following list of 22 drugs was selected by WHO from the full model list of essential drugs as those which might be appropriate for administration by a traditional healer or community health worker. In practice this list needs to be modified for each country to reflect the disease patterns, existing medical coverage, and level of training.

Drug	To Treat
acetylsalicylic acid	pain, fever, inflammation
activated charcoal	swallowed poisons
antacid	indigestion, heartburn, and stomach ulcers
antihemorrhoidal drug	hemorrhoids or piles
atropine	muscle spasms
benzoic acid + salicylic acid	fungal infections
benzyl benzoate	scabies and lice
calamine lotion	skin irritation
chlorhexidine solution	skin infections
chloroquine	malaria
chlorphenamine	allergic reactions
ephedrine	asthma
ergometrine	postpartum hemorrhage
iodine	iodine deficiency, infections
ipecacuanha	swallowed poisons (causes vomiting)
iron/folic acid	anemia
lindane	scabies and lice
mebendazole	parasitic diseases
oral rehydration salts (ORS)	diarrheal dehydration
paracetamol	pain and fever
piperazine	ascaris and pinworm
tetracycline eye ointment	conjunctivitis



Margaret Dodd Britton

Ointment production in the People's Republic of China.

Most developing countries rely on imports for a large part of their annual drug needs. To reduce the need for foreign exchange, increase self-sufficiency, and encourage local employment, some developing countries have adopted policies that facilitate local production of drugs. These policies include restrictions on imports of foreign products, preferential buying from local concerns, and legislation to insure that subsidiaries of transnational drug manufacturers have a high proportion of local ownership. There are still questions, however, as to the cost-effectiveness of these actions. In some countries, local repackaging of imported bulk shipments has been instituted. Regional cooperative efforts, such as the Latin American Pharmaceutical Industry Association (ALIFAR), have been organized as well.

National drug production is also being encouraged through the increased use of herbs, both in traditional forms and as raw materials for drug manufacturing processes. A number of the synthetic chemicals used in drug manufacturing were originally isolated and purified from plant sources. The National Corporation of Herbal Medicine in the People's Republic of China produces 5,700 types of medicinal plants and 700,000 tons of herbs annually. In the Philippines, where herbalists have long provided rural medical care, the Ministry of Health is encouraging research on medicinal plants. Factories are being set up to process herbs, and the national formulary lists more than 30 medicinal plants.

Whether drugs are produced locally or imported, quality assurance is critical to all drug programs. Developing countries with limited resources need to know that the drugs they purchase are both safe and effective. Unfortunately, developing countries often have neither the facilities nor the resources to do quality assurance testing. To help meet the need for quality assurance for imported drugs, WHO has instituted a certification scheme that provides importing countries with information on whether or not a product has been approved for use in its country of manufacture. It also provides assurance that the manufacturing standards employed are in line with those recommended by WHO. Several countries have also legislated good manufacturing practices (GMP) for locally manufactured pharmaceuticals.

Quality assurance laboratories have been set up in some developing countries, and regional laboratories are being used or planned in others to share costs among members. WHO has been coordinating the development of a network of drug quality control laboratories in their Eastern Mediterranean Region. UNICEF and WHO also provide quality assurance testing for drugs purchased through their organizations.

Reducing Costs

In any country, cost is a central issue in drug selection, procurement, and availability. While the annual per capita consumption of pharmaceuticals in developing countries is small in comparison to that of developed countries (U.S. $6 vs U.S. $50), drug purchases can sometimes account for nearly half of a developing country's health budget. If private sector expenditures (including nonprescription drugs) are added, medication can account for upwards of 75% of a country's total expenditure on health care.

There are several steps that can be taken to cut these costs:

- **Limited Formulary.** Reducing the number of different drugs, drug combinations, and formulations can bring about significant savings in the costs of procurement, handling, stocking, and training.

- **Bulk Purchases.** Consolidating the drug requirements of hospitals, clinics, research centers, and other public sector institutions makes it possible to place large orders at reduced rates. Neighboring countries can also combine their orders to negotiate for lower prices. Such joint procurement schemes have been attempted in several regions with mixed success. Algeria and Tunisia purchase drugs together, as do groups in the South Pacific and South America.

- **Competitive Bidding.** Inviting several companies to bid on drug orders has reduced costs in many countries. UNICEF has taken advantage of both bulk purchase and competitive bidding to save money by purchasing drugs for over 100 countries.

COST RECOVERY

In 1982, the Haitian government started operating rural pharmacies in unserved areas. These were initially operated outside of the Ministry of Health (MOH) because they charged for medication. MOH facilities now participate and in some cases use drug sale revenues to pay other health costs. In Dominica, a similar system has been postponed because of political unacceptability.

The recovery of essential drug costs in government health services by charging consumers for their medications is a controversial issue. There are a number of arguments for and against such cost recovery practices:

For	Against
Charging consumers discourages overuse.	The poorest may not be able to afford medicines.
It may improve compliance.	Patients may not choose to purchase necessary preventive medications.
The poor already spend money on nonessential medications.	Charging for previously free services may be politically unacceptable.
Governments can use profits to finance other health programs.	

- **Use of Generics.** Ordering drugs by their generic names can reduce overall costs substantially. A patent gives the developer of a new drug exclusive rights to produce it under a brand name for a certain period of time. During that time, the patent-holder enjoys a monopoly that enables it to sell the new drug at a higher price and recoup research and development costs. After the patent expires, any company can produce the drug under its generic or classification name. Because of the competition to produce generics and the absence of development costs or brand name promotion associated with them (often 20 of the total consumer cost), generic drugs are usually much cheaper.

- **Dosage Forms.** Limiting the variety and type of dosage forms can keep costs down. Often, the same active ingredient is available in more than one dosage form. Antiemetics, for example, are available both as tablets and liquid; ampicillin is available as a tablet, an oral suspension, and an injectable. In general, tablets or capsules are the least expensive dosage forms, followed by oral liquids, and then injectables. For example, the same

dose of a useful antibacterial on a UNICEF list is four times more expensive in liquid than in tablet form. Although liquids are often recommended for small children, most tablets can be dissolved in water or crushed and put in food. There is also less wastage in dispensing and repackaging tablets than liquids.

Distribution Systems

Several systems have been used successfully to deliver drugs to consumers. Most countries have a private market system that includes over-the-counter (OTC) sales of nonprescription drugs as well as prescription drug sales through pharmacies. These systems have the advantage of being in place and usually operating efficiently. Often practitioners dispense some of the medications that they prescribe as well.

Many countries also dispense free or subsidized drugs through the national health system's hospitals and clinics. In some countries, such as the Philippines, Mozambique, and Haiti, the government has also attempted to extend drug access to isolated communities by establishing rural pharmacies that sell essential drugs at a small profit.

Cooperatives, another organizational approach, are currently operating in Thailand and in experimental trials in the Philippines. These are usually financed as revolving funds started with money raised by the community. Usually members of the cooperative purchase drugs at prices set just high enough to cover the costs of restocking, although some in Thailand are generating enough profits to fund other investment projects.

Many countries have more than one of these systems operating simultaneously. Parallel private and government systems are the most common combination. Thailand, with its community revolving drug funds, has all three. Some combinations of systems have also begun to take place. For example, in Kenya, one pilot project has started to train small shopkeepers to distribute free, government-provided contraceptive supplies. Some governments are also looking at ways to reduce their subsidies and make their systems self-supporting by having patients pay the full cost of their medication (see box, page 5).

Transporting drugs is a serious problem for each of these systems, and when transportation is available, exposure to extreme heat and long delays may cause drugs to lose their strength or expire. Loss and theft are also serious concerns.

There have been some creative attempts to solve these problems. Under Kenya's New Management Systems of Drug Supplies to Rural Health Facilities, which started in 1981, sealed, prepackaged "ration kits" of essential drugs are sent out to health posts. The kits, which contain 39 items for health centers and 31 items for dispensaries, are transported by private companies to district and provincial hospitals from which they are then forwarded to the rural clinics. Contracted transportation, which uses companies already carrying merchandise to small shops in rural areas, is cheaper than maintaining a Ministry of Health transportation system for this purpose. In addition, the sealed, prepackaged kits reduce opportunities for pilferage. Tanzania has started using a similar system of "ration kits," but is using its railway system instead and transporting prepacked containers of kits for whole regions.

Some of the small drug cooperatives operating in the Philippines have solved their shipping problems by adopting another strategy: whenever a member has to go to town on an errand, the manager checks stocks and, if supplies are low, asks the member to purchase the necessary items.

Regulation

In many countries, the distinction between those drugs available only on a health worker's orders and nonprescription (OTC) drugs is not always clear. In general, OTC drugs decrease medical staff requirements, decrease the cost of handling and managing drugs through public health systems, and increase the availability of medicines in isolated areas. One disadvantage of OTC drugs is the possible misuse by consumers who may take the wrong medicine or dose; another is that the use of OTCs may prevent or delay some people from seeking urgently needed medical attention. In addition, unless regulated, some OTC medicines may be offered that are useless or even dangerous.

The decision as to which drugs need to be regulated will depend on balancing the potential benefits of widespread availability against the possible harm from misuse. Many countries have placed some type of control on OTC drugs, mostly to exclude those that are known to be harmful. Fewer countries have moved to create OTC formularies that eliminate useless drugs as well as dangerous ones. Cuba and Bangladesh have severely limited OTC preparations. Mozambique has developed a limited OTC retail formulary for rural non-pharmacy establishments.

Up until now, few countries have looked at the need for restrictions on traditional medicines. Bangladesh, with a long tradition of homeopathic medicine, is currently considering creating a formulary of traditional medicines.

Community Strategies

While many of the decisions regarding essential drugs are made at the community level, they are shaped by national policies and consumer needs and reflect issues directly faced by the primary health worker.

Needs Assessment

The estimation of requirements necessary for bulk drug purchasing at the national level is usually a compilation of similar estimates made at the local level. These estimates can be based on patterns of previous use or on epidemiological data on disease incidence and prevalence.

Previous use estimates are easiest with systems that are fairly stable over time and where supply records have been well kept.

Estimates based on use are less helpful if the previous use records reflect shortages of supplies or unnecessary use or if the population being served is changing quickly in either size or composition. For example, an influx of refugees or outflow of a largely male population looking for work would change drug needs in an area.

Estimates based on morbidity data from either records or surveys may better reflect the true needs of the community, but the necessary data are often difficult and expensive to collect. These estimates also require dose and course-of-treatment information for each of the drugs in the formulary. With this information, and by making some projections for disease incidence and demographic profile (the number of people to be served in each age group), an initial estimate can be made of total drug requirements for a population of a given size over a given time. This method will overestimate expected drug use if not all patients who need drugs have access to them.

Often a combination of both estimation processes are used. A microcomputer model for planning drug requirements has been developed (see Materials Available) that can calculate needs based either on previous use or morbidity or both. The model has been field tested in Indonesia and Morocco.

Drug Storage

Drug storage requires a room or building that can be secured against theft, or contamination or loss of drugs from insects or rodents. Additional security, such as a locked cupboard, is necessary for controlled substances like narcotics.

Heat and moisture, especially in tropical countries, can cause drugs to deteriorate. Heat damage can be reduced by choosing a shady, breezy location and by providing adequate ventilation. Refrigeration is necessary to maintain a cold chain for vaccines. Good ventilation also helps reduce moisture levels. Tins of tablets should be kept sealed when not being used. Tablets or capsules that are prepackaged in plastic bags should be used quickly or stored carefully because polyethylene does not completely block moisture or air.

All drugs should be labeled with at least their classification name, dosage form and strength, and date of expiration. Flammable and other dangerous substances should be marked and stored separately.

Stock Control

Following simple stock control principles helps to make the best use of drug resources. Good management procedures can decrease the chances of overstocking and having drugs expire or of running out of an essential drug (stockout). Good stock control procedures include:

- **Check-in System.** Immediately upon their arrival, check drugs against order records and packing slips to make sure that none of the order is missing and that no mistakes have been made in the items sent. They should also be checked for damage and expiration dates at this time.

- **Stock Arrangement.** Arrange drugs alphabetically, by therapeutic category, clinical indication, frequency of use, or a combination of these methods. Which method is selected is less important than that some systematic arrangement is maintained.

ESTIMATING DRUG NEEDS

Morbidity-based needs estimates are calculated by first listing the expected symptoms, number of cases, and proposed treatment. The usual divisions are children (under 15 years of age) and adults (15 years and older). For example:

	Symptom/Disease	Expected Number of Cases	Number of Cases for Each Treatment
Children	Fever	1,000	800 cases: acetylsalicylic acid 200 cases: paracetamol
	Diarrhea	1,500	1,500 cases: oral rehydration salts (ORS)

The expected number of cases can be arrived at by using survey data or from estimates using the population size. Course-of-treatment information from the national formulary is then added to the above estimates of number of cases to give estimated total drug requirements. For example:

	Acetylsalicylic Acid Tablets 300 mg	Paracetamol Tablets 500 mg	ORS Sachet 27.5 mg
Course	½-1, 3x daily for 2 days	¼-½, 3x daily for 2 days	varies
Number of Cases	800	200	1,500
Total Requirements	4,800	600	4,500

The estimated total drug requirement should be increased to allow for wastage and to provide a reserve if need increases or replacement supplies are delayed. An initial order increase of 25% should cover these contingencies. Subsequent orders can be modified up or down to reflect actual use.

- **Stock Rotation.** Rotating stocks means using supplies on a "first in, first out" basis. Note expiration dates and mark supplies nearing expiration so that they can either be used immediately or be redistributed for use elsewhere.

- **Record Keeping.** Keep stock cards with each drug showing the drug name, form and dosage, and minimum reserve level. This card should have spaces where each delivery of new stock, issue, and the remaining balance is shown. The stock card should also show the expiration dates of stocks received. If drugs are dispensed upon receipt of a written prescription, then these prescriptions can be collected and used at the end of the day to update the stock cards. Keep a duplicate of the information on the stock cards in a record book.

- **Timely Reordering.** The reorder levels marked on each stock card are based on how quickly a certain drug is used and on the maximum time it takes to get a new shipment. Reordering must account for both the amount already used at the time of reorder and the additional amount expected to be used before the next order arrives. With the prepackaged "ration kits" used in Kenya, Tanzania, and Ghana, stock control is somewhat simplified, but it is less flexible. In Kenya, surplus drugs are returned to district or provincial hospitals where they are used immediately or redistributed. Shortages are prevented by increasing the number of kits ordered or increasing the frequency of delivery.

Training and Continuing Education

Training and continuing education for both prescribers and dispensers are important in any essential drug system. Whether or not a national formulary has been created, the primary health care (PHC) workers who prescribe medications need to be trained in the indications for and safe prescription of the selected drugs.

WHO has drafted drug information sheets for a core list of essential drugs that can be adapted by each country. Each sheet lists the drug name, indications, summary, dosage form and strength, recommended dosages, precautions, adverse effects, interactions, and directions for storage.

Many countries, including Indonesia, Nigeria, and Peru, have produced local drug information sheets or booklets tailored to their national formularies. Durable, pocket-sized references are most useful. In Sri Lanka, the government publishes a quarterly called **The Prescriber**. It gives up-to-date information on formulary drugs and is distributed to physicians and medical auxiliaries.

In Mozambique, PHC workers are taught not only about pharmacology but also about the economics of drug selection. Bar graphs showing the relative costs of treating an illness with any one of several different drugs are used to increase prescriber awareness.

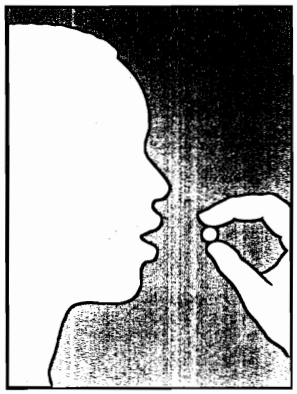
The dispensers of drugs also need initial training as well as continuing education. Although there has been some resistance by health workers to the idea of allowing drug dispensers to diagnose illnesses or prescribe treatment, in isolated areas of many countries pharmacists or OTC drug salespeople serve as the only available link between consumers and modern health care. In Nepal, where many isolated people have no access to government health facilities, extensive training programs have been held for pharmacists and shopkeepers who sell OTC preparations. UNICEF has helped prepare a practical training manual for these courses, which acknowledges the dispenser's role in drug selection.

A reference manual and management training courses for policy makers, prescribers, and dispensers have been developed to cover the selection, procurement, distribution, and use of PHC pharmaceuticals (see Materials Available).

Margot Zimmerman

Community health worker training in Nepal.

Individual Strategies



Individuals may have little control over the national and community level policies that determine the availability of essential drugs. However, they have complete control over how those drugs are finally used. Consumer education and patient information are two important ways to influence appropriate drug use.

Consumer Education

Large scale efforts are necessary in order to educate the public on the appropriate use of drugs. Underuse of drugs is a problem when people wait too long before seeking medical help or fail to complete a course of treatment because they begin to feel relief from their symptoms. Overuse of drugs becomes a problem when health workers treat patients with too many or the wrong type of drugs or when consumers buy useless and expensive OTC medications.

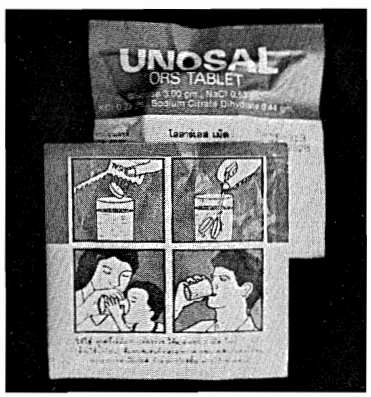
In many countries, there is a prevailing attitude that any medication, however inappropriate, is better than none, or that one dosage form (often injection) is better than others. Another common belief is that purchased medicine is better than what can be prepared at home. This has been cited as a problem in some programs designed to get mothers to prepare homemade oral rehydration solutions. Because these attitudes can result in the waste of precious health resources and can contribute to problems like drug resistance in microbial strains, they need to be considered as serious factors in health education.

Social marketing is one useful approach that examines such community attitudes with the intent of bringing about a change in behavior. It is based on the consumer's point of view. By finding out which aspects of a program, product, or idea appeal to consumers and which ones do not, the positive aspects can be stressed and the unappealing aspects can be minimized. Ideas, programs, or products are then promoted using many of the same techniques used by manufacturers to market products such as soaps and toothpaste. Social marketing has been used successfully in several countries to promote oral rehydration therapy and contraceptive use. A similar approach might be useful for community education on the appropriate use of essential drugs.

Patient Information

The final link in any system designed to provide essential drugs is their proper use through patient compliance. Compliance is a serious problem in both developed and developing countries. Failure to follow the intended course of a drug treatment can occur because the patient does not understand or remember the instructions, dislikes the drug's expected or unexpected side effects, or stops taking the medication earlier than directed because symptoms begin to disappear. Compliance can be increased if patients understand what kind of medicine they are taking and why, possible side effects, directions for the medicine's use, and the importance of finishing the full course of treatment. Limiting the number of different medications that are given at the same time eliminates nonessential treatments and reduces the chance of confusion.

All drugs, both prescription and OTC preparations, should be labeled with information that includes the drug's name, form, strength, proper dosage, and any warnings, contraindications, or special instructions for its use. This information needs to be provided, whether or not patients can read, so that someone who can read can later remind them of the instructions and so other health workers can be aware of what a patient is already taking and prevent possible adverse drug interactions.

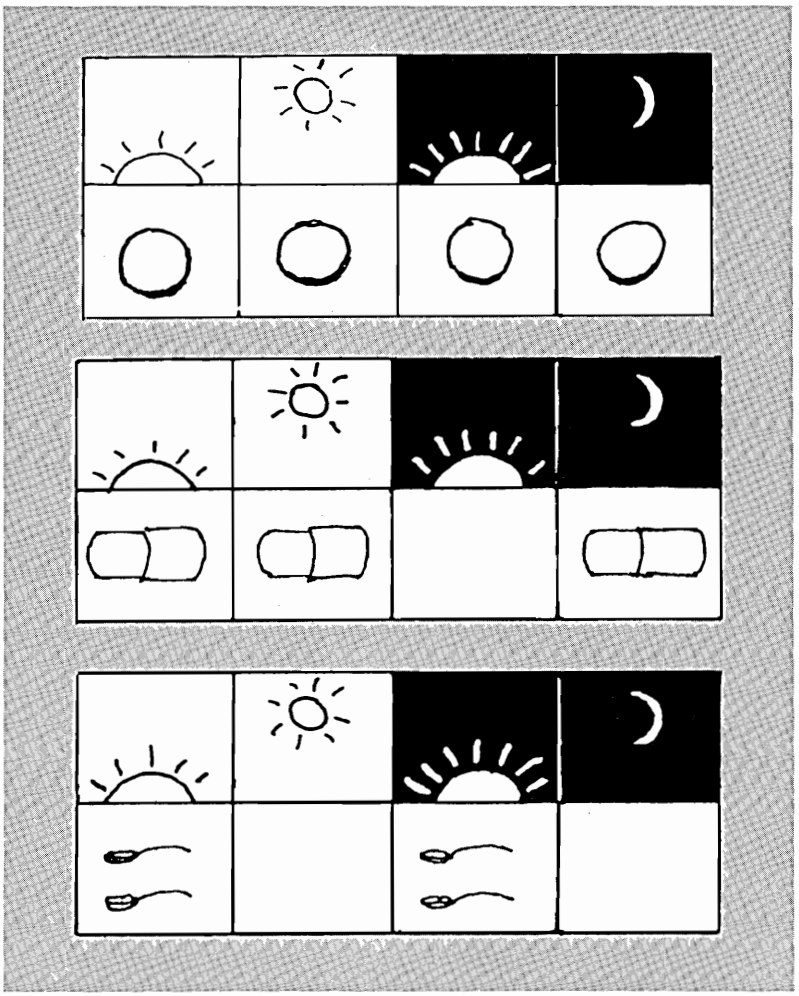


Maggie Kilbourne

Pictorial package instructions for oral rehydration salts.

Drug information materials have been developed for patients who cannot read. These use pictures to represent the amount of medicine to be taken at different times of the day; in some cases, these materials also represent the illness for which the medication is being taken.

If package inserts accompany OTC drugs, they need to be written clearly so that they can be understood by patients and health workers. Brazil recently passed legislation requiring detailed patient information for package inserts. Pakistan has recently decided that package inserts are to be printed in the national language, Urdu, as well as in English, so that they are easier for patients to understand. Pictorial directions for the correct preparation of oral rehydration solution from oral rehydration salt tablets have been developed for OTC packaging (see photo).



David Werner, *Where There Is No Doctor*

Instructions to health workers for using a dosage reminder form.

Since acceptability of a medicine depends on how it is presented, packaging can also be used to increase patient compliance. A recent study in the Philippines suggests that patients had more faith in commercially packaged products than in bulk government supplies. Some countries have increased the acceptance of government condoms and other contraceptive products by packaging them to look more like expensive commercial products.

Packaging can also provide creative ways to encourage safe and correct drug use. In the revolving drug fund in Haiti, drugs are packaged only as a complete course of treatment. This encourages patients to use their medication effectively. Another approach to encourage compliance through packaging is the blister packaging used for many oral contraceptives. By including iron pills for the one week when contraceptive pills are not being taken, the habit of taking one pill each day is not broken.

Essential drugs are vital to primary health care. The provision of these drugs is a complex challenge that needs to be met at the national, community, and individual levels. While the establishment of a drug formulary and standardized treatment schedule is best done as a national policy, there are important drug issues that need to be addressed at other levels by health workers and program managers as well. Needs assessment, storage, stock control, training, and public education are all necessary to make the best possible use of the drugs that are available. National drug policies can only succeed where these community and individual strategies are in place.

Materials Available

The World Health Organization (WHO) has produced several useful publications on essential drugs, including: **The Selection of Essential Drugs**, Technical Report Series 641; **The Use of Essential Drugs**, Technical Report Series 685; and the entire July 1984 issue of **World Health**. These are available from WHO regional offices or by writing to WHO Distribution and Sales Service, 1211 Geneva 27, Switzerland.

□

Information on draft Drug Information Sheets is available from the Essential Drug Programme (DAP), 1211 Geneva 27, Switzerland.

□

The WHO Expanded Programme on Immunization (EPI) has produced a series of 24 booklets on estimating drug needs and on the storage and distribution of drugs and supplies. A list of titles and the booklets are available from EPI at the WHO Geneva address.

A comprehensive text on the selection, procurement, distribution, and use of drugs in primary health care, **Managing Drug Supply**, is available from Management Sciences for Health (MSH), 165 Allandale Road, Boston, MA 02130, U.S.A. A French version is available from I.U.E.D., Service des Publications, 24 rue Rothschild, CH-1211 Genève 21, Switzerland.

□

Information on MSH's microcomputer model for estimating drug requirements is also available at their Boston address.

□

A **List of Indicative Prices for Essential Drugs** is available from UNICEF country offices or by writing to The Director, Supply Division, UNICEF, 866 U.N. Plaza, New York, N.Y. 10017, U.S.A.

□

A bibliography on essential drugs is available from PATH.

INTERCHANGE

The Second International Conference on Oral Rehydration Therapy (ICORT II) will be held December 10-13, 1985, in Washington, D.C. For further information, please write to Ms. Linda Ladislaus, ICORT II Conference Staff, Creative Associates, Inc., Suite 270, 3201 New Mexico Avenue, N.W., Washington, D.C. 20016, U.S.A.

■

Three slide sets, **Immunization: Clinical Signs in Six Target Diseases**, **The Cold Chain**, and **Periodontal Disease**, are now available from Teaching Aids at Low Cost (TALC), P.O. Box 49, St. Albans, Herts. AL1 4AX, U.K. TALC has also produced a series of flannelgraphs on tapeworm, hookworm, and roundworm.

■

A "mini-pack" of teaching materials on leprosy is available from OXFAM at Oxfam Health Unit, OXFAM, 274 Banbury Road, Oxford OX2 7OZ, U.K. The pack contains eight documents and costs £10.00 sterling or U.S. $15.

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health technology
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Infectious Eye Diseases

Trachoma is the world's leading cause of preventable blindness. It affects close to 500 million people, nearly 7 million of whom are blind. Onchocerciasis, or river blindness, infects over 50 million people; over 1 million are blind because of it. Onchocerciasis is the leading cause of blindness in some African and Latin American countries. These two infectious eye diseases are the focus of this issue of **DIRECTIONS.**

Earlier this year, a **DIRECTIONS** issue on primary eye care (Volume 5, Number 1) examined the leading causes of blindness and took an in-depth look at xerophthalmia (nutritional blindness) and cataract and their related technologies.

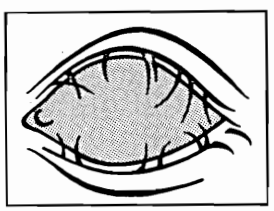
These two diseases, along with onchocerciasis and trachoma, account for nearly all of the difference between the prevalence of blindness in developing countries and the substantially lower level found in many industrialized countries.

Like xerophthalmia and cataract, trachoma is found worldwide. Many of the factors that contribute to its prevalence and spread are closely related to the conditions of poverty under which so much of the developing world lives.

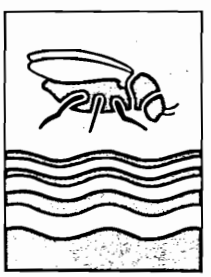
Onchocerciasis, in contrast, has a much more limited distribution, with major pockets of the disease occurring in West and North Africa, Central America and Mexico, and a small part of the Arabian peninsula. In some of the most severely infected areas, virtually whole generations have been blinded, while others face a future of repeated exposure that could lead to the same result.

In addition to their importance as public health problems, trachoma and onchocerciasis are serious obstacles to social and economic development. Not only is the productivity of those who are blinded sacrificed, but there are the additional resource costs of their care. With onchocerciasis, there are also the costs involved when fertile lands are abandoned by those hoping to escape the disease.

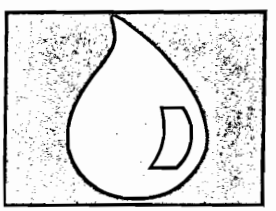
The diagnosis, treatment, and prevention of trachoma and onchocerciasis present serious program challenges. Because of the many ways that trachoma can be transmitted, and because of the area-specific symptoms and consequences of onchocerciasis, programs for both diseases need to consider the local disease ecology, that is, the circumstances in which these diseases are found.



1. Trachoma



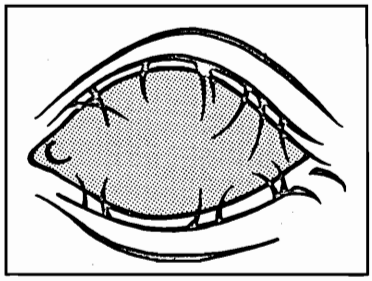
2. Onchocerciasis



3. Local Disease Ecology

Volume 5, Number 3 ISSN: 0730-8620 1985

Trachoma



Trachoma is a chronic inflammation of the eye caused by a bacteria-like organism, **Chlamydia trachomatis.** Chlamydial infection of the lining of the upper eyelid (upper tarsal conjunctiva) causes swelling and eventually scarring of this membrane. A single infection or even a few infections with chlamydia will usually heal with no long-term ill effects. Repeated infection, however, leads to thickening and deformity of the eyelid margin, causing it to turn inward (a condition called entropion). Entropion causes the eyelashes to turn into the eye (a condition called trichiasis). This inward deviation of the eyelashes abrades the cornea, the transparent window covering the iris and lens. Corneal abrasion can cause ulcers and the formation of scar tissue that clouds the vision and can lead to blindness.

Recent research has distinguished two sets of **C. trachomatis** strains or serotypes that usually result in two different disease conditions. One set, **C. trachomatis** serotypes A,B,Ba,C, and sometimes D, causes potentially blinding trachoma characterized by conjunctivitis (inflammation of the conjunctiva). These serotypes are usually spread by eye-to-eye transmission and cause the chronic disease condition found in endemic or hyperendemic communities (ones with many cases of trachoma-caused blindness).

The other set, **C. trachomatis** serotypes D,E,F,G,H,I,J, and K, usually produces a more severe eye inflammation of shorter duration and is less commonly found in hyperendemic communities. These serotypes are associated with conjunctivitis and respiratory infections in newborns and with genital tract infections in adults. This type of trachoma can be transmitted by sexual contact.

Some trachoma experts now believe that the serotypes of chlamydia are a less important determinant of the resulting disease condition than is the clinical setting. This school of thought holds that the severity of eye inflammation results more from factors like the frequency of infection and concurrent bacterial infection than from serotype. There is now some experimental evidence to support this concept.

Endemic trachoma is transmitted from person to person by several means. Direct transmission occurs most often in crowded households or other places where people live in close contact. Chlamydia can be spread in this kind of environment by children touching the watery discharges from their eyes and spreading the infection to the hands or faces of others. Similarly, chlamydia can be spread indirectly by fomite transmission through intermediate objects, such as face cloths, towels, mothers' shawls, and in some Middle Eastern countries, eye make-up applicators.

Carriage of the organism from other reservoirs such as the nose, ears, genital tract, and rectum may be another means of infection and reinfection. Chlamydia has been cultured from discharges from all of these sources, which means that if only the eyes are treated, people can be reinfected from their own extraocular reservoirs. In most cases, however, it is believed that reinfection comes from contact with another infected person.

In some communities there are large numbers of eye-seeking flies, which may also be a mode of chlamydia transmission. In many areas, communities suffer from yearly or twice-yearly epidemics of bacterial conjunctivitis that coincide with increases in the population of eye-seeking flies. Studies have shown that bacteria and possibly chlamydia can be transmitted by these flies and that the combined effect of both types of infection increases the risk of blindness.

When trachoma is hyperendemic, most children are infected before two years of age. Young children represent the main pool of active trachoma infection in communities. The frequency and severity of infection decreases with age, although some adults, especially women, continue to have active signs of the disease even when they get older. That is believed to be because of their close contact with children. Because of the concentration of the active disease in children and their mothers, trachoma has been called "the disease of the creche." It is uncertain why adults generally have less frequent and less acute trachoma symptoms. It is possible that they develop some degree of immunity over time, although this has not been shown conclusively. The lesions of the cornea, which

cause vision impairment and blindness and are usually seen in adults, are believed to be the consequence of scar tissue formation from repeated attacks of inflammatory disease earlier in life.

A community suffering from endemic trachoma can be recognized by the number of adults with trachoma-related vision impairment or blindness from corneal scarring. If a community is endemic for trachoma, then there will also be a large number of cases of entropion/trichiasis.

Diagnosis

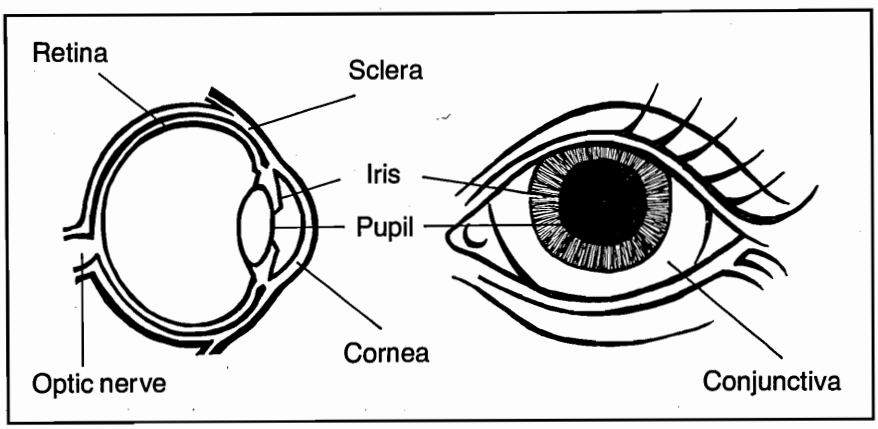
Field diagnosis of trachoma is made by a simple examination using a hand lens. Diagnosis is easier using a slit lamp, but this is a large and expensive piece of equipment usually not available in the field. In a nonendemic area, an individual case must have two of the following signs to be considered positive:

1. Greyish granules on the lining of the upper eyelid (follicles on the upper tarsal conjunctiva).
2. Fine linear and star-shaped scars (typical conjunctival scarring).
3. Greyish granules or pitting of the corneal-scleral border (limbal follicles or their sequelae, Herbert's pits).
4. Shallow infiltration of blood vessels at the upper corneal-scleral border (vascular pannus most marked at the superior limbus).

In an area where trachoma is endemic, the presence of any one of the above signs is considered sufficient for a positive diagnosis. WHO is currently revising its system for diagnosing and grading the severity of trachoma.

There are several other conditions that can cause conjunctivitis similar to that seen in trachoma infections. However, differential diagnosis of these conditions is not absolutely necessary in primary health care situations since the topical antibiotics usually used for treatment of trachoma are not only generally safe but are also useful in the treatment of bacterial infections.

Treatment programs seldom do laboratory analyses to confirm the presence of chlamydia or to determine the infecting serotype because this information is not necessary for treatment. However, such tests are useful for epidemiological studies, for assessing interventions and for monitoring treatment and control programs. The organism itself can be identified after culturing it. Newer diagnostic procedures identify either chlamydia antigens from eye smears or antibodies that are found in tears. These techniques are expensive and not cost effective for use in treatment programs. Research is continuing to develop simpler and less expensive diagnostic tests.



Treatment

The treatment of trachoma falls into two main categories: chemotherapy to treat the chlamydia infections themselves and corrective surgery for entropion/trichiasis.

Chemotherapy

Chlamydia infections respond to treatment with most of the antibiotics that are used for bacterial infections. These antibiotics are administered topically, either as an eye ointment or suspension, or systemically, by mouth or (rarely) by injection.

Topical antibiotics are most frequently used in mass trachoma treatment programs. These are administered using either "intensive" or "intermittent" schedules.

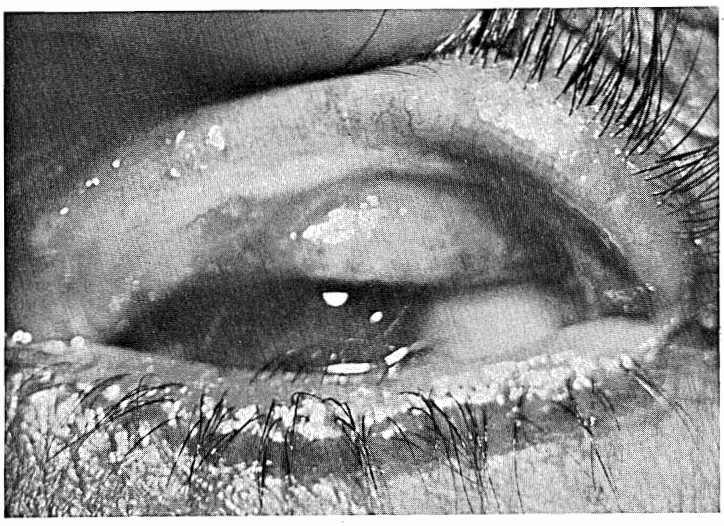
The intensive schedule consists of twice-daily treatment for a period of six weeks or longer and is used to treat moderate or severe cases. The intermittent schedule, which has long been recommended by WHO for treatment of populations in endemic areas, calls for twice-daily treatment for three to five days each month over a period of at least six consecutive months per year. This regimen has been shown to suppress the intensity of inflammation and thus to reduce the occurrence of blinding complications for the period of treatment. Unfortunately, it has little effect in preventing reinfection after therapy ends.

The most commonly used topical antibiotic is 1% tetracycline eye ointment. Erythromycin ointment

(1%) and rifampicin ointment (1%), although as effective as tetracycline, are rarely used because they are much more expensive.

Systemic treatment with oral antibiotics is usually used only in individual cases of moderate or severe trachoma, although oral doxycycline has been used experimentally in mass treatment programs. One advantage of oral treatment is that oral dosages are easier to administer than eye ointment; in addition, systemic treatment is also effective against nasopharyngeal, genital, and rectal carriage of chlamydia.

The main disadvantages of systemic treatment of chlamydia infections are its high costs, the potential for allergic or other adverse reactions, and concern over the possible development of drug resistance. Tetracycline, erythromycin, and sulfa drugs are all effective systemic antibiotics for use against chlamydia infections. Systemic sulfonamides have generally been avoided because of the severe allergic reactions they cause in a very small percentage of patients. Sulfa drugs, however, have been used with great success in a large program in Australia. Systemic tetracyclines are contraindicated for pregnant women because they may cause birth defects. Systemic tetracycline is also not recommended for children under ten years old because it can cause staining of the teeth or slowed bone growth. These side effects are less evident with oxytetracycline and doxycycline. Erythromycin is suggested for pregnant women and nursing mothers; however, it is more expensive than the other systemic antibiotics and it also may be slightly less effective than tetracycline. Streptomycin and neomycin are not effective against **Chlamydia trachomatis.**



Victoria Sheffield

Trichiasis/entropion

The use of systemic tetracyclines, erythromycin, and sulfonamides has not yet been shown to have caused resistant strains of chlamydia. There is concern, however, that their widespread use may lead to resistance in other bacterial pathogens.

Surgery

Trained medical auxiliaries can perform simple corrective surgery for entropion/trichiasis either in community health centers or from a mobile unit. In the most common surgical procedure, an incision is made along the upper eyelid edge; then the incised outer piece is folded back on itself and stitched in place. This repositions the eyelashes so that they face outward again. Antibiotic eye ointment is applied daily until the sixth day after the operation, when the stitches can be removed. Dissolving sutures are sometimes used. The surgery is usually done as an outpatient procedure.

Prevention

Because many factors can contribute to trachoma-related blindness in communities, it is useful to think of trachoma prevention strategies in terms of community ecology.

While eye-to-eye transmission and infection from extraocular sources are the most important modes of trachoma transmission, their relative importance may vary in different settings. It is also important to examine exactly how eye-to-eye transmission takes place. In some areas, dust and smoke may aid transmission by increasing discharges from the eyes. In some communities, a high frequency of other bacterial infections may be an important factor in trachoma-related blindness. Although flies are now generally believed to be a less important mode of chlamydia transmission, they may still play a role in some communities. Understanding the community ecology of the disease is essential to the design of a good prevention program.

Trachoma was a major cause of blindness in North America and Europe in the 1800s. The disappearance of the disease in these countries is often attributed to "progress" or "development" without a clear understanding of which specific changes caused the decline. The availability and use of water for personal hygiene is believed to be one of the changes that may be of particular importance. Some research indi-

cates that while the availability of water is one contributing factor in controlling trachoma, water use practices are even more critical.

Recent work in Mexico found frequent face washing to be the single most important factor in determining the incidence of trachoma in the communities that were studied. The quality or cleanliness of the water and the use of soap were not significant. Drying the face or wiping the nose on clothing, behaviors believed to help spread chlamydia infection, were only a secondary factor in these settings. Similar results were found in Malawi. These findings suggest that frequent face washing may be an important way to prevent trachoma in other communities as well.

In communities where specific practices, such as sharing eye cosmetic applicators, seem to favor trachoma transmission, or where lack of sanitation makes eye-seeking flies a serious problem, these can be addressed in a trachoma prevention program as well.

In endemic trachoma areas, mass treatment with topical antibiotics using the intermittent schedule described above may help control trachoma transmission. However, the ease of reinfection and the expense and complexity of mounting this kind of program make periodic mass drug treatment campaigns unattractive as long-term solutions. Also, systemic antibiotics are not generally recommended for prevention programs for the same reasons that they are avoided in treatment programs.

Much work has been done to develop a vaccine for trachoma, but the first research results were disappointing. The early vaccines were only protective for one to two years. More recently, with the development of monoclonal antibodies and other technologies, researchers are attempting to identify and isolate antigens that could lead to a vaccine with longer-lasting immunity. At present, however, immunization is not used as a prevention strategy.

Program Concerns

Because health staff resources are often over-extended in developing countries, and because reinfection is common in areas with endemic trachoma, programs may need to rely on self-diagnosis and treatment. Also, many of the best trachoma prevention strategies require behavioral change. For these reasons, it is essential to involve the community in trachoma programs.

Community trachoma programs should:

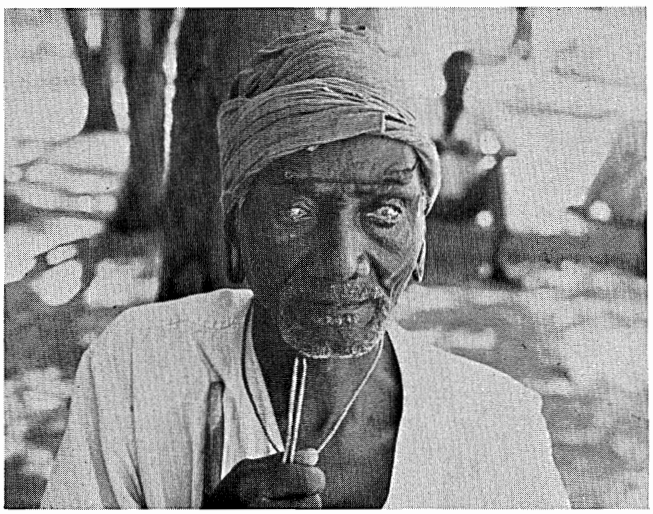
- Analyze the local trachoma ecology, looking at the contexts in which the disease occurs in the community. Assess the severity of the problem, who is being affected, and the most important modes of transmission.

- Design prevention strategies adapted to the specific local conditions. These might include: health education to improve personal hygiene or to change trachoma-promoting behaviors; structural changes to improve water access and sanitation; and in the short term, intermittent provision of topical (and possibly systemic) antibiotic therapy in endemic areas.

- Provide topical antibiotic therapy for individuals with active or acute trachoma, corrective surgery for individuals with entropion/trichiasis, and rehabilitation and other services for those already blinded by trachoma.

- Evaluate the progress of the ongoing program and track changes in the community trachoma situation.

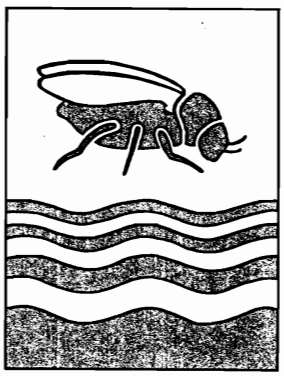
National health programs can find ways to promote these goals by providing necessary personnel, training, equipment, medication, and other resources to support community level programs.



Helen Keller International, Inc.

Trachoma victim with head strap and tweezers to remove inturned lashes

Onchocerciasis



Onchocerciasis is a blinding disease caused by the parasitic filarial worm **Onchocerca volvulus.** Onchocerciasis is transmitted by the **Simulium** species of blackflies, which live near fast-flowing rivers in some areas of West Africa, Central and South America, and Yemen. Because the disease is spread by flies that breed in rivers, it is sometimes called river blindness.

Onchocerca volvulus exists in two forms in human beings: as adult worms (macrofilaria) and as their non-reproducing offspring (microfilaria). When a simulium blackfly bites an infected individual, it picks up some of the microfilariae in its blood meal. The microfilariae undergo changes in the blackfly and become infective larvae that are transmitted back to humans in a subsequent bite. The infective larvae develop into male and female adult worms in their human hosts, often forming nodules, or tightly packed balls of adult worms that are palpable just under the skin. After the adult worms mate, the female releases non-infective microfilarial embryos. Each female can release hundreds of thousands of these embryos over the course of her ten-year life span. These embryos develop into microfilariae that are picked up by biting blackflies to start the cycle again. The number of adult worms is only increased by each new infection from a simulium blackfly.

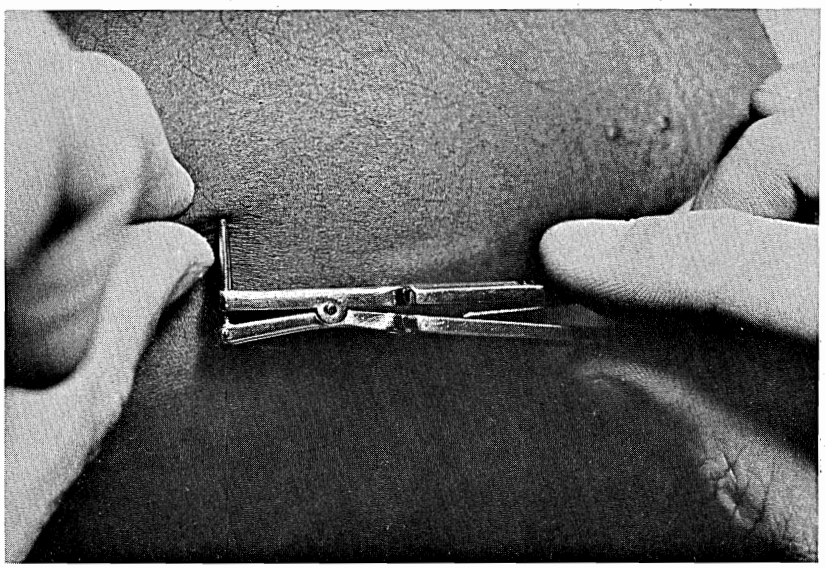
Onchocerciasis is a cumulative disease in the sense that the clinical symptoms increase with the number of infections over time. These symptoms are: nodules, itching, skin changes, lymph blockages, sometimes general debilitation and fatigue, and eye involvement. Most of these symptoms result from inflammatory responses to the death of microfilariae in body tissues. Living microfilariae seem to avoid these host immune responses, possibly either by disguising themselves with molecules borrowed from the host or by inactivating parts of the host's immune response system. When microfilariae die, either of natural causes or because of drug treatment, they are again recognized by the immune system and consequently cause severe localized inflammatory reactions.

Onchocercal eye disease is caused by the inflammation and subsequent scarring of eye tissue that has been infiltrated by microfilariae. The eye symptoms of onchocerciasis are: photophobia, pain, restricted visual field and acuity, and less often, night blindness. Severe cases result in total blindness. Blindness most frequently develops in young adult males between the ages of 15 and 45. It is believed that males are more susceptible because fishing and farming may bring them into more frequent contact with infected blackflies. There is no evidence to date that differences in male and female body chemistry play a role.

The first ocular sign of onchocerciasis is microfilariae in the eye itself. Corneal involvement first appears as "fluffy" cloudiness (punctate keratitis) that may be visible using a hand lens or slit lamp in direct eye examinations. Punctate keratitis is reversible, and sometimes disappears as the dead microfilariae are dissolved and absorbed by the body. Heavy or frequent infections cause irreversible corneal scarring in the form of sclerosing or hardened

Dr. Alfred Sommer

O. volvulus *microfilaria*



Dr. Henry Newland

Corneoscleral punch being used to take a skin snip

keratitis, which results in blindness. Microfilariae invade other eye tissues as well as the cornea; infiltration of the anterior chamber, sclera, iris, lens, and retina can all cause vision problems that can contribute to or cause blindness.

The symptoms and course of onchocerciasis vary with geographic location and possibly with differences in the parasite and the simulium blackfly as well. In the savanna zones of Sudan, for example, onchocerciasis is characterized by a higher prevalence of corneal scarring than is found in the rain forest zone. In Yemen, patchy darkening of the skin with papular eruptions (called sowda) together with lymph node swelling in one extremity is much more common than is found with onchocerciasis in other parts of the world. Research to determine the cause of these differences is continuing.

Diagnosis

The standard diagnostic test for onchocerciasis involves taking a small piece of skin, usually from over each iliac crest (at the hip), using either a razor blade or a special corneoscleral punch. The sample can be standardized for quantitative tests by weighing it. In the past, snips were taken from the juncture of the lower and upper eyelid (outer canthus). However, because outer canthus snips are painful and can leave scars, these are now rarely done, although sometimes snips are taken from the shoulder.

Skin snips are submerged in either Ringer's solution, saline, or distilled water for varying periods of time, usually from one-half hour to two hours, so that the microfilariae will leave the skin. A more sophisticated technique uses collagenase to dissolve the skin, making it easier to locate microfilariae in very light infections. Collagenase is usually used only if a suspected positive snip tests negative. In snips with moderate microfilarial loads, collagenase increases yields by only about five percent. After preparation, samples are examined microscopically and the microfilariae are simply counted. Fewer than 20 microfilariae per milligram (mf/mg) of skin indicates a light load; 20 to 100 is considered moderate to heavy.

The Mazzotti provocative test, a noninvasive qualitative test for onchocerciasis that was once widely used, is no longer recommended. This test made use of an allergic reaction, experienced by people infected with **O. volvulus,** to a single oral test dose of 25-50 mg of diethylcarbamazine (DEC). Even in lightly infected people, Mazzotti reactions are unpleasant, with symptoms including itching, swollen lymph nodes, fever, and head and body aches. In heavily infected people, the allergic reaction can be very severe and can result in shock, loss of consciousness, and rarely, death. These dosage levels of DEC have also been shown to cause eye irritation when microfilariae are present and can increase the risk of permanent damage to the eye. For these reasons, this test is no longer being used.

Researchers have recently developed a patch test for onchocerciasis using the Mazzotti reaction, but based on topical rather than systemic doses of DEC. A small amount of 10% DEC in Nivea cream is applied to the skin and covered with a dressing. The treated skin is examined between 8 and 24 hours later for signs of irritation (a papular rash). The number of false negatives in lightly infected individuals can be decreased by testing multiple sites on the body. Early indications are that the DEC patch test is both safe and fairly reliable.

As with trachoma, onchocerciasis can also be diagnosed by direct examination of the eye. This requires a slit lamp, a piece of equipment not well suited to community-level diagnosis. Also, because individuals may have a moderate infection of **O. volvulus** before any eye involvement occurs, direct examination is often an unsatisfactory means of diagnosis.

Serological tests for onchocerciasis have been developed to test for either **O. volvulus** antigens or the antibodies that the immune system has produced against them. The main drawback of antibody tests is that they do not discriminate between present and past infections. The serological tests that are currently available also have difficulty differentiating **O. volvulus** from other filarial and some nonfilarial infections. These tests are being refined and research is under way to simplify them for use in community settings.

Victoria Sheffield

Slit lamp examination

Treatment

The two main types of onchocerciasis treatment are chemotherapy and surgical removal of the nodes (nodulectomy).

Chemotherapy

The two standard drug treatments for onchocerciasis are DEC and suramin. Each has severe limitations. DEC can cause the Mazzotti reaction described in the section on diagnosis. For that reason, and because it can cause irreversible retinal and optic nerve changes, decisions to use DEC must be carefully considered. DEC is not effective against adult worms; although it immediately reduces the microfilarial load, the number of microfilariae usually increases to pre-treatment levels within a year, as the adult worms continue to reproduce. Lower DEC doses have been tried in order to limit the Mazzotti reaction, but the side effects persist for most patients even at DEC levels too low to be of any therapeutic value. Several studies of combined therapies have been done using DEC and anti-inflammatory drugs to combat the Mazzotti reaction. Antihistamines, aspirin, and steroids have all been successfully used to alleviate some Mazzotti reaction symptoms, but no treatment has yet been found that prevents the reaction itself.

Suramin, which kills adult worms and is somewhat effective in killing microfilariae, is a dangerous drug. At therapeutic dosages, suramin can cause optic nerve disorders, kidney disease, and death. Safer doses are often too low to kill all of the adult worms.

Benzamidazoles have recently been identified as a group of compounds effective against filarial infections. They work by preventing the maturation of microfilarial embryos in the adult female worm. The total number of viable microfilariae decreases as they die off and are not replaced. Because they do not work by killing either adult worms or microfilariae, benzamidazoles do not usually stimulate a Mazzotti reaction. Mebendazole and flubendazole are the two benzamidazoles that have been most widely tested as treatments for onchocerciasis. Mebendazole, which is effective at high dosages, can cause birth defects in animals and is therefore probably unacceptable for use in humans. Mebendazole also kills some microfilariae, which sometimes leads to a slight Mazzotti reaction, and can cause white blood cell imbalances. Flubendazole has neither of these disadvantages, but it is expensive, and the duration of its effect is still under study. Both drugs are difficult to absorb and research is continuing to try to develop better oral formulations.

Ivermectin, a relatively recent drug, has been found to be effective against a related cattle filarial parasite, **O. gibsoni**, and is now being tested in humans. Available as an oral dose, it appears to kill microfilariae without causing a Mazzotti reaction. Initial studies indicate that ivermectin is both safe and effective. If further tests confirm this, ivermectin will be a useful replacement for DEC.

Several other compounds are currently being screened for use against onchocerciasis. Much of this work is being coordinated by the Onchocerciasis Chemotherapy Project within the WHO Onchocerciasis Control Programme (OCP) (see box, page 10).

Surgery

Nodulectomy is a procedure commonly done in Central and South America where macrofi-

larial nodules occur on the head and upper body more frequently than in other regions. One problem with nodulectomy is that deep nodules are often not palpable; also, female adult worms may release microfilariae before they form nodules. Further, there is some debate as to whether the removal of palpable lumps of adult worms from the head decreases the likelihood of microfilariae infiltrating the eye. However, nodulectomy is still recommended, especially for head nodules in children.

Dr. Alfred Sommer

Simulium black fly

Prevention

Four main strategies have been pursued to prevent onchocerciasis: vector control, relocation, chemotherapy, and immunization.

Vector control programs use insecticides to reduce the simulium blackfly population and thereby decrease the spread of the disease. The most extensive control program of this type is the OCP. In the 1950s, onchocerciasis was eradicated in large tracts of Uganda and Kenya where DDT was used to kill off the blackfly population. More recently, local vector control programs have been attempted in the Sudan and Guatemala with some good results. These programs have used applications of a solid larvicide called temephos (an organophosphate marketed under the brand name Abate) in streams where simulium blackflies breed. The success of these programs depends on having access to breeding areas and on the volume of water to be treated. Where the volume is too great, treatment costs are prohibitive. The replacement of earthen causeways by raised bridges and the elimination of dense vegetation from breeding areas have also been effective in experimental trials in the Sudan.

Relocation of villages from the banks of infested rivers is a useful prevention strategy when vector control is either too difficult or expensive. However, many villagers are reluctant to move from the fertile farmland found on river banks. In addition, many villages rely on the rivers either for water supplies or for fishing. In villages where infrastructure such as health centers, wells, or roads is already in place, relocation is even less desirable. In some cases, even relatively minor changes, such as moving 500 meters or changing the river bank area used for washing, can have a dramatic impact on the incidence of infection.

Chemotherapeutic prevention is of two types: chemoprophylaxis to prevent individual infection, and treatment of severely infected cases to slow the spread of the disease in the community. The unpleasant side effects of low doses of DEC make it unattractive for prophylaxis. However, experimentation has recently begun using ivermectin. While neither DEC nor ivermectin is a true prophylactic (because each allows infection and development of adult worms), low-dosage suppression treatment with ivermectin would reduce the microfilariae load to a level where there would be no eye involvement. A new drug implant delivery system, hydrogel lozenges that allow slow, continuous absorption of low dosages of medicines for periods of up to a year, is being investigated as well.

The treatment of severe cases of onchocerciasis to slow the spread of the disease relies on inpatient facilities and will only become feasible with the development of safer drugs. The administration of both DEC and suramin requires careful supervision and controlled conditions for observation and treatment of side effects. Because DEC treatments can sometimes worsen eye conditions, treatment can only be recommended for patients with severe, sight-threatening cases of the disease.

Much research has been done to find a vaccine for onchocerciasis, with little success so far. More information is needed on how the different life stages of the parasite interact with the human immune systems before development of a vaccine is likely.

Program Concerns

Two of the main program concerns for onchocerciasis are the diagnosis and selection of patients for treatment and the

mechanics of treatment distribution. These are important issues because the drugs currently available for treatment may worsen existing eye problems or cause other illness or death.

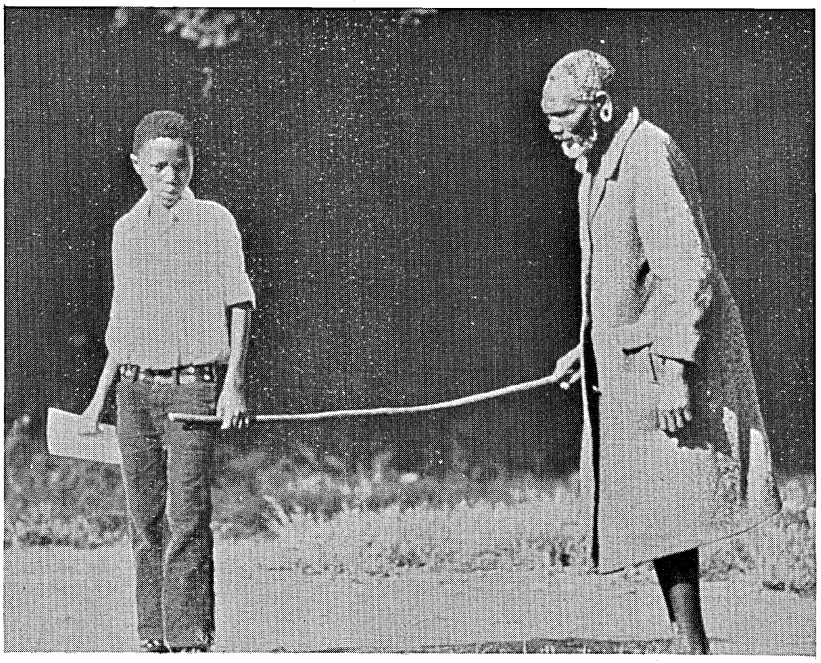
Vector control programs raise other issues. Large scale programs, such as the OCP, are expensive and require international coordination and cooperation to succeed. Devolution, or turning the management of vector control over to the local population, is an important goal of these programs. In local vector control programs, the concerns include limiting the blackfly populations effectively without sophisticated monitoring systems or expertise, and preventing repopulation by flies from outside the treated areas. For both local and international programs, vector resistance and lack of resources are significant constraints.

ONCHOCERCIASIS CONTROL PROGRAMME

The Onchocerciasis Control Programme (OCP) was organized within WHO to combat onchocerciasis in the Volta River basin area of West Africa. In 1974, seven countries—Benin, Burkina Faso, Ghana, Ivory Coast, Mali, Niger, and Togo—joined together with international donor agencies to start an integrated program of vector control, surveillance, and socio-economic development. In 1984, four additional countries—Guinea, Guinea Bissau, Senegal, and Sierra Leone—also joined.

The program relies on vector control and uses carefully orchestrated insecticide treatments and a sophisticated helicopter and airplane delivery system. Temephos is the most widely used insecticide, but in the southwestern part of the region two other insecticides—chlorphoxim and B.t. H-14 (marketed as Teknar)—have been used because blackflies there have developed resistance to temephos. Teams of "vector collectors" regularly monitor 270 adult blackfly catching points throughout the region and provide information for planning the frequency and timing of insecticide treatments.

The OCP also evaluates the progress of the control program by studying the human population for disease transmission and development, does research on new insecticides, chemotherapy, and diagnostics, and has projects for the resettlement of formerly infested areas where the blackfly population is now under control.



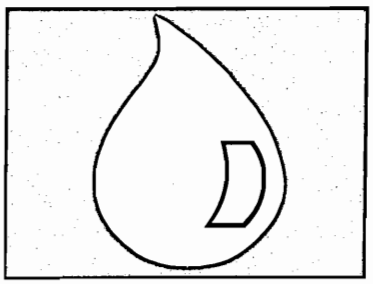
Suzanne Whitfield

Boy leading a blinded elder

The costs of this program have been high. Expenditure in the first phase (1974-1979) was U.S. $58.3 million. Estimated costs from 1980 to the present are U.S. $111.9 million. Total OCP costs measured in 1983 prices peaked in 1980 and have declined slightly since.

The achievements of the OCP after ten years of active control measures are impressive. Almost none of the children born in the last ten years in 90% of the program area have onchocerciasis, and the number of live worms in adults has decreased in many areas by 50%. The transmission cycle has been broken, and many of those infected before the start of the program are recovering from their old infections with little or no risk of becoming blind.

Local Disease Ecology



Local disease ecology is the context or local surroundings and circumstances in which a disease is found. A single drop of water may be a chlamydia-infected tear, part of a face-washing campaign to prevent trachoma, or from a blackfly-infested river. Which of these is the case only becomes clear when it is put into context. In the same way, diseases need to be understood in terms of their local circumstances or surroundings before effective primary health care programs can be designed.

Trachoma and onchocerciasis are both diseases that need to be understood in terms of their local context or ecology. With onchocerciasis, the clinical manifestations of the disease change depending on the geographical area in which it is found. For example, the head nodules common in Central and South America and the patchy darkening of the skin common in Yemen are rarely seen in Africa. Even within a single country, such as Sudan, onchocerciasis in different ecological zones can be characterized by distinctly different symptoms and, more importantly, different disease outcomes. In the Sudan savanna zone, for instance, the prevalence of blindness from onchocerciasis is at least two and one-half times as high as it is in the forest zone, even though forest zone residents are heavily infected with the disease.

Some onchocerciasis programs have looked for ways to adapt to these local variations. Recent work on vector control in the Sudan recommends separate approaches for each of three regions that differ in their disease outcomes and site accessibility for larvacide programs. In Guatemala and Mexico, research indicating that onchocerciasis may be spread partially by annual religious pilgrimages and by the movement of migrant farm workers suggests control methods aimed at these groups.

The ecological issues important to trachoma are less those affecting the variations in the chlamydia organism than those surrounding the transmission of the disease and concurrent factors that contribute to corneal damage. Because transmission of chlamydia takes place both directly between individuals and through a variety of objects, interactions between individuals and the objects they use become important. Patterns of child care and style of clothing may be as important in some areas as family hygiene or a fly vector is in others. Concurrent bacterial infections can add to corneal damage as well as cause inflammation and eye discharges that help spread chlamydia. The same effect is apparent in areas where blowing dust or sand is a problem. All of these factors should be considered in selecting or emphasizing appropriate components for local interventions.

Some trachoma programs have also successfully adapted to local disease ecologies. Trachoma case identification and treatment programs developed in southern Morocco in the 1960s were organized to take into consideration the seasonality of both trachoma and bacterial conjunctivitis. Trachoma programs in Taiwan from the same period studied local disease characteristics to determine treatment schedules and drugs most appropriate to the local forms of the disease.

In Yugoslavia, local programs have been adapted to take into consideration the falling prevalence and incidence rates resulting from the success of their treatment and prevention programs. Detection of new cases became more difficult when health workers saw them less frequently. The choice of treatment was also modified to reflect the changed conditions. With fewer cases, the emphasis on self treatment with topical antibiotics could be shifted towards a greater use of systemic antibiotics under the supervision of health personnel. Finally, the initial level of resources expended for health education and program staff could no longer be justified and had to be reduced.

Community health resources provide another context within which local interventions should be considered. Most trachoma interventions and all but the large-scale onchocerciasis vector control programs are add-ons to existing health programs; few countries have trained health personnel to work specifically with these diseases.

The choice of the best intervention or combination of interventions requires an understanding of community health resources as well as local disease ecology. The availability of a health educator

or good clinical staff and facilities may determine the feasibility of a health education campaign or interventions that rely on good diagnosis, treatment, and follow-up. Active community organizations may enable a community to implement a local vector control program that could not succeed in communities not having these organizations. Careful consideration of local ecology will greatly aid the design and implementation of disease control programs.

Materials Available

Strategies for the Prevention of Blindness in National Programmes. A primary health care approach is available from World Health Organization (WHO) regional offices or by writing to: WHO Distribution and Sales Service, 2111 Geneva 27, Switzerland. WHO also publishes a short, annotated bibliography of their publications and articles on blindness entitled **Prevention of Blindness.** It is available at the Geneva address.

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For information on the WHO Onchocerciasis Control Programme (OCP), write to: OCP, P.O. Box 549, Ouagadougou, Burkina Faso.

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Three slide sets, **Primary Eye Care, Xerophthalmia,** and **Onchocerciasis,** are available from Teaching Aids at Low Cost (TALC), P.O. Box 49, St. Albans, Herts. AL1 4AX, U.K.

Three slide sets on xerophthalmia are also available from Helen Keller International (HKI). They are **Clinical Characteristics and Management of Xerophthalmia: A Teaching Guide for Physicians, The Prevention of Xerophthalmia and Nutritional Blindness,** and **A Manual for Training Health-workers in the Recognition, Treatment and Prevention of Vitamin A Deficiency: Signs and Symptoms of Nutritional Blindness.** HKI has also produced a brochure entitled **Know the Signs and Symptoms of Xerophthalmia,** and a **Xerophthalmia Treatment and Prevention Schedule.** For information on these and other materials, write to their Technical Services Division, HKI, 15 West 16th Street, New York, NY 10011, U.S.A.

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A bibliography on trachoma and onchocerciasis is available from PATH.

INTERCHANGE

Slide sets on **Dentistry, Weaning Foods, Leprosy,** and **Schistosomiasis,** are available from Teaching Aids at Low Cost (TALC) at the above address.

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A new WHO publication, **Essential Drugs Monitor,** is a newsletter produced and distributed by the WHO Action Programme on Essential Drugs and Vaccines. It can be obtained by writing to: Essential Drugs Monitor, WHO, CH-1211 Geneva 27, Switzerland.

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Topics for two future **DIRECTIONS** issues will be tuberculosis and children's accidents and injuries and their related technologies. Readers knowing about or working in innovative primary health care programs in these areas are encouraged to send information or materials to the editor.

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health technology
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Tuberculosis

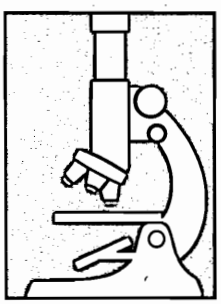
According to World Health Organization (WHO) estimates, at least three million people die each year of tuberculosis. Every year four to five million new infectious cases are added to the statistics, and the same number of noninfectious cases develop, many of which will later become infectious.

In many developing countries tuberculosis is a major health problem. In the Philippines it is the second leading cause of death. It is estimated that in India there are nearly ten million active adult cases. Case rates for Latin America and Africa are also high, and because tuberculosis is often undiagnosed, morbidity and mortality statistics in most countries are believed to considerably underestimate the actual problem. Tuberculosis rates are also difficult to quantify because only a small proportion of those infected by the causative agent develop clinical signs.

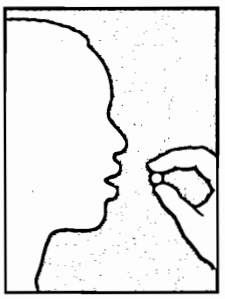
Tuberculosis is not a new disease; the ancient Greeks recognized it, and skeletal remains from other early cultures suggest its presence. It did not become endemic, however, until the rise of urban centers where the disease could spread easily. Today tuberculosis is still most highly concentrated in urban areas where poverty, malnutrition and over-crowding are found.

In 1882, Robert Koch identified the organism responsible for tuberculosis, *Mycobacterium tuberculosis*. Over one hundred years later, in spite of the development of accurate diagnostics, immunization programs, and effective drugs for treatment, the incidence rates in many countries have not declined substantially. Where progress has been made, it is at least in part attributable to the natural decrease in incidence of an infectious disease as more of the population become exposed and develop immunity. Because of population growth, the actual number of tuberculosis cases in most developing countries is still increasing.

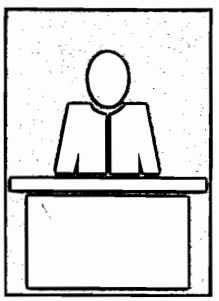
This issue of **DIRECTIONS** focuses on the technology issues surrounding the diagnosis, treatment, prevention and program management of tuberculosis.



Description and Diagnosis



Treatment



Prevention and Program Issues

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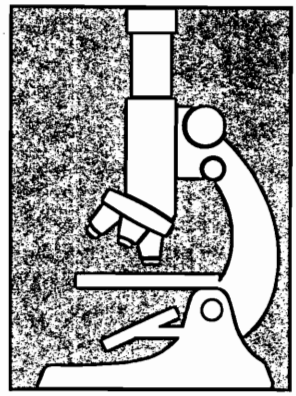
Description and Diagnosis



Description

Tuberculosis is caused by the organism *Mycobacterium tuberculosis*. By convention, the disease caused by a related organism, *M.bovis* (transmitted by infected cows' milk or by direct exposure to infected cows), is also called tuberculosis, although the clinically identified infections caused by other mycobacteria are not. Transmission is usually by inhaling the *M. tuberculosis* bacteria, also called tubercle bacilli, that have been coughed or sneezed into the air by an infected person.

When the tubercle bacilli enter the lungs for the first time, they form a small infection in the lung tissue and often in the lymph nodes that drain it. These two sites of infection are known as the primary complex. At this time, some of the bacilli may also enter the blood stream and spread to other parts of the body where they may start new infections, die off, or remain inactive but viable for many years. Primary tuberculosis can occur at any age, but in countries with high incidence rates, most children are exposed to the tubercle bacilli early in life and become infected. Therefore, primary infections have long been referred to as childhood tuberculosis.

Within three to four weeks of infection, the body produces a cell-mediated immune response, and tissue changes occur in the lungs to encapsulate or wall off the infected area. The lesions formed in this process help prevent the spread of the bacilli to other parts of the body and to other individuals but cause irreversible damage to the lung.

It is important to make a distinction between tuberculosis infection and disease. Many individuals are exposed to tuberculosis bacilli and are infected, but few develop the disease.

The extent of the damage caused by a primary infection depends on the number of bacilli that are inhaled and the nutritional and immunological status of the infected person. An otherwise healthy individual may experience no disease symptoms and the primary lesion may heal completely, resulting in only a small scar in the lung tissue and subsequent positive antibody tests. In individuals who are malnourished or whose immune systems are weakened or overwhelmed by other diseases, the clinical symptoms may be pronounced and the prognosis poor.

In such susceptible individuals, extrapulmonary (outside of the lung) infections are also more common. Miliary tuberculosis, so-called because of the distribution of millet-seed-like infections throughout the body, and meningeal tuberculosis (tuberculosis of the meninges, the membranes surrounding the brain and spinal cord) are often fatal. These and other extrapulmonary forms of tuberculosis are most common within the first year after a primary infection in a child less than five years of age. A case of tuberculosis that is diagnosed in a person infected years earlier is called post-primary or adult tuberculosis. Post-primary disease may be due either to a reinfection or to the reactivation of an original infection. Reactivation of old infections often occurs in periods of growth, such as adolescence or pregnancy, during periods of stress from disease or malnutrition, or in old age.

Diagnosis

Initial diagnosis of tuberculosis usually starts with clinical presentation of the following symptoms: fever, weakness, weight loss and a persistent cough that may produce blood-stained lung secretions or sputum. The severity of these symptoms depends on the stage of the disease at diagnosis and the extent of the lesions. In early stages of infection and especially in primary infections in children, very few symptoms may be present. Diagnosis of early-stage childhood tuberculosis is usually best made by carrying out a tuberculin skin test (described below) on a child who fails to grow, continues to appear sickly after an attack of measles or other disease, or has been in contact with an infectious tuberculosis patient.

The most widely used diagnostic for tuberculosis is microscopic examination of a direct sputum smear. In this procedure the patient is requested to cough deeply to bring up sputum (thick bronchial secretions, not saliva) from the lungs. Sputum is best collected early in the morning and should be placed in a clean, dry, leak-proof container labelled with the date and patient's name. A small amount of the thickest part of the sample is spread on a microscope slide, fixed, stained using the Ziehl-Neelsen technique (see pages 4 and 5) and finally examined using first the 40x objective and then an oil immersion lens. After staining, tuberculosis bacilli appear as small, pink, slightly curved rods on a blue background. The results of the oil immersion lens examination should be reported as follows:

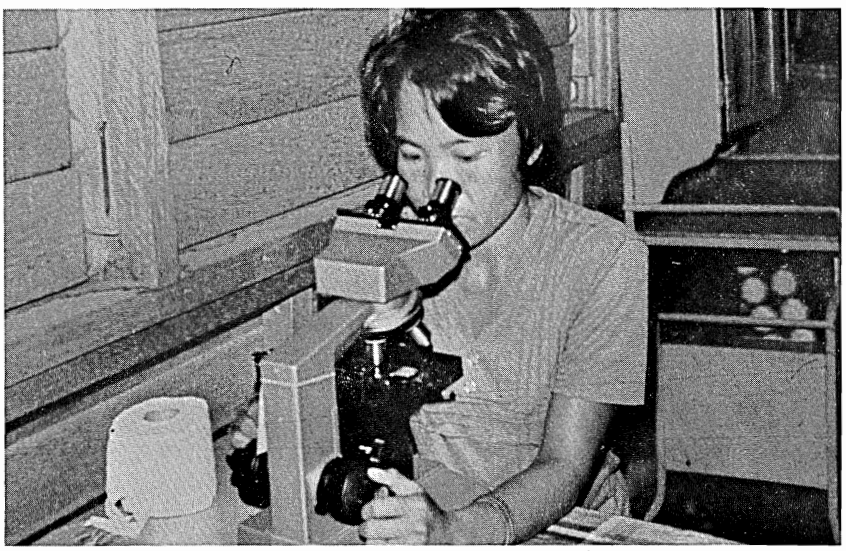
Observation	Report
>10 bacilli/field	+++
1-10 bacilli/field	++
10-100 bacilli/100 fields	+
1-9 bacilli/100 fields	exact number

It has been estimated that it is necessary to have a concentration of 50,000 to 100,000 tubercle bacilli per milliliter of sputum to detect them using the Ziehl-Neelsen staining technique. An alternate method, using an auraminephenol stain that causes the bacilli to glow when exposed to ultraviolet light, makes the bacilli more visible. This allows examination with a 25x or 40x lens, which increases the area that can be examined quickly on a slide. This advantage increases both the number of slides that a single technician can examine in a single day as well as the chance of finding bacilli in a lightly infected case. One disadvantage of this technique is that it requires a microscope with a special light source and filters and only becomes cost effective when there are many slides to examine.

The tubercle bacillus can also be cultured, and this is routinely done in developed countries, especially in the diagnosis of children and extrapulmonary cases and in the detection of contacts. In developing countries, culture techniques are most often used when testing for susceptibility to various therapeutic drugs or in epidemiological studies to differentiate strains of the bacillus. Culturing tuberculosis takes up to six weeks and requires controlled conditions and more advanced training than is necessary for direct smear microscopy.

There are also programmatic reasons for the emphasis that has been put on direct smear microscopy. While smear-positive patients are highly infectious, studies have shown that smear-negative, culture-positive patients rarely infect those around them. Where resources for diagnosis and treatment are limited, it is most important to find and treat the infectious, smear-positive cases to prevent further spread of the disease. Recently, WHO has moved slightly towards the view that the use of culture techniques for diagnosis may be desirable to identify patients for treatment before they become infectious and to identify marginally active patients who have few symptoms but who occasionally spread bacilli.

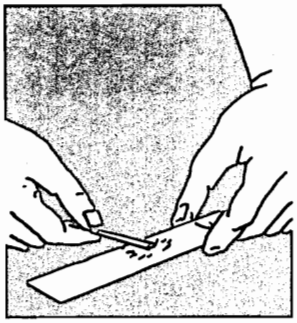
Radiography or X-ray examination was at one time the most widely used mass screening method for tuberculosis. Case-finding for many developing countries relied on mobile X-ray units testing asymptomatic individuals in an attempt to identify cases that would otherwise be positive by culture only. Research has since shown that even regularly repeated radiography is responsible for very few diagnoses. Smear-positive cases develop so quickly that many patients are missed even if X-ray examinations are done every three months, and few countries can afford the resources necessary for this kind of coverage. For these reasons, WHO has recommended against the use of mobile radiography for mass tuberculosis screening of healthy populations.



AKAP/World Neighbors

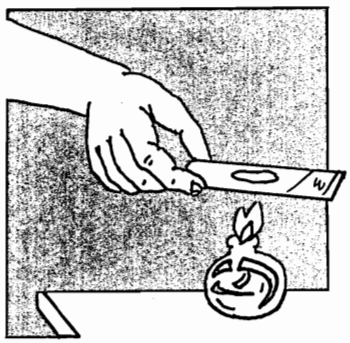
Lab technician examining a sputum smear in the Philippines

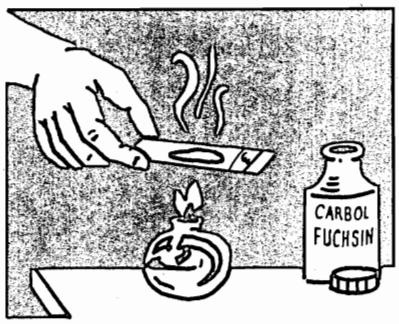
ZIEHL-NEELSEN PREPARATION OF A SPUTUM SMEAR



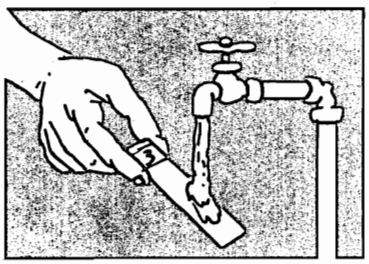
Using a stick or wire loop, transfer a small portion of the thickest part of the sample onto a clean, labelled slide. Make a thin circular smear, about 30mm across, and allow to dry.

Fix the smear EITHER by covering it with 1-2 drops of 70% alcohol (ethanol or methanol) for 2-3 minutes, OR by passing the slide through a flame 3 times.

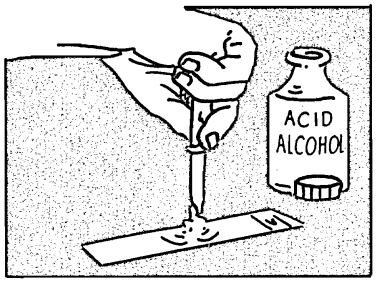




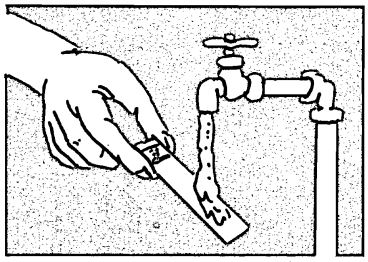
Cover the smear with filtered carbol fuchsin stain and, using an alcohol lamp, heat the stain until steam just begins to rise. Then remove from the flame. DO NOT OVERHEAT.



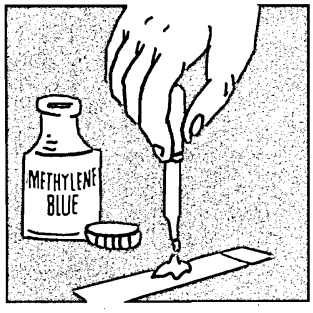
Wait 5 minutes, then rinse the carbol fuchsin stain off with clean water.



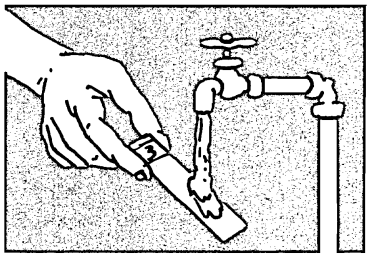
Cover the smear with 3% acid alcohol. CAUTION: ACID ALCOHOL IS FLAMMABLE. KEEP IT AWAY FROM FLAMES.



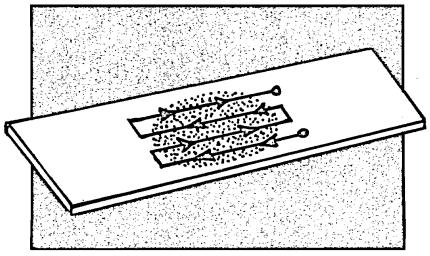
Wait 5 minutes or until the smear becomes pale pink, then rinse the acid alcohol off with clean water.



EITHER cover the smear with methylene blue and wait for 30 seconds, OR with malachite green stain and wait for 1-2 minutes.



Rinse the stain off with clean water, and let the slide air dry. Do not wipe.



Examine the slide first with the 40x objective and then with the oil immersion lens. Move the slide systematically to avoid repeating examination of the same field. Wipe the oil immersion lens off after each positive slide to prevent transfer of bacilli.

Drawings modified from artwork by Lino Montebon from **"Control of Tuberculosis,"** an AKAP/World Neighbors flipchart.

The use of X-ray examinations for diagnosis of symptomatic cases entails some of the same problems encountered in mass screening. Because most symptomatic cases are already smear-positive, direct smear diagnosis is the simplest and least expensive test for confirmation. In addition, X-ray examination requires special equipment and skills, and in primary tuberculosis, especially in children, lesions are often too small to identify easily on X rays. People with old tuberculosis scars or other inactive lung lesions are also easy to misdiagnose as active cases.

Skin testing for sensitivity to tuberculoproteins has been used as a diagnostic for the last 50 years. The test is based on the fact that when a person has previously been exposed to tuberculosis, his or her immune system will quickly respond to the bacilli when exposed again. The tuberculin test can be performed using either old tuberculin (OT) or purified protein derivative (PPD). OT is prepared by heat-killing concentrated tubercle bacilli that have been cultured in a protein broth. PPD is prepared by precipitating the protein in OT using ammonium sulfate or trichloroacetic acid. The most commonly used PPD has been designated RT23.

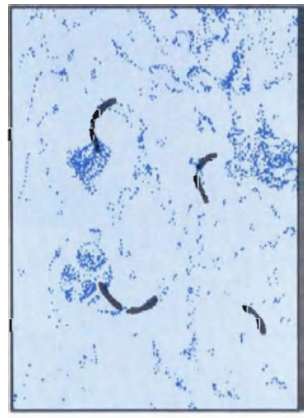
Both OT and PPD are currently used for skin tests. For the Mantoux test, either OT or PPD is injected into the inside surface of the forearm. For survey work, a 5 Tuberculin Unit (TU) dose is used, although higher doses are sometimes used in clinical diagnosis. By the end of 24 hours, the nonspecific reactions to the injection have subsided, and at the end of 48-72 hours, the injection site is examined for an induration or small raised area. The diagnosis is based on the size of the induration. An induration of 10 mm or greater measured 48-72 hours after a 5 TU injection is considered positive. Because the cutoff points and tuberculin strengths used have varied over the years, it is important when giving test results to note the kind of tuberculin used, the dose administered and the size of the induration, instead of simply reporting positive or negative.

In the 1950s a variation on the Mantoux test was developed using a small plastic disk with tuberculin-coated prongs or tines imbedded in it. Results using this tine test correlate fairly well with those from the Mantoux test, but because the exact dosage can be more easily controlled, the Mantoux test is still preferred, especially for epidemiological surveys.

Another method of testing for skin sensitivity, called the chamber test, has also been developed. This test uses small, concave button-like capsules made of aluminum and filled with a cream containing different concentrations of tuberculin. The capsules are taped to the forearm for 48 hours, removed, and the induration is read 24 hours later. The advantages of the chamber test are that the skin is not broken and that the reaction to several different levels of tuberculin strength can be tested at the same time. This test has not been widely used, and more research needs to be done to determine the best concentrations of tuberculin and which cutoff points are most appropriate for clinical diagnosis.

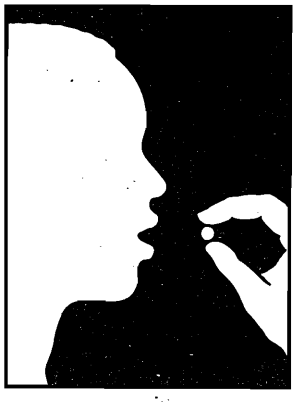
Tuberculin tests have several constraints. Because they only measure cell-mediated immune response, tuberculin tests are unable to differentiate between infection and currently active disease. In endemic areas, where most children are exposed at an early age, a large portion of the population will test positive. Individuals vaccinated against tuberculosis with BCG vaccine also test positive, as do some individuals who have been exposed to other mycobacteria in the environment. Tuberculin tests are most useful in populations or subgroups with low to moderate incidence rates, for epidemiological surveys, and for diagnosing childhood tuberculosis in nonvaccinated children. In this last group, conversion from tuberculin negative to positive is a key diagnostic sign but does not always pick up very recent infections or early tubercular meningitis in children.

Recently, much work has been done to develop tuberculosis diagnostics that use blood or serum. Serological tests face many of the problems discussed under skin sensitivity tests, and it has been especially difficult to develop highly specific tests. So far, no serological test has been developed that is as sensitive and specific as bacteriological techniques.



Tuberculosis bacilli, shown in black, would appear red on a slide

Treatment



For many years the treatment of tuberculosis depended on extended in-patient care. This was done to provide the good nutrition and rest believed to be critical to recovery as well as to protect the public from infection. The development of anti-mycobacterial drugs has radically changed treatment approaches. Research has shown that current drug regimens are not affected by poor diets or normal activity. In addition, tuberculosis patients become noninfectious very shortly after treatment begins. Out-patient care is now recommended for almost all tuberculosis cases.

Several drugs are currently used to treat tuberculosis. Combinations including isoniazid (INH), rifampicin, pyrazinamide, streptomycin, thioacetazone and ethambutol are most common. Traditionally, drugs have been selected and combined based on either their "bactericidal" or their "sterilizing" activity. Bactericidal activity refers to a drug's ability to kill exposed or rapidly reproducing bacteria; sterilizing activity refers to a drug's ability to destroy bacteria protected by tissue growth or inside immune system cells. These bacteria often reproduce slowly or remain dormant for long periods of time, protecting themselves from the bactericidal effects of drugs that only attack actively reproducing cells.

The environment in which the drugs are acting is also important. For example, at a neutral pH, streptomycin has maximum bactericidal effect, but pyrazinamide is inactive. The reverse is true in an acid medium such as found inside some immune system cells. Rifampicin, which is high in both bactericidal and sterilizing activity, is also effective against bacteria that reproduce quickly and intermittently. For these reasons, it is considered one of the best drugs for modern tuberculosis therapy.

The administration of anti-tuberculosis drugs has undergone an important shift in the last 20 years as research has documented the effectiveness of short-course therapy. Traditionally, chemotherapy regimens lasting for 12 to 18 months or more were used to effect a full cure. Six to nine month regimens, with an intensive first phase of one to two months, are now widely used and have produced good results.

