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HealthTech

Technologies for Child Health

Mid-Term Report

Sponsored by

United States Agency for International Development
Office of Health

and

Program for Appropriate Technology in Health
(PATH)

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EXECUTIVE SUMMARY

The United States Agency for International Development (A.I.D.) launched a new program as part of its child survival strategy. A Cooperative Agreement (DPE-5968-A-00-7035-00) between A.I.D. and the Seattle-based Program for Appropriate Technology in Health (PATH), HealthTech focuses on the development and field assessment of key technologies that can be used to improve prospects for child survival.

The $3.6 million HealthTech program is being carried out over a three-year period and supports the development, assessment, and/or introduction of technologies that can have a direct impact on child survival. HealthTech is involved with technologies ranging from vaccine injection systems which self-destruct after a single use to solar-powered weighing devices used in growth-monitoring programs. HealthTech emphasizes the development of technologies to support vaccine delivery that will make it possible to provide low-cost, safe vaccine administration while protecting against possible infection or contamination. The program is also developing other child survival technologies to be used by primary health care programs to protect children in developing countries from nutritional deficiencies and infectious diseases.

HealthTech is part of the Agency for International Development initiative in child survival. Among bilateral donors, A.I.D. is the leading contributor to international efforts to improve health status in developing countries. A.I.D. is committed to reducing mortality and morbidity rates among infants and children under five, as well as mothers. A.I.D. is currently supporting activities in nearly 60 countries that will reduce infant and child mortality and morbidity. These focus on:

- oral rehydration therapy
- immunization
- nutrition
- child spacing

Some programs also include:

- treatment of infections
- vector-borne disease control
- provision of clean water and adequate sanitation

PATH is a Seattle-based, nonprofit organization that works to improve the availability, effectiveness, safety, and acceptance of health products and technologies in developing countries. Its programs work to bridge the gap between the technology and the potential user through a wide spectrum of activities. These include research and development, field assessment, technology transfer, quality assurance, marketing, communication, licensing, and loan financing. Technologies that contribute to the health of mothers and children receive special attention.

I. Background

A. Program for Appropriate Technology in Health (PATH)

The Technologies for Child Health (HealthTech) program is administered by the Program for Appropriate Technology in Health (PATH), in collaboration with the United States Agency for International Development (A.I.D). PATH is an international, nonprofit organization dedicated to improving the effectiveness, safety, availability, and acceptance of health products and technologies in developing countries. Its programs work to bridge the gap between the technology and the potential user through a wide spectrum of activities, including research and development, field assessment, technology transfer, quality assurance, marketing, communication, licensing, and loan financing for primary health care programs.

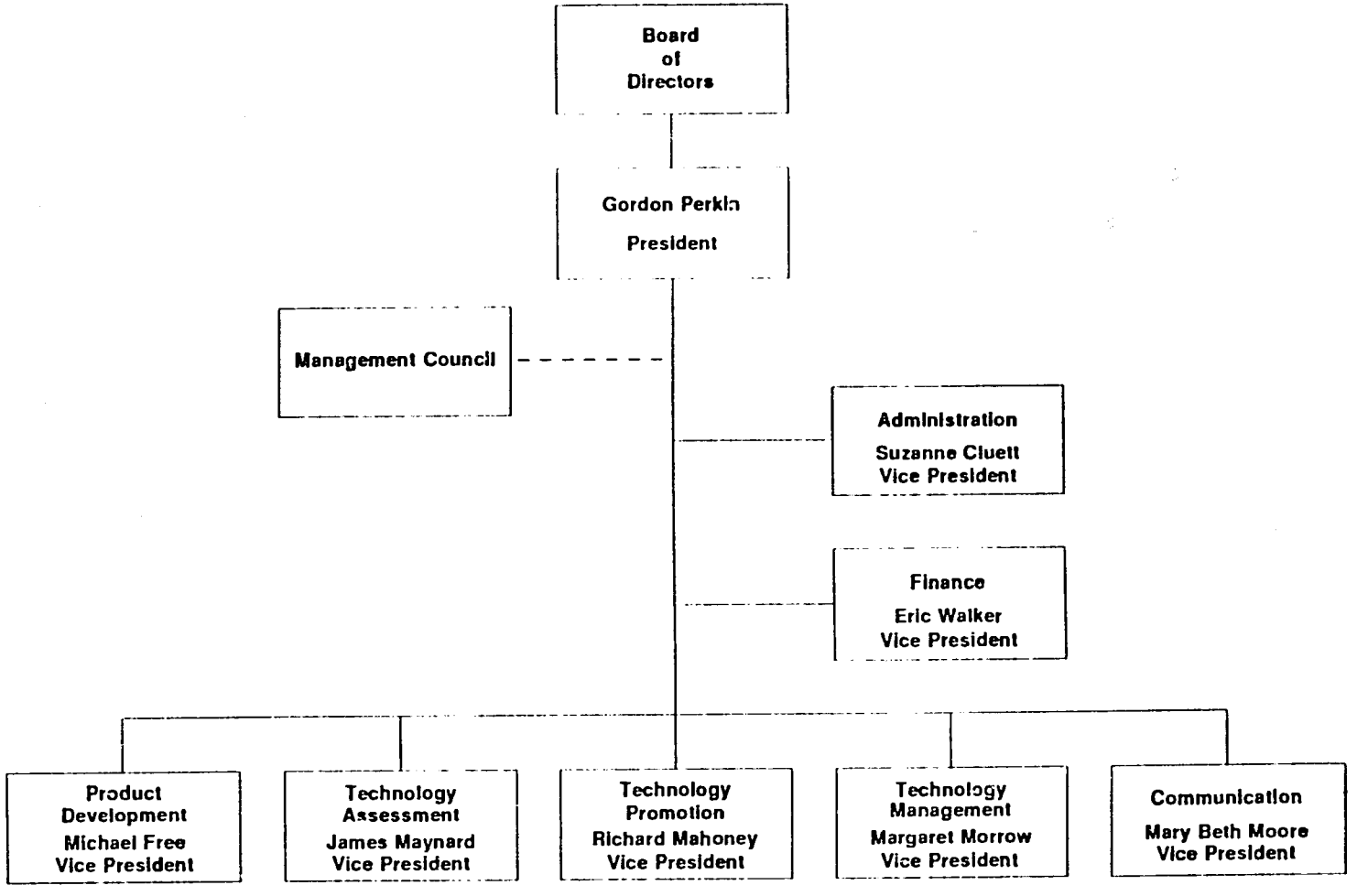
In the organization's 10-year history, PATH and its reproductive health arm, Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), have managed more than 500 health and family planning projects in over 30 developing countries. Support has been received from a wide variety of funding sources, including international health and family planning agencies, national governments, private foundations, and corporations.

PATH is organized into five functional departments, with the HealthTech program assigned to the Product Development Department under the direction of Michael J. Free, Ph.D., the director of the department and a Vice President of PATH (see organizational charts of PATH and Product Development Department on the following pages). The other departments are Technology Assessment, Technology Management, Technology Promotion, and Communication. The range of staff skills is wide, providing expertise in such diverse fields as medicine, health program management, planning policy and administration, epidemiology, biochemistry, environmental health, industrial design and product development, diagnostics, health communications, marketing, international finance, and procurement. In addition to its full-time staff of over 100, PATH draws upon the specialized skills of consultants.

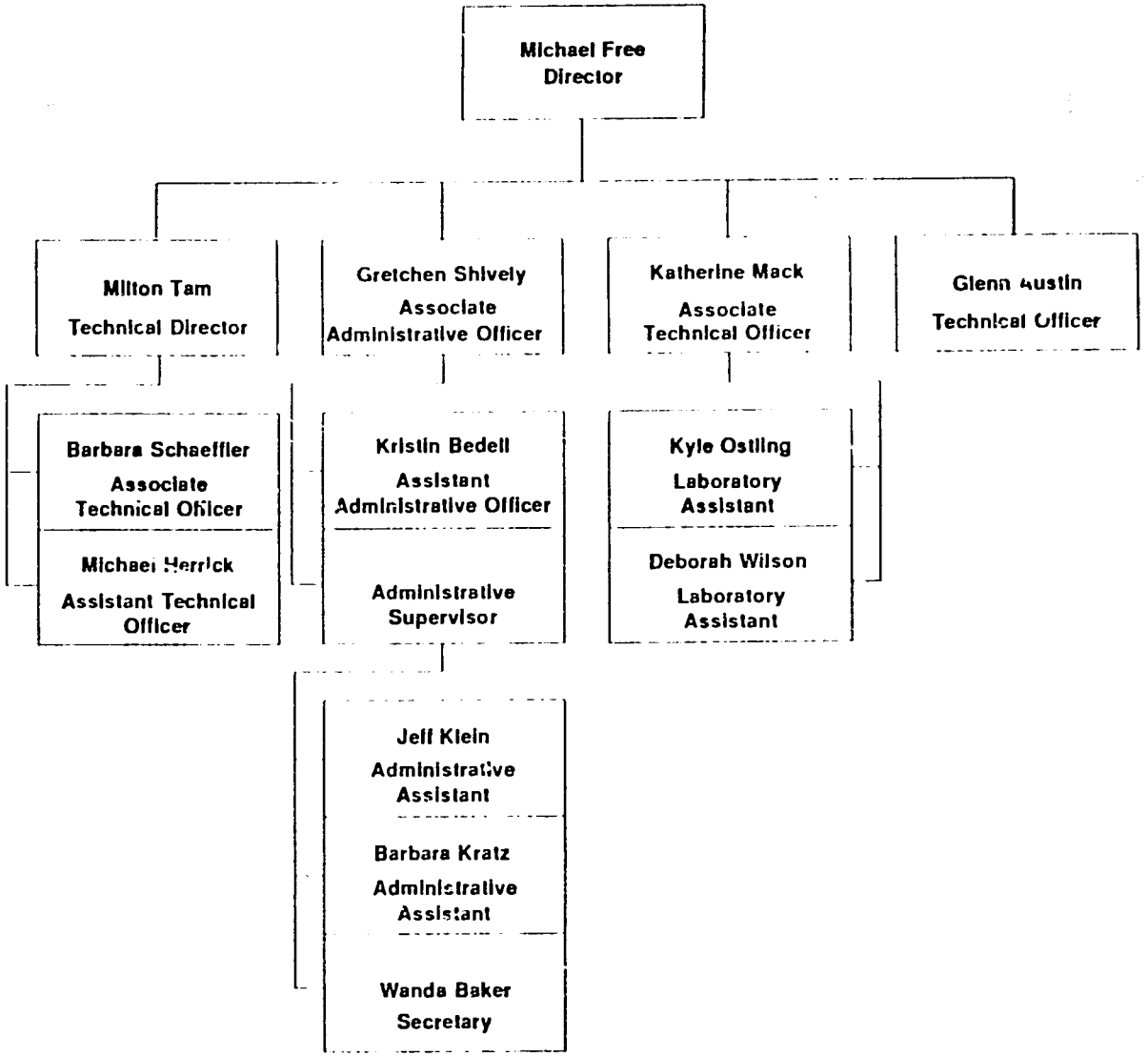
PATH's headquarters are in Seattle, Washington, but it maintains offices in Washington, D.C., Thailand, and Indonesia. Field offices in Thailand and Indonesia have proven especially valuable to programs like HealthTech which require a substantial field involvement.

B. Need for Social Technologies in the Developing World

In the late 1970s and early 1980s, people redoubled their efforts to improve health in the developing world. Following the declaration of "Health for All by the Year 2000," there



Path
Organizational Chart
January 20, 1989



Product Development Department
By Reporting Lines
January 20, 1989

began a period of review, debate, and planning to achieve this goal. A.I.D. played an important role in this debate and helped to pioneer the concept of the child survival priorities. The first priorities were immunization and oral rehydration, following by nutrition, birth spacing, control of acute respiratory infections and vector-borne diseases, and the provision of clean water and adequate sanitation.

The setting of these priorities emerged from a variety of considerations. First, infant and childhood death is unacceptably high in developing countries, varying from twice to ten times the rates in developed countries. Second, the priorities represented those interventions that might contribute most to a significant reduction in mortality and morbidity among children. Third, it was argued that technologies had been developed to carry out these interventions: vaccines, oral rehydration solutions, foods and food supplements, antibiotics, vector control agents, water pumps, and latrines existed, but were not sufficiently available.

The experience of implementing primary health care programs in developing countries, in general, supported the initial enthusiasm. Where programs were applied with strong political commitment and adequate funding, impressive reductions in infant mortality followed. It became increasingly clear, however, that "something was wrong." Infant mortality remained high even in the best programs.

Health experts realized that early optimism that "the technology existed" was naive. In practically every primary health care program, problems with the application of technologies had arisen. These included the following:

- Vaccines exposed to heat lose their potency;
- Cold chains designed to protect vaccines require expensive equipment, fuel, and maintenance;
- Syringes that are not properly sterilized may result in the transmission of disease;
- Mothers do not like the taste of ORS and demand modified solutions;
- ORS does not "cure" diarrhea, stimulating a search for a modified solution that reduces stool output and helps to maintain nutritional status;
- Vector control agents are considered to be dangerous to the environment, resulting in the abandonment of their use and the initiation of research on new products;

- Contraceptives have side effects and are not effective or acceptable in other ways;
- Water pumps break down and cannot be easily repaired;
- Latrines become sites of disease themselves because they cannot be easily maintained.

What appeared to be one of the "givens" of health--availability of safe, effective, acceptable, appropriate technology--was now seen as largely ephemeral. What was needed was the development of new technologies or the adaptation of existing products to meet the unique conditions of developing countries.

The international health community responded aggressively to many of these problems. Programs of research on new formulations of ORS are now well under way. There are major international efforts to develop new and improved contraceptives. A.I.D. has funded the WASH project to work in water and sanitation. WHO has set up the Tropical Diseases Research program which, in part, is concerned with control of vector-borne diseases. A.I.D. sponsors the Diagnostic Technologies for Community Health (DiaTech) program, an international program managed by PATH to develop new diagnostic tools to be used in conjunction with immunization and other disease control programs. Also sponsored by A.I.D. and administered by PATH is Project SUPPORT (Supply, Production, and Promotion of Oral Rehydration Salts in Developing Countries).

It is of interest to note that each of these programs has been set up with public-sector funding. Industry did not step forward to invest the required funds. This is understandable in light of the perception that sales of health products to the public sector in developing countries are of marginal profitability. On the other hand, industry has been a willing collaborator in these programs.

Furthermore, one tendency has been to view primary health care needs as a low-technology imperative; to a certain extent, this approach helps to emphasize the decentralized and self-sufficient aspects of primary health care. However, the impressive array of modern materials, electronic capabilities, pharmaceutical packaging technologies, and mass manufacturing processes offers abundant possibilities for tools that meet the demanding criteria and fiscal constraints of community health care.

In early 1987, PATH submitted a proposal to A.I.D. which outlined an extensive program to address the needs for appropriate technology development. This led to the current three-year Cooperative Agreement (DPE-5968-A-00-7035-00) between the

A.I.D. Office of Health and PATH to carry out the HealthTech program.

HealthTech fits in with A.I.D.'s child survival focus, and provides a flexible and efficient mechanism to deal with the "hardware" aspects of immunization and other child survival priorities, taking into account nonadvanced technologies. This program, which complements the activities of other A.I.D.-assisted projects, builds on PATH's capability to improve health in the developing world through the accelerated development, field assessment, and introduction of needed technologies.

Prior to HealthTech, PATH had screened, evaluated, or initiated the development process on 30 specialized products for primary health care in the developing world. In the process, PATH had established contacts with technology sources and made a number of collaborative arrangements. Strategies whereby products can be developed in a reasonable time at minimum cost were identified. Thus, PATH has created an effective means of bridging the gap between advanced technologies and primary health care needs. This has been accomplished through effective participation in and control of the creative process, strong management of the flow of information and development, and use of a worldwide network for information gathering and dissemination.

The process of product development for developing world needs requires, among other things, knowledge of and sensitivity to different regions and groups. Management must be capable of orchestrating all the financial, technical, and legal inputs required to conceive, create, and reduce the technology to practice. Sponsoring organizations must be willing to manage the financial risk without the usual assurances of a return on the investment and understand the many uncertainties in dealing with public-sector agencies. International public agencies generally have not been able to move sufficiently quickly and with adequate flexibility to manage the vagaries of technology research and development. They can, however, provide valuable resources and inputs for assessing needs as well as networks for international field testing of technologies.

PATH, in general, and the HealthTech program in particular, is set up to manage this process, serving as the intermediary between international agencies on the one hand and private-sector collaborators on the other, to increase the availability of appropriate health technologies in the developing world.

C. Strategies for Improving the Availability of Health Technologies

The HealthTech Cooperative Agreement between A.I.D. and PATH was negotiated and initialized in the summer of 1987. During the first six months, management developed strategies, planned implementation procedures, and built the infrastructure of HealthTech, relying on previous experience and philosophies regarding health technologies for the developing world. This section describes the resulting strategies that guide the overall program and the individual projects.

HealthTech was designed to provide a mechanism for promotion of the development, testing, introduction, and local manufacture of state-of-the-art child survival technologies. It was not intended that sponsors carry the entire burden of risk for these technologies, or that products arising from the project be available exclusively or even primarily through public-sector programs. Rather, it was intended that the products be brought to a stage where they can be transferred to parties whose primary business is manufacturing and/or marketing, so that the products become economically viable and therefore widely available.

The strategies by which this is accomplished differ for each technology. However, in every case a means is devised whereby public-sector interests are protected and not usurped by private market interests. In other words, the incentives for commercial-sector involvement must be balanced with the public-sector need for adapted, low-cost health products. A number of general strategies are described here.

Incentives for Commercial Involvement

Technologies designed and developed expressly for the purpose of meeting a public health need range from simple products suitable for home or cottage industry to highly sophisticated technologies requiring state-of-the-art industrial processes and materials. All of these "social" technologies differ in one important respect from the technologies developed for business: they are produced to meet a perceived health need rather than a measured market demand. Since need does not equate with ability to pay, the economic viability of social technologies is always in question. Because of this, HealthTech must pay attention to gaining commercial-sector interest in the products or finding substitute arrangements that assure availability, quality, and low cost.

The most important factor determining the strategy used to gain commercial-sector interest is whether or not there exists a commercial market for the products. Some social technologies have no significant private market potential (labelled "Type A" in PATH nomenclature).