In either regimen, isoniazid and rifampicin are usually given throughout, with the addition of pyrazinamide and either streptomycin or ethambutol in the initial intensive phase of treatment. The combination of drugs used varies from program to program and is based upon availability, cost, and local patterns of resistant strains and drug side effects. These regimens require the use of more expensive drugs, such as rifampicin, which many developing countries cannot afford. The drug costs of a standard, six month, intermittent regimen consisting of initial daily treatment with isoniazid, rifampicin, pyrazinamide and ethambutol, followed by twice-weekly treatments with isoniazid and rifampicin costs approximately US $18 based on current UNICEF price lists. This is more than five times the cost of the traditional 12 month daily regimen of isoniazid and thioacetazone with the addition of streptomycin in the initial intensive phase. The dosage, costs, and side effects/contraindications of the most commonly used drugs are listed in the table on page 8.

Prevailing thought on the frequency of drug administration has undergone as large a change in the last few years as regimen duration. Studies have shown that with the drugs currently in use, it is not necessary to keep blood levels constant. This means that administration of bactericidal drugs twice or three times weekly is as effective as daily doses, especially in the second phase of treatment. For drugs other than rifampicin and streptomycin, which should not be given in higher doses, the normal daily dose is multiplied by 7 and then divided by either 2 or 3 for a twice- or three-times-weekly schedule.

Intermittent, higher dosing has not generally been found to significantly increase drug side effects. The new short-course regimens together with the move to intermittent schedules has revolutionized tuberculosis care.

Drug resistance, retreatment and follow-up have also been affected by the new treatment programs. The effective use of multiple drug regimens decreases the likelihood of drug resistance. At one time, many developed country programs did routine susceptibility tests using bacillus cultures to determine the selection of each patient's drugs. Research on multiple drug therapy has shown that this is unnecessary, and many programs only do susceptibility tests on patients whose sputum smears are still positive after three months of treatment.

In resistant cases, new combinations of drugs can be substituted or added to insure that at least two drugs are used to which the bacilli are not resistant. This is necessary as well for the retreatment of patients who have not completed a full drug regimen. Short-course, multiple drug regimens are recommended for extrapulmonary tuberculosis as well. Because the relapse rate is so low with the treatments now being used, follow-up sputum examinations for patients who have completed a full course of treatment are no longer recommended.

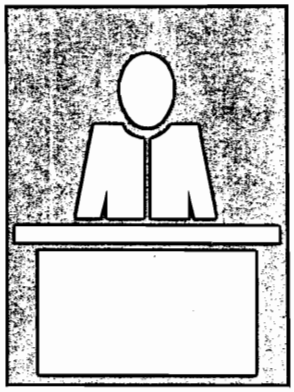
Because rapid periods of growth cause stress that increases the chances of post-primary infection, pregnant women are at special risk. Treatment of tuberculosis during pregnancy presents special problems because of possible effects on the fetus. Research analyzing the pregnancy outcomes of women undergoing treatment for tuberculosis suggests that a regimen of isoniazid (INH) and ethambutol is the safest treatment for nonsevere cases, and that, if necessary, rifampicin can be added as a third drug. Streptomycin should not be given during pregnancy.

ANTI-TUBERCULOSIS DRUGS

Drug	Bactericidal/ Sterilizing Effect	Dose/Day	Cost $U.S.[1]	Side Effects/ Contraindications
Isoniazid (INH)	High/Medium	300 mg	100 mg tablet 1.77/1000	Liver toxicity, polyneuritis, gastrointestinal disorders
Rifampicin	Medium/High	600 mg	300 mg tablet 7.84/100	Liver toxicity
Pyrazinamide	Low/High	1.5-2.5 g	500 mg tablet 4.71/100	Liver toxicity, increased blood uric acid levels
Ethambutol	Medium/Low	15 mg/kg	400 mg tablet 8.93/500	Decrease in visual acuity
Streptomycin	Low/Low	15 mg/kg	Powder for injection 0.10/1 g vial	Hearing damage, kidney damage if pregnant
Thioacetazone[2]	Low/Low	150 mg	150 mg + 300 mg INH 6.82/1000	Gastrointestinal disorders, liver toxicity

[1] Prices from UNICEF Essential Drugs Price List, 1985
[2] Most commonly available commercially in combination with INH

Prevention and Program Issues



Prevention

A main focus of all tuberculosis prevention programs is case-finding and treatment of smear-positive cases. Studies show that smear-positive individuals infect an average of ten contacts per year, and young children living in the same household are at particular risk. Sputum microscopy, rather than culture diagnosis, has been the primary means of case-finding for prevention because smear-negative patients are usually noninfectious even if they are culture-positive. As such, they pose little immediate threat to those around them.

The other main program focus for tuberculosis prevention has been vaccination. The BCG (Bacilli Calmette and Guerin) vaccination is an attenuated live vaccine developed from *Mycobacteria bovis* and has been used for over 60 years. The vaccine is given to newborns and often again to children at school entry or early in adolescence. It is injected intradermally, traditionally over the lower insertion of the left deltoid, and leaves a small scar. The vaccine is now widely available in a stable, freeze-dried form from WHO-approved sources.

There has been controversy over the years as to the safety and effectiveness of BCG vaccination. Strict quality control guidelines have resolved most of the safety issues, but the questions of effectiveness remain. Large-scale, carefully controlled studies done over a period of 50 years have given widely divergent results, with effectiveness varying between 0 and 80 percent. The most recent results, from a WHO-sponsored longitudinal study conducted on adults in Chingleput, India in the 1970s, showed that those vaccinated had no lower incidence of tuberculosis in the first seven years of follow-up.

The reasons for this negative result are not clear. Hypotheses center around local ecological issues such as the presence of a South Indian variant of *M. tuberculosis* or infection with environmental mycobacteria, or the high prevalence of leprosy in the study area (see box on page 10). These issues suggest the importance of epidemiological studies to assess the effect of a BCG program in its local context. The Chingleput trial design did not address the effects of BCG on the prevention of childhood tuberculosis in vaccinated newborns.

While the Chingleput trials raise important questions, other studies have shown BCG to have considerable protective value, and several large vaccine trials done with children have demonstrated protection. For these reasons, WHO recommends the continuation of BCG vaccination programs with an increased emphasis on covering neonates. BCG is one of the vaccines included in the WHO Expanded Programme on Immunization (EPI).

Chemoprophylaxis (usually INH) was at one time recommended for all household members of active tuberculosis patients and especially for young children. INH is now only recommended for infected close contacts, especially children with recent skin test conversions, in programs that can afford it. There is much less risk of infection to contacts of patients who are undergoing the new multi-drug treatments.

Program Issues

There are several program issues that need to be considered when looking at tuberculosis and public health. These include integration with primary health care (PHC) programs, program priorities, patient and public education, staff training, and evaluation.

Integration With Existing PHC Programs

Tuberculosis programs come from a tradition of separation. Because of the need to isolate patients in the days before effective chemotherapy was available, many national tuberculosis

programs developed in parallel to the existing health care systems. Many countries had special tuberculosis hospitals, laboratories and personnel. With the advent of good ambulatory treatment regimens that have made separate facilities obsolete came the challenge of integrating tuberculosis diagnosis and care into the primary health care system.

The problem has been both in adding one more responsibility to often overworked primary health care staff and in the reluctance of specialized tuberculosis health personnel to be displaced. There are also the structural problems of reoutfitting facilities and reallocating resources. Several countries have met these challenges. In the People's Republic of China, a supervised intermittent chemotherapy regimen for rural areas has been developed that employs the barefoot doctors of the village health cooperatives. This program is being expanded. In Cuba, an elaborate tuberculosis diagnosis and treatment system has been dismantled and successfully integrated with existing primary health care programs. Similar successful transitions have been made in Brazil, Chile, Colombia, Costa Rica and elsewhere. In many countries, however, there is still much more to be done.

TUBERCULOSIS AND LEPROSY

Hansen's disease, or leprosy, is caused by *Mycobacterium leprae*. It is estimated by WHO to affect more than 12 million people worldwide with the largest concentration of cases in tropical areas. Leprosy is a chronic disease that affects the skin, mucous membranes and peripheral nervous system. It exists in several forms, ranging from tuberculoid leprosy, which is relatively benign, to the lepromatous type, which can cause rapid tissue degeneration (see **DIRECTIONS**, Volume 3, Number 2).

Tuberculosis and leprosy have long been linked. Hansen first described *M. leprae* with assistance from Robert Koch, who later discovered tuberculosis. Both bacteria are acid-fast and are diagnosed microscopically using the Ziehl-Neelsen staining technique.

The two diseases have epidemiological links as well, and a large body of anecdotal evidence has been collected over the years showing a decline in leprosy in areas where tuberculosis has become widespread. While some scientific studies have also suggested that cross-immunological effect between these two diseases exists, the slow onset and low incidence rates of leprosy have made definitive research difficult.

Research done to look at the protective effect of BCG vaccination against leprosy has faced the same constraints. Results from the work done so far have been encouraging, and some leprosy programs routinely give BCG vaccinations to household members of leprosy patients. A large-scale leprosy vaccine trial is scheduled to begin later this year in Malawi. It will compare the efficacy of a vaccine combining BCG and heat-killed *M. leprae*. The first results from this research will be available in about ten years.

Program Priorities

Setting priorities is a major program concern. Most tuberculosis programs place their main emphasis on case-finding and treatment, since the new multi-drug therapies have reduced concern over the issues of retreatment, resistance and relapse. Case-finding can be either passive or active. Passive case-finding usually relies on sputum-smear diagnosis of patients presenting themselves for testing because of symptoms. Active case-finding includes mass screening, tracking down patient contacts, and routine testing of past patients. Few developing country programs have the resources necessary to pursue active case-finding which has a relatively low cost-benefit ratio. For most programs, smear diagnosis of symptomatic cases and treatment of all those diagnosed is still an unmet goal.

A second focus is often on prevention using the BCG vaccine. Consideration needs to be given to the target groups and efficacy of the vaccine under local conditions. This information will help determine the extent to which resources can be made available for immunization. There is also a need to reassess priorities frequently in light of new diagnostics, treatments, and the changing circumstances in which the disease is found (local disease ecology). As examples, in areas where the incidence of tuberculosis has greatly decreased, BCG vaccination may no longer be necessary; or the adoption of intermittent therapy regimens may alter staffing needs.

Education

The central focus of many tuberculosis education programs has been patient compliance. The social stigma of tuberculosis is a remnant of the pre-antibiotic era when the disease was often fatal and patients were infectious for long periods of time. This stigma discourages those with symptoms from submitting to diagnosis or entering treatment programs. The long course of treatment that had been necessary until recently made it difficult to convince patients to continue taking their medications after their symptoms disappeared.

Several studies have been done on reasons for treatment default or noncompliance. Work in one program in India indicated that a lack of understanding by the patient of the essentials of the disease (i.e., that the treatment program must continue after symptoms disappear and the consequences of default) was a more important predictor of noncompliance than income or literacy.

A study in Ethiopia also found that many patients discontinued their treatment because of clinical improvement. This study uncovered less-expected reasons for noncompliance as well, including lack of transportation, inability to get time off from work, sickness or death in the family, and concurrent illnesses of the patient. In many cases, the health care system must take some responsibility for noncompliance. Well-organized services that are accessible get the best results.

Recently, in Honduras, the Academy for Educational Development and the Ministry of Health undertook a study of tuberculosis and the existing treatment and control programs seen from the public's and patient's point of view. They collected information using small group-directed discussion of open-ended questions (focus group discussions) and then developed two education campaigns, one for the general public and another for patients and their families. The campaigns used radio spots, posters, flip charts, pamphlets and even sputum-sample cups printed with instructions for collecting a good sample (see photo). Early evaluations of both campaigns have shown positive changes in knowledge and attitudes.

Training

Training is essential not only for primary health care staff who will be responsible for diagnosis and treatment within new integrated tuberculosis programs, but also for program managers and tuberculosis specialists who will need retraining to fill new roles. The National Tuberculosis Institute in Bangalore, India is an example of one program that has developed training curricula and materials for PHC workers. Skills need to be continually upgraded to accommodate new diagnostic, treatment, and reporting advances.

Evaluation

Program evaluation is essential to ensure that current program goals are being met and to plan effectively for future needs. This is especially important as tuberculosis programs are integrated into primary health care and find themselves competing for staff time and budget resources. Epidemiological studies, operations research, and qualitative techniques such as focus group discussions can all be used to make sure that programs are suited to current local conditions and that they are adjusted to meet changes in the local disease ecology.

Conclusions

While few changes have been made in the last ten years in the technologies for tuberculosis diagnosis or prevention, there have been great advances in treatment technology that have had profound effects on tuberculosis programs. The advent of short duration, intermittent, multiple-drug treatment regimens has brought great challenges for existing programs.

The elimination of tuberculosis as a major public health problem requires not only the judicious use of the hard technologies of diagnostics and pharmaceuticals, but also the soft technologies of management and education. The latter will ensure that the appropriate hard technologies reach those who need them and are properly used. Beyond these requirements is the need to fully integrate tuberculosis diagnosis, treatment and prevention into primary health care programs.

PATH, Maggie Kilbourne

Sputum cup with instructions

Materials Available

World Neighbors, in conjunction with a Philippines health organization, AKAP, has produced a filmstrip, "**Control of Tuberculosis, A Community-Based Approach,**" and a flip chart and other materials on the same topic. For their free catalog or information, write to World Neighbors, 5116 N. Portland Avenue, Oklahoma City, OK 73112 USA.

Slide sets on "**The Natural History of Childhood Tuberculosis**" and "**Pathology of Tuberculosis in Childhood**" are available from Teaching Aids at Low Cost (TALC), P.O. Box 49, St. Albans, Herts, AL1 4AX, United Kingdom.

□

A bibliography on Tuberculosis is available from PATH at our new address: 4 Nickerson Street, Seattle, WA 98109-1699 USA.

INTERCHANGE

A five day WHO Conference of Experts on the Rational Use of Drugs was held last November. The following are some highlights from the conclusions:

> The prime responsibility for rational drug use rests with individual governments.
>
> Each government should have a rational drug regulatory authority.
>
> WHO will take no direct role in the international regulation of drug promotion but would prepare guidelines for adoption by national governments.
>
> National drug policies should include the provision of impartial, objective drug information for prescribers, patients and policy makers. In addition to governments, the pharmaceutical industry, prescribers, teaching institutions, the public, consumer groups and mass media all have responsibilities for making drug use more rational.

Rational drug use will be one of the topics discussed by the World Health Assembly in May 1986.

Slide sets on trachoma, and other materials on trachoma and blindness control, are available from the Francis I. Proctor Foundation, a WHO-collaborating Centre for Prevention of Blindness and Trachoma, at the University of California, San Francisco, CA 94143 USA.

■

The picture on page 5 of our infectious eye disease issue (Volume 5, Number 3, 1985) was taken by Dr. Allen Foster. In the same issue, the photos on pages 8 and 10 are the property of the International Eye Foundation (IEF).

■

IEF also has two publications on primary eye care, Primary Eye Care: A Manual for Health Workers (English and Spanish) and Prevent Blindness Through Primary Eye Care. Contact IEF at 7801 Norfolk Avenue, Bethesda, MD 20814 USA.

■

World Neighbors has a filmstrip, "**Good Food, Good Health, Good Eyes,**" with text available in several languages (see Materials Available for address).

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health technology
directions

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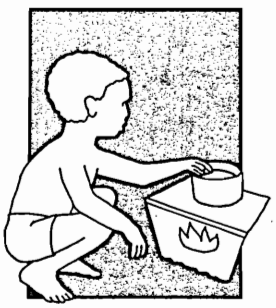
Childhood Injuries

Childhood injuries, long recognized as a leading cause of morbidity and mortality in children under five years of age in the developed world, are at least as important a cause of illness and death in developing countries. In Shanghai County, China, for instance, injuries are the single leading cause of death from ages 1 to 44 years. A recent hospital-based study in Tanzania ranked childhood accidents as the fifth leading cause of morbidity there, and in Sri Lanka, the annual number of deaths from pesticide poisoning reportedly exceeds the combined total for malaria, tetanus, diphtheria, and whooping cough. Similar statistics available from Brazil, India, Jamaica, Malawi, Nigeria, Peru, Thailand, and other countries help to confirm the magnitude of this problem.

While the mortality rates are frighteningly high, they represent only a very small and slightly more visible part of the problem. Morbidity rates have been estimated to exceed mortality rates by more than 100 times, depending on the injury. Accident-related illnesses are a major cause of disability and disfigurement. They also present opportunities for infection, leaving children more vulnerable to other diseases.

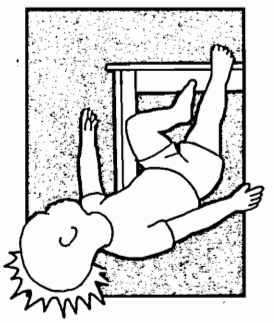
The economic consequences are significant as well. Looking only at the number of deaths due to injuries tends to underestimate their impact, especially with injuries to young people. A better measure is potential years of life lost (PYLL). A recent study of PYLL in Southeast Asia found accident-related deaths to be a major contributing cause. Treatment and rehabilitation costs place an additional strain on health care budgets, and potential income lost due to injury-caused disability increases the economic toll.

This issue of **DIRECTIONS** examines the technology issues surrounding the treatment, prevention and program management of childhood burns, poisoning, and trauma.



Burns

Poisoning



Trauma

Volume 6, Number 2 **ISSN: 0730-8620** **1986**

Why has this problem received so little attention? One reason is that modern preventive medicine has tended to concentrate on infectious diseases and malnutrition. As these problems are being brought under control, illness and death due to injuries become relatively more important. Another factor is that the means most often used to prevent injuries are policy formulation, safe equipment design, and health education, and many health workers are not comfortable in these non-curative roles.

The underreporting of injuries in developing countries has also prevented people from recognizing the importance of the problem. Unlike malnutrition, fatal injuries often cause death before there is time to reach a health center or hospital and thus may not be recorded. In many countries, the systems for reporting or classifying injuries are not as well developed as those for infectious diseases.

Finally, there is the almost universal idea that injuries are due to accidents or acts of God, both of which are often seen as outside of human control. This is contrary to the belief of many experts who prefer to avoid the term "accident" when referring to an injury-causing event in order to focus attention on the fact that most injuries are caused by actions or objects that are very much within human control.

FIGURE 1

Injury Control Measures Classified According to Three Factors and Three Phases

	Factors		
	Human	Equipment	Environment
Pre-Event	1	2	3
Event	4	5	6
Post-Event	7	8	9

There are several conceptual frameworks that have been used to examine injury control. One of these, developed by Haddon, uses a matrix of three factors (human, equipment, and environment) and three phases (pre-event, event, and post-event) as diagrammed in Figure 1. For each of the numbered squares or cells there are countermeasures that can be taken. Taking burns as an example, cell 1 might include teaching mothers to turn pot handles so that children cannot reach them. A countermeasure for cell 7 would include providing first aid for burn victims and transportation for further treatment if necessary.

Another system, also developed by Haddon, considers ten basic strategies for preventing or decreasing the ill effects of interaction between people and the hazards in their environment. These strategies are listed in Figure 2. Using poisoning as an example, strategy 1 would include banning the manufacture of highly toxic pesticides. Strategy 3 would include the use of childproof caps on medicine containers, and selling kerosene in special bottles that do not resemble those used for soft drinks. Strategy 8 might include improving nutritional status to increase a child's chance of surviving a case of poisoning.

A third system looks at primary, secondary, and tertiary prevention. Primary prevention interventions are designed to keep an injury event from happening; secondary prevention interventions are designed to avoid or decrease injury, given that the event will take place; and tertiary prevention is used to decrease the long-term effect of injuries that have occurred. Whichever system is used, it is important to think of accidents as controllable events whose likelihood can be modified through a wide range of actions.

FIGURE 2

Haddon's "Ten Strategies"

1. Not create the hazard in the first place.
2. Reduce the amount of hazard produced.
3. Prevent or reduce the likelihood of release of the hazard.
4. Modify rate of release of the hazard or its distribution in space.
5. Separate the hazard and its release, in time or space, from the people at risk.
6. Put a barrier between the hazard and people at risk.
7. Change the basic characteristics of the hazard.
8. Strengthen the resistance of people to the hazard.
9. Begin to counter damage already done.
10. Stabilize, care, and rehabilitate.

Burns

Burns are a major cause of childhood injury in most countries. In Malawi, a recent study showed them to be the commonest cause for hospitalization in children under four years of age, and in a study of low income areas in Peru, burns and scalds accounted for more than one-third of all injuries to children under five. In India alone, it is estimated that more than one million people suffer from moderate or severe burns each year, and that most of these burn victims are women and children. Studies from several countries have shown that the highest incidence of burns is between 6 and 18 months of age. No distinct sex differences in very young children are apparent, although differences do appear in older children as dress and activities become more sex-specific.

While the causes of burns vary from country to country, two leading causes are fires for cooking or heating and hot liquids such as boiling water, tea, soups, or cooking oil. In many cultures cooking is done at floor level with exposed flames.

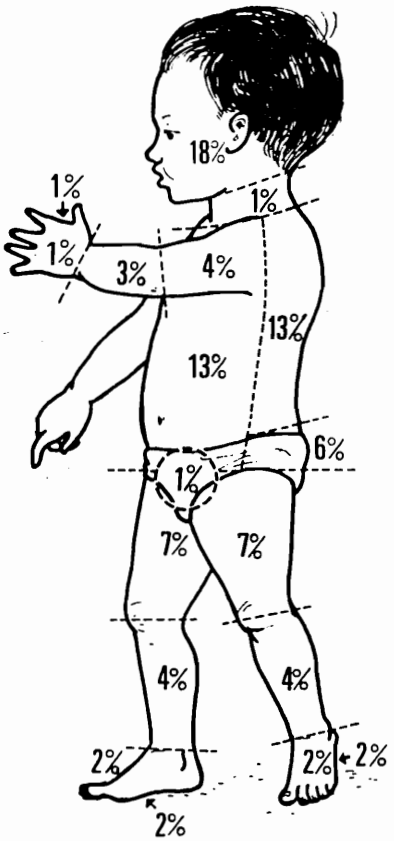
Other causes of burns include loose fitting, flammable clothing such as the saris worn by older girls and women in South Asia or grass dresses worn in Papua New Guinea, and burns caused by children having epileptic seizures and rolling or falling into hot liquid or flames. Epilepsy is more common in developing than developed countries and can be caused by brain damage from tapeworm cysts, malaria, or injury at birth. Burns are also caused by kerosene lamps and stoves and, in some countries, fireworks.

Special issues of concern for pediatric burns are children's small body size and large amount of body surface area relative to volume. This means that small amounts of liquid can cause severe scalds and that once skin tissue is damaged, dehydration and shock from water loss through the burned area is a more serious problem for children than adults. In addition, scar tissue formation that limits movement, called contracture, may hinder further normal body growth and development.

Burns are classified both by how deep they are and by how large a surface has been affected. The percentage surface area that has been affected can be estimated by comparing the burn to a diagram like Figure 3.

The depth of a burn is classified as **superficial, superficial partial thickness, deep partial thickness,** or **full thickness. Superficial burns** are those that only damage the outer skin surface. The skin turns red, but no blisters form and the skin heals quickly. **Superficial partial thickness burns** damage the outside layer of skin and cause blistering. These burns also heal quickly and seldom leave scars.

FIGURE 3

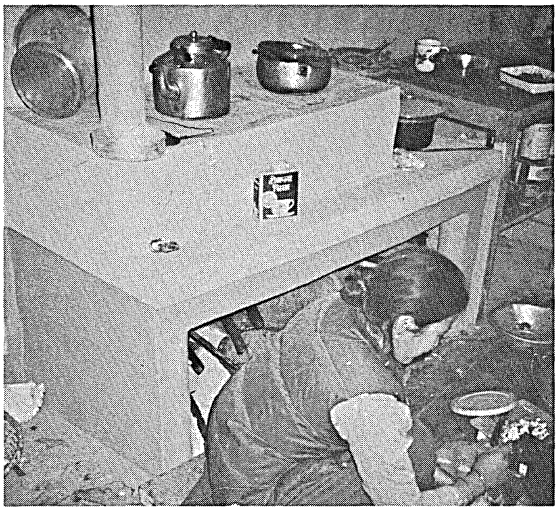


WHAT PERCENTAGE OF HIM IS BURNT?

King, King, and Martodipoero *Primary Child Care*

Deep partial thickness burns are more severe and destroy the outer layer of skin leaving only sweat glands and hair follicles, from which a new layer of skin grows. The most severe burns are **full thickness burns** in which even the hair follicles and sweat glands are destroyed. These burns often require skin grafts, a procedure where pieces of skin are removed from other parts of the body and used to cover part or all of the burned area. Often, different parts of a burn will be different depths and it is sometimes difficult to assess the severity.

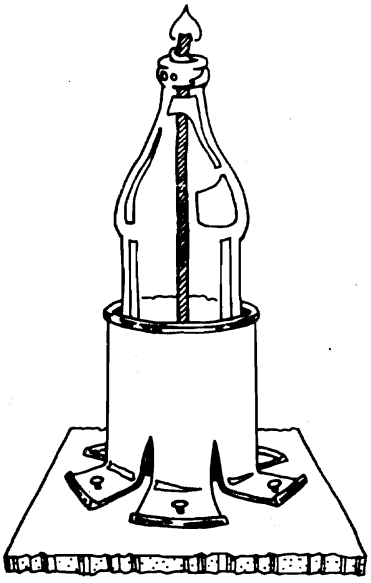
The best treatment for all burns is to apply water as soon as possible. Cold water is best, but even room temperature water will do. If applied within 30 minutes of the burn, cold water will keep the damage from going deeper.



PATH, Gordon Perkin

Raised stove being promoted in Nepal

FIGURE 4



Bottle lamp holder designed by Susan P. Baker, Johns Hopkins School of Hygiene and Public Health

The next important step is to assess the extent of the damage and to decide whether the child should be moved to a hospital. Full thickness burns over 2% or more of the body, or more than 15% partial thickness burns, indicate that hospitalization will be necessary (see Figure 3, page 3). These children should be treated for shock (see page 9).

Less severe burns that cover smaller areas, especially on arms or legs, should be washed carefully with cooled boiled water and without breaking blisters. The burn should then be dressed with gauze soaked in boiled vaseline that has been allowed to cool, covered with cotton wool, and then loosely wrapped with a bandage. Dressings should be changed every few days, penicillin should be given, and joints should be splinted straight to avoid contractures.

Larger burns can be cleaned and left uncovered if the child can be kept under a mosquito net to keep flies away. During the first few days of recovery from a severe burn, a child should be given oral rehydration solution or other extra liquids to prevent dehydration. During recovery a child's nutritional requirement will be increased, and he or she should be given more food than usual.

Prevention of injuries from burns includes the use of raised stoves, and barriers or screens to keep children away from open fires or cooking pots. Where kerosene is used for cooking, the use of new, efficient wick stoves is preferable to pressure models. Kerosene wick lamps made from bottles can be stabilized by building simple bases for them as shown in Figure 4. In addition to preventing burns, training health workers and mothers to use cold water on burns, instead of butter or other creams or ointments, and distributing other information on burn care can help to reduce the lasting effects of burns that occur.

Poisoning

Childhood poisonings are a major cause of illness and death, especially in children between one and five years of age. Research done in one pediatric hospital in Tanzania found poisoning to be the leading cause of all admissions resulting from accidents, and a similar study conducted in a pediatric hospital in Saudi Arabia found more than 10% of all admissions to be due to the ingestion of toxic substances.

The causes of poisoning differ between more and less developed areas and with the patient's age. Recent work done in South Africa showed distinct differences in causes of poisoning in white and black populations, and research in India suggests the increasing importance of drug poisoning compared to other causes of poisoning over time. In most areas, poisoning from household products is much more common in children than in adults, while the opposite is true with pesticide poisoning.

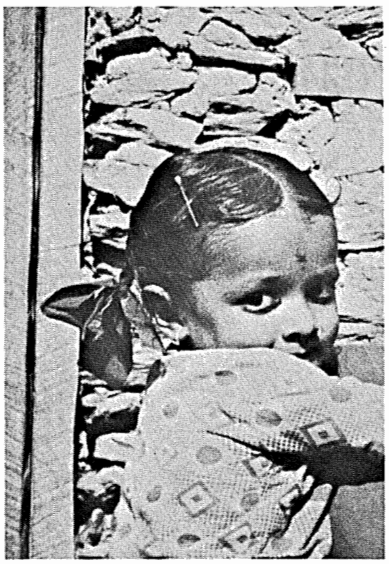
Several studies suggest that kerosene is the poisonous substance most often consumed by children in much of the developing world. Kerosene is used in many households as lamp or stove fuel or to light charcoal or wood fires. It is dispensed in small quantities, often in soft drink bottles, and can be mistaken for water by small children. Several studies have shown a seasonal effect with greater frequency of ingestion during hot, dry months.

Ingestion of medicines is another major cause of childhood poisoning, especially with the increased use of these substances in many households. Antimalarials, barbiturates, iron compounds, and analgesics such as aspirin are substances frequently taken.

Traditional medicines are also a problem. Studies in India have shown medicinal seeds and oils to be commonly involved, and other studies have found poisoning resulting from high levels of lead found in many traditional preparations including eye cosmetics. Studies from Saudi Arabia, Nigeria, and parts of Asia have shown that eye shadow commonly used on small children is often made from the crushed ore, galena, and may contain more than 90% lead. Children rub their eyes and then put their fingers in their mouths, ingesting this highly toxic metal. In parts of Latin America a traditional medicine called azarcon has a very high lead content and is used to treat diarrheal disease.

Pesticides are another common poison, but pose a bigger problem for older children or adults who are exposed to them in the fields. Small children come into contact with pesticides that are not carefully stored or can become poisoned by residue from pesticide containers that have been recycled for water transport or storage. Carbon monoxide poisoning is a problem in poorly ventilated houses that are heated with fires, and in countries where chemical cleaning agents such as bleach are common, these can be a danger.

Again, the special concern with pediatric poisoning is a child's small body size, which means that even small amounts of poison can be fatal. Other concerns are their underdeveloped organ systems which may be more easily overwhelmed and their less refined



Scott Wittet

South Asian child wearing eye make-up

taste acuity which increases the possibility of their ingesting toxic substances.

The treatment of poisoning depends on what has been ingested and how long ago it was taken. For poisons other than petroleum products (kerosene and gasoline) and corrosive substances (lye or acids), the best treatment is to make the child vomit. This can be done either by giving syrup of ipecacuanha (ipecac) or by putting a finger or spoon handle down his or her throat. If the child has not eaten in several hours, it may be necessary to give water or milk so that there is something to vomit. If it has been more than four hours since ingestion of the poison, vomiting will not help. If it has been more than 36 hours since ingestion and there are no ill effects, then the child is probably safe.

With kerosene or gasoline poisoning, the main cause for concern is pneumonia. This results from damage caused to lung tissue by the kerosene vapors and is the reason why vomiting is not indicated. Kerosene poisoning cases should be treated by keeping the child quiet and giving penicillin for five days.

Vomiting is also not indicated when corrosives have been swallowed because they may cause more damage to the esophagus on the way back up. For these substances the best treatment is keep the child quiet and give water, milk, beaten eggs, or activated charcoal to dilute or neutralize the poison.

There are a number of ways to prevent childhood poisonings or decrease the injuries resulting from them. In the United States, laws requiring that drugs be sold only in childproof containers have greatly decreased the number of drug poisonings. Consideration has been given to coloring kerosene blue and selling it in distinctive containers to reduce the chance that a child will mistake it for water.

Lead poisoning by eye cosmetics can be prevented by substituting those made with burnt vegetable matter for lead-based products.

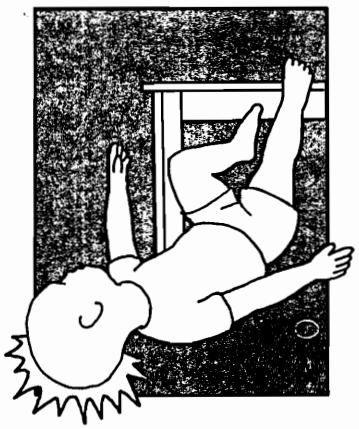
As a simple home test for the safety of these powders, mothers can sprinkle a small amount into a glass of kerosene and watch for it to sink. Lead-based cosmetics will sink after a few minutes as fine particles; burnt vegetable matter cosmetics will float, or sink only after they coagulate.

Some studies also indicate that iron deficiency, a common problem for children with marginal diets or parasitic infections, worsens the effects of lead poisoning. Because of this, improved iron nutrition for young children could be considered as a prevention strategy.

Sierra Leone Home Economics Association, *The Pill*

Illustration from a booklet from Sierra Leone showing safe storage of oral contraceptives

Trauma



Trauma, a term used to include both fractures and soft tissue injuries, is another major cause of childhood injuries. Trauma is often caused by falls and, increasingly, by motor vehicle accidents. Falls were the cause of nearly three-quarters of all injuries of children admitted for accident-related causes in a hospital-based study in Turkey, and were the leading cause of accidental injuries in a similar study done in Peru. A recent study in Southeast Asia concluded that motor vehicle accidents in Thailand, Malaysia, and Singapore rank above both malaria and tuberculosis as a cause of premature death.

Traffic-related injuries have become a major cause of injury and death in the Middle East, Africa, and Latin America as well. When traffic-related childhood fatalities from developing and industrialized countries are compared, the rates from developing countries are often higher. This is true in spite of the under-reporting of deaths in countries with poorly organized health statistics systems. While the lack of traffic controls and unplanned traffic patterns are part of the problem in developing countries, this lack of infrastructure also represents an opportunity. It is easier to design safety into new traffic systems than it is to modify badly planned designs that already exist.

In many countries, falls are the leading cause of spinal cord injury and their related treatment and rehabilitation costs are disproportionately large. An analysis of hospital data collected in Jamaica in the 1970s found a huge increase in the amount of bed space and other hospital resources devoted to the care of trauma as compared to twenty years earlier.

Research from Peru cites playing or climbing on furniture, walls, or roofs as the main circumstances of fall injuries. Work done in Papua New Guinea and Nigeria documents the importance of falls from trees. These occur to children either when playing or when harvesting crops from palm, fruit, or nut trees. In Nigeria, falls from trees most often resulted in fractures of the arm and contributed disproportionately to the number of cases of multiple injury and death from all falls.

Fall injuries and deaths in urban areas often occur when small children crawl out of windows that are left open or fall from rooftops. Kite flying from roofs has been reported as a risk factor in cities in India.

Other causes of traumatic injuries are lacerations from kitchen or agricultural equipment. These occur either when young children encounter implements that have been improperly stored or as older children learn to use these tools.

Special developmental concerns related to childhood trauma are children's large head size relative to the rest of their bodies, their small blood volume, and the inability of infants and young children to report or describe pain from their injuries. Large head size is a problem for several reasons. It makes children top-heavy and more prone to falls and to head and neck injuries in motor vehicle accidents. The increased relative surface area for head wounds is also a concern as studies have shown that most fatal falls in children involve a head injury. The small blood volume of children relative to adults makes it easier for both parents and health workers to underestimate the severity of children's wounds.

The best treatment for bleeding wounds is to apply direct pres-

sure to stop the bleeding. If bleeding is severe, it is also necessary to treat the child for shock (see box, page 9).

Deep cuts, where it appears that tendons, ligaments, or nerves may be severed, require treatment at a hospital. Smaller wounds should be carefully washed with soap and water and then covered with sterile gauze held on with adhesive tape. Cuts can often be closed with butterfly bandages cut from adhesive tape instead of using sutures (see Figure 5).

Cuts that have been left exposed for more than 24 hours or that have pus in them should not be closed. These wounds should be treated as open sores, cleaning them twice daily with a disinfectant (1 teaspoon of liquid laundry bleach in a glass of water will work) and giving the child an antibiotic. Tetanus toxoid should be administered to all children who have not completed a sequence of three tetanus toxoid (or DPT or DT) vaccinations in the last five years. Tetanus antitoxin is indicated as well if the child has not yet received a full sequence of tetanus toxoid vaccinations.

Treatment of fractures begins with careful diagnosis. In the case of an injured arm or leg, the unharmed limb should be placed in the same position as the broken one so that the injured limb can be compared to it for deformity. If the bones in both limbs are not the same shape, a fracture is probable. With a leg injury, a fracture is unlikely if the child was able to walk after the injury, even if there is subsequent swelling and pain.

Because broken bones need to be aligned carefully and immobilized to prevent long term disability, fractures should be referred to hospitals for treatment whenever possible. Before transport, the fracture should be immobilized using padding and splints to prevent further damage.

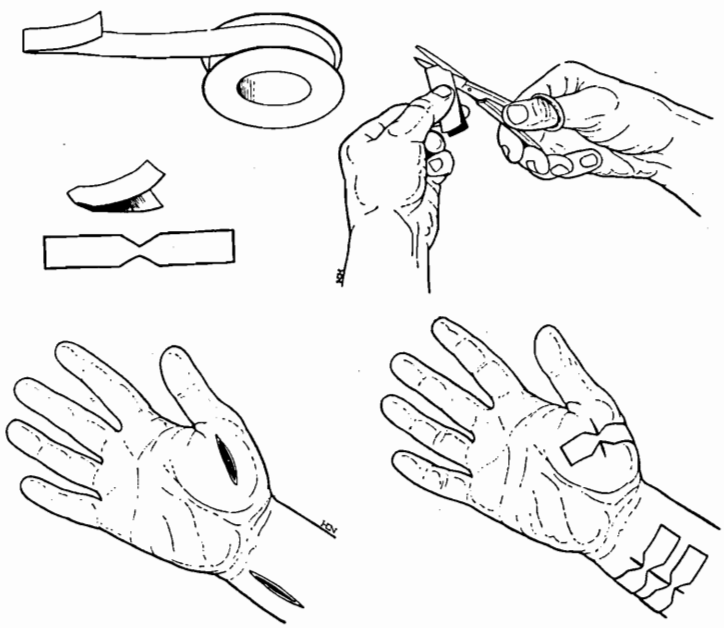
It is especially important with head, neck, and back injuries that the patient be moved as little as possible. Before transporting, the injured person should be carefully secured to a rigid surface such as a door or table top that extends beyond the head and feet.

For fractures where there is a wound caused by the bone having broken the skin (a compound fracture), it is necessary to stop the bleeding by applying pressure around the area of broken skin (not directly on the wound or exposed bone). Compound fracture victims should be referred to hospitals and treated for shock (see box, page 9).

The prevention of traumatic injury can take many forms. Falls from windows and roofs can be prevented by gratings or railings, and the number of injuries due to falls from trees can be reduced by not letting young children harvest tree crops, by planting dwarf tree species, or by using ladders or safety belts. Blocking off kitchen areas with low gates to prevent access by children may prevent traumatic injuries as well as burns. Trauma from motor vehicles can be reduced by safer vehicle design, better traffic planning and road marking, and the use of seat belts or special child restraints.

FIGURE 5

'BUTTERFLY' BANDAGES OF ADHESIVE TAPE



David Werner, *Where There Is No Doctor*

Pediatric Shock

Shock is a condition where too little blood reaches the major organs in the body. This can be caused by a loss of blood due to either internal or external bleeding, loss of blood vessel tone, or a heart problem. Shock can occur after any serious injury or with severe cases of some illnesses such as diarrhea, pneumonia, or cerebral malaria. It is a serious condition and can lead to death.

A child in shock will have cold, damp skin and a weak, rapid pulse. He or she may seem agitated and confused as well. The best emergency treatment is to have the patient lie down, and except when there is a head injury, slightly elevate their feet. A light blanket or cover can be used to maintain body temperature, and if the child is conscious, fluids can be given by mouth. The condition causing the shock should be treated.

Shock patients need to be monitored carefully during the course of treatment, and severe cases should be quickly referred to a hospital if possible.

Program Issues

The first step in developing a program to combat childhood injuries is to define the local problem. Because few countries have adequate record-keeping systems for injury-related morbidity and mortality, most of the existing data are from studies of hospital records and a few small scale community household surveys. While hospital or clinic data may be useful to get a general picture of local injury epidemiology, they may also be misleading. Injuries that cause rapid deaths, such as drownings or snake bites, will be under-represented in hospital records because those injured will often not reach a health facility. Deaths from poisoning due to the high content of lead in some traditional medicines will either not be seen by hospitals or clinics or may be wrongly attributed to the illness that the traditional practitioner was trying to treat.

Mortality data are more frequently available than morbidity data, and this may also lead to poor distribution of program resources. While two or more types of injury may have similar **mortality** rates in a community, the **morbidity** rates may be very different. For example, the same number of children may die from poisonous snake bites as from burns, but there is probably much more burn related morbidity. Even when morbidity rates are available and similar, the resource requirements for different injuries vary widely. The intensity of care necessary for a burn victim is much greater than for a child recovering from a simple fracture. In addition, consideration should be given to the likelihood of long term disability and priority should be given to the prevention of these injuries.

In addition to making an initial assessment of childhood injuries, programs need to integrate accident-related record-keeping into their existing health information systems. Data collected on a continuing basis can be used to initiate new programs, evaluate existing ones, and examine changing trends over time. This information is essential for the design of appropriate training programs, projection of facility needs, and other health resource management purposes.

The World Health Organization (WHO) and the International Children's Center (ICC) have developed both survey forms and checklists for recording injury information on an ongoing basis. WHO has been actively

involved in accident prevention and the coordination of related research since 1966 through its Global Programme for Accident Prevention. International meetings have been held in Turkey, The Philippines, and Cuba. WHO is also currently revising its international classification system for external causes of injury and poisoning to make information collection simpler and more accurate.

The main interventions that are available for injury control are either behavioral or structural. Behavioral interventions address the human factors from the matrix in Figure 1 (page 2) and are what most programs call health education. These interventions are considered to be "active" because they require that someone (in the case of childhood injuries, the child's caretaker) repeatedly take a specific action (such as safely storing medicine or always watching a child when he or she is near a fire) in order to prevent an injury.

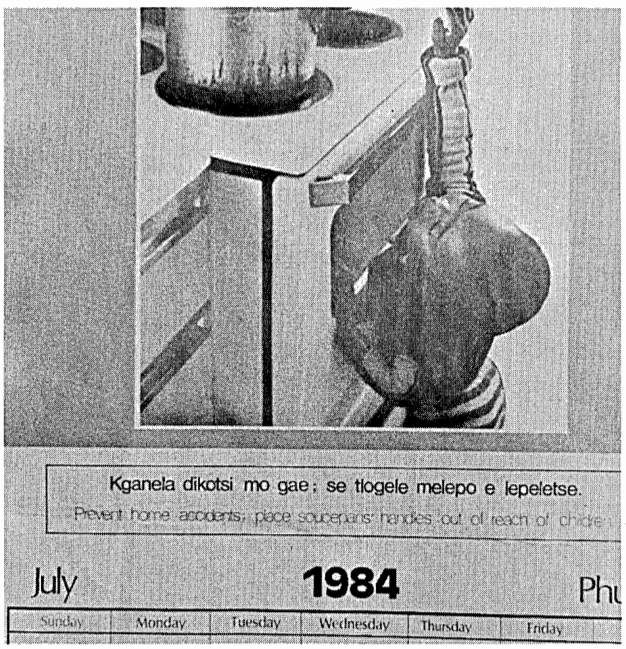
Attempts at changing behaviors to prevent injuries through health education have generally been disappointing. Careful study of several different projects has shown that the percentage of people making the desired changes is low and that without frequent reinforcement most people soon revert to their original behaviors.

These poor results do not rule out health education as an injury prevention strategy, but do suggest that its use should be carefully targeted. Training health workers, educating policy makers about the importance of injury control, and convincing the public to make one-time decisions to prevent injury (such as purchasing a wick stove or building a raised hearth) are all possible roles for health education.

In some cases, it may be possible to promote a safer technology for reasons other than safety. For example, energy-efficient or smokeless stoves may also protect against burns. While mass media health education on injuries may not change specific behaviors in a target group, it could help reinforce the idea that injuries are preventable and may promote community involvement.

Unlike behavioral interventions, structural interventions address equipment or environmental factors, and are considered "passive." Passive interventions do not require any repeated specific action on the part of those being protected (or in the case of children, on the part of their caretakers), and rely instead on technological or environmental changes. Examples of this type of intervention are mandating that refineries dye kerosene blue so that it is not mistaken for water or distributing iron tablets in blister packs or childproof containers so that they are harder for children to open and consume.

Structural interventions are also important to tertiary prevention or the treatment and rehabilitation of injury victims to prevent long term disability. The development of burn and poison information centers, and facilities and equipment for emergency care and transportation are all important components of a childhood injury program.



PATH, Maggie Kilbourne

Calendar designed by the Ministry of Health in Botswana

Conclusions

Burns, poisoning, and trauma are three important causes of childhood mortality and morbidity in all developing countries. The significance of these injuries will become increasingly clear as deaths due to infectious disease and nutritional deficiencies decline. For any given injury problem there is a wide variety of prevention strategies that can be applied if the contributing factors are carefully analyzed and interventions are considered creatively. Often, the use of several interventions simultaneously will be the best approach.

Specific technology issues include the use of appropriate treatments and the development of safer equipment to reduce the risks of childhood injuries. Basic equipment and supplies such as bandages, clean water, a few drugs, and simple splints meet most of the needs of primary health care workers for treating injuries. Efforts by health workers to promote the design and use of safer stoves, childproof containers for hazardous substances, and simple barriers and guard rails can aid in preventing many common injuries. Larger policy issues and engineering interventions such as better traffic control, safer vehicles, and careful regulation of hazardous substances can also have significant impact.

The injury problems that are addressed and the mix of intervention strategies that are selected will depend on a community's injury epidemiology and resources. Regardless of the approach, an awareness of the importance of childhood injuries and the understanding that many of them are preventable could save much unnecessary suffering and death.

Materials Available

A WHO course on Injury Prevention in Developing Countries will be held at the Johns Hopkins University from June 29-July 10, 1987. The course is designed for senior level, developing world health policy makers and planners and will cover the epidemiology of injuries, reporting systems, education, and the role of health authorities. Classes will be conducted in English and registration is limited to 30 participants. The course is similar to one held at Johns Hopkins in 1983. For more information contact: Programme Coordinator, Graduate Summer Programme in Epidemiology, 615 North Wolfe Street, Baltimore, MD 21205, U.S.A.

A WHO publication, **Principles for Injury Prevention in Developing Countries**, is available from the Global Programme for Accident Prevention, WHO Regional Office for Europe 8, Scherfigsvej, DK-2100 Copenhagen O, Denmark or through WHO regional offices.

□

A bibliography on accidents is available from the International Children's Centre in French, English, and Spanish. They also have materials on child abuse and other topics. For information write to: Centre Internationale de l'Enfance, Chateau de Longchamp, Bois de Boulogne, F-75016 Paris, France.

Primary Child Care - A Manual for Health Workers by King, King, and Martodipoero has a good chapter on injuries and poisoning. It is available from Teaching Aids at Low Cost (TALC), P.O. Box 49, St. Albans, Herts. AL1 4AX U.K.

□

Where There Is No Doctor by David Werner has a good section on emergency treatment. It is available from The Hesperian Foundation, P.O. Box 1692, Palo Alto, CA 94302, U.S.A.

□

A bibliography on childhood injuries is available from PATH.

INTERCHANGE

Tuberculosis Update

Our recent issue on tuberculosis (Vol. 6, No. 1) brought a great deal of comment from our readers. Several pointed out that the fluorescent method of sputum slide examination is not more sensitive than the standard test (it only allows the microscopist to work more quickly) and that the bactericidal effect of ethambutol is probably better rated as "low" while streptomycin should be rated as "medium."

One reader asked us to mention the drug interaction that occurs between rifampicin and oral contraceptives (OCs). Studies have shown that rifampicin speeds up the body's metabolism of oral contraceptive steroids and reduces their effectiveness. This effect is especially apparent with low-dose OCs, so women taking rifampicin and trying to prevent pregnancy should use another method of birth control.

Clarification is necessary for the purified protein derivative (PPD) doses that were mentioned for use in skin tests. For tests using PPD RT23, a 2 Tuberculin Unit (TU) dose is specified. This is roughly the equivalent of 5 TU dose of standard PPD. Finally, the most recent price data place the drug costs of a six month, intermittent regimen consisting of initial daily treatment with isoniazid, rifampicin, pyrazinamide and ethambutol, followed by twice-weekly treatments with isoniazid and rifampicin at close to U.S. $32, rather than the $18 figure given in the TB issue.

Reader comments and suggestions are always welcome.

■

Helen Keller International (HKI) has published a manual entitled "Community-based Rehabilitation of the Rural Blind: A Training Guide for Field Workers," by J. Kirk Horton. Single copies cost U.S. $5 and are available by writing to: Director, Division of Education and Rehabilitation, Helen Keller International, 15 West 16th Street, New York, NY 10011, U.S.A.

■

The V International Congress of the World Federation of Public Health Associations (WFPHA) will be held in Mexico City, Mexico, March 22-27, 1987. Abstracts are being accepted for presentations on the theme "International Health in an Era of Economic Constraints: The Challenge."

The abstract deadline is October 15, 1986. For information contact: WFPHA Secretariat, c/o American Public Health Association, 1015 15th Street, N.W., Washington, D.C. 20005, U.S.A.

■

A future issue of **DIRECTIONS** is being planned on the topic of folk health education techniques. It will look at the use of theater, puppetry, music, dance, and similar methods. Readers with information about programs using these techniques are encouraged to contact the editor.

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The following people reviewed outlines or drafts of all or parts of this issue of **DIRECTIONS:** Dr. Ruth Ann Parish, Department of Pediatrics, University of Washington School of Medicine, Seattle; Dr. Gordon Smith, The Johns Hopkins School of Hygiene and Public Health, Baltimore; and Dr. Garen Wintemute, School of Medicine, University of California, Davis. We thank them for their valuable comments. Contents or opinions expressed in **DIRECTIONS**, however, remain the responsibility of PATH.

DIRECTIONS is published three times a year at irregular intervals. Single copies are distributed at no cost to health program managers in developing countries and others interested in primary health care programs.

PATH is a nonprofit, international organization devoted exclusively to the development and application of appropriate health technologies for primary health care (PHC) programs in developing countries. PATH is pleased to acknowledge support from the Agency for International Development (AID) for the research on which this issue was based.

health technology
directions

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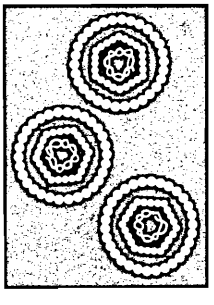
Hepatitis B

Hepatitis B virus (HBV) is a major cause of acute and chronic hepatitis, cirrhosis, and liver cancer (hepatocellular carcinoma or HCC). It appears throughout the world but is highly endemic in China, Southeast Asia, Sub-Saharan Africa, the Amazon basin, and many of the Pacific Islands. In these areas 5-30% of the population are chronically infected with or carriers of the virus, and almost all of the population is infected either at birth or early in childhood. Hepatitis B has low prevalence in North America, Western Europe, and most of Australia and is intermediately endemic elsewhere.

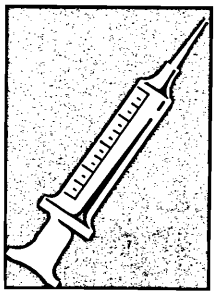
HBV infection can cause an acute attack of hepatitis resulting in death, but this is rare. Most hepatitis B related mortality is due to liver cancer, which is a frequent cause of death in HBV carriers and one of the most common cancers in developing countries. Liver cancer has a long latency period and usually appears in male HBV carriers 30 or 40 years after infection. It is estimated that there are more than 280 million HBV carriers worldwide and that at least 50 million of them will die of HBV-induced liver disease.

While most hepatitis B related mortality in regions of high endemicity occurs in adulthood, the disease is mainly contracted in these regions in childhood or at birth. This fact, combined with the health consequences faced by the thousands of children who lose parents to liver disease, makes hepatitis B an important issue for child survival.

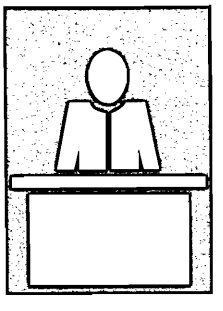
The recent availability of an effective vaccine at a reasonable cost has dramatically altered the options for hepatitis B control efforts. This issue of DIRECTIONS deals with the diagnosis, prevention, treatment, and program issues surrounding hepatitis B.



The Disease



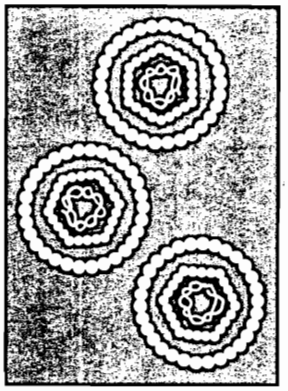
Prevention and Treatment



Program Issues

Volume 6, Number 3 ISSN: 0730-8620 1986

The Disease



Hepatitis B (formerly called serum hepatitis to distinguish it from infectious hepatitis--now hepatitis A) is caused by a small DNA-containing virus. Viruses are simple particles often containing only a molecule of nucleic acid surrounded by several protein molecules. By themselves, viruses cannot move, use nutrients, or reproduce. When a virus attaches itself to a living cell, however, the viral nucleic acid inserts itself into the molecular machinery to make thousands more viruses exactly like itself. In addition, hepatitis B virus DNA is sometimes inserted into the host cell's chromosomal DNA. This favors the induction of a chronic carrier state and is also believed to underlie the mechanism by which this virus causes liver cancer.

The hepatitis B virus consists of three main components: 1) an outer envelope composed of fat, carbohydrate, and the viral coat protein, 2) an inner layer of core protein, and 3) the DNA strand that has coded on it the information necessary to build all three of these parts (see Figure 1). Hepatitis B viruses infect liver cells (hepatocytes) and usually replicate inside them without causing cell damage or death. In an acute case of hepatitis, the body's immune system recognizes a hepatocyte that has been infected with the virus and attacks it. Destruction of the cell releases the newly replicated viruses. As this occurs, whole viruses and their component parts appear in the bloodstream. These viral components are recognized by the body's immune system as antigens or foreign bodies that should be removed from the blood. The immune system develops antibodies or protein molecules that are specific to most of the viral components.

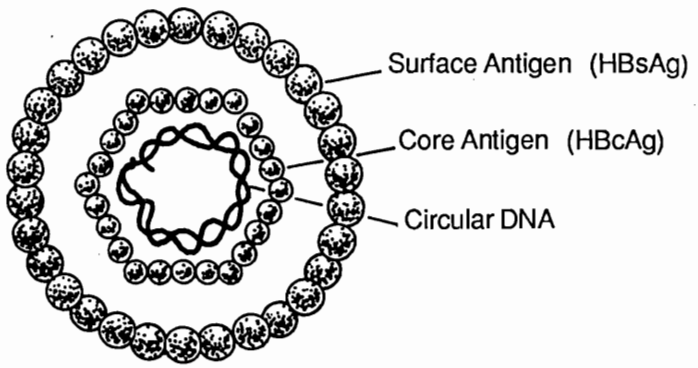
An antibody recognizes the structure of the antigen or viral component that it has been designed to match, attaches to that antigen, and keeps it from attacking any new cells while it is being destroyed. The levels of the different hepatitis B antigens and antibodies circulating in the blood form the basis of most of the serological diagnostics available for this disease (described on page 6).

Course

Exposure to HBV usually results in a self-limiting acute infection that may go undetected. The incubation period is long, and it may be six weeks to six months after exposure before any symptoms are evident. When symptoms are noted, they are often mild. Infected persons may report fatigue, loss of appetite, and some abdominal pain. In more severe cases, jaundice, dark urine, light-colored stools, and enlargement and tenderness of the liver may occur. People rarely die from acute infections.

During the incubation stage or in the early stages of acute hepatitis B infection, the surface protein component of the virus (called hepatitis B surface antigen or HBsAg) first becomes apparent in the blood. This antigen indicates that an active infection exists and

FIGURE 1



THE HEPATITIS B VIRUS

that the infected person can transmit the disease. An individual who still tests HBsAg positive six months after an initial positive test is usually considered an active carrier of the virus. Babies and infants may remain antigen positive for one to two years and then have the antigen disappear. This also occurs with a very small percentage of adults over time.

The antibody formed in response to the circulating hepatitis B surface antigen (designated anti-HBs) usually appears in the blood within a few weeks after the surface antigen disappears, during the early convalescent phase of an acute infection. The presence of this antibody indicates either previous infection with hepatitis B virus or successful vaccination. Anti-HBs continues to circulate in the blood for many years and provides protection against subsequent infection.

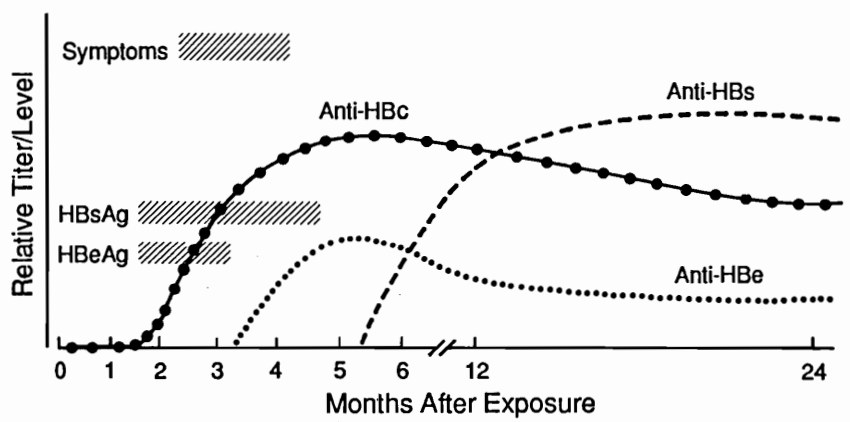
In some exposed individuals anti-HBs does not appear. This indicates either that the individual is still HBsAg positive and a carrier of the virus or, more rarely, that the level of anti-HBs that has been formed is too low for diagnostic tests to identify.

A second viral component that appears in infected liver cells is the hepatitis B core antigen (HBcAg). This antigen has never been found free in the blood, but does occur in the free form inside the liver. A related antigen, designated HBeAg, does circulate freely in the blood and is closely related to how infective the serum is. This antigen is believed to be core antigen that changes its shape when it leaves its liver cell. Measurable HBeAg levels indicate highly infective blood and that an individual either has acute hepatitis or is a highly infectious, chronic carrier.

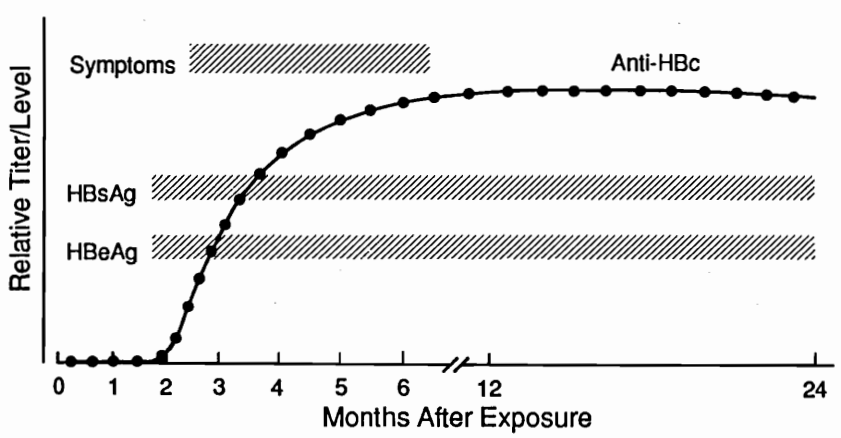
Antibodies to HBeAg and HBcAg (anti-HBe and anti-HBc) are also found in the serum of some patients and can help distinguish both the severity and stage of the infection. Individuals with circulating anti-HBe either are recovering from acute infection or are chronic carriers. Circulating anti-HBc, which appears just after measurable HBsAg, is present in all cases of acute hepatitis, in all chronic cases, and in all cases recently recovered from hepatitis B. Figure 2 shows the levels of antigens and antibodies in a typical acute case of hepatitis B and in the case of a chronic carrier.

In addition to their usefulness in determining the stage of an infection and the potential to transmit hepatitis B, the detection of antigen and antibody levels is also used to identify those at risk for hepatitis B related liver damage, especially liver cancer (HCC). The relationship between HCC and HBV has been demonstrated with data from several different disciplines. Epidemiologic data have shown that people with active HBV infections over a period of

FIGURE 2



Antigen and Antibody Levels in Acute Hepatitis B



Antigen and Antibody Levels in Chronic Hepatitis B

years are much more likely to develop liver cancer than are people who either have never been infected or who have been infected and recovered from an acute HBV infection. People from these last two groups rarely develop liver cancer. Biological data have shown that HBV antigens are found in liver tumor cells, and genetic material (DNA) from hepatitis B viruses has also been found incorporated in the genetic material of these cells.

Epidemiologic and laboratory data have suggested that, although chronic HBV infection predisposes a person to HCC, a second cancer-causing event may be necessary for actual tumor growth to begin. This might explain the higher rates that have been found in rural versus urban HBV carriers if it is assumed that rural carriers have greater exposure to liver cancer promoters such as aflatoxin, which is produced by a mold commonly found in stored food crops. However, it should be emphasized that the close association between hepatitis B and HCC, and the fact that almost all cases of HCC occur in areas of high HBV prevalence, indicate that HBV is the essential cause of this cancer.

In developing countries HCC is the single most important cancer in young adult men. It commonly occurs in the late twenties and thirties in Sub-Saharan Africa and slightly later in Southeast Asian men but can appear at any age. Both the chronic carrier state of HBV and liver cancer occur four to six times as often in men as women, depending on the geographical location studied, and this is believed to be due to hormonal differences.

HCC symptoms include weight loss and abdominal pain that increases after eating. Many patients who drink alcohol also complain of increased pain after consumption. Other signs include muscle wasting, accumulation of fluid in the abdominal cavity (ascites) and jaundice. Early diagnosis of liver cancer can be made by testing for alpha-fetoprotein (AFP) in blood serum. AFP is made by fetal organs and is normally only present in low levels in adults. Very high levels of AFP appear as much as two years before clinical HCC symptoms occur. In some developed countries chronic carriers are given alpha-fetoprotein tests every six months and when AFP levels rise, follow-up tests are done using ultrasound equipment that can detect very small liver tumors. Surgical removal of

HEPATITIS A AND HEPATITIS NON-A, NON-B

Hepatitis A, formerly called infectious hepatitis, is caused by the hepatitis A virus (HAV). The resulting illness has a shorter incubation period than hepatitis B (around 30 days), and transmission is by the fecal-oral route. Most cases in children are asymptomatic, but in adults fever, fatigue, loss of appetite, nausea, and jaundice usually occur. The disease is rarely fatal and there is no evidence of a chronic carrier state.

Hepatitis A can be diagnosed by testing for serum antibodies to the virus. Clinical illness can be avoided if immune globulin is administered before exposure or early in the incubation phase of the disease. There is currently no vaccine available for HAV; however, both killed and live attenuated vaccines are under development.

Hepatitis non-A, non-B (HNANB) is caused by several agents that are serologically distinct from either hepatitis A or B viruses. It is diagnosed by exclusion and there are currently no diagnostic tests for HNANB viruses. Non-A, non-B hepatitis viruses are found worldwide. Epidemiologically there are two categories of HNANB viruses, one that is spread by fecal-oral routes (mostly water borne) and the other, spread by infected body fluids (mostly blood). The water borne disease is usually self-limiting and occurs mainly in young adults. It has a slightly longer incubation period than HAV and also has no known carrier state. This disease is rarely fatal but does have a high mortality rate for women infected during pregnancy. The blood borne form of HNANB induces a chronic carrier state in many of those infected and is thought to be a major cause of cirrhosis.

At present, there is no known effective treatment or preventive agent for HNANB. Research on defining the causative viruses and on developing diagnostics is underway.

these tumors has been shown to significantly improve the five year survival rate of liver cancer patients. The technologies required for this level of care are, however, beyond the resources of most countries. In developing countries the average length of time from diagnosis of HCC clinical symptoms to death is three to six months.

Cirrhosis is a disease in which liver tissue is repeatedly destroyed and rebuilt until the resulting connective tissue obstructs normal liver function. It can be caused by HBV and can result in death. Cirrhosis is often found in the noncancerous liver tissue of patients with liver cancer.

Transmission

Transmission of the hepatitis B virus is either from mother to child (vertical) or between other related or unrelated children or adults (horizontal). Vertical transmission is responsible for much of the spread of hepatitis B in Southeast Asia and China where up to 50% of new cases are infants born of HBsAg-positive mothers. Studies done in Thailand, Singapore, and China suggest that infants are frequently exposed at delivery, with blood markers indicating exposure becoming apparent within the first six months of life. Some children are infected by the virus *in utero* and have measurable antigen levels at birth, but this is very rare, occurring in about 5% of vertical transmission cases. These cases are important because they cannot be prevented by giving vaccine at birth.

Early exposure to the virus is an important determinant of the likelihood of becoming a chronic carrier. Up to 50% of the infants who are exposed at birth will become infected with HBV and of those infected, 90% will go on to become chronic carriers. Children infected after birth, but in the first five years of life, have only about a 30% chance of becoming a chronic carrier and this risk decreases with age. Only 5-10% of infected adults will become HBV carriers. Virus carriage from vertical transmission is more likely if the infant is exposed *in utero*, if the mother is HBeAg positive, or if she suffered from acute hepatitis during the third trimester of pregnancy. One study has shown the rate of transmission not to be affected by Caesarean section delivery.

Horizontal transmission is responsible for most of the spread of hepatitis B in Africa and Latin America. Studies in Kenya, Liberia, Senegal, and Zambia have shown that, unlike Southeast Asia, perinatal transmission in these countries is relatively rare. Children are infected throughout childhood, and in many areas most are exposed by five years of age.

In tropical areas infection through open sores of infants and children is thought to be a major means of transmission. Data from two recent studies suggest an association between prechewing of children's food by infected mothers and the infection of their children. Breastfeeding has not been shown to increase the risk of transmission.

Research on hepatitis B infection in household contacts of acute cases in Singapore found that sharing personal and household items such as razors, toothbrushes, combs, handkerchiefs, towels, and bedding was a risk factor, while eating together at meals and sleeping in the same bedroom did not constitute a risk. Laboratory studies have shown that HBV remains viable on surfaces for several hours even after it has dried, and this may help transmission. There is no evidence of spread through a fecal-oral route. Research is continuing in order to identify the exact modes of childhood horizontal transmission in countries where HBV is endemic.

The horizontal transmission of HBV in medical contexts is relatively less important in developing countries but can occur in both modern and traditional health practices. Improperly sterilized needles used for vaccination may be one mode of transmission. Transfusions of blood or blood products that have not been screened for HBV are another source of infection. In developed countries healthworkers are considered an at-risk group because of their contact with possibly infected body fluids. In developing countries many healthworkers have been infected early in life and have developed antibodies. In traditional medical practices, instruments used for tattooing, decorative scarring, or circumcision may spread the disease.

Heterosexual transmission can occur from men to women or women to men, and individuals engaging in anal intercourse are at higher risk of exposure. The correct use of condoms is effective against the spread of virus found in semen. In general, spouses of persons with acute hepatitis B are at high risk of infection.

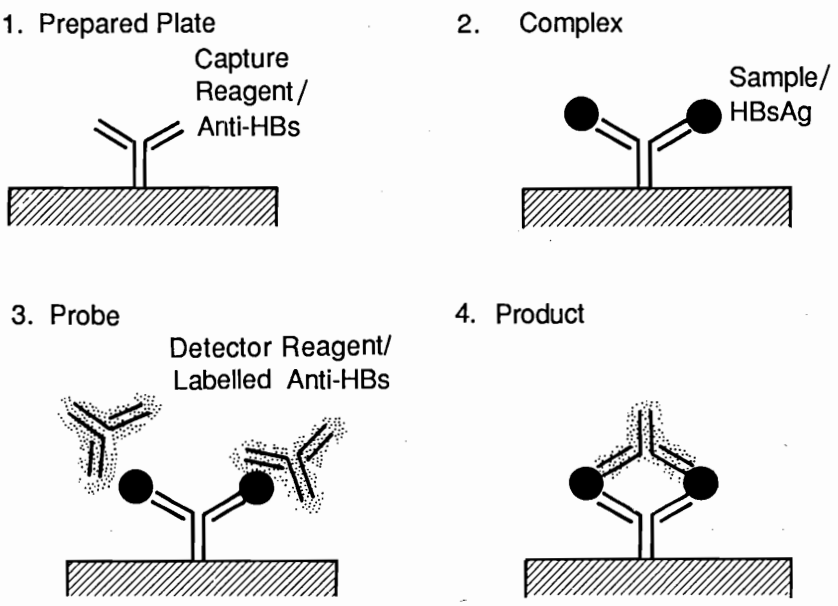
Diagnosis

Hepatitis B cannot be diagnosed using only the clinical signs and symptoms described on page 2; serological testing for HB antigens and antibodies is required. The serum diagnostics fall into three categories: radioimmunoassays (RIAs), enzyme immunoassays (EIAs), and reverse passive hemagglutination tests (RPHAs). RIAs and EIAs are usually solid-phase assays in which a capture reagent is bound to either plastic beads or a plate; the antibody or antigen being sought is then bound to the capture reagent and is finally detected by an enzyme or radioactive isotope-labelled detector reagent.

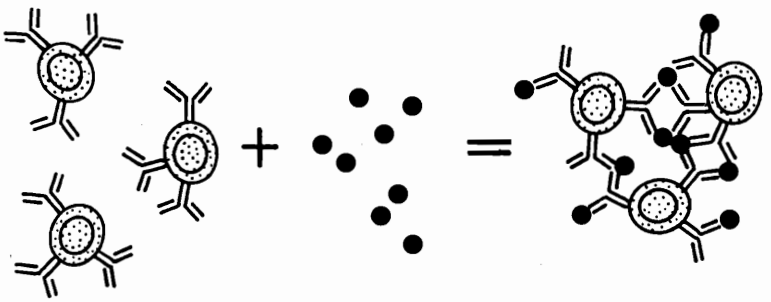
Using HBsAg as an example, an RIA or EIA works as follows: 1) A test plate is prepared onto which anti-HBs (the capture reagent) is fixed. 2) The sample to be tested is coated on the test plate; if HBsAg is in the sample, it attaches itself to the anti-HBs forming an HBs antibody-antigen complex. 3) Then the plate with its attached complex is exposed to the detector reagent, anti-HBs that has been labelled with either a radioactive molecule (in the case of RIAs) or an enzyme that will cause a color change in a further reaction (EIAs). 4) Excess labelled antibody is washed off and the plate is examined. If HBsAg was present, labelled anti-HBs will have attached to it and will be detectable. This process is represented in Figure 3. When testing for antibodies, the process is reversed; antigens are fixed to the test plate as capture reagents in Step 1 and labelled antigens are used as detector reagents in Step 3.

Reverse passive hemagglutination (RPHA) tests for HBsAg use red blood cells that have been coated with purified anti-HBs. When a sample with HBsAg is added, the red blood cells agglutinate or clump together (see Figure 3). RPHA tests are slightly less sensitive and specific than RIAs or EIAs, but can be read visually. All RIAs and most EIAs require electronic equipment to read test results. EIAs and RIAs also require sophisticated plastics for the test plates or beads that are not readily available in most developing countries. RIA or EIA tests are commercially available for all the HBV antigens and antibodies. RPHA tests are available only for HBsAg.

FIGURE 3



Solid-phase Assays (EIA and RIA)



Reverse Passive Hemagglutination

Prevention and Treatment

Prevention

The two approaches central to the prevention of hepatitis B are vaccination programs, designed to slow both the spread of infection and further increase in the number of chronic carriers, and educational programs to promote vaccination and change practices that increase the risk of horizontal transmission.

Vaccination

One of the chief goals of hepatitis B research in the last two decades has been the development of a vaccine that would protect against HBV infection. Vaccines against viral diseases work in the same way as other vaccines: whole viruses in an inactivated or weakened state, or viral parts, are introduced into the bloodstream and specific antibodies to them are formed by the body's immune system. These antibodies will continue to circulate for many years and will quickly recognize and attack the specific viruses that they have been produced against when an individual is re-exposed.

The current approach is to stimulate the production of antibodies against the surface antigen (HBsAg) by injecting individuals with a series of doses of this antigen. Because of the large amount of HBsAg in the plasma of chronic carriers and the difficulty of growing the hepatitis B virus in the lab, the most widely used method of hepatitis B vaccine production is based on the extraction, purification, and inactivation of HBsAg from human plasma. Plasma-derived vaccine production starts with plasma collected from hepatitis B chronic carriers (HBsAg positives). This plasma is purified and any live virus is either removed or inactivated so that only hepatitis B surface antigens remain.

The inactivation processes include treatment with formalin, urea, or pepsin, and heat. The available plasma-derived vaccines have been shown to be very safe, and the purification and inactivation processes that are used eliminate the possibility of contamination with live HB virus or any of the viruses that cause acquired immune deficiency syndrome (AIDS). HB vaccine can be given during pregnancy and to individuals already exposed to HBV without ill effect. Maternal hepatitis B antibodies that have been passed to an infant do not interfere with vaccine-induced antibody production.

The stability of these vaccines under different environmental conditions is still being studied. Initial results indicate that HB vaccines are relatively stable and can be stored for up to 30 days at 37-45 degrees centigrade without significant loss of their potency. More research on vaccine stability and ways to increase it are necessary to make use beyond the "cold chain" more practical and effective.

Research has been done on other hepatitis B vaccine production processes, and a recombinant DNA vaccine is now available. This vaccine starts with yeast cells into which a portion of the HBV DNA that codes for the surface protein of the virus is inserted. Inside the cell, the HB surface antigens are produced following the instructions provided by the inserted DNA. The yeast cells are then broken, and the surface HBsAg is purified. Another process for producing HBsAg uses continuously grown mammalian cells. This process is similar to growth in yeast cells, but in mammal cells the HBsAg is secreted and it is not necessary to break the cells to harvest the HBsAg.

Other recombinant DNA research has focused on the vaccinia virus which is used in the production of smallpox vaccine. HBV DNA is inserted into the vaccinia DNA, and HBV surface antigen appears on the surface of subsequent generations of the virus. Tests are underway to determine the safety and efficacy of this vaccine. Research is also being done on creating vaccines synthetically.

When injected with vaccine, the body produces anti-HBs which circulates in the blood. A series of these vaccinations is usually necessary before the level of

circulating antibodies is high enough to ensure protection against a viral attack. Partial protection may occur in the first few months after the initial injection.

When administered correctly, hepatitis B vaccine induces antibodies in about 95% of healthy people. The antibody response is age-related, with older people having lower rates of seroconversion. Antibody response in individuals who are immune deficient is also lower. Infants and children have excellent response rates and produce very high antibody titers with smaller doses than those recommended for adults. It is still uncertain how long HB vaccine protection lasts, but it is believed to be at least five years. In countries where the disease is endemic, periodic exposure to the virus may stimulate antibody production and prolong protection.

The recommended dosage varies for the specific vaccines (see Table 1); most of them are administered intramuscularly at 0, 1, and 2 or 6 months. In adults, injec-tions seem to be most effective if given in the deltoid muscle; there have been reports of poorer anti-body response to injections given in the buttocks. This is thought to be the result of injection into fatty tissue rather than muscle. In infants and small children the injection is given in the thigh.

Recent experimental work done with low-dosage injections has shown that if the vaccine is given intradermally, 1/10th of the recommended dose is sufficient. Intradermal injections are technically more difficult and may require additional staff training. To date no large-scale demonstration project has been done to see if intradermal injection of lower dosages of vaccine is feasible for use in ongoing programs.

There are two main approaches to prevention of hepatitis B infection using vaccines: pre-exposure immunization and post-exposure immunization. Pre-exposure immunization allows the body to produce anti-HBs before the individual is infected with the virus. Post-exposure vaccination immediately after infection is also effective because the long incubation period of the virus inside of liver cells provides an opportunity for vaccine-induced anti-HBs production before the infection spreads. Post-exposure hepatitis B vaccinations are given to infants who have been infected at birth or to healthworkers who have been accidentally infected at work.

In developed countries exposed individuals are often given

TABLE 1

Hepatitis B Vaccines*

Vaccine	Manufacturer	Dose (micrograms HBsAg)		Dosage Schedule (in months)
		Pediatric	Adult	
Heptavax-B	Merck Sharp & Dohme	10	20	0,1,6
Recombivax	Merck Sharp & Dohme	5	10	0,1,6
Hevac B	Pasteur Vaccin	5	5	0,1,2 booster at 12
HB Vaccine (CLB)	Central Laboratory of the Netherlands Transfusion Service	3	3	0,1,2
Hepaccine B	Cheil Sugar & Co., Ltd.	1.5	3	0,1,2
Hepatitis B	Green Cross of Japan	5	10	0,1,2 booster at 12

*Based on information provided by Hepatitis Branch, CDC, Atlanta. Other vaccines exist for which full information was not available.

hepatitis B immune globulin (HBIG) as well. HBIG is purified from plasma of individuals who have been infected with hepatitis B and contains high titer anti-HBs. These antibodies give immediate protection against HBV but disappear from the bloodstream more quickly than vaccine-induced antibodies. In some developing country programs both HBIG and hepatitis B vaccine are given at birth to infants of HBV carrier mothers. This combined regimen has been shown to be 90% effective in preventing the chronic carrier state. Studies where vaccine alone has been given have shown this treatment to be 70-90% effective. Because HBIG is very expensive and heat sensitive, most existing developing country programs use vaccine alone.

Education

While most of the transmission of hepatitis B is either from mother to child (Southeast Asia) or between children (Africa) and is probably best controlled by vaccination programs, some transmission, especially by health-care-related and sexual routes, could be decreased by education. Healthworkers need to be made aware of the risk of hepatitis B, and the importance of sterilization procedures needs to be reinforced. This requires special emphasis with traditional practitioners whose training or facilities may make sterile techniques unlikely. Routine testing of blood or blood products used for transfusion could also eliminate one source of transmission, although in very high prevalence regions this is not very effective since most blood recipients will already be immune. Sexual transmission of HBV can be reduced by better diagnosis of the disease and education on safe sexual practices, including the use of condoms.

Treatment

Currently there is no known, effective treatment for chronic hepatitis B. No dietary restrictions, rest or exercise regimens, or drugs have been shown to change the natural course of the disease.

The drug therapies that have been tried so far fall into two main categories: those that might stop the replication of the virus and those that might bolster the body's immune system against viral attack. In the first category, drugs like acyclovir and ribavirin have been tested in animal and human studies with mostly poor results.

Therapies to strengthen the immune system that have been tried include hepatitis B immune globulin (discussed in the section on prevention), hepatitis B vaccine, and interferons. None of these has been proven to be helpful in treatment of chronic hepatitis. Research is continuing on both new medications and treatments using combinations of drugs.

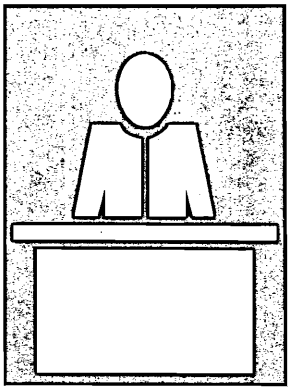
DELTA VIRUS

The delta virus, sometimes called the hepatitis D virus, was discovered in 1977. It is a defective RNA virus that requires hepatitis B virus-infected host cells for it to grow. Delta virus infection can either occur as a co-infection in a person with acute hepatitis B, or can attack a chronic hepatitis B carrier as a superinfection. While either co-infection or superinfection can cause sudden and severe inflammation of the liver, usually only superinfection results in chronic delta infection (the carrier state) and chronic active hepatitis.

Serological research has shown delta virus to have an irregular worldwide distribution with concentrations around the Mediterranean and in parts of Africa, South America, and the Middle East. Recent studies have demonstrated its presence in Asia and the Pacific Islands as well. Transmission is believed to be similar to that of hepatitis B.

Because the delta virus requires a hepatitis B virus for replication, prevention of hepatitis B infection will also prevent delta virus infection. Delta virus diagnostics are becoming commercially available, but there is currently no treatment or vaccine for the virus.

Program Management



Three program issues central to the control of hepatitis B are the local epidemiology of the disease, the resources available to prevent it, and the integration of hepatitis B prevention activities into existing programs.

Local Epidemiology

Any program to control hepatitis B must be designed in light of the local disease epidemiology. Without an understanding of the pattern and modes of transmission, little can be done to break the cycle of infection. The key issues are the endemicity of the disease and whether the transmission is vertical or horizontal.

In countries of high hepatitis B endemicity where transmission is mostly vertical, it is necessary to reach infected infants at birth with either vaccine alone or vaccine plus immune globulin in order to prevent infection and a high probability of becoming a chronic carrier. This will be a difficult task in areas where trained health workers are not available at the village level and where most births take place at home. Such situations require extended cold chains and frequent resupply of fresh vaccine in single-dose containers at the periphery.

In highly endemic areas where transmission is primarily horizontal and hepatitis B is usually spread during childhood, immunization at birth is not as essential and it is possible to rely on more centralized storage and administration of vaccines. This scenario would allow better integration of hepatitis B vaccination into existing immunization schedules.

In countries with intermediate endemicity (carrier rates of 1-5%), it is necessary to consider sexual transmission and transmission by traditional or modern medical practices or other means. The data necessary to determine these patterns and modes can be collected by simple cross-sectional sample surveys, testing blood taken from individuals in different age groups using serodiagnostics. More detailed survey work can later be done on identified high-risk groups. Prevalence surveys have been done in most countries.

Resources

While vaccine costs are the central issue in determining the resources necessary for the prevention of hepatitis B, there are also other considerations. The country's health service coverage and especially the percentage of births taking place in hospitals are factors, as well as health personnel, the availability of laboratory facilities, and the extent of the cold chain.

Until recently the high cost of vaccine has been one of the main obstacles for nationwide hepatitis B prevention programs in developing countries. In the early years of its production, prices for a three-dose series in developed countries ran as high as US $150. Improvements in production, and especially simplification of the purification processes, have brought prices down. Recently one producer has offered to make available large quantities of vaccine for national programs at a price of $1.00 per dose. This reduction in price brings hepatitis B vaccine in line with the other Expanded Programme on Immunization (EPI) vaccines. It seems likely that more simplified production procedures and higher production levels to meet the needs of new hepatitis B prevention programs around the world could reduce prices still further.

The cost issues for a national program of hepatitis B prevention are often examined in terms of cost-per-carrier-prevented (CPCP). The cost can then be compared for several proposed prevention programs to assess relative cost-effectiveness. CPCP takes into consideration factors such as current disease prevalence and incidence, transmission modes and patterns, existing systems for vaccine distribution and the costs of diagnostics, hepatitis B vaccines, and immune globulin. Some of the options that need to be costed out include the use of

immune globulin, testing for high-risk mothers, testing for exposure before immunization, and possible training costs for the use of low-dose regimens.

Hepatitis B immune globulin is used in some countries where vertical transmission is important. It is expensive and cold chain dependent; because the use of vaccine alone has been shown to be almost as effective as vaccine plus HBIG, HBIG is impractical for use in highly endemic areas.

The cost-effectiveness of screening either for carrier mothers or for exposed children depends on the prevalence and incidence of hepatitis B and costs of the tests and vaccine. With the new, low vaccine prices and the high cost of drawing and testing blood, there will be fewer programs where screening will be cost-effective in developing countries. Since hepatitis B vaccine is not harmful to either previously or currently infected individuals, there is no medical reason to screen before vaccinating. Screening may be cost-effective, though, in countries with intermediate endemicity and very well developed health infrastructures.

The use of low-dose intradermal injections is another program option that can be analyzed. Intradermal injection has been reported to reduce vaccine requirements to 10% of what is needed for intramuscular injection, resulting in possible vaccine cost savings. It has been suggested that some of these savings may be offset by the costs of training and monitoring health workers in the administration of intradermal injections which are more difficult to perform correctly. In some countries, where health-workers are already giving BCG vaccinations intradermally, this would not be a problem. A more important issue is the unproved efficacy of intradermal hepatitis B immunization in a large-scale assessment. Data from a recent study done in China suggest that the efficacy of hepatitis B vaccine given by intradermal injection is much lower in post-exposure use than in the pre-exposure trials previously done.

In all cost analyses it is important to consider the time demands that different options make on often already overtaxed health personnel. Although personnel salaries may be covered from a general budget, the time that staff spend on hepatitis B related activities competes with other health activities in an integrated health care program. Models have been created in some countries to assess relative program costs, but these are difficult to estimate accurately. Prevention costs need to be weighed against the high treatment costs and loss of life attributable to acute hepatitis, cirrhosis, and liver cancer.

Integration with Existing Activities

Because of the relatively high cost of vaccine before the recent price reduction, hepatitis B has not been included in WHO's Expanded Programme on Immunization (EPI). WHO advisory groups are active in shaping the direction of hepatitis B prevention strategies and in developing standards for vaccine production using both serum-derived and recombinant DNA techniques.

Some research has been done on combining hepatitis B vaccines with other EPI immunizations. Initial results of studies where hepatitis B vaccine has been given with DPT indicate that there is no decrease in antibody production by either vaccine when this is done. More work will be necessary to confirm these studies and examine possible interactions with other vaccines. At present no combination hepatitis B vaccines are commercially available.

Taiwan is one of the first countries to start a national mass vaccination program. In Taiwan vertical transmission accounts for about half of the chronic carriers and most births take place in hospitals. Taiwan also has a good system of medical laboratories. The program was started in 1985 with the vaccination of all infants who were at risk from infection by carrier mothers. In addition, mothers are screened and the infants of those with high titers of HBsAg are given HBIG at birth. In 1986 the program was expanded to cover all newborns in the country, and in subsequent years the program will grow further to include children and adults.

Recently an international group of experts on hepatitis B have formed a "Task Force on Hepatitis B Immunization." This group is calling for immunization programs against the disease worldwide and is planning large-scale demonstration projects in several countries to show the feasibility of hepatitis B vaccination and to investigate the program issues described above. The Program for Appropriate Technology in Health (PATH) will play a central role in carrying out the activities of the task force.

Conclusions

Infection with hepatitis B virus has a worldwide distribution and is highly endemic in Southeast Asia, China, Africa, and elsewhere. The consequences of chronic infection are serious and include chronic hepatitis, cirrhosis, and liver cancer. The social consequences are serious as well, because those most likely to die of hepatitis B related liver cancer and cirrhosis are males in their most productive years and their loss is acutely felt by their societies and families.

Chronic hepatitis B infection has no known cure or treatment, and health programs need to rely on prevention to interrupt the cycle of infection. In most countries prevention must take the form of vaccination of infants and children if the primary means of transmission is to be limited and the risk of chronic infection decreased.

Immunization will become economically feasible due to improved production processes and increased use. Now it is necessary for each country's health planners to examine the local epidemiology of the disease to see how prevention of hepatitis B can best be integrated into their existing disease control programs.

Materials Available

There are few good materials on hepatitis B that are widely available. Two recent books that provide good overviews are **Hepatitis B: The virus, the disease, and the vaccine**, edited by Millman, Eisenstein and Blumberg, Plenum Press, New York, 1984; and **Hepatitis B**, edited by Robert Gerety, Academic Press, Orlando, Florida, 1985. If readers know of other good sources of information, we would be happy to share them in our next issue.

□

A bibliography on hepatitis B is available from PATH.

INTERCHANGE

Self-Evaluation: Ideas for Participatory Evaluation of Rural Community Development Projects, by Him Rugh, is a useful new publication. Single copies are available for U.S. $5.00 (surface mail) from World Neighbors Development Communications, 5116 North Portland Avenue, Oklahoma City, OK 73112, U.S.A.

■

The Fifth Congress of the World Federation of Public Health Associations will be held in Mexico City, Mexico, March 22-27, 1987. The theme will be: International Health in an Era of Economic Constraints: The Challenge. For information write to: WFPHA Secretariat, c/o APHA, 1015 15th Street, N.W., Washington, D.C. 20005, U.S.A.

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For an update of the WHO **Drug Utilization Bibliography,** write to: WHO Collaborating Centre for Drug Statistics Methodology, P.O. Box 100, Veitvel, 0518 Oslo 5, Norway.

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health technology
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PATH Program for Appropriate Technology in Health

Iodine Deficiency Disorders

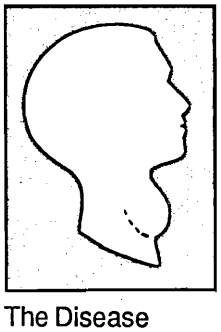
Endemic goiter and cretinism, the two most visible consequences of iodine deficiency, have been recognized as major health problems throughout history. Representation of both conditions appear in art dating back several centuries.

Today 800 million people around the world live in areas that are deficient in dietary iodine. It is estimated that of those living in these areas, approximately 200 million have a demonstrable iodine deficiency disorder (IDD). These disorders include hypothyroidism and reproductive failure in addition to goiter and cretinism. Recent studies suggest that in addition to clinically recognizable disorders, like goiter and cretinism, many more children and adults have less obvious mental impairment due to iodine deficiency.

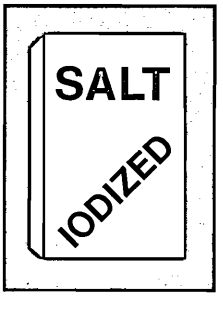
Areas of endemic iodine deficiency are found worldwide. While many of the areas of worst deficiency occur in mountainous regions such as the Himalayas, Andes, and Alps, where glacial activity has stripped away or leached iodine-rich layers of soil, IDDs are found in lowlands as well. Serious problems exist in several African countries, throughout South America, and in many parts of Asia.

The People's Republic of China alone has an estimated 300 million people living in iodine deficient areas and more than 200,000 cretins. In India there are an estimated 150 million people living in iodine-deficient areas and 1 million cretins. In North America and Europe iodine deficiency has been largely controlled, mostly through prevention programs, although small pockets of deficiency remain in Central Europe and several Mediterranean countries.

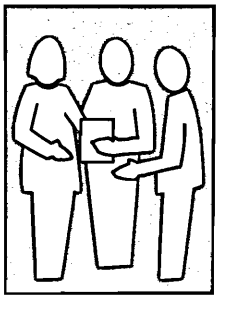
This issue of DIRECTIONS examines iodine deficiency--its diagnosis, prevention and treatment, and the program issues involved in controlling it.



The Disease



Prevention and Treatment



Program Issues

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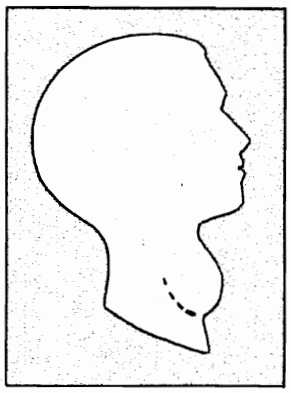
The Disease



Iodine Metabolism

Iodine is an essential constituent of thyroid hormones. These hormones are produced by the thyroid gland which is located below the larynx, behind and around the sides of the throat. The two main thyroid hormones, thyroxine (T4) and triiodothyronine (T3), are the main regulators of the body's metabolic rate. They also play an important role in the normal growth and development of brain, nerve, and other tissue.

Dietary iodine is absorbed through the intestinal wall and is carried in the bloodstream to the thyroid where it is actively transported into the gland. Once inside, the iodine is oxidized and linked together with amino acids to form thyroxine and triiodothyronine. T4 has four iodine molecules and T3 has three. Both forms are stored in the thyroid as part of larger proteins and are eventually released into the bloodstream in small amounts. T3 and T4 travel throughout the body where they increase the metabolic rates of individual cells.

The production of thyroid hormones is regulated by a feedback mechanism that includes thyroid stimulating hormone (TSH). TSH is produced by the pituitary in response to decreases in the circulating levels of thyroxine. It acts to increase the active transfer of iodine into the thyroid and increases the production of T3 and T4. As T3 and T4 levels return to normal, the pituitary responds by decreasing production of TSH.

When dietary iodine intake is insufficient over long periods of time, thyroid hormone production decreases and the pituitary produces more TSH in an attempt to increase T3 and T4 production. High TSH levels over a long period of time stimulate cell growth in the thyroid and the resulting enlargement of the gland is known as goiter. Goiter is the most widely seen result of iodine deficiency, but the least serious. Unless the goiter becomes large enough to put pressure on the throat, it is relatively harmless.

The thyroid also compensates for iodine deficiency by modifying the processes that produce thyroid hormones. For example, relatively more T3 than T4 is produced during iodine deficiency. This is because T3 has a greater effect on cell metabolic rates than does T4 and requires less iodine to produce. If dietary iodine intake is only slightly low, then the increase in thyroid size and modification in T4 and T3 production may be able to compensate for the deficiency and maintain normal levels of circulating thyroid hormones.

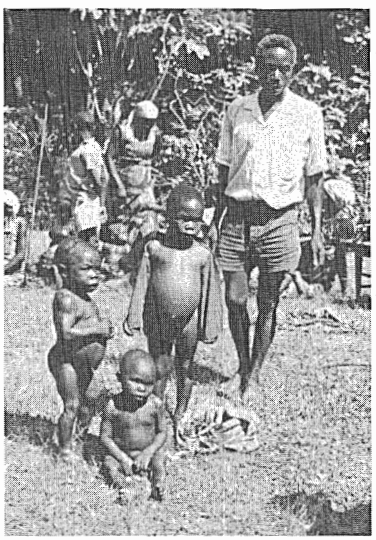
When these measures are not enough to provide sufficient thyroid hormones for normal metabolic function, a person becomes hypothyroid. In adults and older children hypothyroidism results in

John Stanbury

Typical cretin from Andean Ecuador with profound neurological signs and severe retardation.

a general slowing of body functions and decreased physical and mental productivity. In neonates and young children insufficient circulating thyroid hormones cause damage to developing brain and central nervous system tissue. This results in varying degrees of irreversible mental and physical retardation.

When iodine intake is severely deficient, endemic cretinism can result. This term is reserved for severe mental and physical retardation often accompanied by irreversible hearing and speech problems and hypothyroidism. A distinction is made between endemic cretinism which is due to iodine deficiency, and occasional congenital hypothyroidism which has similar symptoms but is due to a defect in the development of the thyroid gland and may occur even when iodine intake is sufficient.



John Stanbury

Three cretins from Zaire (ages 9, 9, and 13). Predominantly signs of hypothyroidism. Severe bone age retardation.

The symptoms of endemic cretinism vary from region to region. Two general syndromes or patterns have been differentiated--nervous and myxedematous endemic cretinism--but many regions have symptoms from each. The main shared characteristic of both disorders is severe mental retardation.

Nervous endemic cretinism is characterized by deaf-mutism, squint, and varying degrees of paralysis. This type of endemic cretinism is the more common type and is found worldwide. Myxedematous endemic cretinism is characterized by growth stunting and a nonpitting edema or swelling that is especially evident in the face. Myxedematous endemic cretinism is generally more rare, but is commonly found in parts of Zaire.

Iodine deficiency has been shown to affect learning ability and school performance. Work done in India has shown that psycho-motor abilities of school children from iodine deficient areas are lower than those of children from the same social level in areas without iodine deficiency.

The contribution of iodine deficiency to reproductive failure is still being investigated. Work done so far suggests that maternal hypothyroidism increases the risk of both stillbirth and spontaneous abortion, as well as the rate of fatal congenital defects .

Iodine Requirements and Sources

The minimum daily requirement for iodine is based on the amount of iodine that is not recovered by the thyroid when T3 and T4 are broken down in the tissues. The requirement varies depending on body size, stage of development, and exceptional needs such as pregnancy. Generally, adults lose a minimum of 40-100 micrograms (µg)/day and suggested intakes are set at 150 µg/day, which should also be sufficient during pregnancy and breastfeeding. Infants need around 35 µg/day at 0-6 months, 45 µg/day from 6-12 months, 60-110 µg /day from 1-10 years, and adult levels thereafter.

The main source of iodine is food. The second most common source is water. The level of dietary iodine in food is directly related to the iodine content of the soil where it was grown. Much of the world's iodine is found in seawater and in areas close to oceans where iodine is carried by rainfall.

Seafood is a good source of iodine as are plants and animals grown in areas washed with rain from nearby seas. Foods raised in dry, rocky, or sandy soil far from oceans are usually poor sources of dietary iodine. Because the iodine content of food is so dependent on where it is grown, food tables showing the iodine content in different foods are of limited value.

Naturally occurring iodine in drinking water is a less important source of dietary iodine. Water systems using iodine derivatives as disinfectants have much higher levels. Iodinated water as a means of preventing IDD is discussed further in the section on prevention.

Other sources of dietary iodine are common in industrialized countries where iodine-containing compounds are used in commercial food preparation processes. Iodophors are iodine-rich disinfectants used in cleaning industrial baking equipment and mechanical milking machines. Iodates, salts of iodic acid, are used as dough conditioners in baked goods, and a common red food dye is another concentrated source of iodine.

Goitrogens

In discussing food sources of iodine it is also necessary to consider goitrogens, common dietary compounds that block the normal action of iodine in the body. Goitrogens occur naturally in both food and water and consist of several different types of compounds, many of which contain sulfur.

Scientists first became aware of the effects of goitrogens on humans when they studied groups of people who were developing iodine deficiency disorders while consuming what appeared to be adequate levels of iodine. Careful study of other components of the diet revealed thiocyanates or similar substances that disrupt the oxidation or binding of iodine in the thyroid. Several goitrogens have been found in members of the plant family *Brassica*, which includes cabbage. Others have been found in cassava and in the milk produced by cows who grazed on goitrogen-containing grasses and weeds. Endemic goiter has been, at least in part, attributed to goitrogens in areas of Colombia, Nigeria, Finland, and Zaire.

Sulfur-containing goitrogens have been isolated from drinking water supplies as well as from food sources. Organic materials like those found in coal or oil-bearing rock formations can have a goitrogenic effect, and bacteriological contamination has also been shown to inhibit normal iodine metabolism. The exact mechanism of these goitrogens is not known.

In addition to sulfur-based compounds, inorganic substances like calcium, lithium and especially iodides have been shown to act as goitrogens when present at high enough levels. These substances block the release of thyroid hormones from the proteins to which they are linked while stored in the thyroid gland. At continously high levels of intake (on the order of 5 mg or more per day), iodine inhibits T3 and T4 release and may eventually cause goiter and hypothyroidism. This has occurred in Japan where large quantities of iodine-rich seaweed are eaten in coastal fishing villages.

Diagnosis

There are several means of assessing the iodine nutrition of populations and individuals. The most common and simple is examination of the thyroid gland for enlargement or goiter. The grading system that has been developed for the classification of goiter is found in Figure 1.

Problems with this means of diagnosis include inter-and intra-observer consistency and the difficulty of diagnosing goiter in infants and very young children.

Measuring dietary iodine intake is difficult. The variability of iodine content in foods in different areas would require laboratory testing of samples of all the foods consumed over a given period of time.

FIGURE 1

CLASSIFICATION OF GOITER

Stage 0: No goiter.

Stage IA: Goiter detectable only by palpation and not visible even with the neck fully extended.

Stage IB: Goiter palpable and visible only when neck is fully extended.

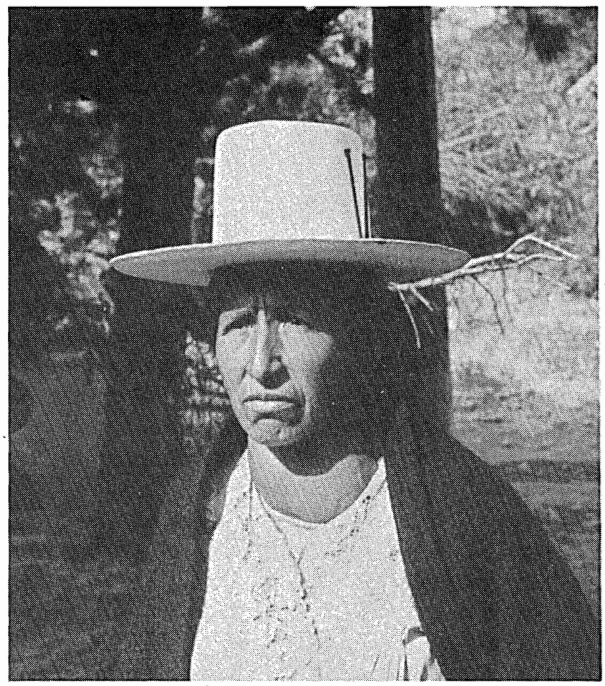
Stage II: Goiter visible with neck in normal position; palpation not necessary for diagnosis.

Stage III: Very large goiter, recognizable at a distance.

Iodine excretion in the urine has proven to be a simpler measurement. When iodine intake is reduced, less iodine is excreted in the urine. Studies have shown that when the amount excreted falls below 50 or 60 µg iodine/day moderate endemic goiter is likely, and at levels of excretion below 20 to 25 µg severe endemic goiter and cretinism are likely. Measurement of the iodine level in urine is a relatively straightforward but exacting laboratory procedure requiring little equipment and few reagents. The main problem with this measurement is that it is difficult to collect a 24-hour urine sample in the field.

To solve this collection problem, researchers take single urine samples and relate the iodine level to either urine volume or the amount of creatinine in the sample. Creatinine is a nitrogen-containing waste product believed to be excreted in constant amounts each day.

Neither of these solutions has been completely satisfactory. Because urine may be either dilute or concentrated depending on an individual's daily water intake and loss, iodine concentration relative to the volume of a single urine sample may not accurately reflect iodine loss over the whole day. Similarly, studies have shown considerable variation in daily creatinine output within individuals on different days and between population groups. This is especially important when malnutrition is evident. Studies done in areas of Zaire where diets are deficient in protein and calories showed markedly decreased creatinine levels when compared to healthy European populations.



John Stanbury

Woman from rural Bolivia with a large, nodular goiter.

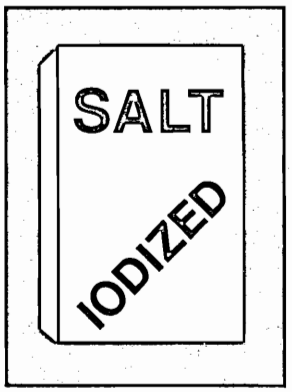
There is still controversy over which measurement is most accurate. Although both methods can be misleading, they are widely used and are believed to be sufficiently accurate for the purpose of community diagnosis when applied to samples of 50 or more individuals.

Iodine deficiency is also sometimes estimated by measuring the thyroid's uptake of radioactively labelled iodine. This procedure requires special equipment and training and at least a two-hour wait between initial and final measurements. It is only appropriate for specialized survey work and is not currently being used in ongoing programs for surveillance or evaluation.

In addition to tests for urinary iodine output and radioactive iodine uptake, there are also laboratory procedures to assess T3, T4 and TSH levels in the blood. During iodine deficiency, serum T4 levels decrease while TSH increases. T3 may be normal or increased in moderate deficiency, or may be decreased in severe deficiency.

Tests have been developed to measure T4 and TSH levels using finger-prick blood samples collected and dried on filter paper. The labelled samples can be mailed to a central laboratory where a standard-sized dot is punched from the dried blood spot and redissolved for testing. This procedure has most often been used to test cord blood from neonates to look for either endemic or congenital hypothyroidism. Collecting even finger-prick blood samples in the general population can be difficult in some cultures.

Prevention and Treatment



Prevention

Two main strategies have been used for the prevention of iodine deficiency disorders: fortification and supplementation. Fortification refers to the addition of small amounts of iodine to foods or liquids regularly consumed by the target population. Supplementation refers to scheduled outreach to the target population with larger doses of either oral or injectable iodine in a form from which the iodine is slowly released.

The success of fortification programs relies on some basic requirements. First, it is necessary to identify an appropriate food to serve as a vehicle for the nutrient. The vehicle food needs to be consumed by the target population on a regular basis in amounts that do not vary much either among or within individual diets. It must be stable when mixed with the nutrient and addition of the nutrient must not change the characteristics of the vehicle, such as taste, color, odor, consistency, or cost, in ways that make it less acceptable to the target group.

In addition, the vehicle needs to be produced in a limited number of places so that the nutrient can be efficiently added and monitored. In the case of iodine fortification, sodium chloride or common salt has usually been the vehicle chosen as best meeting these criteria.

Common salt comes from two main sources, evaporated seawater or deposits of salts found in inland areas. While there are cultural variations in actual consumption patterns, an annual demand of approximately 5 kg per person is average. This allows for some losses in food preparation and for use in food preservation. Daily intakes average 5-15 grams per person.

Four processes can be used to iodinate salt: dry mixing, drip feed application, spray mixing, and submersion. Spray and drip mixing are the two most commonly used methods in developing countries. In the drip feed process an iodate solution is slowly dripped on salt as it passes on a conveyor belt. Spray mixing is a similar process which uses a small spray chamber for iodate application instead of a drip.

For dry mixing, dry potassium iodate is used and it is necessary that the salt and iodate crystals be similar in size. This usually requires that the salt be ground into a fine powder. Because the amount of iodate relative to the amount of salt is so small, mixing is usually done in two or more steps. In the submersion process salt crystals are dipped into a tank of saturated sodium chloride solution with a fixed concentration of iodate. The crystals are then removed and allowed to dry.

In all these processes, iodates are the preferred form of iodine because of their stability in impure salts and under humid conditions. The main source of iodine loss from iodinated salt is due to moisture. Water from the air is adsorbed onto the salt crystal surface and washes away the iodate that has been deposited there. Studies have shown salt stored in jute bags can lose 75% of its iodine in nine months of storage in damp conditions. These losses can be minimized by packing fortified salt in plastic bags.

The correct level of salt iodination depends on both estimated intakes and losses. Assuming a target intake of150 µg of iodine per person per day and an estimated yearly per capita salt consumption of 3.5 kg, the optimal concentration of iodine in the fortified salt in parts per millicn (ppm) would be calculated as follows:

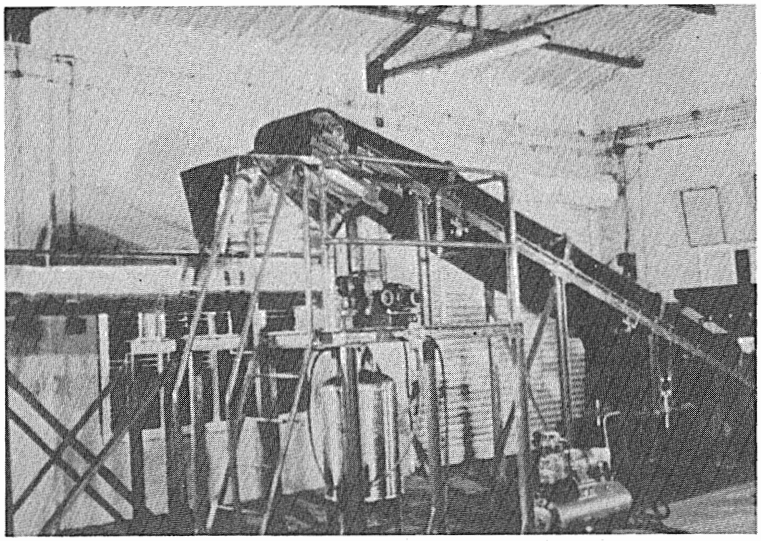
$$\begin{array}{r} 150\ \mu g\ \text{iodine} \\ \underline{\times 365\ \text{days}} \\ 54{,}750\ \mu g\ \text{or}\ .055\ g/\text{year} \end{array}$$

$$\frac{.055\ g\ \text{iodine}}{3{,}500\ g\ \text{salt}} = 15.7\ \text{ppm}$$

The figure of 15.7 ppm would then be adjusted upward to account for the fact that iodate weighs more than pure iodine, and would be increased again, by a factor of two or more, to account for losses in storage. Recommended levels for salt iodination usually range from 30 to 50 ppm of iodine, and higher levels even up to 100 ppm are entirely safe.

The optimal level of iodination can vary over time. In Switzerland, for example, the concentration of iodine has been increased to make up for decreasing salt consumption in recent years. Including the costs of both chemicals and processing, iodination can usually be done at a total cost of US$.02-.04 per person per year.

Production is only one component of a salt iodination program. Monitoring the iodine level at various stages of production, distribution, and use is another important aspect, and simple laboratory tests have been devised to test the iodine content of salt. In areas where there are several commercial sources of salt, government regulation may be necessary to ensure that all manufacturers comply with iodination standards. Where small-scale household or village salt production occurs, price incentives or marketing programs may be necessary to promote use of the iodinated product.



John T. Dunn

Salt iodination machinery in India.

Several countries have successful iodinated salt programs including Argentina, Colombia, and Guatemala. In Tasmania, iodinated flour has been provided to commercial bakeries and fortified bread has been used successfully to prevent iodine deficiency.

Water iodination, like salt fortification, delivers iodine in small daily doses. In large enough doses, iodine can purify water by killing bacteria. There is currently debate over the bactericidal effect of the levels of iodine commonly used to prevent iodine deficiency. The usual procedure used for water iodination is to divert a portion of the water from the main pipeline into a parallel system which incorporates a canister of iodine crystals. The iodine dissolves into the diverted water which later rejoins the main flow. Water iodination has been used successfully in Italy and Malaysia at an estimated cost of approximately US$.04 per person per year. Its main drawbacks are wastage due to the relatively small percentage of household water that is used for consumption and the need for centralized water systems.

The most widely used alternative to iodinated salt is supplemental iodized oil. Iodized oil is administered either as an intramuscular injection or orally and is most often used in remote areas where iodine deficiency is endemic but salt iodination programs are not yet in place. The same preparation is currently used for either injectable or oral doses. It contains poppy seed or other oils and usually 38% iodine by weight.

Injected iodized oil enters the muscle tissue and is slowly released into the bloodstream where it is taken up by the thyroid, excreted in the urine and may be stored in fatty tissue. Initial urinary losses are high but decrease over time and, depending on the dose, a single injection of iodized oil can provide sufficient iodine to prevent deficiency for three to five years.

Oral iodized oil is effective for a shorter period of time than injected doses because it does not have a muscle tissue storage site and more of the dose is initially lost in the urine. Several studies have shown that it provides protection for up to two

years. The advantages of oral iodized oil are the decreased costs and increased safety. There is no risk of transmission of diseases from nonsterile needles if oral routes of administration are used, and skilled health workers are not necessary.

Recommended doses for injections are 0.5 ml iodized oil (240 mg iodine) for children under one year of age and 1.0 ml iodized oil (480 mg iodine) for children over one year of age and adults. Dosages are usually reduced to 0.2 ml for adults with large nodular goiters to avoid iodine-induced hyperthyroidism. In pregnant women, however, the normal adult dose is given to ensure adequate protection for the developing fetus. Iodine-induced hyperthyroidism occurs rarely, but is most often seen in older adults and is a self-limiting condition.

Less work has been done on oral iodized oil and different dosage levels are still being studied. Current recommended doses are 1 ml iodized oil for one year of protection and 2 ml for two years. Estimated costs of a year's protection against iodine deficiency are US$.25-1.00 per person for iodized oil injections and somewhat less for oral oil. Iodized oil has been used successfully in programs in Bangladesh, Bolivia, China, Ecuador, Indonesia, Nepal, Pakistan, Papua New Guinea, Tanzania, Zaire, and elsewhere.

Treatment

The treatment of choice for iodine deficiency disorders is iodine. The administration of either iodinated salt or iodized oil usually reduces goiter size. In addition, studies have shown improved scores on hearing, intelligence, and motor skills tests in normal-appearing children from endemic goiter areas after treatment.

While many of the developmental problems associated with severe iodine deficiency are irreversible, recent studies suggest that early correction of iodine deficiency, especially in the first two years of life, can favorably affect growth and maturation of the nervous system. Pregnant women from severely endemic goiter areas should receive iodized oil before they conceive or as early during pregnancy as possible. Treatment in the second or third trimester has been found to have no harmful fetal effect and may also improve neonatal iodine status.

There is still much to learn about the use of iodine in treating endemic cretinism. Research is continuing in this area.

IODIZED OIL IN NEPAL

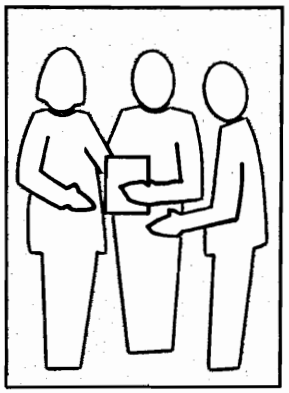
Nepal is a small country with a population of 16 million. It has three distinct geographical regions: a mountainous belt in the north, a hilly central band, and plains to the south. A government survey begun in 1965 found a high prevalence of goiter in all three regions.

In the early 1970s the government decided to import only iodinated salt from its main supplier, India. Because of the highly dispersed population and the lack of roads, subsequent studies found that a large proportion of the population was not being reached by this program, especially in the northern districts. In 1979 the Goitre and Cretinism Eradication Project was begun to carry out a mass iodized oil campaign in these districts.

Since 1980 four districts have been chosen each year for the campaign with a target of 90% coverage of the population. Special emphasis is given to reaching children and women of childbearing age. The dosages used are 0.5 ml for children below one year of age and 1.0 ml for all others. Each vaccination team administers at least 50 injections per day and more than 3 million injections have been given since the project's initiation.

Studies done on the urinary iodine levels in treated areas over time indicate that reinjection is necessary every four years to prevent deficiencies. The use of oral iodized oil is currently being investigated in Nepal, and plans for improving the iodinated salt program are also under way.

Program Issues



Local Epidemiology

Before an iodine deficiency disorder program can begin, it is necessary to assess the severity of the problem. The International Council for Control of Iodine Deficiency Disorders (ICCIDD) recommends that community assessment of IDD begin with a sample survey of school children for goiter. If goiter prevalence is greater than 10% (the cut-off arbitrarily chosen to define endemic goiter), a sample of the whole population should be examined. If the goiter prevalence of this sample exceeds 10%, then average urinary iodine excretion should be determined. With these results, the severity of the endemicity can be classified as in Figure 2.

Grade I endemicity indicates thyroid hormone levels adequate for normal development. Grade II endemicity indicates a risk of hypothyroidism but not overt cretinism, and at Grade III levels endemic cretinism is a serious risk. Additional tests, including dietary studies to look for potential goitrogens, can give a more exact picture of the deficiency problem.

Control Programs

The choice of interventions for the prevention and treatment of IDD will depend on the severity of the problem and the means available to reach those individuals at risk. Where they can effectively reach target groups, iodination of salt (or other foods) and water are the preferred interventions because of their low cost and ease of implementation. However, in areas without central water systems or appropriate vehicle foods, iodination may be impossible. Where there is widespread small-scale local salt production or limited access to centrally processed goods because of either transportation problems or lack of distribution systems, iodized oil may be the best short-term alternative.

Personnel

The level and extent of training necessary to implement an iodine deficiency prevention program will vary with the approach taken. Local epidemiological studies can be conducted easily with existing primary health care personnel who are given minimal training in the identification and classification of goiter. If health personnel are unavailable, school teachers, village leaders, or local volunteers could easily be taught these skills.

Programs using injectable iodized oil may best be integrated with existing immunization programs, sharing those staff. Because of the importance of careful sterilization of reusable needles and possible dangers inherent in injections, the implementation of programs using injectable iodized oil should rely on trained health personnel. Programs using oral iodized oil in either liquid or capsule form may be able to use community health workers with less training or community volunteers.

The costs of any of these interventions vary depending on

FIGURE 2

GRADES OF ENDEMICITY

GRADE I. Goiter common; average urinary iodine excretion in the population is greater than 50 µg/g creatinine.

GRADE II. Goiter common; average urinary iodine excretion in the population is 25-50 µg/g creatinine.

GRADE III. Goiter common; average urinary iodine excretion in the population is below 25 µg/g creatinine.

the availability of personnel, local material costs, and the choice of distribution systems. Cost estimates should be calculated based on total expenditures necessary to prevent a single deficiency. In areas where deficiency is marginal (Grade I or Grade II) or where only subgroups in the population are at risk, targeted interventions such as iodized oil for women of childbearing age and school children become more cost-effective. In choosing between oral and injected iodized oil, the shorter period of effectiveness of the oral dose must be balanced against the higher labor and equipment costs of injections. The latter should include the cost of disposable syringes or the costs of steam pressure sterilizers and fuel necessary for adequate sterilization of syringes in the mountainous areas where IDD frequently occurs.

Regardless of the approach taken, the correction of iodine deficiency in endemic areas is one of the most cost-effective nutritional interventions known. Savings from decreased medical costs related to reproductive failure or deformity, increased educability, increased productivity, and improved quality of life are enormous.

Cooperation and Integration

Intervention programs based on iodination of salt or water require a high degree of cooperation between government agencies. The enactment and enforcement of legislation mandating iodination, public sector or government-controlled salt manufacturing and distribution, laboratory analysis of iodine content, surveillance of population iodine status, and health education activities may each be based in different ministries. The International Council for Control of Iodine Deficiency Disorders recommends that a coordinating committee consisting of representatives from each participating agency be established to direct overall program management and identify appropriate lead agencies for different tasks.

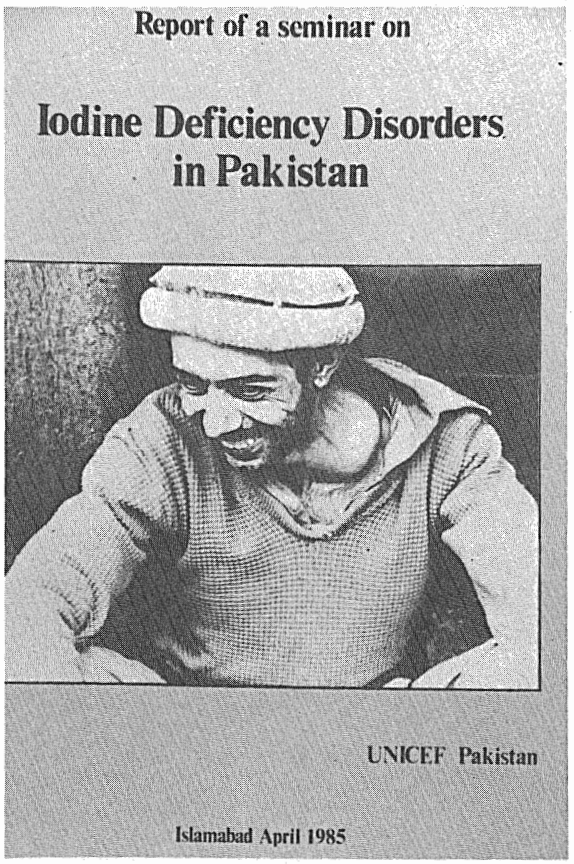
Communications

Because of the level of coordination necessary to carry out an effective program, good communications and health education are essential. Health education programs are necessary to raise the awareness of policy makers, health workers, and the public to the extent and seriousness of IDD and the cost-effectiveness of interventions, and to promote the interventions that have been chosen. These may include sophisticated social marketing campaigns for iodinated salts. Posters, flip charts, pamphlets, radio plays, video, film, and point-of-purchase displays have all been used in different programs.

In Pakistan, for example, where the government and UNICEF launched a major campaign to control IDD, pictorial booklets and banners were developed by the Aga Khan Central Health Board (with assistance from PATH) promoting the use of iodized oil and salt. Audio tapes with a specially written folk song were distributed to shops selling iodized salt.

International Agencies

The ICCIDD was established in 1985 in response to a growing



PATH

understanding of the magnitude of iodine deficiency disorders worldwide. The ICCIDD acts as a clearinghouse for IDD information and promotes research and intervention programs to eradicate iodine deficiency. It also publishes a quarterly newsletter (see Materials Available). UNICEF and WHO have also both taken active roles in the area of iodine deficiency and support the work of ICCIDD in addition to their regional and country-specific activities.

Conclusions

Iodine deficiency causes a wide range of disorders affecting a large percentage of the world's population. The very visible conditions of goiter and endemic cretinism represent only a tiny fraction of the problem. Decreased productivity, delayed or incomplete mental development with the consequent effects on educability, and reproductive failure are less obvious consequences but are much more widespread. There is a new sense of urgency as the scope of this problem becomes better understood.

The prevention of IDD relies on affordable, simple, safe, and proven technologies. These technologies include measures that can be implemented at the local level, such as nutrition education and iodine supplementation, and measures requiring governmental action, such as fortification schemes. Increased awareness of IDD and its social costs by policy makers, health workers, and the public is necessary to ensure that prevention programs are developed and implemented.

IODINATED SALT IN COLOMBIA

Endemic goiter in Colombia was described in writings from the 1500s, and a study carried out in the 1940s showed a prevalence rate of 53% in school children there. In 1950 a salt iodination program was begun by the government that mandated levels of 50-100 ppm of iodide for all salt for consumption by humans and animals. By the mid 1960s this program had drastically reduced goiter prevalence in many of the most severely affected areas.

In some parts of the country, however, goiter prevalence remained high in spite of the increased iodine intake. Studies suggest that this may be due to goitrogens in local water sources.

In recent years the gains of the salt iodination program have been eroded by the increased availability of lower priced, locally-produced salt that is not iodinated. The widespread sale of this salt has undermined the sales of iodinated salt and caused economic problems for the state agencies charged with its production as well as threatening the government's public health goals. Colombia is currently reevaluating its efforts to iodize, distribute, and regulate salt.

Materials Available

The International Council for Control of Iodine Deficiency Disorders publishes the **IDD Newsletter** quarterly. It includes proceedings of meetings, news items, and abstracts, and is available free of charge by writing to Dr. J.T. Dunn, Box 511, University of Virginia Medical Center, Charlottesville, VA 22908, U.S.A.

□

Towards the Eradication of Endemic Goiter, Cretinism and Iodine Deficiency (Scientific Publication No. 502) edited by John T. Dunn, et al, is available from the Pan American Health Organization (PAHO, 525 23rd Street, N.W., Washington, D.C. 20037, U.S.A.). It is the proceedings of the V Meeting of the PAHO/WHO Technical Group on Endemic Goiter, Cretinism, and Iodine Deficiency and provides detailed, updated information on IDD and the status of programs in Africa, Asia, and Latin America.

□

The WHO Regional Office for South-East Asia in New Delhi has produced **Iodine-Deficiency Disorders in South-East Asia** (SEARO Regional Health Papers No. 10). It provides a more general review of IDD and detailed information on the status of programs in Asia.

Materials Available (continued)

The UNICEF Regional Office for South-Central Asia has produced **The Use of Iodated Salt in the Prevention of Iodine Deficiency Disorders--A Handbook of Monitoring and Quality Control** by Robert Tyabji. It includes step-by-step instructions for the estimation of the iodine content of iodinated salt and is available from UNICEF/ROSCA, 72-74 Lodi Estate, New Delhi 110003, India.

□

A bibliography on iodine deficiency disorders is available from PATH.

INTERCHANGE

Oncho Update is published quarterly and lists articles related to onchocerciasis that have been published within the previous three months. It is available free of charge by writing to the Edna McConnell Clark Foundation, 250 Park Avenue, New York, NY 10017, U.S.A.

■

Finding the Causes of Child Malnutrition by Judith and Richard Brown is a community handbook on measuring malnutrition, finding its causes and addressing them. Single copies are available free of charge by writing to: The Presbyterian Hunger Program, 820 Colonial Avenue, Norfolk, VA 23507, U.S.A.

■

The World Health Organization has recently prepared several useful documents related to acute respiratory infections.
- **Respiratory Infections in Children: Management at Small Hospitals** (WHO/RSD/86.26) is a collection of background notes and a manual for doctors.
- Three booklets on supervisory skills are available: **Management of the Child with Cough; Management of the Child with an Ear, Nose, or Throat Infection**; and **Course Facilitator Guidelines for Acute Respiratory Infections Modules.**
- **Acute Respiratory Infections: Laboratory Manual of Bacteriological Procedures** is Western Pacific Education in Action Series, No. 1.
- The Pan American Health Organization (PAHO) has prepared **Acute Respiratory Infections: A Guide for the Planning, Implementation, and Evaluation of Control Programmes within Primary Health Care** (WHO/RSD/86.29); **Basic Documents: Control of Acute Respiratory Infections**; and **Infecciones respiratorias en los ninos: su tratamiento en hospitales pequenos** (No. 15).

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The WHO Drug Information Bulletin and the Drug Bulletins Review have broadened their scope. They will cover economic aspects of drug use and procurement and provide background on regulatory decisions. A new section on essential drugs will include updated versions of model drug information sheets.

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health technology
directions

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Traditional Media

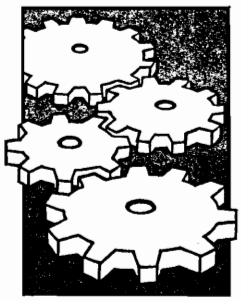
Communication with groups of people is a basic component of public health programs. Modern media (such as radio, television, and printed materials) and traditional media (such as folk theater, dance, and textile arts) are methods societies have developed for communicating social, political, and cultural messages to groups.

While there is a growing realization that effective health communication strategies employ a mix of media, traditional media have sometimes been overlooked in favor of the highly visible, urban-oriented modern mass media. Yet experience suggests that traditional folk media may have significant advantages over modern media in that they are familiar, credible, and accessible to rural people. Traditional folk media, therefore, merit careful consideration as a potentially useful tool for integrated health communication programs.

Communication media may be viewed as "soft" technologies which, like "hard" technologies such as equipment or tools, must be adapted to the users and the context of use if they are to be truly appropriate. Standard methodologies exist which guide users of modern media in creating and adapting health communication activities.

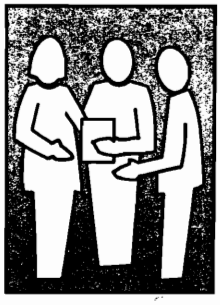
However, development of an appropriate communication strategy using traditional media, which vary extensively in format, style, content, and language, requires careful examination of the individual situation rather than application of set procedures. In place of precise methodologies are general considerations and suggestions which guide managers through the process of developing and implementing strategies using traditional media.

This issue of DIRECTIONS outlines the guidelines for use of traditional media in health communication activities. The first section details the considerations involved in matching an overall communication approach to an appropriate audience, message, and medium. The second section highlights specific implementation decisions. The final section discusses broad program issues of concern to managers.



Matching the Components

Implementation



Program Issues

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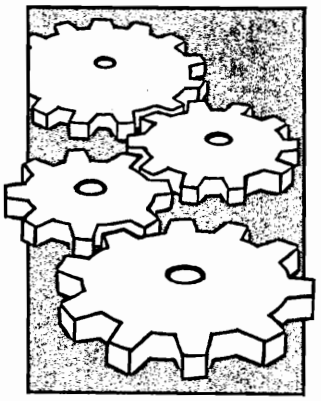
Matching The Components



Planning an effective folk media communication strategy is a two-stage matching process. Initially, the project's stated objectives, whether they are strictly health-related or include other goals like community participation and action, must be fitted to an overall implementation approach. The second stage requires managers to create a well-matched combination among the intended audience, message, and medium that is appropriate within the overall implementation approach of the program.

Approaches

There are four general approaches to implementing a communication activity, and their key characteristics are summarized in the matrix on page 3. Although they are presented individually here, these approaches are not mutually exclusive. In fact, in some situations the best approach may be a mix of approaches.

Each approach has been used in the field, but a lack of evaluation data makes program effectiveness difficult to ascertain. Experience suggests, however, that certain project goals and situations are more suitable for one or two of the approaches than for the others. Considering each method's past uses and individual characteristics along with the specific project's objectives, managers can select an implementation approach which best meets their program's needs.

When governments need to widely disseminate highly standardized messages they often choose the **information campaign** approach. In attempting to reach the widest possible spectrum of audiences, this approach sacrifices the ability to address more specific audiences. Because community input is minimal, there is less likelihood of community follow-up. Many countries have on-going national-level programs of this kind.

The **extension work** approach is also quite common. Typically, field workers create productions which address topics that are promoted by ministries yet are somewhat responsive to local audiences and needs. Although the content is chosen by the government's extension workers, community input varies among projects, depending upon the field worker's interest in adapting messages and utilizing local talent. This approach has been used in East Africa, where traditional birth attendants have created songs and dramas illustrating information from training classes for use both among themselves and in the community.

The **community development** approach greatly increases the villagers' role in development. It stimulates group problem-solving and self-help activities. Community members, together with development workers, develop the content and form of folk media activities and dominate the creative process. Because more powerful community members easily gain control of the process, this approach's ability to reach some less powerful audiences may be compromised.

The **popular education** approach avoids this problem. Specifically targeting the less powerful members of society, it gives them full control of content and attempts to develop their power to think critically and act upon their analyses. Messages produced this way are rarely standardized, but can easily reach specific audiences. This approach empowers audiences and inspires action based upon the message. However, since these productions often address issues which historically have been ignored, the messages may conflict with existing village organizations and activities. This conflict may reduce the ability of organizers to follow through on suggestions and ideas generated during the process, making implementation of this approach more difficult.

Audience, Message, Media

With an overall approach selected, decision makers may begin to assess the important audience, message, and medium characteristics. By understanding these three factors, managers can create an appropriate match

among them which also fits well within the overall implementation approach.

Audience. The characteristics of the specific audience the project wants to reach must be assessed. Important characteristics include the group's socioeconomic status (including literacy levels and occupations), status within the community, and representation in decision-making processes. Their attitudes toward officials become important when projects are government-operated or financed. When message topics are determined by outsiders, the intended audience's perceptions of the topics and the priorities they assign to them become critical.

The community in which the intended audience resides must also be assessed. The community's political and economic organization, its decision-making processes, the infrastructure which supports behaviors advocated by the project, and logistical support for productions affect the intended audience and the overall program.

Asking members of the intended audience about their situations and beliefs is a good way to obtain information. Many people also recommend observational studies to confirm this information and to detect additional behaviors that may be important to the program. Local anthropologists, social scientists, or program staff can do this best by actually living in the community, even if only for a short while. At a minimum, community meetings with leaders and members of the intended audience should be held. An alternative strategy to avoid over-representation of more vocal community members may be preferable in some situations. Local people receive training and then interview all villagers, either individually or in small groups, and document their ideas about health and illness to get a more balanced picture.

Whichever method managers employ, they must have an in-depth understanding of the situational constraints, health perceptions, and behaviors of the

APPROACH

CHARACTERISTIC	*"INFORMATION CAMPAIGN"*	*"EXTENSION WORK"*	*"COMMUNITY DEVELOPMENT"*	*"POPULAR EDUCATION"*
COMMUNITY INPUT	None	Low	Medium	High
CONTROL OF CONTENT	Central government	Local extension workers	Local development workers and community	Least powerful community members
MESSAGE STANDARDIZATION	High	Medium/High	Medium/Low	Low
ABILITY TO REACH SPECIFIC AUDIENCES	Low	Medium	Medium	High
LIKELIHOOD OF COMMUNITY FOLLOW-UP	Low	Medium/High	High	High
EXPECTED OUTCOME	Acceptance of message	Acceptance of message	Community self-help project based upon message	Empowerment, and action based upon message

intended audience in order to plan an appropriate and effective communication activity.

Message. Message topics can originate from either program staff suggestions or priorities expressed by the community. The audience research techniques described above aid in selecting relevant messages.

Message development requires an in-depth understanding of villagers' beliefs about health and illness. A message explaining health and illness within cultural and situational contexts of villagers will be more effective than one that ignores those contexts.

Health educators who understand the audience, for example, can often find analogies between audience members' experiences and modern health practices. Tales of rice not growing well where young stalks were planted too closely together can illustrate the problems of short birth-spacing much more understandably than physiological explanations of the same problems.

Messages must promote issues upon which people can act. For example, if villagers want to address infertility problems, but clinics assisting couples with infertility problems are inaccessible, a message suggesting people visit the clinic is not reasonable. A more appropriate message may be one encouraging the use of condoms to prevent infertility caused by sexually-transmissible diseases (if condoms are available).

Other message characteristics to consider include the message's complexity and social and political acceptability. The message's purpose (motivation, teaching, reinforcement) is also important.

Rohr-Rouendaal/University College of Botswana

Botswana's popular education experience

Exact wording of messages used in folk media may be developed by folk artists, sponsoring agencies or by the two together. Because artists know their art forms and their audiences well, many people feel they can create messages to which audiences will respond quite positively. In addition, artists' experience can allow them to adapt productions immediately when certain audiences require alternate approaches. This spontaneity, however, may threaten the message's technical accuracy.

Training artists about the health issues they promote helps to eliminate this problem. Nevertheless, program managers should monitor the messages and final productions for technical precision. Programs with technically complex messages need high technical accuracy. Bangladesh's Folk Song Program avoids inconsistent technical content by creating messages at the central level for use by local singers. This approach, however, is less adaptable to local situations and may jeopardize an artist's enthusiasm for the project.

Media. A medium's most important characteristic is its ability to attract and appeal to the intended audience. A dental hygiene program in Mexico used puppetry to attract children. However, in another Latin American country, a family planning project failed to adequately research the appeal of the selected medium and was

embarrassed to find children the only attendees at a theater show about condoms!

To be effective, a folk medium's traditional content, tone, and characters must be flexible enough to incorporate health messages. A medium may be more suitable for some messages than for others. For example, a medium whose traditional content espouses large families may be inappropriate for family planning messages. However, that same medium may be quite effective for breast-feeding or nutrition messages.

In addition, the flexibility of similar media may vary drastically in different cultures. The clown in Indonesia's folk opera *Ludruk* successfully promotes development ideas. Audiences in south India, however, refused to give serious consideration to a message delivered by the clown of the *Yakshagana* folk drama.

Finally, the different parts of a folk medium production may vary in flexibility. The section most appropriate for presentation of the health message depends entirely upon the medium's traditional format. For example, if the last act always criticizes existing institutions, that may be an appropriate place to call into question unhealthy practices and to promote new health behaviors. Likewise, if people traditionally arrive late or leave early, then managers should avoid placing the most important message at these points in the show.

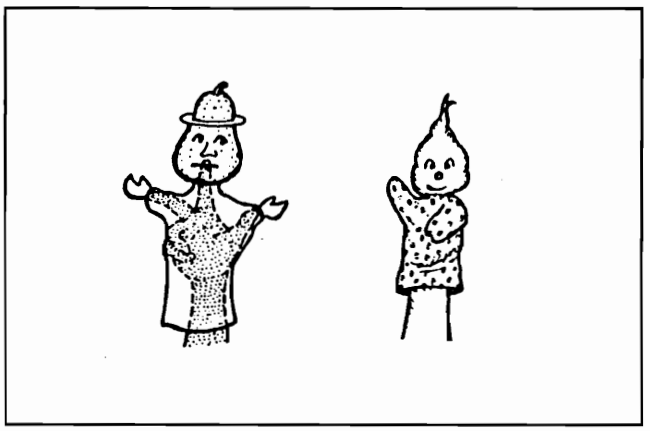
The traditional medium's artists also influence program success. Their enthusiasm for new ideas and for health promotion, as well as the respect they command, strongly affect the community response to the show. For example, a *dalang*, the multi-talented performer of Indonesia's traditional puppet shows, is highly respected and, if receptive to development ideas, could be a powerful promoter of health behavior changes.

Finally, managers should consider productions combining different folk media. For example, puppeteers who sing local songs to draw audiences to performances might adapt song lyrics to promote health behaviors. Likewise, cloth printed with health messages and worn by theater performers reinforces program messages.

In Ecuador, a group of musicians took the *Feria Educativa* (Educational Fair) to villages throughout a remote province. Staying several days in each village, the group performed nightly. Shows usually began with singing and dancing, followed by social dramas involving audience members or puppet shows raising development issues. The group used several media to communicate successfully with villagers about a variety of subjects.

Analysis of the intended audience, message, and available media provides insight to program managers who must determine an effective combination of the three. Unfortunately, there are no general rules to guide managers. Each situation must be analyzed for its own best match.

In an example from the field, a pre-selected audience (the entire community) was matched with a message and then with a medium. A multinational team of health and sanitation workers attempting to change water-related behaviors entered a community in Liberia. The team identified several community health problems and met with a Village Health Committee to discuss the villagers' health beliefs and perceived health problems. The solutions they discussed became the messages, which thus matched the intended audience. The committee suggested a live performance as the appropriate medium. This show, which combined music and drama, became so popular that the performers travelled to neighboring villages and ultimately recorded their show for radio broadcast.



Werner, et al.

Cloth hand puppets

Implementation

The first step in implementation of any communication project is field testing. Once the audience, message, medium, and approach have been selected, a draft version of the folk song, drama, or other communication product must be carefully tested. The field-testing environment should represent, as nearly as possible, the planned project's field situation. Field testing (often called "pretesting") lets project staff see how the strategy will work and allows them to revise it as necessary.

Field testing (an often neglected step) almost always exposes unforeseen problems, even in the most thoroughly researched strategy. If the Latin American project cited above, which attracted only children to its show about condoms, had pretested its show, such disastrous results could have been avoided. Field testing is critical to a project's ultimate success and should be considered mandatory.

Field testing is done by actually staging a performance or creating a first version of nonperformance folk media and presenting it to members of the intended audience. Project staff carefully observe audience reactions and interview members afterwards. Staff may also evaluate audience knowledge and attitudes before and after the test performance to determine whether the intended health message was effectively communicated.

After reviewing the field test results, managers make revisions and test the new product. This testing-revision-retesting process continues until managers are confident that their folk media strategy produces the intended effect.

Assured that the selected strategy will work in the field, managers must consider certain basic implementation issues common to each medium. These issues center around artists, follow-up, and scheduling.

Artists may be professionals, health personnel, or community members, and use of each presents special advantages. Professionals are skilled and experienced and therefore produce high quality products. Health personnel present technically precise information. Community members vividly describe local situations and may act more quickly to solve problems they act out themselves rather than observe. Traditional healers who do group presentations, like Mexico's *merolicos*, can very effectively incorporate modern messages into their traditional routines. Ultimately, however, the manager's project goals and general approach to implementation will determine which type of artist the project uses.

For example, if managers employ the community development approach discussed above, community members are the artists. Likewise, information campaigns will use professional artists. The extension work approach, however, may use any type of artist or combination of types, depending upon particular needs.

Artists who are health personnel or community members are rarely paid. Professional artists, however, may be paid, depending upon whether they work full-time for the development agency and whether they traditionally receive fees. Payment assures that an artist is available when needed. However, payment often attracts artists whose only interest is in money, not in promoting health messages.

In programs advocating use of health supplies, distribution of supplies by artists is somewhat controversial. Many people feel continuity is maintained and the artist's credibility is enhanced if the artist distributes supplies promoted in the production. Others worry that artists lack the background needed to distribute and properly explain the use of products like oral contraceptives. If health personnel are able to attend performances and distribute supplies or supervise distribution by artists, accurate information is given and the overall community health program is strengthened.

One highly recommended compromise is to educate artists

about the health supplies that they promote and distribute.

Follow-up programs may assess changes in community knowledge or behavior, motivate unconvinced villagers, or reinforce new behaviors. The program's objectives determine the appropriate methodologies. Assessing knowledge and behavior change, for example, almost always requires comparison of pre-performance and post-performance data collected by discussions, surveys, or observations.

However, motivation and reinforcement activities can be conducted through a variety of methods. While many programs simply lead discussions and distribute brochures after the performance, others are more extensive. Botswana's *Laedza Batanani* theater productions, for example, trained local extension workers to support the theater's nutrition messages by planting community garden plots.

Finally, managers must select the date, time, locale, and length of performance. Community input in these decisions is essential. Presentations during religious ceremonies, village celebrations, or work seasons may benefit or harm health programs. Some areas require performances at night while others prefer daytime shows. Locales traditionally used for community gatherings, such as the trees under which West African villagers hold their community discussions, often make appropriate performance sites. Crowds may leave early when presentations are too lengthy, and thus miss post-production discussions. These logistical decisions can greatly influence audience attendance. A Bangladesh family planning project, for example, attracted no women to daytime shows performed for large crowds gathered outdoors. When shows were rescheduled to fit women's free evening hours, and performed indoors where a special women's seating section could be provided, women readily attended..

Production issues specific to each medium also require consideration. This section highlights the basic implementation concerns unique to theater, puppetry, song and dance, storytelling and proverbs, and pictures.

Theater

Live drama allows audiences to experience real and hypothetical situations at a personal, non-threatening level. Theater's wide variety of forms provide many different ways of exploring such situations. Specific implementation steps depend upon the form of theater employed.

Social Drama, one form of theater, allows villagers to act out problems and potential solutions to situations they face daily. In group discussions villagers raise problems and suggest potential solutions, which community members then act out. Following the show, audience members discuss and initiate activities needed to solve the problems presented in the show.

Experiential Theater uses skilled performers who involve the audience without their realizing they are part of the action. For example, one group in Ecuador planted actors in the audience, then acted out a scene in which landowners insulted the audience. The actors in the audience responded angrily and were soon joined by real audience members who exchanged harsh words with the stage actors. Once the audience calmed down, the actors led a discussion exploring the audience's explosive reaction to the actors' provocation.

In Simultaneous Dramaturgy, professional actors perform short scenes on topics suggested by community members. The action stops suddenly at crisis points, and the audience is asked to provide solutions. The performers act out each suggestion and the audience decides upon the "best" one.

Forum Theater takes audience participation one step further. Community members suggest a local problem. Performers (local or professional) then improvise a skit about the problem, offering their own solution. If an audience member disagrees, he or she replaces any actor and leads the play in the direction he or she feels is appropriate.

Implementing any theater production requires logistical decisions about the use of a stage, props, and lighting. Many people believe theater should not use a formal stage. They argue that although it lends prestige to a show, a formal stage separates the audience and actors, thus minimizing their interaction. Stages used successfully in the field include open space beneath a tree in India, market streets in Nigeria, and the back of a local truck in Jamaica. Locally available costumes, props, and lighting are highly recommended. Local clothing adds familiarity to the performance and gives villagers a sense of involvement in the production. Props from

people's own homes have the same advantages, and also lighten the transportation load for productions that travel among villages. Local lighting systems are readily refueled and, unlike novel lighting systems, do not distract audiences.

Puppetry

Puppetry, like theater, provides an opportunity for people to explore community problems and potential solutions. Puppets, however, are immune to the personal scrutiny that actors face. No one asks the puppet why it is there, who hired it, or why it knows more than everyone else. Puppets, therefore, safely introduce inflammatory subjects and criticize local situations.

The work of Shankar Singh, an Indian puppeteer from Rajasthan State, provides a striking example of this capability. Singh's legendary puppet character is Jokhim Chacha, a 300-year-old Muslim whose bold, critical, and insightful commentary before high officials and other audiences leads more often to action than to anger. A show on minimum wages, for example, inspired a rare expression of protest by local women who were being asked to sign for more wages than they were receiving.

Puppets are material, tangible items that attract people of all ages to performances. Because they resemble dolls, however, puppets are especially appealing to children. For example, Mexico's Youth Integration Center's puppet shows charm young school children while teaching the dangers of drugs. In other programs children become the puppeteers and create shows to teach health concepts to other children and community members. The Child-to-Child Program, for example, encourages schoolchildren to work with non-schoolchildren in developing puppet shows on health topics to perform before the community.

Daniel C. Aryeequaye

African villagers perform a drama about drunkenness

Puppet show implementation requires the same logistical considerations about stages, props, and lighting as theater. However, the recommended actions differ substantially from those for theater. Puppet shows require a stage that is used primarily to conceal the puppeteer. Therefore, while the audience size and the puppeteer's height will dictate its dimensions, the stage may take any of a variety of forms. However, as with theater, most people believe stages should be made with locally available materials. Otherwise, village groups may feel inhibited about creating their own productions if they lack a fancy stage, as a travelling theater and puppetry troupe in Ecuador discovered.

Stages are constructed from a variety of materials. Many places hang a cloth or blanket over a wooden stick across a doorway or tie it between two trees or chairs. Hausa puppeteers in Nigeria drape their own robe-like garments over their bodies and work the puppets through the robes' neck openings.

Puppet construction also presents special concerns to managers. Groups giving many performances need strong, durable puppets. These may be made of cloth, wood, clay, or papier mâché. Less sturdy puppets may be made from sticks, paper, or even vegetables like pumpkins and potatoes.

As with theater, lighting for most puppet shows should be locally available, but lighting for shadow puppetry is critical and may require special arrangements.

Song and Dance

Music is an integral part of every culture. Its greatest strength is its emotional power, which inspires both song and dance. That same power makes music an excellent medium for behavior change motivation. The Planned Parenthood Association of Thailand, for example, used an emotional, romantic ballad to promote condom use. A Bangladesh village's schoolchildren's chants about dirty water inspired community meetings that addressed water source problems.

Music also allows a high degree of precise message repetition, which can enhance recollection of technical information. Zairean traditional birth attendants, for example, create songs detailing proper techniques for hygienic delivery. Nurses in Nigeria teach mothers a simple song to remember the proper mixing instructions for oral rehydration solution.

Because music readily attracts crowds, songs and dancing are often used to draw people to folk media performances which present health messages. Many managers overlook the possibility of using both the preliminary music and the main show to present health information.

The number of messages included in a song must be limited. Most people recommend presenting one main idea per song to facilitate its retention.

Using tunes familiar to local people is imperative. Inviting popular local musicians to compose songs with selected messages ensures that songs are familiar, well-received, and easily remembered.

Storytelling and Proverbs

Storytelling and proverbs are generally flexible media. Usually told by one person, stories and proverbs easily adapt to local situations. They are especially effective in relating specific instructions and motivating and persuading listeners.

Stories are used in many different ways. Some stories are parables, which use real or imaginary scenarios to teach lessons to listeners. Other stories have no specific lesson, but instead help people think about local problems. Analogies or comparisons present new ideas in familiar settings. For example, in Liberia, nurses compared feeding a small child cow's milk with feeding a young cow goat's milk. The message was clear: a mother's own milk is best for her child.

Stories can be developed by groups or by individuals. In one form of group storytelling the leader begins a story about a family or community, gets them into a difficult situation, and then passes the story to the next person. That person tells how the characters resolve the first problem, creates a new problem and passes the story to the next person. The story is complete when all group members have participated.

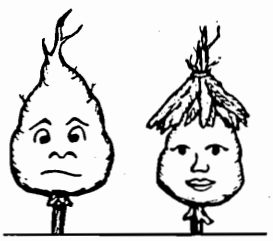
More frequently, stories and proverbs are adapted for use by individuals like health workers or villagers. For example, primary health care workers in Guatemala trained local Community Betterment Committee members to use storytelling to teach villagers about water, waste disposal, child care and food preparation.

Pictures

Mass printing of pictorial materials on paper is a commonly used modern communication medium, but pictures which are painted, woven, or embroidered on cloth have long been a popular form of traditional communication media.

Durable, attractive, and highly visible, cloth may be worn as garments, wrapped around bundles, or hung on the wall. Health messages and symbols printed on cloth thus receive wide exposure. However, because cloth messages are often presented without explanation, any message matched to this medium must be short, simple, and familiar.

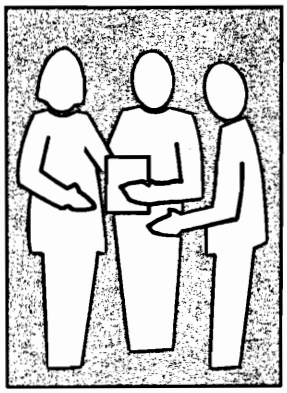
Both health programs and individual artists have used pictures on cloth in many ways. Tanzania's "Healthful Foods" campaign prints its slogans and symbols on cloth. Community health leaders may use cloth to remember concepts learned in training and to illustrate those concepts when teaching villagers. An artist in Kenya has produced batiks expressing concern about family issues, including health. Each batik depicts a single simple message, such as "Breast for me - bottle for the dog."



Werner, et al.

Vegetable puppets

Program Issues



Integration

Controversy surrounds integration of modern and traditional media. Those favoring integration argue that modern media can reach larger audiences. Skilled and patient modern media experts who truly understand the appeal of traditional media can effectively capture those qualities in their productions. In addition, folk media can make modern media more interesting and attractive to rural people.

Others disagree, countering that modern media destroy folk media's interpersonal communication with its audience. The fantasy and grandeur of forms like Thailand's *Nang Yai* shadow play can be lost under the harsh lighting and different emphasis of modern media.

Most people agree, however, that folk media and modern media can sometimes be integrated successfully. Careful preliminary assessment of the available modern and folk media and their compatibility is critical.

In addition, modern media experts need training about the conventions and traditions of folk media performances. Folk performers similarly must understand the technical constraints and requirements of modern media.

The setting of the production also affects the results. Modern settings may enhance technical production quality, but modern media must go to the field to capture the ambience and audience rapport of folk media.

Most commonly, folk media productions are recorded by modern media and disseminated. For example, the Xavier Institute of Communications in Bombay videotaped several puppet shows, including one on health. A film of traditional young Nepali musicians singing a family planning song is played in Nepali theater houses before movies.

Finally, integration may involve a side-by-side use of modern and traditional media rather than an intermingling of the two. For example, forms of each type of media may be used to highlight different aspects of the same problem. Thus, local songs with lyrics about overpopulation may attract villagers to a central location to hear a radio program about the use of condoms.

Alternatively, both types of media may present the same message, thus reinforcing the concept. For example, health workers may teach local women about nutritious weaning foods using printed flip charts, and then present the same message in a puppet show.

Training

All levels of personnel involved in folk media activities require training. Training content and emphasis vary according to personnel needs.

Top-level officials generally learn about the potential uses of folk media and the possibilities of programmatic collaboration among ministries. Mid-level decision makers are given, in addition to the above, program-specific ideas and suggestions. Field workers gain the same general information, but their training emphasizes specific program details, community participation ideas, and sociopolitical issues that affect villagers. Finally, artists learn about development and health issues, program details, and production techniques their peers have found useful. Most people recommend that all training include experienced artists as trainers (along with sponsoring agency representatives). Experienced artists can explain folk media from a first-hand perspective and can use demonstrations, which are particularly powerful training tools, to illustrate their methodologies. They also can learn more about the sociopolitical and development issues folk media programs confront.

When many agencies or ministries are interested in folk media, managers should consider coordinating training programs. This not only decreases expenses but also promotes inter-agency or ministry collaboration in future programs.

Evaluation

Evaluation is a vital element in assuring effective use of folk media as a communication technology, yet few projects have been thoroughly evaluated so far. Lack of resources, disagreement over evaluation methods, difficulty measuring behavioral changes, and imprecise project goals and objectives hinder evaluation efforts.

Managers should build evaluation into programs during the earliest planning stages. Clear program goals and evaluation strategies determined in advance ultimately yield coherent and useful information.

Folk media evaluations can assess program efficiency, program impact or both. Measures of efficiency include attendance, adherence to budget and schedule, and audience characteristics, and are relatively easy to document. Impact measures reveal how well managers achieved the stated project objectives, such as disseminating information, changing attitudes, or initiating actions. Because observed changes may be influenced by external events as well as by the folk media program, measuring the impact attributable to the folk media program is difficult and requires innovative and carefully constructed evaluation methodologies.

Most researchers do this by comparing the folk media program area with a "control" area which is similar in all characteristics except for the presence of the folk media program. More complex schemes use the same folk medium to promote slightly different messages in two different areas. Attitudes and behaviors related to the messages are then compared, with each group serving as the other's control.

Evaluation of efficiency and impact should be conducted during and after the project. Ongoing or formative evaluation, easily carried out by program staff members, provides feedback to guide programmatic adjustments during implementation. Summative evaluation, the final overall assessment of program strength, gives decision makers evidence of program success or failure and flags high and low points for future projects to consider. Most people recommend using outside evaluation experts to assure an objective report.

Evaluation efforts use quantitative and qualitative methods to gather data. Quantitative methods include field questionnaires, surveys, and medical statistics. Qualitative methods can include group discussions, reports from field workers, and observations during performances. Many feel these are better suited to folk media strategies, since they are sensitive to the cultural and situational differences affecting these activities.

Funding

Folk media advocates consider low cost a major advantage of folk media strategies. Folk media projects generally require few materials such as props, artists are often nonprofessionals who volunteer their time, and any necessary lodging is usually provided by the sponsoring communities. Managers may thus be able to fund local projects from their overall communications budgets without relying upon additional allocations from their ministries.

Where outside funding is necessary, donors may be reluctant to finance projects because of the lack of evaluation data, the perceived cost effectiveness of modern mass media, or concerns about inadequate central control. However, donors may agree that the cultural appropriateness and greater acceptability of folk media are strong advantages.

Scott Wittet

A Nepali trainer assists student performers practicing a drama

Conclusions

Traditional folk media offer health program managers a potentially powerful method of reaching rural villagers. While modern mass media may extend messages to larger audiences at lower cost per person reached, their dependence on centralized, urban facilities and staff and their need for uniform, fixed messages often make them less responsive to local situations and specific audience needs. Traditional media use local language and symbols in a format which is familiar, credible and accessible to rural villagers.

To be truly appropriate, traditional media (like other technologies) must be adapted to the overall approach, message, and intended audience with which they are used. Integration with modern media may be successful but must be approached cautiously. Evaluation is critical both for adjusting the specific project and for better assessment of the net effectiveness of folk media communication strategies.

With appropriate matching of a strategy's central components and thorough consideration of implementation and management issues, traditional folk media can become an extremely effective means of communicating health information.

Materials Available

Few materials on folk media are both useful and widely available. Among the best is **Helping Health Workers Learn**, by David Werner and Bill Bower, which contains many creative suggestions for folk media productions, including scripts and song lyrics. Write to: The Hesperian Foundation, P.O. Box 1692, Palo Alto, CA 94302, U.S.A.

☐

Another useful book is **Puppets for Better Health**, by Gil Gordon, a comprehensive puppetry manual for community workers. It is available from Macmillan Publishers, Houndsmills Basingstoke Hampshire RG21 2XS, England.

☐

Finally, **Theatre-for-Development: A Guide to Training**, a manual for managers of drama or puppetry productions, is available from the Center for International Education, Room 287 Hills House South, University of Massachusetts, Amherst, MA, 01003, U.S.A. for US$4.00 plus postage.

☐

A bibliography on traditional media is available from PATH.

INTERCHANGE

A new aid for disinfecting water is available. AQUAtimer is a small acrylic disk that changes color to indicate when water has boiled long enough at a sufficient temperature to disinfect it. Reusable hundreds of times, AQUAtimer was developed by PATH and is sold by Pactec, Inc. AQUAtimer costs US$4.95 plus $1.00 shipping. Write to: Pactec, Inc., 4 Nickerson St., Seattle, WA, 98109, U.S.A., or call (206) 285-4774.

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health technology
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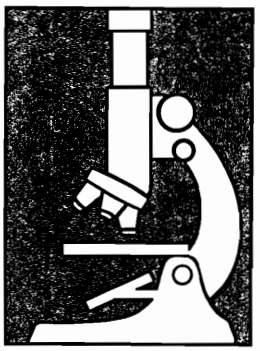
Intestinal Worms

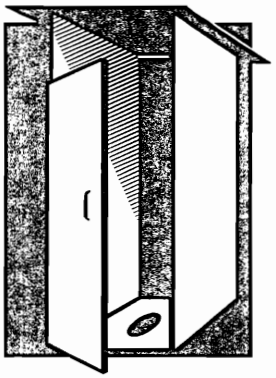
Soil-transmitted intestinal worms are found worldwide. The three most common worms, *Ascaris lumbricoides*, hookworm (*Ancylostoma duodenale* and *Necator americanus*), and *Trichuris trichiura*, are also among the top ten most common infections afflicting people today. Intestinal worm infections are chronic and endemic in many areas and have relatively low mortality rates, so programs to control worms have been a low priority for most countries.

Recent research indicates that worm control programs using new technologies and strategies may, in fact, be quite cost-effective in providing many health and productivity benefits to populations. Many studies have demonstrated the negative impact worm infections may have on nutritional status, growth rates, worker productivity, and overall well-being. Treating the nutritional effects and physical complications of worm infections can place a heavy financial burden upon limited health budgets.

Several safe and effective anthelmintic drugs developed in recent years are now inexpensive and commonly available. Many simple diagnostic and prevention technologies are also available and, with proper modification for specific situations, can assist worm control program managers. Given the harmful effects of worm infections and the widespread availability of simple technologies, it is important for managers to reexamine the value of intestinal worm control programs. This issue of DIRECTIONS explores the diagnostic, treatment, and prevention technologies available for worm control activities and the management issues surrounding their selection and use.



Diagnosis and Treatment



Prevention

Program Issues

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Ascaris. Of the main soil-transmitted intestinal worms, *Ascaris* is the most prevalent, infecting over one billion people. Acquired by ingesting infective eggs that contaminate food, water, or skin surfaces such as hands, *Ascaris* undergoes a larval stage in the liver and lungs and returns to the small intestine to mature. Two months after entering the body as eggs, adult female worms in the small intestine begin producing up to 240,000 eggs per worm per day. (However, like most worms, *Ascaris* does not multiply within an individual, so worm burdens can only increase by repeatedly ingesting infective eggs.) Over time, adult female worms can reach lengths of 45 cm and diameters of 6 mm.

In addition to the well recognized physical effects of ascariasis (such as diarrhea, abdominal pain, nausea, and loss of appetite) there are more severe complications. These include abdominal obstruction and worm migration to the hepatic duct, pancreatic duct, appendix or other organs. Although these complications are relatively rare, they often result in death, especially when they occur in young children.

Although *Ascaris* infection and nutritional status are closely related, the extent to which they affect each other is uncertain. Various studies implicate *Ascaris* in decreased fat and nitrogen absorption, increased nitrogen loss in feces, malabsorption of vitamin A, and malabsorption or intolerance of lactose. Some studies also reveal decreased growth rates in children with ascariasis and increased growth rates after drug treatment. These effects are generally greater in undernourished children. Although these effects are difficult to quantify, they point to the broad impact *Ascaris* may have on nutritional status.

Hookworm. The two species of hookworm, *Ancylostoma duodenale* and *Necator americanus*, infect at least 900 million people. Larvae in soil penetrate the skin (usually the feet) and migrate to the small intestine via the heart and lungs. After two or more months, each mature female begins releasing 10,000-20,000 eggs per day. As with *Ascaris*, hookworm burdens only increase with repeated exposure to infective larvae.

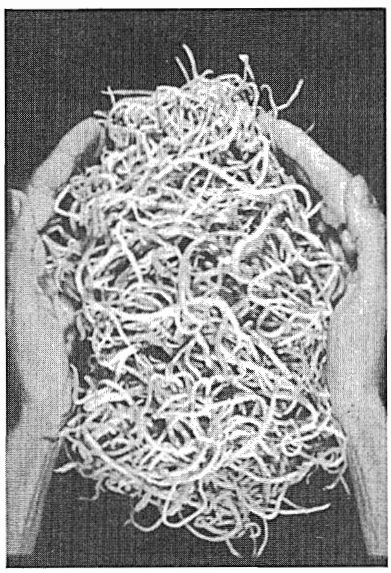
Symptoms of hookworm infection include skin diseases like dermatitis ("ground itch") and cutaneous, migrating larvae ("creeping eruptions"); respiratory irritations like coughing, wheezing, and bronchitis; and intestinal problems such as vomiting, diarrhea, and loss of appetite.

Nutritionally, hookworm infections cause blood loss and depletion of iron stores leading to iron-deficiency anemia. Breathlessness, apathy, headache, and weakness, in addition to low hemoglobin levels, characterize iron-deficiency anemia. Even mild anemia can seriously affect growing children, pregnant women, and persons required to perform heavy physical labor.

Trichuris. *Trichuris trichiura*, or whipworm, infects over 900 million people. Although highly prevalent and geographically diverse, *Trichuris* has received less attention than *Ascaris* and hookworm. Like *Ascaris, Trichuris* is acquired by ingesting infective eggs from soil-contaminated food, water, and hands. After ingestion, the eggs hatch and develop in the small intestine. They migrate to the large intestine where they mature, burrowing their heads into the wall of the cecum (part of the intestine). Within three months, adult females begin producing 2,000-14,000 eggs daily, which cannot reinfect the host before excretion.

Symptoms of trichuriasis vary depending upon the severity of infection. Moderate infections cause generalized symptoms like allergic reactions and long-term diarrhea, which make them difficult to diagnose without laboratory testing. Most severe cases occur in children between ages two and fifteen and may include chronic bloody and mucoid diarrhea, abdominal pain, and rectal prolapse.

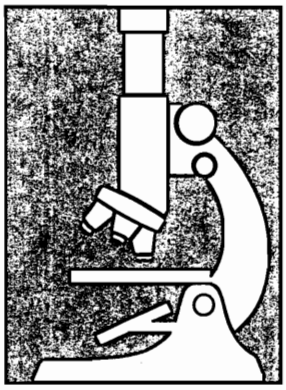
The chief nutritional outcome of moderate and severe trichuriasis is growth stunting. This may be caused by nutrient loss from chronic diarrhea.



Armed Forces Institute of Pathology

Worms from 2-year-old girl who died of Ascaris *complications*

Diagnosis and Treatment



Several simple and effective technologies are available to assist program managers, laboratory technicians, and medical personnel in the diagnosis and treatment of individuals and communities. Selecting appropriate technologies for either purpose requires thorough assessment of program needs, available resources, and environmental conditions.

Diagnosis

There are three main laboratory techniques for detecting the presence of *Ascaris*, hookworm, or *Trichuris* eggs in feces: the direct thin smear, various concentration methods, and the quantitative cellophane thick smear (also called the Kato-Katz method). Each has specific advantages and disadvantages.

The direct thin smear (a wet preparation) is one of the most common methods. A small portion of stool is mixed with physiological saline on a slide to make a thin suspension, and then examined microscopically for worm eggs. By far the simplest, quickest, and cheapest technique, the thin smear requires only standard slides, slide covers, saline solution and a microscope.

Because it uses only a small amount of feces, the direct thin smear may not detect eggs when few are present. Also, slides must be examined soon after being made or they may dry out.

Lab personnel must be experienced enough to distinguish eggs from other stool contents such as vegetable fiber and starch cells. However, *Ascaris, Trichuris,* and hookworm eggs have distinctive forms, so inexperienced staff easily may be trained to recognize them.

Therefore, the direct thin smear technique is appropriate for detecting parasites in heavily infected individuals, where smears may be examined soon after preparation, and where lab personnel are experienced or can be trained. These constraints make the direct smear difficult to use for mass stool examinations.

There are several concentration methods, all of which separate parasite eggs from relatively large amounts of stool and can be modified to give quantitative results. In concentration methods, feces are mixed with liquids of varying densities, and then sieved and centrifuged to separate parasite eggs and larvae from other stool contents.

Concentration techniques can detect low intensity infections and are particularly well suited for detecting the presence of transparent, colorless hookworm eggs. In addition, the required reagents are often readily available. Common concentration techniques include the formol ether method, the simple gravity flotation method and the simple saturated salt flotation method. A newer concentration method, the formol detergent method, is described in the box on page 5.

Concentration steps, however, are often time-consuming and some of the reagents, like ether and its less flammable substitute ethyl acetate, must be used under a hood or in a well ventilated area and well away from flames. Also, some methods may require a centrifuge. Concentration methods are therefore best for diagnosing light worm burdens or assessing the level and intensity of hookworm infections in community-level programs.

The Kato-Katz quantitative cellophane thick smear method is often recommended for mass detection of *Ascaris*, *Trichuris*, and sometimes hookworm. A measured amount of stool (sieved to remove large particles) is placed on a slide, pressed smooth with a glycerine-soaked cellophane coverslip, and examined microscopically for worm eggs. (A thick glass coverslip may be used where cellophane is unavailable.)

Simple, cheap, fast and effective, the Kato-Katz technique requires only wire or plastic mesh, standard slides, glycerine-soaked cellophane pieces, and a microscope. (Malachite green stain is optional.) Because it uses measured amounts of stool, the Kato-Katz method can provide estimates of the intensity of

infection. It can also detect light infections. Several slides may be prepared at once to reduce the time spent on diagnosis.

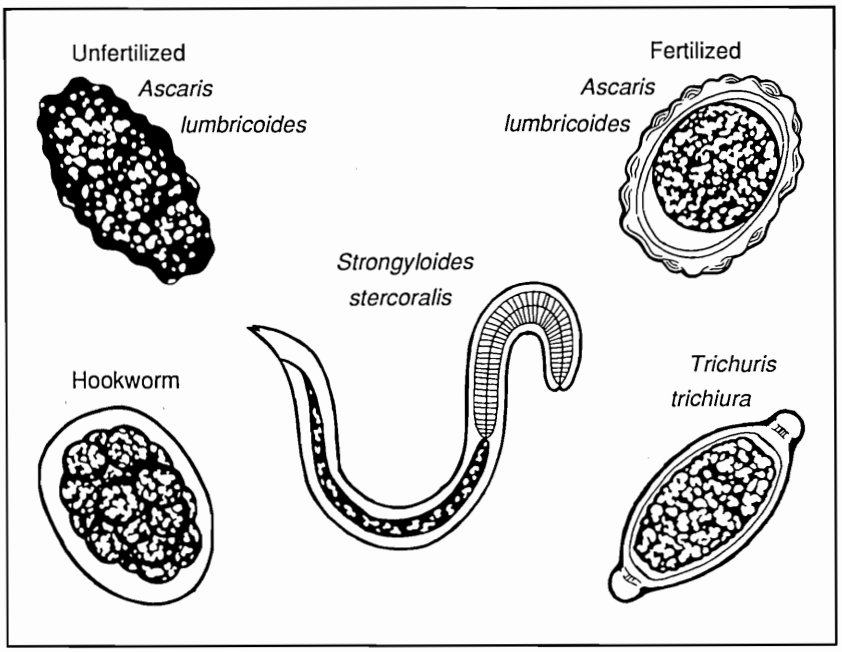
For *Ascaris* and *Trichuris*, the Kato-Katz method will provide accurate results even when examined after lengthy delays. In fact, *Trichuris* eggs are more visible 24 hours after slide preparation, and some studies report accurate results when slides are examined after six months of storage in a dry climate.

Lab personnel must be careful to avoid contaminating work areas with stool when preparing slides with the Kato-Katz method. Also, hookworm slides prepared with this method must be examined soon after preparation, since hookworm eggs become distorted quickly at room temperature. For this reason, a concentration method, like the saturated salt flotation method, is often preferred for field assessment of hookworm infections. (The Harada-Mori "filter paper culture" technique, described in the *Strongyloides* box on page 11, may also be appropriate.)

The best laboratory diagnostic technique for a specific program depends upon the reason for diagnoses and the time and resources available for performing the tests. A program's initial community-wide assessment of the prevalence of *Ascaris* infection, for example, may demand a laboratory diagnostic technique like the Kato-Katz method, which allows quick processing of many stool samples. Programs that need quantitative estimates of worm burdens, such as research efforts or community treatment schemes targeting heavily infected individuals, may prefer a concentration technique but can use the Kato-Katz method for speedier results.

The choice of diagnostic technique is also influenced by the type and number of parasites to be detected. For example, to determine the prevalence of hookworm in a community, a manager would probably select a diagnostic technology specific to hookworm, such as the saturated salt flotation method. However, a program assessing the overall prevalence of several intestinal worms may need a technology like the Kato-Katz method, which can detect a wider variety of worms. (The formol ether concentration method is more reliable for this purpose, but requires a centrifuge. The formol detergent method is also good but needs overnight sedimentation.) Programs that attempt to detect a variety of parasites may need to use two or more techniques. For example, programs assessing hookworm and *Trichuris* infections might use a flotation method for hookworm and the Kato-Katz method for *Trichuris.*

Finally, the manager must assess the adequacy of local laboratory facilities, as well as the availability of experienced lab personnel and the reagents and equipment needed for performing the chosen diagnostic techniques. A laboratory that is not well ventilated to protect lab personnel from harmful vapors should avoid performing techniques that use dangerous chemicals. Techniques requiring uncommon or expensive reagents or a regular source of electricity for a centrifuge may be less appropriate in rural areas. The need for test tubes or other breakable equipment may also limit the usefulness of certain diagnostic methods, particularly if water to clean them is scarce or replacing equipment is difficult.



PATH, by Tom Yagle

Microscopic view of intestinal worm eggs and larva

THE FORMOL DETERGENT CONCENTRATION TECHNIQUE

A recently developed quantitative concentration method that is useful in field surveys is the formol detergent concentration technique. In this simple and inexpensive technique, a measured amount of feces is mixed with a weak formol detergent (like household detergent) solution. After sieving, the suspension is left undisturbed overnight for the eggs and larvae to separate from the rest of the stool. A fine precipitate containing the eggs and larvae settles and is placed on a slide for microscopic examination.

The formol detergent method causes no egg distortion and is safer and more hygienic than the formol ether and Kato-Katz methods. It uses no dangerous reagents and involves little handling by lab personnel. No centrifuge is required and the reagents are standard laboratory chemicals (formalin and detergent). Like the formol ether method, the formol detergent technique can detect *Ascaris*, *Trichuris*, and hookworm eggs and the eggs, larvae, and cysts of other intestinal parasites. (Further details on this and other laboratory techniques can be obtained from Tropical Health Technology at the address listed in Materials Available, on page 11.)

Treatment

Many anthelmintic drugs exist for treating worm infections, and choosing the most appropriate drug for a specific program is vitally important. There are several criteria that managers should thoroughly assess in selecting a drug, and these are outlined for five of the most common anthelmintics in the table on page 6. These drug characteristics, along with specific program and situational needs, will determine the proper drug for treatment efforts.

A drug's safety and efficacy are of primary importance. Selecting a drug with minimal side effects and high cure rates benefits the patient and enhances community acceptance of the project. This is especially true for programs lacking the resources, personnel, or organizational capacity to track individuals with adverse drug reactions. A drug with a short shelf life or specific storage requirements may lose potency by the time it reaches the field. Managers must consider these qualities carefully when comparing different drug manufacturers' products.

A drug should be effective against the widest variety of parasites possible. Since many people use health care facilities infrequently, administering a broad spectrum anthelmintic (such as mebendazole or albendazole) can provide the greatest possible benefit in a single visit. Drugs that are effective against many parasites may also facilitate collaboration among programs. For example, metrifonate, a drug that can treat schistosomiasis effectively and also decrease hookworm burdens, may be used by programs coordinating efforts to control the two diseases.

Dosage requirements and drug availability are factors that drastically affect the drug's cost and ease of administration. To estimate overall costs, managers must calculate the number of persons to be treated and the number of doses each requires for cure. A seemingly expensive drug requiring only one dose may actually be cheaper than one that initially appears inexpensive but requires multiple doses, several field trips by health personnel, or tracking persons who need repeat doses.

If the drug must be transported or obtained from distant sources, these costs must also be covered by the program. (A national "essential drugs" policy, as discussed in *Health Technology DIRECTIONS*, volume 5, number 2, may help minimize some of these costs.)

Finally, the drug must be easy to administer. For example, drug dosages that depend upon age or body weight may require calculations that are difficult for some workers to perform. Also, tablets that are bitter-tasting (like some forms of piperazine are) or large

may be difficult for children to swallow, causing some to refuse treatment. Using liquid suspensions or mixing bitter medicines with squash or other foods may eliminate this problem.

Most people recommend never treating pregnant women or children below age two or weighing under ten kilograms, regardless of the drug selected. However, managers must consult package inserts or national drug regulatory authorities for precise information on drug safety, efficacy, side effects, contraindications, and dosages.

In addition to anthelmintic therapy, managers must consider treating the nutritional deficits that often accompany worm infections. Of primary concern is the iron-deficiency anemia associated with hookworm and *Trichuris* infections. Without iron supplementation, normal iron levels may not be regained for up to 20 months after anthelmintic treatment, during which time reinfection may occur. With iron supplementation, normal levels may be reached within three months, although this varies depending upon normal dietary iron intake and depletion from other causes.

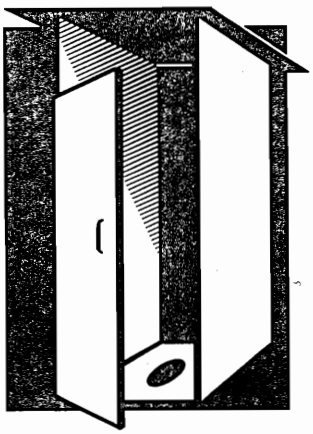
Although anthelmintic therapy plus iron repletion may seem costly, improved maternal and child health and increased worker productivity resulting from treating both anemia and infection can mean much greater economic savings than the initial drug therapy expenses. Therefore, many experts consider iron repletion to be a critical component of the treatment of both hookworm and *Trichuris.* In fact, some advise programs with limited resources to treat patients with hookworm for iron-deficiency anemia before treating the actual hookworm infection.

ANTHELMINTIC DRUG CHARACTERISTICS

	Piperazine	Mebendazole	Albendazole	Levamisole	Pyrantel Pamoate
Active Against:					
Ascaris	√	√	√	√	√
Hookworm		√	√	√	√
Trichuris		√ (a)	√ (a)		
Other Characteristics:					
Treatment time (days)	1 or more	3	1	1	2 or 3
Total number of doses	1 or more	6	1 (a)	1	2 or 3
Relative cost	low	medium	medium/high	low/medium	medium
Side effects (b)	rash, fever, stomach pain	nausea, stomach pain, dizziness, diarrhea, fever			stomach, liver reactions
Contraindications (c)	liver and kidney disease, epilepsy	see (c) below	see (c) below	serious kidney disease	concurrent piperazine use

(a) With repeated doses (3 or more) for heavy infections.
(b) Side effects for all these drugs are uncommon and transient, and are often related to worm movement or expulsion.
(c) Pregnancy, lactation, and under 2 years of age are contraindications for all five drugs, in addition to those listed.

Prevention



Efforts to prevent the spread of soil-transmitted worms should include sanitation measures as well as community-based drug treatments. Health education is a necessary component of all prevention activities.

Because intestinal worms are spread through feces, sanitation-related technologies and behaviors are important in preventing disease transmission. The use of latrines by an entire community is critical for eliminating worms and other fecally-transmitted organisms from the environment. People who use latrines may become infected if the surrounding environment is contaminated by people who do not use them.

Many varieties of latrines are available, including traditional pit latrines; ventilated improved pit latrines, which minimize flies and odors; and double-vault latrines, which allow adequate composting of human excreta for use as fertilizer. An appropriate latrine style is one that is financially affordable; socially and culturally acceptable; technically and environmentally sound; simple to install, operate and maintain; and beneficial to public health. (More information on latrines is available in the SIDA manual listed under Materials Available, page 12.)

But, as many project managers have discovered, constructing latrines does not ensure their proper use. In fact, poor construction or improper maintenance of latrines may actually increase the spread of disease.

For example, pit latrines built in areas where ground water is high or wells provide drinking water must be carefully constructed to prevent leakage from the pit walls. When latrines are built too close to homes and are infested with flies, uncovered food may be contaminated with worm eggs carried by flies. The slabs covering the pits must be kept clean or they may transmit worms like hookworm, which enter the body through the skin of the foot.

Latrines may not completely prevent worm transmission because young children, the age group most susceptible to worm infections, are not likely to use latrines. Few caretakers have time to ensure that every stool of every young child is deposited in a latrine. This is particularly true when the child has diarrhea.