An example of such a technology among HealthTech products is the BIRTHweigh™ risk assessment weighing device for newborns. This simple technology, designed for use by nonliterate traditional birth attendants, has no obvious utility other than in developing world primary health care settings. Little or no commercial interest exists for this device at a price that can be borne by health programs or assistance agencies. For this type of technology, there are no opportunities for gaining economies of scale or for covering the risks of the development and capital costs with profits from commercial-sector sales. The public health sector must bear the entire cost of these technologies by underwriting the development costs, purchasing the capital goods, and paying a price that covers the remaining cost as well as margins.

It follows that this type of technology must always involve simple materials and processes so that the risks are bearable and manufacturing can be carried out locally, on a small or medium scale, within the countries that need the product. It is necessary to turn to small-scale industry or, as in the case of the BIRTHweigh™, polytechnics and the technology departments of universities, for local manufacturing. Generally, it is useful to provide some business and marketing assistance to these manufacturing units, as well as quality assurance auditing, up to the point where production and sale of the product to responsible agencies are well established.

When a social technology has an identifiable commercial market potential ("Type B"), the strategies can be quite different, depending upon the extent to which those private markets are marginal or exist only in the developing world rather than the developed world. Some technologies cannot be scaled up, manufactured, or distributed without the collaboration of a commercial manufacturer ("Type C"). It is often necessary in HealthTech to specify the nature and size of private markets in order to gain commercial-sector interest. Other incentive-raising strategies include: demonstration of public-sector commitment through grant funds for engineering or issuance of purchase orders; reduction of project risks by providing loans at favorable terms; or purchase of capital equipment using public-sector funds.

It is always necessary to preserve, as much as possible, the proprietary nature of the technology through pursuit of patents, licenses, and confidentiality to encourage the commercial party to view the technology as protected and therefore of some value. By the same token, often it is necessary to offer exclusive rights to selected private markets, based on specific geographic regions or market segments. Provided that the private markets are an economic reality or that public agencies are willing to make up-front commitments, a commercial collaborator can be identified, as has occurred with such HealthTech products as SyringeLOCK™, SafeTject™,

and PATHweigh[R]. The next step is to implement other strategies to protect public-sector interests in negotiations with the collaborator.

Protecting Public-Sector Interests

It must be assumed that the commercial-sector collaborator is not motivated by the public health objectives for which the technology was developed. Rather, this collaborator is interested in recovering as quickly as possible any costs incurred by being involved in the project. In addition, the collaborator demands a profit to justify the risks of its investment. Consequently, protecting the public-sector interest, i.e., universal availability of the product, lowest possible cost, and responsiveness to local needs, becomes the full responsibility of HealthTech and other interested parties whose goals and objectives are aligned to the public-sector interest, e.g., the public-sector purchaser. The broad strategies that must be adopted include maintaining sufficient control of the product as it moves into the commercial sector and achieving the greatest possible efficiencies and economies of scale.

Under the first strategy--maintaining control--it is necessary to protect the technology at the outset with patents, licenses, copyrights, design registrations, or even trademarks, so that title is clear and negotiations are not hampered by questions of ownership. Licensing strategies seek to avoid monopolies, maintaining as much as possible the nonexclusivity of public-sector sales in order to promote price competition. If possible, price ceilings are maintained for public-sector sales. The emphasis, however, is on rewarding efficiency since reduction in costs can have a much greater impact than profit margins on the price of the product. Manufacturers in the developing world are employed whenever possible in order to encourage local development, reduce the length of the supply pipeline, and take advantage of lower costs.

Dual pricing is also encouraged so that the commercial sector can carry the burden of cost recovery and return on investment. Commercial manufacturers are encouraged to view public-sector sales, not as a direct source of profit, but rather as a means to achieve an internal economy of scale, thereby reducing production costs and increasing the margins on commercial-sector sales. Achieving economies of scale is the greatest single goal in bringing down the cost of social products to a level commensurate with public-sector needs.

A combination of these strategies must be applied in a highly coordinated and flexible way which takes into account the commercial imperative of economic viability.

Strategies for Ongoing HealthTech Technologies

Three HealthTech technologies currently under implementation--PATHwatch™/PATHmarker™, SyringeLOCK™, and SafeTject™--illustrate the need for the distinct strategies outlined above.

PATHwatch™/PATHmarker™ is a cold chain indicator based upon a proprietary technology licensed from Allied Corporation. There are no evident commercial markets for this technology. It is basically a printing technology, although the nature of the active material used makes it unsuitable for manufacture in a standard print shop. The production economies are such that sufficient units could be made to supply all the world's cold chains in a few weeks of operation of a single production operation. It also does not blend well with other product lines. PATHwatch™/PATHmarker™ is, therefore, almost entirely a Type A social technology; yet it is one that does not lend itself to local or small-shop operations, either economically or technically.

The principal strategy, therefore, is to develop and promote the public-sector use of this device and meet the demand by contracting out the production to a commercial manufacturer. No licensing is therefore involved. Since the development and validation testing of the device have been underwritten almost entirely by a variety of public-sector donors (A.I.D.; Canadian International Development Agency; International Development Research Centre; Clark Foundation), and since no special machinery other than the standard offset printing press is required, there are no project costs to recover. Otherwise, the price of the product would be prohibitive. At this time, the price need only reflect the costs involved in production and distribution to public-sector World Health Organization/Expanded Program on Immunization (EPI) programs. Some economies of scale are still possible, so the strategy is to extend the use of this device to as many EPI programs as possible through introduction trials, cooperation with international and national agencies and governments, and other promotional activities.

SyringeLOCK™ is a component which attaches to an ordinary disposable syringe and renders it capable of only a single filling and injection cycle. Since the developed world relies upon disposable syringes designed to be used only once, a technology that guarantees single use has both health and commercial value. The market for syringes in the U.S. and Europe does not yet demand this single-use guarantee, however. Unless syringe manufacturers anticipate a future demand or future legislative intervention in this regard, they do not have a strong incentive to become involved in these types of technologies.

The strategy to gain commercial-sector interest in SyringeLOCK™ was focused primarily upon demonstrating public-sector commitment, and secondarily, upon pinpointing commercial-sector markets in the developing world. In anticipation of the commercial-sector view of the SyringeLOCK™ as a marginal business proposition, the technology is being protected with patents. Advanced development and engineering, including scale-up engineering, have been carried out under HealthTech. As a result, international syringe manufacturers have expressed interest in it and it has been licensed to one of them. Immediate future strategies include field trials to demonstrate the practicality and acceptance of the new technology in the EPI setting, and negotiations between a key public-sector purchaser (UNICEF) and the licensed manufacturer in order to arrive at a price/quantity structure.

In the case of SafeTject™, a new set of factors prevails. SafeTject™ is a prefilled, disposable, self-destruct injection system that has not previously been used in the commercial sector. It is based upon the Ezeject® technology owned by Merck and licensed to PATH for adaptation to developing world situations. There is, however, a potential commercial market which should be exploited in order to achieve the economies of scale that would bring the public-sector price of the technology down to an acceptable level. SafeTject™ is a Type C technology requiring participation by industry at many levels; this includes the production of custom machinery and components, the assembly and sterilization of SafeTject™ systems, the supply of the product to vaccine and medicament manufacturers, and the filling and marketing of vaccines and medicaments packaged in this form. The key customers in this scenario are the medicament and vaccine manufacturers, who need to be persuaded of the economic value of this technology before they will be willing to make the large investments required in market development, regulatory clearance, and filling and sealing machinery.

Licensing the use of SafeTject™ entirely to a single commercial party in this case would defeat the objective of public-sector interest. In a commercial investment setting, the large capital cost required for the production machinery would need to be recouped in two to three years, forcing the price of the devices to a level beyond the means of public-sector programs. Since the machinery involved generally depreciates over very long periods (15 to 20 years), a system of financing could be offered that can be paid back over the long term, thus relieving the pressure on pricing. Strategies must then be adopted to expand the applications for SafeTject™ as quickly as possible, so that costs can be spread over the greatest number of markets.

Efforts to achieve economies of scale include working with manufacturers of injectable medicines and vaccines to assist

in achieving regulatory approval, identification of new applications for the system, active promotion to the pharmaceutical industry, introductory field trials, and a number of other activities. Licensing strategies are aimed first at a commercial development partner and secondly at the medicament or vaccine manufacturers who will fill SafeTject™ with their various medicines or vaccines. These strategies will assure general public-sector availability, high economies of scale, and dual pricing for primary health care injectables packaged in SafeTject™.

The orchestration of these activities to lead to the introduction of a radically new product requires a high degree of coordination and a good deal of flexibility. Suitable checks and balances are already built into this program, including a fully paid-up, royalty-free, nonexclusive license to the U.S. government; independent evaluation and validation of the technology by each medicine or vaccine manufacturer and their regulatory agencies; independent field evaluation by WHO/EPI; and the availability of the device to any or all vaccine manufacturers for public-sector use on a nonexclusive basis.

The information presented above provides examples of strategies for converting social technologies developed or identified by HealthTech into economically self-sustaining health products available for public-sector health programs over the long term. The application of these strategies by nonprofit agencies dedicated to social objectives represents to some extent a pioneering effort. Another important step is the clear communication of HealthTech's intent, objectives, and strategies to international and national organizations. Such groups have traditionally viewed the public and commercial sector as separate and distinct entities operating in a spirit of mutual mistrust. The synergistic value of collaboration between public and private sector and the many useful ways that commercial entities can facilitate and participate in the process of making social technologies available to the development world are messages that HealthTech and PATH seek to put forward at every opportunity.

II. Goals and Objectives of HealthTech

The goal of HealthTech as defined in PATH's proposal to A.I.D. is to improve the health status of less developed country (LDC) populations, particularly children.

The objectives are:

- To develop a single-use vaccine injector, other immunization-related technologies, and products for other child survival interventions that are appropriate for field use in LDCs;

- To adapt these technologies, and appropriate technologies developed elsewhere, for community health care practice by carrying out field trials, refinement activities, and production engineering, packaging, and other scale-up activities;

- To ensure that HealthTech technologies are produced and distributed by qualified manufacturers and other firms or organizations in LDCs through the granting of licenses to manufacture, market, and distribute the products, and the provisions of technical assistance and financing;

- To introduce the products arising from these developments, as well as appropriate products available from other sources, into public-sector health programs through information dissemination activities, including conferences, workshops, publications, training and demonstration materials, and test markets.

III. Implementation of HealthTech

The HealthTech program provides a flexible mechanism for the development, field assessment, introduction, and financing of a variety of new health technologies, all designed and adapted specifically for developing world health programs. This section describes the methods for developing and introducing health technologies under the program, as depicted diagrammatically in the flow chart on the next page. References are made to sample products which are described in the individual subproject summaries.

A. Selection and Screening Process

The first stage of the process, "Selection and Screening," includes the "concept" and "feasibility" phases on the diagram. This stage is designed to be as flexible and dynamic as possible. PATH conducts a variety of screening activities on an informal basis with minimal A.I.D. participation. This approach is intentional so that HealthTech staff can be creative and open-minded, unencumbered by the more formal mechanisms designed to monitor approved projects later in the process.

Technologies qualify to enter the HealthTech program in one of three ways: 1) as product concepts requiring further research and development; 2) as advanced prototypes ready for field trials; and 3) as marketable products ready for introduction.

HealthTech staff maintain a broad surveillance of developing world health needs and technological opportunities from all sectors concerned with the provision of health products and the development of new processes and materials. Solicited and unsolicited ideas are entered on a data base maintained at PATH.

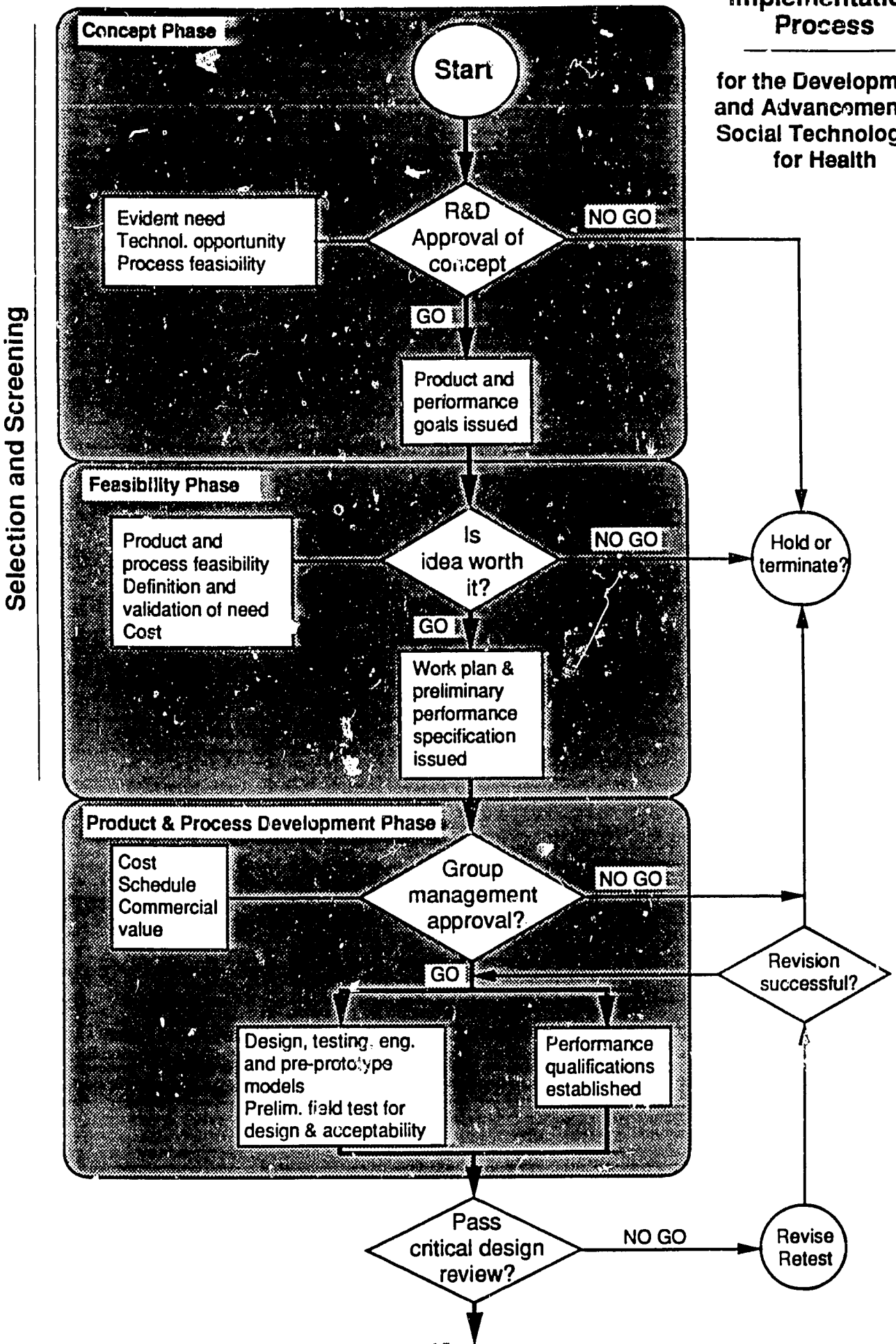
Criteria for Selection of Health Technologies

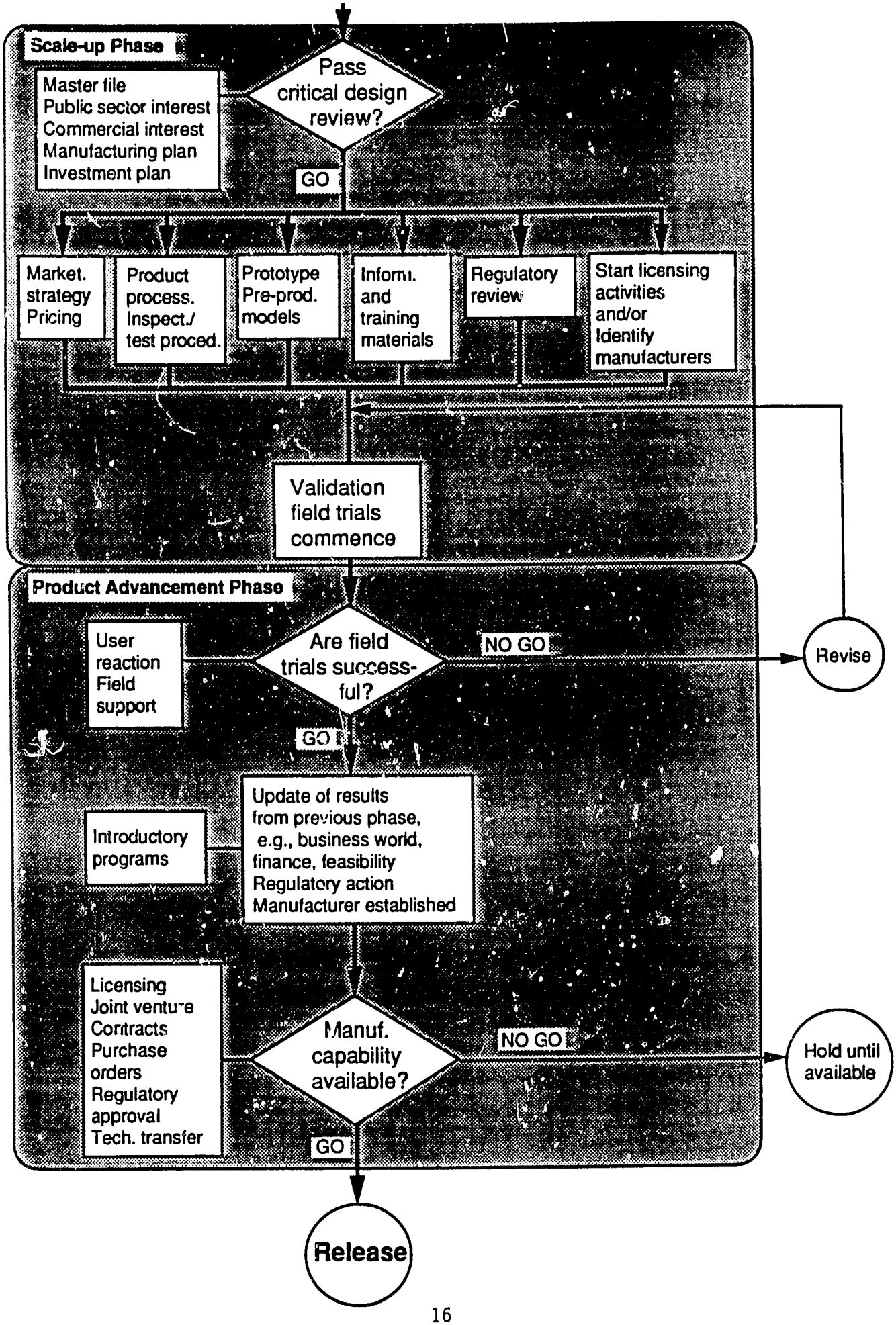
The following criteria are considered in selecting technologies for development. A candidate technology should:

- Address a child health need that is substantial and sufficiently widespread to justify and support a development and manufacturing effort;
- Demonstrate potential to improve the safety and efficiency of delivery of childhood immunization;
- Meet a need not adequately met by other technologies;
- Lack sufficient immediate commercial potential to attract private investment;

Implementation Process

for the Development and Advancement of Social Technologies for Health




Scale-up Phase
Master file
Public sector interest
Commercial interest
Manufacturing plan
Investment plan
Pass critical design review?
GO
Market. strategy Pricing
Product process. Inspect./ test proced.
Prototype Pre-prod. models
Inform. and training materials
Regulatory review
Start licensing activities and/or Identify manufacturers
Validation field trials commence
Product Advancement Phase
User reaction Field support
Are field trials success-ful?
NO GO
Revise
GO
Introductory programs
Update of results from previous phase, e.g., business world, finance, feasibility Regulatory action Manufacturer established
Licensing Joint venture Contracts Purchase orders Regulatory approval Tech. transfer
Manuf. capability available?
NO GO
Hold until available
GO
Release

- Need funding to complete the development process or to convert it into an appropriate technology for developing country use;

- Demonstrate potential for affordability in the developed country context;

- Have a definable market and adequate distribution mechanisms to ensure that it reaches the target population;

- Have good prospects for involvement of host government counterpart training and/or local production in a developing world setting;

- Be complementary with A.I.D. and child survival strategies and, if applicable, with activities and policies of the host government, WHO, other donors, and nongovernmental activities.