Where building latrines is not feasible, health personnel should encourage defecating in one spot or in areas with bright sunlight and low moisture and covering feces with dirt. This often destroys hookworm and *Trichuris* eggs, but *Ascaris* eggs may survive adverse environmental conditions. Ultimately, the best way to decrease worm transmission is consistent, community-wide use of latrines.

Adequate supplies of clean water may also slow transmission of worm infections, primarily by facilitating frequent hand washing. Where water is scarce, simple technologies, like a can with a hole in the bottom that is closed by a stick and opened to release a small flow of water, are useful.

As with latrine use, however, cleaning the hands of young children, who acquire and transmit a major portion of worm infections, may be difficult. Also, since *Ascaris,* hookworm, and *Trichuris* are transmitted by many routes in addition to water, even sufficient quantities of excellent quality water cannot significantly reduce transmission of infection if no other prevention activities are implemented.

Another sanitation strategy involves eliminating or controlling the use of "night soil" (composted human excreta) as a crop fertilizer. Although enriching the soil with which it is mixed, night soil can contaminate vegetables and other crops it touches. Thorough cleaning of vegetables is essential, but if water is scarce or distant this may be difficult.

One way to stop this mode of disease transmission is for governments to pass laws against using night soil. Where eliminating this practice is not possible, composting night soil to a high enough temperature for a long enough period of time, which destroys infective worm eggs and larvae contained in feces, should be stressed.

Most people recommend waiting at least six months before using compost contents, but factors other than time and temperature may speed or slow the process. These include soil moisture and acidity, and the presence of oxygen and other organisms. Composting details are contained in the SIDA manual referenced in Materials Available.

Finally, most hookworm infections could be prevented by wearing shoes consistently. Since the majority of all hookworm infections are acquired through surfaces of the feet, simply preventing contact with infective larvae found in soil is highly effective. In some countries, inexpensive rubber sandals have become widely available through shoe manufacturers' marketing efforts. National government support and promotion can also increase shoe wearing, as has been seen in Tanzania.

Unfortunately, shoes still are not commonly worn by many people in most developing countries, often because of their cost. In the rainy season, cheaper, impermeable plastic and rubber shoes can be uncomfortable and may cause dermatitis, while more expensive shoes may be ruined by water.

Maendeleo Ya Wanawake Organization

A Kenyan booklet promotes shoe use as hookworm prevention

Although sanitation measures will ultimately rid the environment of infective worm eggs and larvae, their effectiveness depends upon widespread use and their results are not visible for years. Community-based drug treatments produce more rapid results but do not interrupt disease transmission pathways permanently. Nevertheless, in countries where major sanitation improvements are unlikely in the near future, many experts recommend community-wide drug treatment schemes as the major approach to prevention.

Regularly repeated, community-based drug treatments can be effective prevention activities for individuals and for communities. In individuals, drug treatments may prevent or eliminate the nutritional and intestinal complications associated with worm infections. In the community, drug treatments may help reduce the number of eggs excreted into the environment, thereby decreasing contamination and lowering the risk of exposure to infective eggs and larvae.

Community health education is an important component of both these approaches to prevention. Education about worms can help people appreciate the impact their behaviors have upon their own and the community's health, and can motivate them to change harmful behaviors. It can also give people specific information with which to improve their health. For example, latrine construction details as well as the importance of washing young children's hands and placing their stools in latrines may be conveyed with health education activities.

Because prevention measures require the cooperation of the entire community, education efforts should include community members. Local theater and puppet shows, songs, and storytelling sessions are good ways to involve villagers in education. (See *Health Technology DIRECTIONS*, volume 7, number 2.)

Local health volunteers should also be involved in community health education activities. Because they understand villagers' perceptions and beliefs, local health educators can draw analogies between villagers' experiences and modern sanitation concepts.

Health education may occur in a variety of places. Community meetings or festivals offer opportunities to present new ideas to large audiences. Smaller groups like women's organizations or local cooperative groups allow more intimate exchanges that may increase understanding and acceptance of ideas.

Many educators recommend teaching health concepts to children in schools. Because schoolchildren often care for younger siblings at home and are themselves at risk of infection, teaching them about worms and sanitation may have wide ranging effects. Also, teaching schoolchildren these concepts may result in health benefits for their own children, multiplying the effects of the initial health education efforts.

Program Issues

Managers developing worm control program strategies need accurate background information about targeted communities. Data on the prevalence of specific worms, the distribution of infections within the different populations of the community, and the intensity of infections can help program managers design the most effective and least expensive approach to worm control for a given community.

Surveys conducted by the government on a nationwide basis or by local health personnel at the community level provide information about disease patterns. Nationwide surveys help in developing national policies and guidelines but overlook community variation. Community-level surveys give locally specific information, but their results may not be applicable to other sites.

Survey results must be interpreted cautiously. A survey conducted at one point in time cannot reflect the changing patterns of infection in communities or changing intensities of infection in individuals. For example, a disease may appear highly prevalent and infections may seem severe when a survey is conducted during the rainy season. However, the disease may actually be decreasing in the community, and the infections may be unusually severe. Even if worm infection levels do not fluctuate drastically, managers must be aware that survey results may not reflect the community's usual disease patterns.

Nevertheless, prevalence data from surveys may help managers with decisions such as the selection of a drug which provides the greatest benefit to the most people. For example, in a community with *Ascaris*, hookworm, and *Trichuris* present in equal proportions, a broad spectrum anthelmintic is best. Where one species of hookworm predominates, a drug specific to that species should be selected.

Survey data describing the intensity and distribution of infections within a community may indicate the best strategy for community-level treatment. Treatment programs may administer drugs to the entire community or only to selected persons within the community. Many factors influence this choice. Where infections are highly prevalent, of similar intensity, and evenly distributed among community members, mass deworming of the entire community may be appropriate. However, sufficient quantities of relatively inexpensive drugs must be available to implement this strategy successfully.

If small groups of people carry the majority of the community's worm infections, as is often seen with hookworm, managers may consider treating only that selected group. For example, if the majority of infections occur in children aged two to fifteen, as occurs with *Trichuris*, managers should consider targeting children in that age group for diagnosis and treatment. However, adequate lab facilities, personnel, and resources are necessary to perform the stool examinations required by selective treatment strategies.

In some places, variations and combinations of the two approaches may be necessary. For example, mass treatment of all community members may be followed by selective repeated treatments for those at higher risk of reinfection or those still exhibiting symptoms of infection.

Effective and economical timing of treatments must also be determined. Seasonal changes in transmission of worm infections are generally small in tropical regions. However, hookworm eggs are more fragile than other eggs, so slight decreases in hookworm transmission may be seen in colder, drier seasons.

Where seasonal variations do occur, managers should consider strategies such as mass treatment at the beginning of the wet season, to decrease the presence of infective eggs and larvae in the environment, and also at the end of the wet season, when overall prevalence of infection is generally high and reinfection is less likely to occur during the coming dry season. A less costly approach is to treat everyone annually, after the wet sea-

JOICFP Review

Philippine schoolchildren receive deworming medicine

son, and selectively treat only the most severe infections during the rest of the year.

Decreases in disease prevalence after a single round of treatment usually disappear within one year, due to reinfection, although infection intensities may remain low for a longer time. Most people recommend repeating treatments at regular intervals to achieve long-term decreases.

Research results vary greatly, but most people recommend at least two treatments yearly, and some favor treatments every three months. Since *Trichuris* is reacquired particularly quickly, shorter intervals may be desirable in places where *Trichuris* is endemic. Hookworm, which has a slower rate of reinfection, may only require annual treatments. *Ascaris* studies, noting that children and heavily infected people are more rapidly reinfected after treatment, may support a selective treatment scheme with shorter treatment intervals for children and heavily infected people and longer intervals for lightly infected people. Other studies, showing that even light *Ascaris* infections may be harmful, imply a need for repeated mass treatments regardless of infection intensity.

Deworming may take place in homes, health clinics or schools. Taking deworming efforts from house to house ensures thorough coverage of entire neighborhoods, where prevalence and intensity of infection may be similar. Treating at health clinics may enhance the credibility of the health system. Deworming at schools may allow broad access to children, the most vulnerable age group. However, this strategy misses preschool children, school dropouts, and, in countries where only wealthy children attend school, the children of poorer families, who often have the greatest need for deworming.

Finally, control strategies may be integrated with other disease control programs. Schistosomiasis control programs, for example, require stool exams that may be able to detect other worm eggs, and may use metrifonate, which also can decrease hookworm burdens. In Samoa, parasite control programs are part of filariasis control efforts. In Vietnam, parasite control is integrated with sanitation and environmental hygiene programs.

Similarly, deworming may be coordinated with other preventive health activities. For example, EPI programs may offer deworming to the older siblings of infants being vaccinated. Deworming may also be linked to growth monitoring sessions.

The Japanese Organization for International Cooperation in Family Planning (JOICFP) has been extremely successful in using deworming strategies to introduce family planning programs. These projects, operated and financed by a variety of organizations around the world, are based on the premises that there is a universal dislike of worms and that by deworming a community, program staff can gain the trust of villagers. That trust then may facilitate introduction of other less tangible primary health concepts, like family planning and sanitation.

All JOICFP projects involve local people in planning and implementing deworming and subsequent health activities. Control of overall project operations is shared by government, private organizations and expert groups. In this way projects can benefit from the specific knowledge of local people and experts, and from the support and experience of private organizations and the government.

STRONGYLOIDES STERCORALIS

Infection with *Strongyloides* is common in many countries, but it differs from other soil-transmitted worm diseases. As with hookworm, infective larvae penetrate the skin, pass through the heart and lungs, and invade the intestinal lining. However, eggs produced in the intestine become larvae that are usually excreted but may reinvade the intestine without leaving the body ("autoinfection"). Acute strongyloidiasis may include coughing, fever, abdominal pain and mucoid diarrhea. Chronic strongyloidiasis is often asymptomatic, although diarrhea, abdominal pain, and "larva currens" (similar to "creeping eruptions" in hookworm infection) may be present. Chronic strongyloidiasis may persist for many years, due to autoinfection. Overwhelming or disseminated strongyloidiasis, the most severe form of disease, is often fatal. People who are immunologically weakened by therapeutic drugs like corticosteroids or by diseases like acquired immune deficiency syndrome (AIDS) are particularly susceptible to this massive invasion of the body's major organs.

Laboratory diagnosis can be difficult, but larvae may be detected with the formol ether method or the Harada-Mori "filter paper culture" technique, in which moistened feces is placed on a strip of filter paper in a test tube with 1 ml of water. Infective larvae appear in the water several days to two weeks later. Thiabendazole is the most common anthelmintic, but may have some side effects and is not always effective. Mebendazole and albendazole have been used with varying success.

Diagnosis is slow and sometimes inaccurate, so anyone with larva currens should be treated. However, community-based treatment should target people at risk of disseminated strongyloidiasis. Where resources are adequate, any immunosuppressed individual or anyone taking immunosuppressive drugs should be tested periodically for *Strongyloides* and treated if positive. Where resources are scarce, managers should consider treating such individuals without testing for *Strongyloides*. Prevention strategies include wearing shoes to prevent soil from contacting skin.

Conclusions

Several simple diagnostic techniques are available and many drugs can treat worm infections effectively and cheaply. The appropriate choice depends on program needs, environmental constraints, and available resources.

Prevention efforts may include sanitation activities, community-based drug treatments, or both. Health education is vital for all prevention activities.

Control strategy development uses data on infection prevalence, distribution, and intensity. The seasonality of infections and the appropriate interval between treatments must also be considered. Integrating worm control with other health programs may be quite advantageous.

With so many simple technologies available to help control such prevalent, harmful, and easily curable and preventable diseases, worm control programs should be considered critical components of public health efforts.

Materials Available

There are many good references on intestinal worms. **Medical Laboratory Manual for Tropical Countries**, by Monica Cheesbrough, is a guide to diagnostic techniques. Volume I (clinical parasitology and chemistry) costs £8.95 (airmail) or £7.75 (surface); volume II (microbiology) costs £4.45 (airmail) or £3.85 (surface). A plastic-coated, color wall chart with large, vivid photographs of 15 helminth eggs and larvae is also available. It costs £3.30 (airmail) or £2.25 (surface). These and other items may be obtained from: Tropical Health Technology, 14 Bevills Close, Doddington Cambridgeshire, PE15 OTT, England.

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Sanitation Without Water, by Uno Winblad and Wen Kilama, details sanitation technologies like latrine construction and composting and is available in English, Spanish, Arabic, and Portuguese. A simplified version is

available in Swahili and Amharic. Request copies from: SIDA, Health Division, S-105 25, Stockholm, Sweden.

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Slides, brochures, and manuals on intestinal worms and their control are available in French, Portuguese, and English from Bureau d'Etudes et de Recherches pour la Promotion de la Sante´. For prices, write to: B.E.R.P.S., P.O. Box 1800 Kangu-Mayumbe (Bas-Z), Zaire.

Finally, **Prevention and Control of Intestinal Parasitic Infections**, a 1986 WHO Technical Report Series (number 749), contains an expert committee's recommendations for controlling worms and other parasites. It is available through WHO Regional Offices or by writing to: WHO, Distribution and Sales Service, 1211 Geneva 27, Switzerland.

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A bibliography on intestinal worms is available from PATH.

INTERCHANGE

Management Sciences for Health (MSH) offers a four-week course May 2-27, 1988, on improving and supporting drug supply programs. An optional fifth week details computer use in managing drug supply and also is open to those not attending the four-week course. Applications are due March 15, 1988. For more information, write to: MSH, 165 Allandale Rd., Boston, MA 02130, USA.

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The Asian and Pacific Programme for Development Training and Commmunication Planning (a regional service unit of UNDP) has announced its 1988 training courses for program managers and communications specialists. Topics to be covered include planning, management, supervision, evaluation, and training. For more information, write to Dr. Muangtong Khemmani, DTCP/UNDP, P.O. Box 2-147, 19 Phra Atit Road, Bangkok 10200, Thailand.

AHRTAG, The Appropriate Health Resources and Technologies Action Group Ltd., is publishing a free quarterly newsletter on AIDS and HIV infection. It includes practical information on AIDS, its prevention and control, integration with other health care activities and a readers' exchange section. To receive the newsletter, write to: AHRTAG, 85 Marylebone High Street, London, W1M 3DE, England.

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The International Women's Tribune Center (IWTC) supports activities promoting women's participation in development. Resource books such as **Communicating Appropriate Technology with Rural Women** and **The Tech and Tools Book: A Guide to Technologies Women are Using Worldwide** are available free or at low cost. For more information, write: IWTC, 777 United Nations Plaza, New York, NY 10017, USA.

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health technology
directions

PATH Program for Appropriate Technology in Health

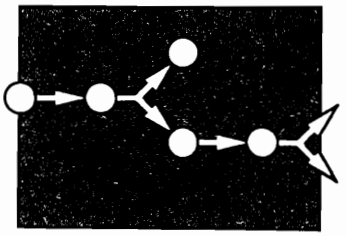
Sexually Transmitted Diseases

Sexually transmitted diseases (STDs) are an important cause of morbidity and mortality in every country in the world. For example, in Kenya gonococcal urethritis represents over 10% of all diagnoses of infectious disease in adult males, while in Asia pelvic inflammatory disease, or PID, a condition frequently due to STD infection, accounts for up to 23% of all acute admissions to gynecology wards. In Costa Rica, a study revealed evidence of past chlamydial infection in over 50% of women of childbearing age.

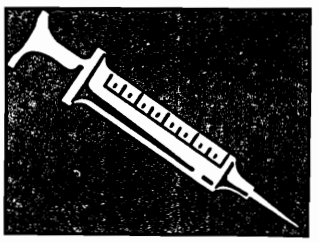
The impact of STDs is seen not only in the men and women experiencing immediate symptoms but also in those who suffer long-term secondary complications and in the infants of infected women. Initially, adult males with STD infections may experience pain from urinary and genital tract infection. Adult females may be symptomless, have pain related to PID or tubal infection, or suffer miscarriage or stillbirth. The damage caused by these primary effects of STDs can lead to infertility in men and women and ectopic pregnancies in women. Newborns of infected women may contract eye infections, pneumonia, and congenital disease, and may die.

Despite the public health significance of STDs, few national governments or private organizations have initiated STD control activities. In many cultures, STDs are not discussed easily in public, and because STDs other than the acquired immune deficiency syndrome (AIDS) rarely cause death in adults, health service managers may not give them a high priority. While the growing impact of AIDS has refocused attention on STDs (in fact, recent evidence suggests that some STDs may facilitate transmission of the AIDS virus) there is a danger that the more common STDs, like gonorrhea, chlamydia, syphilis, and chancroid, may be neglected while efforts against AIDS are undertaken.

This issue of DIRECTIONS examines the technologies available for diagnosing, treating, and preventing four of the most prevalent and serious STDs in the world, and the important considerations for their appropriate selection and use.



Diagnosis



Treatment

Prevention

Volume 8, Number 1 ISSN: 0730-8620 1988

Gonorrhea. *Neisseria gonorrhoeae* infection, the most common STD in developing countries, has an incidence of 10% in many parts of Africa and is found in 12-20% of women at antenatal clinics. In men, gonorrhea causes profuse, pussy discharge and difficult or painful urination. Severe or repeated infections can cause infertility. Women may be symptomless or have discharge and lower abdominal pain from PID or tubal inflammation. Even one episode of PID increases a woman's risk of infertility. Tubal scars from inflammation may cause infertility or tubal pregnancy. Pregnant women may miscarry or deliver prematurely, and over 40% of their newborns may acquire ophthalmia neonatorum, an eye infection that can cause blindness. Gonorrhea also may occur in the anus, rectum, or throat in up to 50% of persons with genital gonorrhea.

Chlamydia. *Chlamydia trachomatis* appears to be the most common STD in developed countries and may be equally important in developing countries. Chlamydia has been found in 29% of pregnant women and in 5% of asymptomatic men in Kenya, and is thought to cause most nongonococcal urinary tract infections in males worldwide.

Chlamydial symptoms are similar to those of gonorrhea, but are less marked. Men have clear or white discharge and difficult or painful urination. Women may be symptomless or have yellowish, mucoid discharge and an inflamed cervix. PID and tubal scarring and their consequences are the main chlamydial complications. Infected women's infants may contract eye or genital infection or pneumonia. Among infants at risk, 35-50% acquire eye infections and 10-20% develop pneumonia.

Syphilis. *Treponema pallidum* infection is common, but its incidence may be changing. Widespread antibiotic use has decreased incidence, but the decline of yaws and pinta (two related, nonvenereal diseases) may reduce the cross-immunity to syphilis that they once provided. Some 30% of men at an STD clinic in India and up to 15% of pregnant women in many African countries test positive for syphilis.

Syphilis has many symptoms. In primary syphilis, a painless, firm single chancre (ulcer) with a clear base and well-defined edge is common. Secondary syphilis is indicated by condylomata lata (a flat, wart-like growth on the genitals and mucous membranes) and a symmetrical, nonitching skin rash with raised surfaces, often on the palms and soles. Tertiary, or late, syphilis, if untreated, may cause insanity and death.

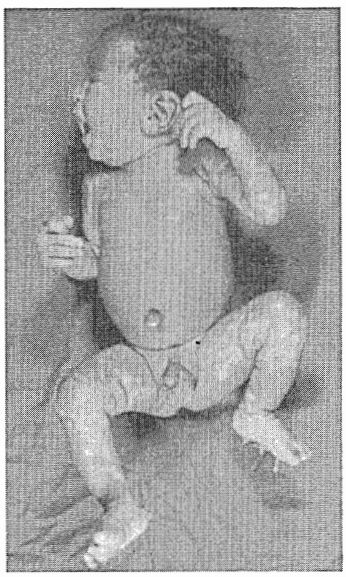
Syphilis at any stage can affect women's pregnancies, but early syphilis causes complications more often than other stages. Of infected women's pregnancies, one third end in fetal or infant death, one third in live infants with congenital syphilis, and only one third in uninfected infants.

Congenital syphilis usually appears within three months of birth. Rash, condylomata lata, swollen and bleeding nasal membranes, and bone or joint swelling may appear. In Zambia, syphilis causes over 40% of stillbirths, and 1% of all newborns have congenital syphilis. In Ethiopia, syphilis causes 5% of all post-neonatal infant deaths.

Chancroid. *Haemophilus ducreyi* is the most common cause of genital ulcers in many developing countries. Overall prevalence is unknown, but in one study over 60% of ulcers were chancroidal and only 22% were syphilitic. Men, especially if uncircumcised, may be at greater risk than women, but women's infections may be harder to detect. Trauma or abrasion may facilitate transmission. Newborns are unaffected.

Infected persons develop many shallow, small ulcers with ragged edges. These ulcers bleed easily and are more painful when they occur on skin surfaces (as they do in men) than when they occur internally (more often in women). In over 50% of infected men, groin lymph nodes swell with pus, becoming "buboes" that may rupture to form large ulcers.

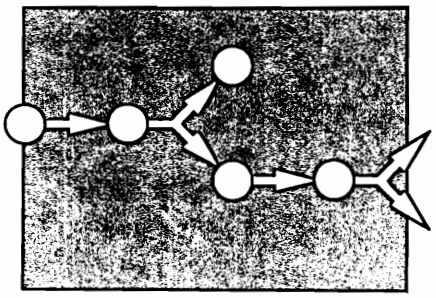
Complications include tissue death in ulcerated areas, which may require circumcision in some men. Recent studies indicate that chancroid ulcers may help spread AIDS.



Sexually Transmitted Diseases, Harper and Row

Infant with congenital syphilis.

Diagnosis



Laboratory diagnosis of STDs requires testing through microscopy, culture, serology, or immunoassay technologies. Although most rural health clinics currently cannot perform laboratory diagnosis, some recently developed or adapted technologies are making laboratory diagnosis in the field more feasible. Where these technologies remain unavailable, however, health workers can diagnose and treat STDs effectively using a WHO-developed approach that relies primarily upon clinical syndromes and patient history.

Microscopy. Simple, fast, and inexpensive, the microscopic examination of specimens is one of the few diagnostic methods that many rural clinics can perform. Microscopic diagnosis requires a standard microscope, slides, slide covers, and a few commonly available reagents.

The most common microscopic diagnostic method is the Gram stain, which can identify eye and male genital gonococcal infections and distinguish gonococcal from nongonococcal urethritis. Methylene blue stain also can be used. Giemsa stain, although not always accurate, can detect chlamydial eye infections.

Dark-field microscopy is used to detect treponemes (spiral-shaped organisms like those causing syphilis). Dark-field microscope condensers create dark backgrounds for viewing thin organisms. Commercial versions are expensive. Standard microscope condensers, however, may be adapted using simple dark-field stops to produce a dark background. No dark-field can distinguish *Treponema pallidum* from other spiral organisms, so results should be interpreted cautiously. This method should be used only when clinical evidence (usually a chancre) strongly supports the diagnosis of syphilis.

To construct the dark-field stops, locate the condenser (below the slide support table) and its circular hole. Cut a piece of cardboard (or dark paper that allows no light to penetrate) that fits into the hole but allows a thin rim of light to come up around the edges. Glue a same-sized piece of clear glass or plastic to the stop and place the stop into the hole. A very bright light is critical, and separate stops are required for the 10x and 40x objectives. (Stops cannot be made for the 100x oil immersion objective.)

Culture techniques. Culture techniques can identify specific organisms causing infection, determine effective drugs for treatment, and detect drug-resistant organisms. In most rural locations, however, they remain impractical.

Obtaining good specimens, especially vaginal or cervical specimens, may be technically or socially difficult. Cultures require refrigeration for storage and stable temperatures for organism growth, and culture media may be expensive or difficult to obtain.

Because cultures take time to grow, patients must return later to learn the results and receive the appropriate drug treatment. Some patients instead may treat themselves immediately with drugs purchased from local pharmacies. These drugs may be ineffective (particularly where drug resistance is prevalent) or taken in incomplete courses.

Also, a negative culture result does not always mean the disease is absent. For example, if chlamydial infection has spread from the cervix into the fallopian tubes, cultures of cervical specimens may be negative, although the disease is present.

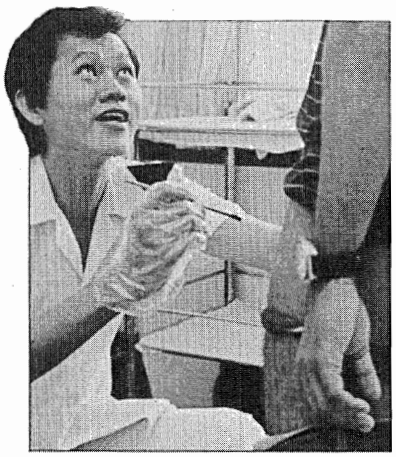
Where cultures can be done, they are used most often for diagnosing gonorrhea in women, chancroid, and penicillin-resistant gonorrhea. Cultures for chlamydial organisms require a special type of medium that may be difficult to obtain, and syphilis organisms cannot be cultured.

Serology. Tests of blood sera detect the body's own antibodies to infecting organisms (antigens). Of the four STDs discussed above, serological testing is used primarily to detect syphilis and includes nontreponemal and treponemal tests. Nontreponemal tests detect antibody to cardiolipin antigen, which is found in conjunction with syphilis. These tests are relatively fast, inexpensive, and easy to perform, and therefore are effective tests for

screening programs. Since non-treponemal tests can quantify infection, they can be used to monitor the progress of a treatment regimen.

The two most common non-treponemal tests are the Venereal Disease Research Laboratory (VDRL) and the rapid plasma reagin (RPR) tests. The VDRL is performed on a slide, while the RPR uses a disposable card. In In both cases, the antigen solution is mixed with serum and mechanically rotated for four minutes. (Some versions of the RPR are rotated by hand.) The VDRL requires heated serum, while the RPR uses unheated serum or plasma. Clumping in either test indicates a positive result, but the VDRL must be read with a microscope while the RPR can be evaluated with the naked eye. The VDRL is generally less expensive.

The unheated serum reagin test (USR) is like the VDRL except that the antigen solution is slightly modified and the test does not require heated sera. Modifying the VDRL antigen for this test is simple and can be done in central or regional laboratories.



World Health Organization

Technician taking a specimen.

The more recently developed TRUST card is identical to the RPR except that red pigment in the antigen indicates a positive result. The antigen solution (the same as that of the USR test) uses fingerstick blood, is inexpensive and simple to prepare, and gives accurate results that are available at the time of the visit. Using glass slides instead of cards further reduces costs.

Treponemal tests detect antibody to the syphilis organism. Equipment and reagents are often expensive, and well-trained, experienced personnel may be needed to perform them. These tests are therefore most appropriate for intermediate or central laboratories.

A significant obstacle to the use of serological tests for STDs is the collection and transport of blood specimens. An experimental technique using specific types of filter paper to collect blood samples offers one solution. Blood from a finger prick is collected on two 12 mm-wide circles drawn on a piece of filter paper, which is then air-dried and shipped in slide boxes to a central laboratory. Including a drying agent, such as a silica gel packet, in the box may improve the preservation of the samples in wet or humid conditions.

Upon arrival, specimens may be analyzed immediately or frozen. Several 5 mm circles punched from the blood-soaked paper (or the entire 12 mm circle) are placed in 0.1 ml of absorbant to soak at least 1 hour (preferably overnight). After squeezing the circles to remove remaining blood, serial dilutions are prepared.

Tests of blood collected this way give accurate results up to eight weeks after collection, although heat and humidity may shorten this time. Since types of filter paper and other supplies and local conditions may vary in different locations, the filter paper blood collection method (like any new technology) must be tested under the conditions in which it will be used before it is implemented widely. (See the Materials Available section on page 12 for an address where more information on the TRUST and USR tests and filter paper blood collection method may be obtained.)

Immunoassays. Relatively new, these techniques use specially developed, marked molecules that can detect even low levels of antigen or antibody in sera or smears. Although some of these tests are commercially available in developing countries, most are too expensive and complicated for general use. Research to simplify them for wider use in developing countries is under way.

The ELISA (enzyme-linked immunoassay) test mixes an enzyme and antibody or antigen solution with the specimen. The presence of chlamydial or gonococcal antigen or AIDS antibody is indicated by a color change. ELISA tests usually are run on plates that allow up to 96 tests to be run at once, so ELISA tests are most efficient for screening or testing relatively large numbers of samples. (Individual tests are being developed by many companies.)

Immunofluorescence tests use fluorescently marked antibody solution to detect antigen. Trained laboratory workers and a special fluorescence microscope

are required to read the results. Reagents must be refrigerated and a correctly obtained specimen is essential. In some developing countries, like Brazil, immunofluorescence tests already are used widely.

Agglutination testing is currently the most appropriate immunoassay method for many developing countries. Antibody affixed to small beads is mixed with the specimen on a card or slide. Visible clumping indicates antigen presence. Agglutination tests require no refrigeration and are simple to read, relatively inexpensive, and well suited for individual tests. Technological advances may allow several developing countries to produce the reagent (antibody-affixed beads) in the near future.

Syndromic Approach. Although laboratory diagnostic technologies are becoming increasingly suitable for use in developing countries, most still remain impractical for the majority of rural health centers. Even without laboratory technologies, however, health workers can diagnose the most common STDs using a method developed by the World Health Organization called the syndromic approach. (See examples on page 6.)

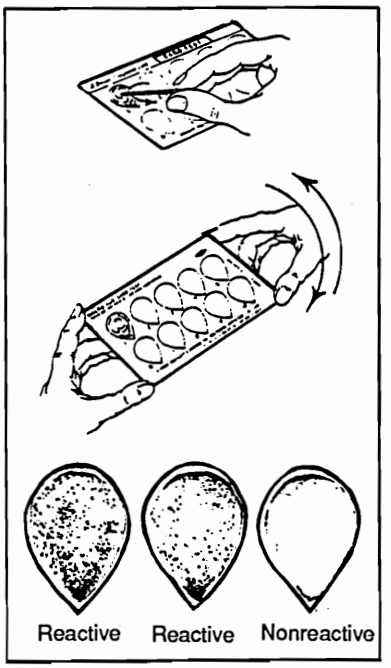
The syndromic approach uses standardized decision trees, or protocols, to guide health workers in diagnosing STDs based on personal history and the presence or absence of clinical syndromes (groups of symptoms). The appropriate first-line treatment is dictated by the diagnosis. If an initial treatment is unsuccessful, health workers make a secondary diagnosis and provide the corresponding second-line treatment. Since several STDs may cause similar syndromes (for example, both gonorrhea and chlamydia may cause pelvic pain and vaginal discharge in women), diagnosis should utilize any available laboratory tests, and first-line treatments also should be able to cure the most severe and prevalent diseases.

The syndromic approach gives health workers a systematic way to diagnose STDs when laboratory support is unavailable (as is often true for chlamydial infection) and allows patients to begin treatment immediately. Standardized treatment regimens simplify drug selection and can help control drug resistance. Record-keeping that is required for the syndromic approach also can provide data on disease patterns, treatment efficacy, and cost effectiveness.

Once syndromic protocols are developed, however, they require frequent and careful review if they are to reflect quickly changing disease patterns, such as increasing drug resistance or changing syndromes. The costs involved in secondary treatments for the patient and his or her contacts in the event of failure of the primary treatment must be weighed against the costs of laboratory diagnosis. A smoothly operating record-keeping system, which is difficult to maintain on a large scale in most developing countries, is essential for monitoring individual diagnoses and treatments.

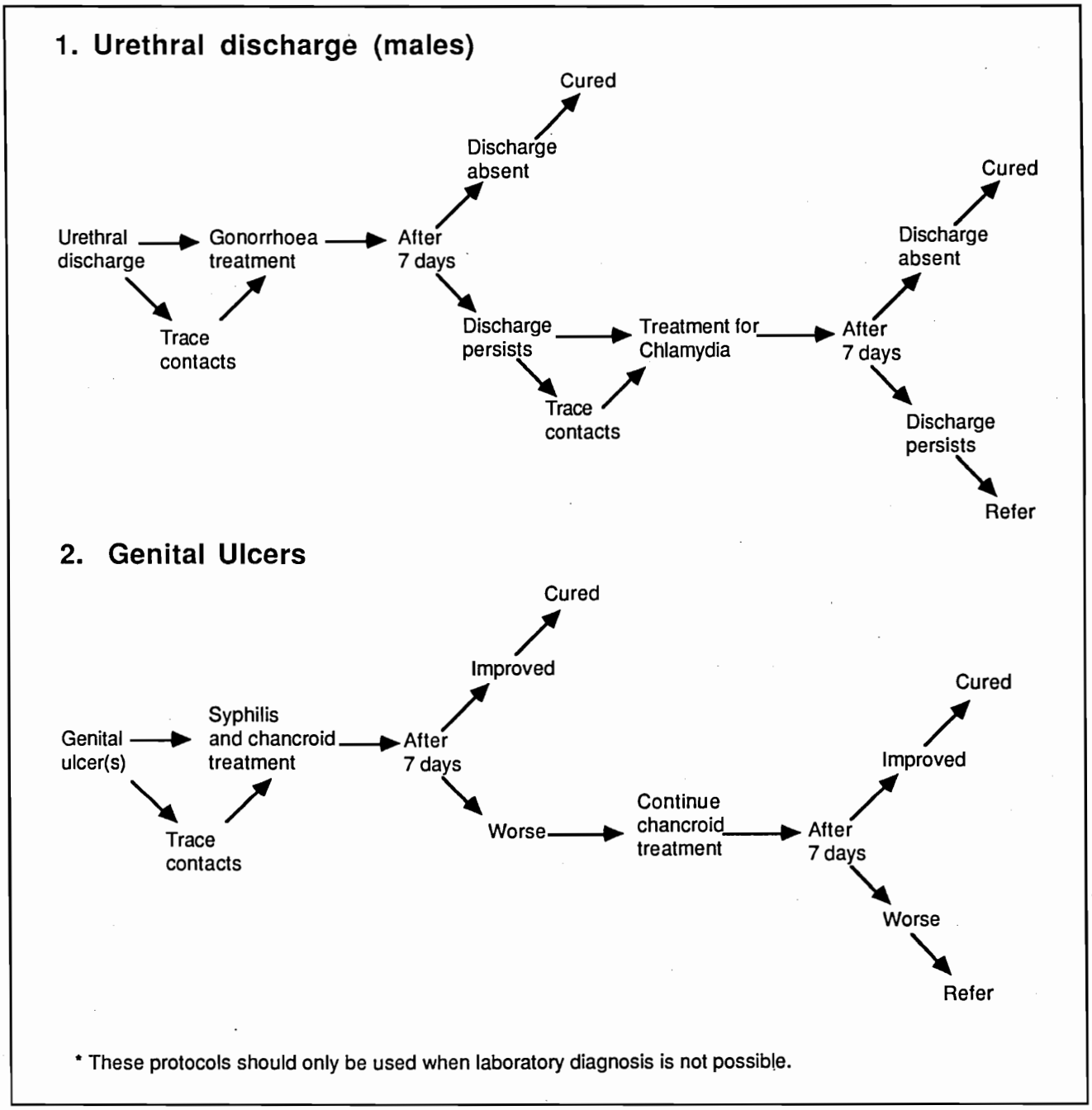
Because the prevalence and symptoms of STDs and the availability of lab tests and drugs vary extensively, syndromic protocols must be tailored to match local conditions. Many factors must be considered in developing and monitoring syndromic protocols. This information may be obtained by examining existing records or by conducting small field surveys. Any newly developed or altered protocol must be field tested before being implemented.

The most important consideration is how consistently the presence of the selected diagnostic syndrome correctly indicates that the disease is present (sensitivity), and how often its absence correctly indicates that the disease is not present (specificity). These qualities may be measured by comparing the diagnosis based on the presence or absence of the syndrome with the diagnosis based on a highly accurate laboratory test.



Becton Dickinson and Company

The Teardrop *card, a version of the RPR test.*



World Health Organization

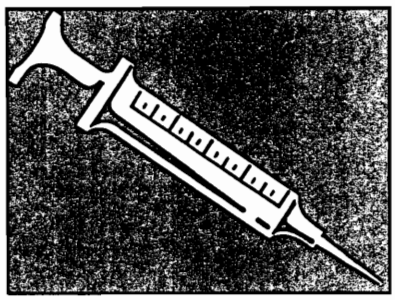
Sample protocols for the syndromic approach.

Syndromes with low sensitivity can fail to identify someone who is ill, delaying provision of proper treatment. Those with low specificity can give false diagnoses that can result in unnecessary or incorrect treatment.

Acceptable levels of sensitivity and specificity must be determined locally. These levels will be affected by the seriousness of the impacts of delayed treatment and of incorrect or unnecessary medication, and by the availability of laboratory diagnostic testing. Where microscopy can be performed, for example, a Gram stain test can confirm or eliminate the possibility of gonorrhea early in the protocol for male urethral discharge.

Finally, patients' health attitudes and behaviors influence the protocols. For example, if vaginal examinations are not culturally acceptable, protocols for females must rely solely on the patient's report of discharge or ulcer. Where patients are not likely to complete a two week drug regimen, treatments should be limited to drugs with short courses.

Treatment



A variety of drugs are available and many different strategies may be used to treat STDs. However, some STDs, particularly gonorrhea and chancroid, no longer respond to drugs that formerly were effective, and the problem is growing. Selecting appropriate drugs and treatment strategies and slowing the growth of drug resistance are the major issues in STD treatment.

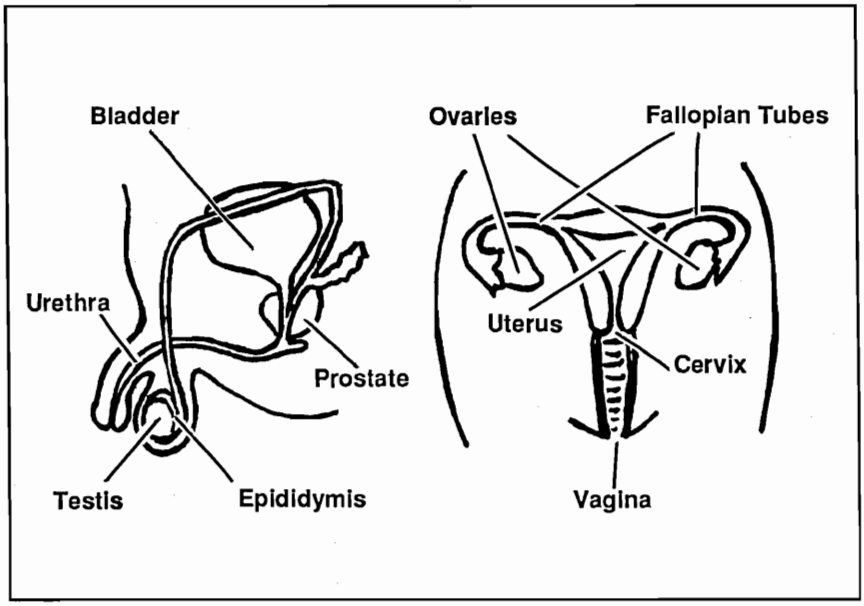
Ideally, drugs completely cure single and preferably multiple infections, have few side effects, and are inexpensive and commonly available. They also are easy for health workers to administer and patients to take and are culturally acceptable. Few drugs meet every criterion. For example, tetracycline can cure chlamydia and nonresistant gonorrhea, causes few side effects, and is inexpensive and available in most countries but requires several doses. Some newer drugs, like ceftriaxone, cure gonorrhea and chancroid with one dose and are generally acceptable. Although they are currently expensive, once their costs decrease these newer drugs may offer the best option for STD programs. They have few side effects and are highly effective, safe in pregnancy, and easy to administer.

There are several approaches to STD treatment. The syndromic approach described in the diagnosis section prescribes treatment with predetermined drug regimens based on clinical signs of disease. Because several diseases cause similar symptoms, the first-line treatment should be capable of curing diseases that cause the most frequent, severe, or costly complications. For example, chancroid and syphilis are equally prevalent in some areas. Since the complications of syphilis are more severe, the first-line treatment (if no diagnostic tests are available) should be for syphilis. Chancroid is often painful, however, so chancroid treatment should begin as soon as it appears that syphilis therapy has failed.

Epidemiological treatment is the mass treatment (without diagnosis) of groups that may be at high risk of disease or complications, such as pregnant women or prostitutes. This strategy is rarely recommended for STDs, primarily because it can increase the problem of drug resistance. It should only be considered for special groups like remote or nomadic populations or the contacts of certain groups with STDs.

If epidemiological treatment is selected, several steps must be taken before implementation. An epidemiological study must confirm high disease prevalence in the selected group; the group must accept the idea of mass treatment; the chosen treatment must be highly effective and produce few side effects; reinfection rates must be examined to decide if or when repeat treatments will be necessary; and the chosen strategy must be evaluated in a pilot study.

Drug resistance is a serious and increasing problem in the treatment of STDs, particularly gonorrhea and chancroid. Resistant



Male and female reproductive organs.

strains reduce the value of proven drugs, complicate the selection of effective treatments, and often necessitate the use of more powerful and expensive drugs.

Resistance to several drugs used to treat these STDs has been reported worldwide. Penicillin-resistant gonorrhea has become extremely common, accounting, for example, for over 30% of all gonorrhea cases in Panama City. Gonorrhea and chancroid strains that are resistant to spectinomycin, tetracycline, kanamycin, and chloramphenicol also have been reported.

Drug resistance can develop when a few disease organisms that survive drug therapy replicate and spread. A common strain of gonorrhea, for example, produces penicillinase, an enzyme that inactivates penicillin, allowing it to survive penicillin therapy. Evidence indicates that drug resistance also may be transferred from one disease to another through an exchange of genetic material, as is found between gonorrhea and chancroid. Some believe resistance to one drug facilitates development of resistance to other drugs. (Penicillin and tetracycline resistance in gonorrhea may be linked in this way.)

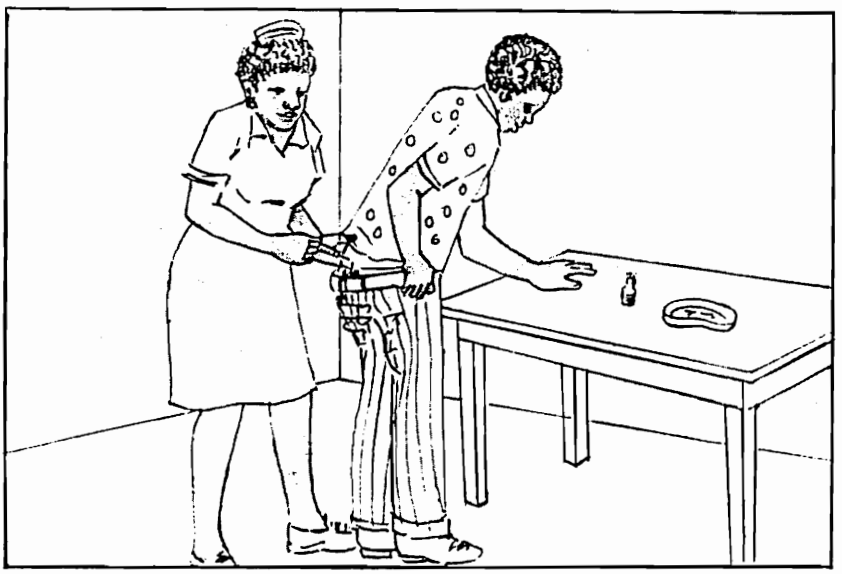
Drug resistance complicates drug selection, particularly for mixed infections where one or both of the diseases is drug resistant. For example, in an infection of both chancroid and syphilis, treating syphilis with penicillin may be ineffective if the strain of chancroid is one that produces penicillinase. Successful treatment in this case may require that chancroid be cured before treatment for syphilis begins.

Regardless of the way in which drug resistance develops, the basic actions health workers may take to slow growth of drug resistant STDs are the same. Limiting the variety of drugs used against a disease is a good way to limit the opportunity for resistance to develop against each of them. The World Health Organization recommends that, once a drug is chosen, only that drug be used as long as it can cure over 90% of cases. If resistance appears in more than 10% of cases, a different drug should be advocated as the first-line treatment. Monitoring treatment outcomes, as is done where protocols are used, facilitates early recognition of a drug resistance problem.

The wide variety of drugs available in many developing countries contributes to drug resistance problems. National legislation instituting essential drugs policies can help limit the number and kinds of drugs available. Even if drug supplies cannot be controlled, national treatment guidelines can be used to promote consistent use of effective doses of carefully selected drugs.

Drug resistance often develops or worsens when treatment regimens are not completed, allowing the hardiest organisms to survive and replicate. Strong health education at the time of treatment about the importance of completing the full course of the drug is essential. Follow-up visits to patients' homes or intensive questioning at return visits can also improve compliance.

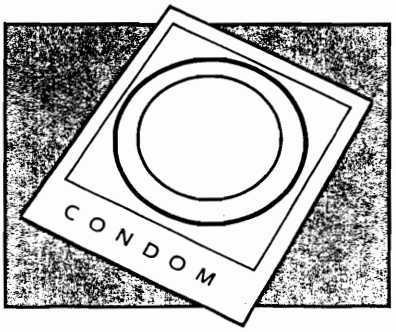
Another way to slow the transmission of drug resistant STDs is to treat all of a patient's contacts. (Contact tracing is discussed more fully on page 10 of the Prevention section.)



Sierra Leone Home Economics Association

Simple pictorial message from booklet promoting condom use and early treatment.

Prevention



Although they have not been used widely, there are several simple, inexpensive, and effective activities and technologies for preventing STDs. Appropriate prevention efforts target STDs that affect many people and have frequent, severe complications. Gonorrhea, syphilis, and chlamydia therefore are considered high priority STDs for prevention in most countries. Where AIDS is present, chancroid also should be a high priority.

If used properly, these prevention activities and technologies can reduce the incidence and severity of the targeted STDs. Prevention efforts reach the most people if they are conducted by national level control programs, but they are valuable when applied by health workers at any level.

One of the best ways to prevent STD transmission is to provide strong health education. At community and individual levels, health education should relay information on STD symptoms and complications, how STDs are spread, how to avoid them, where to get treated, and the importance of informing contacts.

Radio and cinema messages, school education, posters and other print materials, and community presentations by local health workers are good ways to provide STD information to large groups of people. The most appropriate medium will depend upon the targeted groups and available resources. If resources are limited, some feel education efforts should target only the groups at highest risk. Where medicines are widely available without prescriptions, pharmacists and storekeepers also should be targeted.

Individual counselling at health clinics can motivate patients to complete treatment regimens, contact their partners, and adopt behaviors that reduce the risk of acquiring and transmitting STDs. Studies show that having messages delivered by respected persons and repeating them can increase patient compliance.

Condoms, when used correctly and throughout all sexual contact, can prevent genital or rectal STD transmission. A condom's effectiveness, however, greatly depends upon its consistent and correct use. Family planning and fertility clinics should encourage regular and correct use of condoms to prevent the spread of STDs.

Other contraceptives also may affect STD transmission and the severity of STD infection. Diaphragms with spermicide may reduce the risk of acquiring STDs. Intrauterine device (IUD) use increases the likelihood of PID (which is often related to STD infection), primarily during the first three months after insertion. Contraceptive pills may reduce the risk of gonococcal PID by causing formation of thick cervical mucus that may prevent disease from spreading into the uterus. The risk of chlamydial infection, however, may be increased in pill users. (These findings have been questioned, since pill use simply may make chlamydia easier to detect.)

Preventing gonococcal and chlamydial neonatal eye infection is easy and inexpensive and should be a top priority. Crede's method prevents gonococcal eye disease by placing one drop of 1% silver nitrate solution in each of a newborn's eyes.

Because silver nitrate sometimes causes a slight, temporary chemical irritation, many countries have discontinued its use. Without these drops, however, up to 40% of infants of infected mothers acquire eye disease; with them, only 2% are affected. Erythromycin and tetracycline ointments are effective without causing irritation but are more expensive.

Silver nitrate may be administered by hospital staff or by traditional birth attendants. The solution should be stored in small, dark bottles to protect it from light and evaporation, which can alter the chemical and its concentration, thereby increasing the possibility of eye irritation.

Chlamydial eye infection may be prevented with erythromycin or tetracycline ointment placed in newborns' eyes immediately after birth. Some studies have shown silver nitrate to be partially effective against chlamydia. Others

suggest that none of these topical drugs is very effective. Oral erythromycin may be a better, although more expensive, alternative because it also is effective against chlamydial ear, nose, throat, and lung infections.

Improving diagnostic and treatment techniques is another way to reduce the spread of STDs. More appropriate laboratory diagnostics or standardized diagnosis protocols for rural health clinics will help health workers identify STDs more accurately and at earlier stages and correctly treat patients before the disease has spread to many others.

Treatment prevents STD spread if drug regimens are completed and if syringes and needles are adequately sterilized between injections. Patients receiving injections to treat STDs may be at risk of AIDS if syringes and needles are not sterilized.

Finally, tracing and treating patients' sexual contacts and screening high risk groups are very good ways to reduce STD spread. Formal contact tracing, conducted by health personnel or others, is expensive and time consuming. Informal contact tracing relies upon the patient's own motivation for informing partners but is inexpensive and takes little staff time. Although formal methods are more effective, informal methods are more practical for health clinics with limited budgets. Informal methods of contact tracing include asking patients to give referral cards to their sexual contacts. Strong health education efforts and individual counselling also help motivate patients to inform contacts.

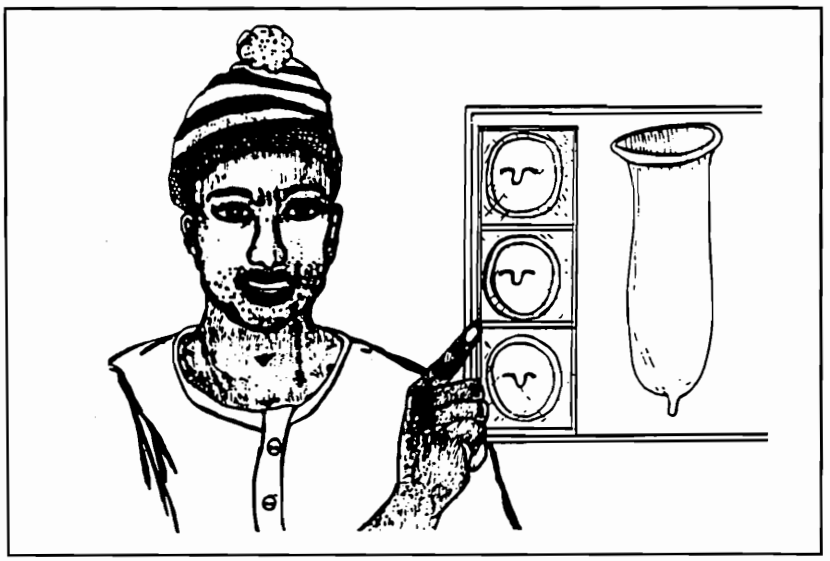
Approaches to treating contacts vary, but if laboratory diagnosis is not feasible and the risk of STD transmission is high every contact should be treated. Clinics should set priorities for treating contacts based upon area-specific disease and complication patterns.

Most places, however, should consider treating any of the following sub-groups in an order consistent with local disease patterns and program targets: symptomatic women, symptomatic men with repeat infections, symptomatic men with first infections, and groups at high risk for infection (such as prostitutes).

Screening selected groups is a cost-effective control measure if the disease prevalence in the group is high, the complications of the disease are severe, and the diagnostic test is not expensive. Screening is only effective if it can detect a significant proportion of existing cases and those cases were likely to be transmitted. Gonorrhea screening by culture, for example, may only be cost effective in groups such as prostitutes. In Singapore, a program screening prostitutes for gonorrhea and syphilis significantly lowered the incidence of both diseases within one year.

Screening pregnant women for syphilis is a highly recommended and effective control strategy. Although syphilis is not as prevalent as other STDs (except in Africa), its complications in this risk group are particularly severe and diagnosis can be done inexpensively at rural clinics using an RPR or TRUST card test. Since Zambia instituted syphilis screening for pregnant women in three study centers, the incidence of miscarriage, newborn death, and congenital syphilis has decreased by more than 50%. Costa Rica reduced its syphilis problem with a comprehensive program including screening, public education, and national reporting of cases.

Several other countries are beginning to address the serious problem of STDs. Ethiopia is planning to initiate a prenatal screening program in Addis Ababa, and the Central African Republic has set up a system of regional STD clinics.



Planned Parenthood Federation of Nigeria

Nigerian health education booklet on condoms.

Program Issues

In addition to a thorough understanding of the technologies, program managers should be aware of the importance of two key aspects of program implementation–collection and use of epidemiological data and training and supervision of personnel.

Useful epidemiological data can be derived from well kept records or small field surveys. Examples of valuable information include the incidence and prevalence of STDs and their complications among specific groups, sensitivity and specificity of diagnostic syndromes and lab tests, number and types of treatments given, and treatment failures.

Present rates and trends over time can guide decisions on patient care and program resource allocation. For example, syndromic protocol development and monitoring depends on sensitivity and specificity measures and the incidence and prevalence of drug resistance.

Changes in the sensitivity of a given protocol (because of an increased incidence of a new disease not present in the area when the protocol was first developed, for example) may signal the need for revisions. Identifying priority groups for screening also requires information about disease incidence and prevalence, the extent and severity of complications in specific groups, and the cost and effectiveness of the screening test. Groups at risk may vary from area to area, so effective targeting of priority groups for provision of services depends on data that accurately represents local disease patterns.

Program resource allocation and impact evaluation also require sound epidemiological data. Knowing the number of cases expected and the amount and nature of treatment needed is essential for program budgeting. Measuring the program's ability to meet its goals is an important management function that calls for basic data collected routinely and systematically. For example, decreases in the rates of treatment failure or in the incidence of congenital syphilis or gonococcal eye disease among newborns can be used as measures of a control program's success.

Training at all levels is critical for STD control programs. All health workers must understand which behaviors facilitate drug resistance and which hinder it. Where syndromic protocols are used, workers need thorough training to be able to recognize consistently the subtle signs of STDs and to proceed through the protocols accurately. Strong record-keeping skills are important for follow-up and appropriate use of second- and third-line treatments. Finally, health workers must recognize the importance of sensitivity, patience, and follow-up in counselling STD patients about changing behaviors to reduce the risk of reinfection and about contact tracing.

Conclusions

STDs are prevalent worldwide and their complications greatly affect the health of men, women, and infants. With AIDS calling attention to the more general problem of STDs, governments and private organizations are beginning to address these serious diseases.

Few diagnostic technologies are feasible for use outside central laboratories, but some techniques, like dark-field microscopy, can be adapted for local use. Where laboratory diagnostics are unavailable, the syndromic approach to diagnosis and treatment can be practical and effective.

Many drugs are effective, but they must be used correctly to avoid drug resistance. National treatment guidelines and essential drugs lists can help slow the spread of resistant STDs.

Health workers can take several highly effective, low-cost steps to prevent STDs. These include health education efforts, promotion of condom use, antenatal syphilis screening, and use of silver nitrate in newborns' eyes.

Appropriate technologies for the diagnosis, treatment, and prevention of STDs are available. Given the feasibility of controlling STDs, it is time for health program managers to recognize the huge impact of STDs and to give serious consideration to the value of programs for their control.

Materials Available

Details on the TRUST and USR serology diagnostic tests (including reagent preparation) and the filter paper blood collection method are available from: The WHO Collaborating Center for Reference and Research in Treponematoses, Building 1, Room 3329, Centers for Disease Control, Atlanta, GA 30333, USA.

□

WHO's Technical Report Series number 736, **WHO Expert Committee on Venereal Diseases and Treponematoses**, discusses the major STDs and STD control methodologies. It costs US$ 5.40 for persons in developing countries. Planning and operating STD control strategies is covered in **Control of Sexually Transmitted Diseases** (US$ 4.20). Contact regional WHO offices or write: WHO, Distribution and Sales Service, 1211 Geneva 27, Switzerland.

The syndromic approach is discussed thoroughly in **Simplified Approaches for STD Control at the PHC Level: Report of a WHO Working Group** (document number WHO/VDT 85-437). Write: WHO, Programme of Sexually Transmitted Diseases, 1211 Geneva 27, Switzerland.

□

Many laboratory diagnostic techniques (including the simple dark-field method) are described in volumes I and II of **Medical Laboratory Manual for Tropical Countries**, by Monica Cheesbrough. For details, write to: Tropical Health Technology, 14 Bevills Close, Doddington, Cambridgeshire PE15 OTT, England.

□

A bibliography on STDs is available from PATH.

INTERCHANGE

Where There is No Doctor: A Village Health Care Handbook for Africa is written and illustrated specifically for Africa. New topics include snake bites, stings, guinea worm disease, skin problems, and sickle cell disease. Copies in French, Portuguese, and many regional African languages are available from Teaching Aids at Low Cost (TALC), P.O. Box 49, St. Albans, Hertfordshire AL1 4AX, England.

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Mediterranean Medical and Healthcare Resources, Ltd. translates and adapts useful books on primary health care and development for use in Arabic-speaking countries. Books like **Helping Mothers to Breast Feed** and **Primary Child Care** are available from them at P.O. Box 7163, Nicosia, Cyprus.

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AHRTAG, the Appropriate Health Resources and Technologies Action Group Ltd., now publishes a Spanish version of **ARI News**, an international bulletin about acute respiratory infections. Write: Grupo CID, **Noticias sobre IRA**, P.O. Box 39256, Washington D.C. 20016, U.S.A.

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health technology
directions

PATH Program for Appropriate Technology in Health

Technology Introduction:
The Safe Birth Example

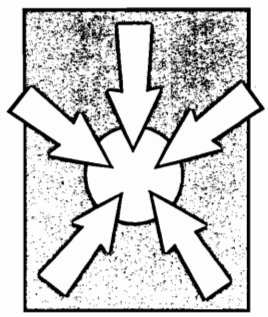
Although giving birth is a natural event in life, all women risk injury and death during pregnancy, labor, delivery, and the post-partum period. Many existing technologies, if used appropriately and widely, could substantially decrease pregnancy-related illness and death. (Two 1984 issues of DIRECTIONS reviewed some of them.) Widespread and effective use of these technologies, however, particularly at the primary care level, depends upon carefully planned introduction programs.

Most maternal deaths and injuries are caused by pre-eclampsia (toxemia), obstructed labor, infection, hemorrhage, anemia, and unsafe abortions. These risks are up to 200 times higher for women in developing countries than in developed countries. Death rates in some areas exceed 1 in 100 pregnancies, and for every death, another 15 women experience injury or illness from pregnancy. Almost all of these deaths and injuries are preventable. Maternal deaths are particularly devastating because they affect women early in their adult lives, depriving their families and society of their care and economic and social contributions.

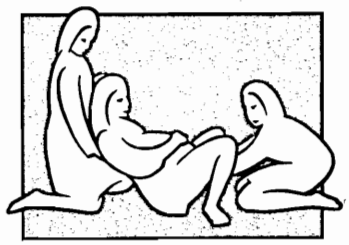
Infants are also at risk. Up to half of all infant deaths occur in the first month of life and are mainly due to birth injuries, tetanus, sexually transmitted infections, and low birthweight (LBW).

In 1987, the World Health Organization issued a resolution calling for increased efforts to improve maternal health. Officials attending the Safe Motherhood Conference in Kenya that same year produced a Call to Action to stimulate activity at all levels to address the tragedy of maternal mortality and morbidity.

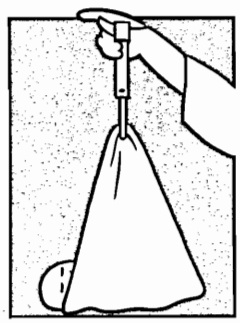
Because well planned introduction programs are essential if people are to benefit from new birth-care technologies, this issue of DIRECTIONS includes a focus on strategies for health technology introduction. It discusses essential components in developing a technology introduction strategy, presents PATH's Safe Birth Program as a case study of the process, and offers an update on pregnancy-related technologies.



Technology Introduction Process



Case Study: PATH's Safe Birth Program



An Update on Safe Birth Technologies

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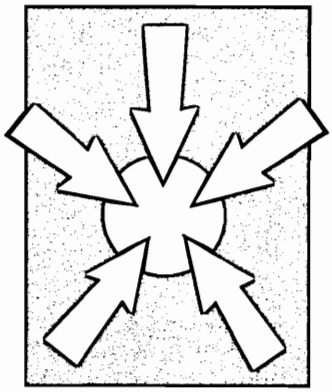
Technology Introduction Process



Technology introduction is the process by which a technology (e.g., a scale, maternal record, or supervision method) is field tested, refined, retested, and introduced into widespread use. Technology introduction can be formal or informal and carried out by public or private groups.

Technology introduction programs are often implemented by groups, but people outside those groups also can facilitate introduction of beneficial, appropriate technologies or delay or prevent adoption of harmful or inappropriate technologies. Anyone involved in technology introduction must, therefore, understand how people decide to adopt or reject a technology, how to design an appropriate technology introduction program, and how the implementer influences the type of approach.

Deciding to Adopt or Reject a Technology

Decision-making processes may seem quite variable, but in fact potential users usually proceed through five steps in deciding about a technology. (Several of the steps, however, may occur at once or out of sequence.) First, the potential users **learn about the technology** (through radio, for example, or word of mouth); then they **form an opinion** about it based upon the new information. If possible, they **try the technology** and then make a tentative adoption or rejection decision. If the decision is to adopt, they **use the technology regularly** and may modify it for personal needs. Finally, **periodic reinforcement** or confirmation of the decision is sought, usually by consulting friends, respected elders, or health clinic staff. In this last stage, even a technology used for years may be rejected, either because a better method is found or because the users become dissatisfied with the technology.

Speedier decisions to adopt are made by people who are open to new ideas or technologies, see a need for the new method, and live in social settings favoring its use. Technologies that are simple, supported by respected and influential community members, and able to be observed and tried without great commitment or cost (financial, psychological, or social) are more easily adopted.

Designing Technology Introduction Programs

A new technology does not exist alone. It is part of (and depends upon) a whole network of people and systems, each of which reacts to changes in any of the other network components. To introduce a new technology smoothly, implementers must design a program that takes into consideration the many ways that the technology and the other network components may interact.

While many components of the network affect and are affected by technology introduction, some play a larger role than others. The most influential are the users, the technology's characteristics, related policy issues, logistical supports, and other repercussions of introducing the technology. (See box, page 3.)

These components should be evaluated with both quantitative (e.g., baseline numerical information) and qualitative (e.g., opinions and beliefs) data. Existing service statistics or new, small surveys provide quantitative data. Existing anthropological research or a series of focus group discussions (FGDs) yield qualitative data. In FGDs, representative members of a user group meet with a facilitator to discuss their beliefs and practices related to the health problem and technology under consideration. (A program in Egypt, for example, revised its policy of referring LBW newborns to health clinics to one of making home visits because mothers were reluctant to take young babies outside, where spirits might harm them.)

Influence of the Implementer

Implementer characteristics (e.g., nationality, funding level, association with government) affect, to varying degrees, the way an introduction program is designed. The implementer's motive in

TECHNOLOGY INTRODUCTION

Understanding user groups—Vital information about actual users, beneficiaries, and influential community members includes: age, education, values, innovativeness, daily activities, social status, work environment, and perceptions of local health and health care.

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Identifying appropriate technology—Appropriate if: safe and reliable; affordable and cost-effective; culturally and politically acceptable; easy to use; locally sustainable; harmless to environment; has measurable impact; and requires minimal changes in time allocation, behavior, or community relations.

+

Revising related policy—Vital, but often overlooked. Examples include changes in import regulations, treatment guidelines or protocols, or resource allocation.

+

Developing logistical support—Includes training, supervision, maintenance, resupply, record-keeping, and evaluation.

+

Anticipating other repercussions—Other areas affected by introduction include: social networks, community structures and interactions, work patterns, expectations, health care seeking behaviors, and resource allocation at all levels.

introducing the technology, for example, strongly influences its strategy design. Commercial groups are primarily motivated by profit, so they concentrate on creating a product that appeals to users who can afford it and on ensuring reliable distribution systems so the product is readily available.

Nonprofit, nongovernmental organizations (NGOs) also want a product to appeal to targeted users, but the users are often those with the most need and not always those most able to pay. Logistics systems must ensure both product availability and effective use. Training, supervision, record-keeping, and evaluation are as important as distribution systems.

Governmental groups may be motivated by economic or political concerns, such as meeting cost constraints or responding to public pressures. These concerns may result in introduction programs that target special user subgroups or that keep the costs of technologies and needed logistical support to a minimum.

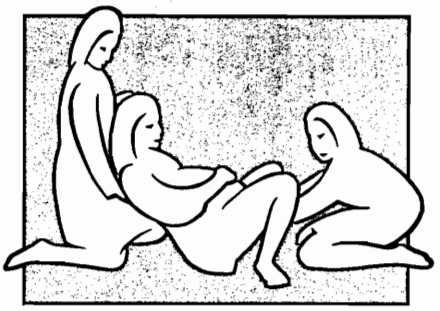
The motives of both nongovernmental and governmental organizations are often influenced by the priorities of international donors, who fund many of their activities. Donor preferences often dictate the users targeted, the technology selected, and the logistics systems emphasized. In these situations, the program that is carried out may not be entirely consistent with the implementer's usual priorities.

Roles for People Outside the Implementing Group

Persons not directly involved in an introduction program can still influence the process in several ways. Education programs can be developed to provide accurate information about the technology to the local users. Support systems that can be influenced locally, such as supervision and record-keeping, can be encouraged and supported. For example, an outreach worker in a malaria project who visits homes in an area where traditional birth attendants (TBAs) are field testing home-based maternal records could reinforce the importance of record-keeping by asking local TBAs to help him or her identify pregnant women with malaria (a factor included on most maternal records). At higher levels, a person can suggest new technologies to introduce, point out needed policy changes, or devise creative solutions to logistical problems, such as unreliable transportation systems.

Whether or not these technology introduction issues are formally considered by implementers (or those outside the implementing group), they have a large influence on the process. Health program managers who understand these issues can make better decisions in introducing appropriate health care technologies.

Case Study: PATH's Safe Birth Program



Because situational characteristics vary greatly, every appropriately developed introduction program should be distinct. PATH's Safe Birth Program is presented as a case study of a technology introduction program.

The Safe Birth Program's primary objective is to improve maternal and newborn health through the use of appropriate technologies at the primary care level. Equally important is the goal of enhancing local capacity for assessing and introducing technologies effectively.

Technologies related to pregnancy, delivery, and newborn care are selected, field tested, refined, and introduced into national programs through the Safe Birth Program. Technology introduction activities emphasize user involvement (usually TBAs) throughout the process; identifying and refining technologies that are technically, culturally, and environmentally appropriate; and solid logistical support systems. Each project begins with a needs assessment to identify local health problems and technology gaps. Field testing includes developing pictorial instructional and data collection materials. After field testing, national recommendations are developed for each technology.

PATH's program began in 1984 and includes project sites in Bangladesh, Malawi, the Yemen Arab Republic, and Zambia. While the projects in Malawi, Yemen, and Zambia have been conducted in collaboration with Ministry of Health TBA training programs, the Bangladesh project and a new project planned for Sierra Leone both involve collaboration with a local NGO. In Bangladesh, where use of TBAs is not very widespread, the project will work directly with mothers as well as TBAs.

Users. Every phase of technology introduction includes thorough consideration of the views of local health personnel, TBAs, and sometimes mothers themselves concerning maternal and newborn health problems and health care needs. To understand users' perspectives, staff in each project collect qualitative and quantitative data. They most commonly review existing data from research studies or service statistics, interview local experts, conduct FGDs, and carry out small surveys.

In the Malawi Safe Birth project, a TBA survey was used to obtain information on TBA practices and perceptions of maternal health problems. In Zambia, FGDs revealed that mothers would fear bewitchment if asked to give urine samples to a TBA in order to diagnose protein in urine. The mothers' fear was addressed by altering the testing method so that the mother holds the cup of urine while the TBA dips the test strip in and then disposes of the urine herself.

Technologies. Three PATH technologies, developed in response to needs expressed in the field, are currently being introduced through the Safe Birth Program. BIRTHweigh* is a handheld, color-coded scale that detects low birthweight (LBW) in newborns. A window on the scale handle shows some yellow if the child weighs less than 2500 grams and only blue if the child weighs more than 2500 grams. (WHO considers 2500 grams to be a useful international LBW cut-off point.) The newborn is weighed in a sling made of sturdy cloth that bears a message or image (selected by users) conveying a sense of protection or good health.

PATHstrips* are dipstrips to detect proteinuria (an indicator of pre-eclampsia and other problems). The strips are dipped in urine and turn from yellow to green to blue with increasing amounts of protein in urine.

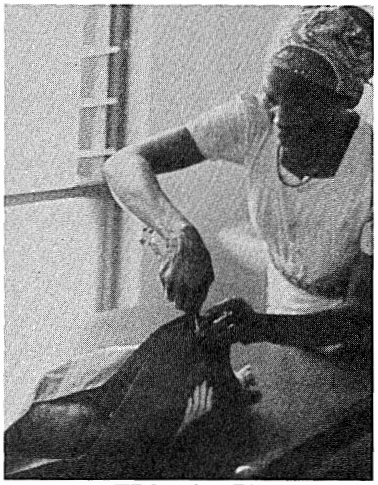
Pictorial record-keeping and referral cards are used by non- or semiliterate TBAs to track antenatal care and to decide if a pregnant woman should be referred to a health center. The illustrations and record forms are created, pretested, and refined in each country based on user feedback. Full user involvement in all stages of developing the forms ensures widespread comprehension and uniform interpretation of information collected.

These technologies fit many of the criteria mentioned earlier.

BIRTHweigh and PATHstrips, for example, are effective, inexpensive, and easy to use. They are culturally and politically acceptable, environmentally harmless, and can be manufactured locally. In fact, the Polytechnic Institute in Malawi is now a regional manufacturer of BIRTHweigh, and efforts are being made to identify an African manufacturer for transfer of the relatively simple PATHstrips technology.

Absolute cost must be fairly low for a technology to be considered feasible for TBA use. BIRTHweigh, for example, is about 1/3 the cost of the next least expensive child growth monitoring scale and can be used for many years. Cost-effectiveness of BIRTHweigh, however, is uncertain because other methods of assessing risk in newborns are not directly comparable. Health benefits of scale use are not yet well documented. Until now, the scales have only been used in small field studies and for limited periods of time, and the value of illnesses prevented or deaths averted by early detection of higher risk infants is difficult to determine. (Two additional technologies, the PATHtimer* for disinfecting instruments and the PATHweigh* electronic weighing scale, may be tested in future projects.)

Related Policy. Effective use of these technologies requires that several policy decisions be made. BIRTHweigh, for example, is ineffective without a policy indicating what TBAs should do when they detect LBW. Should LBW babies be referred to health clinics, receive home visits from clinic staff, or receive special care from



Malawian TBA using BIRTHweigh.

their mothers? If TBAs are asked to record numbers of LBW infants, how will the data be used?

Each project introducing BIRTHweigh has addressed these questions and several different policies have resulted. In Zambia, for example, TBAs refer LBW newborns to the health center. In Yemen, however, home-based care is encouraged, and a pictorial booklet illustrating home care for LBW newborns is being developed for TBAs to use with mothers.

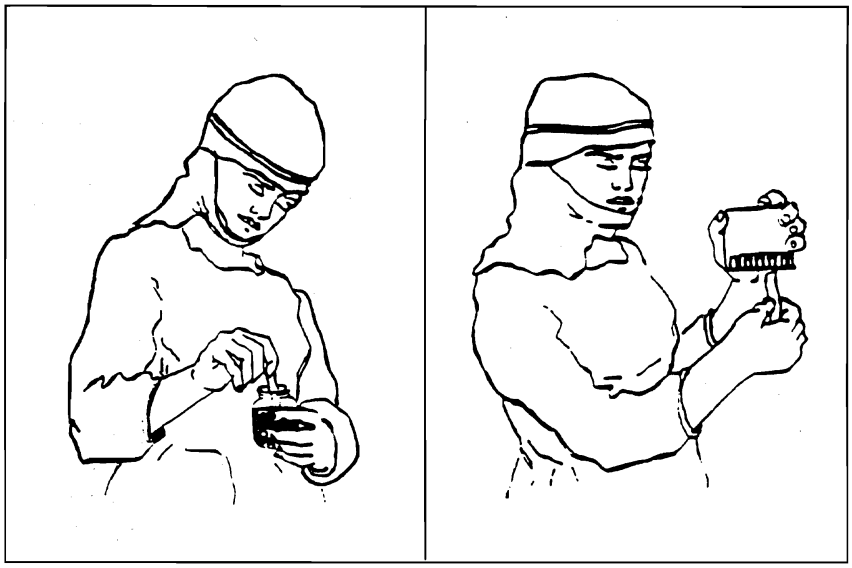
Effective use of pictorial records and referral cards also requires policy decisions. Where will TBAs send women at high risk of complicated delivery? What use will records of antenatal care serve? Will a change in services be possible if information collected from records indicates that change is needed? For example, will adequate facilities be available to care for the increased number of high-risk women being referred? (Policy-makers in Malawi and Yemen may study this issue by looking at changes in referral rates for delivery complications when referral card systems are in use. Results can guide resource allocation.)

Logistics. The Safe Birth Program emphasizes solid logistical support for technology introduction. Training, for example, consists primarily of hands-on experience with BIRTHweigh, PATHstrips, and pictorial records rather than lecture-style classes. Local artists produce pictorial instructional booklets with drawings of women dressed in local clothing using the technologies. Once TBAs have returned to their communities they can use these booklets to recall correct use of the technologies.

Consistent, effective supervision is very important in the Safe Birth projects, especially for data gathering during field trials. It was decided at the start, though, that project needs must fit into existing supervisory systems so that artificial support systems are not created. Structured supervision guidelines used in Safe Birth field trials help reinforce the importance and standardize the content of supervision. Supervisors visit TBAs monthly, reviewing TBA records and recording information from the visits on specially developed monitoring forms. In Malawi, pictorial referral cards, which are sent with clients to the health center and are then returned to TBAs, are the basis for feedback and supervision.

Maintenance and resupply issues are addressed before national introduction begins. In the case of BIRTHweigh, the scales have proven so sturdy that the only maintenance concern is

**BIRTHweigh™ and PATHstrips™ are trademarks and PATHweigh ® and PATHtimer ® are registered trademarks of the Program for Appropriate Technology in Health.*



Two pages from PATHstrips training manual for TBAs in Yemen.

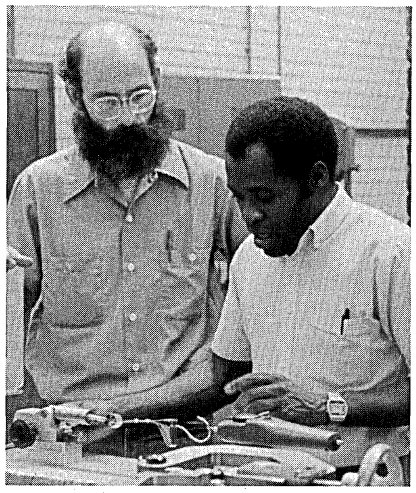
recalibration (estimated to be needed once every four years). Broken scales or orders for new scales will eventually be handled by Malawi's Polytechnic Institute, one manufacturer of the scale. Efforts are underway to provide simple recalibration equipment and training to each project's Ministry of Health. Those Ministries must then develop systems for bringing scales to the recalibration center and returning them to TBAs.

The importance of resupply is well illustrated with dipsticks for proteinuria. No dipstick is reusable, so regular delivery of dipsticks is essential to ensure that all pregnant women are tested. In field trials, TBAs using PATHstrips referred women with proteinuria to health clinics. Clinics, however, often had no dipsticks to confirm the results because the standard dipsticks are expensive and require foreign exchange for purchase. Local or regional production should help solve these problems. In Bangladesh, commercially available disposable delivery kits will be restocked through existing commercial distribution systems. Important questions that remain to be answered there include who will put the kits together, how quality will be assured, and how instructions will be given.

Other Repercussions. Because the Safe Birth Program is relatively new, many of its effects are not yet visible. Planning, implementing, and evaluating the field trials, however, has helped improve program management skills, particularly concerning technology introduction theory and methods. Also, TBAs using BIRTHweigh and PATHstrips in Zambia's field trials found that these technologies attracted pregnant women, thereby increasing TBA case loads and, thus, the number of women seeking help from trained TBAs.

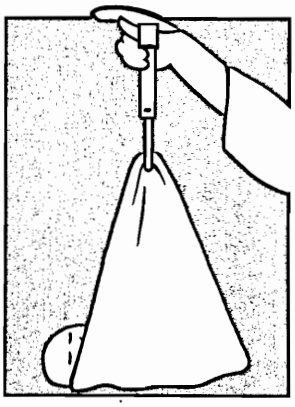
Future effects of longer term use of the technologies may be even more striking. Where pre-eclampsia is detected with PATHstrips, for example, basic community attitudes may have to change to allow for prescribed bed rest (and, therefore, redistribution of household responsibilities) for pre-eclamptic women.

The Safe Birth Program is still in progress and, although much has been accomplished, a great deal remains to be done. Ministries of Health in Safe Birth project countries now are capable of carrying out systematic assessment of new technologies and developing accessory pictorial materials. BIRTHweigh scales are manufactured now at low cost in Malawi and will be introduced nationwide in Malawi, Yemen, and Zambia over the next two years. Field trials of high risk guides are beginning in Malawi and Yemen; future plans include more complete mother's records and community records. Further PATHstrips use is delayed until health center back-up supplies and PATHstrips manufacture issues are resolved. A commercially available delivery kit for mothers is being developed in Bangladesh. Ultimately, the hope is to develop models for and skills in technology assessment and introduction that are applicable far beyond the original project.



BIRTHweigh technology transfer to Malawi's Polytechnic Institute.

An Update on Safe Birth Technologies



This section presents technologies that are new or have been revised since the 1984 issues of DIRECTIONS and that can be used locally to improve antenatal, delivery, or postpartum care. Technologies covered in the 1984 issues are outlined in the box on page 9.

Antenatal Care Technologies

Maternal Records—Maternal records help TBAs identify and refer high-risk women, promote antenatal care, and improve women's understanding of maternal health problems. They also help managers supervise TBAs, prioritize maternal health problems, collect basic health statistics, and evaluate program effects. Where TBA training programs exist, TBAs can be taught to use pictorial forms to record information, such as mothers' pre-existing conditions and care received during pregnancy. Although TBAs may keep the cards, mothers also keep cards quite effectively, particularly if the cards are easily understood by them. When health clinic visits are made, clinics may keep their own records and a "reminder file" that reminds staff when the woman is due for follow-up.

Problems in use include not filling in cards completely at the time of the visit, needing a literate person to help fill in or interpret nonpictorial cards, and not understanding pictorial records. To avoid these problems, TBA records should be pictorial, pretested locally, and short, containing only the most critical risk factors. Pretesting methods (such as FGDs) are vital to help ensure clear, relevant drawings. Plans for using the data collected on the records and for giving the TBA or health worker feedback should be made well in advance.

Risk factors tracked on the cards must be based on local problems. These might include maternal height, fundal height, weight gain, bleeding during pregnancy, blood pressure and/or edema, proteinuria, anemia, STDs, malaria, and other infections. Maternal history should include number of previous births, stillbirths, and early infant deaths; age; and previous Cesarean section and/or obstetric complications. Cards may also record antenatal care, such as tetanus immunization, nutrition education, and provision of iron, folic acid, or antimalarials.

Records should indicate the need for referral. Some cards assign a numerical value to the presence of each risk factor; a high total score dictates referral. (Home-based records, however, should not use these complex kinds of scoring systems.) Others, for example in Malawi, color the spaces where presence of risk factors are checked so that any woman with checks in the colored spaces should be referred.

Anemia—Diagnosis remains difficult in rural areas. Several different hemoglobinometers have been developed, but none has yet proven satisfactory in field trials. Screening by examining the tongue or inner eyelids for paleness is less accurate than blood tests but identifies most women who are severely anemic. Anemiometers (small charts with three colors corresponding to mild, moderate, and severe anemia) are compared with inner eyelids. CHETNA, an Indian organization, developed plastic-coated cards with photos of normal and anemic tongues to compare with mothers' tongues. (See Materials Available, page 12.)

Women with anemia may need iron and folic acid tablets to regain normal iron levels during pregnancy. Increased dietary iron often is sufficient for women with slight iron deficiency. Other dietary practices are also important. For example, the tannin in tea reduces iron absorption while a diet rich in vitamin C enhances iron absorption. Malaria and hookworm infection also contribute to anemia. Where these infections are endemic, prevention (e.g., netting, repellent, home spraying, chemoprophylaxis for malaria; shoes or sandals for hookworm) is important. Some worm medicines are dangerous for the fetus, so any potential drug therapy for hookworm should be thoroughly investigated before it is given to pregnant women. To treat malaria in pregnancy, chloroquine phosphate is safe but pyrimethamine (such as

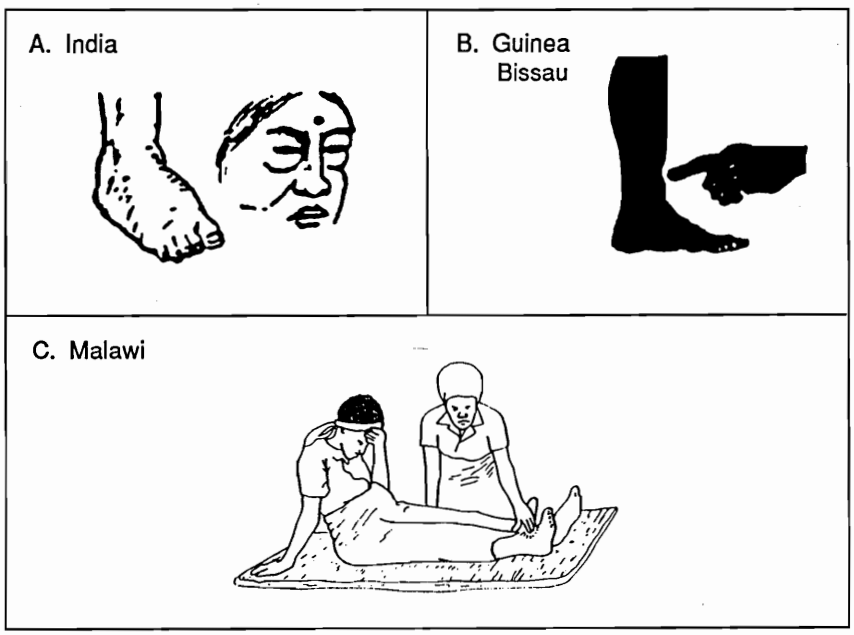
Fansidar or Maloprim) is risky and should only be used when other options are not available. (Pyrimethamine should never be given prophylactically during pregnancy.)

Maternal Stature—A strong, consistent association exists between short height and cephalopelvic disproportion (maternal pelvis small for fetal head size), or CPD. Stature can be determined in several ways. For example, a stick marked with an appropriate cut-off height (1.50 m, 1.48 m, or 1.45 m are most common) can be used in the field, while a mark drawn on a wall is sufficient at the health clinic. (In mud huts, if floors are frequently remudded, the mark must be remeasured periodically to verify its accuracy.)

A substitute stature measure under investigation is a maternal foot box (if the foot does not extend beyond the end of the open-ended box, the mother is at risk). This measure, however, needs further study and should be considered for use only after local trials confirm a CPD association.

Maternal Weight Gain—During pregnancy most women gain weight in locally determined standard increments. Weight gain that differs from normal may reflect problems in the pregnancy. Beam balance scales are reliable but are expensive and bulky. Other scales can be difficult to read and are usually not accurate enough to detect small weight increases. New electronic scales, such as Salter's Electra-Thin, may solve some of these problems, but current models require batteries to run. PATH-weigh, a digital, solar-powered scale in stand-on and hanging models, is being refined and should be available in 1989.

Where scales are unavailable, measuring uterine growth, although less precise, may substitute for weighing mothers. Local standards, however, must be determined. Abdominal girth (distance from the small of the back around the largest part of uterus) and symphysis-fundal height (distance between top of uterus and pubic bone) can be assessed with tape measures or with string with knots tied at points corresponding to the standard measurement for each month of pregnancy. Symphysis-fundal height can also be measured in finger widths from the top of the uterus to the pubic bone (two fingers per month of pregnancy is average). These measures are not useful on a one-time basis unless women can accurately estimate the length of gestation. Where women are seen regularly, though, the periodic measurements can be recorded on charts that indicate appropriate gains over time. These charts (gravidograms) indicate need for referral.



Examples of edema symbols from maternal records.

Tropical Doctor (B)

Pre-eclampsia—Several tests for detecting proteinuria (a pre-eclampsia indicator) exist, but most are too expensive or impractical for community use. Edema of the ankles, hands, and face is therefore commonly used to diagnose pre-eclampsia. (WHO studies show that edema is only a good predictor of pre-eclampsia where overall prevalence of pre-eclampsia is high.) PATHstrips, an inexpensive dipstick for detecting protein in urine, have been used successfully by TBAs in the field (described in the Case Study). In some countries, TBAs test urine by adding acetic acid (or lemon juice), heating it, and looking for cloudiness in the urine; interpretation, however, is difficult.

Delivery Care Technologies

Delivery Kits—Locally produced delivery kits are gaining favor in developing countries. Resupply

of expendable items must be arranged, and kit contents should be tailored to the users. Kits sold to mothers, for example, should contain only items needed for normal home deliveries.

Basic kits should contain items for clean hands, clean cord care, clean delivery surface, and neonatal warmth. These items typically are soap and nail-cleaning sticks (clean hands); razor blade, boiled and sun-dried cotton ties, and cotton balls (clean cord care); a plastic or cloth sheet (clean delivery surface); and a cloth towel or blanket (newborn warmth). Exact contents depend upon local traditions and locally available items. For example, a woman's family may be expected to provide a new razor blade as part of the TBA fees; fresh banana leaves or clean flour sacks may be used for a clean delivery surface.

Because these items (or comparable substitutes) are generally available, kits can be put together locally by women's organizations or by TBAs. They may be distributed through health clinics or commercial outlets (pharmacies or stores) to TBAs or directly to mothers.

Disinfection—Delivery instruments should be disinfected by placing them in boiling water for 20 minutes. Few TBAs, however, can accurately determine when 20 minutes have passed. PATHtimer is a reusable, plastic device that is placed in the water along with the instruments and turns blue-green when water has boiled sufficiently to disinfect the instruments.

Obstructed Labor—Unfortunately, referral remains the main option at the local level for dealing with obstructed labor. Health clinic staff in several African countries use laborgraphs (or partographs) to prevent prolonged and obstructed labor and delayed referral. The laborgraph shows cervical dilatation on the vertical axis and time on the horizontal axis. (Stages of the descent of the baby's head are also included in some laborgraphs.) Two vaginal exams are required, the second performed four hours after the first. If the cervix has not dilated at least 4 cm (1 cm per hour) the woman should be referred. To avoid infection, very clean hands or gloves are critical. The ability to monitor time is also essential. (For WHO prototype laborgraphs, see the Materials Available section, page 12.)

External cephalic version (ECV), the external, manual turning of a breech or transverse fetus, may be valuable in the antenatal period to prevent obstructed labor and avoid the dangers of Cesarean delivery, particularly where ECV or regular external uterine massage are traditional skills of local TBAs. Where these skills are not traditional, however, the tradeoff between the benefits of a gently and skillfully performed ECV and the dangers of a forceful, poorly performed ECV must be carefully considered before initiating training.

Symphysiotomy (separating the pubic bone at the central cartilage to enlarge pelvic space for vaginal delivery) is gaining renewed interest for use in health clinics and hospitals. It provides an alternative to Cesarean section for women with mild or moderate CPD for whom squatting positions and adequate hydration and nourishment do not sufficiently widen the birth canal. Blood transfusions are not required, and subsequent deliveries can be vaginal without increased risk of uterine rupture. However, skill, strict adherence to procedure guidelines, and maternal nourishment are required for good results. Bed rest for two or three days and, in some cases, binding the legs together for 48 hours after the procedure are

"PREGNANCY CARE" AND "SAFE BIRTH" ISSUES

Pregnancy Care:

Basic antenatal care needs of all women: tetanus immunization; education about nutrition, hygiene, and rest; and signs of potential danger. **Risk factor assessment**: checklists and scoring systems. **Signs of immediate danger to pregnant women**: eclampsia, anemia, malaria, sexually transmitted diseases, and fetal growth abnormalities. **Management issues**: setting intervention priorities, developing local strategies, training and supervising workers, maintaining records, and providing support materials.

Safe Birth:

Delivery kit contents: drugs, disinfecting equipment, specialized instruments, and labor timers. **Maternal records. Training and educational support materials. Program management issues**: logistics, referral procedures, and training and supervision.

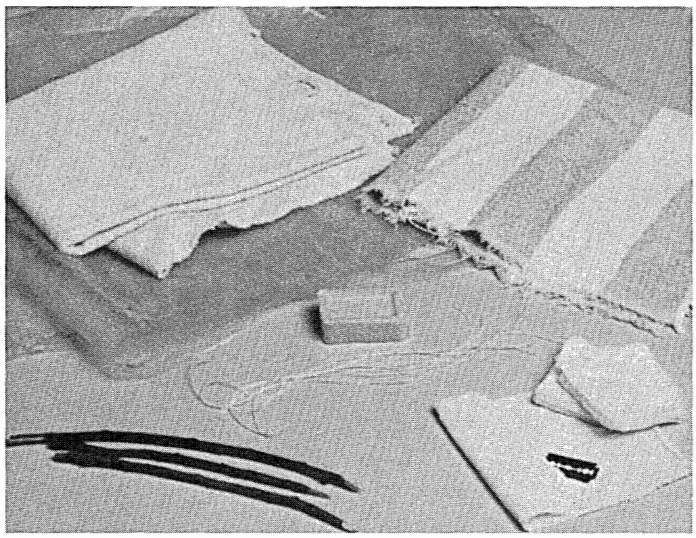
required for cartilage to mend. Incorrectly performed procedures may leave some women walking with pain and a slight "waddle."

Postpartum Technologies

Hemorrhage—TBAs should refer women hemorrhaging from retained placenta or placental fragments immediately, before the uterus completely contracts. Midwives, however, may be trained to remove the placenta manually and administer antibiotics to prevent infection.

If the placenta has been removed but the woman continues bleeding, several steps may be taken. Immediate breastfeeding or manual stimulation of the mother's nipples can cause uterine contractions. Administering oxytocin, ergometrine, or some native drugs, such as teas or bark (for chewing), can be very effective. (While health workers or midwives usually administer these drugs, a program in Somalia successfully trained TBAs to give ergometrine tablets, using specific protocols, to women with or at risk for post-partum hemorrhage.) If bleeding continues, bi-manual external uterine compression can be performed. Bi-manual internal compression should be the last resort, because the risks of infection and trauma are high.

Low birthweight (LBW)—Many technologies can detect LBW, a risk factor for newborn illness and death. The BIRTHweigh scale for newborns, an inexpensive color-coded device for TBAs, is described in more detail in the Case Study section. Hanging spring scales can be marked with colored tape, so that nonliterate users can determine infants at risk. Chest circumference is a valid birthweight substitute, but cutoffs must be determined locally. (Most, however, will be around 29 or 30 cm.) Middle upper-arm circumference, or MUAC, is less useful because it is difficult to measure accurately. Although many groups use color-coded measuring tapes, an Indian group successfully assessed MUAC by passing a bangle of 7.5 cm diameter (corresponding to 2000 g birthweight) up the arm. If the bangle passed to the middle arm without force, the child was considered LBW. Use of newborn foot length, measured with a foot box (similar to that for mothers) or from a foot print (suggested cutoff around 6.5 cm), is still undergoing research.



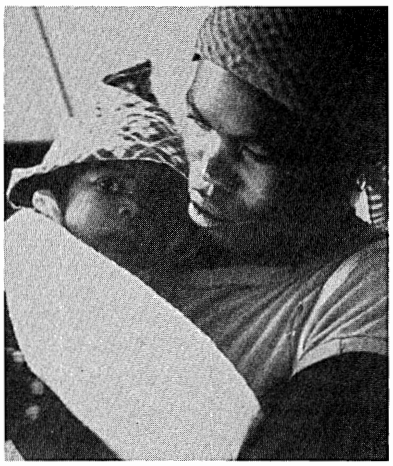
WHO

Basic delivery kit contents.

STDs—TBAs can give silver nitrate drops to prevent gonococcal (and some chlamydial) eye infection or erythromycin or tetracycline ointment to prevent both infections. Single-dose application systems (to ensure correct concentrations and doses) under development include PATH's prefilled plastic device that is squeezed to empty.

Newborn warmth—Heat regulation is inadequate in the first month of life, particularly in premature or LBW infants, so a newborn's environment must provide the necessary warmth. At birth, babies should be wiped dry, not washed, and then wrapped in blankets. Putting on warm hats, holding newborns close to the body, and keeping them out of breezes also help. Carrying premature or LBW infants in an upright position under the mother's clothes against her chest is an excellent way to maintain warmth.

Contraception—Women who have just delivered (particularly those for whom another pregnancy is dangerous) should be encouraged to breastfeed and to use contraceptives to space or prevent subsequent births. Combined estrogen-progestin pills may inhibit breast milk formation and generally should not be used by nursing mothers. Progestin-only pills, injectables, IUDs, and sterilization do not affect milk supply and are suitable for postpartum use.



WHO, by Jean Mohr

Hats help keep babies warm.

Management Technologies

Referral Systems—Many systems exist for referring women to clinics. TBAs may be given different colored referral slips to send with women. (Color represents reason for referral.) More durable, locally available devices also could be used (e.g., pieces of plastic or metal). In the Sudan, runners are sent to health clinics with colored tokens (red for hemorrhage, green for labor delay, and white for malpresentation); clinic staff then bring appropriate supplies to the village. Home-based maternal records could replace these devices and provide more information to clinic staff. Alternatively, a nurse might visit periodically to see women selected by the TBA.

Transportation—The great distance between most women's homes and health clinics is a problem when deliveries become complicated and outside assistance is required. Many communities have developed "ambulance" systems consisting of strong men who can transport women (or others) on their backs or on stretchers to clinics or hospitals in emergencies. In some areas, two-way radios can be used to get advice or call for assistance. Even homing pigeons can be trained to fly to health clinics with emergency messages strapped to their feet. Where clinics have vehicles, a runner can go to the clinic to request that the vehicle pick up the woman, who may also need to be carried to the road. A flag can be placed at the road to stop passing vehicles to transport women to the clinic or hospital.

Some communities have built waiting centers, small buildings near the clinic or hospital where pregnant women at high risk of complications can stay with a family member or TBA shortly before expected delivery. Many centers also provide daily or weekly examinations.

Supervision—The quality of supervisory visits is more important than the quantity. Nonetheless, the first visit should generally be within a month after a new technology has been introduced or training has been given, with later visits spaced further apart. Both individual visits and group meetings can be used for supervision. If supervisors cannot travel to the users' sites, users may be invited to clinics. Visits can also occur when new supplies (such as delivery kit contents) are needed.

Before visits, supervisors should review program objectives, previous supervision notes, and potential obstacles to effective use that may be encountered and make a checklist of things to observe and ask. For example, during visits supervisors should: observe the TBA using (or demonstrating use of) the technology, ask what is done in the event of malfunction or if a diagnosis requires action, inspect the technology for disrepair, review TBA records, meet with other users and local leaders, solicit feedback, and give in-service training.

Conclusions

Pregnancy and delivery are critical and potentially dangerous times in the lives of women and their families. The vast majority of births occur at the primary care level of the health system. Correctly used appropriate technologies could greatly reduce risks to mothers and their newborns.

Health program managers who understand the technology assessment and introduction process are better able to determine which technologies fit local needs and how best to encourage their appropriate use. Based on PATH's experience in the Safe Birth Program, active participation of the users in the entire process, systematic field testing of the technology, and careful attention to how the technology interacts with health care and social systems yield the best results.

TBAs, health workers, and mothers recognize the urgent need for safer pregnancies and births. Innovative technologies and procedures and new ways of using existing technologies are tools that can help them make these essential improvements.

Materials Available

Management of Obstetric Emergencies in a Health Centre, by Dr. B. Essex, is an excellent manual for midwives that outlines the management of 15 obstetric problems and answers practical questions. For information, write: Churchill Livingstone, Robert Stevenson House, 1-3 Baxter's Place, Leith Walk, Edinburgh EH1 3AF, U.K.

□

The Maternal and Child Health Unit of the World Health Organization has several good publications that are free to developing countries. **Guidelines for Introducing Simple Delivery Kits at the Community Level** (MCH/87.4) outlines steps for producing and introducing delivery kits. A manual on laborgraph use is also available. A prototype home-based maternal record card with guidelines for local adaptation and a revised version of **Essential Obstetric Functions at the First Referral Level** will be ready in 1989. Write to: MCH Unit, WHO, 1211 Geneva 27, SWITZERLAND.

□

The "Anemia and Women's Health Kit" includes plastic-coated anemia detection cards, a training manual, posters, and a flip chart. For price information, write: CHETNA, Drive-in Cinema Building, 2nd Floor, Thaltej Road, Ahmedabad-038 054, INDIA (Telex: 121618 RASA IN).

□

A bibliography on technology introduction and safe birth technologies is available from PATH.

INTERCHANGE

Practical suggestions for community involvement in program evaluation are contained in **Partners in Evaluation: Evaluating development and community programmes with participants**, by Marie-Thèrése Feuerstein. Write: Teaching Aids at Low Cost (TALC), P.O. Box 49, St. Albans, Hertfordshire, AL1 4AX, U.K. (Cost: £1.50.)

■

Where There Is No Doctor: A Village Health Care Handbook for Africa, listed in the last issue of **DIRECTIONS**, is NOT available in French. It is, however, available in Portuguese and English from TALC (address above).

■

On Being In Charge: A guide for middle-level management in primary health care is an excellent resource book with practical techniques and suggestions for improved management. It is available to developing countries at reduced rates from WHO Regional Offices or WHO, Distribution and Sales Service, 1211 Geneva 27, SWITZERLAND.

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health technology
directions

PATH Program for Appropriate Technology in Health

Skin Diseases

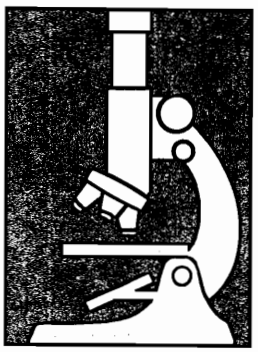
Skin diseases are among the most common health problems in every country in the world. However, the most disfiguring and disabling skin diseases (infections caused by bacteria, fungi, or parasites) are more common and severe in tropical climates, particularly among young children and people in poor living conditions. Community studies in Peru, Chad, and Afghanistan, for example, show that skin disease prevalence rates approaching 80% are not uncommon. Studies in Botswana and Tanzania show that up to 60% of health clinic visits are skin disease related.

Skin infections may develop progressively or appear suddenly. Some begin where insect bites, small cuts, or other skin surface breaks occur and progress to pus-filled infections or open ulcers. Others develop from parasitic lesions that are scratched open or from fungal infections that cause deep tissue destruction. Some bacterial infections lead to severe systemic infection, such as blood poisoning and heart and kidney disease.

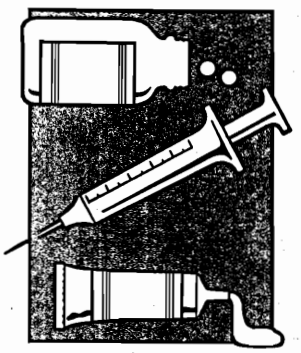
People with skin diseases often suffer not only physical discomfort but also the social embarrassment of having diseases that are stigmas in many cultures. Even diseases that occur on unexposed skin surfaces can cause the patient embarrassment when health care workers must examine the lesions.

The vast problem of skin diseases, however, can be addressed economically and effectively with existing appropriate technologies. For example, village health workers can be trained to recognize skin infections and treat them with inexpensive, locally available drugs.

Skin infections receive relatively little attention in developing countries and among international agencies. This is despite the fact that skin infections are widely prevalent, can have serious physical and social effects, and are simple and inexpensive to diagnose, treat, and prevent. This issue of DIRECTIONS explores technologies available to address the problem of skin diseases.



Diagnosis



Treatment

Prevention

Volume 8, Number 3 ISSN: 0730-8620 1988

Bacterial Infections. The most common and potentially harmful skin diseases are due to bacteria. Two, *Staphylococcus aureus* and *Streptococcus pyogenes*, alone or in combination, cause most pyogenic (pus-causing) bacterial skin infections in developing countries.

These bacteria cause a variety of diseases. Pyodermas, for example, are acute, pus-filled infections. Two common pyodermas are boils (pus-filled sacks under the skin) and impetigo. Impetigo is a contagious disease common in children in which yellow, shiny, crusted sores appear primarily on the face.

Any local bacterial infection is serious because it can spread throughout the body. Streptococcal infections are particularly dangerous because they can cause rheumatic heart disease, septicemia (blood poisoning), gangrene, or glomerulonephritis, which can lead to kidney failure and death. The main signs of spreading bacterial infections are increased pain, swelling, and red lines near the infection site; swollen, tender regional lymph nodes; and fever.

Bacteria cause disease directly or indirectly. Boils, for example, are caused by direct bacterial infection of healthy skin. Other bacterial infections, such as impetigo and chronic ulcers, are complications of existing skin disorders, such as insect bites, cuts, or dried and cracked skin.

Fungal Infections. Many fungi, including some yeasts, can cause superficial or deep infections; most are very contagious. Superficial infections (generally called ringworm) are common and occur in hair, nails, or external skin layers. Hot, humid climates favor fungi growth; in such conditions multiple fungal infections in one person are common.

Superficial infections of the body or groin are the most common fungal infections in developing countries, especially in adult males. Children under age ten with body infections often have scalp infections as well. Scalp infections have three forms; all may leave bald spots. The dry patch type appears as few, large, round patches that heal spontaneously during puberty, or many, small, irregularly shaped patches that require treatment. The wet, inflamed, sometimes pus-filled type is often acquired from soil or animals. The third type is favus, a lifelong disease in which red, scaly patches progress to large, yellow crusts that cover most of the scalp, leaving permanent scars and a few isolated hairs.

Most superficial infections are reddish, flat, ring-shaped lesions that are dry and scaly, but some are moist and crusted, especially at the edges. Light colored patches or normal skin surrounded by active lesions are common.

Deep infections, due to a different group of fungi, may cause disability or even death. Chronic and slowly progressing, these diseases show few broad symptoms until spreading from the primary infection. This is usually a cut or other skin opening, but is sometimes a lung infection. Diagnosis is complicated by the unique geographic distribution of each disease and the need to identify the precise fungus through culture.

Candida albicans, the most common yeast fungus, can cause both superficial and deep infections. Many of these occur internally, in the gastrointestinal tract and mucous membranes of the mouth and vagina. Candidiasis also affects skin folds, causing intertrigo, a red, oozing lesion with a white, soggy center and scaly border.

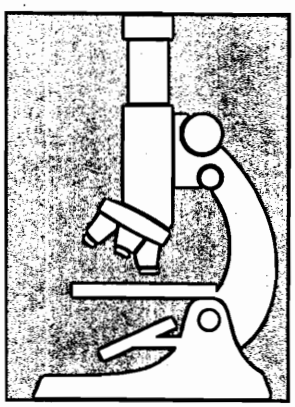
Parasitic Infections. Scabies, caused by the mite *Sarcoptes scabiei*, is the most common parasitic skin infection in developing countries and is highly contagious. It is spread by contact with an infected person (passed, for example, between those sharing a bed or between mother and child) or, less commonly, by contact with recently used blankets or clothing of an infected person.

After mating, the female mite burrows into the outer layer of skin and lays eggs for one month before dying. Young mites hatch and mature within 15 days, then mate and either reinfect the same individual or infect others.

Scabies appears as short, thread-like burrows ending in small, pointed elevations that itch severely, especially at night. The first infection, however, is often asymptomatic. In adults, the face is rarely involved, but fingers, wrists, trunk, thighs, and ankles may all be affected. In infants, infection frequently occurs on the face, palms, and soles of the feet.

Pediculosis, or lice infection, can affect the head, body, or pubic areas. The lice bite the skin, causing severe itching. They lay visible, tiny, white eggs called nits on hair shafts (head and pubic lice). Body lice are especially dangerous because they can transmit the organisms that cause typhus and relapsing fever.

Diagnosis



Most skin diseases can be diagnosed without laboratory tests simply by conducting a careful visual examination of the skin surfaces and lesions. Where observation is insufficient for diagnosis, however, laboratory testing using microscopy or culture often provides enough information for treatment decisions.

Observation

The physical appearance of the lesion can provide valuable information to the examiner. Where other technologies are unavailable, physical appearance may be the only information the examiner has for diagnosing and treating the infection.

A good method for guiding health workers in diagnosis and for standardizing treatment is to develop a national or district level "syndromic protocol" for skin diseases, similar to that advocated for sexually transmitted diseases (see DIRECTIONS, vol. 8, no. 1). In syndromic protocols, treatment choices are made based upon the presence or absence of certain key symptoms. Secondary treatments are given for use should the primary treatment fail. Protocols are developed based on the epidemiological distribution of specific diseases within a given geographic area, so they should be adapted for each area in which they are used. (See sample protocol, page 4.)

Whether or not a syndromic protocol is used, the initial examination of a patient should be thorough and methodical and should be carried out in good light to avoid overlooking subtle but important symptoms on the skin surface. Specialized training for health workers who conduct such examinations is essential. Effective training utilizes observation of actual patients and good color photos of common skin diseases.

To diagnose a skin disease by observation, health workers should try to obtain answers to the following questions:

1) **Where are the lesions?** Impetigo most commonly occurs on the face, but scabies is rarely found there.

2) **How big are the lesions and how many are there?** Many small lesions suggest scabies; few bigger lesions suggest ringworm.

3) **Are the lesions symmetrical?** Scabies lesions appear in similar patterns on the right and left sides of the body; impetigo is different on each side.

4) **What shape are the lesions?** Most are round, but a few, such as some types of fungal scalp infections, are irregular.

5) **What color are the lesions?** Most are reddish or darker than surrounding skin. Some ringworm lesions, though, are lighter than the surrounding skin.

6) **Are the lesions flat or raised, solid or fluid-filled?** Lesions often change from one type to another. For example, boils may be raised and fluid-filled at first but become flat when pus drains out.

7) **Are the lesions dry or wet?** Impetigo is wet beneath the crusts; fungal infections are usually dry.

8) **How do the lesions' borders appear?** Borders of impetigo are flat; those of some chronic ulcers may be hardened and cord-like.

9) **Do the lesions itch?** Lice and scabies itch terribly, especially at night; boils don't itch.

10) **How fast have the lesions developed?** Impetigo develops within a few days; fungus infections may take weeks.

IF THE SKIN HAS:	AND LOOKS LIKE:	YOU MAY HAVE:
small or pimple-like sores	Tiny bumps or sores with much itching—first between fingers, on the wrists, or the waist.	scabies
	Pimples or sores with pus or inflammation, often from scratching insect bites. May cause swollen lymph nodes.	infection from bacteria
	Irregular, spreading sores with shiny, yellow crusts.	impetigo (bacterial infection)

Sample guide for identifying skin diseases by observation.

Where There Is No Doctor

For most diseases, answers to these questions provide a fairly accurate diagnosis, particularly if comparison with photographs is possible. For some fungal diseases, diagnosis by observation can be improved with the use of Wood's light. Wood's light is a hand-held tool that produces ultraviolet light rays which, when held over affected areas in a dark room, cause the lesions of some diseases to fluoresce specific colors.

For example, the fungi causing dry patch scalp infections can be distinguished with Wood's light. Those causing few, large, round patches fluoresce pale green under Wood's light, whereas favus fluoresces dull green, and fungi that cause many, small, irregular patches do not fluoresce at all. Unfortunately, Wood's light requires electricity or batteries and is generally too expensive for use in peripheral health units.

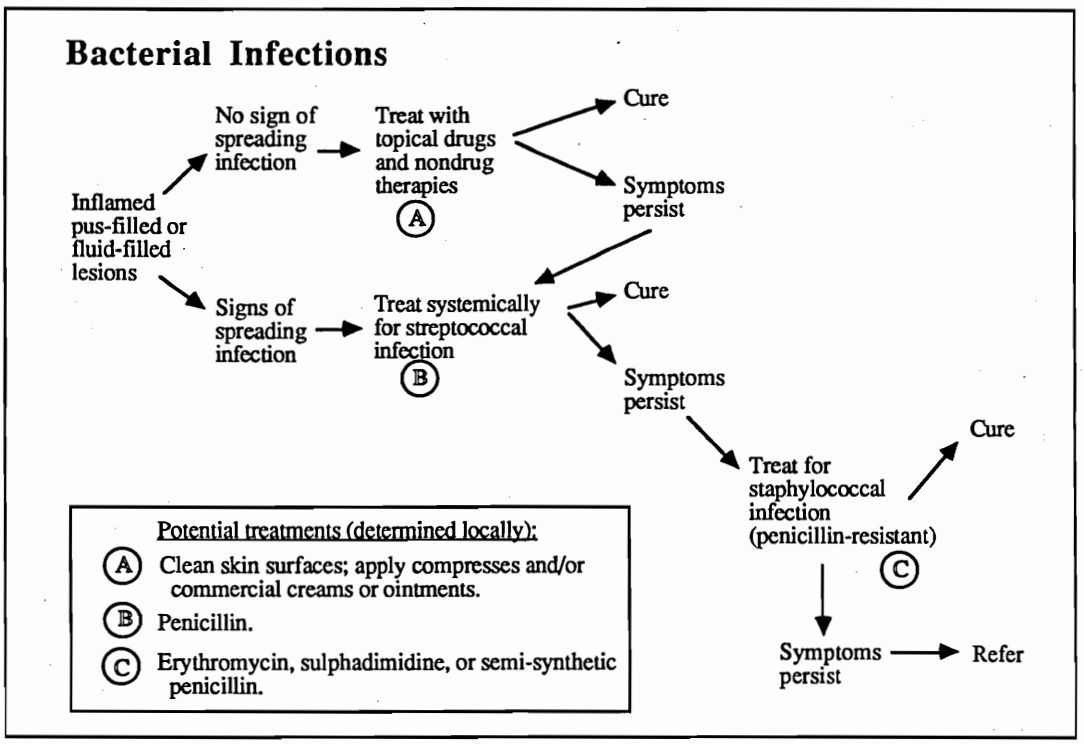
With lice, the actual parasite or its eggs are visible to the naked eye. Clothing and the affected body parts should be searched thoroughly for the lice or nits, either of which confirms lice infestation.

Laboratory Diagnosis

When observation does not provide a diagnosis and where diagnosis by microscope or culture is possible, skin specimens from the affected areas should be examined to determine the infecting organism. Skin specimens, however, must be obtained carefully to maximize the chances of detecting the organism. For example, the crusts of sores that may be impetigo should be soaked off (without antiseptics) and a sample swabbed from the fluid below the crusts. The top of a boil or abscess should be cleaned carefully with alcohol or iodine, if possible, and cut open with a sterile scalpel or razor blade; pus should be removed with a swab.

The surface of a suspected scabies burrow that is not scratched open should be scraped with a plastic knife, sterile scalpel, or razor blade to remove the top skin without drawing blood. This is done to pick up the mite or fecal pellets (scybala), either of which is diagnostic of scabies. A drop of mineral oil on the scalpel and burrow can improve results.

The active portions of suspected fungal lesions (usually the edges of flat lesions or the tops of bump-like lesions) should be scraped with a blunt plastic knife or scalpel held at a right angle to the skin surface. Fungal specimens that must be transported to a central laboratory should be collected on a piece of paper (dark paper is better) that is then folded and secured. Ringworm spores do not dry out easily, and



Sample syndromic protocol for bacterial infections.

this method helps avoid the excess humidity and bacterial growth that transport in a screw-cap bottle can promote. Spores kept dry in folded paper can survive several weeks or longer.

Microscopy. Microscopic examination is often used to confirm a preliminary diagnosis based on observation. Bacterial infections usually can be detected microscopically with a simple Gram stain. Staphylococcal and streptococcal organisms, however, sometimes appear too similar to distinguish, even when the Gram stain is repeated several times. If definitive differentiation is important, the organism first must be isolated on a culture. The growth is then scraped from the culture medium with a wooden stick or glass rod and placed in a test tube with hydrogen peroxide. Staphylococcal organisms cause the hydrogen peroxide to bubble, while streptococcal organisms do not. False positive results may occur if the hydrogen peroxide is not shaken first to remove dissolved oxygen, or if nichrome wire loops are used to scrape the growth from the culture.

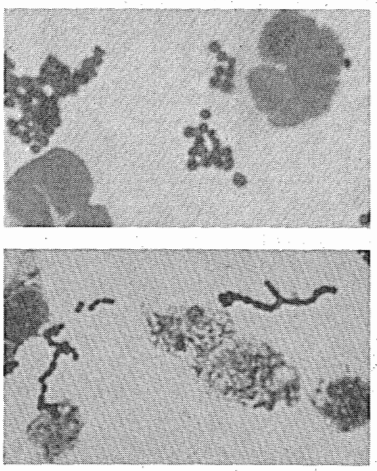
Superficial, candidal, and deep fungal infections can be diagnosed microscopically by placing scrapings taken from the edges of expanding lesions or tops of small, blister-like lesions on a slide with 20% potassium hydroxide. Gentle warming facilitates dissolving of nonfungal parts of the specimen so that the hyphae (branching filaments) and sometimes the spores of the fungi become visible. Low microscope light should be used.

The scabies mite is readily identified from skin scrapings viewed under low magnification. Clusters of fecal pellets are better seen under higher magnification.

The scabies mite may also be identified by the "plastic box" method. Skin scrapings are placed in a dark colored plastic box or petri dish and left at room temperature for 12 to 24 hours. The mites separate from the scrapings, dropping to the bottom of the box or dish. They can be seen through a low power (9x) magnifying glass or a dissecting microscope as slowly moving white spots.

Finally, where centrifuges are available, the skin scrapings may be mixed in a beaker or small test tube with 10% potassium hydroxide and heated gently. The warmed mixture is then added to a saturated sugar solution in a centrifuge tube and spun. The surface solution that results is examined on a slide under a microscope. This method yields particularly good results because it concentrates the mites and eggs from the specimen in the top portion of solution.

Culture. The most definitive means of diagnosing both bacterial and fungal infections is by culture. Unfortunately, diagnosis with cultures requires regular supplies of culture media, electricity and ovens or incubators for growing cultures at constant temperatures, and sterile and heat-stable transport media. Trained technicians and reliable follow-up systems to ensure that results are incorporated into the treatment strategy are also essential. In some areas, for example, contacting a patient three weeks after a specimen is taken may be difficult, so health workers usually treat the patient immediately and give instructions to return for a secondary treatment if the disease persists.



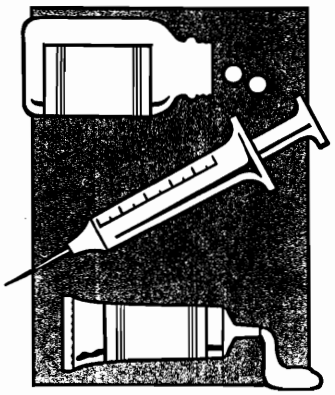
Tropical Health Technology

Clumped staphylococcal and linear streptococcal organisms in Gram stained smears.

Where cultures are possible, however, they are useful for both bacterial and fungal infections. For bacterial infections, they can be used to differentiate staphylococcal from streptococcal infections as well as to determine which antibiotic will be most effective against the specific infecting organism. Virtually any of the common media will grow the staphylococcal organism, while blood-, serum-, or glucose-rich media work best for streptococcal organisms.

The exact organism responsible for a ringworm infection can be identified by its characteristic appearance when grown in cornmeal agar, Sabouraud's dextrose agar, or a malt extract agar with cycloheximide and chloramphenicol added. For detecting candidiasis organisms, Sabouraud's dextrose agar is preferred. While some fungi grow immediately, others take up to four weeks, so cultures with no growth can only be considered negative after that length of time.

Treatment



Treatment of skin diseases may involve topical ointments, creams, or lotions (some can be made locally); systemic drugs; or simple, nondrug therapies. Several drugs are available for treatment, but the widespread lack of diagnostic equipment makes selecting the correct drug difficult. Inappropriate drugs can allow further growth of the infection, leave substantial scars, and contribute to drug resistance, a large problem with some diseases.

Drug Resistance

Selecting drugs for treating bacterial skin infections is difficult because in many areas *Staphylococcus aureus* has acquired resistance to penicillin and other drugs. Treatment, therefore, must be determined with careful consideration of local resistance patterns. Where penicillin resistance is prevalent, patients with bacterial infections should be treated cautiously and monitored closely.

Where possible, health workers should monitor drug resistance in their areas and share that information with their fellow workers and with district, regional, and national level institutions that monitor drug resistance. Data from good records can help slow further development of resistance and reduce wasteful use of ineffective drugs.

Topical Treatments

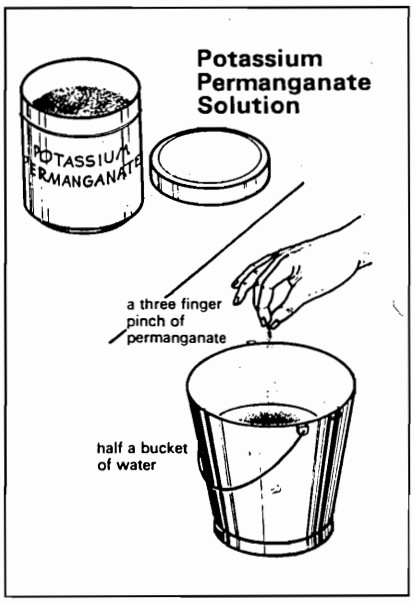
Bacterial, fungal, and parasitic infections can be treated entirely or in part with medicated ointments, creams, lotions, or shampoos. The major rules of topical therapy are: 1) If the lesion is wet, treat it with a wet dressing; if the lesion is dry, treat it with a salve or ointment; if the lesion itches, oozes, or stings, treat it with cold compresses; if the lesion is hot, elevate it and treat it with hot compresses; 2) Skin lesion types can change quickly--change the treatment with the lesion; 3) Begin with the least potent therapy and work up as needed; and 4) Give careful instructions to the patient.

Minor bacterial infections may be treated solely with commercially available or locally made topical medications, while more severe infections usually require systemic antibiotics or a combination of topical and systemic therapies. Because many bacterial infections are staphylococcal, however, penicillin-based ointments should be avoided.

Appropriate commercial drugs for topical treatment of bacterial infections include neomycin, bacitracin, triple antibiotic (generic form of Polysporin and Neosporin), Betadine (povidone-iodine), gentian violet, and potassium permanganate solution (one part potassium permanganate per 5,000-10,000 parts water). Most of these will be relatively inexpensive and generally available. The latter two, however, leave a temporary purple stain on the skin.

Superficial fungal infections often can be treated exclusively with topical preparations, although stubborn cases may require systemic drugs. Commercial creams, lotions, and ointments that contain ketoconazole, clotrimazole, tolnaftate, or miconazole are effective. Clotrimazole lotion that includes a corticosteroid to reduce inflammation and itching may be particularly soothing for the patient. Unfortunately, many of these newer drugs are either unavailable or too expensive for widespread use.

Other preparations, such as Whitfield's ointment (benzoic and salicylic ointment) and Castellani paint (a liquid in magenta or clear forms), are equally effective,



Making permanganate solution.

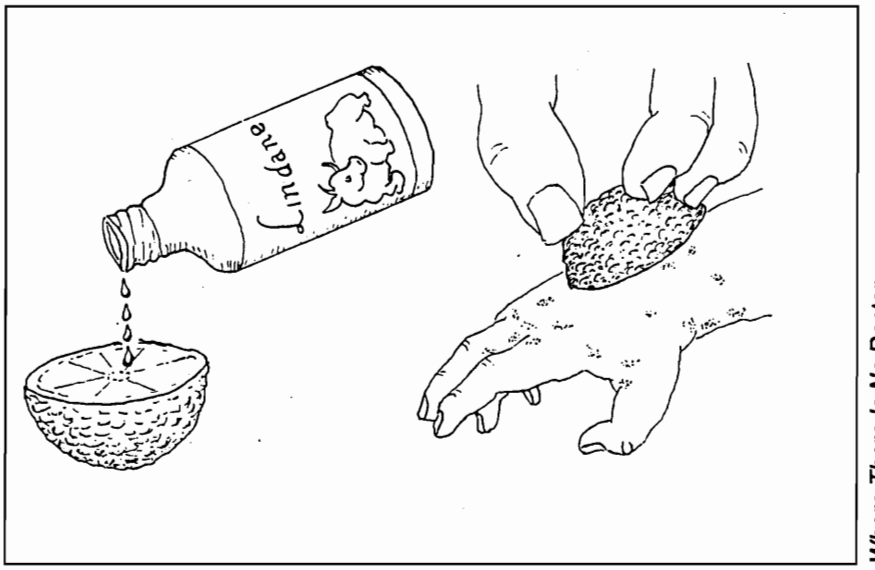
Primary Child Care

more commonly available, and less costly. Tincture of merthiolate with 3% salicylic acid is also useful, especially for candidal infections. Acute stages of fungal infections of the groin, foot, or arm pit may be treated with wet dressings of potassium permanganate (1:10,000) or silver nitrate solution (1:400) twice daily. Sulfur mixed with vinegar in a 1:20 solution or mixed with lard in a 1:10 ratio can also be used to treat superficial fungal infections.

Effective scabies treatment requires both topical application of lotion, cream, or shampoo that contains lindane (gamma benzene hexachloride) or benzyl benzoate and thorough cleaning of clothes and bedding, as described on page 9. Approximately 30 grams of the selected drug are required for one adult to be treated once. (Children are given one-half the adult dose.) The entire body, except the head, should be covered with a thin film that is left on overnight. Repeat treatment one week later may be necessary. Even if the treatment has eradicated all parasites, itching may continue. If possible, corticosteroid ointment or oral antihistamines may be given to relieve these symptoms.

Because scabies is a disease that often infects whole families, and because symptoms may be mild or absent for the first month the first time it is acquired, many experts recommend treating the whole family simultaneously. Many also recommend that scabies treatments extend to all sexual contacts as well.

Commercially available lindane solutions (such as Kwell) effectively kill the scabies mite and relieve itching. Where concentrated lindane for treating cattle or sheep is available, health clinic staff can make topical treatments that are equally effective and less costly than commercial solutions for people. For example, one part lindane can be mixed with 15 parts petroleum jelly, warmed slightly, and applied as usual. Alternatively, four drops of lindane can be placed on half a lemon and then rubbed over the body, starting with the most affected areas.



Applying lindane with a lemon to treat scabies.

Where There Is No Doctor

Unfortunately, lindane can have serious side effects on the central nervous system, so it must be used conservatively. No more than one application per week should be given; pregnant women should receive no more than two treatments during pregnancy; and infants, older people, and physiologically compromised individuals should be treated with other medicines, such as crotamiton (e.g., Eurax), if possible. For lice infestations of the scalp, lindane should only be used in dilute, shampoo formulations and should be washed completely from all skin surfaces after the prescribed time, usually about one-half hour.

Other commercial scabies drugs include concentrated benzyl benzoate lotion that is diluted to one part per 19 parts water. Alternatively, one part sulfur can be mixed with 20 parts lard or rubbing oil. Where children traditionally are rubbed with oil, one part monosulfiram in spirit can be added to 20 parts rubbing oil and given to mothers to apply.

Head or pubic lice are also treated with lindane in shampoo, lotion, or cream forms. Nits can be combed out after lindane treatment or removed by soaking the hair in hot vinegar water for 30 minutes and then combing. Body lice, however, live on clothing, so treatment must include thoroughly cleaning clothes and bedding. If nits are present on body hair, lindane may be used.

Systemic Treatments

Oral or injectable medication is generally reserved for spreading bacterial infections or severe fun-

gal infections. Because people often wait until their infections have become painful, noticeably unattractive, or somewhat disabling before seeking medical care, systemic medication is frequently indicated.

Bacterial infections in particular become painful and pus-filled and, if the infection is streptococcal, may progress to more serious disease. When diagnostics are unavailable for distinguishing between staphylococcal and streptococcal infection, health workers should treat the infection as if it is streptococcal first because the complications of streptococcal infections can be more severe.

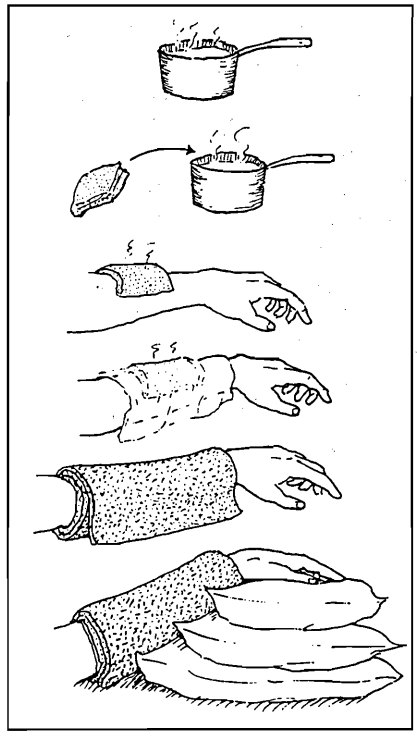
The treatment of choice is usually intramuscular or oral penicillin. For patients with systemic disease, it is especially critical to begin intramuscular penicillin immediately. Severe cases may require intravenous penicillin. If penicillin is ineffective, treat with a non-penicillin drug, such as sulphadimidine, erythromycin, or a semisynthetic penicillin (e.g., oxacillin, methicillin), as the infection may be staphylococcal.

For most fungal infections that are not resolved with topical therapy, griseofulvin and ketoconazole are available in tablet or liquid form. Treatment should be continued for two weeks after symptoms disappear, which often means up to six weeks. Griseofulvin, however, should not be used for fungal infections of the feet or nails unless there is no other alternative because response is slow, the recurrence rate is high, and the cost is greater than that of the rapidly acting topical therapies discussed above. It also should not be used by pregnant women. Candidal and deep fungal infections should never be treated with oral griseofulvin or systemic or topical antibacterials. These drugs will not cure deep fungal infections and will worsen candidal infections.

Nondrug Treatments

Nondrug therapies also can help treat skin diseases and relieve their symptoms. For small, pus-filled or oozing bacterial infections that crust over, such as impetigo or infected insect bites, apply a wet, hot compress to the sores to remove the crusts. This exposes the sores to air and aids healing.

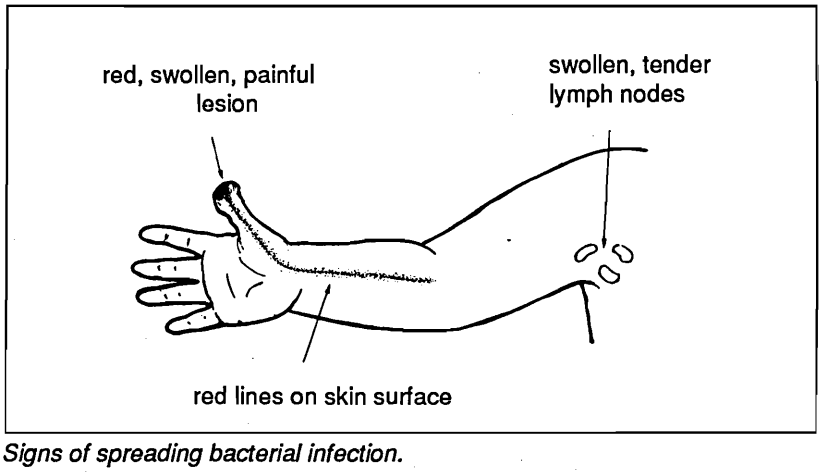
Boils can be treated entirely or partially with nondrug therapy. Small boils should be left alone, and no boil should ever be squeezed or pressed. Pressure may force the infective organisms back into tissue or into the blood, leading to serious systemic infection. Larger boils often require application of hot compresses to help pus form more quickly and to soften any skin openings so that pus can seep out. This natural seepage slows as the boil heals.



Where There Is No Doctor

Using a hot compress.

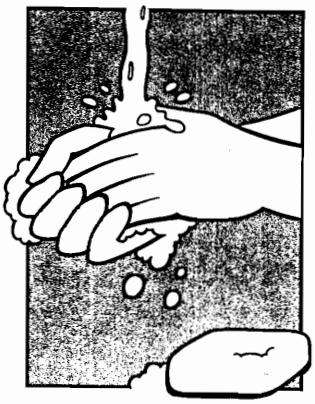
Some boils must be lanced (opened with a sterile scalpel or razor blade) by health workers. The top of the boil must be cut carefully, in order to avoid pushing the end of the scalpel into the wound and cutting blood vessels or nerves. The skin opening is then separated with forceps, allowing the pus to flow out. A length of wet gauze (soaked in Betadine, if available) is placed into the hole and slowly removed as the boil heals. The opening should be kept covered to prevent flies from landing on it.



Primary Child Care

Signs of spreading bacterial infection.

Prevention



Many simple technologies and activities can help prevent skin diseases from spreading within a single individual as well as from one individual to another. None is costly, few require external assistance, and most are very effective.

Personal Hygiene

Both harmless and potentially harmful bacteria normally inhabit the skin surface. When breaks in the surface occur, these bacteria can enter the skin and cause infection. Regular, thorough bathing and hand washing with soap can minimize the number of bacteria on the skin surface. Using soap can help prevent initial skin infections and reduce the spread of existing skin infections to other skin surfaces and other persons. Infection transmission also can be avoided by carefully discarding dressings used by infected persons.

For parasitic diseases, personal hygiene extends to keeping bed linens and clothing clean. Lice, for example, can live in clothes for up to 30 days and lay their eggs in clothing fibers. Scabies can transfer from one person to another via shared bed linens. Washing clothing and linens is one way to rid them of the parasites. Another is to place clothes, linens, pillows, and mattresses in direct sunlight for several hours or in the cold at night as frequently as possible. This will help to kill any mites or lice in those articles, thus preventing reinfection of the same person or infection of a close contact.

Education

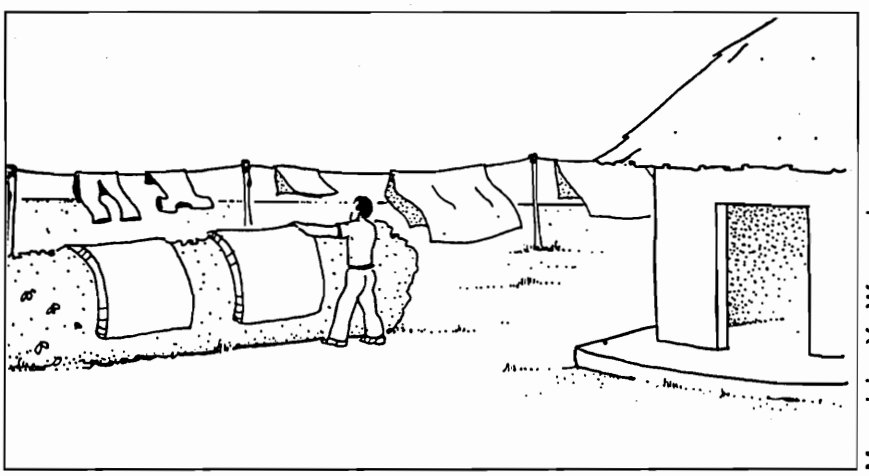
Community-wide prevention of skin diseases requires the active participation of several different groups of people. Education efforts should focus on as many of the following groups as possible: health workers, teachers, parents, children, and respected and influential members of the community.

Several different types of educational tools are needed for use with these groups. For example, leaflets with simple drawings may be useful with children and their parents. Brochures with more extensive information or audio-visual materials, such as slides or videos, may be effective with teachers. Simple textbooks with good photos for more accurate diagnosis and geographically relevant syndromic protocols for effective treatment will be important for educating health workers. Traditional media, such as puppetry or local theater, may be a good way to reach many members of the community.

Focus group discussions (FGDs) help planners create effective educational materials. In FGDs, members of the group who will use the materials meet with a facilitator to discuss their beliefs and practices concerning skin diseases. Information gained from FGDs is used to create educational materials, which are then pretested with the group after they are developed to ensure that the materials are appropriate and understandable.

Early, Effective Treatment

As with personal hygiene, early, properly administered treatment with effective medication is vital



Maendeleo Ya Wanawake

Drawing from booklet on hygiene showing clothing and bedding in sun.

to prevent the spread of disease within an individual or a community. Local health workers or respected community members who have been taught to recognize skin diseases and provide appropriate therapy, whether medicinal or nonmedicinal, can contribute substantially to the prevention of skin diseases.

Early treatment to prevent disease spread within the body is especially critical with streptococcal infections, which can quickly progress to serious disease if left untreated. Early treatment for less serious infections, such as superficial fungal infections, is also important. Daily washing with soap and water or application of potassium permanganate to skin surrounding areas with boils are good ways to prevent additional boils from developing.

Thailand Ministry of Health

Bathing with soap and water.

Some bacterial infections may begin as small insect bites that are scratched, becoming infected secondarily. These secondary bacterial infections can be avoided both by preventing the initial insect bites and by reducing subsequent itching. Individual insect bite prevention technologies include repellent, mosquito netting, and screening for windows. Community-wide prevention technologies, such as packing dirt into depressions that hold standing water where insects can breed and spraying homes with insecticides, are also important. Itching can be reduced by applying talcum powder, calamine lotion, or compresses of cold water or cool water from cooked oatmeal or other starch.

Treating an individual also helps slow or prevent transmission to other individuals, minimizing both the morbidity and mortality in a community and the drain on health system resources. Impetigo, for example, is very contagious and can spread rapidly among small children who live or play together. By treating the initial case early and isolating the child while the sores are still visible, the spread of this potentially serious skin infection can be minimized.

Conclusions

Skin diseases are among the most common infections in the world and, if left untreated, can progress to serious systemic illness. Skin infections cause pain, embarrassment, and disability to those suffering from them. Not surprisingly, skin infections are the primary complaint registered at health posts. Fortunately, they are usually simple and inexpensive to diagnose, treat, and prevent.

Nevertheless, national governments, international agencies, and private organizations pay relatively little attention to this major health problem. There are at least two important reasons, however, for these groups to begin to address skin diseases. First, by treating skin diseases, governments and other groups can significantly decrease physical pain and discomfort for a large number of people at a relatively low cost. Second, treating these visible and often stigmatizing diseases may enhance the credibility and reputation of health workers in the eyes of community members. This increased respect may then improve local acceptance of other less tangible health services, such as immunization and family planning.

Evidence from projects conducted by the Japanese Organization for International Cooperation in Family Planning (JOICFP), in fact, supports this idea. Earning a community's respect and mobilizing community participation by treating a well recognized and commonly disliked disease facilitates later efforts to introduce other health care ideas. JOICFP's general strategy is to involve the community in a deworming campaign and then utilize the resulting increased credibility of the workers and built up infrastructure to introduce the idea of family planning.

It is clear that programs to treat skin diseases can benefit those who suffer from them as well as health care personnel who provide a variety of health services. Given these multiple benefits and the ready availability of inexpensive technologies to diagnose, treat, and prevent skin diseases, it is time for national and international groups to address this widespread problem.

DIRECTIONS Evaluation: Results

An evaluation questionnaire was sent out earlier this year to all non-U.S. and some U.S. readers of DIRECTIONS. It was completed and returned by some 11% of those who received it. This report provides a brief background on the general objectives of DIRECTIONS, a summary of respondents' comments, and suggestions for those with specific interests outside the domain of DIRECTIONS.

Background. DIRECTIONS information is focused on health program managers and aims to provide enough information about health technologies to enable them to make wise choices for their own programs. Topics are selected if they are important health concerns in every major region in the developing world, they are not covered by other publications, and specific relevant technologies exist that can be used at the primary care level.

Respondents' Characteristics. Figure 1 shows the distribution of respondents' occupations. The largest number indicated administrative/managerial duties as their main occupation. When secondary and primary occupations are considered together, nearly 65% of the respondents are involved in program management. Respondents are generally highly educated, as shown in Figure 2. More than 80% have a university degree. Figure 3 shows the geographic distribution of respondents was similar to that of readers in general. The majority are from Africa, which is probably due in part to the fact that countries where English is spoken are more heavily represented on the mailing list.

Respondents' Views. Generally, respondents are quite pleased with DIRECTIONS. Approximately 71% read each paper thoroughly, 65% share their copies, and 74% save each copy for later reference. Some 78% find the technical information to be about right; among managers this proportion was slightly higher (82%). The information is mostly or somewhat new to 90% of respondents. About 69% of respondents think DIRECTIONS contains enough examples; 30% feel it should contain more.

Each of the past eight issues of DIRECTIONS was ranked "useful" or "very useful" by more than 75% of respondents. Of the future topics ranked by their importance for respondents' work, immunization and malaria were rated "very important" by more than 50% of respondents. More than 70% considered water use, malaria, immunization, skin disease, and child-to-child health promotion to be important concerns. Topics suggested by respondents include AIDS, nutrition, diarrhea, and health education.

Other Comments

1) Other Languages Sought--We would like to offer translations of DIRECTIONS but do not have funds to do it. Any groups that may be able to undertake or help finance translation and printing should contact us at PATH.

2) Foreign Exchange for Materials--This is difficult to address. For some, UNESCO coupons may be a solution. For more information, write to UNESCO, 7 place de Fontenoy, 75700 Paris, France.

3) Issues on Diarrhea, Respiratory Disease, or AIDS--These topics are covered in substantial depth in other free publications. To receive **Dialogue on Diarrhea, ARI News,** or **AIDS Action**, write to AHRTAG, 1 London Bridge Street, London SE1 9SG, U.K.

We would like to extend sincere thanks to those who took the time to answer the survey and share their views and comments with us.

Figure 1: OCCUPATIONS
(n=342)

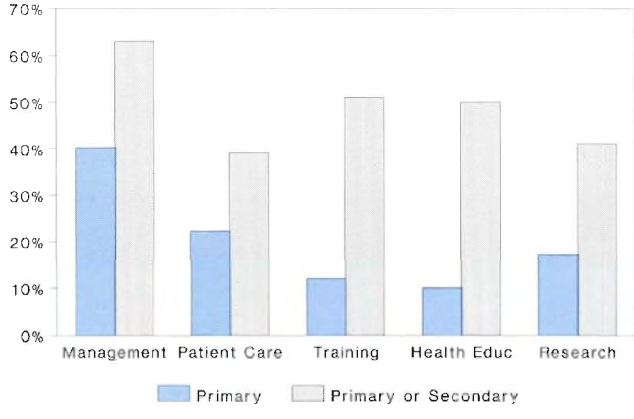


Figure 2: HIGHEST EDUCATION LEVEL
(n=443)

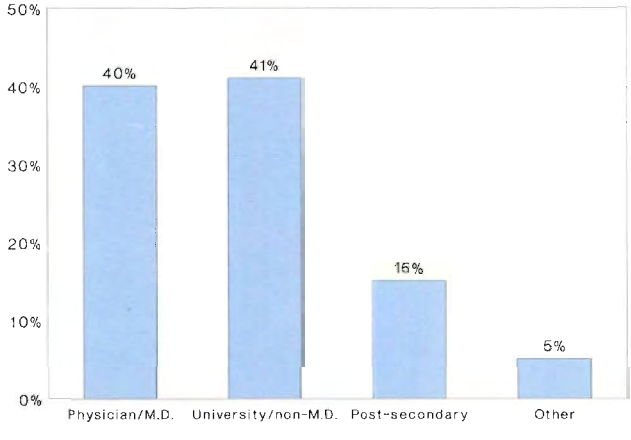
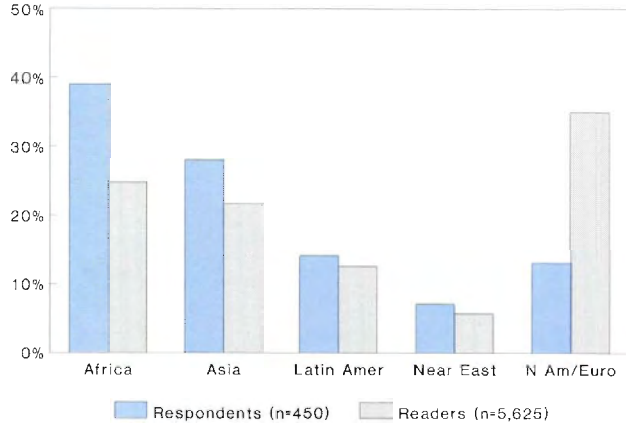


Figure 3: REGIONAL DISTRIBUTION



Materials Available

Slide sets with English scripts for training doctors, nurses, and auxiliary health workers about skin diseases are available from TALC (Teaching Aids at Low Cost). "Common Skin Diseases of Children in the Tropics" is in self-mounting (£2.75) or mounted (£4.40) slide sets. For airmail, add 60 pence. Address: P.O. Box 49, St. Albans, Hertfordshire AL1 4AX, U.K.

□

Primary Child Care (Book 1) is an excellent resource with an entire chapter on diagnosing and treating skin diseases. It is available from TALC and costs £4.50.

□

Where There Is No Doctor also contains a good section on skin diseases, including drawings and directions for making topical treatments locally. It is available in more than 18 languages. For ordering information, write to: Hesperian Foundation, P.O. Box 1692, Palo Alto, CA 94302, U.S.A

□

"Caring for Skin Infections and Sores" is a filmstrip on preventing and treating skin diseases with soap and water. It is available in English, Spanish, and French for US$10 each, plus shipping. (Surface is US$1; air is US$2 for Latin America and US$3 elsewhere.) Order it from: World Neighbors, 5116 North Portland Avenue, Oklahoma City, OK 73112, U.S.A.

□

A bibliography on skin diseases is available from PATH.

INTERCHANGE

The Liverpool School of Tropical Medicine offers a new twelve week training course, "Management for Primary Health Care," for managers of health, nutrition, and population programs from developing countries. Other short courses include "Teaching Primary Health Care" and "Information Needs for Health Care." For details, write to them at: Pembroke Place, Liverpool L3 5QA, U.K.

■

AHRTAG (Appropriate Health Resources and Technologies Action Group) has published **AHRTAG Resource List: Free International Newsletters**, a list of 73 free newsletters that cover primary health care issues. For a free copy, write: AHRTAG, 1 London Bridge Street, London SE1 9SG, U.K.

■

World Immunization News, a free bi-monthly newsletter with practical suggestions for immunization programs, is available in English, French, and Spanish. Request it from: Carter Presidential Center, Task Force for Child Survival, One Copenhill, Atlanta, GA 30307, U.S.A.

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DIRECTIONS is published three times a year. Single copies are distributed at no cost to health program managers in developing countries and others interested in primary health care programs.

PATH is a nonprofit, international organization devoted exclusively to the development and application of appropriate health technologies for primary health care programs in developing countries. PATH is pleased to acknowledge support from the U.S. Agency for International Development (AID) for the research on which this issue was based.

health technology
directions

PATH Program for Appropriate Technology in Health

Water for Health:
Behavior and Technology

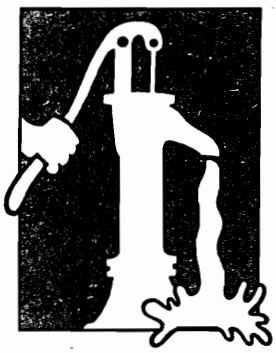
Between 10 and 25 million people die annually from diseases caused or aggravated by unclean or insufficient water or inadequate sanitation. The World Health Organization estimates that improvements in water and sanitation-related behaviors and technologies could reduce morbidity by up to 80 percent. Important economic and social gains also would result.

To address these problems, many outside agencies have provided communities with large, capital-intensive "hard" technologies, such as dams and wells, or sometimes simpler interventions, such as handpumps and rainwater collection systems. After several years, these often are broken and no longer used because the training or support systems needed to maintain the technology have been omitted.

One lesson learned during the International Drinking Water Supply and Sanitation Decade (1981-1990) is the importance of a direct link, or "soft" technology, to connect users with hard technologies. Successful water projects use soft technologies, such as radio programs and print materials, to motivate, instruct, and support people in improved water-related behaviors and hard technology use. Program planners have also discovered that long-term sustainability is enhanced through community participation, particularly involvement of women in all stages of project development, and coordination with existing development projects.

This issue of DIRECTIONS reviews management issues involved in implementing water technologies, behavioral issues surrounding water use, and hard and soft technologies that have been used successfully in various countries in the past decade.

Behavior and the Community



Hard Technologies

Soft Technologies

Volume 9, Number 1 ISSN: 0730-8620 1989

Management Issues

Regardless of the behavior change or hard technology being introduced, certain key issues in managing water projects must be addressed to ensure project sustainability. Among the most critical are involvement of community members, particularly women, whose lives are most directly affected by such changes, and integration with other community development projects.

COMMUNITY PARTICIPATION. Water projects that do not involve the community in all aspects of project design, education, and maintenance are often short-lived. When the community participates, its members are more likely to feel ownership of the program, use and maintain the technologies, and participate in other health programs. In addition, community members develop organizational and technical skills that can be applied to other water, health, or development activities.

Communities can participate in planning projects by working with managers to assess local needs. Local leaders and groups (especially women's groups) may be particularly adept at prioritizing needs, identifying resources, and assisting in motivating others.

Community involvement in implementing a project might include, for example, developing and maintaining a fund-raising system for obtaining contributions of labor, materials, and money. Local volunteers also can help motivate and train other community members for project maintenance. Community members' evaluation of the water project is crucial, as they are the only ones who can truly determine if the project has met its objectives.

INVOLVEMENT OF WOMEN. In most cultures, women perform a large proportion of tasks related to water collection, food production, and food preparation. They also are usually the principal teachers of children in water and sanitation practices. Therefore, women's participation in planning, implementing, maintaining, and evaluating water projects is critical for long-term health benefits.

Women are often experienced in the selection of water sources, a process in which they weigh a number of criteria, including time, effort, price, taste, other uses of the sources, and systems for sharing source use. Studies show that when women are involved in water projects, reliable water sources are identified, appropriate hard technology designs are used, construction costs are reduced, and improvements in safety, especially for small children, are made. When women's views and participation are overlooked, water and other programs are often ineffective. For instance, communal laundry sinks built in a rural Iranian community stood unused because women were not consulted about their preferences. The sinks were built at waist height, but the rural women preferred to wash in a squatting position.

Although women play a central role in making household decisions about water, women's public roles vary among different cultures. In some cultures it may be prudent, and even necessary, to obtain fathers' or husbands' consent or approval when seeking women's involvement in water projects.

INTEGRATION WITH OTHER COMMUNITY PROJECTS. Water and sanitation projects that are integrated with other, ongoing community projects have improved chances of success. Resources can be shared, conflicts avoided, and the desired results, which are often similar, can be supported by more than one project. For example, education about hygiene and sanitation complements other primary health care and nutrition activities. One study evaluated the impact of community participation in water supply projects on immunization completion rates and found that villages with participatory projects achieved 60 percent immunization completion rates, while those with nonparticipatory projects achieved only 49 percent completion.

In Botswana, family welfare educators are trained to construct water carts, water filters, and latrines and to promote them through popular theater at health centers. In many projects gardens have been planted near water sources, where they thrive on water run-off that otherwise would be lost. In Kenya and Polynesia, women who had learned masonry as part of an income generating project used their skills to construct rainwater collection tanks and latrines for their own use as well as to earn income.

Behavior and the Community

Many health interventions, such as antibiotic treatment, surgery, and emergency care, do not depend on long-term behavior change to improve health. Water-related interventions, however, require sustained behavior change over time on the part of all members of the community in order to affect health.

Opportunities for contamination of water arise at many points: at the water source, during transport and storage, and in use. While technological improvements to water supply and quality (such as pump installation) can be made, these interventions will not be effective by themselves. This section examines some of the behavioral obstacles to clean, safe water as well as program issues that affect the success of efforts to overcome these obstacles. Specific technological interventions to improve water quality and quantity will be discussed in the following two sections.

WATER AT THE SOURCE. Communities obtain water from below the ground (via wells and pumps), on the surface (rivers, ponds, lakes, and springs), and above the ground (rain and snow). The source of the water determines the opportunities for its contamination. For example, water from ponds, streams, and rivers may contain parasites or may become contaminated with bacteria when water in the immediate area or upstream from the community is used for laundering clothes, watering livestock, or disposing of human waste. Although water from below the ground is often safest, it can be contaminated if a latrine is placed less than 30 meters away from the source.

Disposal of human waste is a key issue in protecting water at its source. Human waste disposal behaviors often depend on deep-rooted cultural values as well as cost, convenience, and comfort. Villagers have objected to new latrines because the doors did not completely cover the entrance, partially exposing the user, or because the latrines were positioned inappropriately, for example, facing Mecca. People in some cultures are comfortable squatting over a hole, while those in others prefer to sit on a platform. In many countries, including Bangladesh, Malawi, South Korea, Swaziland, and Tanzania, providing only one household latrine, which requires men and women to share, can be a constraint to latrine use. Cultural attitudes toward human waste disposal should be thoroughly investigated before starting latrine building projects.

WATER TRANSPORT AND STORAGE. Even when the source is protected, water still may be contaminated when dirty containers or dipping utensils are used during transport and storage. In addition, water stored in an uncovered receptacle may be contaminated easily by insects, dirt, or other debris. Utensils used to remove water may stir up sediment from the bottom. Use of a container with a spigot placed above the sediment level will help prevent this problem.

WATER TREATMENT AND USE. Water use determines the necessary standard of cleanliness. Water used for bathing and washing (external use) requires the least degree of cleanliness; water used for drinking and food preparation (internal use) must be free of parasites and viruses and largely free of harmful bacteria; and water used in medical procedures must be aseptic (no disease-causing organisms) or sterile (no particles or living organisms present).

Water for external use need not be completely free from disease-causing organisms. Some simple precautions are needed, however, when water is taken from sources exposed to organisms responsible for certain diseases. Where schistosomiasis is prevalent, for example, water taken from exposed sources (streams and rivers) may be unfit for bathing and washing since the parasites in the water can enter the body directly through the skin. A simple intervention, such as leaving water to sit for 24 hours, kills the schistosomiasis parasite and usually makes water fit for external use.

Water for washing dishes can transmit bacteria and parasites when washed items that have not been thoroughly dried are used. Disease can also be spread when dishes are left to soak until the next use rather than washed and dried between uses.

Safe external use of water also depends upon sufficient quantities of water for regular, thorough hand washing. Studies have shown that washing hands after defecation and before food preparation decreases disease transmission.

Water for internal use should be as clean as is economical and feasible over time. The simple behavioral interventions that make water safe for bathing and washing may not be adequate for drinking or food preparation. Water that has been allowed to stand for an extended period of time has reduced levels of bacteria and may be safe to drink; it may, however, still contain harmful organisms, making further interventions, such as filtering, boiling, or chemical treatment, necessary.

Water for medical use should meet the highest standards of cleanliness. Invasive medical procedures, such as injections or surgery, require an extreme degree of cleanliness. Most disease-causing organisms are destroyed after two to five minutes at a rapid boil. For disinfecting medical instruments, however, the World Health Organization recommends boiling for a full 20 minutes. This is particularly important in places where more complicated technologies for disinfection and sterilization, such as steam sterilizers, autoclaves, dry heat, and chemicals, are unavailable or inappropriate. Where there are fuel shortages, however, the necessity for prolonged boiling should be assessed according to the specific medical need.

Categories of Water- and Sanitation-Related Diseases

A) *Water-borne diseases:*

Spread by contaminated water or dirty hands.
(Examples: typhoid, cholera, dysentery, hepatitis A, gastroenteritis.)

Behavioral Issues:
- unsanitary food preparation.
- unsanitary methods of washing and drying dishes and utensils.

B) *Water-washed diseases:*

Aggravated by insufficient water for washing.
(Examples: scabies, lice, trachoma, conjunctivitis.)

Behavioral Issues:
- unhygienic practices in bathing and laundering.

C) *Water-based insect/vector transmitted diseases:*

Carried or transmitted by insects or animals living or breeding in or near water.
(Examples: malaria, yellow fever, sleeping sickness, guinea worm, schistosomiasis, onchocerciasis.)

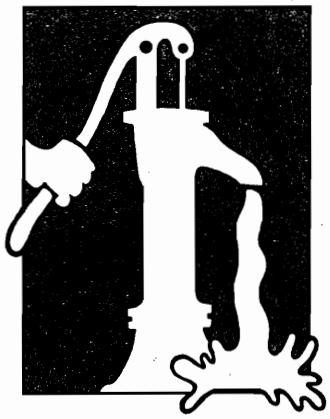
Behavioral Issues:
- time spent at, in, or near unprotected traditional water sources.
- presence of insects in homes and compounds.
- methods of collecting, storing, and using water.

D) *Sanitation-related diseases:*

Spread via unsafe human or animal waste disposal.
(Examples: hookworm, tetanus.)

Behavioral Issues:
- unsanitary disposal of human waste.
- presence of animals and their waste in living areas.
- unprotected feet.

Hard Technologies



Technological solutions to the problems cited in the previous section focus on improving water quality and quantity at the source, in transport, and during use.

WATER AT THE SOURCE. In selecting a water source technology, the following issues should be considered: What is the highest level of service the community has the institutional capacity to sustain? What is the highest level of service the community is able to pay for?

Some experts have suggested that for a water project to achieve long-term health benefits, water source technologies should:

- yield 20 liters of water per person per day;
- be located within 0.5 km of the community;
- be available to the entire population; and
- fulfill perceived needs of the community so continued use, maintenance, and repair are likely.

Water project planning should include thorough ecological study of the new project's impact on parasite and vector transmission. The expansion of water sources and the year-round supply of water can create conditions favoring the spread of intermediate hosts and vectors of parasitic diseases such as schistosomiasis, onchocerciasis, guinea worm, and malaria.

Groundwater: Wells are a good choice where rainfall is scant and surface water from springs or other sources is absent. Deep wells often can provide a reliable, year-round supply of water.

Wells can be dug manually or bored by machine. The choice of method, however, depends upon the geology of the area and the financial resources of the community. Proper design, construction, and support can greatly reduce well and pump maintenance. Drilled wells usually can be made deeper than dug wells; very deep wells require a handpump, rather than a bucket, to draw water to the surface.

Well water has been cleansed by natural filtering systems in the ground and is usually free from harmful bacteria, but the well and surrounding area must be protected from contamination. Restricted access to open wells helps prevent accidents. A cover over the opening allows access to the well but keeps contaminants (and children) from falling into it. A sloped, concrete apron around the perimeter directs waste water away from the well and prevents water from pooling. Run-off water also can be diverted for washing and irrigation.

Pumps draw groundwater from wells to the surface and must suit local geological and operating conditions. If, for example, the groundwater level is very low, a pump with high lift capacity is required. The presence of sand and corrosive elements in the water also must be assessed, as resistance to corrosion and abrasion varies among pumps. Number of users, well construction (for example, with built-in filters), pump maintenance requirements, and availability of spare parts must be considered in planning a pump project. (See Materials Available, p. 12, for a handpump selection guide in "Community Water Supply.")

One of the most important elements in a sustainable pump project is thorough training of users and local maintenance personnel. A 1977 survey in Sierra Leone, for example, found that only 40 percent of handpumps were working. In 1982 in Sri Lanka, only 60 percent of recently installed handpumps were still functioning. Even when all other issues are addressed adequately, the presence of users trained in maintenance and the availability of spare parts often determine the success of a pump project.

Surface Water: Traditional sources, such as water holes and rivers, can be improved by constructing bridges or platforms to stand on when collecting water. These help prevent the spread of schistosomiasis and guinea worm, for example, by eliminating the need to stand in the water. Other protective measures, such as gates or

fences around the source, help prevent contamination of water by animals and people.

Most **springs** occur where groundwater is blocked by an impermeable layer of rock and is forced to the surface. Springs are a good source of clean water if they are protected at the point where the water reaches the surface of the ground. Water availability may vary seasonally, depending on the type of spring, so the year-round reliability of springs should be assessed before attempting spring improvements.

For most springs, access to water may be improved by constructing a concrete "spring box," a structure built into the ground where the spring emerges. Spring boxes increase water supply by collecting the outflow. They also serve to protect spring water from contamination. This is accomplished by "capping" the spring box with a removable wood or concrete cover and fencing off the area. The water can be piped from the spring box to a storage reservoir at a slightly lower level and distributed for community use through standpipes. Water is then more easily available, and fewer people have to travel to the source, thereby decreasing the risk of contamination.

Dams of concrete, rock, brick, or earth built across small streams and rivers harness the flow of water and create a reservoir for a community water supply. As with springs, water from the reservoir can then be pumped closer to the community. Because of the potentially serious consequences of dam failure, expert advice should be sought when planning any dam.

World Neighbors

Woman pouring water through cloth filter fitted with rubber rim.

Above-Ground Water: Rainwater catchment systems collect rainfall from a roof and channel it through a gutter and downspout into a storage container. The amount of water available depends on seasonal rainfall variations, total annual rainfall, the size of the rainwater catchment area, and the capacity of the storage tank or jar.

Netting or screening placed over the storage containers and downspout prevents mosquitos from breeding in the water and keeps pipes and storage containers free of debris. The gutters, screens, and storage jars must be cleaned periodically. The first rain after a dry period usually washes dirt and other contaminants from the roof and should be diverted from the collection vessel.

Human Waste Disposal: Safe human waste disposal is essential for protecting a water supply and preventing the spread of disease. If latrines are unavailable, waste should be buried away from houses, footpaths, animals, and small children and at least 10 meters away and downhill from the water supply.

Latrines should be built at a distance that does not prohibit regular use but at least 30 meters from any water source to avoid human waste leaching into the water supply. If possible, the bottom of the latrine should be more than 1.5 meters above the highest groundwater table. Latrine sites should be dry, well drained, and above flood level.

There are many variations on the latrine, including the ventilated improved pit (VIP) latrine and the pour-flush latrine. The standard pit latrine consists of a hole in the ground bridged by a floor slab or squatting plate and surrounded by a hut to provide privacy. The VIP latrine adds a vertical ventilation pipe to minimize odors and discourage the breeding of insects in the pit. The pour-flush latrine has a squatting slab constructed with a water trap below floor level. With a small amount of water, human waste is flushed from the trap down a short length of pipe to the pit. The lower walls and bottom of the pit should be permeable to allow liquids to escape, while the upper walls should be waterproof to prevent liquids from leaching into the topsoil and the latrine from collapsing.

WATER TRANSPORT AND STORAGE. Receptacles for water storage and transport can be made of almost any locally available material. They should be cleaned carefully before use, however, especially if they have been used to store oils, chemicals, or petrol. Empty pesticide containers should never be used

to store drinking water. Clay pots and other porous containers must be raised off the ground slightly to prevent contaminants on the ground from seeping into them.

A spigot near the bottom of the container eliminates the possibility of polluting the water by dipping into it with dirty hands or utensils and allows sediment to settle to the bottom. If a spigot is unavailable, care should be taken to dip water with the same clean utensil every time so that the water remains clean. The container should be kept covered and should be rinsed periodically with clean water and left to dry thoroughly.

The "Three Pot System" of water storage provides a continuous supply of water that has stood for 24 hours. Two large pots are used for retrieving water on alternate days. Each pot is allowed to stand for 24 hours. The clear top water is then carefully poured into a third (smaller) pot for drinking. The remaining water can be used for washing. In this way each day's drinking water has been standing for at least 24 hours before it is used.

Storing water in capped, clear or light blue plastic or glass containers that are then placed in direct sunlight for approximately 90 minutes completely destroys bacteria that cause several common diseases. Round or cylindrical containers are preferred to square ones because a rounded shape receives maximal exposure as the sun moves across the sky. Labels on containers should be removed.

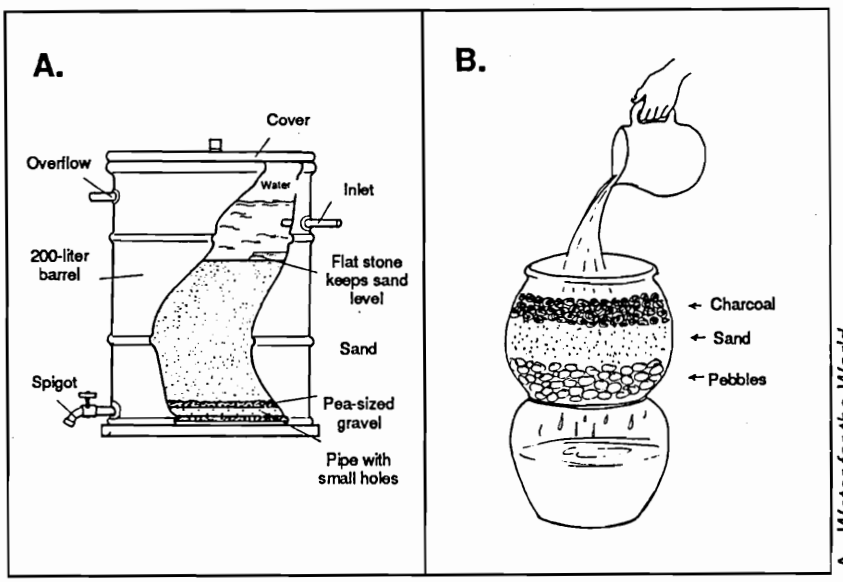
WATER TREATMENT AND USE. The choice of water treatment methods depends on local availability of resources such as cooking fuel (for boiling), sand, charcoal, and bleach or other disinfectants. Depending on water quality, a combination of these technologies, such as filtering and then disinfecting by boiling or adding chemicals, may be appropriate for making water safe for internal or medical use.

Simply allowing water to sit for over 24 hours before use can prevent transmission of schistosomiasis. Storing water for five to six days will significantly reduce the level of other bacteria in the water. If the water quality is very poor, additional measures must be taken to make the water safe to drink. Certain contaminants, such as giardia, will not be destroyed by any length of storage.

Filters are simple, low-cost, appropriate water treatment technologies that can have enormous health benefits. The use of filters alone, for example, can eliminate the spread of guinea worm (see Case Study, p. 11).

Sand or charcoal filters provide basic treatment for water that will be drunk or used to prepare food. These can be effective in removing most bacteria from water if fine sand is used and a constant flow of water covers the sand at all times. (Water filtered through dry sand or sand that is not covered by a constant flow will need further treatment.) Filters can be built entirely with locally available materials, such as sand, charcoal, gravel, a steel drum or clay pot, and a spigot.

Cloth filters can strain from water the insect that carries the guinea worm larvae and other comparatively large particles, but not bacteria or viruses. They can be made with locally available, tightly woven cloth. In some programs, rubber has been sewn around the edge of the cloth to hold it in



A. *Water for the World*
B. Adapted from *Peace Corps Times*

*A. **Charcoal filter.** 1. With a sharp instrument, punch holes in bottom of container. 2. Place pebbles, sand, and charcoal in container to make a filter, which is set on top of second receptacle. 3. Pour water into top filter and collect drinking water from bottom filter. B. **Sand filter.***

place over the receptacle into which the water is poured. Two-layer filters can be made of two different colors of cloth so that the user knows to place the same side up (receiving the unclean water) each time the cloth is used. This prevents organisms and debris previously caught in the filter from recontaminating the water. In a Ghanaian program, the top of the filter is distinguished from the bottom by means of a logo printed on one side of the cloth.

Chemical disinfectants can be used to treat clear drinking water that is slightly contaminated with bacteria. Chlorine is an effective, easy-to-use, relatively inexpensive chemical commonly used in laundry bleaches. It should be stored in a sealed container in a cool, dark place to retain its strength. The main disadvantages of chlorine are that it may not be readily available, its taste may be objectionable, it must be used consistently to be effective, and, if used incorrectly, it is potentially lethal. A chlorine solution to use for disinfecting water can be made by mixing 1 cup of laundry bleach with 3 cups of water to make 1 liter. To disinfect water, add 3 drops of this solution to 1 liter of water and allow the water to sit 30 minutes. (Add 6 drops if the water is clear but colored.)

Temephos, commonly known as "Abate," is a chemical pesticide that is used every four weeks during guinea worm season in ponds known to be affected. It can also be used to control mosquito and black fly larvae. It is recommended by the World Health Organization for use in sources of drinking water. Unlike many other pesticides, temephos does not appear to be toxic to mammals, fish, or amphibians and is effective in low concentrations (one part per million) for a reasonably long period. Adding temephos to a closed cistern, however, may adversely affect the taste and odor of water temporarily. A program in Pakistan addressed this problem by treating the water late in the evening so that the smell and odor could dissipate overnight.

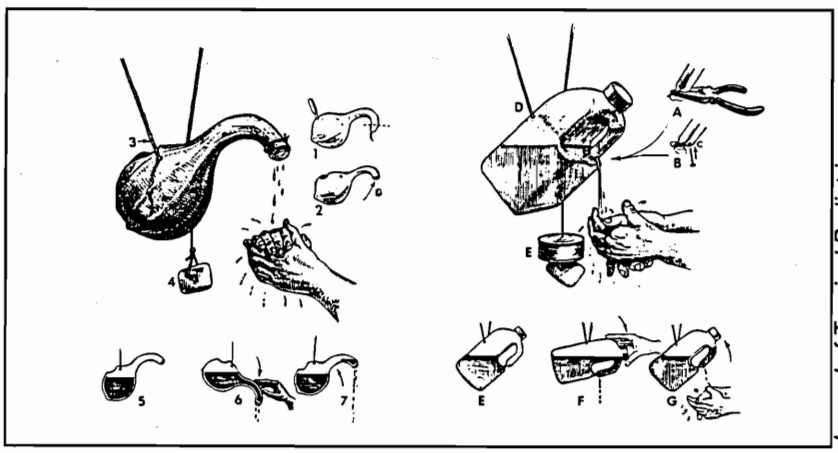
Boiling water rapidly for about two to five minutes destroys all disease-causing organisms except bacterial spores. Simply bringing water to a rolling boil (100°C at sea level) will kill most microbial pathogens, but longer boiling is safer. Stirring the boiled water with a dirty utensil or pouring it into a dirty container, however, may recontaminate it.

Several technologies can be used with water to improve hygiene. For example, **soap**, along with vigorous, thorough scrubbing, can remove over 90 percent of bacteria from the skin. Soap can be made in the home or village cheaply and easily; its main ingredients are fats and lye. The two basic methods for small scale soap-making rely on commercial lye (caustic soda) or lye leached from ashes (potash). (See Materials Available, p.12, for details on making soap.)

The use of **indigenous disinfectants** (plants with antiseptic properties) has been observed in several cultures. For example, in Zimbabwe a root known locally as "devil's thorn" contains high levels of carbolic acid, an antiseptic agent. It is used by traditional birth attendants as a hand soap and as a wash for eye infections.

Water dispensers for hand washing can be made from gourds or plastic bottles. These save water and thus time spent collecting water and can facilitate hand washing near the latrine and food preparation areas.

Screened **drying racks** raised off the ground and out of the reach of animals can be used to dry dishes thoroughly. This helps protect against bacterial growth and transfer from infected dishwater or damp, dirty dishtowels. The racks should be fitted with covers of screen or netting to protect dishes from flies and debris.



Journal of Tropical Pediatrics

Hand washing devices made from gourd (left) and plastic bottle (right).

Soft Technologies

Soft technologies, such as communication materials and training programs, are the less tangible interventions that link hard technologies with the users. Although soft technologies are often neglected, they are critical to the success of hard technologies. Field experience with water technologies shows that programs that introduce hard technologies without attention to soft technologies often fail.

The main purpose of soft technologies is to promote, explain, or reinforce the adoption of a behavior or the use of a hard technology. Soft technologies take a variety of forms. Promotional or motivational activities might include community theater to encourage people to keep animals away from wells or a participatory demonstration using hot pepper to show the fecal-oral route of disease transmission. (Hot pepper placed on the hand is wiped off; when participants touch their tongues to their "clean" hands, they learn that "dirt" is not always visible.) Instructional efforts might include a handpump maintenance manual for nonliterate women. To reinforce behaviors, discussion groups might be formed to tackle problems that arise in adopting a new hygienic behavior.

Information can be presented using a variety of media. The most appropriate medium is selected based upon the message, intended audience, and available community resources. For example, pump maintenance instruction for villages might be presented with a skit performed by volunteer health workers. Maintenance and repair personnel, however, would probably need detailed print materials for later reference. The chart on page 10 contains examples of motivating, instructing, and reinforcing information that might be useful in a water project.

Mass media, including radio, television, newspaper, and billboards, can reach large numbers of the population and are useful for raising awareness and encouraging new behaviors. In Honduras, for example, large-scale sanitation activities undertaken without soft technologies had no effect on high mortality and morbidity rates due to diarrhea. A large health communication project was then begun using several methods, including radio "novels" and short spots focusing on four water-related behaviors to improve health. An early project evaluation indicated that 75 percent of the target population was putting two or more of the behaviors into practice.

Print media (e.g., leaflets, booklets, flip charts, logos on cloth and utensils) can be used for a variety of audiences and are particularly effective for instructional and reinforcing messages. Well written and illustrated instructions are essential as part of the packaging on bleach or temephos, for example, where very specific steps must be followed to ensure success and avoid harmful consequences.

Traditional media (e.g., town criers, Koranic plaques in mosques, theater, games) can also promote awareness and adoption of new health practices. In many cultures, for example, health or sanitation messages are set to traditional music and delivered by singing volunteer health workers. Puppet shows, used in many cultures to present "morality plays," might be appropriate for behavioral messages. (See DIRECTIONS,Vol. 7, No. 2.)

Interpersonal communication is one of the most effective ways of reaching people with any message because it is direct and immediate, thus encouraging commitment and participation. Interpersonal communication methods include seminars, demonstrations, formal or informal education programs, discussion groups, and home visits.

Regardless of the medium or purpose, the soft technology must be developed appropriately to be effective. Careful research, production, pretesting, training, and evaluation are critical for soft technology development; close target audience involvement in each step is essential.

Research on local beliefs, attitudes, and practices concerning water is vital for understanding

issues or beliefs that affect behaviors. For example, many societies believe a baby's feces are not dangerous. Awareness of such beliefs and their impact on behaviors is essential in designing messages to address sanitation issues.

There are several research techniques. Direct observation allows managers to see what practices might be factors in health problems. In Bangladesh, for example, observers found that women use the edge of their saris both to clean children and wipe their own hands, a potential factor in disease transmission. Observation, however, usually does not explain why people behave certain ways or what they believe.

In-depth individual interviews are another way to understand local beliefs, attitudes, and customs. They are a good choice when few target audience members are available. Focus group discussions (FGDs) are like interviews but use larger groups of 8-10 people of similar background. In FGDs a facilitator follows a guideline to ensure that all of the main issues are discussed. Conducting several FGDs increases the likelihood that issues identified in the sessions will reflect community-wide concerns.

Target audience members themselves also can collect data. In Bangladesh, for example, mothers helped collect data on the incidence of diarrhea, scabies, and conjunctivitis using pictorial calendars. The mothers placed a thumbprint on the appropriate picture whenever one of these diseases occurred. Research results, which were compiled by the community, demonstrated the need for action to eliminate these diseases.

Once research is conducted and problems are identified, messages are developed to address these problems. Research helps determine the best way to present selected messages. For example, if traditional theater is a main source of entertainment in a community, it might be an appropriate medium for motivational messages. Conversely, research might reveal the sensitive nature of certain subjects, such as defecation practices, which would make using theater or other public presentations inappropriate.

In **pretesting**, target audience members preview the prototype materials or performance to

MEDIA FOR DIFFERENT AUDIENCES AND PURPOSES

AUDIENCE	PURPOSE: MOTIVATING	PURPOSE: INSTRUCTING	PURPOSE: REINFORCING
Villagers	A, B, C, D, E (e.g., theater show on benefits of latrines)	A, B, C, E (e.g., group discussions on handpump maintenance)	A, B, D, E (e.g., radio spots encouraging hand washing)
Maintenance and Repair Personnel	A, C, D (e.g., community meetings to recruit water project volunteers)	A, C (e.g., printed manuals on building rainwater collection systems)	A, C, D (e.g., radio spots on importance of regular maintenance)
Community Leaders	A, B, C, D, E (e.g., film on hygiene and water use)	A, C, E (e.g., printed information on pump styles)	A, C, D, E (e.g., meeting with leaders from other communities to compare experiences)

A = Interpersonal Communication; B = Folk Media; C = Print; D = Radio; E = Television, Film, Video

determine whether or not the message is presented clearly and appropriately. The technology is revised and refined until it is understood by and acceptable to most of the target audience.

Training health workers is essential to the proper use of soft technologies in the field. For example, health workers must know how to explain print materials to nonliterate audiences.

Finally, periodic **evaluation** of the soft technology will determine if it is reaching its intended audience, is being used appropriately, and is effective in its intended purpose. Soft technology evaluation can be conducted separately or as part of the evaluation of an entire program.

In program evaluation, it is important to try to determine whether or not soft technologies have brought about health behavior changes. Evaluation has shown, for example, that health education programs encouraging hand washing can reduce diarrhea rates by up to 50 percent.

CASE STUDY: Guinea worm project in Kati, Togo. This case study illustrates the value of simple water-related technologies in achieving improved health and quality of life.

About 5 to 15 million people suffer from guinea worm annually. Guinea worm disease (or dracunculiasis) is transmitted through contaminated drinking water. The parasite travels through the body and causes skin ulcers through which larvae pass that can eventually infect others. Although seldom fatal and eventually self-limiting, the disease is painful and makes walking, working, and attending school nearly impossible. Yearly reinfection is common. Guinea worm has no known cure, and no vaccine exists for immunization. It is prevented by filtering water before storage and by building pumps, platforms, wells, or cisterns to prevent carriers from reinfecting the water.

World Neighbors has worked with the village of Kati since 1980 to eliminate guinea worm. Village leaders and representatives had identified guinea worm as a health problem likely to generate widespread interest within the community. Initially, most people believed that guinea worm was due to witchcraft. Rather than condemning these beliefs, the project team conducted programs that demonstrated the existence of organisms in the water and then explained the transmission, consequences, and prevention of guinea worm.

Community participation at all stages of the project has been the key to its success. Early in the project, a health committee was formed, and both men and women were trained to teach others about guinea worm using role plays, small group discussions, demonstrations, dramas, visuals, and field trips. Microscopes were used to reveal to villagers the presence of organisms in water. Practical techniques in guinea worm prevention also were taught. This process took two years to complete.

As people became convinced that water was the source of the guinea worm the use of prevention techniques, such as boiling and filtering water, increased, and the number of guinea worm cases decreased. To futher reduce exposure to guinea worm, the people of Kati raised US$3,000 to pay for wells to be drilled.

By 1988, the incidence of guinea worm disease in Kati had dropped to zero. The enormous success of this program is striking evidence of the potential health impact of community participation in health education and water supply programs.

Conclusions

Water-related diseases are highly prevalent and have substantial impact on the daily lives of people throughout the world. A majority of these diseases can be prevented by adopting the use of several simple technologies and changing potentially harmful water-related behaviors.

Although water-related health problems may have simple technological solutions, sustained implementation of those solutions requires appreciation of the support components that are critical for water project success. Water projects that ignore these components, which include community participation, involvement of women, collaboration with existing projects, and use of appropriate soft technologies, often fail. Carefully developed projects, however, such as the guinea worm project in Kati (see above), illustrate the tremendous health benefits that can be gained from introducing simple water-related technologies and behavior changes.