Procedures for Screening and Selection of Technologies

To qualify as a full-scale project under HealthTech, a technology must pass through two screening stages, starting as a Product Idea which, if merited, becomes a Product Lead.

- Product Ideas

  Product Ideas include any product, process, or concept that, in the opinion of the HealthTech staff, potentially meets an established need. HealthTech staff conduct a continuing search for new technology ideas to meet documented needs. This search includes: 1) discussions with health ministry personnel and others involved in health care delivery in developing countries; 2) review of medical technology publications, catalogs, and trade journals; 3) interaction with known inventors and innovative technology development groups and companies to encourage an exchange of ideas and to promote new technologies; 4) presentations to innovative and prominent companies in the health industry to describe how the health industry can become involved in developing world health care, as well as to screen marketed and shelved technologies with a view to their adaptation for developing world use; 5) close communication with A.I.D. field staff and missions, WHO program staff, and other coordinating bodies; 6) development and maintenance of a free advisory service for inventors and developers seeking to advance health technologies for public-sector use.

  PATH's field offices in Thailand and Indonesia also provide an important role in the identification of needed technologies--in particular, proven but locally unavail-

able health products that are candidates for local production under the introduction activities of HealthTech.

One potentially valuable source of new ideas is the offices of Technology Transfer at large university campuses. HealthTech staff have recently joined a professional organization for such administrators (Society of University Patent Administrators). The University of Washington has shared information about technologies available for licensing, several of which look promising for developing world application. Initial contact has also been made with MIT and the Harvard Medical School.

Technologies which show promise are entered into a Product Idea file. The Product Idea file is reviewed by HealthTech staff regularly and the most promising are selected for further investigation via a Product Profile.

A Product Profile outlines the need addressed by the technology, the scope of that need, how the need is currently being addressed by health service providers or acceptors, and who the potential user of the technology might be. Any available information on the nature of the technology, its availability, cost, durability, and suitability for local production is summarized. Profiles are distributed to HealthTech and other PATH field staff, and, in some cases, to collaborators or consultants. An example of a Product Profile form is shown on the next page.

- Product Leads

Technologies that receive favorable responses are considered Product Leads and are subject to further feasibility study. During the feasibility study, the financial and technology resources required to complete the project are assessed and regulatory implications are studied. Licensing and adaptation of existing products are considered as an alternative course of action to determine whether existing products address the need in question adequately and appear to be more cost-effective than the technology under consideration. Business opportunities for the product in private markets are explored as a way to offset the cost of development. General functional appropriateness of the technology and the likely cultural acceptability are taken into consideration. The feasibility study often includes preliminary laboratory and product design assessment.

PROFILE

Product Idea

A. **Respondent's Name:**_____ **Date:**_____

Public Sector: Technical Advisor ☐ Service Provider ☐
International Agency ☐ PATH Staff ☐

Private Sector: Manufacturer ☐ Distributor/Retailer ☐
Target User ☐

B. Product Description

C. Major Product Specification Issues

1.

2.

D. Comments from Sections B & C. (Use letter and number to reference your comments)

E. Target Price

Public Sector: _____ Private Sector: _____

F. Rating (Rate this product idea as a PATH product)

0	1	2	3	4	5	6	7	8	9	10
Low					Mid				High	

Currently, the following technologies are being evaluated under the selection and screening process. These include:

- ColClip antistick device
- Needleless injector with disposable nozzle
- Urinary iodine dipstick
- Noninvasive hematocrit instrument
- Labor timer
- Umbilical cord safety clamp

Project Work Plan

If the feasibility study suggests a favorable outcome, a project work plan is developed. The project work plan includes estimated costs, schedule, go/no-go checkpoints, expected outcomes (including desired performance specifications), and potential collaborating institutions or individuals. A Record of Patent/Title Licensing Status is also prepared. (See forms on the following pages.)

Most feasibility studies and associated project work plans are reviewed by members of the Technology Assessment Panel (TAP), including A.I.D. and WHO representatives. Recommendations of this group, and of the Project Director, are submitted to A.I.D. for review and approval. Projects approved for full-scale HealthTech action are implemented according to the project work plan.

The following technologies have been reviewed and approved by A.I.D.

- SyringeLOCK™
- SafeTject™
- Nonreusable hypodermic needle
- STERItimer™
- PATHtimer®
- PATHwatch™/PATHmarker™
- Solar refrigerator/ice maker
- PATHweigh®

HealthTech

Project Work Plan

TECHNOLOGY	
Project Code	Date

PRODUCT STAGE		CHILD SURVIVAL PROGRAM FOCUS			
Development: R & D	☐	Immunization	☐	Nutrition/Growth Monitoring	☐
Engineering	☐	Birth Spacing	☐	Maternal/Newborn Care	☐
Field Assessment	☐	ORT	☐	Vector-Borne Diseases	☐
Introduction	☐	ARI	☐	Water/Sanitation	☐

SUMMARY

COUNTRIES

EXPECTED OUTCOME AND FOLLOW-ON ACTIVITIES FROM THIS BUDGET PERIOD	ESTIMATED BUDGET
	$ _____

Attachments:

1. Project Rationale
2. Project Work Plan
3. Budget
4. Schedule

A.I.D./CTO: _____ _____ date

Name: _____

PATH/Project Director: _____ _____ date

Name: _____

Project Code

PROJECT RATIONALE

PROJECT WORK PLAN

BEYOND HEALTHTECH

HealthTech Technologies

Record of Patent/Title/Licensing Issues

Name of Technology (assigned by PATH):

Generic Name of Technology:

Description:

History of Technology

Inventor/Assignee:

Date of original concept (if known):

Date of patent application or other public disclosure:

Date of first reduction to practice, and circumstances:

Date and file number of patent:

PATH's Involvement With Technology

Person introducing technology to PATH:

Date of introduction:

PATH personnel:

Stage of development when introduced to PATH:

Date of disclosure to A.I.D.:

Date of first expenditure of A.I.D. funds on the technology:

Patent Application in United States

Date and country of first filing:

Person(s) filing/Assignee:

Date of application approval:

Other countries in which patent has been filed:

Other Legal Actions

Confidentiality/Disclosure agreements:

Representation agreements:

Licensing agreements:

Statement of Ownership

- PATHstrips™
- BIRTHweigh™
- Eyedrop unit-dose delivery system
- Iodized oil
- Biological larvicides

B. Product Development Cycle

After selection and screening of a product, including proper approvals, a project enters the product development phase. Various HealthTech products are currently in this phase. Product design and development is an iterative as well as a cyclical process. Each step in the process is based on information learned in previous steps or trials. This cycle passes through three separate domains--design/definition, creation/implementation, and evaluation/analysis--many times during a project. Each time the field of "unknowns" is reduced. If evaluation indicates a solution is unworkable, then the problem may be redefined. This process is outlined in the flow chart labeled "The Product Development Cycle" on the next page.

Consistent with the product development cycle, each step from concept and feasibility to scale-up for manufacturing and product advancement includes definition, implementation, and evaluation tasks. A "no-go" upon evaluation will trigger an additional iteration of a given phase of a project. The entire product development process can take from one to five years or longer.

Stages of Product Development

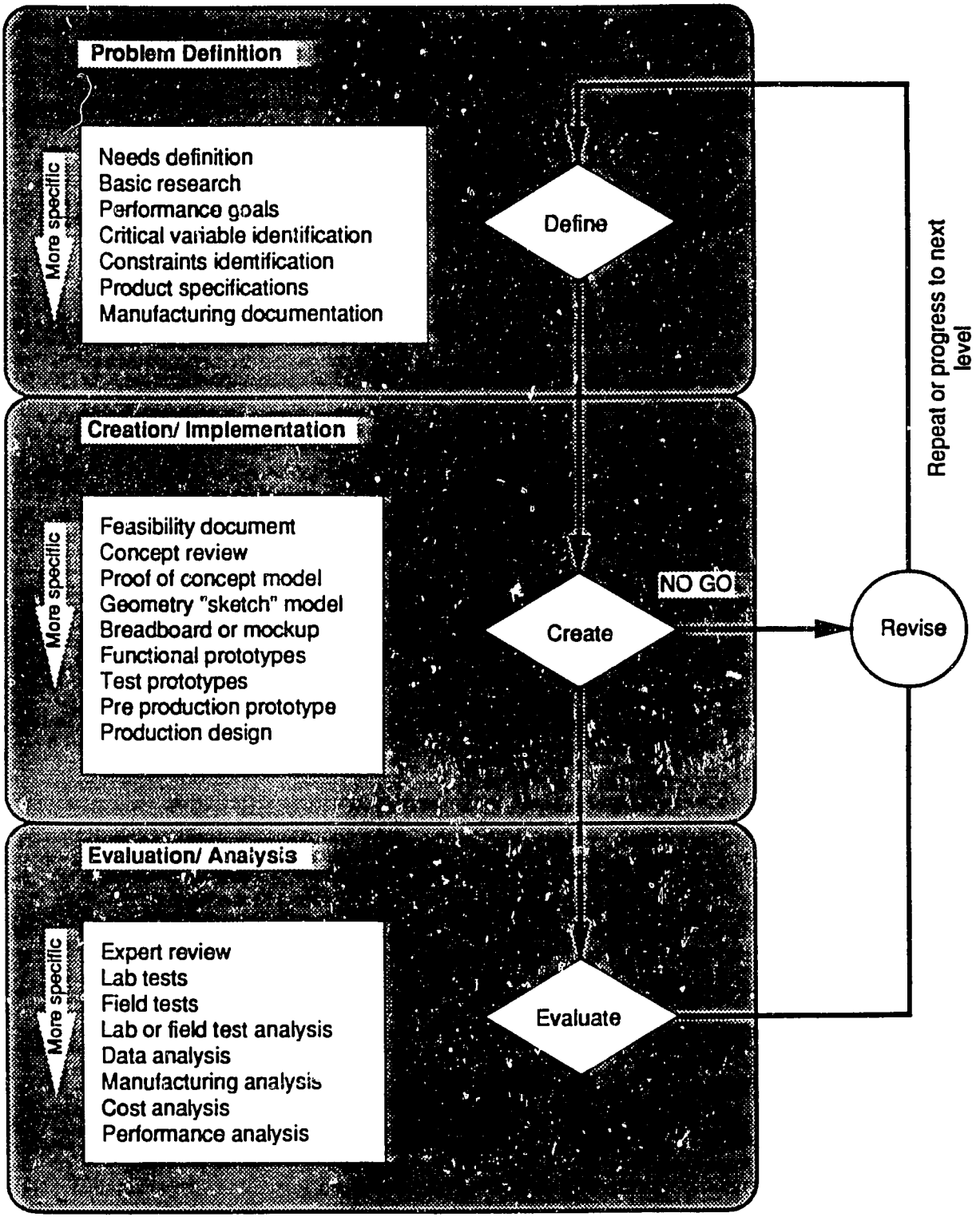
Stage 1 - Design and Definition

Product performance criteria are outlined and critical variables identified. Tentative specifications and mechanical designs are drafted. Screening and evaluation processes prompt refinement of design documents. Creative problem solving or "brainstorming" can only occur after the problem has been succinctly defined.

Stage 2 - Prototype Construction and Refinement

Functional prototypes are constructed and refined until they approach the desired specifications defined during the technology screening process or some improved definition based on subsequent studies. For instance, the desired specification for PATHtimer® is a clearly discernible color change after 20

The Product Development Cycle



minutes in boiling water. The prototype stage is cyclical, alternating with both laboratory and field testing stages.

Stage 3 - Laboratory Testing

Every prototype refinement is followed by laboratory testing. Tests are devised to simulate the conditions and operations of use under normal and worst-case conditions. Detailed records are kept. Regulatory requirements are reviewed and initiated. On the basis of this testing, prototypes may be subjected to further refinement or field evaluation. SyringeLOCK™, for example, went through several prototype refinements, after results of laboratory testing revealed features requiring improvements.

Stage 4 - Preliminary Field Testing

Prototypes which function satisfactorily in the laboratory are subjected initially to a small-scale field assessment using focus groups, demonstration sites, or limited trials. On the basis of this assessment, prototypes are subjected to further refinements or replicated for field trials. Field assessment of PATHstrips™ revealed the need to change labelling on the dispenser box.

Stage 5 - Replication of Advanced Prototypes

The advanced prototype is constructed in sufficient quantities for full-scale field trials as well as preliminary market assessment. In some cases, such as SafeTject™, this is a pilot manufacturing operation which can be used to identify qualified manufacturers as well as to develop manufacturing techniques, quality assurance tools, and protocols.

Procedures for Product Development

The nature of HealthTech staff involvement in the prototyping stages differs according to the stage of development of the technology, the existence of outside groups associated with the technology, and the nature of the technology itself. Two different descriptions of involvement can be defined. First, HealthTech staff supervise the design and construction of functional prototypes utilizing in-house and outside expertise, i.e., STERItimer™. Alternatively, HealthTech staff review and approve designs at all stages and monitor the activities of an outside firm or group of collaborators, i.e., the nonreusable hypodermic needle being developed by The John Hopkins University Applied Physics Laboratory.

Careful consideration is given at all stages to the ultimate manufacturing process and the implications for costs and potential for local production.

Early prototypes are subjected to laboratory tests; these are sometimes conducted in-house and at other times are referred to outside consultants or independent firms. For example, the materials to be used for SafeTject™ are being validated by an external laboratory. Ultimate use of the product is simulated in the laboratory to the greatest extent possible and under the full range of climatic and environmental conditions to which it may be subjected in actual use. Shelf life and product durability testing of protocols are started at the earliest possible opportunity. An example of this is the eyedrop unit-dose delivery system for silver nitrate into the eyes of newborns.

HealthTech staff ensure that product components and prototypes conform to USFDA and other agency requirements, as well as to the local regulations of the target countries. In some cases, such as SyringeLOCK™ and SafeTject™, the preparation of the drug master file is conducted by the company to which the product has been licensed.

When a small number of functional prototypes that meet laboratory test requirements become available, are sufficiently robust to endure some mishandling, and have visual or other user appeal, a preliminary field assessment is carried out. These field assessments are often conducted in conjunction with travel by PATH staff to appropriate countries or regions in the course of other programs. They take the form of demonstrations, focus group discussions, or small pilot studies designed to identify any major problems overlooked in the design stage. On the basis of this information, the prototypes are refined and retested prior to scale-up for formal field trials.

C. Field Trials

After the initial development or identification of a new technology, it is essential that HealthTech staff carry out a field assessment of the product's appropriateness, given the local needs and resources in the area of its intended use. Experience from a field evaluation serves as the basis for decisions about:

- The appropriate users of the technology;
- The need for further development or adaptation of the technology; and
- Other factors related to a successful introduction of the technology into routine use.

The assessment process is applicable not only to products emerging from the HealthTech research and development program, but also to new technologies developed in the private sector

and identified by PATH and A.I.D. The nature of assessment activities varies widely with the characteristics and state of the particular technology involved.

Field assessment provides valuable feedback at three stages. The first is when the initial design is being evaluated. Design trials are intended to provide basic qualitative feedback on technical performance with regard to function, acceptability to users (ease of use, training required, cultural concerns), and ruggedness/maintainability.

Trials at this stage are carried out with early prototypes that have previously been evaluated in a laboratory to ensure basic performance and safety. For the BIRTHweigh™ scale, for example, important issues were the accuracy of the scale, the ability and willingness of TBAs to use it, the willingness of mothers to have newborns weighed, and signs of wear and tear (for scales and slings) or loss of calibration. At the end of the field trials, scales were returned to the laboratory where the calibration was rechecked.

Information collected during design field trials is used to plan design modifications before large-scale production or introduction of the technology is begun. At this point the technology may be ready for widespread use if there are no major modifications needed. Once a technology has been thoroughly tested in one or two countries, it is unlikely to need major design refinement for technical or durability reasons. When it is introduced in another setting, though, it may need some adaptation for cultural reasons.

Performance validation trials provide health program managers with information they need to decide whether or not to adopt a new technology. Although in some cases these trials may overlap with design trials, they usually differ from them in the following ways:

- Final prototypes or mid-level production models are used;
- Quantitative as well as qualitative data are gathered;
- Performance is compared to predetermined specifications and to existing technologies (where relevant);
- Trials are carried out in a variety of settings;
- The adequacy of training programs is tested; and
- Potential impacts on the health care system and system constraints are identified.

Performance validation is designed more for external evaluation than for feedback to the developers. To achieve the broadest possible picture, the technology is used in a variety of settings that represent different social, cultural, and environmental challenges. This is a time when health programs compare and contrast the use of the new technology with existing alternatives. Validation trials allow evaluators to see how the health care system can accommodate new practices created by the use of the technology.

Once a technology has been validated, introductory trials test different strategies for introducing the product into the health care system. Usually, several aspects of the introduction strategy need to be tested. During this phase, program planners and managers:

- Identify the local niche for product;
- Adapt the training program to local circumstances;
- Establish supply and maintenance systems (including local production, if feasible; regular resupply, if necessary; and maintenance and repair services); and
- Identify system adjustments needed (policy conflicts or gaps, logistics, record-keeping systems, supervision responsibilities).