Materials Available

The Water of Ayole, a film about a West African village that used community participation in providing safe water, is available for US$15. Also available: **Guinea Worm: The Fiery Serpent** (film). (Both films in English and in French.) Write: United Nations Development Program, Division of Information, One UN Plaza, Room DC1-1904, New York, NY 10017, U.S.A.

□

Soap recipes may be obtained by writing to: Volunteers in Technical Assistance (VITA), 1815 North Lynn Street, Arlington, VA 22209, U.S.A.

□

World Neighbors has film strips, flip charts, and case studies in English, French, and Spanish. For a free catalogue, write: 5116 North Portland Avenue, Oklahoma City, OK 73112, U.S.A.

□

The **Water for the World** series includes technical notes on design of specific water technologies. For information and prices, write: A.I.D. Library, Room 105, State Annex 18, United States Agency for International Development, Washington, D.C. 20523-1801, U.S.A.

□

A Water and Sanitation for Health Project (WASH) publications list may be obtained from: 1611 North Kent Street, Room 1002, Arlington, VA 22209, U.S.A.

□

Case studies, country reports, field research, and general information are available from PROWWESS/UNDP (Promotion of the Role of Women in Water and Environmental Sanitation Services/United Nations Development Program). Write to them at: 304 East 45th Street, Room FF-12-108, New York, NY 10017, U.S.A.

□

Local ordering information for **Community Water Supply: The Handpump Option** is available from the World Bank, Publications Department, 1818 H Street, N.W., Washington, D.C. 20433, U.S.A.

INTERCHANGE

Community Eye Health is a free bulletin covering topics such as world blindness and malnutrition. Write: Dr. Murray McGavin, Editor, "Community Eye Health," 27-29 Cayton Street, London EC1V 9EJ, U.K.

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The Appropriate Health Resources and Technologies Action Group (AHRTAG) now publishes **CBR News**, a free newsletter on community-based rehabilitation. Write: AHRTAG, 1 London Bridge Street, London SE1 9SG, U.K.

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Upcoming issues of **DIRECTIONS** will cover immunization and leprosy technologies. We welcome readers' suggestions for appropriate technologies or descriptions of innovative programs to include in those issues.

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health technology
directions

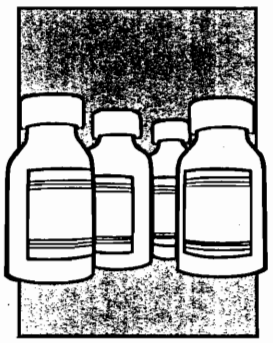
PATH Program for Appropriate Technology in Health

Immunization

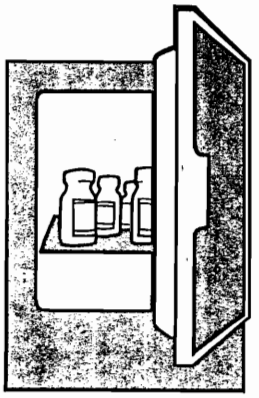
Immunization is an essential component of primary health care and child survival activities throughout the world. Since the establishment of the World Health Organization's Expanded Programme on Immunization (EPI) in 1974, the estimated incidence of childhood vaccine-preventable diseases has declined significantly. Today, immunization against the six diseases targeted by EPI—diphtheria, measles, pertussis, polio, tetanus, and tuberculosis—prevents approximately two million childhood deaths per year. Nevertheless, many women and children in the developing world remain unimmunized, resulting in the death or disability from vaccine-preventable diseases of over three million children annually.

Currently, efforts are focused on expanding immunization services for women and children with the goal of protecting all children against the six EPI-targeted diseases. Recent initiatives call for the eradication of polio by 2000, the elimination of neonatal tetanus by 1995, and a 95 percent reduction in measles incidence by 1995. Expanding immunization coverage against hepatitis B and yellow fever also are objectives in areas where these diseases are endemic. To achieve these goals, current immunization program priorities include: (1) the continued use of current vaccines as well as the introduction of new, more effective, and more stable ones; (2) the development and improvement of cold chain technologies to safely transport, store, and distribute vaccines; (3) the development and improvement of injection technologies to ensure proper administration of vaccines and safe handling of injection equipment; and (4) efficient program management that strives to achieve and sustain expanded coverage and service delivery through improved training, supervision, evaluation, and community mobilization.

This issue of DIRECTIONS reviews the most recent developments in these areas. It also serves to update our 1983 issue on the same topic.



Vaccines

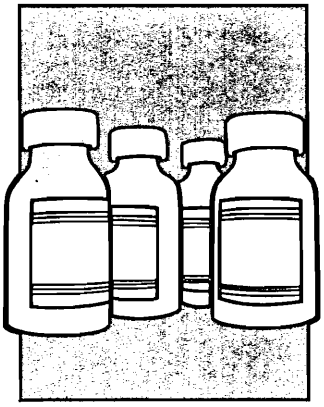


The Cold Chain

Injection Technologies

Volume 9, Number 2 **ISSN: 0730-8620** **1989**

Vaccines



This section describes the six diseases targeted by EPI and the vaccines currently available to prevent them. New vaccine developments also are described.

Immunization protects individuals against infectious diseases by conferring either passive or active immunity. Passive immunity occurs when antibodies against a particular infectious agent or antigen are transferred from one individual to another, such as maternal antibodies passed through the placenta or via breast milk. This kind of immunity is not long-lasting, and additional protection against infection is required soon after birth. Active immunity occurs when the body produces its own antibodies in response to the presence of an antigen that is introduced by either natural infection or immunization.

Vaccines that induce active immunity come in three forms: live, "attenuated" (weakened) viruses or bacteria such as the measles, the Bacillus of Calmette and Guerin (BCG, against tuberculosis), and oral polio vaccines; killed or inactivated viruses or bacteria such as the pertussis and intramuscular polio vaccines; and toxoids such as the tetanus and diphtheria vaccines, in which the toxins produced by microorganisms have been treated so that they no longer produce disease. These three forms vary in their effectiveness and stability. Vaccines containing live organisms generally are more effective than those containing killed organisms or toxoids because the induced immunity lasts longer. Vaccines made of killed organisms or toxoids, however, are usually less sensitive to heat and light. All vaccines are susceptible to damage from heat, and some, such as the combination diphtheria-pertussis-tetanus toxoid (DPT) vaccine, are damaged by extreme cold. Of the EPI vaccines, DPT and tetanus toxoid (TT) are the most stable, while oral polio and measles are the most sensitive.

Measles: Despite the availability of an effective live, attenuated vaccine, measles causes more childhood illness than any other vaccine-preventable disease. About 1.5 million children with measles die each year. Because unvaccinated children are virtually assured of contracting measles, which can be particularly serious for children already suffering from malnutrition or diarrhea, WHO recommends that a single dose of the Schwarz strain vaccine currently used in developing countries be given as soon as possible after nine months of age. Although measles can occur at younger ages, this vaccine is not routinely administered earlier because its efficacy is compromised by the presence of maternal antibodies. In special, high risk populations, such as hospitalized children and those in refugee camps, immunization at six months and again at nine months is recommended.

Researchers have been investigating more potent vaccine strains and higher titer preparations that could overcome interference by maternal antibodies and be administered at six months of age or earlier. The most promising of these is the Edmonston-Zagreb vaccine. If its safety and efficacy are confirmed during the next two years, this vaccine could represent a major breakthrough in reducing the incidence of measles worldwide.

Another option being explored is a two-dose schedule whereby infants would routinely receive doses of the current vaccine at six and nine months. The main concern, however, is that some infants would not receive the second dose and therefore would not be protected adequately. Such a schedule also would be more costly to administer. Until these alternatives can be studied sufficiently, achieving high coverage with the existing vaccine and schedule should be a top priority.

Tetanus: Tetanus can be contracted at any age, but newborn infants are at particular risk. Newborns often are infected through the unsterile cutting of the umbilical cord or the application of mud, dung, ghee, or other contaminated substances to the umbilical stump. Although an effective and stable toxoid vaccine has existed for years, neonatal tetanus is second to measles as the leading cause of childhood mortality from immu-

nizable diseases. Protection against neonatal tetanus is achieved by immunizing previously unimmunized women of childbearing age, especially pregnant women. Current high neonatal tetanus mortality rates are due to very low immunization coverage among these women.

The first dose of tetanus toxoid (TT1) should be given at the first contact with the health care system or as early as possible in pregnancy. A minimum of two doses are needed during or prior to the first pregnancy. The second dose should be given no later than two weeks before delivery. Up to five doses of TT are needed to provide protection throughout the childbearing years. Minimum intervals between TT1 and TT2 are four weeks; between TT2 and TT3, six to twelve months; and between TT3 and TT4, and TT4 and TT5, one year or more. During pregnancy maternal antibodies against tetanus cross the placenta, providing protection for the infant for the first few months of life. At six weeks of age, the child begins a three-dose series of TT, in combination with diphtheria and pertussis, to provide continued protection.

Research regarding a single dose, slow-release tetanus vaccine for women during pregnancy is still in early stages of development. If this vaccine proves safe and effective, eliminating neonatal tetanus may be possible in the future.

Recognition of the severity of the neonatal tetanus problem has led to accelerated efforts to expand coverage worldwide. WHO now recommends two strategies for achieving this goal: first, all women of childbearing age, especially pregnant women, should be screened and, if indicated, immunized with tetanus toxoid at *every* contact with the health system; and second, midwives and traditional birth attendants (TBAs) should be trained in more hygienic delivery practices.

Pertussis: Pertussis, or whooping cough, is highly contagious and kills approximately 600,000 children each year. About 80 percent of unimmunized children exposed to the bacteria will contract the disease. A whole-cell, killed vaccine has been used for many years in combination with the diphtheria and tetanus vaccines in a three-dose schedule begun at six weeks of age. Three doses given at least four weeks apart are necessary for adequate protection.

Mild side effects such as pain and swelling at the injection site and fever occur in about one-third to one-half of those vaccinated. Some controversy also exists regarding potential neurologic complications from the pertussis vaccine. The benefits of the vaccine, however, far outweigh the slight risk of these more serious complications occurring.

Work continues on a new acellular pertussis vaccine that uses only parts of the pertussis bacterium, rather than the whole cell, to induce immunity. It reportedly causes fewer side effects while remaining equally effective. More conclusive results are needed, however, and general use of this vaccine is several years away.

Diphtheria: Diphtheria is a bacterial infection that can affect the respiratory, cardiovascular, and nervous systems and may result in death. In the developed world, widespread immunization has virtually eliminated diphtheria. In many developing countries, partial immunity from diphtherial skin infections protects some children from serious systemic infection. The three-dose DPT vaccine provides protection against all forms of diphtheria.

Poliomyelitis: The polio virus is transmitted orally via food, water, and other objects contaminated with the feces of infected persons. It is also transmitted orally through pharyngeal secretions. Polio is associated more frequently with paralysis than with death and disables several hundred thousand children each year. Many more are infected with the virus but do not have symptoms.

Two existing vaccines provide immunity against polio: a live, attenuated, oral vaccine (OPV) and an inactivated vaccine (IPV) injected intramuscularly. Both vaccines are trivalent, meaning that all three strains of wild polio virus are combined into one vaccine. WHO recommends OPV for developing countries because it is easy to administer, inexpensive, and effective in conferring intestinal as well as systemic immunity. Intestinal immunity is important because persons immunized with OPV excrete the vaccine virus in their

Age	Immunizations
Birth	BCG, OPV
6 weeks	DPT, OPV
10 weeks	DPT, OPV
14 weeks	DPT, OPV
9 months	Measles

Schedule recommended by WHO.

feces. When unimmunized individuals are exposed to the vaccine virus through fecal contamination, they receive some protection as well. This process lowers the rate of polio transmission in areas where the majority of people is immunized.

The major disadvantage of OPV is its extreme sensitivity to heat and light. Furthermore, in very rare instances the attenuated virus excreted by immunized persons reverts to a more virulent form and causes illness in vaccine recipients or in individuals exposed to it through fecal contamination. The incidence of vaccine-associated disease, however, is extremely low. The use of OPV versus IPV has been debated for many years. IPV is much less sensitive to heat and light than OPV, and it has not been associated with any vaccine-induced cases of polio since an outbreak in the 1950's. Only two doses of IPV are required to provide protection equivalent to at least three doses of OPV. The IPV virus does not replicate in the intestine, however, and therefore cannot protect others through oral-fecal transmission as can OPV. In addition, IPV is more expensive than OPV.

One alternative being considered is to give IPV and OPV in combination. The combination would produce intestinal immunity conferred by OPV while reducing the risk of vaccine-related paralysis. No schedule has been established, however, and the logistics of administering OPV and IPV in combination may be cumbersome and costly. Assuring that children receive the full series of doses, regardless of the type of vaccine being administered, is essential to achieving WHO's goal of eradicating polio by the year 2000.

Tuberculosis (TB): TB is a chronic bacterial disease spread in sputum droplets when infected individuals cough. TB can affect numerous systems in the body and is a major cause of death and disability in developing countries. Some estimate that nearly half the population in the developing world is infected. Few are symptomatic; once infected, however, symptoms can develop at any time.

The Bacillus of Calmette and Guerin (BCG) vaccine, consisting of a live, attenuated bacterium, is administered intradermally at birth or soon after and has been used for many years to prevent infection in infants. BCG's efficacy has been questioned, however, and considerable disagreement exists surrounding the level of protection it provides. The latest studies indicate that the BCG vaccine does confer immunity in children, particularly against the more severe forms of the disease such as miliary TB and tubercular meningitis.

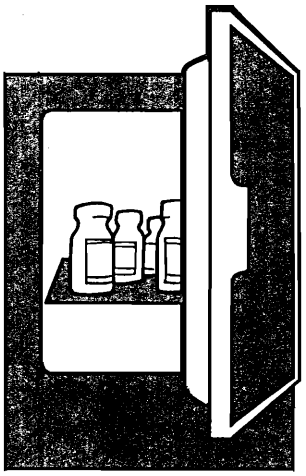
NEW VACCINES

New vaccines may be incorporated into EPI's recommended immunization schedule according to regional need. For example, WHO/EPI has recommended including hepatitis B vaccine in EPI schedules in countries where the carriage rate (rate of asymptomatic infection) of hepatitis B virus is 2.5 percent or greater.

Hepatitis B is an infectious virus usually acquired at birth or in early childhood; chronic infection is associated with cirrhosis and liver cancer in adulthood. Over 250 million people in developing nations are chronic carriers of the virus. Recently, the cost to public health programs in developing countries of plasma-derived vaccine (which uses antibodies from the plasma of carriers) to immunize infants has been reduced to about US$0.95 per dose, making its inclusion in EPI more feasible. It is compatible with other EPI vaccines and could be produced in a multivalent form with DPT or with DPT-IPV. The plasma-derived hepatitis B vaccine is safe and effective, and immediate side effects are rare. (For information on hepatitis B, see *Health Technology DIRECTIONS*, 6(3), 1986.) Newer, DNA-derived vaccines are safe and effective but more expensive.

Yellow fever is endemic in parts of Africa, especially West Africa. In 1988, WHO/EPI recommended routine inclusion of a live, attenuated yellow fever vaccine into EPI schedules in West Africa. Japanese encephalitis is endemic in parts of Southeast Asia and the Western Pacific. An inactivated vaccine is being considered for EPI schedules in those areas, but its high cost currently prohibits wide-scale use. Other vaccines under development include live, oral vaccines against rotavirus, cholera, and typhoid. The new typhoid vaccines, particularly the live, oral and the purified, subunit vaccines, show particular promise due to their effectiveness and relative lack of side effects compared to the existing vaccine.

The Cold Chain



The cold chain is a system of procedures, personnel, and equipment required to maintain vaccines at safe temperatures through delivery, storage, and distribution from the manufacturer to the vaccination site. An intact cold chain is essential at the national, regional, district, and local health post levels because all vaccines are sensitive to heat exposure. For example, cumulative exposure to heat over time will destroy vaccine potency. Some vaccines, such as TT and DPT, also are damaged by freezing temperatures.

At the national and sometimes regional levels, vaccines are usually kept in a cold room designed for long-term storage. Large cold rooms equipped with temperature recorders, alarm systems, and back-up generators are needed at this level to preserve bulk quantities of vaccine. At the regional and district levels, refrigerators and freezers are used to store vaccine, while local health centers and outreach units rely primarily on cold boxes and vaccine carriers as well as on small refrigerators. At every level of the cold chain, temperatures must be monitored closely and, ideally, back-up facilities should be available in the event of equipment or power failure. Crucial to the success of the cold chain are health care personnel trained in proper storage, transport, and administration of vaccine and correct use, maintenance, and repair of equipment.

Conditions in many countries pose serious challenges to the operation of the cold chain. Tropical climates, fuel and power shortages, long distances between vaccine storage facilities and vaccination sites, lack of spare parts for vehicles and equipment, inadequate transportation, and inadequate training of personnel in equipment maintenance and repair can cause breaks in the cold chain and threaten the vaccine supply. Many technologies exist that can facilitate the safe passage of vaccine through the cold chain.

Refrigerators powered by electricity, gas, kerosene, or solar energy are fundamental to an effective cold chain. Electric refrigerators are the least expensive to run and maintain, but they may not be reliable in areas where the electricity supply is irregular. To address this problem electric, ice-lined refrigerators have been designed that maintain the core temperature of the refrigerator at a safe level (0°C to 8°C) using only 8 hours of power during a 24-hour period. In the past, ice-lined refrigerators were available from only one manufacturer; however, WHO has recently tested and approved three new models from different manufacturers. One is a combined refrigerator/freezer unit that is less expensive than the older refrigerator model. Smaller ice-lined refrigerators and separate freezers are now also available at very reasonable cost.

In areas where the supply of electricity is nonexistent or very sporadic, kerosene- or gas-powered refrigerators often are used. Unfortunately, these refrigerators need frequent maintenance, and fuel shortages or problems with low grade kerosene often occur. Kerosene burners currently under development will enable these refrigerators to operate using low grade or unclean fuel without damaging the equipment. These also can be converted for use with bottled gas. In addition, several kerosene refrigeration accessories have been modified to improve performance. For example, the burner lamp glass now available for many refrigerator models is reinforced with steel, making it much less breakable. New fiberglass wicks are a major improvement over cotton wicks because they last longer.

Solar-powered refrigerators and ice-makers also may provide a reasonable alternative and may be the only choice in areas without other regular energy sources. The biggest drawback to solar refrigeration is the relatively high cost of purchasing and installing the unit and, for photovoltaic systems, replacing storage batteries. Prices vary, however, according to the type and size of the system. For example, areas with low solar radiation or needing ice-making capability will require larger solar panels with more

batteries, which are more expensive.

Benefits of solar refrigeration include lower long-term operating costs and improved performance and reliability. The price of solar technology is dropping, and solar refrigeration is fast becoming a feasible alternative to conventionally powered units. Currently, over 500 solar-powered vaccine refrigerators are in use worldwide. National training courses on solar refrigeration are planned in various countries in 1990, and regional training centers have been established in Colombia, Cyprus, Mali, and Thailand.

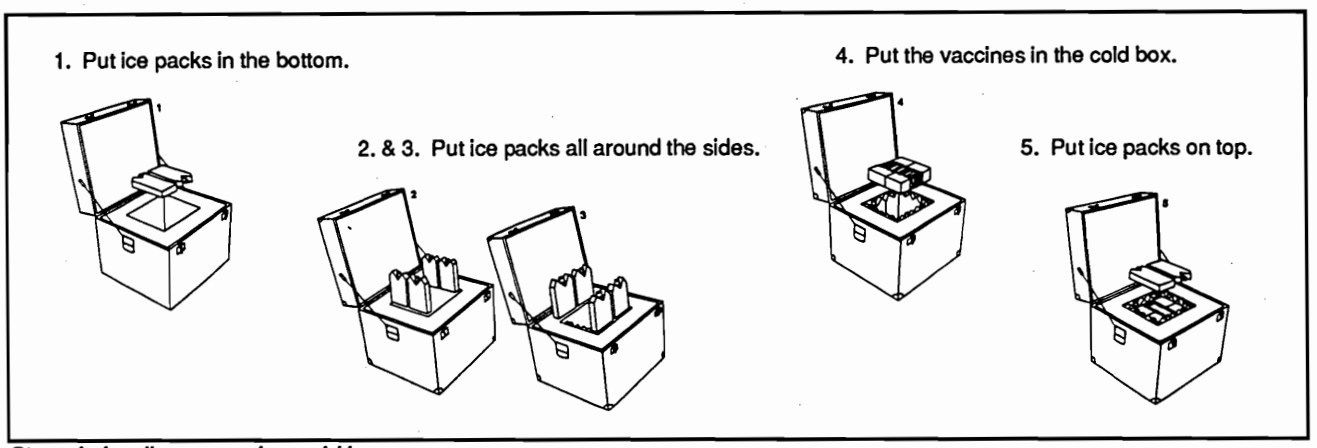
Poor maintenance of cold chain equipment, lack of spare parts, and lack of funds to cover maintenance costs are serious problems for many cold chain users. WHO has prepared a 15-module training series and a number of handbooks on the installation, use, and repair of all types of refrigerators and freezers. In addition, they have designed a "universal spare parts kit" containing parts and equipment essential to most cold chain equipment repair.

Cold boxes and vaccine carriers keep vaccines at the appropriate temperatures during transport from district or regional stores to local health posts and when conducting outreach activities in remote areas. Both are lined with icepacks and insulated to retain the cold. A container's "cold life," or length of time a vaccine can be kept safely in it, depends on the outside temperature, the thickness and quality of insulation, the number of icepacks used, and the number of times the box is opened in a given period. How well the icepacks and vaccines are packed and how tightly the lid is sealed after each opening also will affect cold life. Some of the larger cold boxes can maintain a safe internal temperature for up to eight days. Because of their weight and bulk, however, they are less portable than smaller boxes and only practical for four-wheel drive vehicles and fixed facilities.

Vaccine carriers are smaller than cold boxes and are able to keep vaccines cold (4°C to 8°C) for short periods of time (24-48 hours); however, the internal temperature of vaccine carriers depends in part on the climate and weather. In the absence of vaccine carriers, insulated flasks can be used to transport small quantities of vaccine. Unfortunately, some flasks are made of glass and can break easily. The cold life of flasks is about 12 hours. In choosing cold boxes and vaccine carriers, managers should consider storage capacity, cold life, weight when loaded, durability, and price. To ensure maximum effectiveness, training personnel in the proper packing and handling of cold boxes and vaccine carriers is crucial.

Monitoring the cold chain at all levels is essential. In large central stores, alarm systems and recording thermometers, which continuously document temperature changes over 7-day cycles on a circular graph chart, serve this purpose. During transport and storage, inexpensive and easy-to-read liquid crystal thermometers with cardboard backings can be used; however, they do not function at temperatures below freezing and are not as durable as some other thermometers. Dial thermometers that record or indicate minimum and maximum readings and trigger alarm systems also are useful at all levels of the cold chain.

Chemical heat-sensitive indicators are management tools used to monitor the temperatures to which the vaccines themselves are exposed as they move through the cold chain and, in some countries, the temperatures



J. Elford, AHRTAG

Steps in loading a vaccine cold box.

of the storage units. They do not measure changes in vaccine potency. Daily monitoring and recording of temperature is very important. For example, the 3M Monitor Mark detects cumulative heat exposures between 10°C and 34°C and any short exposures over 34°C during shipping and in-country transport of large quantities of vaccine to regional centers. It is placed inside the shipping carton, and one monitor is included with every 3000 doses of UNICEF shipments of vaccine. The indicator does not begin to register heat until manually activated by the vaccine supplier or when received in the country. A record-keeping table on the monitor helps determine where and when cold chain breaks occur. Other monitors include a diphtheria toxoid and tetanus toxoid shipping monitor that changes color when exposed to temperatures above 48°C.

PATHwatch™ and PATHmarker™, now being field tested in several countries as a step towards becoming more widely available, are indicators used to detect cumulative heat exposure for all EPI vaccines except OPV. PATHwatch is attached to the outside of small boxes of vaccine. Its companion, PATHmarker, is a point-of-use indicator attached to each individual vial of vaccine, allowing monitoring of cumulative heat exposure of the vial until the end of the cold chain. Both are based on a heat-sensitive chemical that changes color from pink to black, reaching its end-point (black) after the equivalent of eight days at 37°C. Because OPV is so sensitive to heat, a point-of-use polio indicator is also being considered. Currently, no point-of-use indicators are used routinely.

VACCINE STORAGE TEMPERATURES

SITE: MAXIMUM STORAGE TIME:	Central Store up to 8 months	Regional up to 3 months	Health Center up to 1 month	Transport up to 1 week
Measles Oral Polio (OPV)	-15°C to -25°C			
DPT Tetanus Toxoid—(TT) IPV BCG	+2°C to +8°C			

NOTE: Storage times are recommended maximum figures. Never freeze DPT, IPV, or tetanus toxoid vaccines, all of which freeze at temperatures below -30°C. Remember to check expiry dates with each use.

Adapted from *Manage the Cold Chain*, WHO

Freezewatch is used to determine whether vaccines that are damaged by freezing temperatures, such as TT and DPT, have ever been frozen and therefore need to be destroyed. The indicator resembles a small thermometer containing red ink and is attached to a white filter paper. It is included in the shipping carton or hung inside the refrigerator. When exposed to temperatures below -3°C for more than one hour, the ink expands and bursts, staining the filter paper red.

To combine the benefits of both the 3M Monitor Mark and the Freezewatch indicator, WHO is testing a single card, known as STOP!Watch, to which both monitors are attached. Rather than monitoring the temperature to which a particular box or vial of vaccine is exposed, it monitors the temperature inside refrigerators.

Cold chain monitors depend on good supervision to ensure that temperature monitoring is conducted daily. Program commitment to providing support for effective supervision is crucial.

Transportation is essential to the success and sustainability of the cold chain. Reliable transportation requires the availability of funds to cover recurrent costs associated with the vehicles, fuel, and drivers needed to transport vaccine shipments and personnel to all points of the cold chain.

Transport of vaccine in remote regions is particularly challenging. Vehicles appropriate for the terrain and distances, such as jeeps, refrigerated vehicles, lightweight motorcycles, and bicycles, are essential. When selecting a vehicle, it is important to consider where it will be used and for what purpose. Other considerations include the cost of fuel and maintenance and availability of spare parts. In general, light, four-wheel drive vehicles are more cost-effective than larger vehicles, and diesel models have lower fuel costs than gasoline models. Multi-purpose trips also can reduce fuel consumption. In Kenya, the national EPI has made arrangements with local commercial air services to deliver vaccines to remote areas when carrying out other business.

Injection Technologies

Three types of injection equipment currently exist: reusable equipment, disposable equipment, and jet injectors. Although WHO and UNICEF strongly recommend that a sterile needle and a sterile syringe be used for each injection, disposable or improperly sterilized needles and syringes frequently are reused. Practices such as changing needles but reusing syringes also are unacceptable because infection can be transmitted by blood that occasionally flows back from the needle into the syringe barrel. Recent studies have raised questions about the risk of infection, particularly with HIV (AIDS virus), from injections with inadequately sterilized equipment. At this time, no evidence exists that transmission of HIV or any other organisms occurs when vaccinating with properly sterilized reusable equipment. As a safeguard against improper reuse of injection equipment, WHO has called for the development of nonreusable, single-use injection devices. The first of these is now undergoing field trials.

Reusable needles and syringes are recommended for use in most developing countries due to their low cost and safety when properly sterilized after each use. Syringes are relatively long-lasting (50-200 uses, depending on field conditions) and are available in glass and durable, sterilizable plastic or nylon.

Glass syringes may break, however, and damage to plastic or nylon syringes may occur due to hard water deposits during sterilization, which may cause the plunger to stick. Other problems associated with reusable syringes include improper sterilization practices leading to the reuse of unsterile needles and syringes.

Disposable syringes and needles are designed to be discarded after a single use. These syringes are made of inexpensive plastic that cannot withstand the heat of sterilization. The primary advantage of disposable equipment is that its single use ensures sterility with each injection. In addition, immunization outreach programs and mass campaigns can be conducted more efficiently since sterilization equipment is not needed.

The primary disadvantage of disposables is that, despite recommendations to the contrary, they sometimes are reused. In addition, the purchase, shipping, and transportation of disposables is more expensive than of reusables because greater quantities of disposable syringes and needles are needed. Shortages of disposables also may lead to unsafe reuse of equipment or missed opportunities to immunize eligible women and children due to lack of equipment.

Needleless jet injectors use high pressure to propel a thin stream of vaccine through the skin when the nozzle is held firmly against the skin surface. No needles are necessary. Existing jet injectors have been used primarily to conduct mass campaigns because multiple doses of vaccine can be given rapidly and in quick succession; however, purchase and maintenance costs are high. Furthermore, several years ago a particular nozzle on a single jet injector was implicated in a hepatitis B outbreak in the United States. Cross contamination occurred during vaccination when infected blood droplets on the nozzle mixed with vaccine. A subsequent study confirmed that risk of disease transmission, while small, does exist when using these older-model jet injectors. At this time, WHO/EPI does not recommend jet injectors for general use.

Hand-held, single-dose, low-workload injectors that incorporate safeguards against disease transmission are under development. Sterilization between uses is considered unnecessary since no needles are used. In one design, the vaccine is contained in small, single-use capsules that are inserted in the injector, positioned against the skin, and destroyed during vaccination, thereby eliminating the risk of

PATHwatch™/PATHmarker™ and STERItimer™ are trademarks and PATHtimer® is a registered trademark of the Program for Appropriate Technology in Health (PATH).

blood traces remaining on a nozzle after an injection. Because the vaccine capsule is destroyed and must be replaced after each injection, these injectors are more appropriate for low-workload situations than for mass campaigns. In addition, they are expected to be less expensive and easier to maintain than the older models.

Auto-destruct and pre-filled injection equipment is being developed by WHO and several collaborating organizations so that the reuse of disposable or improperly sterilized reusable equipment can be avoided. Currently, various designs are being field tested. One auto-destruct model incorporates into a standard disposable syringe a mechanism that locks the plunger at the base of the syringe after the injection is given, making a second use impossible. Another design relies on a small plastic insert that expands to block the passage of fluid through the needle within a few minutes of exposure to an aqueous solution.

Because single use is assured, auto-destruct syringes do not require sterilization. Drawbacks, however, include higher cost relative to existing reusable and disposable injection equipment. Current designs will undergo further research and testing before full-scale production begins.

Single-dose, pre-filled, non-reusable injection systems also are under development. They provide the same benefits as auto-destruct designs and reduce vaccine wastage and filling errors. In one design, vaccine contained in a plastic reservoir and integral needle assembly is administered by squeezing the reservoir until it fully collapses. Once collapsed, the reservoir cannot be refilled. This simple design, which requires minimal training to use, will allow health providers, such as TBAs, to give injections. Current plans are to fill these devices with tetanus toxoid. Extending tetanus immunization beyond the official health system will be important in achieving WHO's goal of eliminating neonatal tetanus by 1995.

Improper **needle and syringe disposal** can be hazardous to health workers and community members due to the risk of accidental needle-stick injuries. Used needles and syringes can cause injury as well as transmit numerous pathogens, including the AIDS and hepatitis B viruses and tetanus. Waste management is therefore an important program component.

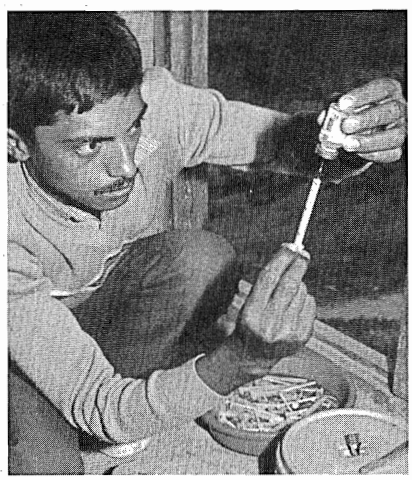
To reduce needle-stick injuries, several "anti-stick" needle cover designs are available, and many more are being developed. Generally these devices remain attached to the needle and syringe and permit safe recapping and disposal of the needle after use. Existing "anti-stick" devices are expensive.

To reduce exposure to contaminated blood on syringes, new containers for used disposable syringes are undergoing field testing. One model is designed to be used first as a shipping box for needles and syringes and then converted to a disposal box. Once full, a fuel stick provided with the box is lit, and the used syringes, with needles attached, are incinerated.

Boxes designed to securely hold used needles are known as "sharps boxes" and are recommended. Needle-stick injuries, however, still can occur as needles are carried to the box for disposal and when the box overflows. Alternative needle disposal devices are being investigated.

Sterilizing reusable needles and syringes kills pathogenic bacteria and viruses and prevents inadvertent transmission of infection. Immediately after use, the needle and syringe should be taken apart and soaked in clean water to rinse away traces of blood, pathogenic organisms, and vaccine. Water should be drawn through the needle and expelled several times into a different container to minimize contamination of rinse water. Use of detergent to wash equipment is not recommended, because vaccine that comes in contact with residual soap may lose its potency.

In areas where AIDS and hepatitis B are prevalent, soaking injection equipment for ten minutes in a 0.5% chlorine bleach solution before washing is recommended. This measure can protect health workers from



Anne B. Keiser/REACH, JSI

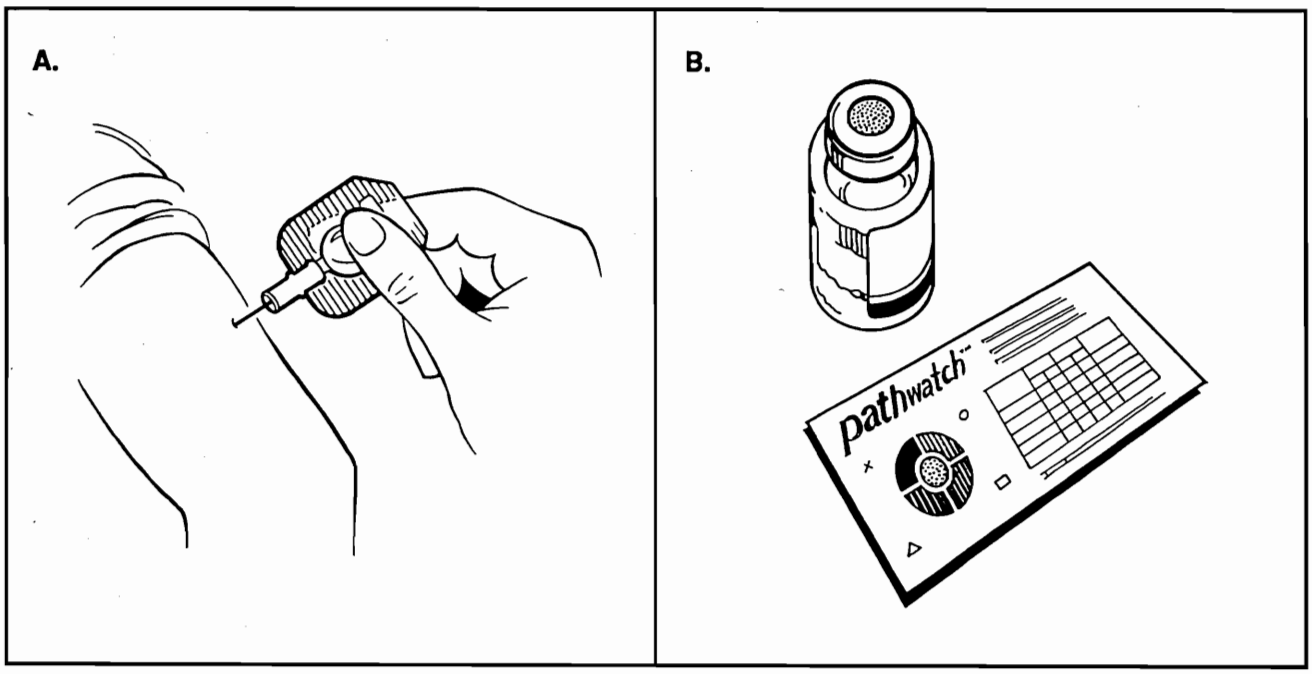
A sterile needle and sterile syringe should be used for each injection.

possible infection when handling equipment during the wash process. Infection can occur through cuts or broken skin on hands.

Steam-pressure sterilization, or "autoclaving," for 20 minutes at 121°C is the most effective method of sterilization. In health centers and other small facilities, this method is increasingly employed using portable steam sterilizers that have been modified from home pressure-cooker designs and are equipped with racks for needles and syringes. They can be powered by electricity, kerosene, bottled gas, or high efficiency wood stoves. Solar-powered steam sterilizers also are being developed and field tested in several countries. Upon completion of these trials in 1990, WHO/EPI will issue recommendations regarding their use. Additional innovations include removable steam-sterilizer racks to facilitate portability of equipment and triple-rack sterilizers to hold up to126 syringes. When sterilization is not possible, high-level disinfection by boiling for 20 minutes is an acceptable, though less effective, alternative. Boiling will destroy most bacteria, all viruses, and other pathogens, but not bacterial endospores. Because the temperature at which water boils decreases at increasing altitudes, boiling time should be extended by five minutes for every 300 meters (1000 feet) above sea level. At very high altitudes, however, boiling may not be efficient or effective.

Attempting to disinfect or sterilize injection equipment by soaking in liquid disinfectants is not recommended. Some pathogenic organisms, such as tetanus spores, are not killed using this method, and the disinfecting solution may not reach all necessary surfaces.

Timing is important to ensure proper sterilization and high-level disinfection. According to WHO, equipment that is steam sterilized for less than 20 minutes may not be sterile, and boiling or steam sterilizing for more than 20 minutes wastes fuel. Reusable indicators of heat exposure over time are being developed for use with steam sterilization or open-pot boiling disinfection. The chemical in the devices changes color irreversibly from black to green when equipment has been exposed to the proper temperature for a sufficient amount of time. STERI-timer™, for example, is attached to the steam sterilizer lid so that one side reacts to the temperature inside the sterilizer while the other displays the color change outside the lid. Early field trials are planned for 1990. PATHtimer® is a similar reusable device that changes color after 20 minutes in boiling water. It is currently being evaluated.



A. Example of a single-dose, pre-filled, nonreusable needle and syringe. B. PATHwatch™/PATHmarker™ cold chain indicators.

Program Management

EPI program management encompasses a wide variety of tasks including program planning and goal setting, resource allocation, cold chain management, record-keeping and disease surveillance, training and supervision, and evaluation. Recent initiatives calling for the eradication of polio, the elimination of neonatal tetanus, and a 95 percent reduction in the incidence of measles have led to increased interest in innovative management tools and delivery strategies for new and existing technologies. In particular, sustaining program accomplishments over time has become a high priority.

The ideal schedule currently recommended by WHO/EPI protects an infant against all six EPI-targeted diseases with five immunization visits between birth and nine months of age. Alternative schedules also have been devised to accommodate special regional or cultural circumstances. WHO suggests that each country adopt the recommended schedule that best meets its own needs.

Factors influencing immunization schedules include the accessibility of immunization services and resources, type of vaccine used (e.g., OPV versus IPV), cold chain requirements, and patterns and rates of disease transmission in target areas. For example, immunizing infants according to the recommended schedule can be difficult in many areas because most infants are born at home, far from fixed health posts. In remote regions in West Africa, where achieving even minimal immunization coverage is challenging due to long travel distances and difficulties maintaining a cold chain, a two-contact schedule using mobile teams has been devised (first visit: DPT-IPV, BCG; second visit: DPT-IPV, measles). This schedule is not ideal, however, since three doses of pertussis, not two, are required for optimal protection.

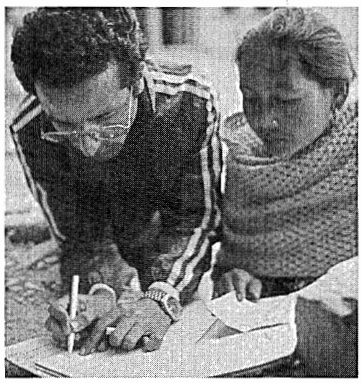
Biomedical factors also influence scheduling. Ideally, vaccines should be given before infants are at high risk for infection. If given too early, however, the vaccine will not be fully effective due to competition from maternal antibodies. Delaying immunization prolongs the infant's time at risk of disease, especially if a series of doses is required. Excessive delays between successive doses, however, do not justify restarting the series. Rather, the next dose should be given at the earliest opportunity.

Immunization coverage rates reflect the percentage of eligible persons who have received the complete series of doses of vaccine. For some vaccines, coverage levels of less than 100 percent may be acceptable based on the theory that when the majority of individuals in a community is immune to a disease, the risk of transmission to the rest of the group is reduced. This phenomenon is known as "herd immunity." It is advisable, however, that programs strive for coverage levels of 100 percent because vaccination failure (e.g., due to using vaccine that has lost its potency) does occur, and the extent to which herd immunity is effective is uncertain. In addition, it does not apply to all diseases. For example, tetanus is not transmitted from person to person. Instead, tetanus spores live in soil, so any unimmunized person can be infected upon contact with spores.

EPI managers must decide among a number of strategies for achieving high coverage. Combining strategies to suit regional circumstances and resource availability usually is most effective.

The least expensive strategy provides services from fixed health facilities, such as existing health posts or clinics. Relying solely on this strategy, however, may result in lower coverage, because the facility may not be accessible to many people.

Another strategy incorporates outreach efforts from fixed facilities to reach people in remote areas. To conduct outreach operations, fixed facility health staff organize and deliver systematic vaccination services to local communities. Permanently assigned mobile teams are another form of outreach for communities that have no access to



Anne B. Keiser/REACH, JSI

Vaccinator records immunization.

Anne B. Keiser/REACH, JSI

Raising tetanus toxoid coverage among women is an important goal.

health facilities. Outreach strategies are more expensive due to transportation costs. Maintaining immunization schedules and record-keeping also may be more difficult. Despite these drawbacks, outreach activities play a major role in improving and sustaining immunization coverage.

Finally, in some countries, mass campaigns or "immunization days" can supplement regular, ongoing immunization activities and help strengthen existing primary health care services. When conducting these activities, thorough planning and community mobilization and awareness are vital. Managers must ensure that these kinds of short-range activities are consistent with long-term goals. A single day or series of vaccination days is not enough to sustain programs. Follow-up and evaluation to assess the results of an accelerated immunization strategy are essential.

Regardless of the strategy, community mobilization is crucial to achieving and sustaining high immunization coverage. A combination of educational and promotional techniques should be used to motivate families to have their children immunized. Stimulating energy and commitment among health professionals and community workers also helps assure increased coverage rates as well as high quality service delivery.

Regularly **monitoring** specific indicators allows continuous adjustment of program operation. Indicators include vaccine usage and demand and current stock value, budget expenditures, number and frequency of immunization sessions, frequency and content of supervisory visits, training activities, community mobilization activities, and mileage and records of vehicle use.

Record-keeping is essential to managing a successful immunization program. Immunization status by vaccine, dose, and age group of the populations served should be recorded routinely on simple vaccination reporting forms. Because families often move and clinic-based records may be incomplete (if they are kept at all), many programs require families to keep vaccination or "road-to-health" cards documenting immunization status. Separate cards for women showing tetanus toxoid status also should be kept. Data from these home-based cards are very useful when estimating coverage levels for a particular area.

To **evaluate** program progress, all immunization programs should have clearly defined, measurable goals and objectives, such as raising coverage to a certain percentage in specific regions or populations, or reducing the incidence of a particular disease. Evaluation techniques, such as disease surveillance and coverage surveys, are used to measure progress in achieving these goals. These activities, conducted routinely and at all program levels, also enable managers to identify problems and revise priorities. Routinely reporting all new cases of targeted diseases and investigating outbreaks also is very important.

Disease surveillance is used to monitor trends and patterns in incidence and document the impact of immunization programs. In countries where routine surveillance is not well-established, WHO recommends developing networks of sentinel monitoring sites. Sentinel sites are selected clinics, hospitals, or local health posts throughout a region or country that monitor incidence and report outbreaks of EPI-targeted diseases. Overall program effectiveness and appropriateness is measured using data from these sites.

Local area monitoring, a similar technique, uses well-developed hospital units to monitor disease incidence trends over time. Polio, measles, and neonatal tetanus are monitored most effectively because they are relatively easy to diagnose.

Coverage surveys also help determine immunization coverage rates, program achievements, and possible reasons for immunization failure. Cluster sampling is a relatively inexpensive and quick technique developed by EPI to assess coverage. The process involves two steps. First, thirty representative groups, or "clusters," are identified within a country, region, or urban area in proportion to their population (i.e. larger communities contribute more clusters). Second, one household per cluster is randomly selected as a starting point. From that point, visits are made house-to-house until seven

children of the appropriate age (usually 12-23 months old) are found. Tetanus toxoid vaccine status of mothers with infants 0-11 months old is determined during the same survey, so seven women also are chosen from each cluster. The immunization status of each of the 210 mothers and children selected (7 x 30 clusters) is determined by looking at vaccination cards and by interviewing parents. Based on cluster sampling results, coverage estimates are made for the entire area selected. Cluster sampling can reveal trends in coverage rates over time. Data from single clusters, however, are not statistically valid.

The U.S. Agency for International Development (A.I.D.)'s Demographic and Health Surveys (DHS) are used to collect comprehensive health data, including immunization status. The surveys involve extensive house-to-house interviews, nutritional assessments, and checks of vaccination or "road-to-health" cards. Summary reports are submitted to national health ministries, and data sets on nearly 30 countries are available. (See Materials Available, p. 16).

The "drop out" rate after the first dose of vaccine in a series is a major concern of many programs. In some countries, less than half of children receiving the first doses of DPT and OPV receive the final doses. To improve coverage rates, women and children should be screened for eligibility at every contact with health care services, and, if possible, immunized on the spot. Missed opportunity studies have been carried out in many countries to determine why eligible women or children are not immunized despite contact with the health system. These studies reveal several common reasons why immunization often does not occur. For example, potent vaccines may not be available at all times, health care workers may refuse to vaccinate ill children or pregnant women in the first trimester, schedules may be miscalculated, vaccination records may be inaccurate, or vaccinators may be reluctant to open a new vial of vaccine for just one child.

Improved training and supervision of health care providers can help reduce these problems. Also, parents need easily understood information about the benefits of immunization and the importance of returning to receive the full series of doses, the time and location of the next visit, and how to treat common immunization side effects such as soreness at the injection site and fever.

UNICEF and WHO also promote "rapid assessments" to provide quick feedback on specific program interventions. These assessments are comprised of open-ended interviews, site visits, and document analyses and are less formal than standard evaluations. They are problem-oriented and are intended to answer basic questions such as what worked, what did not, and why. Rapid assessment steps include defining the evaluation problem, developing a set of questions to be addressed, identifying particular experiences from which to learn, conducting the evaluation, and preparing a brief, final report.

To analyze the data from these various evaluation methods, EPI managers and personnel can use any number of the new computer software packages being introduced to national EPIs. (See box, p. 14).

Evaluation Strategies

OBJECTIVE	METHOD
Measure coverage	-WHO cluster sampling method -Comparison of doses delivered to eligible population
Detect disease trends	-Sentinel monitoring sites -Routine disease reporting
Assess program impact	-WHO cluster sampling method -Disease surveys; questionnaires -Rapid assessments -WHO outbreak investigation method
Assess cold chain	-Thermometer, cold chain monitor readings -Inspection of equipment
Review overall program	-In-depth evaluation of costs, personnel, transport, logistics, community mobilization

Adapted from Monitoring of National Immunization Programmes, *a WHO publication.*

Qualitative evaluation methods, in conjunction with quantitative methods, are useful in redefining program goals and assessing progress in meeting these goals. For example, knowledge-attitude-practice (KAP) surveys, which use long and detailed questionnaires, evaluate what people know about an issue, whether or not their behavior reflects their knowledge, and where they obtained their information.

Focus group discussions provide another way to gather qualitative data. Six to eight people of similar background are brought together to discuss a particular issue such as attitudes towards immunization among mothers-in-law. The discussion, which is guided by a trained group leader, is intended to reveal attitudes and opinions about the issue that may not be expressed in other types of surveys. Results of these qualitative evaluation methods are used to devise more effective information, education, and communication strategies and to better understand community health beliefs.

Training and supervision are crucial to the success of immunization programs. Training activities should be ongoing, task-related, and practical, especially as new immunization technologies and program initiatives are introduced and services are extended to more peripheral areas. A major challenge to effective training is frequent staff turnover due to extended leaves of absence, reassignment to other regions, or job termination. Training programs must try to address this problem by establishing contingency plans and by training back-up personnel. Technical training of health personnel alone does not guarantee immunization program success. Training also should be extended to community leaders, local politicians, school teachers, social workers, and other citizens.

Supervision ensures that procedures are being followed and provides feedback to health workers on job performance and program effectiveness. Regular supervisory visits and filling out weekly, monthly, and quarterly checklists enable supervisors to assess program progress and identify problems. A weekly list might include the following questions. Were all scheduled vaccination sessions held? Was sterile equipment used for each injection? Were sufficient quantities of vaccines available? Was the refrigerator checked daily? Checklists also help monitor program management activities such as inventory control, record-keeping, and cold chain maintenance.

Job descriptions and performance standards should be established, and tasks should be clearly defined and understood by all personnel. Regular supervisory visits to the field enable supervisors to meet face-to-face with workers, understand operational issues, and observe performance. Positive feedback enhances motivation and may reduce high worker turnover rates, which can disrupt program activities. These visits also allow workers to ask questions and clarify procedures. Since transport is often a limiting factor for supervisory visits, more effort to coordinate field visits of different health program staff is important.

WHO has developed numerous training courses for both program managers and field workers. Courses for senior and mid-level managers include topics on estimating disease prevalence, program goal-setting, coverage survey methodology, program evaluation, and cold chain management. A new course for senior level EPI managers is being prepared for testing in 1990. These courses are about two weeks long and are conducted by national and international staff.

EPI COMPUTER SOFTWARE

Several new computer software packages are being refined and introduced to national EPIs:

* **Computerized EPI Information System (CEIS)** stores and analyzes demographic data, disease incidence, coverage rates, and budget information. It is used for ongoing evaluation of program activities and facilitates the exchange of data on local, regional, national, and international levels.

* **Coverage Survey Analysis System (COSAS)** analyzes data from coverage surveys and produces computerized graphs and tables summarizing coverage levels, drop-out rates, and missed opportunities for immunization.

* **COSAS-TT** is being developed to assess tetanus toxoid coverage rates.

* **EPICost** uses a spreadsheet format to perform cost analyses.

* **EPI Cold Chain Monitoring System (EPIC)** analyzes the results of cold chain monitoring surveys.

HEALTHTECH AND REACH

Among the programs launched by A.I.D. to improve child survival in developing countries, two have a particular impact on immunization delivery: the Technologies for Child Health (HealthTech) program and the Resources for Child Health (REACH) project.

Begun in 1987 and managed by the Program for Appropriate Technology in Health (PATH), HealthTech focuses on the development, field assessment, and technology transfer of appropriate technologies related to child survival. Many HealthTech technologies are designed to improve immunization practices, particularly vaccine storage and delivery.

Technologies developed and promoted by HealthTech are referred to as "social technologies." These are designed to meet perceived health needs rather than measured market demands. A major HealthTech strategy is to develop self-sustaining products by involving private sector companies in product development and advancement. Effective partnerships between public sector agencies, such as UNICEF, WHO, and A.I.D., and private sector organizations are key to the success of this approach. Immunization technologies currently being developed include various single-use, nonreusable injection systems, time/temperature indicators for boiling and sterilization, cold chain monitors for vaccine supplies indicating cumulative exposure to heat, and a solar refrigerator/icemaker.

The REACH Project was launched in 1985 and is managed by John Snow, Inc. REACH provides technical support primarily in the areas of health care financing and program management and evaluation. For example, new surveillance and evaluation techniques, such as specific coverage survey methodologies and computerized information systems, have been developed under REACH. Cost-effectiveness studies of EPI have been conducted in several countries. REACH also has assisted in social science research to improve immunization acceptability among certain populations and has played an important role in operations research to assess new technologies being developed by HealthTech and other programs, including nonreusable injection systems. New training materials on logistics and management of EPI also have been developed. Finally, REACH has helped to shape national immunization policy through dialogue with host countries and nongovernmental organizations, such as UNICEF and WHO, and has participated in sustainability studies and formal EPI reviews.

WHO courses for health workers in the field include topics on cold chain logistics, cold chain equipment repair, and handling of vaccines and injection equipment. These courses are conducted by national, regional, and district staff who already have taken the course. Countries may modify course content to suit regional circumstances.

Handbooks and guidelines that cover more specific topics on recent technological developments and program initiatives also are available from WHO. In addition, audio-visual materials, such as posters and slides, can be obtained from EPI through regional representatives.

Conclusions

Each year immunization programs worldwide prevent millions of childhood deaths. Yet millions more women and children remain unimmunized and at risk of death and illness due to vaccine-preventable diseases. Recent WHO/EPI initiatives call for the reduction or eradication of several of these diseases, and increased efforts are under way to achieve universal vaccine coverage within the next decade. New technologies will be essential to achieving this goal. Some are available now, and many more are under development and should be ready for widespread use over the next several years.

These technologies span areas such as vaccines, vaccine delivery and cold chain equipment, and program management techniques. For example, improved refrigeration and cold chain monitoring devices will preserve vaccine more effectively at all levels of the cold chain. Similarly, new injection and sterilization technologies will make vaccine administration safer, both for health workers and for those being immunized. These new technologies, in conjunction with political commitment and community involvement, will greatly enhance the prospects of achieving and sustaining universal immunization and protecting all children against vaccine-preventable diseases.

Materials Available

Several good resources are available in small quantities free of charge from WHO/EPI:

For information on cold chain equipment, consult the **Product Information Sheets** published in English, French, and Spanish. **The Cold Chain Newsletter**, issued periodically in English and French, contains the latest information on cold chain developments. **Evaluation and Monitoring of National Immunization Programmes** provides detailed information on strategies to monitor and evaluate all aspects of national EPIs. Further references are listed in the **EPI Bibliography**, which is updated annually. To obtain these materials, write: WHO/EPI, 1211 Geneva 27, SWITZERLAND, or to WHO regional offices.

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World Immunization News, a free bi-monthly newsletter with practical suggestions for immunization programs, is available in French, English, and Spanish. Request it from: Carter Presidential Center, Task Force for Child Survival, One Copenhill, Atlanta, GA 30307, U.S.A.

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For information on EPI activities in the Americas, consult the **EPI Newsletter**, which is published bi-monthly in English and Spanish. Contact EPI, Maternal and Child Health Program, Pan American Health Organization, 525 Twenty-third Street, N.W., Washington, D.C. 20037, U.S.A.

The Resources for Child Health (REACH) project has published **EPI Essentials: A Guide for Program Officers**, an excellent manual that covers all aspects of EPI management and evaluation. The guide is available in English for US$20, plus $3/copy for overseas orders. Contact: REACH, John Snow, Inc., 1100 Wilson Boulevard, Ninth Floor, Arlington, VA 22209, U.S.A.

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A 1986 issue of **Population Reports** covered immunization. "Immunizing the World's Children" describes in detail EPI diseases and vaccines, cold chain logistics, injection and sterilization technologies, and program management and evaluation. For a free copy, write to: Population Information Program, The Johns Hopkins University, 624 North Broadway, Baltimore, MD 21205, U.S.A.

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Demographic and Health Surveys (DHS) data sets are available for nearly 30 countries. Sets include immunization coverage estimates. For country lists and copies of published data, write to DHS Data Archives, Institute for Resource Development, 8850 Stanford Boulevard, Suite 4000, Columbia, MD 21045, USA.

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A bibliography on immunization is available from PATH.

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health technology
directions

PATH Program for Appropriate Technology in Health

Leprosy

Leprosy is a chronic, infectious, mycobacterial disease that affects about 10 million people, mainly in developing countries. The World Health Organization (WHO) estimates that approximately 1.6 billion people currently live in regions where the prevalence of the disease exceeds one case per 1,000 persons.

Leprosy, also known as Hansen's Disease, primarily affects peripheral nerves, skin, and mucous membranes. The disease exacts a high social as well as physical toll. If left untreated, leprosy can result in deformity and disability, causing those afflicted to be needlessly shunned and feared in many parts of the world because of myths and prejudices associated with the disease. Although effective drugs to cure leprosy have been available for several decades, many sufferers are reluctant to identify themselves by seeking treatment. This is partly because they fear that families, friends, community members, and employers may reject or ostracize them. Yet leprosy is curable, and if it is diagnosed and treated early, deformity and disability can be prevented.

During the 1980s, several new technologies were developed that have led to major improvements in the treatment and control of leprosy. The most important of these is multidrug therapy (MDT), which uses a combination of drugs to treat the disease and was developed to address the problem of drug resistance associated with single drug therapy. Other technologies related to program management, service delivery, patient and community education, and the prevention and correction of disabilities also have led to more effective leprosy control activities worldwide.

This issue of DIRECTIONS describes leprosy and reviews the technologies used in its diagnosis, treatment, and prevention.

Description and Diagnosis

Treatment and Prevention

Program Management

Volume 9, Number 3 ISSN: 0730-8620 1989

Description and Diagnosis

Description
Mycobacterium Leprae, the bacillus (rod-shaped bacteria) that causes leprosy, is a slow-growing organism closely resembling the tuberculosis bacillus. Because *M. Leprae* has never been cultivated successfully *in vitro*, knowledge about it is limited.

Leprosy generally is more common among males than females. This difference, which is less pronounced in children, may exist because adult males in many societies have greater mobility than their female counterparts and thus more opportunities for exposure to the bacillus. Leprosy's average incubation period ranges from two to seven years and sometimes longer.

Transmission: The exact mode of leprosy transmission is still unclear. For many years, leprosy was believed to be transmitted through direct skin-to-skin contact. Because leprosy bacilli usually are not found on the skin's surface, however, experts now consider this mode unlikely. Instead, they believe that *M. Leprae* is transmitted primarily via the upper respiratory tract, which may harbor millions of leprosy bacilli. With each cough or sneeze, the bacilli are discharged on droplets or dust particles that healthy individuals then inhale. Prolonged, close contact with infectious persons is likely to increase the risk of transmission.

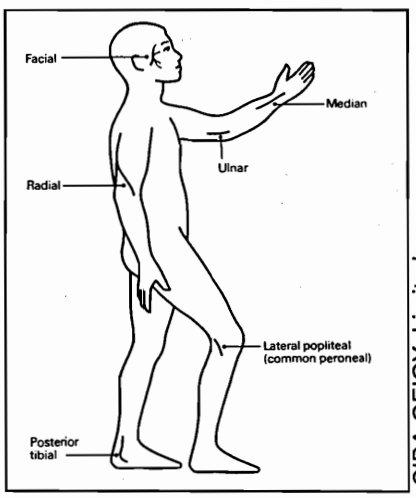
Susceptibility: The incidence and distribution of leprosy varies widely and irregularly within endemic regions, suggesting that the risk of acquiring the disease varies among individuals. Thus, while leprosy bacilli may be transmitted easily, perhaps 95 percent of people who are infected with the bacilli never develop the disease. Cell-mediated immunity (CMI), or the ability of individual cells to resist infection, is the mechanism that protects against leprosy. CMI also influences the type of leprosy that develops.

Factors influencing the strength of the CMI response in individuals include prior exposure to other mycobacteria, pregnancy, the presence of other diseases, and genetics. For instance, experts have known for years that a relationship exists between leprosy and tuberculosis (TB), which is also caused by a mycobacterium. Where TB is widespread, declines in leprosy incidence have been observed, possibly due to a cross-immunological effect between the two diseases. (For more information on TB, see DIRECTIONS, 6(1), 1986.)

Pregnancy may lead to the development of active disease in women already infected with the bacillus or to exacerbation and relapse in untreated or inadequately treated existing cases. This may occur because elevated estrogen levels associated with pregnancy lower CMI. WHO recommends that women with active leprosy postpone pregnancy until completion of treatment.

Some experts fear that the increased incidence of human immunodeficiency virus (HIV) infection, which causes acquired immune deficiency syndrome (AIDS) and is associated with depressed CMI, may lead to an increase in leprosy incidence or deterioration in existing cases. More research is needed, however, to confirm such a relationship.

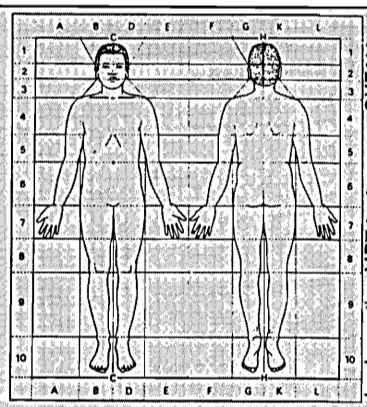
Diagnosis
Because individual resistance to leprosy varies, the disease appears in many different forms and exhibits a wide range of signs and symptoms. This sometimes makes diagnosis difficult, yet early diagnosis is critical to prevent disability and deformity.



CIBA-GEIGY, Limited

Peripheral nerves commonly affected by leprosy.

Slit-Skin Smears



Lesion and smear sites should be documented on a body diagram.

Skin smear examination is important for accurately diagnosing, classifying, and treating leprosy. High standards are vital when performing the procedure; smears that are mishandled or interpreted incorrectly after they are stained yield misleading results. Selection of smear sites should be made by an experienced leprosy clinician. Smears usually are taken from at least one ear lobe and from the most active edges of two to four typical skin lesions. They should be taken in good light so that lesions can be seen easily. After the samples are fixed to slides, they are stained using the Ziehl-Neelsen technique. The density of the stained bacilli in smears is called the bacterial index (BI). The morphological index (MI) indicates the percentage of uniformly stained bacilli in the slide. Taking good smears requires clean microscope slides and a slide box; slide labels or a grease pencil for marking slides; a sharp, sterile scalpel; matches, spirit, and a spirit lamp (if possible); cotton wool swabs; and surgical gloves.

After taking a smear, all materials contaminated with blood should be sterilized, if possible, or disposed of safely. To reduce risk of infection, especially with HIV, health workers should use scalpels with sterile, detachable blades that are discarded after a single use. Reusable scalpels or blades require steam sterilization or high-level disinfection by boiling between uses. Chemical disinfection is much less reliable and should be avoided. Where possible, workers should wear surgical gloves when taking smears and handling slides to prevent contact with blood or smear material. For information on resources regarding smear collection and interpretation, see Materials Available, page 12.

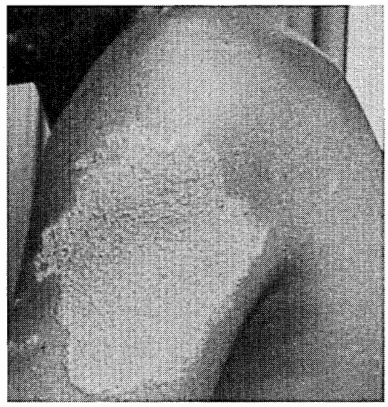
The three definitive diagnostic signs of leprosy are: (1) reduction or loss of feeling in skin lesions, (2) enlargement and tenderness of one or more peripheral nerves, and (3) the presence of acid-fast bacilli in a skin smear. Diagnosis is made when one or more of these signs is present. Technologies for diagnosis are limited, but health workers at all levels of the health care system can use basic clinical and laboratory techniques to improve diagnostic accuracy.

Skin lesions often are among the first signs of leprosy. While other diseases may cause lesions, only leprosy lesions have impaired sensation. A wisp of cotton wool, a nylon thread, thin paper, or a feather can be used to test for sensory loss. After asking the patient to close both eyes, the examiner touches normal and affected skin with one of these items. With eyes still closed, the patient points to the spot where sensation is felt. This test is repeated in affected and unaffected areas. Sensitivity to temperature is tested the same way with two test tubes, one filled with hot water and the other with cold. WHO recently field tested a new, inexpensive, battery-powered thermal sensibility tester. About the size of a pen, it provides a quick and easy way to test thermosensitivity. Pain sensitivity is tested by pin-prick.

Peripheral nerves may be tender and enlarged due to leprosy infection. (See diagram, page 2.) Nerve damage symptoms include sensory loss, muscle weakness, paralysis, and tingling sensations, especially in the face, hands, and feet. Impaired eyelid function, corneal anesthesia, and inflammation of the iris can lead to eye damage. Since nerve damage often results in painless injuries and burns, potentially leading to ulceration and disability, early identification of nerve involvement is crucial.

Slit-skin smear results are used to confirm leprosy diagnosis, classify the disease, and monitor the efficacy of chemotherapy. Accurate interpretation of smears depends on effective training and supervision of health workers and laboratory personnel and on the condition of laboratory equipment such as microscopes, glassware, and reagent supplies. (See box above.)

When clinical and bacteriological examinations are inconclusive, skin biopsies can provide needed information. Nerve biopsies are recommended in exceptional



The Leprosy Mission International

Paucibacillary leprosy lesion.

cases where peripheral nerves are enlarged, but skin lesions are absent. Major sensory and motor nerve trunks should not be biopsied.

Skin and serological tests to detect subclinical leprosy infection currently are under development. If adequately sensitive and specific, such tests could facilitate early identification and treatment and enhance understanding of risk factors relating to leprosy infection and disease.

Leprosy classification helps to determine treatment strategies and identify patients who are highly infectious or at risk of disease complications. The different forms of leprosy are classified along a continuous spectrum of disease. Three different classification systems are in use: the Madrid system, the Ridley and Jopling system, and the WHO system.

The Madrid system divides leprosy into three forms: (1) the lepromatous form, which is the most severe and indicates that the patient's CMI is extremely weak or nonexistent; (2) the tuberculoid form, which is the least severe; and (3) the borderline form, in which the patient shows some resistance but may have a variety of symptoms, depending on the strength of resistance.

The Ridley and Jopling classification system is somewhat more precise and divides leprosy into five groups from least to most severe: (1) polar tuberculoid, (2) borderline tuberculoid, (3) mid-borderline, (4) borderline lepromatous, and (5) polar lepromatous.

Both of these classification systems also recognize an indeterminate form of leprosy in which patients have one or a few ill-defined skin lesions. Peripheral nerves usually are unaffected, and skin smears are negative. Sensory impairment, however, is always present. These cases may develop into more serious forms of the disease or may resolve without treatment.

The WHO classification system divides leprosy into two groups: paucibacillary and multibacillary. Paucibacillary leprosy is usually noninfectious. It includes all smear-negative polar tuberculoid, borderline tuberculoid, and indeterminate forms. Multibacillary leprosy includes all smear-positive mid-borderline, borderline lepromatous, and polar lepromatous cases. The multibacillary patient has little or no resistance to leprosy bacilli and may be very infectious until treated.

Of these systems, the Ridley and Jopling system places the disease most precisely on the immunological spectrum, while WHO's classification is simplest and most applicable to developing country control programs. The WHO system's primary goal is to ensure that leprosy patients receive the appropriate MDT regimen. The relationship among the three systems is illustrated below.

The lepromin test, which consists of an intradermal injection of autoclaved *M. Leprae* into the patient's forearm, sometimes is used to classify the disease after diagnosis by indicating the strength of a patient's CMI response. Paucibacillary patients will have a positive test result, indicating a strong immune response. Multibacillary patients will have a negative test result, indicating that there is little or no resistance to infection. In mid-borderline and indeterminate cases, the results vary. The long waiting time (three to four weeks) between administration and interpretation of the test, however, makes follow-up difficult, especially in rural areas. Obtaining lepromin and training health workers to use the test add to the logistical difficulty.

CLASSIFICATION SYSTEMS	SPECTRUM OF LEPROSY				
Ridley & Jopling	Polar Tuberculoid	Borderline Tuberculoid	Mid-borderline	Borderline Lepromatous	Polar Lepromatous
Madrid	Tuberculoid		Borderline		Lepromatous
WHO	Paucibacillary			Multibacillary	

ALERT/German Leprosy Relief Fund

Treatment and Prevention

After diagnosis and classification, appropriate treatment is selected. Chemotherapy is the most important technology for treating leprosy and managing complications such as changes in immunological status (reactions) and relapse. If chemotherapy is started early, recovery from leprosy usually is complete, and disability can be prevented. New treatment and prevention technologies, such as vaccines, also are under development. Technologies to control disabilities include tools and techniques to facilitate physical functioning and protective devices to prevent further damage.

Chemotherapy: For nearly 40 years, leprosy has been treated with a single sulfone drug called dapsone. Dapsone revolutionized leprosy control. Isolation of leprosy patients no longer was considered necessary, and patients could treat themselves with daily doses at home. Dapsone is inexpensive, has few side effects at recommended dosage levels, and is very effective in arresting leprosy and its transmission. Complete cure, however, may require treatment for three years to a lifetime, which often results in poor patient compliance. Compliance problems, as well as exclusive reliance on a single drug administered in low doses over a long period of time, have led to the emergence of dapsone-resistant strains of *M. Leprae* in over 40 countries. Resistance causes frequent relapse or failure to improve with treatment, and patients resume infectiousness. (For details on drug resistance, see DIRECTIONS, 3(2), 1983.)

Treatment failure due to resistance can be avoided by combining drugs to treat leprosy. In 1981 WHO recommended that multidrug therapy (MDT) replace dapsone monotherapy for treating leprosy. The goals of MDT are to eliminate patients' infectiousness, interrupt disease transmission, shorten the duration of treatment, and prevent or overcome further development of drug resistance. WHO defined specific drug regimens for paucibacillary and multibacillary patients that are effective and feasible under a variety of field conditions. (See box, page 6.)

MDT uses three anti-leprosy drugs: dapsone, rifampicin, and clofazimine. Multibacillary patients receive all three, while paucibacillary patients receive only dapsone and rifampicin. Rifampicin is well-tolerated and very effective; a single 600 milligram dose kills almost all bacilli within several days, leaving the patient noninfectious. Multibacillary and paucibacillary patients both receive monthly, supervised doses of rifampicin.

In addition to dapsone and rifampicin, multibacillary patients take daily and monthly doses of clofazimine. Though very effective, clofazimine side effects can include reddening of skin lesions and darkening of skin exposed to sun, which causes some patients to object to its use. If a patient refuses clofazimine, a thiomide (ethionamide or protionamide) may be considered. Thiomides, however, are much more toxic than clofazimine, possibly causing liver damage when taken with rifampicin, and generally are not advisable.

MDT is a major development in leprosy treatment and control. Sustained use of MDT may reduce leprosy prevalence by 75 percent in five years, making possible the eventual eradication of

A.

B.

CIBA-GEIGY, Limited

A. Multibacillary patient before MDT. B. The same patient after one year of MDT.

leprosy. Patients can be completely cured in six months to two years (depending on the form of leprosy), and those who receive MDT early in the course of the disease are much less likely to develop permanent disabilities.

Vaccines: Research on leprosy vaccines has been under way for many years. Progress has been slow mainly because *M. Leprae* cannot be cultivated *in vitro*, and large quantities of the bacillus can be obtained only from experimentally infected, nonhuman sources such as the armadillo. The Bacillus of Calmette and Guerin (BCG) vaccine, which protects against tuberculosis, was the first vaccine considered for leprosy because of possible cross-immunological benefits. BCG's protective effect against leprosy has been tested in four field trials. Because results ranged from 20 percent protection in Burma to over 80 percent in Uganda, BCG is not recommended for use against leprosy.

Current research is focusing on a vaccine combining heat-killed *M. Leprae* (HKML) with BCG to induce strong CMI responses in leprosy patients who previously had little or no response. Combining these mycobacteria may prevent infection as well as generate immune responses in patients already infected. Field trials of HKML alone and in combination with BCG began in Malawi and Venezuela several years ago. Study results will not be available for almost ten years.

Treatment of reactions: Reactions are acute episodes associated with changes in the patient's immunological status. They can occur in all forms of leprosy except indeterminate leprosy, regardless of whether or not the patient is on chemotherapy. Unless reactions are treated promptly and adequately, they can lead to severe and permanent neural and tissue damage.

Two basic reactions occur in leprosy patients. Type One lepra reactions, also known as reversal reactions, primarily occur in borderline cases and involve a sudden strengthening of the CMI response. Of greatest concern are the changes in peripheral nerves, which swell rapidly, become painful, and impair nerve function. If untreated, severe and permanent nerve damage may result, causing loss of sensation, muscle contractures, and permanent paralysis. Corticosteroids should be given to treat inflammation, and analgesics may be administered to relieve pain.

Type Two lepra reactions occur in lepromatous patients. They are caused by changes in humoral (systemic) immunity response and also are called erythema nodosum leprosum (ENL) reactions, which means red nodes of leprosy, because of their clinical features. Like Type One reactions, ENL reactions often affect nerve functioning. Unlike Type One reactions, however, they also may involve eyes, kidneys, spleen, testes, joints, and muscles. Corticosteroids and thalidomide or clofazimine are used to treat ENL reactions. Women of childbearing age should be given clofazimine instead of thalidomide, which can cause serious birth defects.

For either reaction, patients on MDT should continue the prescribed regimen, rest affected limbs, and limit activity until the reaction has passed. Severe reactions may require hospitalization.

Disabilities: Approximately 30 percent of registered leprosy patients suffer from deformities and disabilities. Damage to peripheral nerves, which maintain skin sensation and muscle movement, causes the majority of disabilities. Complications such as blindness, paralysis, and loss of

MULTIDRUG THERAPY FOR LEPROSY

	PAUCIBACILLARY LEPROSY	MULTIBACILLARY LEPROSY
WHO Recommended Regimen	Rifampicin--600 mg once-monthly, supervised Dapsone--100 mg (1-2 mg/kg body weight) daily, self-administered	Rifampicin--600 mg once-monthly, supervised Dapsone--100 mg (1-2 mg/kg body weight) daily, self-administered Clofazimine*--300 mg once-monthly, supervised, and 50 mg daily, self-administered
Duration of Treatment	Six months	At least two years or, when possible, until skin smears are negative
Surveillance after Completion of Treatment	Annual exams for at least two years	Annual exams for at least five years

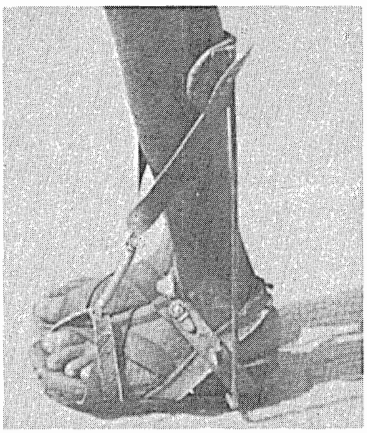
*If patients refuse clofazimine, substitute ethionamide or protionamide in daily, self-administered doses of 5-10 mg/kg body weight.

skin sensation are preventable with early diagnosis, treatment, and patient education. If disabilities develop, prompt measures to control them and prevent further damage are critical.

Although all areas of sensory loss are at risk of injury, the feet and hands are most susceptible. Infected wounds leading to ulceration of the foot is one of the most common problems of leprosy. Almost all ulcers heal with rest over time. If the patient does not detect the wound due to sensory loss and continues to walk without protection, however, severe tissue damage and eventually bone loss may result. Untreated hand injuries lead to similar problems including loss of fingers. Leprosy also may impair skin secretions, such as the ability to sweat, and affected areas often become dry, cracked, and therefore susceptible to infection.

Protective devices help prevent injury to hands, feet, and eyes. For example, gloves should be worn to avoid hand burns when cooking or tending fires, and shoes or sandals should be worn at all times. Deformed feet require specially designed shoes to fit abnormal contours and distribute weight evenly. Footwear with stiff soles and insoles of microcellular rubber or plastazote (a soft, heat-moldable foam plastic) are ideal. Extra high arch supports relieve pressure on toes, and soft, cotton sandal-strap lining protects against chafing and blistering. Nails never should be used in shoes for leprosy patients.

About 250,000 people may be blind due to leprosy, yet leprosy-related blindness is preventable



Churchill Livingstone

Modified sandal for dropped foot.

in most cases. Blindness may occur for several reasons. Muscles in the eyelid may be paralyzed due to peripheral nerve damage, thereby preventing blinking; the cornea may lose sensitivity (corneal anesthesia), making the patient unaware of eye damage or infection; or the iris may become inflamed during a Type Two reaction, potentially causing permanent damage.

Dark glasses can protect eyes from dust and dirt. A low-cost eye shield made of transparent plastic and adhesive also can be worn for protection.

Self-care techniques: Patients suffering from sensory loss must conduct regular, daily exams of hands, feet, and eyes to check for minor infections and injuries. To prevent infection and moisturize the skin, leprosy patients should soak affected hands and feet in water for 20 to 30 minutes every day. After soaking and patting the skin dry, the patient should apply petroleum jelly or a vegetable oil over the skin to help retain moisture. If eyelid muscle weakness is evident, patients should close eyes regularly as tightly as possible ("think and blink"), apply antibiotic eye ointment, and flush eyes with specially formulated disinfectant or tear substitute, or for iris inflammation, with steroid drops.

Clinical care: If ulcers develop, they should be cleaned thoroughly with soap and water. Adhesive zinc tape or other dressings or in severe cases, a plaster cast for about five weeks to rest the limb also may be necessary. A cast should not be used, however, until the ulcer is clean and the infection is controlled.

Physical therapy: Simple, daily exercises such as repeatedly extending paralyzed fingers can prevent muscle wasting and contractures and increase muscle strength. Conditions such as dropped foot or claw hand may require splints or braces to prevent further damage. Plaster or molded plastic splints also stabilize affected limbs during reactions, reducing pain and preventing contractures. To facilitate the use of small objects, gripping aids made of epoxy putty can be molded to items such as tools, pens and pencils, and eating utensils.

Surgery: Common surgical procedures include removing dead bone, draining abscesses, and debriding ulcers. Tendon transfer to straighten clawed fingers and toes and correct dropped feet, as well as reconstructive surgery to rebuild collapsed noses or replace lost eyebrows, also are possible. Severe deformity or infection may warrant amputation. Surgery also may be required to treat eyelid paralysis. Unfortunately, most leprosy control programs are not equipped to provide such specialized care.

Program Management

The essential components of successful leprosy control programs are: (1) early case-finding and treatment; (2) effective monitoring and follow-up of patients under treatment; (3) education of the patient, family, and community; (4) training and supervision of health care personnel at all levels of the system in leprosy diagnosis, case management, and referral; (5) program monitoring and evaluation; and (6) social integration and rehabilitation of persons with leprosy.

Early case-finding and treatment: Early case identification and registration allows prompt administration of chemotherapy to prevent disabilities and eliminate infectiousness. WHO defines a leprosy case as "a person having clinical signs of leprosy with or without bacteriological confirmation of the diagnosis, and requiring chemotherapy." WHO recommends that this definition be adopted worldwide so that data may be compared among different countries.

Both active and passive case-finding methods commonly are used. Case-finding activities, however, are valuable only if efficient, reliable treatment services are available for every case identified. Essential service components include well-trained personnel; well-organized, fully-stocked clinics; accessible laboratory facilities for smear and biopsy analysis; and referral facilities for patients with reactions, drug side effects, or deformities requiring surgical corrections.

Active case-finding methods include contact surveillance and screening of schoolchildren. In contact surveillance, health workers obtain smears and conduct clinical examinations on all previously identified patients and their household contacts to confirm diagnosis. It is most useful in areas of low to moderate endemicity and in urban slum areas, where cases often are clustered. Screening schoolchildren is useful in highly endemic areas. In Bombay, India, school surveys have been conducted since 1970.

Active methods with more limited use include total population surveys, job site screening, and rapid surveys. Total population surveys are useful only in highly endemic areas. Job site screening can be effective but may result in job loss for workers identified as having leprosy. Rapid surveys, usually organized at centrally located screening sites, are particularly effective when combined with general health examinations.

The Leprosy Mission International

Active case-finding methods include screening schoolchildren.

Despite these efforts, most cases are identified through self-reporting, referral, and notification. These passive methods absolutely require effective health education to dispel myths about leprosy, teach people to recognize early signs of the disease, and inform people about available treatment services.

Once cases are identified, MDT should be initiated immediately. Unfortunately, the pace of MDT implementation has been slow. Of the estimated 10 million leprosy cases worldwide, about 5 million cases are officially registered, and of this number only about 2.1 million cases, or less than half, have been put on MDT. In Africa, less than 20 percent of leprosy cases are receiving MDT.

Several factors contribute to this problem. First, initial costs of MDT are higher than dapsone therapy. The duration of MDT, however, is much shorter, especially for paucibacillary leprosy (six months instead of three to five years), making the long term cost-effectiveness of MDT much greater than dapsone therapy. In addition, drug costs are dropping steadily, as are total expenditures for treating disabilities, since disabilities occur less frequently among patients receiving MDT.

Blister Calendar Packs

Blister calendar packs provide a one-month supply of all necessary drugs for MDT. The upper portion of the pack contains the drugs to be taken monthly under supervision. The clinic worker tears off and retains this portion when the drugs are dispensed. The lower portion contains the daily doses of dapsone, organized by weeks into four rows. Different packs are available for both paucibacillary and multibacillary adult patients as well as for paucibacillary child patients. Multibacillary leprosy in children is rare, making blister calendar packs less cost-effective for this group. Study results from India, the Philippines, and Thailand indicate that patient compliance improves when these packs are used. In addition, non-medical personnel can be trained to dispense the packs, and time previously spent counting out pills and instructing the patient can be devoted to other control activities. Blister calendar packs appear to facilitate drug planning and supply, improve delivery of proper treatment from peripheral health posts to rural populations, reduce drug wastage and misuse, and improve clinic attendance. They are more expensive than "loose" drugs, however, and although it appears that using blister calendar packs is cost-effective, further studies are needed to confirm this.

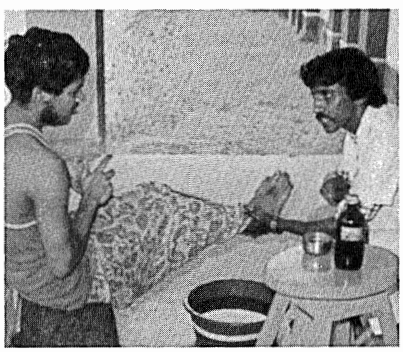
Experience over the last seven years has shown that effective MDT programs need adequate resources and well-trained personnel to carry out support activities related to MDT. Prior to implementing MDT in an area, all registered cases must be reviewed and those patients no longer requiring treatment should be released from the registers. In areas where resources are limited, MDT should be introduced on a small scale in one area or district and then slowly expanded to other areas as resources become available. A systematic method of tracing patients who have dropped out of treatment also should be established.

Follow-up: Monitoring and follow-up of patients on MDT is crucial to promote compliance and minimize interruption of treatment. Drug intake can be monitored by consulting with the patient and counting remaining tablets or capsules or by taking urine samples to test for the presence of anti-leprosy drugs. Dapsone is easily detected in urine using a spot test on filter paper treated with Ehrlich's reagent; a yellow ring immediately appears if the urine contains sulfones. Simply checking the urine for a reddish color will indicate if rifampicin has been taken in the last six to ten hours. Health workers also should make home visits to remind patients of appointments.

Because MDT regimens require coordinating the supply of different drugs and taking a mixture of daily and monthly dosages both at home and under supervision, assuring timely and correct drug intake can be difficult. One innovation to improve treatment compliance is the development of blister calendar packs to facilitate the delivery of drugs. (See box above.)

Once the prescribed course of treatment is completed, WHO recommends that, if possible, paucibacillary patients and their household contacts be kept under surveillance for at least two years, with annual clinical examinations. Multibacillary patients and their household contacts require five years of surveillance. Patients who have completed treatment should be instructed to return to the clinic at the first sign of relapse.

Health education: Because leprosy inspires such fear and misunderstanding, programs to control the disease require intensive health education for patients, families, and the community to dispel myths and reduce prejudice. Training people to recognize leprosy signs and symptoms also is important. Health education campaigns must take into account local attitudes and beliefs about leprosy. Campaigns are most effective when respected community members such as village chiefs, traditional healers, religious leaders, and school teachers are involved. Existing leprosy education materials can be adapted to specific settings to support effective leprosy education campaigns. (See Materials Available, page 12.)



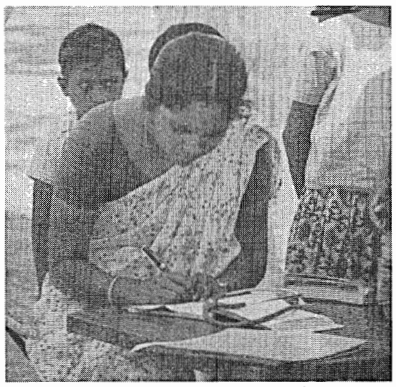
CIBA-GEIGY, Limited

Health worker explains importance of foot care to leprosy patient.

Patient education begins at diagnosis. To improve compliance, patients must understand what chemotherapy can accomplish and how long treatment is required. They also must develop a personal sense of responsibility for preventing disabilities and deformities and have a clear understanding of appropriate self-care techniques.

The patient's family also must be educated about the disease so that they do not reject or ostracize the patient. If family members understand the disease and the need for regular treatment, they can play an important role in achieving patient compliance with MDT and self-care.

Mass media can help educate the general public about leprosy. For example, in India, posters and billboards with simple phrases such as "leprosy is curable" and "leprosy is not hereditary" have been posted throughout the railway and bus systems in certain provinces. Similar messages are printed on railway timetables. Exhibitions and check-up stations allow waiting passengers to see videos, read pamphlets, and be screened for leprosy, if desired.



The Leprosy Mission International

Keeping accurate records is an essential component of effective leprosy control programs.

Radio and film presentations, pamphlets, community education campaigns, and school-based health education also can reduce the social stigma and prejudice often associated with leprosy. In Sierra Leone, a local theater staged several performances about a person with leprosy to raise community awareness.

Training and supervision: MDT implementation and other new control activities make training of health care personnel at all levels very important. Clearly defined tasks accompanied by good supervision increase efficiency, develop skills, and promote positive work attitudes. A manual with all essential information on leprosy diagnosis, treatment, management, and prevention must be developed for health workers. Adequate training in leprosy must be included in the curricula of medical and paramedical training institutions, especially in countries where the disease is endemic.

Monitoring and evaluation: Simple, standardized information systems should be established to monitor and evaluate the operational, clinical, and epidemiological aspects of leprosy control. Ideally, the following data should be collected: number of registered cases, case detection rates, disability rates among new cases, MDT coverage and drop-out statistics, and relapse rates. At a minimum, leprosy control programs should maintain patient record cards or a treatment register for active patients. Patient record cards should contain demographic information, diagnosis, treatment initiation and completion dates, and follow-up examination results.

To ensure accurate statistics, program managers should establish routine quality control systems. The nature and extent of random quality control checks depends on the availability of supervisory staff and laboratories. Activities that should be reviewed routinely include leprosy diagnoses and classification, smear results, record-keeping systems, and statistical calculations.

To determine the effectiveness of leprosy control activities, WHO has helped develop the OMSLEP Recording and Reporting System, which is used in many countries. The system can be adapted to the specific information system used in each country, and its standardized format facilitates the comparison of data among different countries. Information can be compiled and interpreted with or without the use of microcomputers.

Social integration: The social isolation of leprosy patients, though less prevalent than in the past, is one of the last remaining barriers to the eradication of leprosy. Social isolation is unnecessary and inflicts untold suffering on patients and their families. Community programs help encourage social integration of leprosy patients. For example, community-based rehabilitation (CBR) for the disabled integrates leprosy patients by treating disabilities through existing health services within the community. CBR promotes awareness and responsibility for care among community members, increases self-reliance, and encourages the use of simple, affordable, and culturally acceptable methods and technologies for physical therapy and rehabilitation.

NATIONAL PROGRAM STRATEGIES

When establishing a national leprosy control program, important considerations include whether or not it will be integrated into general health services and how MDT will be introduced. In most countries, separate, vertical, leprosy control programs have been established. It is generally agreed, however, that leprosy care should be integrated into primary health care where possible. Although specialized care for leprosy patients still is needed, integration helps to reduce the stigmatization of leprosy patients, to improve access to comprehensive and continuous care, to prevent duplication of services, and to minimize dependence on donor agencies.

Integration requires extensive planning, a well-supported primary health care system, and effective supervision of staff. In highly endemic areas (more than 5 cases per 1,000 persons) a vertical program may be necessary to avoid overloading the system until additional resources are available. In India, which has an estimated four million leprosy cases, integration is occurring in phases. In highly endemic districts, leprosy control is organized vertically. In remaining districts, the program is managed through the general health care system.

MDT introduction has been a national policy in India since 1983, with the goal of curing all known cases by 2000. As of March, 1989, MDT had been introduced in phases into 112 of 201 highly endemic districts, with 2.3 million people receiving MDT. These phases are outlined below. In ten districts where MDT has been available for five years or more, overall prevalence rates for all districts have dropped from 20.7 cases per 1,000 to 2.4 cases per 1,000. The incidence and disability rates also are declining.

PHASES OF MDT IMPLEMENTATION

Mobilization	Planning and Preparation	Intensive	Maintenance
• organize positioning of infrastructure • provide basic training to staff • conduct active case-finding surveys to detect at least 80% of cases	• perform rapid surveys to detect remaining cases • conduct sample surveys to validate existing data and obtain baseline figures • screen all cases to verify classification and MDT eligibility • conduct intensive public awareness campaigns	• deliver MDT to eligible patients • follow-up on MDT drop-outs • monitor drug intake	• monitor patients completing MDT • conduct ongoing case detection: screen household contacts, school children • general health care staff assume more responsibility • phase out vertical program as prevalence declines

Adapted from report by Dr. N.S. Dharmshaktu, Ministry of Health, India

Conclusions

Leprosy is a serious public health problem affecting millions of people worldwide. In addition to physical suffering, leprosy patients often endure social ostracism and prejudice because of myths and misconceptions surrounding the disease.

Yet never before have the prospects been better for controlling and eradicating leprosy. New diagnostic, treatment, and program management technologies are being developed that may revolutionize the control of the disease. The most important of these is MDT, which represents a crucial breakthrough in the treatment of leprosy. Where chemotherapy has been introduced and sustained, marked reductions in leprosy prevalence have occurred. The future development of technologies such as vaccines to prevent and treat leprosy also promise to have profound effects on the control of the disease. In addition, health education and program management techniques to encourage public support of leprosy patients are receiving greater attention. For patients who have developed disabilities and deformities, rehabilitation tools and techniques now exist to improve functioning and prevent further physical deterioration.

All of these technologies can reduce the needless physical and psychological suffering of leprosy. Concerted efforts to improve health care delivery to leprosy patients and educate the public about the disease must continue, however, so that people with leprosy will seek and receive the treatment they need without fear of social reprisal.

Materials Available

WHO has produced several excellent publications on leprosy. They include: **A Guide to Leprosy Control, Second Edition**; **Epidemiology of Leprosy in Relation to Control**; **Chemotherapy of Leprosy for Control Programmes**; and **WHO Expert Committee on Leprosy**. All publications are available from WHO, Leprosy Unit, Division of Communicable Diseases, 1211 Geneva 27, Switzerland, or from WHO regional offices.

□

Implementing Multidrug Therapy for Leprosy, by Dr. A. Colin McDougall, covers all essential issues related to MDT introduction. It is available for US$7.95 per copy (includes shipping costs). Write to: OXFAM, 274 Banbury Road, Oxford, OX2 7DZ, U.K.

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Many resources are available from The Leprosy Mission International (TLMI). For example, **Preventing Disability in Leprosy Patients**, by Jean M. Watson, contains basic information and illustrations on care and prevention of disabilities. **Health Education in Leprosy Work** is an excellent manual for training health care workers. For details on taking smears, consult the **Technical Guide for Smear Examination for Leprosy by Direct Microscopy**. TLMI also produces a magazine every six months called **Partners**. It is available at no charge to leprosy health workers. For a complete list of English language teaching and learning materials and ordering information, contact: The Leprosy Mission International, 80 Windmill Road, Brentford, Middlesex, TW8 0QH, U.K.

Two comprehensive and well-illustrated guides entitled **Leprosy: Basic Information and Management** and **Leprosy for Medical Practitioners** are available in limited quantities free of charge from CIBA-GEIGY, Ltd., CH-4002, Basle, Switzerland.

□

Teaching Aids at Low Cost (T.A.L.C.) produces a wide range of training materials, slide sets, and guides on leprosy for training medical and paramedical personnel. For more information, write to: T.A.L.C., Box 49, St. Albans, Hertfordshire, AL1 4AX, U.K.

□

David Werner's books, **Where There Is No Doctor** and **Disabled Village Children**, contain excellent sections on the diagnosis and treatment of leprosy and on the care and prevention of disabilities resulting from leprosy. For ordering information, write to: Hesperian Foundation, P.O. Box 1692, Palo Alto, CA 94302, U.S.A.

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A bibliography on leprosy is available from PATH.

CORRECTIONS

In the last issue of DIRECTIONS ("Immunization," 9(2), 1989), the sentence at the bottom of the Vaccine Storage Temperature chart on page seven should have stated that DPT, IPV, and TT vaccines freeze at temperatures below -3° C, not -30° C.

On page ten, STERItimer's™ color change due to heat exposure was described as being irreversible. In fact, it reverts back to the original color as it cools.

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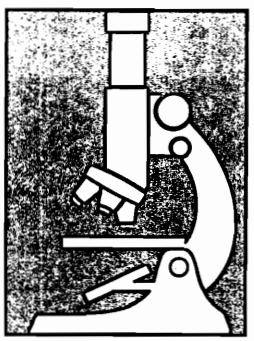
Malaria

Malaria is one of the most prevalent and debilitating tropical diseases. Nearly half the world's population—over 2.1 billion people in 103 countries—live at risk of the disease, and about 250 to 300 million cases of malaria occur annually, many among young children. The World Health Organization (WHO) also estimates that about 270 million people may be carrying the malaria parasite. In sub-Saharan Africa alone, one to two million cases per year are fatal.

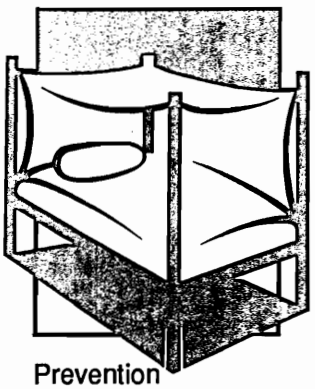
Malaria is caused by a single-celled blood parasite of the genus *Plasmodium.* It is transmitted by the bite of the female Anopheles mosquito. Early efforts against malaria focused on **eradication** using DDT insecticide to destroy the mosquito vector and anti-malarial drug treatment to destroy the parasite in the human bloodstream. In the 1970s, however, WHO shifted its focus to malaria **control** due to a major resurgence of malaria in many countries that was caused by the emergence of parasite resistance to chloroquine, the antimalarial drug of choice for years, and vector resistance to DDT and other insecticides. Alternatives to these compounds were costly, and other ecological, sociocultural, and operational factors such as resource shortages, poorly planned development projects, deforestation, war, and human migration also confounded efforts to eradicate the disease.

To effectively control malaria despite increasing drug and insecticide resistance and continuing economic and social hardship, attempts are being made to develop new technologies to diagnose, treat, and prevent malaria. Alternative antimalarial drugs are now being administered in some regions where chloroquine resistance has emerged. New biological, environmental, and chemical techniques to destroy the mosquito and prevent human-vector contact also are being advocated.

The first two sections of this *DIRECTIONS* issue describe malaria diagnosis, treatment, and prevention. The third section reviews malaria control strategies.



Diagnosis and Treatment



Prevention

Control Strategies

Volume 10, Number 1 ISSN: 0730-8620 1990

Disease Cycle

Four species of the *Plasmodium* parasite cause malaria infection in humans: *P. falciparum, P. vivax, P. ovale,* and *P. malariae*. Symptoms for all forms include shivering, fever, and profuse sweating, as well as nausea, headache, spleen enlargement, anemia, and muscle pain. Incubation period, type of symptoms, and duration of attack vary depending on the *Plasmodium* species and on the individual's level of acquired immunity to malaria infection.

P. falciparum, the most severe and prevalent species, causes 90 percent of all malaria infection in Africa and the majority of malaria deaths worldwide. It can lead to liver and kidney failure and brain and lung complications; cerebral malaria is a severe, often fatal result.

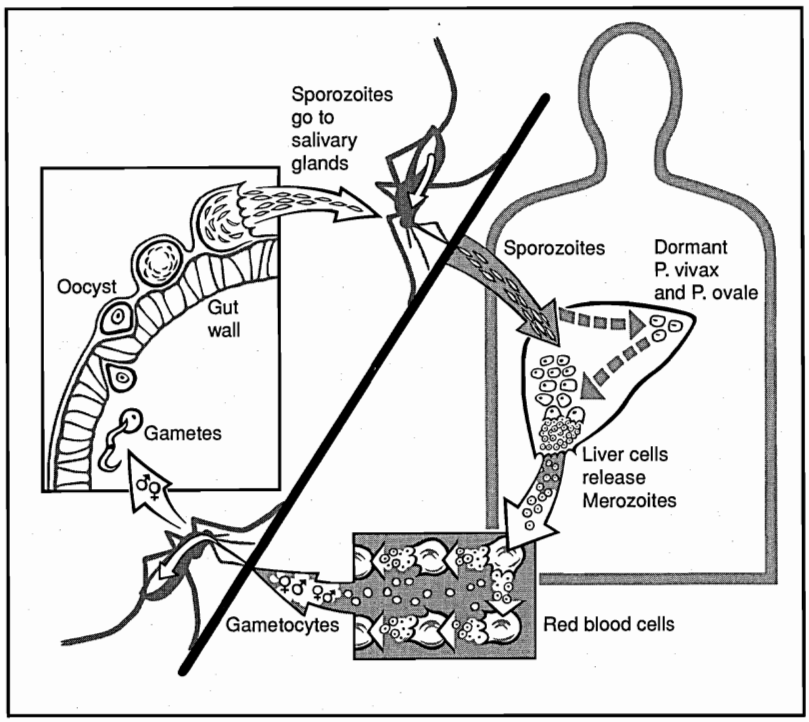
P. vivax, which is also widespread, and *P. ovale,* which is less common, may cause acute illness and relapse but are seldom fatal. *P. malariae*, also known as quartan malaria, has a spottier distribution and causes a chronic, less severe illness that can persist for decades.

Malaria transmission depends on four factors: the vector (mosquito), the parasite, the vertebrate host, and the climate and environment. Various species of the female Anopheles mosquito transmit the malaria parasite to the human host by taking blood from an infected person, harboring the parasite while it reproduces, and then infecting a different person during a subsequent bite. The parasite's life cycle is complex, requiring both a human and mosquito host in which to undergo two distinct developmental stages: the asexual and the sexual. In the asexual stage, the parasites, in the form of **sporozoites** when the mosquito injects them into the bloodstream, invade liver cells where they multiply, producing daughter parasites called **merozoites**. When the infected liver cells burst, the merozoites enter the blood stream where they invade red blood cells and multiply. The red blood cells rupture, releasing more merozoites. Some develop into male and female **gametocytes**, while the majority continue the cycle of invading and bursting red blood cells. Malaria's clinical symptoms of fever and chills relate directly to the rupturing cells. Unlike *P. falciparum* and *P. malariae*, *P. vivax* and *P. ovale* may remain dormant in the liver for months or years before rupturing and reentering the blood stream, causing relapses, sometimes long after initial infection.

The sexual stage begins after the mosquito feeds on infected blood, ingesting male and female gametocytes. These cells mature into **gametes**, which combine sexually, eventually forming **oocysts**, which then produce **sporozoites**. These are released into the mosquito's gut, migrate to the salivary glands, and are injected into the human host during the next blood meal.

In highly endemic regions, repeated infection can lead to partial immunity in the human host. Infected adults in such hyperendemic areas may be asymptomatic or experience only mild clinical illness when reinfected. Infants under six months are partially protected against malaria due to the presence of maternal antibodies transferred via the placenta. By contrast, in children between the ages of six months and five years, when maternal antibodies are gone and active immunity has not yet developed, malaria infections can be severe, causing high fever, chronic anemia, and an enlarged spleen. Children who are malnourished are at increased risk of severe illness once infected.

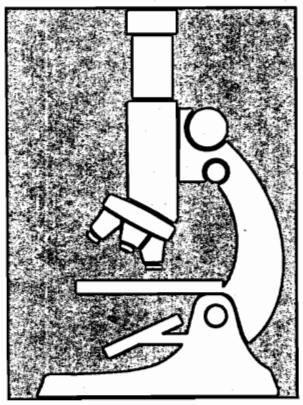
Other groups that are particularly vulnerable are pregnant women (see box, p. 7) and nonimmune migrants and travelers coming from nonendemic to hyperendemic areas. Individuals with the sickle cell trait or related conditions are partially protected against *P. falciparum* malaria. To date, no association has been established between HIV infection and increased susceptibility to malaria.



PATH/Tom Yagle

Malaria parasite life cycle.

Diagnosis and Treatment



MALARIA DIAGNOSIS
Definitive malaria diagnosis depends on the accurate detection of malaria parasites in the blood. For individual care, early parasite detection and treatment, especially of *P. falciparum*, is critical since complications of infection may be severe and sometimes fatal.

For decades, microscopic detection of parasites in stained blood smears has been the mainstay of malaria diagnosis. New diagnostic methods are being developed and tested, but at this time, they are in experimental stages and are being applied primarily to epidemiological studies rather than to individual diagnosis.

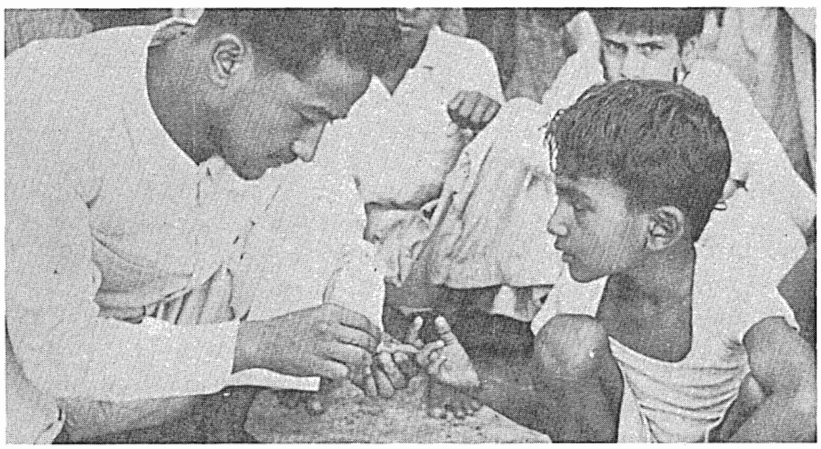
Blood smears for microscopic diagnosis require materials for blood collection, slides, stain, and a well-maintained microscope. To examine blood, both thin and thick smears are prepared, usually from finger pricks, and stained with Giemsa's stain. Other stains such as Field's, Leishman's, or Wright's also may be used.

Thick films are used for initial parasite detection due to their greater blood cell concentration. Thin films then may be used to determine parasite species and the percentage of infected red blood cells. Red blood cells from symptomatic individuals often contain enough parasites so that diagnosis is easy. In endemic areas where adult populations may have a high level of acquired immunity, however, parasite density may be lower, making microscopic diagnosis more difficult. When initial blood smears are negative but malaria is still suspected, additional specimens should be taken every six hours.

When performed properly with good equipment and a trained microscopist, microscopic diagnosis is very accurate; however, the procedure, which requires about 30 to 60 minutes from sampling to result, is labor-intensive and tiring. Rapidly and accurately screening large numbers of samples is difficult. Other disadvantages of microscopy include microscope cost and availability and difficulty in maintaining quality control. For these reasons, while microscopy currently is the most reliable diagnostic method, it is not performed in rural areas in many countries. Instead, diagnosis is often based on clinical signs alone, which can be inaccurate.

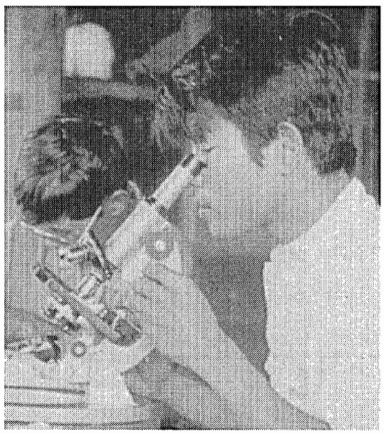
Alternative diagnostic techniques currently being developed may be able to screen large numbers of blood samples to detect current or previous infection. They are intended primarily for epidemiological studies to assess and monitor malaria endemicity, the level of malaria transmission, and the impact of control methods. Samples are processed at a central laboratory where skilled technicians and well-maintained equipment are generally available.

For example, nucleic acid hybridization tests are under development to detect *P. falciparum* genetic material in infected blood. These methods use natural or synthetic parasite-specific DNA and RNA sequences labeled with radioisotopes or enzyme detection systems. When mixed with an infected blood sample, these sequences combine with complementary *P. falciparum* genetic material. This assay can be done on many samples in a few hours.



U.S. Agency for International Development

A health worker collects blood to screen for malaria parasites.



WHO/M. Ettling

Microscopy is the most common technique to diagnose malaria.

Another research tool using DNA probes is the polymerase chain reaction (PCR). Although PCR is still in the early stages of development, research indicates that it is extremely sensitive in identifying *P. falciparum* DNA and eventually may be able to differentiate between *P. vivax* and *P. falciparum* and detect chloroquine-resistant parasite strains.

Malaria-specific antibody detection tests also are being refined. At this time, however, they are unable to distinguish between active and previous infection and are less useful as primary diagnostic tools. Examples of antibody detection tests include indirect fluorescent antibody (IFA) tests and enzyme-linked immunosorbent assays (ELISA).

Tests for detection of malaria antigen in blood are also experimental. These include ELISA and radioimmunoassay (RIA) methods. In addition, researchers currently are exploring noninvasive methods using urine specimens as indicators of infection instead of blood or plasma for antigen detection.

A relatively new parasite detection test, called the Quantitative Buffy Coat (QBC) technique, was introduced recently and is now commercially available. Compared to thick film microscopy, the QBC technique is more rapid and often more sensitive when performed by well-trained technicians. Disadvantages include the high cost and maintenance of equipment including a specially designed centrifuge, capillary tubes, and a fluorescence microscope, and its difficulty in distinguishing different *Plasmodium* species. If less costly assay tubes and fluorescent attachments for conventional microscopes become available, the QBC method may become more practical in regional and specialized peripheral laboratories in highly endemic areas.

Potential benefits of these methods are that, compared to microscopy, "reader-bias" and quality control problems could be greatly reduced. For now, however, microsocopy remains the simplest and most reliable technique for malaria diagnosis. It is relatively inexpensive to perform and is ideal for low-volume laboratories. For other diagnostics to become useful, particularly at the peripheral level, they must be less complex and less dependent on expensive technology and on the expertise of available laboratory technicians.

MALARIA TREATMENT

The goal of chemotherapy is to eliminate malaria parasites in the human host, thereby relieving clinical symptoms and reducing the pool of infection from which the mosquito can transmit the disease. Different antimalarial drugs act on different phases of the parasite life cycle.

Effective treatment of malaria originated in the 17th century with quinine, extracted from the bark of the cinchona tree. Among the synthetic antimalarials later introduced, chloroquine became the drug of choice for both treatment and prophylaxis because it is safe, reliable, inexpensive, and effective against all malaria parasite species.

In the early 1960s, chloroquine-resistant strains of *P. falciparum* began to emerge in southeast Asia and Latin America and, much later, in parts of Africa. Currently, chloroquine resistance has been confirmed or is probable in all countries with *P. falciparum* except the Dominican Republic, Haiti, parts of Central America, the Middle East, and Egypt (see map, p. 5). *P. vivax* resistance to chloroquine also has begun to emerge in Papua New Guinea and Indonesia.

The precise reasons why *P. falciparum* chloroquine-resistant strains developed are not known. It is generally agreed, however, that the widespread use of chloroquine during the past 40 years both for prophylaxis and treatment may have encouraged parasite resistance to develop, particularly where malaria transmission is high. Incomplete, irregular, or inadequate chloroquine doses also may have encouraged resistance. Finally, human migration probably has played an important role in the spread of resistance to new regions, particularly in southeast Asia and Africa where military operations have occurred and groups infected with resistant *Plasmodia* strains have relocated.

As second-line alternatives to chloroquine, combinations of sulfadoxine and pyrimethamine (Fansidar) or dapsone and pyrimethamine (Maloprim) have

been used to treat chloroquine-resistant *P. falciparum* strains. Unfortunately, these compounds have been associated with side effects, and over the last decade resistance to both has developed in many regions around the world.

Because of increasing chloroquine resistance, quinine has reemerged as an important antimalarial drug, both as an effective alternative to chloroquine and as an injectable treatment for severe *P. falciparum* infection. Where resistance to chloroquine and Fansidar are present, quinine alone and in combination with tetracycline may be used to increase effectiveness. Unfortunately, resistance to quinine in some countries such as Thailand is now being reported.

New drugs such as mefloquine, halofantrine, and artemisinin (which is extracted from the Chinese herb, qinghaosu) are now being used in certain regions for treatment and prophylaxis and show much promise. Mefloquine, in particular, appears to be very effective against both chloroquine- and Fansidar-resistant *P. falciparum* strains. Still, cases of mefloquine resistance have been reported in Thailand, the Philippines, and Tanzania, highlighting the importance of administering such drugs under strict control.

In general, drug resistance should be suspected when acute cases of *P. falciparum* malaria do not fully or rapidly respond to proper treatment, or when a resurgence of symptoms and parasites in the blood occurs soon after their temporary disappearance following treatment.

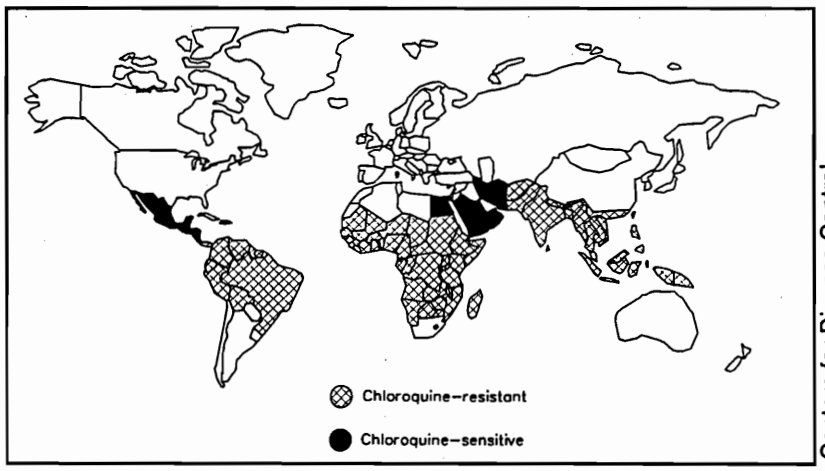
Response of malaria parasites to chemotherapy can be assessed by both *in vivo* and *in vitro* methods. Testing for resistance has two main goals: to ensure that appropriate drug regimens are used and to monitor the occurrence and spread of drug resistance. *In vivo* methods require sequential blood smears before and after treatment to see if parasitemia is reduced in response to the drug. An *in vitro* microtest kit to detect *P. falciparum* sensitivity to various antimalarial drugs is available from WHO. (See Materials Available, p. 12.)

Unfortunately, current tests are time-consuming, require technical expertise, and are not always suitable for field use. Research is under way to develop simplified, rapid chemical and immunological assays to measure drug sensitivity and monitor serum or plasma levels of antimalarials to ensure that proper treatment regimens are being followed. Such tests also could help distinguish between treatment failure due to noncompliance or malabsorption as opposed to drug resistance. The main barriers to developing simplified tests are cost and reagent stability under field conditions. (For information on drug resistance, see *DIRECTIONS*, 3(2), 1983.)

Drugs that can be administered intravenously to treat severe chloroquine-resistant *P. falciparum* malaria also are needed. Of the new drugs, artemisinin may be the most promising. In addition, halofantrine eventually may be available in an intravenous form, but mefloquine likely will continue being administered orally.

Many regions of the world do not have access to chloroquine alternatives because of cost and limited availability. WHO therefore recommends that chloroquine be used wherever it still has some clinical benefit. In regions where resistance is suspected and chloroquine is still being administered, however, regular monitoring of parasite density in blood samples to assess the drug's effectiveness is encouraged.

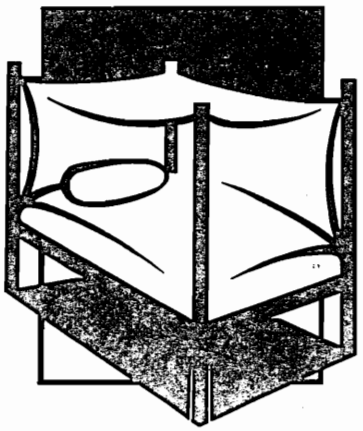
Where other drugs are available, choosing the appropriate regimen requires a solid understanding of local malaria epidemiology and the degree and type of existing drug resistance. Specific diagnostic criteria and referral guidelines also are important to preserve the efficacy of antimalarial drugs and prevent severe illness.



Centers for Disease Control

Areas of chloroquine resistance and chloroquine sensitivity, 1990.

Prevention



Most malaria prevention methods focus on four main goals: 1) eliminating malaria parasites in the human host; 2) preventing human-vector contact; 3) reducing mosquito breeding sites; and 4) destroying mosquitos. To achieve these goals, both personal protection measures and community measures involving environmental, biological, and chemical techniques are required.

Elimination of Parasites. Chemoprophylaxis is used to prevent parasite infection in humans and to suppress clinical symptoms if infection already has occurred. Absolute prevention of infection would require the destruction of sporozoites soon after they are injected into the bloodstream; no existing drug is capable of this.

Drugs such as primaquine and proguanil eliminate parasites in the liver cells before they enter the bloodstream. Chloroquine, when taken prophylactically over time, kills parasites in red blood cells, thereby suppressing symptoms. Quinine is not taken prophylactically because side effects at protective doses are not well tolerated. Mefloquine recently has been recommended for short-term visitors to malarious regions, particularly where chloroquine resistance is evident.

Recommendations for prophylaxis depend on local parasite endemicity and drug sensitivity, and drug effectiveness depends on drug type, timing and regularity of drug distribution, and the degree of community coverage.

Chloroquine has been used most widely for chemoprophylaxis and treatment because of its effectiveness, low cost, and safety. Mass chemoprophylaxis with chloroquine in the past, however, likely contributed to the development of chloroquine-resistant *P. falciparum* strains. Other problems associated with mass chemoprophylaxis include high cost and distribution and compliance problems.

For these reasons, mass chemoprophylaxis with any drug is no longer recommended for indigenous populations in endemic areas, except for pregnant women, especially during first pregnancies (see box, p. 7). Giving prophylaxis to young children is controversial due to concerns that development of natural immunity will be inhibited. Recommendations, therefore, may vary among regions. Prophylaxis also is suggested for non-immune travelers.

Vaccine development has been a priority in malaria research for over two decades, but it has been a lengthy and complex process. Effective vaccines are still years away from being generally available, though clinical trials for candidate vaccines currently are under way.

Malaria vaccines are being developed against three stages of the parasite life cycle, with a particular focus on *P. falciparum* malaria due to its severity and high prevalence. Vaccines that destroy the initial stages of *Plasmodia* after it enters the body have progressed the most. Such vaccines would prevent sporozoites from developing after being inoculated into the human host, blocking infection and preventing clinical disease and future transmission. Another type of vaccine targets the asexual blood stage, blocking the invasion, development, and spread of merozoites in red blood cells. This would not prevent liver infection but would reduce or possibly prevent illness. Finally, a vaccine to prevent transmission by destroying gametocytes also is being developed. It would prevent future transmission but would not directly protect the vaccine recipient. Combining these vaccines eventually may be considered, as each provides protection at different parasite stages.

Even if an effective vaccine can be developed and distributed, prevention and treatment of malaria should continue to rely on current integrated primary health care measures such as chemotherapy, chemoprophylaxis for special populations, and mosquito control.

Prevention of Human-Vector Contact. Several self-protection techniques exist that, if used consistently, can greatly reduce human-vector contact and, in some cases, destroy the vector. For example, because Anopheles

Malaria and Pregnancy

Because pregnancy lowers resistance to infection, it is associated with increased susceptibility to malaria, especially during the last two trimesters and during first pregnancies. Epidemic *P. falciparum* malaria in populations with little or no acquired immunity is particularly dangerous during pregnancy. It often causes severe or fatal illness, spontaneous abortion, stillbirth, or low birthweight due to parasite infection of the placenta. Malaria also may cause or worsen maternal anemia.

WHO recommends that pregnant women living in malarious regions receive chloroquine prophylactically starting at least three months before delivery. Chloroquine, unlike other antimalarial drugs, is not harmful to the fetus when taken in recommended doses. One study indicated that pregnant women receiving prophylactic doses of chloroquine had fewer malarial attacks and a lower incidence of anemia and delivered higher birthweight babies than women who were not taking chloroquine. The differences were most marked among women pregnant for the first time. A Nigerian study suggested that chemoprophylaxis plus iron and folic acid supplements can significantly reduce the incidence of maternal anemia.

Chemoprophylaxis of pregnant women presents logistical problems, however. For example, many women cannot come regularly to receive drugs, and limited resources may prevent local health facilities from delivering chemoprophylaxis to all pregnant women, especially in rural areas where pregnant women are less likely to seek medical care. Therefore, in some countries, village health workers and traditional birth attendants distribute chemoprophylaxis. Furthermore, although new drugs such as mefloquine are being evaluated for safety as a prophylactic during pregnancy, no alternatives to chloroquine currently exist in chloroquine-resistant areas. In Central and East Africa, however, combining chloroquine and proguanil is recommended.

Pregnant women should be treated promptly with chloroquine during a malarial attack. Administration of quinine at recommended doses also may be considered. Drugs such as sulfadoxine, tetracycline, and primaquine should not be taken during pregnancy because of potentially harmful effects on the fetus.

mosquitos tend to feed from dusk to dawn, bed nets to protect against mosquito bites while sleeping are very useful. In recent years, trials have shown that using bed nets in malaria-endemic areas, particularly nets impregnated with a synthetic pyrethroid (a type of insecticide) such as permethrin, can be a safe and effective barrier between humans and mosquitos. Some studies indicate that their use reduces mosquito numbers and malaria incidence. Even if the net is damaged or improperly hung, it still is effective in killing mosquitos and other disease vectors that come in contact with the net such as flies, lice, and fleas.

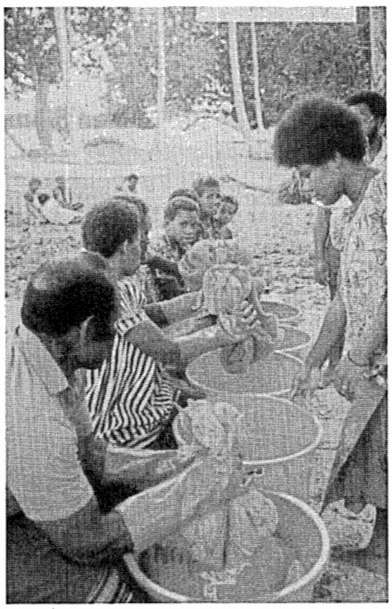
Treating nets is simple. Nylon or polyethylene nets are dipped into a 15-25 liter plastic or aluminum container filled with 1-2 percent insecticide solution (diluted in water). After dipping in the solution, the nets should drip for about one minute and then be laid flat to dry. They should be completely dry before sleeping under them. Treated bed nets remain effective for about 6-12 months.

Ideally, this form of mosquito control should be implemented at the village level and integrated into a comprehensive primary health care program. Village health workers can be trained in safe and effective net treatment. In several provinces of China, over two million treated nets are in use, and an 87 percent reduction in malaria cases in those areas has been observed. In Vietnam, bed net use has coincided with an 80 percent reduction in the number of reported malaria cases among the 40,000 people using them. Still, the wide-scale impact of correct and regular use of bed nets on malaria transmission rates needs to be assessed further, as does their acceptability among various populations. Reducing the cost of nets and pyrethroid solutions to make them affordable to low-income groups also is essential.

Additional individual measures to prevent human-vector contact and reduce vector populations include impregnating curtains and small fumigation mats with pyrethroids, burning coils, applying repellents, and spraying living spaces. Fumigation mats have limited application as they must be inserted into a small electric heater to release the repellent vapor. Mosquito coils containing pyrethroids also produce a vapor to repel mosquitos and are used extensively in developing countries. Their effectiveness varies depending on coil

quality. Repellents such as N,N-diethyltoluamide (DEET) are inexpensive, long-lasting (up to ten hours), and effective against biting insects. They are applied to exposed skin (especially neck, ankles, and wrists) and to clothing and bed nets for extra protection. Soap containing permethrin and DEET currently is being evaluated in parts of Asia for its insecticidal properties. Space spraying with insecticides, usually pyrethrum (a natural insecticide derived from a flower), kills mosquitos around sleeping areas.

Installing window and door screening and wearing protective clothing, particularly after sunset, also reduces contact with the mosquito. In addition, selecting a site for new housing, temporary or permanent, that is not adjacent to mosquito breeding sites and improving housing construction may protect humans against contact with mosquitos. Because several Anopheles species are equally attracted to humans and animals,



WHO/L. Self

Dipping bed nets in insecticide solution increases their effectiveness.

situating domestic animals such as cows and sheep between human dwellings and mosquito breeding sites may divert mosquitos away from human populations, thus reducing human-vector contact. This technique, however, still permits mosquitos to thrive.

Reduction of Breeding Sites. Draining or filling places around human dwellings where water collects, such as pot holes, small ponds, ditches, and old cans, and covering wells or water tanks will reduce mosquito breeding sites. This practice is known as source reduction. Planting trees in low-lying or marshy areas to dry the land also prevents mosquito breeding sites from developing. In addition, careful planning of rural and urban development projects such as construction, road-building, irrigation systems, and well-digging is critical. Without proper environmental management, such projects often worsen health risks by creating vector habitats, fostering mosquito breeding, and creating new opportunities for human-vector contact. Collaboration and communication between malaria control programs and other sectors is crucial.

Destruction of Mosquito Vector. With technical guidance and supervision from specialists, several techniques may be used to destroy the mosquito in both its larval and adult stages.

Biological control methods involve introducing mosquito pathogens or predators such as bacteria and larvivorous (larvae-eating) fish. Certain bacterial agents, such as *Bacillus thuringiensis* H-14 and *Bacillus sphaericus*, have been used successfully as larvicides and are now commercially available. Their use is encouraged because of growing mosquito resistance to insecticides and because they are environmentally safe and harmless to humans and other animals. These bacillus strains produce a toxic protein that, when ingested, kills mosquito larvae. This toxin can be produced in large quantities and incorporated into granules, wettable powders, or floating briquets that are used in water supplies for domestic or agricultural use. They are most effective in conjunction with other control activities and in regions where breeding areas are limited and well known. Repeated applications are necessary, as current biological larvicides have limited effectiveness over time. Other considerations include the training and supervision of personnel and the availability and cost of larvicides and equipment.

Fish that feed on mosquito larvae also may be effective for biological control in some breeding habitats. Larvivorous fish are small, allowing them to survive and reproduce in shallow, nonpermanent waters. In addition to feeding on larvae, some fish species provide a secondary benefit of reducing rooted aquatic vegetation and floating algae, destroying mosquito breeding sites and making it easier for the fish to prey on mosquitos. Larvivorous fish are only effective if present in large numbers, however, and frequent inspection is necessary to ensure that the fish population is maintained. In India, this form of vector control has been linked to economic development. Income generation projects in several communities have introduced both edible and larvivorous fish into local ponds. Edible fish are harvested and sold while larvivorous fish keep the ponds free of algae and

WHO/P. Almasy

Larvivorous fish may be used for mosquito control.

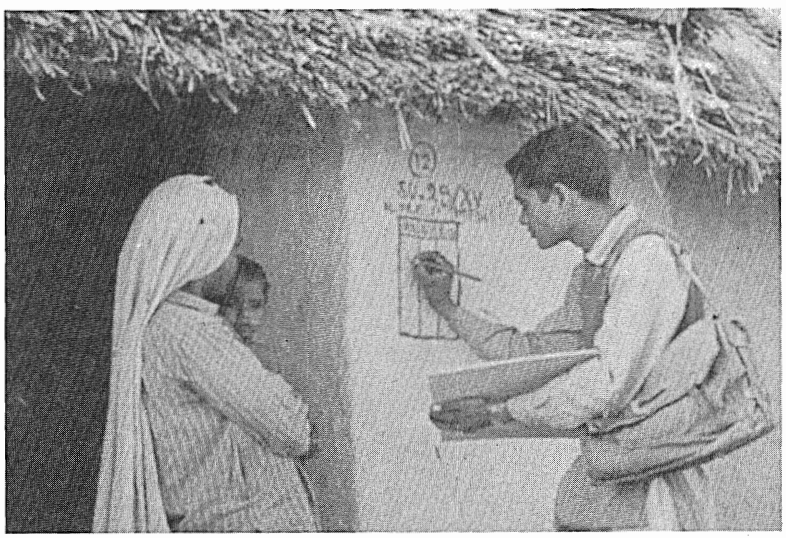
mosquito larvae. Other community projects have removed algae to facilitate predation of mosquito larvae. The algae are then dried and sold to make handmade paper. In China, fish are being raised in rice fields to reduce larval populations.

Long-acting ("residual") chemical insecticides, such as DDT (dichloro-diphenyl-trichloroethane) and malathion, have been the mainstay of most malaria control programs for decades. After one spraying, residual insecticides remain effective for six months or longer. They are most commonly applied by spraying internal walls and ceilings on which mosquitos rest during the day. If spraying is to have any effect, however, extensive coverage is required. Spraying only a few houses in a given community will not affect the vector population.

In recent years, problems associated with residual insecticide use have emerged. Resistance to DDT and other insecticides has developed in many regions due to their widespread use in both agricultural and health programs. Malathion is unacceptable to many people for use in their homes due to its smell. Concerns over environmental contamination and long-term toxic effects in humans also have increased, and insecticides have become more expensive. Nevertheless, DDT, as well as other compounds, is still widely used in malarious regions. Chemical larvicides, such as petroleum oil and organophosphate compounds (e.g., temephos/abate) also are used.

Because insecticides can be hazardous both to humans and to the environment, extreme care should be taken to ensure their safe use. The degree of hazard depends on the insecticide, its concentration and formulation, method of use and storage, and the type and extent of exposure. People who mix undiluted formulas and those who spray are most at risk. Protective clothing, such as gloves, boots, overalls, and a broad-brimmed hat, is essential when handling insecticides. Proper labeling, storage, and disposal of insecticides also are critical. (WHO has published several reports on insecticide use. See Materials Available, p.12.)

The issue of environmental contamination due to insecticide use, especially organochlorines such as DDT, is very controversial. In many countries, the risks are weighed against the benefits; where vector-borne diseases like malaria are still a major cause of human suffering and death, recommendations regarding insecticide use are more liberal than in other areas. In general, if insecticides are deemed necessary, they should be used focally (i.e., near breeding sites and in major resting sites, and just prior to major malaria transmission seasons) and accompanied by thorough training, supervision, and education regarding safety. This approach will minimize individual and environmental exposure, reduce costs, and discourage the development of insecticide resistance. In the meantime, practices that are more cost-effective and achieve more permanent effects over time should be advocated, such as biological control methods, environmental management and source reduction techniques, improvements in housing construction, and changes in individual behavior.



U.S. Agency for International Development

Case finding and surveillance are important to effective malaria control programs.

Control Strategies

A wide range of malaria control and prevention technologies exists. Their successful use requires sufficient technical and financial resources, thorough planning and evaluation of control operations, adequate training and health education, and political commitment. Laboratory and field research is also important to solve technical problems such as drug and insecticide resistance and to improve current control strategies.

WHO currently recommends that countries adapt malaria control methods to local epidemiological conditions and establish objectives that are technically and financially feasible and sustainable. Before selecting a strategy, factors such as local malaria incidence, prevalence, mortality, and risk groups should be understood. When possible, information also should be collected on local mosquito feeding and breeding behavior; mosquito species, density, and infectivity; ecological and seasonal conditions; and parasite and mosquito response to drugs and insecticides.

Whether malaria transmission is endemic (stable) or epidemic (unstable) is also important to consider. Where malaria is epidemic, incidence varies widely from year to year or at irregular intervals. Changes in climate and variations in the local population's immune status also influence incidence. Prompt diagnosis and drug treatment, chemoprophylaxis for high risk groups, and aggressive vector control measures such as focal spraying minimize illness and death during epidemics. Where malaria is endemic, transmission rates are more or less constant over long periods of time, though seasonal variations can occur.

Eradication is very difficult in endemic areas. Where transmission rates are high and partial immunity is prevalent, short-term control methods such as space spraying and mass drug administration should be used cautiously as they may result in loss of immunity, leaving the population vulnerable to malaria epidemics.

All control programs should be able to promptly diagnose and manage severe clinical malaria cases; recognize, evaluate, and monitor parasite resistance to drugs; establish information systems to monitor transmission patterns at the periphery; recognize and manage epidemics; prevent and control transmission; and support and guide field research. Evaluation of control operations is particularly important, but it must target each country's goals (e.g., reduced mortality and morbidity, improved diagnosis). Most programs maintain surveillance systems that carry out case-finding based on blood examinations of fever cases. Peripheral laboratory facilities are important for improved surveillance, as is mandatory case notification and referral at all levels. Studies also may be important to assess the impact of vector control measures on mosquito populations, including mosquito susceptibility to insecticides. In Thailand, static and mobile rural malaria clinics have been established that offer immediate microscopic diagnosis and effective treatment at no cost. Although Thailand's program faces challenges such as increased parasite resistance to several drugs, it has been very successful in monitoring transmission patterns and reducing malaria morbidity and mortality among remote populations.

Integrated Control. A single control strategy is unlikely to be appropriate for an entire country. Therefore, dividing a country or region into zones of similar climatic, topographical, or other physical characteristics when planning and implementing interventions may be helpful. WHO also advocates combining complementary environmental, biological, and chemical methods ("integrated vector control") within each region, instead of relying on a single approach. Combining methods is more cost-effective and helps prevent the development of insecticide resistance. For example, Indonesia's malaria control program includes case detection and treatment; indoor residual spraying with insecticides; biological control with larvivorous fish; various environmental techniques such as tree-planting and drainage; and bed net use.

Community Involvement. Ideally, integrating malaria control into the primary health care system

MALARIA CONTROL MEASURES		
Goal	**Individual Measures**	**Community Measures**
Prevention of human-vector contact	• Repellents • Impregnated bed nets • Protective clothing • Window door screening • Coils • Fumigation mats	• Site selection of housing • Window and door screening • Vegetation clearance • Improved housing construction
Destruction of adult vector	• Interior house spraying	• Interior house spraying • Residual spraying
Destruction of larvae	• Improved domestic sanitation • Intermittent drying of water containers • Covering of water catchments and wells	• Biological larvicides • Larvivorous fish • Intermittent drying
Reduction of breeding sites	• Small-scale filling or drainage	• Collaboration with other sectors to improve: - irrigation practices - environmental sanitation - water management - natural methods of control (e.g. tree planting)
Destruction of parasite	• Prompt recognition of symptoms and referral for diagnosis and treatment • Chemophrophylaxis for special populations (e.g., pregnant women)	• Public education about symptoms • Establishment of village health centers • Education of health workers on referral and initial treatment of severe cases • Establishment of prenatal clinics
Adapted from *Essential Malariology*, by L. Bruce-Chwatt		

enhances community participation in malaria control and strengthens peripheral health services. Community participation is especially important for long-term effectiveness of malaria control programs. Communities can take responsibility for local control measures, including drug delivery, vector control, and personal protection.

Greater community involvement requires that health education and training be conducted. Community members need training to recognize specific malaria symptoms. Where private sources of malaria drugs are available, education of pharmacists and the public is necessary so that only appropriate drugs are used and complete courses of drugs are taken. Posters, slides, and films can be presented to adults and schoolchildren. Guides and manuals should be provided to schoolteachers, community leaders, and health workers. In various endemic regions in India, for example, vector control activities are an important part of community development. Integrated control methods in some villages include organizing labor groups to eliminate mosquito breeding sites through drainage and filling; introducing larvivorous and edible fish; planting trees in low-lying marsh areas to dry the land and discourage mosquito breeding; health education, including lectures in schools and community centers; and chemotherapy of parasite-positive cases.

CONCLUSION

Malaria continues to be one of the most devastating tropical diseases in the world, with nearly 2.1 billion people at risk of infection. Eradication efforts have failed in most regions due to a variety of biological, ecological, and other technical factors, including drug and parasite resistance.

Despite these setbacks, researchers remain committed to developing and introducing alternative technologies such as new anti–malarial drugs and more efficient diagnostic techniques. Vector control technologies that are more environmentally sound and cost-effective also are being investigated. In addition, while important advances such as vaccine development have not been achieved yet, alternative control strategies using both new and previously existing diagnostic, treatment, and prevention technologies in more effective ways are being tested.

It is now clear that combining technologies, rather than relying on a single approach, is necessary to control malaria successfully and will help limit further development of drug and insecticide resistance. Local conditions affecting malaria transmission also must be understood. With this knowledge, and with individual, community, and national commitment to controlling the disease, significant reductions in malaria morbidity and mortality eventually may be achieved.

Materials Available

WHO has produced a wide range of publications on malaria and its control, some of which are listed below. For a complete list and ordering information, write: WHO, Malaria Action Programme, CH 1211 Geneva 27, Switzerland, or to WHO regional offices.

□

For general reviews of malaria and its diagnosis, treatment, and control, consult: **WHO Expert Committee on Malaria, Eighteenth Report; Clinical Management of Acute Malaria, Second Edition; Chemotherapy of Malaria, Second Edition**; and **The Biology of Malaria Parasites.**

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WHO publications on vector control include: **Vector Control as Part of Primary Health Care; Integrated Vector Control; Safe Use of Pesticides; Manual on Environmental Management for Mosquito Control, with Special Emphasis on Malaria Vectors**; and **The Use of Impregnated Bed Nets and Other Materials for Vector-borne Disease Control.**

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Bench Aids for the Diagnosis of Malaria, a set of 8 washable, plastic charts depicting the four *Plasmodia* species in thin and thick blood smears, are also available from the WHO Malaria Action Programme. The charts provide technical information on how to stain and prepare blood samples and how to care for laboratory equipment used in microscopic malaria diagnosis.

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WHO has developed an *in vitro* microtest kit to test *P. falciparum* sensitivity to various antimalarial drugs as part of its global drug-resistance monitoring programme. For more information, contact the WHO Malaria Action Programme.

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Breaking the Pesticide Habit: Alternatives to 12 Hazardous Pesticides, published by the International Alliance for Sustainable Agriculture (IASA), reviews 12 widely-used pesticides, including their health and environmental effects, and recommends possible alternatives. It costs US$20 for individuals, $27 for institutions, and $15 for IASA members. For ordering information, write: IOCU Regional Office for Asia and the Pacific, P.O. Box 1045, 10830 Penang, MALAYSIA, or IASA, Newman Center, University of Minnesota, 1701 University Ave., N.E., Minneapolis, MN 55414, USA.

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A bibliography on malaria is available from PATH.

INTERCHANGE

A Practical Guide to the Correction of Iodine Deficiency, an easy-to-read manual produced by the International Council for Control of Iodine Deficiency Disorders, is available at no cost from regional WHO and UNICEF offices.

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The Norwegian Association of the Blind and Partially Sighted has published **Eye Care Programmes in Developing Countries**. This comprehensive manual is available at no charge to developing countries from: Director, Norwegian Church Aid, P.O. Box 52802, Nairobi, Kenya.

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Guidelines for the Control of Maternal Nutritional Anemia is now available free of charge to developing countries (US$ 3.50 to developed countries) from: INACG Secretariat, The Nutrition Foundation, Inc., 1126 Sixteenth Street, N.W., Washington, D.C. 20036, USA.

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health technology
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PATH Program for Appropriate Technology in Health

Anesthesia

Anesthesia is essential to delivering safe, effective surgical services at all levels of the health system. Without adequate anesthesia, surgery can be painful and dangerous for the patient and difficult for the surgeon.

Much of the surgery in developing countries is due to preventable complications of common conditions. Unfortunately, surgery often is delayed for many reasons, including poor anesthesia services. The results are premature death, disability, or reduced ability to earn a living or care for a family.

Three types of problems affect anesthesia. First, many countries do not have enough trained personnel such as specialist physicians, nurse anesthetists, and medical officer anesthetists. Second, essential anesthetic drugs are unavailable or in short supply. Finally, the equipment necessary to administer anesthetics and monitor patients undergoing surgery may be inappropriate for the setting in which it is used, poorly maintained, not compatible with other pieces of equipment, or dependent on expensive consumable parts.

One promising, recent step towards solving these problems is the improvement of the portable oxygen concentrator. Several models that meet the new World Health Organization/World Federation of Societies of Anesthesiologists standards are currently being tested. The oxygen concentrator's ability to provide a local, reliable, inexpensive, and readily available supply of oxygen has the potential to improve anesthesia services dramatically even in the most economically deprived countries.

The first two sections of this DIRECTIONS issue describe equipment and drugs for general and regional anesthesia. The third section reviews personnel and management issues related to anesthesia service delivery.

General Anesthesia

Regional Anesthesia

Managing Anesthesia Services

Volume 10, Number 2 ISSN: 0730-8620 1990

General Anesthesia

General anesthesia is used for both major and minor operations. Under general anesthesia, the patient becomes unconscious and unable to feel pain in any part of the body. Muscle relaxant drugs may be used so that certain kinds of surgery are possible, and the patient must have a clear airway for breathing before general anesthesia is given. Drugs for intravenous administration and equipment to assist or control breathing also must be immediately available.

The anesthetizing process usually occurs in four stages: premedication, induction, maintenance, and recovery. Premedication may include sedation to relieve anxiety and use of the drug atropine to make some procedures safer. The need for either sedation or atropine, or both, depends on the patient's mental and physical condition and the type of anesthesia used. Induction involves administering an anesthetic drug. This stage is complete when the patient is sufficiently anesthetized to undergo surgery. Induction occurs either by inhalation of a mixture of anesthetic gases or by intravenous injection of a drug to depress the central nervous system. Intubation, the insertion of an airway through the nose or mouth into the trachea, may be done at this point. Intubation provides a clear airway and prevents aspiration of stomach contents. It is usually done in conjunction with a short-acting muscle relaxant drug. Maintenance of unconsciousness and pain relief during the operation can be done by inhalation alone, by intravenous injections alone, or by either of these two in combination with a long-acting muscle relaxant. Since muscle relaxants cause paralysis of the respiratory muscles, the anesthetist must be able to ventilate the patient using a mechanical ventilator. Appropriate drugs for reversing the paralysis at the end of the operation also must be available. Lastly, during the recovery stage the anesthetic effect wears off and the patient regains consciousness.

EQUIPMENT

The most important piece of equipment required for inhalational anesthesia is a machine to mix the anesthetic agent with a carrier gas and deliver it to the patient. A variety of intravenous apparatus and breathing equipment is also necessary. The type of inhalation machine that should be used, however, has been debated extensively in many developing countries. Two types currently exist: the drawover system and the continuous flow system.

Drawover systems use ordinary room air as the carrier gas for the anesthetic agent. The gas mixture is pulled through the system either by the patient's own breathing or, if the patient has been paralyzed by muscle relaxants, by means of a bag (or bellows) controlled by the anesthetist. Oxygen can be added to the mixture if needed. The system consists of two parts, a vaporizer and a breathing system connecting the vaporizer and the patient. The vaporizer transforms the liquid anesthetic to a vapor for inhalation, adding a controlled portion of the vapor to the mixture. The breathing system is comprised of tubes, valves, connectors, self-inflating bags, and either a face mask or a tracheal tube through which the patient breathes the anesthetic gas/air mixture.

The standard drawover apparatus is the Epstein-Macintosh-Oxford (EMO), which is simple and sturdy and has been tested in many countries. Its main drawback is that it can only be used with ether. The Oxford Miniature Vaporizer (OMV) is another useful model. It can be used with halothane, isoflurane, or trichloroethylene by using different calibrated faceplates to "dial up" the correct concentrations of the different anesthetics. The OMV is frequently hooked up in series with the EMO, so that, for example, the patient may be induced with halothane and maintained with ether. It is also the basic component of the drawover Triservice apparatus. The OMV's main disadvantages are that the faceplates may be mixed up, resulting in the delivery of the wrong drug concentration; a temperature compensation mechanism to ensure the correct concentration of halothane regardless of any cooling during the vaporization process does not exist; and the anesthetic agent may spill into the breathing system tubing if the vaporizer is tipped over. In addition,

INHALATIONAL ANESTHESIA EQUIPMENT		
System	**Advantages**	**Disadvantages**
Drawover (e.g., EMO, OMV, Triservice, PAC, Afya)	• Simple to understand and operate • Uses room air so less need for oxygen • Easy to maintain and repair • Less expensive to purchase • Safer, if oxygen supplies are uncertain • Rugged and reliable	• Non-rebreathing valve uses more anesthetic gas than circle system • If ether is used with oxygen, must take precautions to avoid explosion • Additional supply of oxygen is needed for patients with certain medical conditions (e.g., anemia) and when using certain anesthetic drugs (e.g., halothane)
Continuous Flow (Boyle's)	• Flow meter allows more accurate regulation of gas mix • Easier to use with infants • Easy to provide extra oxygen when necessary • Easier to monitor breathing • Mask leaks are less important • If circle breathing system is used, uses less gas	• Requires compressed oxygen - dangerous if supply runs out during anesthesia • Usually used with nitrous oxide - expensive • More complex to operate and maintain • Needs special facilities for servicing • Expensive to purchase • Circle breathing system requires soda lime

Table 1

thymol, which is added to halothane to stabilize it, tends to accumulate in the vaporizer and make the control lever stick. To avoid this, the vaporizer should be rinsed out periodically with ether. The PAC system has vaporizers for ether, halothane, trichlorethylene, and enflurane. It has an efficient temperature compensation device, is durable and reliable, and is not significantly affected by shaking, tilting, or overturning.

Continuous flow machines (also known as Boyle's machines) are more complicated than drawover systems. Instead of using room air to carry the anesthetic vapor to the patient, they use compressed oxygen and nitrous oxide. Positive pressure from the compression of the gases within the cylinders, rather than the patient's own breathing, pushes the gases through the system to the patient. If the patient is paralyzed, the anesthetist uses a reservoir bag to assist breathing. Nitrous oxide is an anesthetic as well as a carrier gas, but it is not very powerful. Thus, continuous flow systems always contain one or more vaporizers so that other anesthetics may be added. Breathing systems may be semi-open, as in drawover systems, or closed. In a circle (closed) system, the gases go continually around a loop, and soda lime absorbs the exhaled carbon dioxide before the patient rebreathes it. Table 1 summarizes the relative advantages and disadvantages of the two systems.

Attempts have been made to design machines that can be switched from drawover to continuous flow. The only recent commercial effort to do this is taking place in Malawi as part of a larger program supported by DANIDA. A portable oxygen concentrator has been adapted to supply air and oxygen through a pipeline to a combination continuous flow/drawover machine. Certain problems remain, but the consensus of those who have used the new machine is that it is a promising innovation.

Despite the apparent technical advantages of drawover systems in some settings, continuous flow machines continue to be widely used and preferred by many anesthetists. Factors having little to do with either medicine or technology have affected the continuous flow versus drawover debate. For example, specialist anesthetists who have studied abroad may insist on using continuous flow machines in the teaching hospitals where they work. Generally, physicians and many non-medical personnel are trained first on continuous flow systems and only secondarily on drawover systems, regardless of the type of system used in their hospitals. Economics also plays an important role. Countries that have purchased or been given continuous flow systems are finding it difficult to maintain them, yet they cannot afford to purchase new drawover equipment. Often this problem is compounded by administrative difficulties in obtaining approval and foreign exchange. Donors also have supplied equipment, often without considering whether it can be reliably operated and maintained.

The most important point in this debate is that this technology must be matched to the country. Continuous flow machines are useful and appropriate for countries that manufacture oxygen, have reliable transport and supply systems, are able to do repairs locally, and have adequate foreign exchange to purchase spare parts, soda lime, and nitrous oxide. Countries that experience difficulties in one or more of these areas are better served by using drawover systems instead.

INHALATIONAL AGENTS

No single anesthetic drug provides a gentle, easy passage into unconsciousness, is completely safe for both the anesthetist and the patient, and creates optimal operating conditions for the surgeon. Instead, a combination of drugs and methods is usually required. The drugs most commonly used with drawover systems are ether and halothane. A third drug, trichloroethylene, has been used for many years and stocks of it still exist, but its production has been discontinued for economic reasons. Chemical-reagent trichlorethylene is still widely available.

Ether, used for many years, has several advantages. It provides excellent pain relief, muscle relaxation, and unconsciousness. It stimulates breathing and blood circulation and thus is the safest anesthetic for personnel with limited skills to administer. Finally, it is widely available and inexpensive. Combining ether with other drugs for induction and muscle relaxation is cost-effective and decreases the incidence of nausea and vomiting.

Ether also has several disadvantages. First, the induction stage is long (at least ten minutes), which is unpleasant for the patient, difficult for the anesthetist, and inefficient when surgeons are faced with long operating lists. When high concentrations of ether are used, recovery is slow. Problems with vomiting and airway obstruction may occur. Under certain conditions, ether is both flammable and explosive. In hot climates, special precautions must be taken to avoid sparks and combustion. It is highly volatile and may partially evaporate in bottles during transport. Medical ether is produced in England, India, and Italy. Manufacturers, however, are limiting production as use declines in industrialized countries and profits decrease. It is unlikely that medical ether will disappear from the market, but it may become more expensive.

Halothane is very widely used in both developed and developing countries, but it is more expensive than ether. It is also a poor analgesic and may cause severe cardiorespiratory depression. Because it is more potent than ether, dosages must be precise, and more skill is needed to administer it. Nevertheless, induction and recovery are much faster and more pleasant, and less of it is required. Halothane is normally used in conjunction with ether or nitrous oxide, a combination that is quite cost-effective. It is neither flammable nor explosive, and it is not as volatile as ether. Two newer inhalational agents—enflurane and isoflurane—are similar to halothane. They are used in some countries and have certain medical advantages, but they are also expensive, not substantially better than halothane, and require their own calibrated vaporizers, which are costly.

Nitrous oxide, used in continuous flow machines, is a strong analgesic and relatively nontoxic. However, it must be used with other drugs because, used alone, it does not provide sufficient muscle relaxation or unconsciousness. Other disadvantages of nitrous oxide are that it is expensive, it is not manufactured in many countries and thus has to be imported, and transport of the cylinders is difficult due to their weight and bulk.

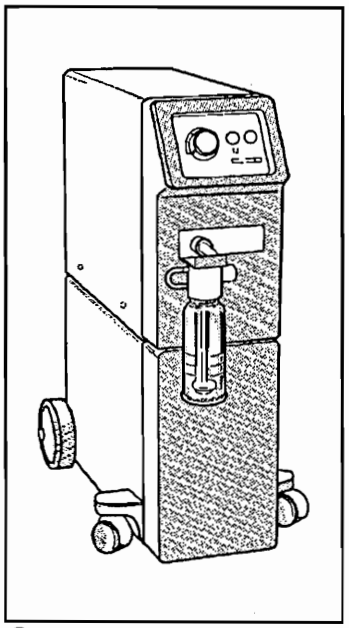
Oxygen is very important in the practice of anesthesia and, at times, saves lives. Oxygen is manufactured in many countries for both industrial and medical purposes. Industrial grade oxygen is safe for use in anesthesia and may be less expensive than medical grade. Some large hospitals use liquid oxygen, but it is usually supplied as a compressed gas in cylinders. These cylinders either can be attached to a particular machine in use or can be part of a central bank of cylinders from which the oxygen is piped to operating and recovery rooms. In more-industrialized developing countries such as India, Mexico, and Thailand, oxygen cylinders are widely available, although less so in rural or isolated areas.

In many less developed countries, chronic financial and logistical problems hinder maintenance of adequate and reliable supplies of oxygen. It may have to be imported, or equipment for local production may be old and subject to frequent failure. Cylinders of oxygen are difficult to transport, especially where roads are poor and transport is unreliable. Transportation to distant rural hospitals can as much as quadruple a cylinder's cost. Advance planning by hospital staff, so that trucks are sent for resupply on a regular schedule and with an adequate number of cylinders, is essential. When possible, adequate buffer stocks should be kept in case of delivery delays or other emergencies.

One promising new technology that may help avoid these problems and ensure a more reliable supply of oxygen for rural hospitals is the portable oxygen

concentrator. These devices extract oxygen from room air. The only cost is for the electricity required to run them and for the replaceable filters.

Until recently, their use in developing countries was limited due to problems with electricity, climatic conditions, and unreliability. In the last five years, however, many of these problems have been overcome, and in 1989 the World Health Organization (WHO) and the World Federation of Societies of Anesthesiologists (WFSA) jointly drafted a set of specifications for the manufacture of oxygen concentrators appropriate for use in developing countries. These specifications have been officially adopted by WHO. Three different manufacturers are currently testing models built to the specifications; results are expected in 1991.



Oxygen concentrator

From Dobson, M.B. *Anaesthesia at the District Hospital.* Geneva, WHO, 1988 (Fig. 7.11, p. 70).

MUSCLE RELAXANT DRUGS

In addition to inhalational agents, muscle relaxant drugs are needed to facilitate intubation, induction, and abdominal surgery. Those most commonly used are suxamethonium (succinylcholine, Anectine, Scoline), pancuronium (Pavulon), gallamine, alcuronium, and tubocurarine. Suxamethonium is a short-acting relaxant mainly used for intubation. In hot climates, it is best to purchase it as a heat-stable powder rather than as a liquid. The other drugs are long-acting relaxants used during operations and lasting approximately 30 minutes per dose. Alcuronium is a good general purpose relaxant that is heat stable and relatively inexpensive.

OPIATE ANALGESICS

These drugs provide pain relief during and after surgery. Morphine and Demerol, also known as pethedine, are the most frequently used opiates. Both are quite powerful and may depress respiration. Therefore, they need to be given slowly with careful monitoring. Naloxone and nalorphine are opiate antagonists that reverse respiratory depression. Nalorphine is cheaper but more dangerous; it may cause respiratory depression if too much is given. Diazepam and pentobarbital are tranquilizers that often are used to relieve anxiety prior to general anesthesia. Both can be given orally or by intramuscular injection.

INTRAVENOUS ANESTHETIC DRUGS

Intravenous general anesthesia is achieved by injecting one of two types of drugs, which act as central nervous system depressants, into a vein. These anesthetic agents work quickly, an advantage when operating lists are long. Unlike inhalational anesthesia, whose effect can be discontinued promptly if necessary, intravenous anesthesia cannot be removed or its effects altered once the drug has been injected. Thus, because it is relatively easy to give an overdose or stop a patient's breathing, intravenous doses should be precisely calculated, and equipment for suction, ventilation, and intubation must be instantly available. Intravenous anesthesia is best used to provide a quick, comfortable, and easy induction, followed by the administration of inhalational anesthesia to maintain the anesthetic effect. It also is used for short procedures such as dressing burns or reducing fractures.

One type of intravenous anesthetic is the drug ketamine, also known as Ketalar. Ketamine was first introduced in the 1970s. It differs from other general anesthetics because it produces a trance-like state called "dissociative anesthesia" in which the patient's eyes may be open but the patient is unconscious, feels no pain, and will not remember the anesthesia or the operation. Although no anesthetic is completely safe, ketamine is one of the safest because the dose range is wide, making overdoses rare, and most patients continue to breathe well and keep some normal pharyngeal and laryngeal tone. Due to its safety, ease of administration, and amnesiac qualities, ketamine is an extremely useful drug in many difficult circumstances. In particular, it has made pediatric anesthesia much easier and less dangerous. Children's anatomical and physiological characteristics require the use of special breathing apparatus when using inhalational anesthesia. This equipment often is not available. Thus, if supplies are limited, many anesthetists recommend saving ketamine exclusively for children. It is also useful for adults, especially for patients with complicating conditions such as asthma and in short-staffed hospitals without a specialist anesthetist or where nurses may not be available for proper monitoring of recovering patients.

The main medical disadvantages of ketamine are that the patient's muscles do not relax, it causes blood pressure to rise, and some

Portable Oxygen Concentrators

The majority of modern oxygen concentrators work by separating nitrogen, water vapor, and oxygen according to the relative size of their molecules. Room air is drawn into the machine by a compressor and is processed so that a high concentration of oxygen (mixed with a small proportion of nitrogen and argon) flows into an accumulation tank where it is ready for use by the patient. An external coarse air filter, an internal air filter, and a bacterial filter are needed to ensure the purity of the oxygen. The concentrator needs a stable electrical source and is normally run off regular power lines, but it can be powered by a generator if necessary. One machine in Malawi was modified to run on solar batteries. A few cylinders of oxygen can be kept in reserve in case of power cuts.

The concentration of oxygen in the gas delivered to the patient varies with the flow rate. Higher flow rates have lower oxygen concentrations. The rates of oxygen flow delivered by the portable oxygen concentrator are sufficient for oxygen administration before intubation, during resuscitation, or with drawover apparatus, but they are not at a sufficiently high pressure to push the gas mixture through a conventional continuous flow machine. The first large scale test of oxygen concentrators in a developing country was carried out in Malawi with support from DANIDA. The concentrators were serviced by trained local technicians every six months and proved useful and reliable, as well as cost-effective. It has been estimated that over a 26-month period, the average combined savings for all Malawian district hospitals was approximately US$30,000 per month. Savings resulted from not having to buy and transport oxygen in cylinders and not having to transport patients to central hospitals due to lack of oxygen at district level.

The WHO/WFSA specifications set stringent standards for portable oxygen concentrators. In addition to meeting existing International Standards Organization (ISO) standards for humidity and alarm systems in domestic oxygen concentrators, the devices must be able to operate properly at temperatures up to 40° centigrade and 100 percent relative humidity, simultaneously. Reliability and ruggedness requirements are also high; for example, machines must have a mean time between failure of at least 15,000 running hours, which is equivalent to about 5 years of use at a district hospital.

Servicing the new models of oxygen concentrators is meant to be simple. The external filter can be taken off and washed with tap water as necessary. Every six months the internal air filter and the bacterial filter need to be changed and the oxygen concentration checked. Other parts may need to be replaced after every 20,000 hours (5 to 10 years) of use. The manufacturer must provide a service manual and a two-year supply of spare parts with each new machine. In principle, it can be serviced with a standard set of metric tools, and any special tools needed must be supplied by the manufacturer with each machine purchased. Servicing does require a technician with some basic training.

adult patients may experience hallucinations during recovery. These hallucinations can largely be controlled by administering intravenous diazepam and by allowing the patient to recover in a peaceful environment. Due to this side effect, though, ketamine is not generally appropriate for outpatients.

Ketamine has been expensive and its availability limited. The price is now decreasing because the patent has expired. For short procedures, ketamine may be more cost-effective than ether, the cheapest general anesthetic, because more ether is needed to achieve the same anesthetic effect.

Barbituates are the second type of intravenous agent. Thiopental, a short-acting barbituate, has been used for many years as a standard induction agent for balanced general anesthesia. It takes effect within 30 to 40 seconds of injection and produces sleep but does not provide pain relief or muscle relaxation. Thiopental is a dangerous agent, with possible side effects of depressed breathing, decreased blood pressure, and weakened airway reflexes so that a patient may vomit or regurgitate. Thiopental, also known as thiopentone or Pentothal, is sold as a powder. It must be dissolved in sterile distilled water or saline to make an injectable solution. Although slightly more expensive, purchasing thiopental in single dose rather than multidose ampoules is recommended to lessen the risk of contamination during reconstitution.

Regional Anesthesia

Regional (or conduction) anesthesia is the second major type of anesthesia. Unlike general anesthesia, the loss of sensation is confined to one part of the body, and the patient is conscious during the operation. Locally acting drugs are injected around specific nerves, anesthetizing nerve fibers and nerve endings and blocking passage of nerve impulses before they reach the central nervous system. Regional anesthesia sometimes fails completely or partially, so the anesthetist must confirm that the patient cannot feel pain before surgery is initiated.

Regional anesthesia is a generic term for several different procedures. In topical (or surface) anesthesia, the anesthetic is applied to the mucous membranes. It is used to assist in intubation or for procedures such as minor eye or nose surgery. In local infiltration, a drug is injected directly into the painful area or surgery site. It can be used by itself, for example for suturing wounds, or with a nerve block, for operations such as cesarean sections. For regional nerve blocks, the anesthetic is injected some distance from the site of the operation to interrupt nerve transmission to that site. Regional blocks can be used either alone or with general anesthesia. Combining methods reduces the amount of general anesthetic needed and allows a more rapid recovery. It also provides postoperative pain relief and is more cost-effective.

Spinal (subarachnoid) and epidural anesthesia are used for abdominal, pelvic and lower limb surgery, and for maternity cases. In both, a small volume of concentrated local anesthetic solution is injected to anesthetize the spinal nerve roots. The major differences between the two methods are the depth of the injection site and the dose. Epidural anesthesia uses a volume of solution 5 to 10 times larger than spinal. In some areas, it is used less widely because it is a more difficult technique, and specially designed catheters are often not available. In China, however, epidurals are frequently used and are often performed by nurse anesthetists.

In many situations, regional anesthesia is cheaper and more practical than general anesthesia. Equipment (which includes spinal and epidural needles of various sizes, syringes, and epidural catheters) is simpler and less expensive. Equipment for resuscitation and artificial ventilation, however, is just as essential as for general anesthesia, and intravenous fluids always should be available. Regional anesthesia is also cost-effective. It is a useful technique for a general physician working without a specially trained anesthetic assistant because the doctor can administer the anesthetic. An assistant should be available, however, to monitor blood pressure and other vital signs. Another advantage is that the patient is conscious and can cooperate with the surgeon's instructions. Because the patient breathes normally and larynx and pharynx reflexes are preserved, the risks of an obstructed airway or of aspiration of stomach contents are lessened. This makes it an excellent method for emergency cases. Because recovery time is short, regional anesthesia also frees up hospital beds and supplies.

The main medical dangers of regional anesthesia are hypotension and respiratory arrest. It is also less reliable than general anesthesia. Even the most expert practitioner will sometimes have a failed or incomplete block and must be prepared to supplement the block with intravenous analgesia, to use general anesthesia, or to postpone surgery. Correct needle placement and sterilization are essential. Because the patient is conscious, it is not usually a suitable method for children or an uncooperative or anxious adult. Regional anesthesia must not be used if an infection surrounds the injection site. All local anesthetic drugs have some side effects.

Local anesthetics come in premixed and powdered forms. The most widely used regional anesthesia drugs are lidocaine (lignocaine, xylocaine), with or without adrenaline (epinephrine), and bupivacaine. "Heavy" lidocaine or bupivacaine is used for spinals. Procaine is also still widely available and cheap, but it is not as effective for some blocks. Bupivacaine costs about four times as

much as lignocaine and is not as widely available. Other drugs sometimes used are dibucaine (cinchocaine), mepivacaine, and prilocaine.

Since all local anesthetic drugs are toxic, doses must be limited. The total maximum safe dosage varies according to the drug chosen, its concentration in solution, the anesthetic technique used, and the patient's weight and physical condition. For example, for a 3 kilogram infant, the toxic dose of 1% lidocaine is 1.2 ml.

The length of time an anesthetic is effective is related to how long it is in contact with nervous tissue. When an anesthetic is injected, some of it is fixed locally, while the rest is absorbed in the blood and carried to other parts of the body. A vasoconstrictor drug (which constricts blood vessels) often is added to a lignocaine solution to slow down solution absorption and decrease side effects. This also lengthens the anesthetic's effectiveness. The most commonly used additive is epinephrine. Epinephrine solutions cannot be used for procedures such as intravenous regional anesthesia or operations on the digits or penis.

For local infiltration and for nerve and field blocks, the following equipment is needed: needles in a range of sizes; plastic syringes that can be autoclaved; and, for dental procedures, double-pointed dental hypodermic needles and dental cartridge syringes. Needles should be kept sharpened to reduce pain to the patient, and syringes should have Luer-lock fittings to prevent the syringe and needle from coming apart. Spinal and epidural anesthesia require syringes, special spinal and epidural needles, and epidural catheters and/or epidural catheter tubing. A Sise introducer can be useful for spinal injections as it allows the anesthetist to use a very thin spinal needle, thus preventing excessive leakage of cerebrospinal fluid. Most anesthetists advocate using 25 to 26 gauge needles with a stylet. A recent report from Uganda emphasized the importance of appropriate equipment, stating that epidurals were not possible because catheters, needles, and syringes were not available.

If disposable equipment is not available or affordable, both the biological and the chemical sterility of reusable equipment, such as needles, must be ensured. Using equipment that is not sterile may result in severe complications such as meningitis. For biological sterility, equipment must be autoclaved as boiling is not sufficient. To avoid chemical contamination, needles and syringes should not be stored in antiseptic solutions or cleaned with any sort of cleaning solution. All equipment should be rinsed with sterile water before autoclaving.

Monitoring and Accessory Equipment

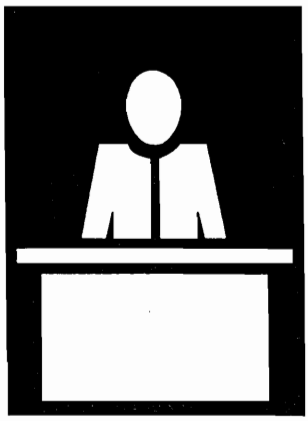
For all methods of anesthesia, careful, continuous patient monitoring for safety, adequate pain relief, and unconsciousness is essential. Sophisticated automatic monitoring equipment improves anesthesia, but it is also expensive, needs constant maintenance, and may require disposable inputs such as ECG electrodes.

Most patients in district and provincial hospitals can be monitored safely with simple, inexpensive equipment. Close, continuous attention by the anesthetist is the most important safety factor. Basic equipment to monitor patients includes blood pressure cuffs in varying sizes, precordial stethoscopes with extra long tubes that can be taped to the patient's chest, and esophogeal stethoscopes.

In certain specialist hospitals, the consensus is that the pulse oximeter is the most important recent advance in monitoring. This device monitors pulse and oxygen levels in the blood, providing valuable information that stethoscopes and blood pressure cuffs do not. Pulse oximeters have two parts: a small monitoring box and a noninvasive probe that attaches to the patient. Pulse oximeters are expensive; current prices are US$2000 to US$3000 for the monitoring box, approximately US$100 for the reusable probe, and US$30 for a disposable probe (which can be washed and reused 10 to 15 times). They also need regular, skilled maintenance because the electrical circuits are complex and the probes break easily. Although suitable for only some specialist hospitals, pulse oximeters may be more cost-effective than other complex monitoring equipment.

The most important considerations for accessory equipment are that it should be reusable and be standarized with existing equipment. Differing sizes of face masks, oropharyngeal airways, and endotracheal tubes are needed to fit children and adults; plastic types allow the anesthetist to see problems such as vomiting or blockages. Endotracheal tubes also require adaptors, connectors, suction catheters, and catheter mounts to attach them to breathing systems. For intubation, the anesthetist needs laryngoscopes with an ample supply of bulbs and rechargeable batteries and metal or plastic stylets. Both the surgeon and the anesthetist need suction pumps; electrically powered machines are the most convenient, but foot- or hand-powered models break down less easily. Tilting trolleys also are needed.

Managing Anesthesia Services



Three major problems slow the development of safe and sustainable anesthesia services in developing countries: drug shortages; lack of appropriate, functioning equipment; and lack of trained medical and non-medical anesthetists. Basic management strategies can enhance services without adding greatly to the costs.

Drug Supplies. The heavy reliance of most countries on imported drugs creates several problems. For instance, inadequate drug budgets are further limited by competition for scarce foreign exchange. Drug transport and storage costs raise prices and increase the risk of deterioration. Furthermore, the variety of drugs available is limited by the need to purchase in bulk, and governments must find reliable local suppliers who will not sell expired or adulterated drugs. Some of the poorest countries rely heavily on drug donations, which are sometimes inappropriate, outdated, or no longer in use in industrialized countries.

Drugs may vary widely in price among different countries and suppliers. One recent survey of 18 Latin American countries found prices 2.5 to 30 times higher for the same item. The higher prices were found in the poorer countries within the same geographic area. New drugs are actively promoted by companies and are often more expensive than existing drugs. Only occasionally do they warrant their additional cost, although ketamine and halothane clearly do. Essential drug lists can help countries select the most cost-effective drugs; a 1987 anesthesia conference in Addis Ababa, Ethiopia emphasized that such lists should be used by all hospitals and ministries. For certain basic drugs such as lignocaine and epinephrine, UNICEF is a reliable and low-cost supplier. Charity hospitals can order ketamine and certain other drugs very cheaply from the British organization ECHO (Equipment to Charity Hospitals Overseas). Buying drugs in bulk and repackaging for in-country distribution is more economical if a drug comes in powder or tablet form, but opportunities for improper storage, mislabeling, contamination, and theft are greater.

Within many countries, distribution is a serious problem. Large, central hospitals often consume 50% or more of the drugs purchased, leaving provincial and district hospitals chronically short. Within hospitals, the single most important area for improvement is better communication between the anesthetist and the pharmacy so that both know which drugs are needed each day, which are available, and which supplies are running short. Transportation and refrigeration problems were noted earlier.

Equipment Maintenance. A second major problem with anesthesia services is how to obtain strong, reliable anesthetic equipment appropriate to local circumstances and keep it in working order. In many countries, particularly in sub-Saharan Africa and the Pacific Islands, expensive anesthetic equipment remains unused and in disrepair because personnel trained in maintaining the equipment are not available, or necessary or consumable parts are missing. Improvised repairs can be dangerous for the patient.

Equipment-related problems fall into three categories: inappropriate choice of equipment, lack of standardization, and inadequate provision for maintenance. Inappropriate equipment may be chosen because of a desire for technical sophistication. In addition, purchasing officers may not have the necessary technical background to choose appropriate equipment. Donors don't always consider complications such as the cost of ancillary disposable parts or the effect of irregular power on delicate electrical equipment. Finally, purchasing decisions may be based on the initial purchase price rather than on the lifetime cost, which includes buying, installing, operating, and maintaining a piece of equipment. The lifetime cost of medical equipment may be two to three times the initial purchase price.

Lack of equipment standardization creates four problems: (1) different pieces of equipment may not be compatible and assembly must be improvised; (2) staff must learn how to operate many different kinds of machinery, thus

increasing the risk of dangerous mistakes; (3) parts from older or broken machines can't be used to repair others; and (4) maintaining a supply of spare parts is difficult and expensive. Donors are often responsible for the variety of equipment; regardless of what is already being used, they usually donate only equipment that is produced by their country's medical industry. With frequent changes in models by manufacturers, spare parts for older models become unavailable. Many national health services do not have complete equipment inventories, and systems are not in place to ensure that new equipment is compatible with existing stock. Unfortunately, severe financial constraints leave many countries dependent on donated equipment.

Lack of routine maintenance greatly shortens the life of most equipment. Maintenance problems are due to serious shortages of trained technicians in the public sector; insufficient funds for purchasing spare parts; and lack of the necessary tools, spare parts, and equipment manuals to make repairs. Spare parts may not be ordered until a machine actually breaks down or supplies of accessory equipment are exhausted. Rural hospitals, in particular, have maintenance problems because they must rely on central hospitals to send technicians to them. In addition, equipment in rural areas must endure harsher physical conditions such as humidity, fluctuating electricity, and dust that clogs moving parts.

Service contracts either with the equipment manufacturer or with the in-country supplier are one way of addressing maintenance problems. Purchasing agreements often include such contracts. However, direct service from manufacturers can be very expensive due to the distance involved, and local suppliers vary enormously in their capacity and willingness to undertake repairs and routine servicing. Thus, one of the most cost-effective steps that donors could take would be to include supplies of spare parts and provide training in routine maintenance when equipment is donated.

Anesthesia departments are usually unable to solve maintenance problems alone, but they can take certain measures. One is to recommend standardization whenever new equipment is being purchased or donated. Another practical measure is to include instruction in routine and preventive maintenance of anesthesia equipment in general staff training. In Ghana, bigger teaching hospitals have trained technicians to maintain equipment, but in smaller hospitals, nurse anesthetists are trained to maintain and service the equipment. In Zimbabwe, seminars have been conducted to train users on the proper care and operation of equipment. In addition, a professional society for medical engineers and technicians in both the private and public sectors has been established to raise the status of such work. Within individual hospitals, emphasizing routine cleaning and checking of equipment by all staff, anticipating the need for replacement of spare parts and consumable parts such as batteries and bulbs, and making a special effort to establish good working relationships with available technical services may help reduce problems related to equipment maintenance.

Personnel. Although many people believe that anesthesia should be administered by specialist physicians whenever possible, the limited number of physician anesthetists in developing countries has necessitated the development of alternative approaches. One alternative to physician anesthestists is to include more training in anesthesia in the general medical curriculum to ensure that all physicians are competent in basic anesthesia and resuscitation techniques. Another strategy, being used in countries such as Zimbabwe and Ghana, is to provide special short training programs (3 to 6 months), which include basic anesthesia techniques, to general duty doctors who are to be posted to rural areas. Where even general physicians are few in number or have many competing demands for their time and skills, many countries have trained other cadres of health workers such as nurses and clinical medical officers to do basic anesthesia. The length of training varies from intensive six-week courses to the more usual one- or two-year programs. Training programs should emphasize safe, straightforward techniques. If possible, a standard approach to common conditions and problems also should be taught. Such training programs should be based on the equipment and drugs that will be available to the trainees when they practice.

Regular refresher courses are important to update knowledge and maintain interest for all levels of personnel. Opportunities for career advancement based on experience and further training are very important to retaining personnel. Educational material specifically for anesthesia personnel in developing countries is also available (see Materials Available, pp. 11-12). When possible, visits to district hospitals by physician anesthetists from provincial or national referral hospitals for education and supervision can be very useful. The importance of this is widely recognized, but it is often not practiced because distances are great, transport is lacking, and workloads are too heavy.

Basic Management. Within larger hospitals, communications

Medical Concerns for Special Patient Groups

Because of important physiological differences, certain groups of patients require special attention during anesthesia. **Children** require special breathing systems for both drawover and continuous flow machines; plain, uncuffed endotracheal tubes in small sizes; and child- and infant-size blood pressure cuffs. Doppler blood flow monitor machines are also helpful. In addition, the operating room should be kept warm, and an adequate supply of intravenous fluids and dextrose should be available.

Pregnant women and **patients with underlying medical conditions**, such as anemia or tuberculosis, may need extra supplies of blood or oxygen. Special care also is needed in choosing anesthetic drugs.

Medical Concerns for Anesthetists

Infection. To protect against exposure to blood and other bodily fluids contaminated with infectious organisms (e.g., HIV, HBV), it is recommended that anesthetists wear gloves, goggles, and other protective clothing such as gowns and masks; that hepatitis B vaccination of anesthetists be considered in low prevalence HBV areas; and that sterilization of equipment be done carefully.

Inhalational gases. Possible health risks associated with chronic exposure to anesthetic gases have not been clearly proven. Nevertheless, to avoid inhalation of waste gases due to exposure to the patient's exhaled air or to leaks in tubing, vaporizers, valves, reservoir bags or during various procedures such as connecting and disconnecting cylinders, several precautions are recommended. These include proper design and ventilation of operating rooms, cleansing of anesthetic tubing after use and hanging it to dry in a well-ventilated room, regular checks of equipment for leaks, improvised scavenging systems, increased use of regional and intravenous anesthesia, and increased use of low-flow inhalational methods.

are often a problem. Special systems should be set up to ensure that on-call staff can be summoned for emergencies. Adequate staffing should be clearly assigned and enforced. Recovery facilities should be a priority area. A separate recovery area should be set up, and patient monitoring by carefully trained nurses is vital.

For the anesthetist, improvements in quality of care can result from instituting three basic routines and adhering to them. Routinely and thoroughly assessing a patient's condition before surgery is perhaps the most important management strategy. The goals of preassessment are to identify any abnormalities; to correct them, if possible; and to choose a type of anesthesia that poses the least risk for that patient. The preassessment includes a full medical history, a physical examination, and a simple but careful explanation to the patient of the procedure. Second, checking anesthetic equipment for proper assembly, leaks, and malfunctions before every operation is imperative. Finally, keeping complete, regular records of every anesthetic given and the course of each operation and recovery is also important. Weekly meetings to discuss records, problems, or interesting cases also promote good care.

CONCLUSION

Anesthesia is an essential part of the referral services that must be available to support primary health care. Technology options for equipment and drugs are complex and deserve careful consideration in light of local constraints. Innovative ideas like the oxygen concentrators and training programs for equipment maintenance technicians can play a valuable role in overcoming the existing problems, as can a greater emphasis on systematic assessment of local equipment needs and standardization of equipment, whether purchased or donated.

Materials Available

The World Federation of Societies of Anesthesiologists (WFSA) is a professional association for physician anesthesiologists, with member societies in 82 countries. For information on its semi-annual newsletter and its educational activities, write to: Dr. John S.M. Zorab, President, WFSA, Frenchay Hospital, Bristol BS16 1LE, U.K.

□

The German Agency for Technical Cooperation has sponsored the publication of a comprehensive handbook entitled **Primary Anesthesia.** It covers anesthesia techniques, drugs, and equipment for developing countries, focusing on rural hospital practice. It costs US$18.00 plus shipping. Write to: Oxford University Press, Walton Street, Oxford OX2 6DP, U.K. or to regional Oxford University Press offices.

□

A bibliography on anesthesia is available from PATH.

Materials Available (Continued)

WHO, in collaboration with the WFSA, has produced a manual for general doctors providing anesthesia. **Anaesthesia at the District Hospital**, by Michael Dobson, describes basic anesthesia techniques, procedures, and equipment. It is available in English, Spanish, French, Portuguese, and Russian for US$16.00. Translations into Arabic, Indonesian, and Hindi are also planned. A companion volume, **General Surgery at the District Hospital**, costs US$24.00, and a third volume, **Surgery at the District Hospital: Gynaecology, Orthopaedics, and Traumatology** is being prepared. Also available is an excellent booklet entitled **WHO Model Prescribing Information: Drugs Used in Anaesthesia**. For ordering information, write to: WHO, Distribution and Sales, 1211 Geneva 27, Switzerland.

□

Also available from WHO, above, is an important document discussing medical equipment maintenance and its management: **WHO 1987 Interregional Meeting on the Maintenance and Repair of Health Care Equipment, Nicosia, Cyprus, 24-28 November 1986.**

□

Medical Equipment in Sub-Saharan Africa: A Framework for Policy Formation contains an extensive annotated bibliography and costs £9.00 plus shipping. Request the IDS Research Report Rr 19 November 1988 from the Institute of Development Studies, University of Sussex, Brighton BN1 9RE, U.K.

□

World Anesthesia produces a newsletter that reports on working conditions and problems faced by physician and non-physician anesthetists around the world. For information, contact: Dr. Iain Wilson, Department of Anaesthetics, Royal Devon and Exeter Hospital, Exeter, U.K.