Identification of the appropriate niche for a new technology is important, since the product may only be useful in a limited number of settings. Once these have been defined, plans for training and logistics can be finalized. Training programs for technology use are established at all levels, preferably integrated with other training activities. In the case of the PATHwatch™/PATHmarker™ monitors, for example, introductory trials in Thailand and Kenya are under way to collect data on the ability of health workers to use the monitors correctly given the current training modules. Trainers are demonstrating to EPI staff how the monitors can be used to improve the management of the cold chain.

Methods of Field Assessment

The methods used to carry out a field assessment depend on the type of information needed. For a well-established technology being transferred to local production, a careful review of existing documentation on product performance and specifications and an on-site inventory of resources (facilities, equipment, raw materials, technical skills, financing) may be sufficient. Where more extensive feedback on product performance and acceptability is needed, a period of monitored field use of prototypes is required. This small-scale field trial usually involves a relatively limited number of users (because

of the cost of prototypes and the difficulty of supervision and extensive data collection) over a time period of several months (depending on the intensity of use anticipated). Structured interviews and focus group discussions with product users, systematic observation of field use, experimental testing of the product's ability to meet performance specifications, and interviews of key informants are used to generate valuable data.

The performance validation trials are often implemented by a group independent of HealthTech or the owner of the technology to assure an unbiased and credible evaluation. This is especially true when questions of commercial interests are involved. The integrity of a validation assessment can be maintained even if the developer is involved, for instance, in areas such as training, protocol development, and data review as long as the collaborating agency maintains control of the raw data and has the skills and authority to be involved in research design and data analysis at every stage. This is the procedure planned for field trials of SyringeLOCK™ in Pakistan which will be conducted by the A.I.D.-funded project, REACH.

An assessment of the need for associated "soft" technologies to support the correct use of the target product is also important at this stage. Training materials for health care providers or others using or distributing the product and instructional and promotional materials, such as package labels, posters, and booklets for product users, must be developed either during the field assessment or early in the introduction program.

Procedures for Site Selection

Several criteria are considered in selecting sites for technology field trials. First, the technology must meet a demonstrated need in the proposed site. There must be a sufficient health infrastructure present to use the technology correctly, e.g., the cold chain must be adequate if a heat-sensitive vaccine is involved. There must be sufficient institutional resources available to monitor the trial and carry out data collection effectively, e.g., trained personnel, transportation, communication services. Finally, sites are chosen to represent a broad spectrum of the potential users of the technology, including geographical, cultural, climatic, and health system considerations.

To meet these criteria, PATH uses a regional approach in selecting sites. The PATH field offices in Bangkok, Thailand, and Jakarta, Indonesia, have served as valuable bases for activities in Asia. The Bangkok office is well placed not only for work in Thailand but also for nearby countries, such as Bangladesh, Burma, and Nepal. The Jakarta office is criti-

cal if major projects are to be undertaken in Indonesia (a priority child survival country) and can also serve as a regional base for activities in Papua New Guinea, the Philippines, and other Pacific nations.

Building on this regional approach, PATH is developing a field presence in Nairobi, Kenya, in order to facilitate work in Africa. Nairobi is well placed for work in Eastern, Central, and Southern Africa and PATH has other projects in these areas that could share the cost of the field office. One arrangement being explored now is the possibility of a collaborative link with the African Medical and Research Foundation (AMREF) which has good facilities and staff for carrying out other field trials.

In the third year of the project, as more technologies reach the field assessment stage and as initial field trials move on to the stage of more widespread replication, a field operations base for Latin America will also be considered. A likely site for this office would be Guatemala City, a convenient location for Central American and Caribbean activities and headquarters for Institute of Nutrition for Central America and Panama (INCAP), a well-respected research organization.

Within each region PATH draws on the variety of connections developed during ten years of work in more than 40 developing countries to identify appropriate sites for field trials. In particular, PATH's contacts with immunization programs in 18 countries and its Safe Birth activities in five countries, as well as the A.I.D. missions and WHO collaborating centers, facilitate arrangements for field trials.

The chart on the following page lists current and potential field sites for different HealthTech technologies.

Procedures for Monitoring and Data Analysis

For greater efficiency, most data collection is carried out through collaborative arrangements with local governmental or nongovernmental agencies. Under these circumstances, however, close monitoring by HealthTech staff is essential to ensure adherence to study protocols and work schedules. Uniform guidelines must be followed and comparable data collected. Linking field sites with necessary technical backup services, such as engineering assistance for modifying or repairing prototype technologies, is critical to the success of the field assessment. Regional field operations staff serve as liaisons between field sites and PATH headquarters and provide cost-effective, on-the-spot monitoring of the field trials.

HealthTech Activities By Region

Africa

Kenya

SafeTject™

PATHwatch™/
PATHmarker™

Malawi

PATHtimer®

BIRTHweigh™

PATHweigh®

Zimbabwe

PATHstrips™

Asia/Near East

Bangladesh

PATHweigh® ?

Egypt

BIRTHweigh™

Indonesia

SafeTject™

PATHwatch™/
PATHmarker™

STERItimer™

Biological Larvicides

Iodized Oil

Pakistan

SyringeLOCK™

BIRTHweigh™

PATHweigh®

Thailand

PATHwatch™/
PATHmarker™

Solar Refrigerator/
Ice Maker

Biological Larvicides

Latin America and the Caribbean

Eyedrop Unit-dose
Delivery System

Guatemala

BIRTHweigh™ ?

All data (or abstracted or translated versions, where appropriate) are returned to PATH headquarters for analysis. A copy of the data is retained by the local collaborating organization. Quantitative analysis is carried out at PATH using statistical package software (SPSS-PC+ for IBM microcomputers). In addition, PATH has access to biostatistical expertise through its affiliation with the University of Washington School of Public Health.

D. Product Advancement

Once the product has been field-tested and information on performance and acceptability has been generated, work proceeds on the introduction of the technology. The appropriate level of use and production of a new technology varies substantially among countries. The best application of the product depends on both country and product factors. A range of possibilities for technology introduction, from simple distribution to full local production, exists.

Distribution

If local production is not economically or technically justifiable, it may be best for a developing country to simply import and distribute the product from developed world manufacturers. PATHwatch™, the cold chain time/temperature monitor, is a good example of this situation, since the necessary scale of production is too large for single country needs. There is a strong rationale for centralizing the manufacture of PATHwatch™ and focusing local efforts on its promotion, distribution, and proper use.

Quality Control/Local Assembly

Whether a developing country is to produce locally or not, it should have the capability to assess the quality of the product. With biological larvicides, for example, large capital investment requirements make local fermentation too expensive. Quality control and local formulation (preparation of the larvicide in a delivery vehicle) are, however, feasible.

A reduction in costs may be accomplished by expanding distribution and quality control to include local assembly. In many cases, the source of a technology continues to manufacture a key ingredient of the product, then arranges for local assembly. The introduction of a solar refrigerator/ice maker, for instance, might involve purchasing a kit that contains patented items. Local parts would be added, and the final product would be assembled according to the specifications of the original manufacturer.

Local Production

In cases where the market is of adequate size and there are no commercial or technical reasons that make local production undesirable, a complete transfer of the technology can take place. The BIRTHweigh™ scale produced by the Polytechnic Institute in Malawi is the best example of the successful transfer of a HealthTech product to a developing country.

Local production is evaluated to determine if this approach can contribute to reducing the price or otherwise increasing the availability of the product. Each product requires a certain volume of consumption to justify local production. Each country faces a different market situation based on its population and its potential for export. In addition, the availability of trained personnel and capital resources varies from country to country. Climatic conditions, such as heat and humidity, also affect the economy of some production processes. All of these factors must be taken into consideration when judging the feasibility of local production.

HealthTech staff examine the country and product variations and, through feasibility studies, establish the economically appropriate level of use. PATH often serves as a broker, introducing the sources of a technology to local partners in developing countries. The local firms and the technology sources must, in each case, negotiate the level of local production.

Geographic Considerations

In deciding where to locate initial product introduction efforts, several factors are taken into consideration. As with field trials, a significant need for the product should be demonstrated. Prior successful experience with the product, for example, through participation in field trials, confers priority on a locale for early introduction efforts. Infrastructure elements, such as trained personnel, necessary facilities or equipment, transportation and distribution systems, and sufficient financial resources, must be available to increase the likelihood of correct use of the product, adequate distribution of it, and necessary maintenance and/or repair services. The potential for local manufacture of the product favors certain sites since it increases the supply of the product and contributes to national self-sufficiency and development goals.

Consideration is also given to the need for introduction in a variety of settings representative of the climatic, cultural, economic, and health system diversity of the overall potential market for the technology. Evidence of the political support of relevant local government officials for the introduction

and sustained use of the technology is also taken into account.

Assessing all these considerations ensures that the limited resources available for product introduction activities are targeted to those countries where successful use is probable, where the technology can have a valuable impact, and where lessons can be learned that will be useful in broader introduction efforts.

Establishment of Manufacturing and Distribution Mechanisms

The stages of activity required to scale-up a product and establish the means of production and distribution are as follows:

Stage 1 - Assessing the Market

Preliminary market assessment is done concurrently with any development stage and may be necessary before any major commitment of resources can be made to the program. For SafeTject™, a thorough analysis of the market for prefilled, disposable syringes was conducted in conjunction with licensing the technology. When advanced specifications and field prototypes are available, the best quantitative assessment of the market can be made. Both domestic and international markets are examined. The results of all market assessments determine the best strategies for manufacturing, private-sector marketing, and public-sector introduction. For example, a complete marketing plan for SafeTject™ will be developed by PATH in cooperation with Horizon Medical Packaging.

Stage 2 - Planning for Manufacture and Marketing

Strategies for risk-sharing and early cost recovery are developed. Key license agreements are negotiated, and regulatory compliance is reviewed. SyringeLOCK™, for example, has been licensed to Becton, Dickinson and Company, a major manufacturer of disposable syringes, which is now absorbing the major costs of scale-up and manufacture. An Option to License Agreement has been negotiated with Horizon Medical Packaging (Acacia Laboratories) for SafeTject™.

Stage 3 - Specifying the Final Product

Final specifications are prepared in the form of a draft master document containing details of all materials, components, processes, and characteristics relevant to the final prototype. A manufacturing manual is being compiled for PATHstrips™ manufacture in a developing country setting. This document contains technical information describing the raw material specifications, equipment descriptions, quality

control and quality assurance practices, and the manufacturing processes.

Stage 4 - Engineering the Product

Detailed final drawings are prepared, processes selected, raw materials procured, tools designed and developed, alternative manufacturers identified, and quality assurance tools and protocols devised. The draft master document is finalized. Validation runs are carried out. Product schedules are finalized. Ground work for some of these activities is often carried out in preparation for full-scale field trials.

Stage 5 - Manufacturing the Product

The product is manufactured according to the requirements of the public introduction and commercial sales programs. Both quality control at the factory and quality assurance on receipt of the goods are carried out according to set protocols.

Stage 6 - Developing Appropriate Product Information

Product information is developed and tested for application in sales, training of health service providers, and use by the consumer. Ground work for materials is sometimes done during field trials. The instructions for PATHtimer[R], for example, are enclosed in the packaging (see following pages).

Stage 7 - Introducing the Product

Distribution channels are identified and licensed. Health authorities and NGOs are informed of the product and its potential impact on country health programs. Training programs are carried out, orders are filled, and timely stock deliveries are made. Throughout the stage of product advancement, HealthTech staff continue to manage the process and serve as the coordinator for PATH resources, A.I.D. input and requirements, and participation by collaborating organizations, both public and private sector.

E. Program Information

The systems and strategies for resource identification and information sharing have been developed under HealthTech with three objectives in mind: first, to identify needs and sources of technology; second, to facilitate fruitful collaboration among PATH, A.I.D., and other groups and individuals participating in the HealthTech program; and third, to ensure that information about the program, or information resulting from the program, is shared widely and in a timely fashion.

PATHtimer®

PATHtimer is an inexpensive, durable device used by health workers to ensure that water has boiled sufficiently to disinfect medical instruments.

The World Health Organization recommends that syringes, needles, and other medical instruments be boiled at least twenty minutes to destroy most microbial contaminants. The color changes of the PATHtimer during boiling clearly indicate when heat exposure has reached the equivalent of twenty minutes at 100° centigrade. WHO/EPI conducted successful laboratory tests of PATHtimer in 1987.

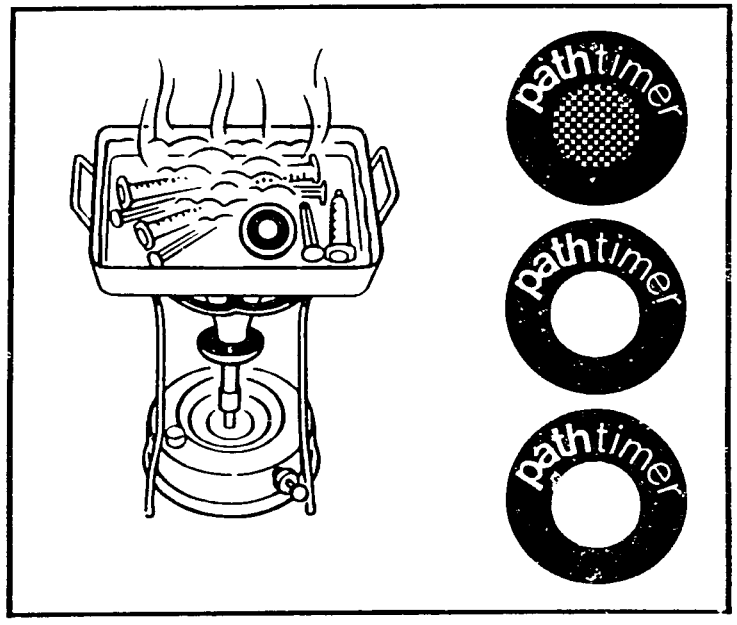
PATHtimer contains a heat-sensitive disk that appears black at room temperature. When placed in water and heated with medical instruments, the disk changes to pink, then grey, green, and a bright blue/green. The green and blue/green stages appear only after the equivalent of twenty minutes boiling at sea level. At higher altitudes, PATHtimer changes color more slowly to compensate for reduced boiling temperature.

PATHtimer is ready to use again after cooling for at least thirty minutes. It may be used hundreds of times.

The water in which PATHtimer is placed should not be allowed to boil dry, and the device should not be burned. It should not be used above altitudes of 2100 meters (7000 feet).

PATHtimer®

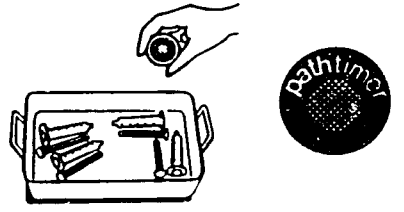
Reusable Boiling Monitor for Disinfection of Medical Instruments



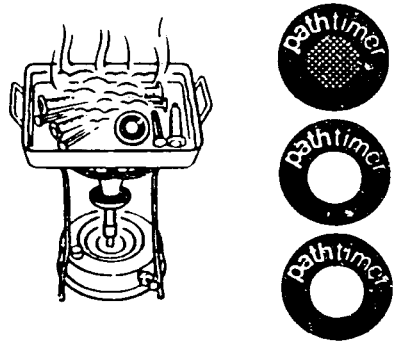
Program for Appropriate Technology in Health (PATH)
4 Nickerson Street, Seattle, Washington 98109, USA

How to Use PATHtimer®

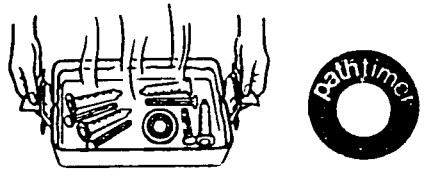
1. Place **PATHtimer** in the boiling tray or pot with the instruments you are disinfecting. Cover **PATHtimer** and the instruments with water.



2. Cover the boiling tray and heat the water. As the water heats and boils, **PATHtimer** changes color from black to pink to green to blue.



3. When **PATHtimer** becomes green or blue, the water and instruments are disinfected.



After PATHtimer cools for 30 minutes, it can be used again.

WARNING: Heat PATHtimer only in water. Do not allow water to boil dry.

A fact sheet on HealthTech has been prepared and sent to groups or individuals who are encouraged to use HealthTech as a clearinghouse for child survival technology needs, product ideas, or potentially useful technologies. A brochure to be distributed initially to all A.I.D. missions, as well as UNICEF and WHO representatives, has been drafted and is included in this report as Appendix 1. Product bulletins on each HealthTech technology are prepared as products reach the stage when they are available for field trial or introduction. Examples of bulletins are also included in the Appendix.

During 1989, one issue of the PATH publication *Health Technology DIRECTIONS* will focus on immunization technologies developed under HealthTech. *DIRECTIONS* is sent to 7,000 readers worldwide who represent international health agencies and organizations. In addition, PATH staff are drafting an article on HealthTech to appear in an issue of the A.I.D. publication *Frontline* in 1989.

A current publicity effort focuses on personal presentations to the A.I.D. bureau personnel in Washington, D.C., who can then brief A.I.D. staff in the field on projects of interest. In addition, PATH staff visiting developing countries on behalf of HealthTech or other projects are encouraged to brief local A.I.D. missions on the status of HealthTech products. To assist in this effort, packets of information, including sample products, are being prepar

HealthTech staff participate in [illegible] ational meetings and workshops dealing with appropria[illegible] lth technology whenever possible. For example, staff [illegible] entations at the annual National Council on Internation[illegible] h (NCIH) meeting in 1988, and will do so again in 1[illegible] PATH has submitted an abstract of a presentation on soc[illegible] technologies to be considered for the agenda of a national meeting of the Society of University Patent Administrators in 1989.

Using this variety of publicity efforts, interest in HealthTech and the ensuing products has been and will continue to be generated at all levels of international health care.

IV. Management of HealthTech

A. Staffing

The figure on the next page illustrates the management and staffing for HealthTech. While the President of PATH, Dr. Gordon W. Perkin, has institutional responsibility for the program, Dr. Michael Free, Director of Product Development, serves as the Project Director. He has direct day-to-day responsibility for the management and implementation of HealthTech and serves as the principal contact with the A.I.D. Office of Health.

HealthTech draws on the technical resources of PATH in a variety of ways. The Product Development Department, which includes Mr. Glenn Austin, Technical Officer, and Ms. Katherine Mack, Associate Technical Officer, is responsible for technologies which are being screened for possible inclusion in HealthTech.

Each technology that is accepted as a HealthTech product is assigned to a product manager and a product advancement manager. The product manager is usually, but not always, in the Product Development Department which includes a staff of three laboratory technicians. Mr. Austin and Ms. Mack are product managers for several different technologies. SafeTject™ development is the responsibility of Mr. Ron Thomas, Senior Technical Officer, who is in the PATH's Technology Management Department. The product advancement manager, who works closely with the product manager as the product moves out of development, is from either the Technology Assessment Department or Technology Promotion Department. The product advancement manager is responsible for activities ranging from field trials, in-country introduction, and market research studies to licensing and technology transfer.

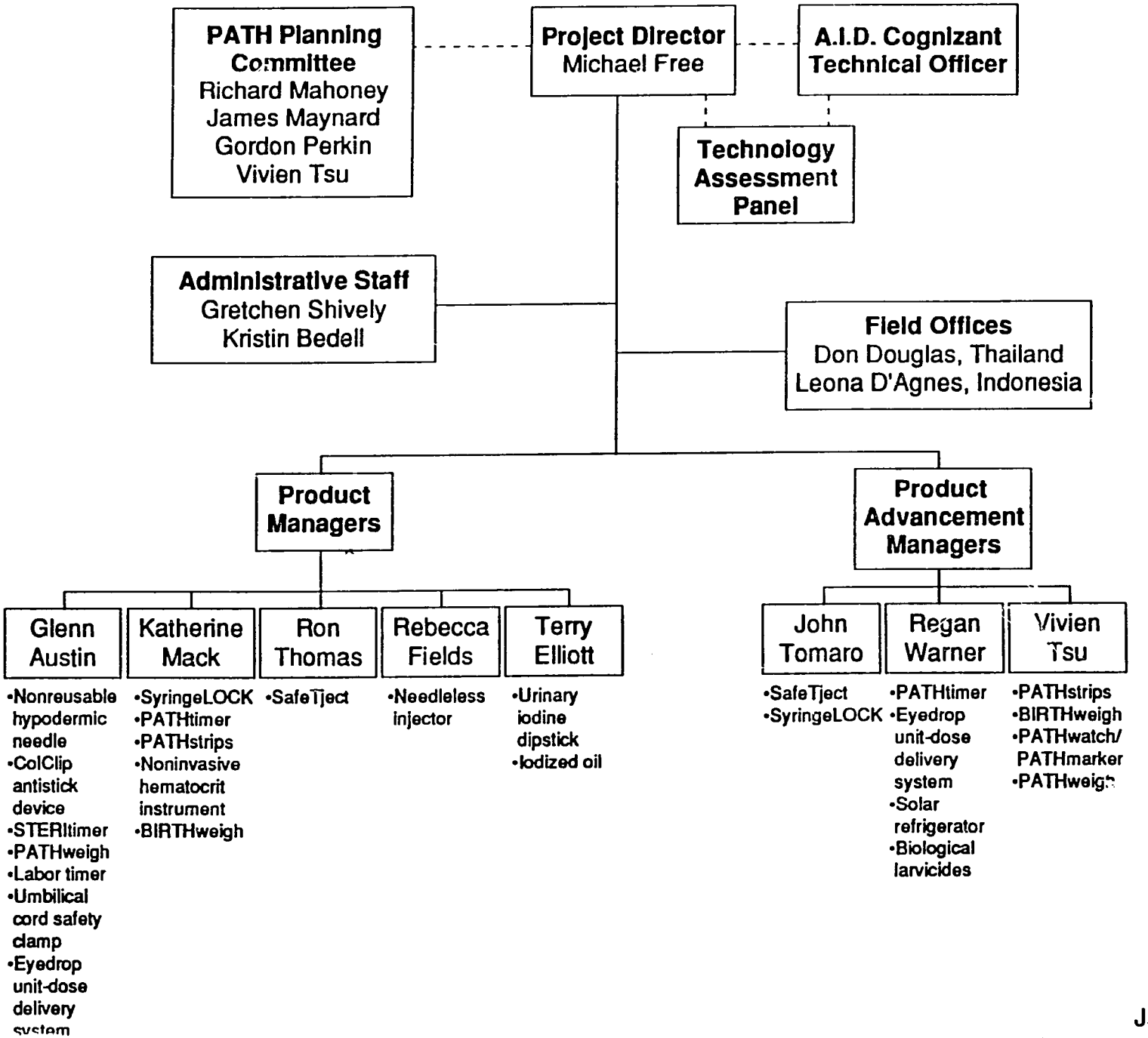
The two managers are assisted by legal advisors from the Technology Promotion Department in developing and managing licensing activities.

Administrative issues and responsibilities are handled by Dr. Free, Ms. Gretchen Shively, Department Administrative Officer, and Ms. Kristin Bedell, Assistant Administrative Officer, supported by a team of administrative and clerical staff.

Ms. Vivien Tsu, Deputy Director of the Technology Assessment Department, oversees the field assessment component of the program.

The Procurement Department participates in management of procurement needs of the program.

HealthTech Management



January 1, 1989

Dr. Richard Mahoney, Director of the Technology Promotion Department, manages the overseas operations of HealthTech and supervises the field-based project officers and staff in Thailand and Indonesia. These staff members, Mr. Don Douglas in Bangkok, and Ms. Leona D'Agnes in Jakarta, provide local and regional coordination as products are introduced into the field. PATH has also used the services of local consultants in primary health care in Nairobi, Kenya.

B. Coordination with A.I.D.

HealthTech staff have developed and maintained a close and efficient working relationship with A.I.D. This has been done with three objectives in mind. First, close communication ensures that the technologies arising out of the HealthTech program conform as closely as possible to the needs and objectives of the child survival program. Second, HealthTech staff take full advantage of the field experience and perspectives of the Office of Health, as well as the facilitative powers of A.I.D. in general, to ensure a successful project outcome. Frequent communications between PATH and A.I.D. reduce to a minimum the time required for the A.I.D. review and approval process.

The following seven procedures have been adopted. First, a fax machine has been set up in the A.I.D. Office of Health so that the Cognizant Technical Officer (CTO) can review documents and approvals transmitted between A.I.D. and PATH quickly and effectively. Second, an overall work scope submitted to A.I.D. semi-annually provides opportunities for mid-course corrections and changes in strategy or priority. Third, HealthTech staff prepare a detailed monthly checklist of tasks requiring A.I.D. action. Fourth, HealthTech staff provide A.I.D. with updated project work plans and time lines for each HealthTech project. Fifth, HealthTech staff submit a concise quarterly summary of progress on each project or major activity within the HealthTech program. Sixth, meetings between key HealthTech staff and A.I.D. staff occur at least once every two months. Seventh, PATH staff consult several times a week via telephone with the A.I.D. CTO and other personnel in the Office of Health on both procedures and issues relating to HealthTech.

These mechanisms have resulted in a stimulating working relationship between PATH and A.I.D., and dynamic project management. A.I.D. has continuous and timely information on the project. At the same time, this approach enables project staff at PATH to focus primarily on the development, adaptation, and introduction of child survival technologies.

C. Technology Assessment Panel (TAP)

To provide an independent review mechanism for candidate and approved HealthTech technologies, management has established an independent Technology Assessment Panel (TAP). The panel consists of experts in international health and product development, with an emphasis on individuals who have worked or are currently working in developing country child health programs. The panel incorporates a range of disciplines (epidemiology, vaccinology, maternal and child health, and bioengineering) and includes representatives of both private and public-sector organizations. Current and past members of the panel and their institutional affiliations are:

Neil Andersson, M.D.
London School of Hygiene
and Tropical Medicine
University of London

Nancy K. Cain
Medical Procurement Officer
Supply Division
UNICEF

Peter Carrasco
Technical Officer
Expanded Program on Immunization
Pan American Health Organization

Gordon W. Duncan, Ph.D.
Director
International Research
and Program Management
The Upjohn Company

Peter Evans
Technical Officer
Expanded Program on Immunization
World Health Organization

Neal Halsey, M.D.
Director
Division of Disease Control
School of Hygiene and Public Health
The Johns Hopkins University

Gerald Rosenthal, Ph.D.
Associate Director for EPI
REACH, John Snow, Inc.

David J. Sencer, M.D.
Chief Executive Officer
Management Sciences for Health

Ad Hoc

John B. Tomaro, Ph.D., M.P.H.
Director
PRITECH

Proposals to incorporate candidate technologies in the HealthTech program are submitted to A.I.D. and the TAP for evaluation. Each technology is assessed and rated according to the evaluation mechanism described on the evaluation form following this section. Only technologies receiving the support of a majority of the reviewers are considered for inclusion in the program.

The TAP met for a 1½-day meeting in April 1988 at which time 15 proposed technologies were thoroughly examined. A summary of the individual technology assessment evaluations is provided on page 49. PATH and A.I.D. have used these evaluations to prioritize the various projects. In many cases, the TAP's comments and advice on particular products have been incorporated into work plans.

A second meeting of the TAP is scheduled for February 1, 1989, when members will assess progress on already approved activities and evaluate new proposed technologies.

D. Linkages with Other Organizations

HealthTech personnel consult regularly with appropriate WHO staff in Geneva and in regional and country WHO offices, both to seek expert advice and to share information on HealthTech projects. Key WHO staff serve on the TAP.

WHO staff input is actively sought in three particular areas--first, determination of priority health needs as they relate to technology selection; second, expert evaluation of candidate technologies and definition of desirable attributes; and third, identification of field trial sites, e.g., through the network of WHO Collaborating Research Centers. Communication with other WHO staff, including Pan American Health Organization (PAHO) staff whenever appropriate, are initiated as required.

PATH interacts directly with three A.I.D.-assisted child survival projects. With REACH (Resources for Child Health), a project managed by John Snow, Inc., that focuses on activities in immunization and health financing, PATH works on country strategies, technical assistance, field testing of immunization technologies, and procurement of vaccines and related equipment. REACH has been asked by WHO to conduct field trials of SyringeLOCK™ in Pakistan. Two A.I.D.-sponsored programs mentioned earlier--DiaTech and Project SUPPORT--share staff and PATH resources with HealthTech.

HealthTech Evaluation Matrix

Technology _____

Evaluator _____

Factors Needed for Product Success	Relative Importance (A)	Product Rating (B) 0	1	2	3	4	5	6	7	8	9	10	Rating (A x B)
A. Performance													
Universal application	0.5												
Priority of need	1.0												
Appropriateness (does it meet the need?)	1.0												
Potential for misuse/abuse	0.8												
Safety with correct use	0.8												
Low need for other equipment/supplies	0.7												
Adaptable to local conditions	0.5												
Ease of disposal	0.3												
B. Cost/Ease of Manufacturing													
Availability/cost of key materials	0.5												
Compatibility with current manufacturing processes	0.5												
High degree of current industrial interest	0.4												
Suitability for local LDC manufacturing	0.4												
Advanced stage of development	0.6												
C. Cost/Ease of Introduction													
Obviousness of use (training burden)	0.7												
Suitability for commercial markets	0.6												
Transport and storage	0.4												
Positive cultural impact	0.3												
Total Rating Score													

Comments:

HealthTech
Summary of Technology Assessment Matrixes

Technology	Average Raw Score (Max=170)	Rank	Average Weighted Score (Max=100)	Rank	Average Raw Score Performance (Max=80)	Rank	Average Raw Score Cost/ Ease Manuf (Max=50)	Rank	Average Raw Score Cost/ Ease Intro (Max=40)	
PATHtimer	145.1	(1)	83.9	(1)	66.1	(1)	44.9	(1)	34.2	(1)
SyringeLock	130.2	(2)	78.4	(2)	60.1	(7)	38.6	(2)	31.5	(2)
BIRTHweigh	129.9	(3)	76.0	(4)	64.1	(2)	38.3	(3)	27.5	(9)
Silver Nitrate	128.3	(4)	76.7	(3)	62.5	(5)	34.7	(7)	31.1	(3)
PATHwatch/PATHmarker	128.1	(5)	75.9	(5)	63.4	(3)	36.3	(6)	28.4	(7)
SteriTimer	125.4	(6)	74.2	(6)	63.4	(4)	32.5	(8)	29.5	(4)
PATHstrip	125.0	(7)	73.3	(7)	60.5	(6)	36.0	(5)	27.7	(8)
PATHweigh	111.2	(8)	67.3	(8)	55.2	(8)	38.3	(4)	29.1	(6)
Nonreusable Hypodermic Needle	111.0	(9)	66.8	(9)	53.5	(11)	28.2	(10)	29.2	(5)
safeTject	107.5	(10)	65.8	(10)	54.7	(10)	27.6	(11)	25.3	(10)
Iodized Oil	106.5	(11)	61.4	(12)	53.2	(12)	30.3	(9)	23.1	(12)
Jet Injector	100.7	(12)	61.6	(11)	54.9	(9)	22.1	(13)	23.7	(11)
Biological Larvicide	88.1	(13)	52.1	(13)	44.9	(15)	25.6	(12)	17.7	(15)
Iodine Dipstick/Salt	87.3	(14)	51.9	(14)	48.6	(13)	20.0	(15)	18.8	(13)
Iodine Dipstick/Urine	87.2	(15)	50.7	(15)	47.3	(14)	21.4	(14)	18.5	(14)

TECHSUM.HT

Another collaborating institution involved in health care projects in the developing world is the International Development Research Centre (IDRC) of Canada. IDRC has provided funding to PATH to assist in the screening, assessment, and development of health technologies which complement the HealthTech technologies. Similarly, PATH receives funding which supplements A.I.D. funding from the Carnegie Corporation and the Ford Foundation for the Safe Birth program. The Clark Foundation has provided funds for the start-up of the PATHstrips™ (hematuria) project.

CONCLUSION

During the first 1½ years of the three-year HealthTech program, management has developed effective infrastructure for the program, cohesive strategies, a dynamic implementation process, and working relationships with the major participants in the international health arena. Significant progress has been made in the development and advancement of 12-15 approved technologies. Several more technologies are currently being evaluated for inclusion in the program.

During the next 1½ years, many of the products are expected to be field tested and transferred to the developing world. The model for advancing health technologies to the developing world, as described in PATH's 1987 proposal to A.I.D., has proven to be a realistic, workable, method of developing and introducing needed health technologies. The next 1½ years will demonstrate whether this model will also have a significant impact on child survival in the developing world.

MS00929R

HealthTech

Technologies for Child Health

Sponsored by

United States Agency for International Development
Office of Health

and

Program for Appropriate Technology in Health
(PATH)

January 1989

52

Introduction

The Technologies for Child Health (HealthTech) project is a joint effort of the United States Agency for International Development (A.I.D.) and the Program for Appropriate Technology in Health (PATH), under Cooperative Agreement No. DPE 5968-A-00-7035-00. PATH is a nonprofit, nongovernmental organization with headquarters in Seattle, Washington. The focus of HealthTech is the development, assessment, and/or introduction of health technologies that can have a direct impact on child survival in the developing world.

Technologies chosen for HealthTech are referred to as "social technologies" and are designed to meet perceived health needs rather than measured market demands. One strategy of the project is to strive for economically viable, self-sustaining products through the involvement of the private sector in the research, development, and manufacture of products. 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.

A.I.D. Missions are invited to participate as partners in HealthTech at various stages of the project. This document describes technologies which are currently or soon to be available for field assessment, introduction, local production, and/or distribution in developing countries. Where countries are already identified as potential sites for field trials or technology transfer, Mission participation has been or will be sought. Other Missions wishing to participate in any stage of country-specific activities or interested in more information are encouraged to contact:

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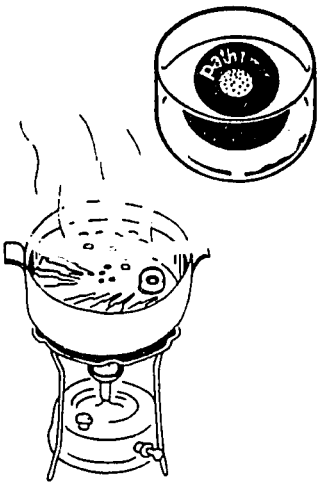
PATHtimer[R]

A reusable plastic device that indicates when water has been boiled sufficiently to disinfect medical instruments.



SIGNIFICANCE TO THE DEVELOPING WORLD

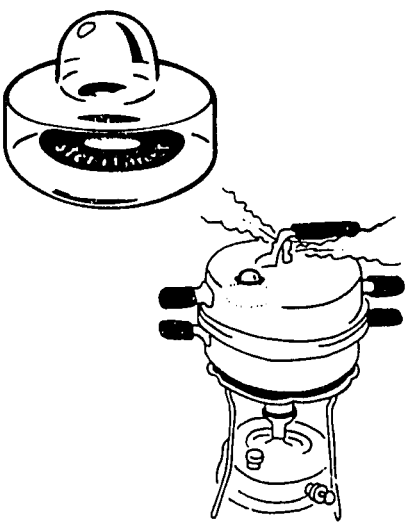
For disinfection by boiling of syringes, needles, and other medical instruments, WHO recommends boiling for 20 minutes to destroy most pathogenic microbes. PATHtimer[R] is a plastic device embedded with a disk of heat sensitive material. This disk is black at room temperature and changes to green after 20 minutes in boiling water. When placed with instruments in boiling water, this inexpensive, reusable, durable indicator ensures proper disinfection.

STATUS AND AVAILABILITY

PATHtimer[R] has been laboratory tested by WHO/EPI; developing world manufacturers are currently being sought; and an introduction trial is being planned in Malawi for 1989 under another program. The devices are currently available directly from PATH for US$1.90 each, with a minimum order of 100.

STERItimer™

A heat exposure monitor which indicates when medical instruments in pressure cooker-type steam sterilizers have been properly sterilized.



SIGNIFICANCE TO THE DEVELOPING WORLD

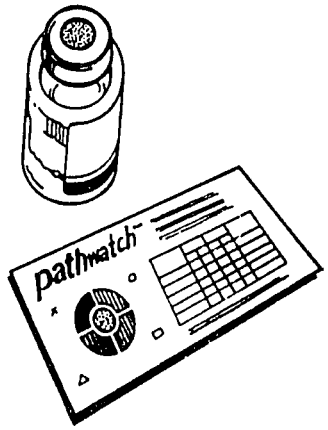
Sterilization by steam for 20 minutes is recommended by WHO as the method of choice for reusable medical instruments, including needles and syringes. STERItimer™ is an inexpensive and easy to use indicator which is retrofitted to pressure cooker-type sterilizers. The heat sensitive material in the disk is black when the sterilizer is not heated; it changes to green after 20 minutes of exposure to steam heat. The device eliminates the need for timers to assess the length of time for steam sterilization.