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DIRECTIONS is published two times a year. Single copies are free to health program managers in developing countries and others interested in primary health care programs. PATH is a nonprofit, international organization devoted to the development and application of appropriate health technologies for primary health care programs in developing countries.

INTERCHANGE

Rural Water Supplies and Sanitation–A Test from Zimbabwe's Blair Research Laboratory, by Peter Morgan, is a practical handbook for field workers on how to design and construct simple, low-cost handpumps, wells, latrines, and other water-related devices. Helpful photos and drawings are also included. The handbook is available free of charge to water and sanitation personnel. Write to: Sales and Marketing Manager, International Division, MacMillan Publishers, Ltd., Houndmills, Basingstoke, Hampshire, England, RG21 2XS.

■

Teaching Aids at Low Cost has produced three sets of 24 color slides on **HIV Infection/Clinical Manifestation; Virology and Transmission; and Prevention and Counselling.** The cost for all three is £2.75 (seamail), £0.60 extra for airmail. Write to: TALC, P.O. Box 49, St. Albans, Herts AL1 4AX, U.K.

The Appropriate Health Resources and Technologies Action Group (AHRTAG) recently published a booklet about the **Oral Health Self Care Project** in Delhi, India, which has developed, tested, and evaluated teaching materials on oral health education for primary school curricula. AHRTAG has also published a booklet, called **Low Cost Medicine Packaging**, which describes a project in Mexico that recycles waste plastic to produce small drug containers. For more information on either of these innovative projects, write to: AHRTAG, 1 London Bridge Street, London SE1 9SG, U.K.

■

The International Vitamin A Consultation Group (IVACG) has published **Guidelines for the Development of a Simplified Dietary Assessment to Identify Groups at Risk for Inadequate Intake of Vitamin A** to assist community workers in vitamin A program development. IVACG has also published **Methodologies for Monitoring and Evaluating Vitamin A Deficiency Intervention Programs.** Single copies of both are available free of charge to developing countries. Write to: IVACG Secretariat, The Nutrition Foundation, Inc., 1126 Sixteenth Street, N.W., Washington, D.C. 20036, U.S.A.

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health technology
directions

PATH Program for Appropriate Technology in Health

Major Equipment for Peripheral Laboratories

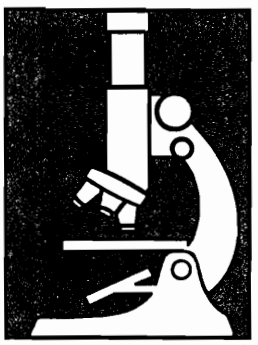
Laboratories are essential to optimal health care delivery; patient management; and disease detection, control, and surveillance at all levels of the health care system. Laboratory services provide disease diagnoses, determine severity of infection, and help monitor treatment effectiveness and pace of recovery.

In developing countries, establishing and maintaining an effective and appropriate laboratory, especially at the district or health center level, poses many challenges. Among them is how to select equipment given the frequent constraints of funding shortages, insufficient numbers of trained personnel, lack of technical support, inadequate essential reagents, unreliable water and power supplies, and lack of information on appropriate laboratory equipment. Since manufacturers typically do not design or adapt most laboratory equipment for use in developing countries, the range of appropriate technologies from which to choose is limited.

Equipment selection must take into consideration local disease prevalence and priority health needs of local populations, the conditions of use, and how well equipment can be maintained. Consulting with district or central laboratory personnel to select tests and identify available resources for ongoing support to the laboratory is also essential.

This issue of *DIRECTIONS* discusses major pieces of laboratory equipment used in district and health center laboratories. The first section describes basic criteria for laboratory equipment selection. The second section reviews particular types of equipment and describes new developments. The final section focuses on the need for basic services, such as electricity, that are required to support laboratory operations, as well as the importance of training, communication, and quality control.

Selection Process



Major Equipment

Laboratory Support

Volume 11, Number 1 ISSN: 0730-8620 1991

Selection Process

The role that district and health center laboratories play in supporting health care delivery in developing countries varies widely depending on local resources and on regional health problems. For example, in Indonesia, over half of its 6000 health centers provide some laboratory services. These laboratories are expected to conduct a minimum of 21 tests in clinical chemistry, hematology, and microscopy, as well as simple water quality tests. In other countries, particularly in Africa, health center laboratories may perform only simple tests using visual comparison methods or microscopy and must refer patients to larger facilities for more sophisticated analyses. District laboratories in some countries may perform a wider range of tests using more advanced immunological or chemical methods.

All laboratories, however, face similar problems regarding selection of essential tests and equipment. Many factors must be considered during the selection process. Funding and other resource constraints guide many key decisions, yet properly selected tests and equipment may contribute to improving long-term laboratory cost-effectiveness (see chart, p. 3).

Equipment selection directly depends on the types of laboratory tests and the volume of testing required. A thorough understanding of local disease prevalence, the local population's health concerns, and what people can afford to spend is crucial to selecting appropriate tests. Determining required tests also should be based on discussions between health providers and laboratory personnel. To be clinically useful, tests should be simple, accurate, and easy to perform in settings with limited resources.

Typically, health center and district laboratories may perform bacteriological investigations to diagnose diseases such as leprosy, tuberculosis, cholera, gonorrhea, syphilis, and urinary and respiratory tract infections; parasitological tests to diagnose malaria, schistosomiasis, filariasis, leishmaniasis, trypanosomiasis, intestinal parasitic infections, and many others; and broader investigations to diagnose and monitor other conditions such as anemia, diabetes, and organ disorders.

Once essential tests are identified and resources such as staffing and supervision are assessed, the most appropriate test techniques and a list of required equipment then can be determined. Appropriate equipment should meet local needs, be adaptable to local circumstances and conditions, be scientifically sound, and be acceptable to laboratory personnel.

Selection Criteria

The following issues must be considered when selecting equipment. Depending on the local situation, some criteria may be more significant than others and trade-offs may be required:

Usefulness. Is the equipment compatible with and relevant to local health needs and concerns and existing diagnostic and treatment services? Is the equipment compatible with the types and volume of tests being performed? Desirable equipment must be distinguished from essential equipment.

Performance. How reliable and exact is the equipment under specific conditions of use? How accurate must results be in the target setting? Are timely results necessary or possible?

Durability and Robustness. The conditions under which the equipment will be used may have a serious impact on its short-term and long-term performance. Will the instrument be moved frequently? Must it be stored in a protected environment? Will it be exposed to high or low temperatures, humidity, drought, or dust? Manufacturers should include estimates of reliable performance ranges according to temperature and humidity. Well-ventilated storage space should be available for the equipment.

Cost. Both the initial and operating costs of the instrument as well as costs of necessary accesso-

ries and maintenance, must be assessed. Shipping and insurance will add expense to overseas orders.

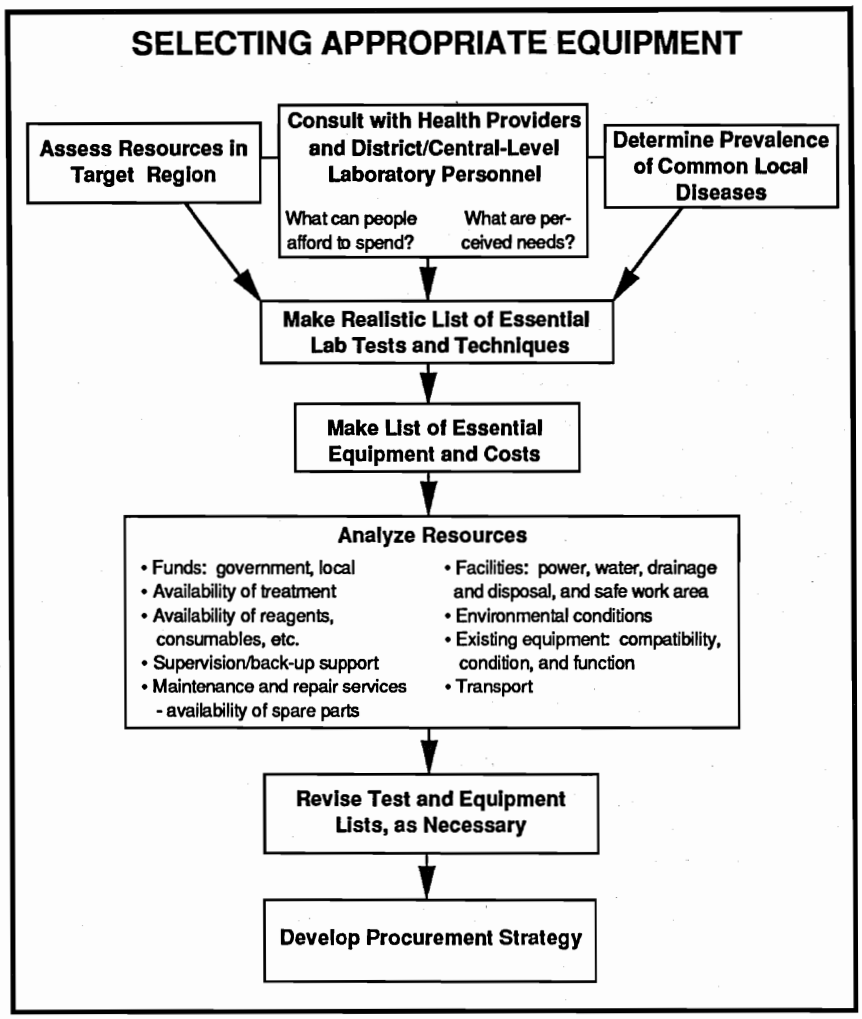
Sustainability. Even if affordable, are replacement parts such as bulbs and fuses, as well as other consumable supplies and reagents, still being made and easy to procure? Ideally, the majority of consumable supplies should be locally available.

Technical Complexity. Equipment that is simple to operate and easily assembled and disassembled for cleaning, repair, and decontamination is most appropriate. Equipment requiring numerous accessories and attachments is less desirable. Tools and trained staff for maintenance and repair also must be available.

Training Requirements. What level of technical training is required to operate the instrument? Are sufficiently trained laboratory staff available? How much training on equipment operation and maintenance is the manufacturer or agent willing to provide? Are appropriate maintenance, service, and calibration manuals included (in local languages, when necessary) that can be reviewed before purchasing?

Power Requirements. Lack of stable electricity is a major problem facing developing country laboratories. Before selection, it is essential to consider the equipment's power requirements in relation to the availability of electricity to the laboratory. Can the instrument be used with a voltage stabilizer or inverter to counteract surges of current, or can alternative power supplies such as batteries be used?

Safety. What risks are associated with equipment use or misuse? Is the manufacturer able to install the equipment and provide advice on maintenance to help ensure safe performance? Does the equipment's design limit or prevent contact between the laboratory worker and infectious agents?

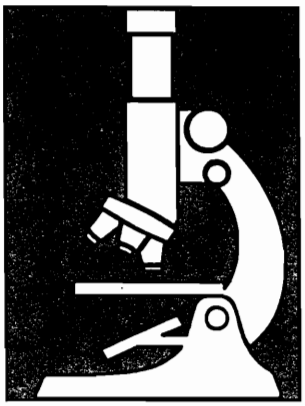


Procurement

Purchasing most pieces of equipment from one or two manufacturers or suppliers, rather than from multiple suppliers, makes it easier and less expensive to maintain equipment and procure spare parts. Equipment should be ordered only after complete product information, including operation and repair manuals, have been received and reviewed, especially if the manufacturer is unable to provide on-site demonstrations. When placing an order, clear and adequate specifications, using the manufacturer's reference codes and stating required voltage, are necessary. To the extent possible, equipment should be standardized at all levels of a country's laboratory service. Decisions regarding standardization must be made in consultation with peripheral laboratories to ensure that equipment, chemicals, reagents, and other supplies are appropriate and consistent with local needs and facilities.

Supplies and equipment often are ordered at intervals of one, three, or six months. It is essential that individual laboratories order supplies in sufficient quantity and in advance. Keeping an ongoing record of what is needed may facilitate timely resupply of essential items.

Major Equipment



Microscopes
The microscope is the most important laboratory instrument and is the principal diagnostic tool in developing countries. For example, in health center laboratories in Kenya, microscopy constitutes about 90 percent of a laboratory worker's time.

Magnification. Microscopes enlarge an object's image through the use of lens systems consisting of objectives and eyepieces. Total magnification is calculated by multiplying the magnification of the objective by that of the eyepiece. Thus, if a microscope uses a 100x objective with a 10x eyepiece, the total magnification is 1000x. For most routine medical work, 10x, 40x, and 100x (oil immersion) objectives with a 10x eyepiece are sufficient. Sometimes wide-field eyepieces are used, which increase the scanning area by 25 percent or more.

Monocular vs. Binocular. Although binocular microscopes (two eyepieces) do not provide better detail than monocular (single eyepiece) ones, they allow the specimen to be viewed with both eyes at once, which reduces eye fatigue. This may increase the number of specimens that can be examined in one session. Monocular microscopes, however, can be fitted with a blank eyepiece to reduce eye fatigue. Binocular microscopes are more expensive than monocular ones.

Illumination. Sufficient, steady light is essential. Some microscopes use external sources or natural light; others have built-in light sources. Natural light is sufficient for monocular microscopes, but work is restricted to daylight hours. To enhance brightness and provide steadier illumination, sunlight can be used indirectly by reflecting it from a white board and directing it through a laboratory window or towards a microscope set up in the shade outside. Direct exposure to sunlight must be avoided.

When using binocular microscopes with 100x oil immersion objectives, natural light is generally insufficient, and reliable external or built-in sources of light are needed. If electricity is available, a light bulb placed about 0.5 meters from the microscope is sufficient for most routine work. A microscope with a built-in lamp, however, is preferred. Quartz halogen lamps provide excellent, high-intensity illumination, and they do not become discolored as tungsten bulbs do after extensive use. Halogen bulbs, however, are more expensive, less widely available, and quicker to burn out than tungsten bulbs.

Most binocular microscopes have built-in sources of light, using tungsten or quartz 6, 8, or 12 volt (12v) lamps with transformers. If electricity is not available, a 6v lamp can be connected to a battery. The microscope supplier should provide the necessary accessories for battery connections.

Unfortunately, a low cost, reliable microscope with good optics does not yet exist. Several organizations, however, have tried to develop microscopes that are suitable for developing country use. For example, *Tropical Health Technology* sells binocular and monocular "Tropical Medicine Microscopes," which have built-in halogen light and come with inputs and leads that allow them to be powered either by mains electricity or by a 12v car battery. A special 12v battery charged by a solar panel also can be ordered. A mirror that fits over the lamp in case of battery or mains failure is also provided. Equipment for Charity Hospitals Overseas (ECHO) also supplies monocular and binocular mirror microscopes that have been specially designed for developing countries. (For more information, see Materials Available, p. 12.)

Attachments. Dark field microscopy (or dark ground illumination) is used to examine microorganisms suspended in fluid (e.g., the spirochetes that cause syphilis) that cannot be seen using ordinary transmitted light. Rather than passing directly through the condenser to the objective, light is reflected to the outer edges of the condenser lens and brightly illuminates the microorganisms against a black background. Clean slides, cover slips, and a high intensity microscope lamp are required. Most dark field microscopy also requires 10x or 40x

objectives and an opaque disk or "stop" made of metal or thick cardboard. A special dark field condenser is required when using a 100x objective.

Fluorescence microscopy is used to diagnose some bacteriological and parasitic diseases such as tuberculosis and malaria. Invisible ultraviolet or visible deep blue light illuminates specific parts of microorganisms stained with fluorescent dyes. Usually, a special fluorescence microscope is required for this method, but they are very expensive. A conventional microscope may be modified using a fluorescence lamp (quartz iodine lamps are less expensive than mercury vapor ones); primary ("excitation") and secondary ("barrier") filters; a dark ground condenser; and a non-fluorescing immersion oil such as liquid paraffin if an oil immersion objective is used.

Recently, a simple fluorescent attachment for conventional light microscopes was developed. The attachment was designed to identify malaria parasites stained with BCP or acridine orange, but eventually it also may be used to diagnose other diseases, such as tuberculosis, using other stains. The attachment costs much less than a full fluorescence microscope and permits a faster diagnosis than conventional microscopy. Determining parasite species, however, is difficult. Using the attachment would require only minimal additional training for experienced microscopists. The main drawback is cost, currently projected at US$1,200. (See Materials Available, p. 12.)

Maintenance. Microscopes must be carefully maintained, particularly in harsh environments. In hot, humid climates, fungus tends to grow on the lens surfaces, which can ruin a microscope within weeks. Sealing the microscope in a plastic bag with a drying agent such as self-indicating silica gel is the ideal method to prevent fungus growth. If this is not possible, placing the microscope in a small cupboard or compartment that is heated continuously from below by at least one low-watt bulb also will help prevent fungus. Where electricity is not available, the microscope may be left on the bench if it is protected by a lightweight cover and kept in the shade. The microscope must not be stored in its wooden box in these climates.

In hot, dry climates, dust is the biggest threat. The microscope must be kept in an airtight plastic bag, and, unlike in humid climates, it may be put in its wooden box after each day's use. In any climate, to avoid common problems caused by lens smears, the surface lenses of the objective, eyepiece, and condenser should be cleaned after each day's use with a dry lens tissue or a soft, clean cloth.

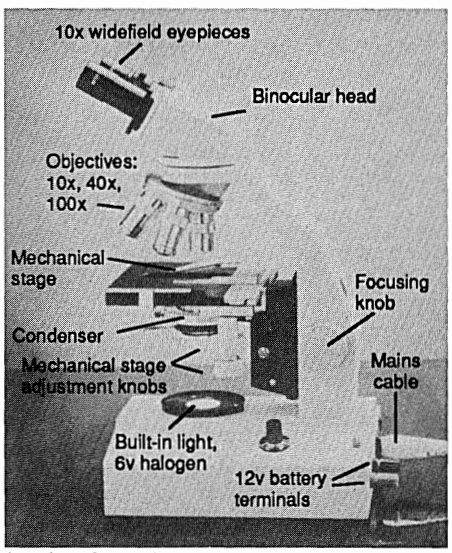
Colorimeters

These devices are used to measure the concentration of particular substances ("analytes") in a colored solution. Sometimes the analyte itself is colored, such as hemoglobin, but often a reagent is added to react with an analyte and produce a colored solution. Spectrophotometers are more sophisticated and more expensive than colorimeters and are rarely needed at the district level.

Simple colorimeters measure analyte concentration only within a certain wavelength range in the visible area of the spectrum. Basic analytes that can be measured include hemoglobin, bilirubin, urea, total protein, cholesterol, uric acid, and glucose. Principal components include a lamp, a lens and mirror, interchangeable color filters (for wavelength selection), a photosensor, an amplifier system, and a readout device that records analyte concentration. Some models have replaced the lamp and filters with a light emitting diode (LED) that produces light of a specific wavelength and often makes the instrument more portable. Using an LED, however, limits the range of measurable analytes.

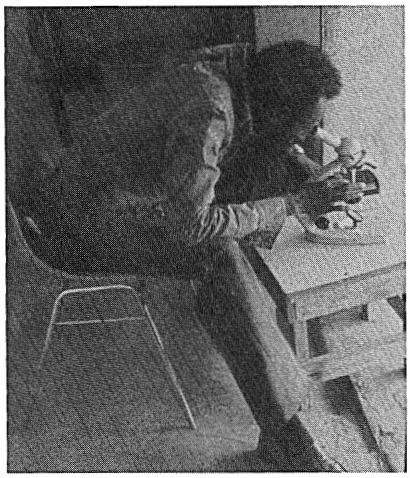
The colorimeter's photosensor receives the selected wavelength's light after it has passed through the sample. It is converted to an electrical signal, which is amplified, measured, and displayed. Colorimeters must be calibrated using reference solutions of the analyte being measured. Supplies, such as cuvettes, and specific reagents, such as Drabkins solution for hemoglobin determination, are required. A stable source of electricity also is needed. Some models, like the WPA CO700D Colorimeter, operate from mains power, a 12v battery, or a special 12v battery that can be recharged from a solar panel. Most colorimeters cost US$400 or more.

Maintenance. Following the manufacturer's recommended operation and maintenance



Basic microscope components.

Tropical Health Technology



WHO

Sufficient light is essential for microscopy.

instructions helps ensure optimal performance. Turning off colorimeters when not in use helps preserve the bulb's life and allows the instrument to cool. When not in use, the instrument should be covered with a cloth, and objects must not be placed on top of it as they might block air flow and cause overheating. Colorimeters require cleaning after each use, and the filters and other external optical components should be inspected regularly for clarity and dusted with a soft cloth, if necessary. Extra lamps should be ordered at the time of purchase.

Whenever a new lamp is installed, the instrument's alignment needs to be checked. The photosensor rarely needs replacing. Plastic cuvettes are now available from many suppliers and can be used in most colorimeters. If handled carefully, they can be reused several times if the optical sides are not scratched.

Hemoglobinometers

Millions of people in developing countries, especially women and children, suffer from anemia. Because of anemia's prevalence and severity, district and health center laboratories should have some means to diagnose it. Laboratory diagnosis of anemia generally involves measuring hemoglobin concentration in the blood. Hemoglobinometers are colorimetric instruments that measure hemoglobin concentration. Though still expensive, they are less costly and simpler to use than colorimeters. The decision to purchase a colorimeter, which can measure several analytes, versus a hemoglobinometer that measures hemoglobin only, depends on available resources, local need, access to electricity, and level of staff training. It may be more cost-effective in some situations to purchase a colorimeter if it can be supported, as it has a broader application. If the primary need, though, is to determine hemoglobin concentration reliably and resources are limited, a hemoglobinometer may be more suitable.

Most health center laboratories still need a simple, reliable, and affordable hemoglobinometer. Despite a strong demand, the choices are limited, and available instruments are over US$300, making them unaffordable in many settings. Currently, many health centers must resort to using simple but highly subjective anemia screening methods, such as conjunctiva inspection or the Tallqvist, copper sulfate, or Sahli methods. For example, all health centers in Indonesia must rely on the Sahli technique. These methods do not provide accurate hemoglobin measurements and should not be used for this purpose. (A somewhat more reliable alternative to hemoglobinometry than simple screening methods is using a Lovibond Comparator with undiluted blood.)

Two basic types of hemoglobinometers exist: electronic, digital display systems that require blood dilution; and visually read or electronic systems that do not require blood dilution. Examples of widely used electronic systems requiring dilution include the Delphi Hemoglobinometer and the BMS CYNOX I. The Delphi uses standard-size cuvettes and can be operated from mains power or a small 9v battery. The instrument is quite compact and performs reliably in tropical climates. The BMS CYNOX I requires diluting blood with Drabkins solution. The instrument requires mains electricity but can be adapted to operate from a 12v battery. It uses special, half-size cuvettes. Disadvantages of both models are that they are expensive and correct blood dilution is essential to achieve accurate results.

Most models not requiring blood dilution must be read visually. These models are reasonably precise, but they are less accurate and more expensive than electronic models. An example of a visually read instrument is the BMS Hemoglobinometer. It is easy to use and is mainly appropriate for low-volume peripheral laboratories. To operate, a drop of blood is placed on the surface of a glass chamber, and the red blood cells are lysed (dissolved) with a saponin stick. The chamber is then pushed into a clip to even out the layer of blood and is inserted into the instrument. The sample is illuminated and viewed through an eyepiece, where hemoglobin concentration is measured against a scale displayed in the viewing field. The instrument comes with one calibration standard and a complete chamber set. It can be operated by mains electricity with an adaptor or by two C (1.5v) batteries. Drawbacks are that cleaning the fragile chambers is difficult and operating costs are high, especially if saponin sticks are bought commercially instead of made on-site. Saponin sticks also may lose their effectiveness in tropical climates, and using two sticks instead of one may be necessary, which increases costs.

Electronic hemoglobinometers using undiluted blood are preferable over visually read models where staff training, facilities, and resources are limited. An electronic, direct-readout system called HemoCue was introduced a few years ago. It photometrically measures converted hemoglobin in undiluted blood. The blood sample is collected in a microcuvette lined with dry reagent that lyses red blood cells and converts the hemoglobin to a measurable form. A microprocessor displays results within 60 seconds. Field tests show that the HemoCue is durable and able to withstand high humidity. It is lightweight, portable, and easier to use than tests using diluted blood. Without technical training, however, erroneous results may occur. It is powered by a 12v nickel cadmium rechargeable battery, ordinary AA batteries, a solar panel, or mains electricity using a transformer. Unfortunately, it costs over US$500. The reagent-lined microcuvettes are disposable, which means they must be supplied continuously. They are also very expensive, at US$0.40 to 0.80, depending on the quantity.

A new, lower cost, electronic, direct read-out hemoglobinometer made by Artel has been field tested in Jamaica with assistance from PATH and found to be useful and accurate. Further testing is planned for Kenya and Indonesia. It is portable and its cuvettes are reusable, which helps keep testing costs low. Undiluted blood is stirred with a saponin stick on a standard microscope slide and placed in a cuvette, which is inserted into the instrument. Results, displayed digitally, are ready almost immediately. It can be powered by mains electricity or by two rechargeable AA 1.2v batteries. A solar power attachment is being investigated. Introduction is expected in 1993.

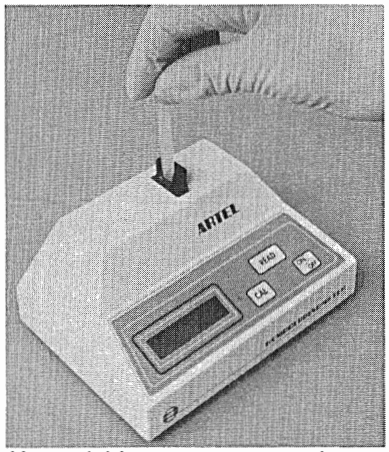
Centrifuges

Centrifuges accelerate sedimentation of particles in fluid. Two basic types of centrifuges exist: general-purpose centrifuges, which are used to obtain sediments of specimens such as blood, cerebrospinal fluid, and urine; and microhematocrit centrifuges, which measure packed red cell volume to diagnose anemia as well as to detect blood parasites such as trypanosomes and microfilariae.

General-purpose Centrifuges. Most general-purpose centrifuges require mains electricity and can be fitted either with fixed-angle or swing-out rotors. A fixed-angle centrifuge applies greater centrifugal force, and separation occurs more quickly than with a swing-out model. For many investigations, however, swing-out rotors are preferred as sediments collect horizontally in the tube.

For most district laboratories, a general-purpose centrifuge, preferably fitted with a swing-out rotor with six or eight buckets (tube holders), will suffice. Variable speed control and a brake are also desirable, though they increase the cost. An operations and maintenance manual and key replacement parts, such as carbon brushes and bucket cushions, are essential to obtain at time of purchase. It may be more cost-effective for some laboratories to purchase a small, general-purpose centrifuge with a microhematocrit rotor attachment instead of a separate microhematocrit centrifuge, but models with this option tend to be expensive.

Hand-powered centrifuges are used in many areas as they do not need electricity and are less expensive (under US$100) than electric models. Drawbacks are that many current hand-powered models are unsafe, and it is difficult to maintain a constant and



Hemoglobinometers are used to detect anemia.

sufficient speed. Two new, portable hand-powered centrifuges, however, are being field tested. One is a dual-purpose model intended for rural health centers. A microhematocrit head can be switched with a swing-out rotor holding four 75 mm tubes. The other is a smaller, field centrifuge that holds ten 50 mm capillary tubes. Both models are enclosed to ensure safe use. They should be available at the end of 1992.

Microhematocrit Centrifuges. Anemia diagnosis also can be based on hematocrit determination. This method avoids problems associated with unreliable visual or complex colorimetric hemoglobin tests. Undiluted, nonlysed blood is used, which makes this a good method if skilled laboratory workers are not available. However, microhematocrit centrifuges are expensive, and most require mains electricity.

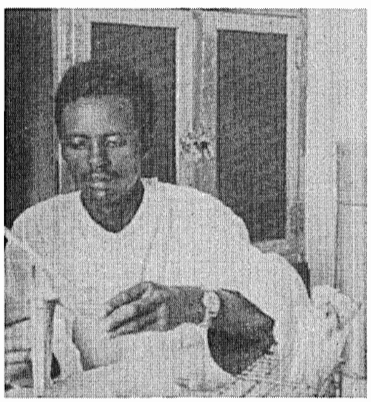
Because most small health centers do not have regular supplies of electricity, battery- or hand-powered microhematocrit centrifuges currently are being developed. A mains/battery-powered microcentrifuge has recently been field tested in the Gambia and may be available in the near future. It holds 20 tubes and can be used with both capillary and 2 ml tubes. It can be powered by a 12v battery, or a battery unit

chargeable from a solar panel can be supplied. It is equipped with a timer, speed control, and a battery indicator.

A portable, inexpensive "microfuge" is also under development. It is compact, lightweight, and powered by an internal 9v battery. Solar power is also being investigated. Whether the 9v battery can provide a constant speed over extended periods of use to ensure consistent packing of red cells is still unclear. In addition, the microfuge uses special disposable capillary tubes, which may add expense and be difficult to resupply.

For infomation on mains or battery-powered centrifuges, contact Solmedia Tropical Laboratory Supplies (see Materials Available, p. 12).

Safety. Centrifuges can be hazardous to use. For example, contaminated airborne droplets or particles (aerosols) from specimens being spun can be released if the centrifuge is opened before rotation has stopped, particularly if specimens are in open tubes or if tube breakage occurs. Newer models are fitted with interlocking lids that prevent the centrifuge from starting before the lid is secured or being opened before rotation has stopped. Some are equipped with warning devices that indicate centrifuge imbalance. Other precautions include using plastic centrifuge tubes with tightly fitting screw tops when possible, and inspecting glass tubes for cracking and scratches before use. Protective gloves should be worn when using and cleaning the centrifuge.



FAO

Incubators are required to culture specimens.

Incubators, Heat Blocks, and Water Baths

Bacteriological cultures, as well as some clinical and hematological tests, require incubation at a controlled temperature. Most of these tests are done in district or central laboratories rather than in health centers.

Only laboratories that carry out culture and sensitivity tests need incubators. In most cases, a small capacity model will suffice. Unfortunately, electric incubators are dependent on a stable source of power. When possible, incubators should be purchased from in-country suppliers to ensure proper maintenance and reliable supplies of replacement parts.

Less expensive, 12v battery-powered, portable incubators are also available. One model, the GQF Laboratory Incubator, is made of thermal plastic and requires only 30 watts to operate. It can maintain temperatures between 28°C and 42°C using a thermostat, and a thermometer can be attached to the incubator's side. A spare thermometer and thermostat should be ordered at the time of purchase.

Heat blocks and water baths are used to incubate specimens in test tubes or to heat bottles of culture media or other substances. Although this equipment is available with variable temperature controls, most situations require only 35° to 37°C, 56°C, or 100°C heat.

Heat blocks tend to be less expensive to buy and operate than water baths and require little maintenance. One model, the Stuart Test Tube Heater SHT1, is portable and comes with four interchangeable blocks that hold various test tube sizes. Two blocks can be held in the heater at the same time. It can be powered only from mains electricity.

Many variable-temperature, thermostatically controlled water baths are currently available. Some are equipped with propellers to circulate the water and maintain a constant temperature. These are more expensive than small models without propellers. One of the main disadvantages of water baths is that clean, distilled water is recommended and must be maintained. Hard water deposits also must be removed. In addition, moisture may enter open tubes (through condensation) and affect test results.

Scales and Balances

Laboratories can save money if they prepare their own reagents and stains. A scale that is sensitive to 0.01 grams (10 mg) is adequate for accurate preparation of most reagents and stains. Models with integral weights are more convenient to use than those with separate weights.

Many types of manually operated scales and balances exist. Ohaus scales and balances with integral weights are recommended most widely by experts. The Ohaus 505 scale is small, rugged, easy to use, and inexpensive. It is most useful in small health centers. Sensitive to 0.01 grams, it has a capacity of 50.5 grams. The Ohaus 311 balance is also sensitive to 0.01 grams but is more accurate and has a capacity of 311 grams, which makes it more appropriate for hospital laboratories. The Ohaus Harvard Trip balance is used for weighing large quantities of chemicals and for balancing

centrifuge tubes; it has a sensitivity of 0.1 grams with a 2000 gram capacity.

Though easier to read, electronic direct read-out scales are considerably more expensive and more difficult to maintain than manually operated scales. They are also less durable and require a stable source of electricity.

Stills and Water Filters
In addition to an appropriate balance or scale, a still or deionizer is required to prepare water for making reagents, reference solutions, and stains. Boiled, filtered rainwater may be used in some situations where rainfall is sufficient and can be collected in large quantities. Purified water is needed, however, to prepare many reagents and standard solutions. During distillation, water is boiled and the condensed steam is cooled, resulting in clear, purified water. About 50 liters of cool water per hour must flow through the condenser and condense the steam, though this water can be reused. Electric stills are expensive, but some countries, such as Kenya, have begun to investigate simple but effective solar stills where electricity is not available.

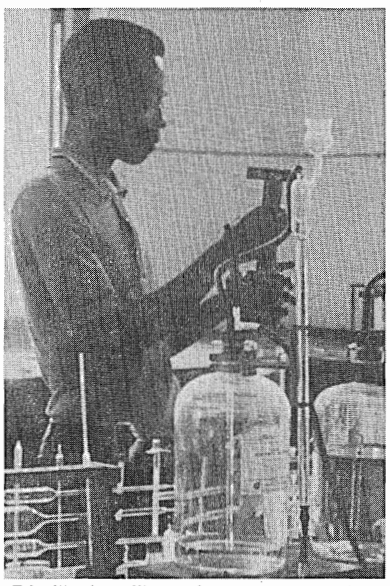
Filtered water that is free of bacteria and other particles can be used to make some reagents and stains and to rinse glass and plastic ware, as long as dissolved chemicals in the filtered water do not interfere with staining or chemical reactions. This must be tested before using the water for patient testing. Gravity water filters using a candle filter (single or double) are easy to use and maintain.

Deionizing water may be the most economical way to purify water. Mains power is not necessary, and less water is needed than when using stills. Ion-free water is ideal for making reagents and solutions for clinical chemistry tests and is essential for preparing reagents and standards for electrolyte tests. Simple hand-held and bench deionizers with self-indicating resin currently are available. Hand-held models are inexpensive and portable, making them particularly useful for small district and health center laboratories that require only small quantities of deionized water. The deionizer resin in each filter cartridge produces about 15 liters of deionized water, depending on the water's salinity. Bench models, such as the Bibby ADH Deionizer, are more appropriate for district level laboratories and are capable of producing about 110 liters of water per resin cartridge, depending on the water quality. Impure water should be filtered before being deionized to prevent the resin from becoming exhausted too rapidly. Drawbacks are that replacing cartridges may be difficult due to cost and unavailability.

Refrigerators and Autoclaves
Antisera and various specimens and reagents, in addition to vaccines and many essential drugs, require refrigeration. If blood is stored for transfusion, a thermostatically controlled refrigerator for blood storage and infrequently used reagents is essential. In the absence of reliable electricity, kerosene-, gas-, or solar-powered refrigerators are used. Unfortunately, kerosene- and gas-powered refrigerators need frequent maintenance, and fuel shortages or problems with low-grade kerosene may occur. In addition, not all are able to control the temperature adequately for storing blood. Solar refrigerators are expensive to purchase, but the long-term operating costs are lower and maintenance is minimal. Because the price of solar-powered devices is steadily dropping, solar refrigerators may soon become the best alternative to conventionally powered units.

Many district and health center laboratories require autoclaves for steam sterilization and specimen waste disposal. For example, laboratories may use autoclaves to prepare sterile swabs and sterilize needles, syringes, lancets, and culture media. Portable autoclaves are available that are powered by electricity, gas, kerosene, or wood, depending on local facilities. In smaller facilities, portable steam sterilizers have been modified from home pressure-cooker designs. Solar-powered autoclaves also are being used in some countries such as Kenya.

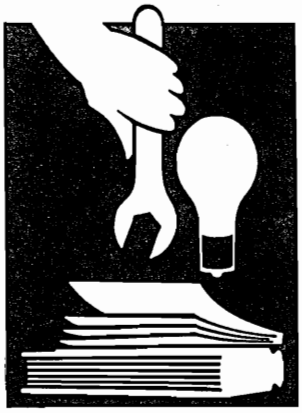
WHO has produced a number of documents and *Product Information Sheets* regarding specifications, availability, maintenance, and repair of refrigerators, insulated cold boxes, and autoclaves for use in the Expanded Programme on Immunization (EPI). (See Materials Available, p. 12.) For more details, readers also can consult *Health Technology DIRECTIONS,* "Immunization," Volume 9, Number 2, 1989.



D. Menriood/WHO

Distilled or filtered water is needed to make many reagents and solutions.

Laboratory Support



Power Supplies
Most laboratory equipment must rely on some form of electrical power, which may be provided by mains electricity, fuel-driven generators, rechargeable and disposable batteries, solar energy, or hand- or foot-cranking or wind-powered devices. Mains electricity is unreliable or nonexistent in many countries, especially at the district and health center levels, or it may be supplied only for a few hours per day. Even when supplied, the voltage may be irregular. Voltage regulators can help protect equipment from power surges, but they are ineffective at protecting equipment from sudden voltage drops.

In the absence of regular mains electricity, many larger health facilities use fuel-driven generators to power equipment. Yet these units require frequent maintenance and are subject to fuel shortages. Many instruments can be powered by rechargeable 12v lead-acid batteries, such as car batteries. These batteries, however, require access to intermittent or constant mains or generator power for recharging. For smaller instruments, such as hemoglobinometers and microcentrifuges, disposable batteries may provide sufficient power. In some countries, these batteries are available and inexpensive, but their quality may be unreliable. Rechargeable small-voltage batteries are also available in some places.

Perhaps the most promising form of power for use with laboratory equipment is solar power. Initial costs may be high, but solar panels are easy to maintain and very cost-effective over time. The African Medical Research Foundation (AMREF) is currently installing solar panels in health center laboratories in Kenya to power microscopes and hemoglobinometers. In peripheral laboratories in Tanzania, where mains electricity does not exist, some laboratories use a generator to provide power for three hours per night. Since power is also required during the day and for emergencies at night, a solar panel is used to recharge a 12v car battery, which can power several laboratory instruments.

Maintenance and Repair
Because most equipment in peripheral laboratories is exposed to harsh environmental conditions and climates, facilities for maintenance, repair, and equipment calibration are essential. Laboratory staff can be trained in preventive maintenance and simple repair, which reduces dependence on highly trained maintenance technicians. Unfortunately, many countries face shortages of maintenance staff, equipment operators, and replacement parts. WHO advises that a separate national maintenance and repair service for laboratory equipment be established in all countries. Manufacturers and donor organizations also must take more responsibility in providing information on equipment maintenance.

Local unavailability of replacement parts, such as light bulbs, fuses, and essential connectors, is a serious problem in many countries. Ordering spare parts at the time of initial purchase is essential, particularly if parts are not locally available. Specifications of necessary spare parts should be included in product information supplied prior to purchase and distributed with equipment being procured.

Operation, service, and calibration manuals must be supplied with both purchased and donated equipment. These manuals, provided by the manufacturer, should have detailed instructions regarding installation, standard operating procedures, daily and long-term preventive maintenance, trouble-shooting, and recommended spare parts. When possible, manuals should be provided in the local language.

Training
Adequate training, including regular refresher courses, for laboratory workers at all levels is essential. Training should include basic epidemiologic principles, biosafety, hazards prevention, and safe disposal of wastes. For example, a training course for community laboratory workers in Ecuador included information on parasitology, local diseases and

organisms, method of infection, treatment, preventive care, and communications skills, as well as information on essential tests, equipment use, and laboratory policy and organization.

Since most peripheral laboratory workers must operate with limited resources, training also should include information on efficient use of available resources, anticipation of supply needs and prompt reordering, calculation of operating costs, proper storage of reagents and chemicals, preventive maintenance and simple repair of equipment, internal quality control, and record keeping. Since peripheral laboratory workers often must refer specimens to larger laboratories, training in the proper collection, packing, and transport of specimens is also needed. In addition, staff responsible for transporting specimens need training in correct handling procedures.

Using locally prepared training materials and visual aids for laboratory worker training is preferable. If materials are used that are not locally produced, they must be carefully evaluated and, if necessary, adapted to suit local circumstances. Simple manuals with color photographs and step-by-step instructions on preparing and reading slides would be very useful for laboratory workers.

Finally, regular refresher courses are needed to evaluate and update skills and techniques and to re-emphasize good laboratory practices and quality control. Personnel working in remote areas particularly need regular supervisory and training visits.

Communication

Establishing a reliable system of referral among laboratories at all levels of the health care system is vital to maintaining high standards of practice (see chart). For example, district laboratories play a key role in supervising health center laboratory work. They are responsible for testing or forwarding referred specimens, making regular supervisory visits, and conducting ongoing training courses for community-based laboratory workers. District hospital and central-level laboratory staff also should assist in selecting, maintaining, and operating equipment, as well as in establishing quality control procedures.

District laboratories must report regularly to regional or central staff on the needs and conditions of laboratories under their supervision, including usage rates of key supplies. In this way, not only are the needs of peripheral laboratories met more easily, but regular communication enhances coordination of services at all levels and helps ensure that equipment is standardized and regularly maintained. Coordination with other health sectors and programs is also important, and laboratory workers must be viewed as part of the complete health service delivery team.

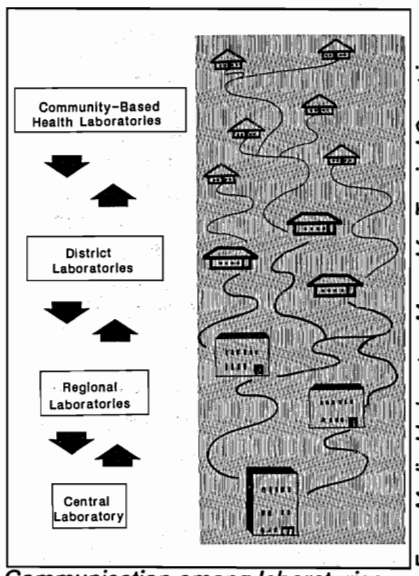
Quality Control

District laboratory personnel have a key role in instituting internal quality control and external quality assessment measures. Internal quality control procedures established by laboratory staff must be followed strictly to achieve accurate test results. At the health center level, quality control procedures should be simple and appropriate to local conditions and resources. External quality assessment ensures comparable results between laboratories and evaluates effectiveness of internal quality control.

CONCLUSION

Peripheral laboratories play an important role in health care delivery and disease surveillance in developing countries. It is essential, therefore, that laboratory equipment be appropriate to local conditions and health needs and that manufacturers be encouraged to design such equipment. It is also important to view equipment needs as a coordinated, interdependent package; selecting separate pieces of equipment without considering what is needed to support their use and how they work together may not improve laboratory operations and, in fact, may hinder services.

Some developing countries may want to consider establishing a committee of medical, laboratory, epidemiology, and procurement experts to help coordinate equipment selection by issuing recommendations based on local conditions and priorities and on the experiences of equipment users. Such a group could also communicate their equipment requirements to manufacturers, help assess local equipment needs, analyze available resources, and advise and coordinate with donor agencies. This would help ensure that despite the constraints faced by peripheral laboratories, the most appropriate equipment possible is selected and used effectively.



From *Medical Laboratory Manual for Tropical Countries, Vol. I*, by Monica Cheesborough/Tropical Health Technology

Communication among laboratories at all levels is essential.

Materials Available

Some of WHO's documents on developing country laboratories are listed below. Write: WHO, Health Laboratory Technology and Blood Safety, CH-1211, Geneva 27, Switzerland, or to WHO regional offices.

For overviews of laboratory operations, consult **Laboratory Services at the Primary Health Care Level** and **Health Laboratory Technology.** For information on equipment, see **Supply, Maintenance and Repair of Health Care Laboratory Equipment in Developing Countries** and **Self-Instruction Sheets for Users of Primary Health Care Laboratory Equipment.**

WHO documents on refrigerators and autoclaves are available from the Expanded Programme on Immunization (WHO/EPI) at the address above.

□

Tropical Health Technology provides low-cost publications, learning aids, and microscopes to developing countries. Publications include: **The Medical Laboratory Manual for Tropical Countries, Volumes I and II** and the **Community Health Laboratory Manual for Tropical Countries,** which will be available in June 1992. Write: Tropical Health Technology, 14 Bevills Close, Doddington, March, Cambridgeshire, PE15 OTT, U.K.

□

The African Medical Research Foundation (AMREF) has produced **A Practical Laboratory Manual for Health Centres in East Africa.** AMREF also provides laboratory evaluation and training and tests appropriate laboratory equipment. Write: AMREF Laboratory Programme, P.O. Box 30125, Nairobi, Kenya.

□

The following organizations provide low-cost equipment, supplies, and/or technical assistance to developing country laboratories:

Solmedia Tropical Laboratory Supplies, 6 The Parade, Colchester Road, Romford, Essex RM3 OAQ, U.K.

Equipment to Charity Hospitals Overseas (ECHO), Ullswater Crescent, Coulsdon Surrey CR5 2HR, U.K.

HAMLO (Aid to Medical Laboratories in Developing Countries) Wilhlminapark 52, 3581NM Utrecht, The Netherlands.

The Hands to Clinical Labs of Third World Countries, Inc., c/o Dr. Sharon Roberts, Cal. State University, Bakersfield, Medical Technology Program, 9001 Stockdale Highway, Bakersfield, CA 93311-1099, U.S.A.

The International Dispensary Association (IDA) P.O. Box 3098, NL-1003, AB Amsterdam, The Netherlands.

□

The International Association of Medical Laboratory Technologists (IAMLT), has produced a **Curriculum for Health and Safety.** It also publishes a newsletter, **Med Tec International,** twice a year. Contact: IAMLT, Ostermalmsgatan 19, S-114 26 Stockholm, Sweden.

□

For information on the flourescent microscope attachment, contact: K.W. Kirk and Sons, Ltd., The Winship Industrial Estate, Milton, Cambridge, CB4 4BD, U.K.

□

A portable "Mini-Medlab" has been developed for both field and laboratory use in developing countries. Contact: Margaret Coles, M.T., RR 1, Box 43AA, Delhi, Iowa, 52223, U.S.A.

□

A bibliography on laboratory equipment is available from PATH.

Due to funding constraints, this is the only issue of *Health Technology DIRECTIONS* produced in 1991. *DIRECTIONS* is totally dependent on donor support, and, at present, only one issue is funded for 1992. We regret any inconvenience to our readers.

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health technology
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PATH Program for Appropriate Technology in Health

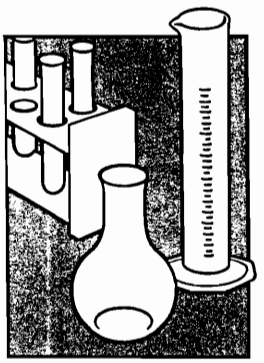
Small Equipment and Supplies for Peripheral Laboratories

Peripheral laboratories, which are attached to health centers and first referral hospitals, vary widely among countries but generally perform basic microscopy and specimen analysis using certain stains and reagents. These laboratories are essential to diagnosing disease and prescribing appropriate treatments in primary health care settings. In addition, they provide important data for disease surveillance and control efforts. In developing countries, where limited resources are spread over a variety of needs, the benefits of a simple diagnostic laboratory that uses appropriate technology are being increasingly recognized by health program managers.

Due to the spread of AIDS, hepatitis, and other infectious diseases, greater attention is being paid to laboratory safety. In particular, concerns about safety in handling specimens prompt a closer look at pipetting devices, protective clothing, and at plasticware as a viable alternative to breakable glassware.

While last year's issue of *Health Technology DIRECTIONS* covered major equipment for peripheral laboratories, this issue focuses on the topics of small equipment and essential supplies. The first section describes some of the more commonly used pieces of small equipment. The second section focuses on consumables and reusable supplies. The final section addresses management issues including safety, quality assurance, and procurement of equipment and supplies.

Small Equipment



Supplies

Management Issues

Volume 12, Number 1 **ISSN: 0730-8620** **1992**

Selection of Diagnostic Tests

To support primary health care services, peripheral laboratories need diagnostic tests that are inexpensive and easy to perform. In selecting appropriate diagnostic tests for the peripheral level, key features to assess include cost, simplicity, reliability, safety, equipment requirements, sensitivity, and specificity. Local disease prevalence and the amount of testing needed are also important considerations. Other issues include staff training requirements, availability of appropriate equipment and reagents, and access to treatment for the diseases and conditions being diagnosed.

The table below lists tests that the World Health Organization (WHO) considers appropriate for peripheral laboratories. Health program managers might use this list as a starting point for selecting tests. They then can modify it according to the local context, taking into consideration the issues mentioned here. A brief discussion of some new rapid diagnostic tests appears on page 8.

Essential Tests for Peripheral Laboratories

Test	Method
Blood	
Hemoglobin	Hemoglobinometer, comparator, ✣copper sulfate,* or hemoglobincyanide
Hematocrit	Microhematocrit centrifuge
Leukocyte count	Counting chamber
Glucose	✣Reagent test strips
Parasites	Giemsa, Field's, or Romanowsky-stained preparations
Differential count/cell morphology	Romanowsky-stained film
Erythrocyte sedimentation rate (ESR)	Westergren Method
Urine	
Nitrite	✣Reagent test strips, or:
Protein	Sulfosalicylic acid method (for protein)
Glucose	Benedict method (for glucose)
Ketone bodies	Rothera's test (for ketone bodies)
Bilirubin	Fouchet's test (for bilirubin)
Blood	Direct microscopy
Sediment for leukocytes, erythrocytes, casts, and parasites	Direct microscopy
Pregnancy	✣Test tube or slide method
Specific gravity	Gravimetric method
Sputum	
M. tuberculosis	Ziehl-Neelsen-stained smear
Stools	
Blood	O-toluidine or guaiac reagent
Protozoa and ova	Direct saline and iodine preparation
Skin	
M. leprae	Modified Ziehl-Neelsen-stained smears
O. volvulus microfilariae (onchocerciasis)	✣Wet preparation
Pus and Exudates	
Bacteria	Gram-stained smear (especially for gonococci) or ✣wet preparation
Trichomonas in vaginal discharges	✣wet preparation

✱Equipment and Reagents

Equipment

Slides and coverslips
Microscope
Hemoglobinometer, photometer, or comparator and comparator tubes
Microhematocrit centrifuge and capillaries
Neubauer counting chamber with coverglass
Hand tally counter
Graduated and dropping pipettes
Staining rack
Dip-staining jars
Interval timer
Differential cell counter or bead counter box
Westergren ESR stand and tubes
Rubber bulb or thumb wheel aspirator
Alcohol lamp
Centrifuge and centrifuge tubes
Urinometer
Thermometer
Measuring cylinders, beakers, and flasks
Test tubes
Scalpel or razor blade
Sterile loop
Wash bottles
Tissue forceps

Reagents

Anticoagulant (EDTA)
Stains: Giemsa, Field's, Romanowsky, Ziehl-Neelsen, Gram, Leishman's, Carbol Fuchsin, and Wright's
Sulfosalicylic acid
Benedict's solution
Sodium nitroprusside crystals
Glacial acetic acid
Ammonia
Immersion oil
pH paper
Fouchet's reagent or Lugol iodine
3% acid alcohol
NaCl solution
O-toluidine or guaiac reagent
Reagent test strips for urine and blood
Formaldehyde
Latex reagent particles for pregnancy test
Drabkin's reagent
Alcohol, 95% ethanol
Barium chloride

Adapted from WHO/Lab/87.2, p. 12-17.

✣Methods that can be used in health centers with minimal equipment and reagents.
*Copper sulfate is used for anemia screening rather than for accurate measurement of hemoglobin concentration.
✱This list can be adapted to suit local testing needs.

Small Equipment

The measurement of volume, temperature, and time is essential to many laboratory procedures. Equipment for performing these tasks is generally less expensive than larger pieces of equipment but plays an important supportive role. Since they are used daily for long periods of time, these devices deserve the same careful consideration as major pieces of equipment. (For source information on the equipment described, see Materials Available, p. 12.)

Pipetting Devices

The measurement of small quantities is usually performed with a pipette and pipetting device. Pipettes and graduated cylinders (primarily used for measuring larger volumes) are discussed in the section on supplies.

Pipetting devices are needed in the laboratory to measure and dispense substances safely and precisely. Good laboratory practice dictates that mouth-pipetting must be avoided because it is hazardous. It may result in transmission of infections or in chemical or other injuries.

For the basic health center laboratory, several simple and inexpensive instruments are available to protect the technician from the dangers of mouth-pipetting. Rubber bulb aspirators are made in several different sizes and shapes for use with graduated capillary tubes and pipettes. They are inexpensive and effective for measuring specimens and reagents accurately. To prevent fluid from entering the bulb, pipettes can be plugged at the end with non-absorbent cotton wool, when available. Glass pipettes should be grasped firmly at the upper end when being inserted into a bulb aspirator to prevent breakage. A newer type of aspirator is the three-way-valve rubber bulb, which has an air vent and provides excellent pipetting control. Its three stainless-steel ball valves allow precise filling and delivery. Nevertheless, it is more expensive than a regular bulb aspirator.

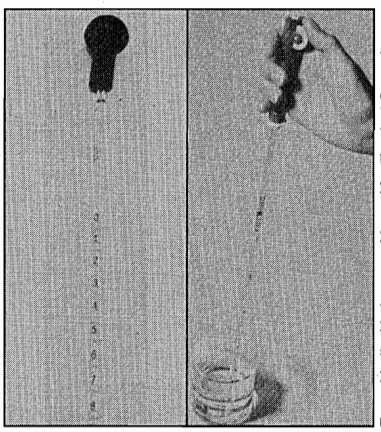
Thumb wheel aspirators also have a flexible end that allows pipettes of different sizes to be inserted and held firmly. The level of fluid is easily controlled by moving the wheel up or down with the thumb.

Plastic bulb pipettes (pipette and pipettor combined) are inexpensive and can be used with both specimens and reagents. Many laboratories use them for removing plasma from centrifuged blood samples. They can be decontaminated with sodium hypochlorite solution (bleach) and washed and reused many times. They cannot be sterilized in a hot air oven, autoclaved, or boiled.

Pipettors. When more accuracy in specimen measurement is desired, pipettors can be used, either with glass pipette tips or disposable plastic ones. They are considerably more expensive than bulb or thumb wheel aspirators (about US$100-200). Because of their high cost, they may not be appropriate for use in peripheral laboratories.

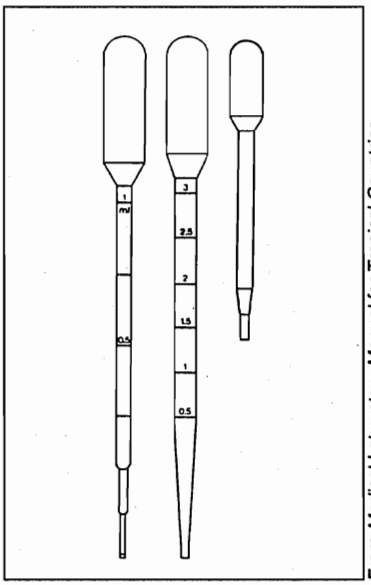
Fixed-volume pipettors are calibrated to measure a single volume of fluid, whereas variable-volume pipettors are calibrated to measure and dispense a range of volumes. The calibration must be checked periodically by setting the pipettor to its mid-range and measuring that quantity of distilled water. The water is then weighed on an accurate scale, and the result is compared to the standard weight for the same volume.

Other Measuring Devices. Bottle-top dispensers can be used to dispense reagents directly from a holding container and are sold with adapters for a



From *Medical Laboratory Manual for Tropical Countries, Vol. 1*, by Monica Cheesbrough/Tropical Health Technology

Rubber bulb and thumb wheel aspirators can be used for pipetting specimens and reagents.



From *Medical Laboratory Manual for Tropical Countries, Vol. 1*, by Monica Cheesbrough/Tropical Health Technology

Plastic bulb pipettes are reusable if properly disinfected.

wide range of bottle sizes. They are durable and precise but expensive (US $120-250). Digital pipettors and microplate dispensers can perform rapid reagent pipetting but are also very expensive (US $150-400). They are probably not necessary for the testing needs of most peripheral laboratories.

All of the pipetting devices described are safe, reliable, and easy to use. Nevertheless, they vary substantially in price and availability. Laboratory managers can select those most appropriate to local needs based on cost, available facilities, and the amount of testing performed.

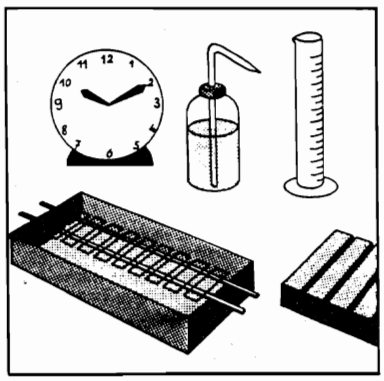
Staining Equipment

Several basic laboratory tests require staining. For example, differential white blood cell counting and diagnosis of diseases such as malaria, tuberculosis, leprosy, and gonorrhea all require staining. The basic equipment required for these procedures includes staining racks, stain and reagent dispensing containers, and staining jars.

Staining Racks. Dip-staining units with a 25-slide capacity are available in black polyacetal plastic, which is resistant to most stains and solvents. When dip staining is not appropriate, as in the case of Gram and Ziehl-Neelsen procedures, smears can be stained by placing two parallel rods across a sink or staining trough. If a staining trough is not available, buckets or empty cooking-oil tins can be used. The parallel rods should be made of a non-corrosive metal, such as stainless steel, which can withstand heat. Plastic or wooden rods cannot withstand the heating process during Ziehl-Neelsen staining. Iron rods corrode when exposed to acids such as those used in the modified Ziehl-Neelsen technique for leprosy diagnosis. Glass rods are also problematic because they are breakable.

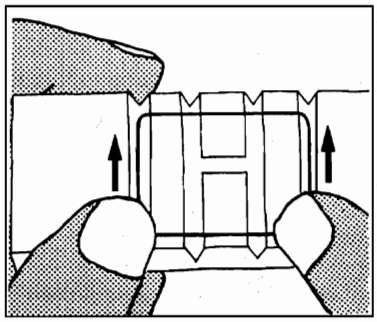
Combination staining, washing, and drying racks are also available. The entire staining process can be performed on these racks without removing the slides.

Containers. Containers for holding and dispensing stains and reagents must be leak-proof, fully sealed to prevent evaporation or exposure to moisture, and easily opened without staining or contaminating fingers. Stain and reagent storage bottles that meet these criteria can be purchased in either glass or plastic. The plastic ones are break-resistant and therefore safer to use.



From *Manual of Basic Techniques for a Health Laboratory*, WHO, Geneva, 1980.

A simple metal or plastic container with two rods firmly attached to it can serve as a staining rack.



From *Manual of Basic Techniques for a Health Laboratory*, WHO, Geneva, 1980.

When the coverglass is properly attached to the Neubauer counting chamber, colored bands appear between the two glass surfaces.

Staining Jars. Coplin staining jars made of polypropylene and capable of holding up to ten slides are available. They include a screw-cap lid that is airtight to prevent evaporation.

Cell Counters and Counting Chambers

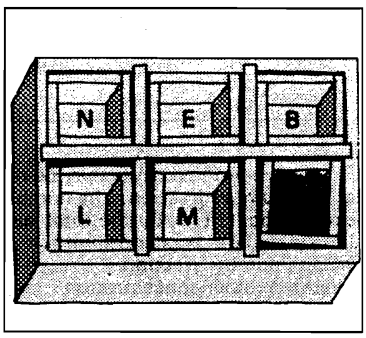
Several devices exist for counting blood cells and platelets. Basic equipment includes instruments for measuring and diluting blood (such as pipettes), hemocytometers (counting chambers) equipped with a cover glass, hand tally counters, and differential cell counters.

For counting cells under the microscope, an improved Neubauer ruled chamber is recommended. It features a metallized platform with bright rulings that divide the microscopic field into distinct sections to facilitate the counting process. It is supplied with a special cover glass. A simple hand tally counter is usually used for counting cells. This is achieved by depressing the button on top of the counter. After the count is completed, the side knob is rotated to return the counter to zero. After the cells are counted, the number of cells per liter of blood is calculated.

Some procedures require a multi-channel counter for differential white cell counting. Mechanical devices that operate like the hand tally counter are available but are very expensive, largely because they are made of non-corrosive metal. A manual differential cell counter made of cheaper materials, such as durable plastic, is needed. Alternatively, a bead counter box can be used to count cells, or they can be tallied by hand.

Kits are available for total white blood cell counting, complete with instructions and all necessary equipment. They can be used indefinitely if an adequate supply of diluting fluid is available and if the capillary tubes are disinfected with bleach after each use.

Multi-purpose Racks
Nylon-coated wire racks are rugged, easy to clean, light-weight, and autoclavable. They are used for holding test tubes, centrifuge tubes, and universal containers. In addition, plastic racks are available, some of which can be autoclaved. Sturdy, non-breakable racks also can be produced inexpensively from locally available materials such as wood. WHO suggests that wooden racks be used with caution, however, because they cannot be sterilized and therefore may increase the risk of disease transmission. A wooden block with wedges cut at about 75 degrees is useful for drying fixed slides.



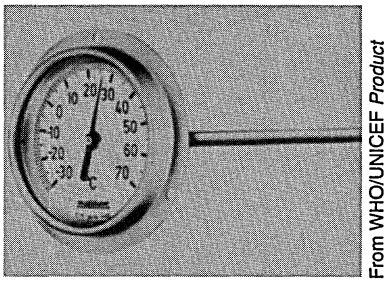
From *Manual of Basic Techniques for a Health Laboratory*, WHO, Geneva, 1980.

A bead counter box with six marked compartments can be used for differential cell counting.

Timers
Mechanical timers are necessary for various laboratory procedures such as staining. Most interval timers with ringers can time reactions lasting from less than one minute up to two hours. Simple, inexpensive kitchen timers can be used for this purpose. Some procedures, such as Field's staining for malaria, require a device that measures in seconds. Many timers are equipped with an overwind protection mechanism and can be purchased from various supply houses. Inexpensive digital watches with timers also can be used to time laboratory reactions. These devices are useful because they have a long battery life.

Calculators
Some laboratory procedures require simple mathematical calculations. For example, in blood cell counting, it is necessary to calculate the number of cells per liter of blood. In laboratories that make up their own stains and reagents, quantities of stock solution have to be determined. Other procedures require calculations for appropriate dilutions of reagent or specimen. Simple, durable, solar- or battery-powered calculators can be useful laboratory tools. They are inexpensive and widely available. Solar-powered calculators, however, need strong light for recharging and therefore may be less practical in peripheral laboratories with low-light conditions. A slide rule can be used for calculations if a calculator is unavailable.

Thermometers
Thermometers also have many uses in the laboratory setting. They can be used in water baths, incubators, refrigerators, and for procedures that require heating reagents or specimens. Mercury thermometers are highly accurate and can be used in ovens, water baths, incubators, or refrigerators. Nevertheless, they are toxic if broken and more expensive than most other types of thermometers. Some are accurate up to 0.2°C. Newer thermometers made with thermochromic liquid crystal are inexpensive, durable, and safer to use than mercury thermometers. The main drawbacks to thermochromic liquid crystal thermometers are that they are less accurate than mercury thermometers, and observer bias may occur when reading the temperature.

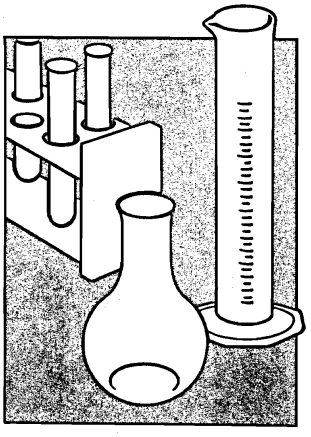


From WHO/UNICEF *Product Information Sheets*, 1991.

Bimetallic dial thermometers are accurate and easy to read.

Alcohol-filled glass thermometers can be used in refrigerators, freezers, and for low-temperature measurements. They cannot be used in heating reactions, however, as alcohol boils at a low temperature. In addition, they are fragile, difficult to read, and sometimes not as accurate as mercury thermometers. Bimetallic thermometers are a good alternative because they have an easy-to-read dial, are durable, and measure temperature with the same accuracy as mercury thermometers. Nevertheless, both mercury and bimetallic thermometers are expensive. All thermometers should be calibrated against a high-quality mercury thermometer of known accuracy.

Supplies



The difference between small equipment and supplies is not always clear since many types of glassware, though not disposable, need regular restocking just like reagents and consumables.

Glassware *vs.* Plasticware
Most of the commonly used materials for collecting and manipulating specimens and handling and storing reagents are available in both glass and plastic. Borosilicate glassware (glass treated with boron) has the advantage of being resistant to heat and to most strong acids and bases. Nevertheless, laboratory plasticware is a viable alternative to glassware because it is break-resistant, less expensive, and safer to use than glassware. Plastic goods also can be transported at lower cost than glass because they weigh less. In addition, they are resistant to most chemicals used in routine laboratory procedures. The table on page 7 lists some of the common forms of plastic as well as their uses and characteristics.

Glassware and reusable plasticware need careful cleaning. They can be disinfected in domestic bleach. Abrasive cleaning powders should not be used for cleaning plasticware as they mar the plastic surface. (For more details regarding proper cleaning of plasticware and glassware, consult the *Manual of Basic Techniques for a Health Laboratory* and *Medical Laboratory Manual for Tropical Countries, Volume 1.* Both are listed in Materials Available, p. 12.)

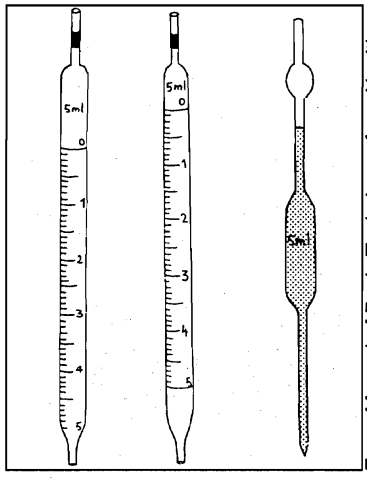
Pipettes
Several different kinds of pipettes are available, some of which are made in both glass and plastic. Graduated pipettes are more versatile because they can be used to measure different volumes. For example, a 5 ml graduated pipette can be used to measure any volume from 0.5 to 5 ml. Two types of graduated pipettes are available: to contain (TC) pipettes and to deliver (TD) pipettes. TD pipettes are graduated to the tip, and all of the measured fluid is dispensed. These pipettes are often used for transferring liquids being diluted into other solutions or reagents. They can be washed in the diluting fluid after their contents have been delivered. When TC pipettes are used, some of the measured fluid remains in the tip after dispensing.

Volumetric pipettes can measure only one fixed volume, but they are more accurate than graduated pipettes. They are mainly used in clinical chemistry tests and cost about the same as graduated pipettes.

Dropping (Pasteur) pipettes are designed to deliver very small quantities. (One drop equals approximately 0.05 ml of liquid.) They should be calibrated periodically to ensure that they are delivering the standard volume of 20 drops equal to 1 ml of distilled water. This is done by pipetting one ml of water into a small tube. The water is then drawn into the dropping pipette and expelled into another container one drop at a time to ensure that 20 drops are delivered.

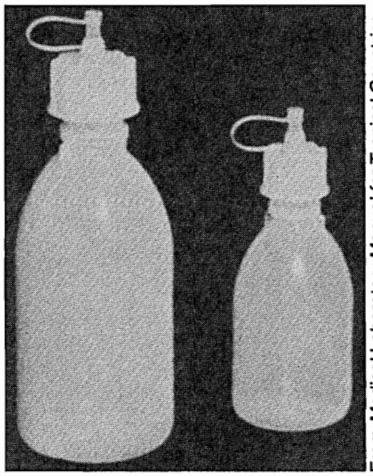
Graduated cylinders and flasks
For measuring larger volumes of liquid and for preparing working solutions, graduated cylinders and flasks are used. They are available in both glass and plastic. The plastic ones are made of polypropylene. They are easier to clean than pipettes and are safer and more durable than glassware. Brushes for cleaning these cylinders are made in various diameters and lengths.

Slides and Coverslips
Glass microscope slides and



From *Manual of Basic Techniques for a Health Laboratory*, WHO, Geneva, 1980.

TD and TC pipettes can measure varying quantities of liquid, whereas volumetric pipettes measure only one fixed volume.



From *Medical Laboratory Manual for Tropical Countries, Vol. 1*, by Monica Cheesbrough/Tropical Health Technology

Stain and reagent storage containers should be leak-proof and firmly sealed.

coverslips are usually purchased in bulk. After use, slides must be washed, disinfected, and rinsed several times. Immersion oil should be removed before the washing and soaking process. Detergents can be effective for cleaning slides and coverslips, but they may leave residues that can alter test results if rinsing is not thorough. Plastic slides and coverslips often react badly to detergents and hot water. Thin coverslips are very fragile and difficult to clean. Therefore, only thicker coverslips tend to be reused. When handling coverslips, gloves are recommended to prevent accidental cuts.

Stains and Reagents

Most of the commonly used stains and reagents can be locally made. Alternatively, stock solutions and powders can be purchased in bulk and used as needed. Local laboratory programs may want to conduct a cost/benefit analysis of local production versus external purchase. Factors such as availability of raw materials and equipment, production costs, transport and storage, production volume, and the availability of quality control facilities should be considered when conducting this analysis. Good manufacturing practices must be applied to ensure product reliability. In some countries, such as Indonesia, small companies produce low-cost reagents and stains. In other regions, it is difficult to obtain good-quality stains and reagents at low cost.

Whether purchased or locally made, all stains and reagents have special storage requirements. For example, Giemsa stain must be stored in dark, airtight bottles. If dark bottles are unavailable, regular glass or plastic bottles can be wrapped in aluminum foil to protect the stain from light, which causes a breakdown in its chemical composition. If kept properly stoppered, the stain is stable for several months. All stains should be checked to ensure that they maintain effectiveness and are not contaminated.

Filtered rainwater rather than distilled water is often adequate for routine reagents. If distilled water is required, it may be necessary to arrange for a supply from local district hospitals.

Laboratory Plasticware*

Type	*Uses*	*Autoclavable*	*Chemical Resistance*	*Strength/Durability*
Polypropylene (PP)	Centrifuge tubes, syringes, flasks, funnels, beakers, containers	Yes	High	High
High-Density Polyethylene (HDPE)	Reagent bottles	Yes (up to 15 min.)	High	High
Low-Density Polyethylene (LDPE)	Wash bottles, dropper bottles, plastic bulb pipettes	No	Medium	Medium
Polystyrene (PS)	Disposable laboratory ware	No	Low (but can be disinfected with bleach solution)	Low
Polyvinyl Chloride (PVC)	Tubing, trays	No	Low (but can be disinfected with bleach solution)	Low

*Based on information obtained from *Medical Laboratory Manual for Tropical Countries, Volume 1*, 1991, by Monica Cheesbrough, pp. 44-45.

The quality of the stain or reagent cannot always be determined visually, and using poor-quality substances may reduce the effectiveness of the test and increase costs by making repeat testing necessary.

Needles and Syringes
Collection of blood specimens requires an adequate supply of sterile syringes, needles, and lancets. For collecting venous blood, a Luer-type polypropylene or nylon syringe with 2.5 ml, 5 ml, or 10 ml capacity is recommended. Both polypropylene and nylon are break-resistant and can be autoclaved or sterilized by other methods for reuse. For collection of venous blood, 19-gauge (size 18, bore 1.016 mm) or 21-gauge needles are recommended. A supply of 23-gauge needles (size 22, bore 0.610 mm) also should be purchased for collecting blood from children. In addition, scalp-vein needles are needed for children. When purchasing needles, it is necessary to specify that they must have a Luer mount and long bevel. It is also important to purchase reusable needles that can be sterilized adequately.

Specimen Collection Containers
Specimens should be collected in leak-proof, break-resistant containers that have screw-cap lids. Containers with snap-on lids should be avoided because infectious aerosols can escape from them.

Rapid Diagnostic Tests

Early and rapid diagnosis of disease is crucial to the health of individuals and the community as a whole. Because many laboratory tests are time-consuming, expensive, and dependent on reagents and costly equipment, efforts have increased to develop inexpensive, rapid diagnostic tests that can be performed at the health center or first-referral hospital with minimal equipment and supplies. Many of these tests are simple to perform, very accurate, and provide immediate results. The key factors that should be considered in evaluating rapid diagnostic tests are cost, stability, sensitivity, specificity, internal quality control, and observer bias. Examples of such tests include reagent test strips to detect protein and blood in urine, dipstick tests for viral diseases such as human immunodeficiency virus (HIV) or hepatitis B virus (HBV) in blood, and rapid agglutination tests for pregnancy and viral or bacterial diseases. (For further information on tests, see Materials Available, p. 12.)

Reagent Test Strips
Single- and multi-purpose reagent test strips for urine and blood have been available for a long time and are very convenient. Despite high initial costs, they may be cost-effective in low-volume testing situations because they save time and do not require additional reagents. A low-cost proteinuria test strip, made with paper instead of plastic, is now being manufactured in Zimbabwe. Low-cost paper test strips for other diseases may soon be available.

Agglutination Tests
Another rapid diagnostic tool is the agglutination test. These tests use particles coated with a substance that is sensitive to the antigen or hormone being sought. A positive test is indicated by a visible clumping of these particles after exposure to the specimen, usually within a few minutes. Rapid agglutination tests exist for a variety of conditions including hepatitis B, streptococcal infection, pregnancy, and syphilis. The test for syphilis uses a Rapid Plasma Reagin (RPR) card treated with an antigen called cardiolipin. An alternative to the RPR test is the TRUST reagent. This test consists of antigen-coated paint pigment particles, which produce a visible clumping in the presence of syphilis antibody. The TRUST reagent is more heat-stable than RPR and can go without refrigeration. In addition, plasma separation cards can be used with finger-stick blood samples, thereby eliminating the need for centrifuged venous blood. The TRUST reagent test using the plasma separation card is inexpensive and can be performed in about 20 minutes.

Dipstick Tests
Dipsticks tests may facilitate immunologic testing where ELISAs are unavailable or unaffordable. For example, an inexpensive dipstick to detect HIV was recently developed to screen blood for antibodies to HIV 1 and 2. It is currently being manufactured in India and Indonesia. The WHO Global Programme on AIDS (GPA) has evaluated a wide range of rapid tests to detect HIV antibodies and can be contacted for further information. Other rapid immunologic tests are available for infectious diseases such as hepatitis B, toxoplasmosis, cytomegalovirus, rubella, and chlamydia.

Management Issues

One of the most important aspects of laboratory management is safety, both for the worker and the environment. Safety measures begin with a firm policy followed by effective worker practice and adequate supervision.

Laboratory Safety

Safety Rules and Policy. Laboratory work can be very hazardous unless good safety practices are followed. Avoidable accidents are usually the result of inadequate training and supervision of the laboratory staff. Each laboratory should have a set of written guidelines, including a code of conduct to follow in case of accidents and a description of how hazardous waste materials are to be handled. At least one person should be appointed to monitor adherence to safety measures and to inform the medical supervisor of any problems or deficiencies that exist in the laboratory.

It may be helpful to appoint a regional safety officer to inspect all laboratories in a given catchment area and to meet with each laboratory supervisor. Records should be kept of all the safety measures taken in each laboratory.

It is important to visit employees regularly to ensure that they follow safety procedures; use safety equipment; and report incidents, accidents, and injuries. All accidents should be investigated and staff retrained as necessary.

Safe Working Practices. Safe working practices include simple personal hygiene measures such as washing hands with soap and water before and after procedures and covering cuts and wounds to prevent infection. Eating, drinking, and smoking in the laboratory must be prohibited to reduce the risk of disease transmission. Where possible, the health of laboratory personnel should be monitored through yearly physical examinations that include chest X-rays.

To prevent contamination of street clothes and skin, the laboratory technician should wear a special coat or back-fastened outer garment. Protective clothing should be cleaned at the work site rather than at home. Laboratory clothing can be soaked in bleach for disinfection. Wearing shoes, rather than sandals, is recommended in case chemicals spill or glassware breaks. If dangerous chemicals are being used, eyeglasses or goggles and gloves can provide extra protection. Having an eyewash bottle in the laboratory is also useful in case of emergency.

Bottles and tubes should be placed in racks to avoid spills and contamination of work surfaces. When mixing solutions, opening culture containers and ampoules, and pouring infectious material, laboratory staff should try to avoid splashes and spills. In addition, a large tray should be used to contain spills (especially if the bench is made of porous materials) when testing all specimens. Aerosol formation can be avoided by using screw-cap containers.

Safe working environment. A well-organized working space, with designated areas for performing specific procedures, will increase efficiency and facilitate disinfection of equipment. Designating a separate area for receiving specimens also will help avoid contamination of bench surfaces. If spills occur, the bench surface should be disinfected with bleach. Bench furniture should be sturdy and well-constructed.

Adequate ventilation is also necessary to allow fumes to escape. All windows should be screened to prevent insects and rodents from entering. Any equipment that requires ventilation should be properly positioned. For example, the chimney opening of a gas or kerosene refrigerator must not be placed under a shelf or in another obstructed area that would prevent exhaust from escaping.

Electrical equipment must be checked on a regular basis. Faulty equipment should be removed from the laboratory and not used until properly serviced. Fire extinguishers are useful in case of chemical fires. Otherwise, flames can be smothered

with dry sand, earth, or a thick woolen blanket. When possible, glassware and delicate pieces of equipment should be stored in a custom-made cupboard with a shelf, lock, and space for a microscope.

Safe Use and Storage of Chemicals and Reagents. All chemicals and reagents must be clearly labelled with the correct name, the date received, and the date of expiration. They should be kept out of direct sunlight to avoid overheating. Hazardous chemicals must be marked with symbols indicating whether they are flammable, toxic, or corrosive.

Flammable chemicals, such as alcohols, acetone, and alcoholic Romanowsky stains, should be stored in a fireproof metal box on the floor, preferably in a cool, locked storeroom. If a metal box is not available, a container lined with aluminum foil may be used. Only small quantities of flammable solvents should be kept on laboratory benches and shelves. Bottles containing flammable chemicals must not be opened near an open flame, and matches must not be used near them. Any fire caused by a flammable chemical should be put out with an extinguisher or smothered with sand, earth, or a blanket.

Corrosive chemicals, such as concentrated sulfuric acid and sodium hydroxide, should be stored on lower shelves or at floor level to prevent injury caused by spills. Wearing eye protection when opening or pouring corrosive chemicals is advisable. If a corrosive chemical spills on the floor, the laboratory technician should always wear gloves and closed shoes when cleaning the area. Caution should be taken when diluting concentrated acids, especially sulfuric acid. Adding a small amount of water to sulfuric acid produces sufficient heat to break a glass container. Therefore, the acid must be added to the water.

Chemicals that are toxic or harmful on skin contact, such as iodine and formaldehyde, are best stored in a closed, locked cupboard rather than on an open shelf.

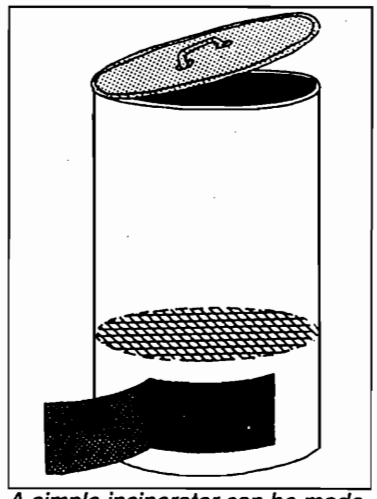
Disposal of Harmful Waste Products. All infectious waste should be autoclaved. If autoclaves are not available, boiling or burning waste are the recommended alternatives. Waste may be boiled in field kitchen cookers or drums for at least one hour. A preferable method for disposal of sputum and stool collection bottles, cotton, gauze, and other waste products is to douse them with kerosene and burn them in a locally made incinerator. The incinerator can be constructed from a metal drum fixed with a strong metal grating, an air vent, and a lid. The fire should reach a temperature that is high enough to achieve complete combustion. The ash produced is not dangerous and can be buried.

If burial is selected as a final disposal method for infectious wastes, they should be autoclaved, burned, soaked in disinfectant, or boiled first. A pit that is four to five meters deep and one to two meters wide with a lid is recommended for burial. The upper rim of the pit can be strengthened by lining it with bricks or stones. Once a week, the refuse can be covered with a layer of dried leaves or quicklime. This is not recommended for disposal of plastic containers because they are not biodegradable and should be burned.

Chemical disinfection of waste products is considered a first-line measure that should be followed by incineration. The chemicals must be prepared at the correct dilution and must not be kept beyond their useful life, which varies according to the substance. The articles to be disinfected must be in full contact with the chemical (usually for at least 30 minutes) and not protected by films of grease or protein. All disinfectants, such as phenols, bleach products, and alcohols, are inactivated somewhat by natural materials such as protein and rubber and by synthetic materials such as plastics and detergents. They are also toxic, and eyeshields are recommended when making dilutions of these chemicals.

Quality Assurance

Quality assurance (QA) is conducted to ensure that the final results reported by a laboratory are accurate. QA includes every parameter affecting test results and final reports. It therefore requires attention to pre-analytical and post-analytical factors as well as to the analysis itself. Pre-analytical factors include selection of the appropriate test by the health care provider or epidemiologist, proper collection of the specimen, and proper transport and storage of the specimen so as to prevent a change in its composition before analysis. Post-analytical factors involve



From *Manual of Basic Techniques for a Health Laboratory*, WHO, Geneva, 1980.

A simple incinerator can be made from an oil drum equipped with a metal grating and lid.

accurate recording and correct interpretation of laboratory results and their timely delivery to the appropriate person. It is crucial for every laboratory to undertake a program of quality assurance. The QA procedures to be undertaken will depend on the type of tests performed in the laboratory, the equipment used, the size of the laboratory, the level of staff training, and the number of specimens handled each day. This requires training in laboratory management, proper communication between the laboratory and other health care staff, and maintenance of high standards in laboratory technique.

QA at the Peripheral Level. The recommended procedure for quality assurance at the peripheral level calls for designated personnel from the first-referral hospital to supervise the work of health center laboratories by conducting regular visits. During these visits, all positive and random negative specimens kept by the technician should be examined. Any specimens for which diagnosis was unclear also should be discussed. In addition, it is important to examine the quality of reagents and equipment being used and to hold periodic in-service training sessions for laboratory staff. Finally, specimens can be referred to the next level of the laboratory network for analysis. In Indonesia, QA is carried out in the periphery by taking all positive slides and 10 percent of negative slides for malaria, TB, and leprosy and cross-verifying the reported findings at the next highest level. In other countries, this may be difficult because of staff shortages and long distances between peripheral and reference laboratories.

In addition to this common form of external quality assessment, two other types of QA require close supervision at the local level. These are internal quality control and surveillance proficiency. Internal quality control addresses the level of accuracy in measuring specimens, preparing reagents, and calibrating equipment. Examples of internal quality control include performing tests in duplicate and comparing the results, or performing repeated tests on control specimens to see if identical results are achieved each time.

Surveillance proficiency relates to the overall organization and supervision of laboratory services. It encompasses specimen collection and labelling, recording and reporting of test results, equipment maintenance, personnel training, and laboratory safety.

Because these aspects of quality assurance are not yet widely practiced, it is necessary to develop appropriate mechanisms for implementing them at the peripheral level. Laboratory managers may want to explore different approaches to arrive at the most feasible method of assuring quality.

Procurement of Basic Equipment and Supplies

An organized scheme for ordering supplies and equipment is necessary if a laboratory is to function properly and avoid discontinuity in service. The person in charge of ordering and purchasing should be an experienced laboratory technologist who is well-acquainted with the conditions under which the supplies and equipment will be used. Decisions about standardization of equipment, supplies, and reagents must be made in consultation with peripheral laboratories to ensure that they match local needs and facilities. Standardization of equipment facilitates purchasing and can improve the availability of spare parts. This lessens the likelihood of an unnecessary disruption in service.

An ongoing dialogue should exist between government health services, non-governmental health organizations, and donors. Countries should provide donors with a list of the equipment and supplies they have found to be most appropriate for local use. This will give donors important guidance about what to purchase and allow countries to play an active role in deciding what they really need. For example, in Mozambique, equipment donations are not accepted unless they pass the scrutiny of experts who provide advice on the country's capacity to ensure their adequate repair and maintenance.

In general, costs can be greatly reduced by procuring supplies in bulk directly from the manufacturers or from low-cost supply houses. Equipment also should be purchased with an adequate supply of spare parts.

CONCLUSION

With a modest stock of basic equipment and supplies, peripheral laboratories can enhance patient care and optimize the use of therapeutic drugs. They can also provide crucial information for disease surveillance and control efforts if they are well-integrated into a network of regional and central laboratories. Health planners can enhance the value of laboratory services at the peripheral level by making sound decisions on appropriate tests and equipment such as pipetting devices, rapid diagnostics, and other important tools. Proper decision-making will help make laboratories safer and more efficient.

Materials Available

Information on laboratory equipment, supplies, and management issues can be obtained from WHO. For a useful overview, consult: WHO/LAB/87.2. For other publications listed below, write: WHO, Health Laboratory Technology and Blood Safety (WHO/LAB), CH-1211, Geneva 27, Switzerland, or to WHO regional offices.

Other WHO publications on laboratory operations include: **Basic Laboratory Methods in Medical Parasitology, Basic Laboratory Procedures in Clinical Bacteriology, Manual of Basic Techniques for a Health Laboratory, Laboratory Biosafety Manual,** and **Bench Aids for the Diagnosis of Malaria.**

The WHO AIDS series is a set of 9 documents on HIV prevention and control. Document No. 9 presents guidelines on preventing laboratory-acquired HIV infection.

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For information on thermometers, syringes, and needles, consult: **Product Information Sheets** from WHO/EPI at the above address.

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Information on various diagnostic tests also can be obtained from the following WHO divisions at the above address:

HIV tests: consult the WHO Global Programme on AIDS (WHO/GPA).

Tests for hepatitis B and other blood viruses: consult the WHO Global Blood Safety Initiative (GBSI). Information on other significant rapid diagnostic tests also can be obtained from WHO/LAB.

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For information on **tests to detect sexually transmitted diseases (STDs),** write: Secretariat, STD Diagnostic Initiative, PATH, 4 Nickerson Street, Seattle, WA 98109-1699 USA.

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Low-cost publications from Tropical Health Technology include: **The Medical Laboratory Manual for Tropical Countries, Volumes I and II** and **The Community Health Laboratory Manual for Tropical Countries.** Write: Tropical Health Technology, 14 Bevills Close, Doddington, March, Cambridgeshire, PE15 OTT, U.K.

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The African Medical Research Foundation (AMREF) has produced **A Practical Laboratory Manual for Health Centres in East Africa.** Write: AMREF Laboratory Programme, P.O. Box 30125, Nairobi, Kenya.

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For information on low-cost equipment and supplies, contact the following organizations:

HAMLO (Aid to Medical Laboratories in Developing Countries), Wilhlminapark 52, 3581 NM Utrecht, The Netherlands.

Solmedia Tropical Laboratory Supplies, 6 The Parade, Colchester Road, Romford, Essex RM3 OAQ, U.K. (Solmedia publishes a yearly list of equipment including white blood cell counting kits, and plastic bulb pipettes.)

Equipment to Charity Hospitals Overseas (ECHO), Ullswater Crescent, Coulsdon Surrey CR5 2HR, U.K.

UNICEF Supply Division Procurement and Assembly Centre, UNICEF Plads, Freeport, DK-2100, Copenhagen Ø, Denmark.

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A bibliography on laboratory equipment is available from PATH.

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