STATUS AND AVAILABILITY

STERItimer™ prototypes are being developed for possible testing in Indonesia. The device may be available by early 1990.

PATHwatch™/PATHmarker™

Irreversible, color-coded indicators of cumulative heat exposure of vaccines, used for cold chain monitoring.



SIGNIFICANCE TO THE DEVELOPING WORLD

Vaccines require careful monitoring to avoid harmful heat exposure during transport. PATHwatch™ (used on cartons) and PATHmarker™ (used on vaccine vials) contain heat-sensitive ink that changes color from pink to purple to black. Black appears after cumulative heat exposure equivalent to eight days at 37°C. Used together, PATHwatch™ and PATHmarker™ provide a complete system for monitoring cumulative vaccine heat exposure from manufacturer to vaccination site, for identifying breaks in the cold chain, and for improving vaccine stock management.

STATUS AND AVAILABILITY

Tested by WHO/EPI and approved for introductory trials, the devices are currently being field tested in Thailand and Kenya. Trials are in progress in Zambia and Sierra Leone under other projects, and trials are planned for Indonesia in 1989. PATHwatch™/PATHmarker™ will be available to national EPI programs from PATH in conjunction with a training package starting in late 1989.

PATHstrips™

A low cost, color-coded test strip for detecting protein in urine.

SIGNIFICANCE TO THE DEVELOPING WORLD

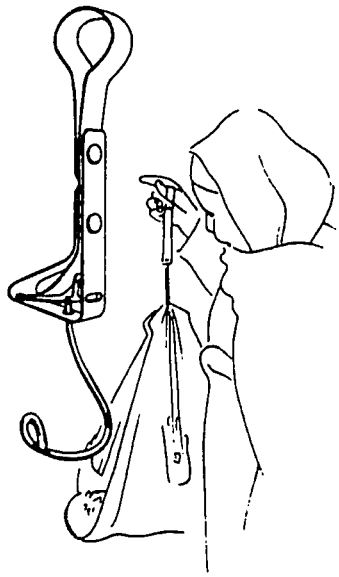
The presence of protein in urine may indicate preeclampsia during pregnancy, urinary schistosomiasis, urinary tract infections, or kidney disease. PATHstrips™ are simple, ready-to-use indicators of proteinuria which eliminate the need to prepare chemical reagents. To use PATHstrips™, a health worker tears a strip from the box and dips it into a urine sample; then protein amounts are determined by comparing the strip color to a color reference chart on the box. PATHstrips™ are well suited for local production.

STATUS AND AVAILABILITY

PATHstrips™ have been field tested, and a potential local manufacturer in Zimbabwe has been identified. Other local manufacturers are being sought. PATHstrips™ are available in limited quantities from PATH for US$3.25/box of 50 tests, plus shipping costs.

BIRTHweigh™

A hand-held, color-coded scale for identifying low birthweight newborns.



SIGNIFICANCE TO THE DEVELOPING WORLD

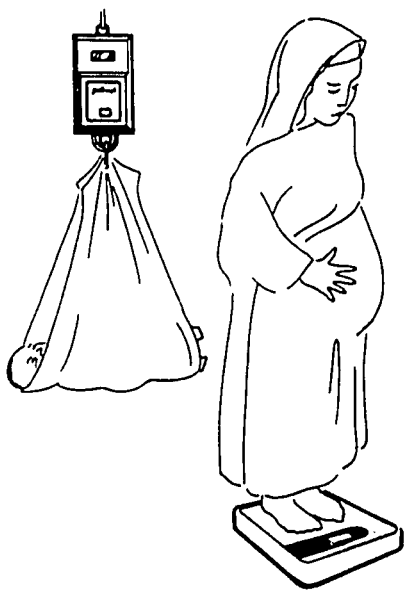
BIRTHweigh™ is a portable, color-coded spring scale made from a band of stainless steel. The newborn baby is placed in a cloth sling that is suspended from the scale. A viewing window on the handle reveals a simple yes/no indicator when the baby is weighed. A yellow color in the window indicates weight of less than 2,500 grams and the need for special care, while blue indicates the baby's weight is normal. BIRTHweigh™ gives traditional birth attendants and primary health care workers a simple and accurate way to assess the newborn's weight in the home or at a health center.

STATUS AND AVAILABILITY

Already field tested, BIRTHweigh™ is being manufactured in Malawi and has been introduced into five other countries using other funding sources. Potential manufacturers in Pakistan and Egypt are also being sought. The device is available from PATH for US$3.00 plus shipping costs, but should be introduced in-country via a PATH training program. The pattern for local manufacture of slings is also available from PATH. It is anticipated that BIRTHweigh™ will be available directly from Malawi by mid-1989.

PATHweigh[R]

Hanging and stand-on models of solar-powered, digital weighing scales.



SIGNIFICANCE TO THE DEVELOPING WORLD

Growth monitoring is one of UNICEF's child survival strategies. Monitoring maternal weight gain during pregnancy can help improve pregnancy outcome. PATHweigh[R] is available in two models: a hanging scale for infants and a stand-on version for adults or adults carrying infants. PATHweigh[R] scales do not require batteries or electricity. They are lightweight with a display that can be easily read by low-literate health workers.

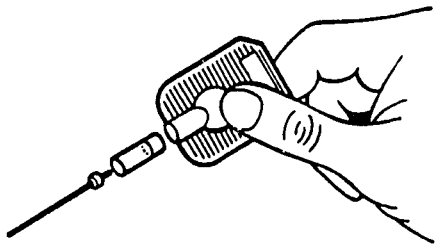
STATUS AND AVAILABILITY

Field trials of PATHweigh[R] may occur in Malawi where preliminary discussions have been held with the A.I.D. Mission. The A.I.D Mission in Pakistan has expressed interest in the project, and Bangladesh is another tentative site. A limited number of prototypes are available until mass production starts. Production scale-up of the device is expected by late 1989.

SafeTject™

A prefilled, single-dose, nonreusable injection device for vaccines or other fixed-dose injectables.

SIGNIFICANCE TO THE DEVELOPING WORLD



There is concern by health care providers about the risk of infections transmitted by improperly sterilized syringes and needles. SafeTject™ offers improved safety through its design as a single-use, self-contained injection device. It is a prefilled, single-dose device with an attached needle and cannot be reused after the injection is given. In addition, SafeTject™ can improve inventory control, reduce vaccine wastage, and reduce the cost of immunization equipment.

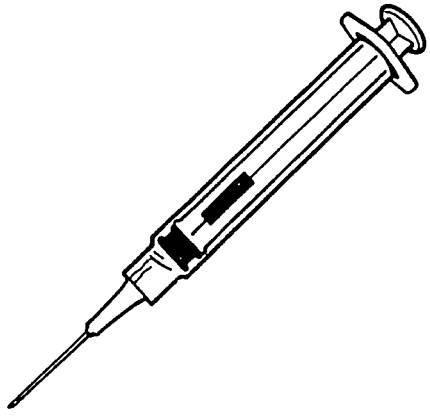
STATUS AND AVAILABILITY

Currently licensed to a U.S. company for manufacture, SafeTject™ may be field assessed in Kenya and/or Indonesia in Fall 1989. Field trials are to be conducted by WHO/HRP in Mexico. The device may be available to developing countries by 1990.

SyringeLOCK™

An autodestruct system for standard disposable plastic syringes.

SIGNIFICANCE TO THE DEVELOPING WORLD



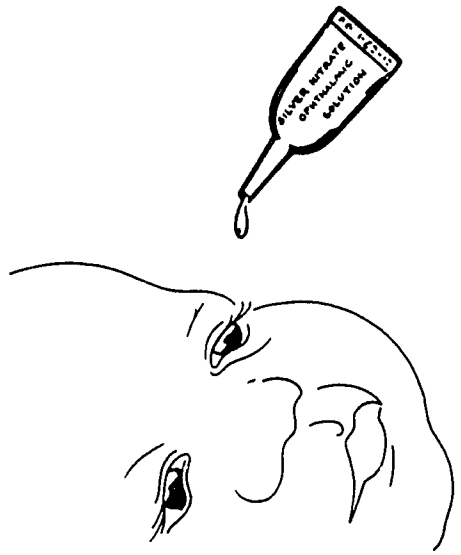
Presterilized disposable needles and syringes are in increasing demand due to concern about improper sterilization. However, disposable syringes are frequently reused without sterilization. SyringeLOCK™ is a device that allows only one filling of the syringe. After the injection is given, SyringeLOCK™ permanently locks the plunger at the base of the syringe, thereby prohibiting reuse. SyringeLOCK™ is assembled into standard syringes and requires minimal training.

STATUS AND AVAILABILITY

SyringeLOCK™ has been licensed to a U.S. manufacturer. Field trials through the REACH project in collaboration with WHO/EPI are planned for Spring 1989. SyringeLOCK™ may be available to developing countries by 1990.

Eye Drop Delivery System

Single-dose packages of silver nitrate solution for routine prophylaxis against gonococcal ophthalmia neonatorum.



SIGNIFICANCE TO THE DEVELOPING WORLD

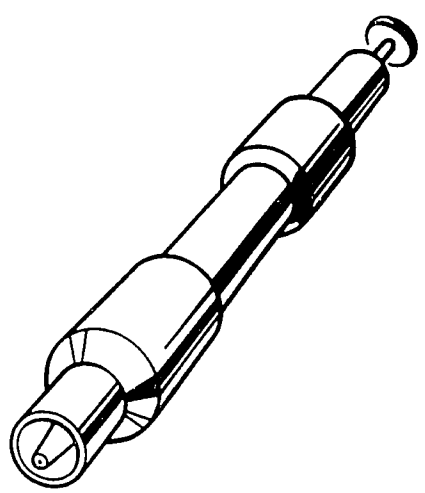
Conjunctivitis in the newborn caused by *Neisseria gonorrhoea* is a potentially blinding condition and can be prevented by administering silver nitrate drops or tetracycline into a newborn's eyes. Single-dose packaging of silver nitrate eliminates the problem of concentration of the solution through evaporation. The single-dose packaging is also easy to transport. Application of the silver nitrate drops can be carried out by traditional birth attendants and other community health workers.

STATUS AND AVAILABILITY

Prototypes of an eye drop, unit-dose delivery system of silver nitrate are under development with anticipated availability in early 1990.

Needleless Injector with Disposable Nozzle

Hand-held needleless injector for vaccines using prefilled, single-use reservoir and disposable nozzle.



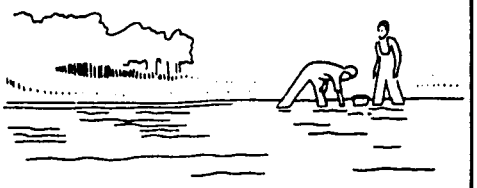
SIGNIFICANCE TO THE DEVELOPING WORLD

The safety and acceptability of vaccination are growing concerns in efforts to achieve global goals for immunization. The proposed design would address these issues through the use of a needleless injector which uses prefilled capsules. The disposable single-dose capsules also incorporate a jet nozzle which is the only portion of the device in direct contact with the skin surface. As with traditional jet injectors, acceptability is expected to be higher than with needles and syringes. Unlike existing jet injectors, the process of changing the disposable capsule after each use makes the device better suited for low-volume vaccination settings than for mass vaccination campaigns.

STATUS AND AVAILABILITY

Prototypes of this device are currently undergoing feasibility assessment.

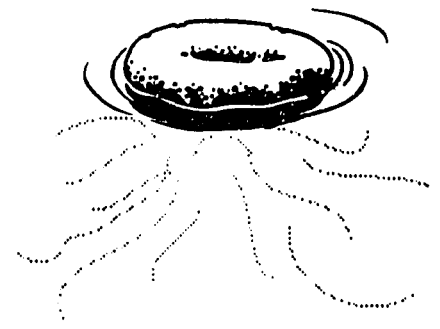
Biological Larvicides



Biological larvicides for use in vector control programs for dengue fever and malaria.

SIGNIFICANCE TO THE DEVELOPING WORLD

Biological larvicides are bacteria which destroy mosquito larva and thus can be used to control mosquito-borne diseases such as malaria, filariasis, Japanese encephalitis, and dengue fever. Biological larvicides are an alternative to chemical agents such as DDT, which is harmful to the environment and to which some strains of mosquitos have developed resistance. Biological larvicides can be used as part of an integrated strategy for controlling mosquito-borne diseases in combination with repellents and insecticide spraying.



STATUS AND AVAILABILITY

Field trials may be conducted in Indonesia and Thailand. Larvicides would be available after further validation through field assessment programs.

Other Technologies

The following technologies are currently being reviewed for feasibility as potential HealthTech products:

- Anti-stick needle device
- Nonreusable hypodermic needle
- Noninvasive hematocrit instrument
- Labor timer
- Umbilical cord clamp
- Urinary iodine dipsticks
- Iodized oil
- Solar refrigerator/ice maker

Announcements of availability of products for testing, production, or in-country distribution will be made periodically. Suggestions or inquiries regarding these or other appropriate technologies for child health are invited.

path

Program for Appropriate Technology in Health

Self injection –

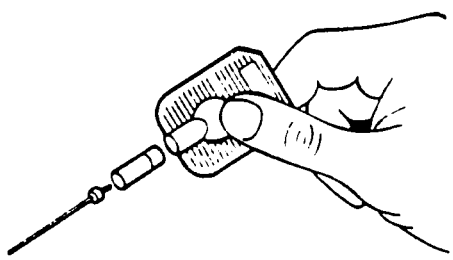
SafeTject™

Single-Dose, Nonreusable Injection Device

A prefilled, single-dose, nonreusable injection device for vaccines or other fixed-dose injectables.

SIGNIFICANCE TO THE DEVELOPING WORLD: There is concern by health care providers about the risk of infections transmitted by improperly sterilized syringes and needles. SafeTject™ offers improved safety through its design as a single-use, self-contained injection device. It is a prefilled, single-dose device with an attached needle and cannot be reused after the injection is given. In addition, SafeTject™ can improve inventory control, reduce vaccine wastage, and reduce the cost of immunization equipment.

STATUS AND AVAILABILITY: Currently being licensed for manufacture by a U.S. company, SafeTject™ may be field assessed in Kenya and/or Indonesia in the fall of 1989. Field trials are to be conducted by WHO/HRP in Mexico. It may be available to developing countries by 1990.



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path

Program for Appropriate Technology in Health

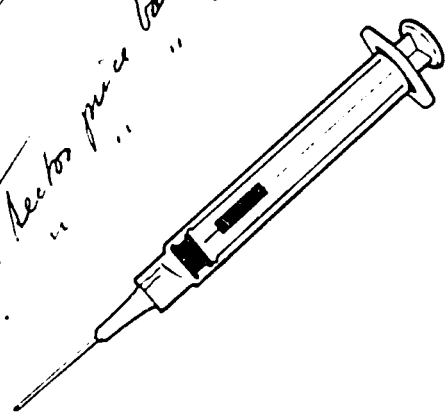
SyringeLOCK™

Auto-Destruct System for Disposable Syringes

An auto-destruct system for standard disposable plastic syringes.

SIGNIFICANCE TO THE DEVELOPING WORLD: Presterilized disposable needles and syringes are in increasing demand due to concern about improper sterilization. However, disposable syringes are frequently reused without sterilization. SyringeLOCK™ is a device that allows only one filling of the syringe. After the injection is given, SyringeLOCK™ permanently locks the plunger at the base of the syringe, thereby prohibiting reuse. SyringeLOCK™ is assembled into standard syringes and requires minimal training.

STATUS AND AVAILABILITY: SyringeLOCK™ has been licensed to a U.S. manufacturer. Field trials through the REACH program, in collaboration with WHO/EPI, are planned for the spring of 1989. SyringeLOCK™ may be available to developing countries by 1990.



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path

Program for Appropriate Technology in Health

BIRTHweigh™

Low-Birthweight Indicator

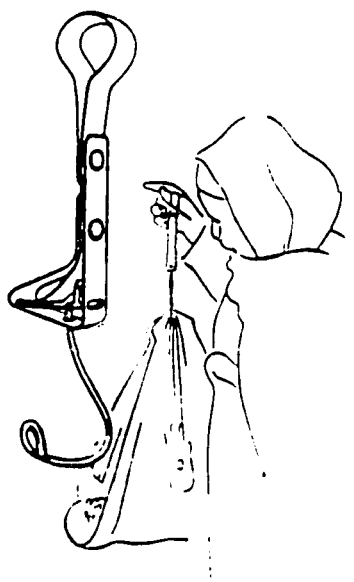
Hand-held, color-coded scale for identifying low-birthweight newborns.

RATIONALE: Each year millions of infants born in developing countries are underweight. Low-birthweight babies are at high risk of death or illness. Early identification of these infants can help target them for special care. A large number of children in developing countries are born outside a hospital or clinic setting. BIRTHweigh gives traditional birth attendants and primary health care workers a simple and accurate way to assess the newborn's weight in the home.

PRODUCT AND ITS USE: BIRTHweigh is an inexpensive, portable, color-coded spring scale made from a band of stainless steel. The baby is placed in a cloth sling, which is suspended from the scale. A viewing window on the scale handle reveals the simple yes/no color indicator when the infant is weighed. The presence of any yellow in the window indicates that the child weighs less than 2,500 grams and needs special care. When only blue is visible, it indicates that the child weighs more than 2,500 grams. (Weight less than 2500 grams is considered by the World Health Organization as the international low-birthweight standard.) The scale is accurate within 100 grams.

Model pictorial instructional materials and record forms are available for BIRTHweigh users. PATH works closely with local staff and traditional birth attendants (the target audience) to develop materials that are easily understood and culturally appropriate.

PRODUCT STATUS: BIRTHweigh prototypes and pictorial instructional materials and record forms have been field tested in North Yemen, Zambia, and Malawi. Results from all three countries show the scale to be durable, easy to use, acceptable, and useful. Changes may be made in the design on the sling, the indicator colors, and the low-birthweight threshold levels to meet local conditions. BIRTHweigh was designed with local production in mind; the Polytechnic Institute in Malawi began producing the scales for regional use in 1987.



BIRTHweigh scales are available from PATH for countries interested in field testing and introducing them. Introduction activities, however, must be carried out as part of a package that includes training, supervision, and relevant policy formulation. If you are interested in further information, please write to:

PATH
4 Nickerson Street
Seattle, Washington 98109 U.S.A.
Telex: 4740049PATH UI
Phone: (206) 285-3500
Fax: (206) 285-6619

Product Development Update: May, 1988

path

Program for Appropriate Technology in Health

PATHstrips™

Urinary Protein Dipstrips

Color-coded, semi-quantitative dipstrips for detecting urinary protein.

RATIONALE: The presence of protein in urine may indicate preeclampsia during pregnancy, urinary schistosomiasis, urinary tract infections, nephrotic syndrome, or renal disease. PATH has developed simple, ready-to-use indicators of proteinuria for local use. PATHstrips eliminate the need to prepare reagents and are significantly less expensive than commercial protein dipsticks. They are a risk assessment tool for local use by health workers and are well suited for local production.

PRODUCT AND ITS USE: PATHstrips are packaged in a convenient, tear-off form. After dipping the PATHstrip into urine, protein levels can be read immediately by comparing the PATHstrip color to a color reference chart on the PATHstrips box. Yellow indicates no protein, yellow-green and green indicate increasing protein levels, and blue-green indicates protein levels of 300 mg/dl or greater. (Standard acid-precipitate tests for proteinuria require users to estimate the relative cloudiness of reagent solutions.) PATHstrips give results that are accurate to within one color block, and are sensitive to protein levels as low as 10 mg per 100 ml of urine.

Model pictorial instructional materials have been developed for use in training PATHstrip users. PATH works with local health staff and members of the target audience to prepare easily understood and culturally acceptable materials.

PRODUCT STATUS: PATHstrips have been field tested in Malawi, Zambia, and Yemen and were found to be generally well understood and able to withstand tropical environmental conditions. Efforts are under way to identify manufacturers of PATHstrips in developing countries.

Once a manufacturer has been identified, PATHstrips will be available for public use. If you would like updated information as it becomes available, please write to:

PATH
4 Nickerson Street
Seattle, WA 98109, U.S.A.
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Product Development Update: May, 1988.

path

Program for Appropriate Technology in Health

PATHwatch™/PATHmarker™

Cold Chain Monitors

Irreversible, color-coded indicators of cumulative heat exposure of vaccines.

RATIONALE: EPI vaccines require careful monitoring to avoid harmful heat exposure as they pass through the cold chain. Short periods of heat exposure may not harm the vaccine, but cumulative exposure to heat over time could inactivate it. Heat exposure does not change the vaccine's appearance, so health workers have had no way to know where or when a cold chain break has occurred.

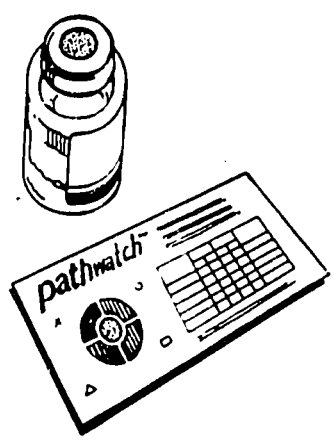
PATHwatch and PATHmarker are smaller and less expensive than other cold chain monitors. Because they can be used with individual vaccine cartons as well as with individual vials, they provide useful information to workers in peripheral sites, where heat exposure often occurs. Also, they integrate varying levels of time and temperature rather than responding to a single threshold temperature, thus giving a more accurate indication of heat exposure history. Like any cold chain monitor, however, PATHwatch and PATHmarker only indicate heat exposure history of the vaccine, not vaccine potency.

PRODUCT AND ITS USE: PATHwatch and PATHmarker contain heat-sensitive ink that changes color from pink to purple to black, becoming black after cumulative heat exposure equivalent to 8 days at 37 degrees C. PATHwatch, a label attached to the outside of vaccine cartons, consists of the indicator (a small dot of heat-sensitive ink surrounded by a color reference ring) and a recordkeeping table. The color reference ring is divided into four quadrants. Every time vaccine is received or dispatched, the date, location, and quadrant with the color most like the dot are recorded. PATHmarkers are small adhesive dots that are applied to each vaccine vial or ampule at the vaccine manufacturer or the national vaccine storage facility.

The combination of PATHwatch and PATHmarker provides a complete system for monitoring cumulative vaccine heat exposure from manufacturer to vaccination site, for identifying breaks in the cold chain, and for improving vaccine stock management. They also can be used in outreach programs where vaccines are carried into rural communities. Although PATH indicators change color before most EPI vaccines lose potency, they are less conservative than other indicators presently in use. After extensive testing, WHO has declared them "safe to use in the Expanded Programme on Immunization."

PATH also has developed model training materials for several levels of EPI personnel. Training for middle-level managers includes introduction and evaluation of the indicators. Middle-level managers then train field-level health workers in indicator use.

PRODUCT STATUS: In initial field trials in ten countries, sponsored by WHO, the indicators were well understood, useful in identifying which vaccine vials to use first, and effective in identifying cold chain breaks. Assessment of the introduction of the monitors into several different EPI programs is scheduled for 1988.



PATHwatch and PATHmarker are available for field assessment and introduction by national EPI programs. For specific information on current use or to receive updated information as it becomes available, please write:

PATH
4 Nickerson Street
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Product Development Update: May, 1988

path

Program for Appropriate Technology in Health

STERItimer™

Heat Exposure Monitor for Steam Sterilizers

Plastic heat exposure monitor for indicating when medical instruments in steam sterilizers have been disinfected sufficiently.

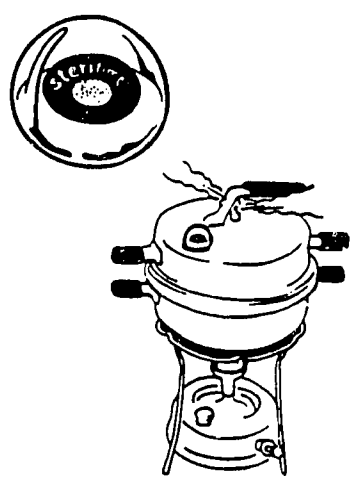
RATIONALE: The World Health Organization recommends that syringes, needles, and other medical instruments be exposed to steam in pressure-cooker-type sterilizers for at least twenty minutes to destroy all bacteria and viruses. The STERItimer was developed to eliminate the need for timers to assess the length of time of steam sterilizing. The STERItimer, attached to the lids of steam sterilizers, gives health workers an inexpensive and easy to use indicator for ensuring that instruments have been sterilized according to the WHO recommendation.

PRODUCT AND ITS USE: STERItimer is a plastic, shallow-dome shaped device that is approximately 4 cm in diameter and 1 cm deep. A disk of heat sensitive material is embedded in the monitor and is black when the sterilizer is not being heated. The disk changes to green after twenty minutes of steam release from the sterilizer, in response to heat conducted through the sterilizer cover.

The base of STERItimer has a high bonding-strength adhesive. To affix STERItimer to the sterilizer's cover, the paper backing is peeled from the adhesive and STERItimer is placed in the appropriate position on the cover. Once it is affixed to the sterilizer's cover, STERItimer remains in place virtually permanently.

STERItimer can be reused hundreds of times. The monitor is ready for the next use one hour after the previous sterilization cycle. Since STERItimer is affixed to the cover, it remains with the sterilizer at all times and cannot be misplaced.

PRODUCT STATUS: This product is in early stages of development. A few demonstration STERItimers have been supplied to WHO/EPI. If you would like updated information as it becomes available, please write to:



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Product Development Update: May, 1988

65

path

Program for Appropriate Technology in Health

PATHweigh[R]

Solar-Powered Scales

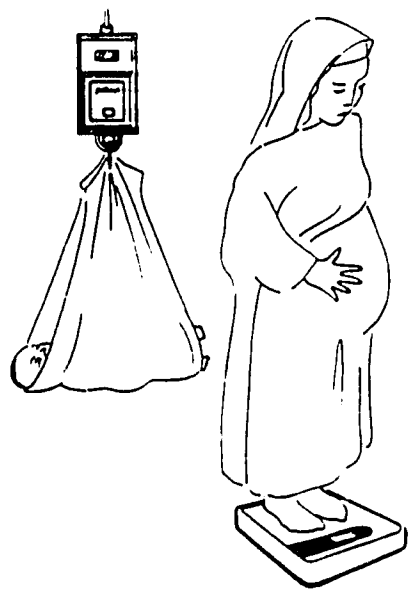
Hanging and stand-on models of solar-powered, digital-display weighing scales.

RATIONALE: Growth monitoring is one of UNICEF's recommended strategies for improving child survival in developing countries. Monitoring maternal weight gain during pregnancy can help improve pregnancy outcome. Most scales for weighing infants are cumbersome, inaccurate, or difficult to use in developing countries, and few scales are available for adults.

Sensor International, Inc. (a joint venture between PATH and Masstech, Inc., an Australian corporation) developed the PATHweigh scales to meet these needs. The two models of PATHweigh, a hanging scale for infants and a stand-on version for adults or adults carrying infants, offer many advantages. Infants may be weighed using the hanging scale or in the mothers' arms on the stand-on scale. The scales accurately average the weight of moving loads. The PATHweigh electronic scales do not require batteries or electricity. They are lightweight and the digital display is easy for low-literate workers to interpret.

PRODUCT AND ITS USE: The PATHweigh scales are solar-powered and digitally display the weight in 100-gram increments. The scales can be tared (reset to zero after an object, such as a container or a person, is placed on them). They will damp moving loads with an averaging function, hold their calibration, and require little maintenance. The hanging scale has a capacity of 30 kg, while the stand-on scale has a capacity of 150 kg. Both scales are accurate within 100 gm throughout their ranges.

PRODUCT STATUS: Prototype PATHweigh scales have been prepared for field trials to be carried out by UNICEF and WHO. PATH will also conduct its own assessment. If you would like to receive updated information on the scales as it becomes available, please send your name and address to:



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path
Program for Appropriate Technology in Health

PATHtimer[R]

100° C
20 Minutes

A reusable, plastic device that indicates when water has been boiled sufficiently to disinfect medical instruments.

RATIONALE: The World Health Organization recommends that syringes, needles, and other medical instruments be boiled for at least twenty minutes to destroy most microbial contaminants. The PATHtimer, placed with instruments in boiling water, gives health workers an inexpensive, durable indicator to ensure that instruments have been boiled according to the WHO recommendation.

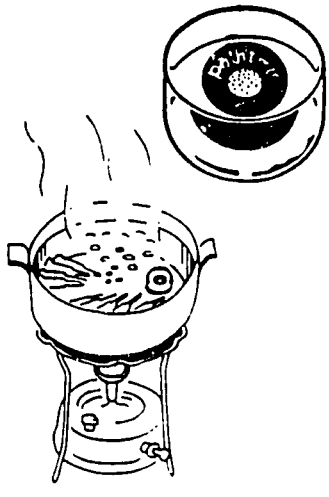
PRODUCT AND ITS USE: PATHtimer is a plastic capsule approximately 4.5 cm in diameter and 2.5 cm deep. A disk of heat sensitive material embedded in the capsule is black at room temperature and changes to green after 20 minutes in boiling water, indicating that the WHO recommendation has been met.

At sea level, the complete color change occurs after the device has been in boiling water for 20 minutes. At higher altitudes, PATHtimer requires longer exposures for color change, thereby compensating for the lower boiling temperature. For example, at 1,000 meters altitude, water boils at 96.5° C and PATHtimer changes color after 22 minutes.

PATHtimer may be reused hundreds of times. After each use, the monitor is removed from boiling water and kept at room temperature. The monitor is ready for the next use within one hour.

PRODUCT STATUS: Laboratory validation of PATHtimer by WHO/EPI was completed in 1987.

PATHtimer is in the scale-up phase of development. Prototype units for field evaluation or introduction are available from PATH. If you would like updated information as it becomes available or are interested in hosting field trials in your country, please write to:



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HealthTech Technologies

Reference Chart

	Type of Product	Stage of Development
Injection Technologies		
• SyringeLOCK™	C	4
• SafeTject™	C	2
• Nonreusable Hypodermic Needle	C	2
• Needleless Injector	C	1
• ColClip Antistick Device	C	1
Adjunct Technologies to Immunization/Vaccination		
• STERItimer™	C	2
• PATHtimer®	B	4
• PATHwatch™/PATHmarker™	A	3
• Solar Refrigerator/Ice Maker	B	1
Maternal Care Technologies		
• PATHweigh®	C	2
• PATHstrips™	B	4
• Noninvasive Hematocrit Instrument	C	1
• Labor Timer	A	1
Newborn Care Technologies		
• BIRTHweigh™	A	4
• Eyedrop Unit-dose Delivery System	B	2
• Umbilical Cord Safety Clamp	B	1
Other Primary Health Care Technologies		
• Urinary Iodine Dipstick	C	2
• Iodized Oil	C	4
• Biological Larvicides	C	1

Type of Product:
A = no commercial market potential
B = commercial partner optional
C = commercial partner required

Stage of Development:
1 = selection and screening
2 = product development
3 = field trials
4 = product advancement

HealthTech
Selection and Screening Activity
January 1989

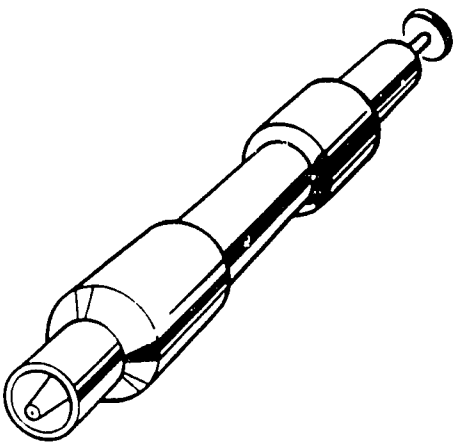
Type: C ; Stage: 1

Needleless Injector With Disposable Nozzle

Hand-held needleless injector for vaccines using prefilled, single-use reservoir and disposable nozzle

Product Description

The needleless injector is a self-contained, hand-held device in which a disposable plastic capsule filled with vaccine acts as both single-dose reservoir and disposable nozzle. The process of releasing the contents under high pressure to accomplish injection results in the destruction of the nozzle, thereby prohibiting reuse and the potential for cross-contamination that has occurred with existing jet injectors.



Stage of Product at Inception of A.I.D. Funding

Prototypes of two different designs had been engineered by at least three private companies. PATH has been in contact with VCI in the U.S. and Vitajet in Brazil. A third company, Bioject, based in Canada, has also developed a prototype with features similar to those of the Vitajet injector.

Current Status

This project is currently a selection and screening activity, although a work plan has recently been approved. PATH has signed secrecy agreements with two companies to allow for review of prototypes of the two designs. Reviews of prototypes have indicated that both designs possess desirable attributes but neither is ideal in its current configuration. The VCI design ensures trauma-free injection, eliminating the possibility of skin tears or contusions; however, it requires the use of carbon dioxide canisters as a source of power, a requirement that contributes to both a higher price and the difficulty of ensuring a reliable supply of components. The Vitajet model, while a fully self-contained unit requiring no external energy source, currently employs an unwieldy winding mechanism for cocking the spring, and is easier to misuse. This implies a higher training burden for health workers who administer vaccines.

Rationale

The safety and acceptability of vaccination are growing concerns in efforts to achieve global goals for immunization. The proposed design would address these issues through the use of a needleless injector which uses prefilled capsules. The disposable single-dose capsules also incorporate a jet nozzle which is the only portion of the device in direct contact with the skin surface. Because the capsule is automatically destroyed by injection, cross-contamination from splashback of blood is impossible. As with traditional jet injectors, acceptability is expected to be higher than with needles and syringes. Unlike existing jet injectors, the process of changing the disposable capsule after each use makes the device better suited for low-volume vaccination settings than for mass vaccination campaigns.

Performance Specifications

The nozzle should be:

- Designed to adapt for intramuscular and subcutaneous injections, as well as for patients of all ages.
- Designed to avoid contamination or cross-transmission of blood-borne disease, skin cuts due to movement during injection, and unobvious blockage causing suboptimal or failed immunization with knowledge of the operator.
- Damage-resistant.

The reservoir should:

- Be designed for all types of vaccine.
- Be able to handle rapid change from one vaccine to another.
- Be disposable.
- Provide single-dose application.
- Provide long-term vaccine storage.
- Withstand minimum cold storage space requirements.

The pressure generator should be:

- Fully contained within the hand-held unit.
- Operational without a replaceable energy supply.
- Maintenance-free or very low maintenance.
- Easy to use by male or female operators.

The housing and assembly should:

- Provide for a large margin of safety against explosions at operating pressure.
- Be easy to handle and transport.
- Facilitate proper use (have good human engineering).
- Be easy to clean.

It should be possible for the status of the instrument to be easily assessed by the field operator. Examples of status would be "device loaded," "device ready to inject," "type of vaccine loaded," "number of doses available," and "proper operating order of the device."

Progress to Date

A meeting of representatives from UNICEF, WHO/EPI, HealthTech, and the International Loan Fund of PATH was held at VCI to discuss design criteria and pricing issues. PATH has been in ongoing communication with Vitajet to learn of its refinements in prototype design and to advise of the appropriateness of these refinements in light of the intended application of the device. PATH has also initiated investigation of a similar device under development by a third company, Bioject, to learn if its product utilizes design features that better meet field needs.

Informal discussions have been conducted with EPI officials from some African countries to ascertain the need for and desirable features of the needleless injector. These discussions reflected varying levels of enthusiasm and the need to better understand the device before being able to judge how well it serves vaccination program needs. The International Health Program Office of the Centers for Disease Control has provided valuable assistance to the needleless injector selection and screening process by allowing the country representatives of the Combating Communicable Childhood Diseases program (CCCD) to respond to a questionnaire that will solicit input on the utility and appropriate properties of this device.

Future Plans

HealthTech will develop and distribute a survey instrument that includes questions and generalized diagrams for the purpose of identifying such key considerations for product development as:

- Type of health workers most likely to use the needleless injector.
- Level of health center at which these users are likely to work.
- Perceived benefits and obstacles to use of the device, as identified by the users.
- Frequency and types of vaccination administered by the likely users.

- Anticipated impact of the device on the routine delivery of immunization services, including safety and acceptability of vaccination; training of health workers; procurement of supplies required for vaccination; logistics management; and maintenance of the cold chain.

The questionnaire will be distributed to country representatives of the CCCD program, who are generally quite knowledgeable about the delivery of immunization services in the countries where they work. In addition, the survey, or questions from the survey, will be asked of EPI officials in countries where HealthTech or PATH is working with national immunization programs. The individuals contacted will also be asked about their interest in participating in design-stage field trials. The information gathered from the questionnaire will be used to further establish critical design features, to develop realistic pricing parameters, and to contribute to an overall assessment of the potential impact of the needleless injector on immunization programs.

At the same time, HealthTech will continue dialogue with VCI, Vitajet, and possibly additional companies to encourage their further development of the needleless injector, but at the company's own risk. When prototypes are available that meet the basic criteria as outlined by the questionnaire results and performance specifications, HealthTech will undertake limited-scale design-stage field trials.

Title/Licensing Status

All technologies being considered are proprietary technologies. Information about patents is not yet available.

Collaborating Institutions

None at present.

A.I.D. Mission Involvement

Field activities to be determined.

Expenditures to Date: Selection & Screening

Future Expenditures Expected Through June 1989: $ 98,169

ColClip Antistick Device

Syringe needle cover which folds back for injection and can be returned to the cover position without danger of accidental stick

Product Description

The ColClip antistick device fits over a hypodermic needle in place of a standard tubular needle cap. It can also be made as an integral part of a plastic disposable syringe with a fixed needle. The device consists of two hinged leaves which fold out of the way for filling and injection. The leaves are returned to a protective position by squeezing them with finger and thumb away from the needle point until the leaves clip shut. This eliminates the motion of the hand towards the needle point which is required to replace the standard needle cap.

-- Proprietary --

Stage of Product at Inception of A.I.D. Funding

The concept for the ColClip was developed and reduced to practice prior to HealthTech involvement by John Cole of Great Britain. Prototypes of syringes which included the ColClip were produced for WHO in May 1988. Prototypes for analysis were purchased under HealthTech in Fall 1988.

Current Status

Prototypes have been received by PATH, and initial functional and manufacturing analyses have been completed. Efforts are under way to represent the technology to major syringe manufacturers.

Rationale

Needle stick injuries can transmit at least 20 different pathogens, including the AIDS virus and hepatitis B. The Centers for Disease Control has estimated that 200-300 health care workers in the U.S. alone have died from occupationally acquired hepatitis B. Rates of infection for developing countries may be much higher. Despite safety guidelines, employee education, and new disposal techniques, needle stick injury incidents have not abated. Over one-third of needle stick injuries are related to recapping of the needle and an additional 10% are related to missing caps. A full 70% of injuries occur during efforts to dispose of the used needle.

Currently, standard needle covers are fully removable. These covers may be lost, misplaced, or confused with covers that are of inadequate size to fully and safely engage the needle. Recapping removable covers requires a motion of the health care worker's hand toward the point of the needle. The motion is much like threading a sewing needle and often results in several "misses" before the needle cap is safely engaged. Nearly 100 patents have been filed for alternative needle cap designs. Most concepts retain a fully removable configuration. Designs which attach the cover to the syringe or needle eliminate lost or misused caps; however, all patented designs involve large tubes of plastic which will significantly increase the cost of disposable syringes and which make the syringe more awkward to use.

The ColClip remains with the needle; it does not impair view of the gradations on the syringe or inhibit use of the syringe. The device is a relatively small single-molded piece which can be integrated into existing manufacturing processes easily and inexpensively. It permits safe recapping of the needle.

Performance Specifications

The device should:

- Require safe movement by the user to re-engage the cover after use, with fingers or hands never moving <u>toward</u> the needle point.
- Remain attached to the syringe/needle combination so it cannot be misplaced.
- Allow complete needle covering to be accomplished as the needle is withdrawn from patient's skin.
- Be able to be added to fixed needle/syringe assemblies during production.
- Be able to be added to removable needle/hub assemblies.
- Be suitable as an add-on unit to be placed over the needle hub.
- Work with or without a standard needle cap.
- Be made of the same material as the syringe body/plunger rod.

- Be easily molded in an inexpensive injection mold.
- Be small enough to be added to existing syringe molds.
- Be moldable as a unit with needle hubs.
- Withstand humid environments during storage.
- Require minimal retraining of health care workers.
- Have little or no impact on the cost of a disposable syringe and needle.

Progress to Date

Prototypes of the ColClip produced in London by the inventor, John Cole, have been evaluated for manufacturability; compatibility and fit with existing needles and syringes; sterilization properties; shipping and handling properties; and function. In several key areas, the current prototype was found to be deficient or less than optimal. Additional documentation has been prepared which illustrates design alternatives and extensions.

A presentation has been prepared for demonstration to syringe manufacturers. Contacts have been made with Becton, Dickinson and Company and with Terumo. These major syringe manufacturers were deemed to have the necessary large-scale capacity and interest in public sector markets to achieve the unit cost targets. These firms also own or are negotiating rights to autodestruct single-use technologies which are adapted for developing world use. An additional list of five smaller-scale manufacturers has been developed for further licensing activities.

Future Plans

Efforts to find a manufacturing collaborator for ColClip will be vigorously pursued. Once a potential collaborator has been identified, HealthTech assistance will be offered to the inventor in negotiations regarding a licensing agreement and collaboration arrangements. In addition, HealthTech will offer to coordinate refinement of the ColClip design and subsequent field trials of prototype devices.

Title/Licensing Status

John Cole, the inventor of the ColClip, has filed for four United Kingdom patents on the device. A 90-day Agreement to Represent for the technology was signed with PATH under HealthTech Selection and Screening in August 1988. An extension of that agreement has been requested.

Collaborating Institutions

Neil Andersson, M.D., London School of Hygiene and Tropical Medicine, has assisted the inventor in reducing the technology to practice and coordinating activities with PATH. WHO/EPI has purchased prototypes which incorporate the ColClip technology.

A.I.D. Mission Involvement

Field activities to be determined.

ColClip Antistick Device

This technology is covered by a confidentiality agreement. The report on the technology can be reviewed after a confidentiality agreement has been signed. The report and the agreement will be available from Gretchen Shively at the TAP meeting on February 1, 1989.

HealthTech
Subproject Summary
January 1989

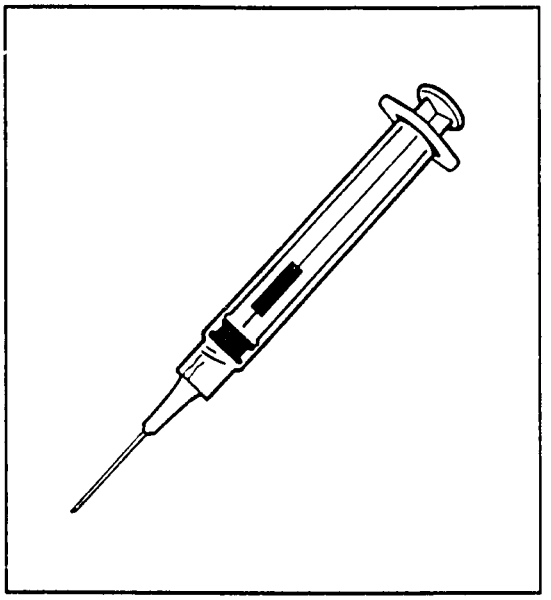
Type: C ; Stage: 4
Budget: Year 1 $ 150,215
Year 2 $ 54,335

SyringeLOCK™

An autodestruct system for standard disposable plastic syringes

Product Description

SyringeLOCK is a component that fits into a standard disposable plastic syringe and allows only one filling and emptying cycle. After the injection is given, SyringeLOCK permanently locks the plunger at the base of the syringe, thereby prohibiting reuse. SyringeLOCK is assembled into standard disposable syringes at the factory and does not alter the normal handling and operation of the syringe.



Stage of Product at Inception of A.I.D. Funding

Prior to the start of HealthTech, several embodiments of the SyringeLOCK principle were reduced to practice at PATH.

Current Status

The SyringeLOCK technology was demonstrated to WHO/EPI through the EPITECH panel in July 1987. EPITECH judged SyringeLOCK to be promising as an autodestruct technology which could be used in support of the EPI program. Under HealthTech, an intensive program was initiated to optimize the SyringeLOCK technology as quickly as possible. Late-stage development of SyringeLOCK, including engineering for large-scale manufacture, was carried out under HealthTech from July 1987 to November 1988.

SyringeLOCK was licensed to Becton, Dickinson and Company (BD), the leading manufacturer of syringes in the U.S., in July 1988. The exclusive license provided for royalty-free supply of the technology to the public sector as well as continued surveillance and intervention in the event of failure to perform. SyringeLOCK received regulatory approval from the USFDA in November 1988, based on a 510(k) application, and is therefore cleared for international field trials under the auspices of U.S. government agencies. Preliminary approval has recently been received from WHO/EPI and the process of formal approval by that agency has begun. Two hundred SyringeLOCKs are being prepared and will be sent to Geneva at the end of January for EPITECH panel review as well as laboratory testing at a WHO/EPI-designated laboratory. A field trial of the device is planned for June 1988 in Pakistan, to be conducted by the REACH program funded by A.I.D. Training and instructional materials on the use of SyringeLOCK are being prepared under HealthTech.

Rationale

The reusable plastic syringes of the type supplied by UNICEF/UNIPAC provide a low-cost option for vaccine delivery when used and sterilized according to approved protocols. However, proper sterilization is not carried out in many cases. Because of this, there has been increasing demand for presterilized disposable needles and syringes in EPI programs in recent years. However, these are usually not disposed of and are frequently reused without proper sterilization.

There is a consensus among international health agencies that new autodestructive methods of vaccine delivery systems are urgently required in order to ensure that vaccinated individuals or EPI programs are not put in jeopardy because of disease transmission resulting from improper use of needles and syringes. To be effective, an autodestruct technology should require no purposeful action on the part of the user and should allow only one filling and emptying cycle of the syringe contents (i.e., vaccine or medicament). Ideally, the technology should require no additional training or cost.

Performance Specifications

The device should:

- Automatically render an autodestruct syringe unusable after delivering one 0.5 ml (or 0.1 ml) dose of vaccine.
- Allow only one filling and injecting cycle of the syringe.
- Be tamper-proof.
- Be compatible with current manufacturing processes.
- Have a minimal effect on training regarding syringes.
- Cause minimal vaccine wastage.
- Cost within 10% of the cost of standard disposable syringes.
- Have a shelf life in the field equal to that of standard disposable syringes (approximately three years).
- Require a force to move the plunger that is similar to the force required for conventional syringes.

Progress to Date

SyringeLOCK has proceeded rapidly from initial invention to license negotiations, USFDA registration, and scale-up in less than two years. During the first quarter of 1988, PATH screened several licensees, according to a strategy devised under the HealthTech program in collaboration with A.I.D. Office of Health staff. As a result, BD, a world leader in the

manufacture of disposable syringes and a supplier of disposable syringes to UNICEF, was granted a license in July 1988.

Prior to the licensing of SyringeLOCK to BD, significant refinement and testing of the devices occurred, using handmade prototypes. Early technical problems with the device included a sporadic tendency of the barbs to embed in the syringe barrel wall, thus allowing reuse of the syringe, and an intermittent ability to pull the device out of the syringe when excessive tension force was applied. Both of these technical problems have been solved with the addition of more barbs to the device.

To further reduce any possibilities of tampering with SyringeLOCK, a final development activity was required to prevent a twisting motion of SyringeLOCK which could disengage or damage the device. This technical issue was resolved by a collaborative effort between PATH and BD. To prevent the damaging twisting motions, a BD 3 cc syringe has been modified with a breakaway plunger and SyringeLOCK has been modified to possess greater spring force. A temporary forming die has been built to reduce variation in critical dimensions which lead to failure in 10% - 20% of handmade (acid etched) prototypes.

In parallel with these technical development activities, instructional and training materials have been developed. A one-page brochure with illustrations on how to use SyringeLOCK has been drafted and will be finalized prior to initiation of the Pakistan field trial. REACH has been responsible for protocol development for the field trial and PATH staff have reviewed and recommended some changes to the protocol.

Future Plans

Two hundred SyringeLOCKs will be sent to Geneva in late January for EPITECH panel review and for laboratory testing at a WHO/EPI-designated laboratory. If these tests are successful, 30,000 packaged sterilized disposable syringes, fitted with SyringeLOCK, will be made available to REACH and WHO/EPI for a field trial in Pakistan and two other countries. The Pakistan field trial, to be carried out by REACH, is scheduled for June 1 to July 1, 1989. During the planning and field prototype production for this field trial, PATH will continue to provide technical support to the syringe manufacturer for any technical problems that arise.

Prototyping of modified SyringeLOCK designs to fit into 1 cc syringes (tuberculin syringes) has been initiated and will continue to be advanced. (Existing SyringeLOCKs are assembled into BD 3 cc syringes.)

Title/Licensing Status

SyringeLOCK was invented by PATH in January 1987. HealthTech has supported the advancement of this PATH technology. Patents are applied for in several countries and assigned to PATH without encumbrance. A license agreement is in place with a major U.S. syringe manufacturer: Becton, Dickinson and Company.

Collaborating Institutions

Becton, Dickinson and Company (Rutherford, New Jersey).

A.I.D. Mission Involvement

The A.I.D. Mission in Pakistan has been informed by REACH of upcoming field trials.

Expenditures to Date: $ 108,275

Future Expenditures Expected Through June 1989: $ 96,275

HealthTech
Subproject Summary
January 1989

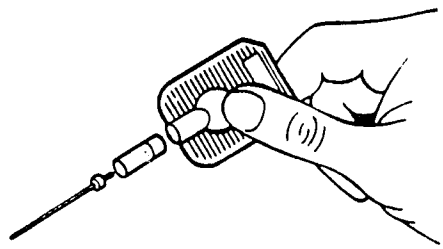
Type: C ; Stage: 2
Budget: Year 1 $ 226,774
Year 2 $ 151,090

SafeTject™

Prefilled, unit-dose injection system for vaccines and other intramuscular injectables

Product Description

SafeTject is a combination package and injection device for delivery of vaccines and other intramuscular injectables. The reservoir with an integral needle assembly is manufactured on high-speed equipment and subsequently sterilized. The reservoirs are then provided to producers of pharmaceutical and biological injectables for filling with vaccine or medicine under aseptic conditions using high-speed equipment designed specifically for this application.



Stage of Product at Inception of A.I.D. Funding

The concept for this product originated under a National Institutes of Health (Fogarty Center) program in 1986. The project was also funded by A.I.D. prior to HealthTech as part of the Bureau for Private Enterprise Health Link program.

Current Status

SafeTject has advanced through several design iterations and is ready for scale-up. Production and filling machinery have been designed. One filling and sealing machine has been built for preparation of field trial prototypes. A contract for co-development leading to an option for the manufacture and distribution of SafeTject has been signed by Acacia Laboratories, Santa Ana, California. Terms of the agreement call for HealthTech to support remaining development activities, while Acacia is obligated to fulfill regulatory approval tasks as well as identify and establish agreements with producers of vaccines and other injectables.

The remaining technical development tasks include studies of storage stability of SafeTject and engineering support of initial manufacturing.

Rationale

There is a long-standing concern on the part of health care providers about the risk of infections transmitted by improperly sterilized syringes and needles. The concern is particularly great for immunization programs, since they depend heavily on injections. This concern has been heightened in recent years by the recognition of the substantial risk of hepatitis B infection and associated liver diseases, by the new epidemic of acquired immunodeficiency syndrome (AIDS), and by the greatly increased scope of immunization coverage.

The use of SafeTject, a low-cost, nonreusable, prefilled, single-dose, self-contained injection device, would result in a decrease in the risk of contamination and cross-infection. This format is well-suited to delivery of tetanus toxoid to pregnant women by traditional birth attendants. For general EPI use, SafeTject is currently restricted to vaccines stored in liquid media such as DPT and tetanus toxoid. For these vaccines, the increase in required cold storage will be offset to some degree by reduced vaccine wastage, improved program efficiency, and reduced cost of equipment. In addition, the system will provide increased safety, improved logistical control, and reduced training burden.

Performance Specifications

A prefilled, autodestruct syringe should:

- Be rendered unusable after delivering one 0.1 ml dose of vaccine or medicament.
- Not allow any liquid to be forced into the reservoir at pressures under 35 kPa.
- Allow filling and sealing of the device only under manufacturing conditions and employ existing designs of sterile filling and sealing machinery.
- Be tamper proof and display clear evidence if the device is tampered with.
- Be composed of plastic that is transparent and rated excellent according to a standard test for opalescence.
- Not allow water loss from the sealed reservoir to exceed 1% over a six-month period at 37°C and 60% humidity.

Progress to Date

Although the current design appears extremely simple, the execution of the design requirements has caused many iterations of tooling. In order to meet the conflicting requirements of nonreusability and aspiration, a shape had to be developed that would allow suction for aspiration when the reservoir is full, yet prevent suction when the reservoir is empty. In addition, the design had to achieve a dispensing accuracy equal to that of a standard syringe.

Since the product depends on efficient, high-speed, sterile filling and sealing, a filling and sealing machine has been designed, built, and installed at Acacia Laboratories. Functional prototypes for *in vitro* testing are now available. Preparations are now in progress to fill field trial prototypes with sterile water for nonclinical field assessment. Testing to meet USFDA requirements began in January 1989. Individual filler/producers will be required to complete the regulatory approval process for use of SafeTject with their own specific medicament.

Future Plans

The activities for 1989 focus upon regulatory approval requirements which drive the development and production activities. The form 510(k) USFDA registration is currently being developed, as is a Drug Master File submission. Significant technical efforts will be required to validate the design and production according to USFDA requirements. Compatibility and storage stability studies for SafeTject filled with several different injectables will be conducted.

Acacia Laboratories will continue to actively market, identify, and negotiate agreements with biological and pharmaceutical companies. Acacia Laboratories will also provide substantial resources to assist with an Abbreviated New Drug Application approval.

HealthTech will continue to actively encourage prospective public-sector vaccine suppliers and customers to collaborate with Acacia Laboratories in achieving regulatory approval for specific vaccines, in particular tetanus toxoid and hepatitis B virus.

In addition, initial design feedback will be sought from health care workers in developing countries on an informal basis as soon as prototypes become available. A field trial using SafeTject with tetanus toxoid will begin in Kenya in collaboration with AMREF as soon as filled prototypes have been produced and have met regulatory requirements.

Title/Licensing Status

The basic patent for this technology is owned by Merck, Sharp and Dohme and is licensed to PATH for advancement to meet public-sector needs. An additional patent is being sought for the self-destruct concept and other novel features. This additional patent, if granted, will be subject to certain rights of the U.S. Government regarding inventions made under publicly funded projects.

PATH has negotiated an 18-month Option Agreement with Acacia Laboratories, Inc., for the commercial development of SafeTject. Acacia will work toward validating the design, materials, and filling of SafeTject and implementing a marketing and sales campaign in exchange for the option of an exclusive U.S. and nonexclusive worldwide license to make, use, and sell SafeTject. Public-sector pricing protection has been included in the agreement. The terms of the agreement include:

1. Provision by PATH of continued technical and marketing resources.
2. Funding by PATH of scientific studies to support the Drug Master File.
3. Continued pursuit of patents regarding this technology.
4. Securement by Acacia of the Drug Master File regulatory submission.
5. Achievement by Acacia of a prospective supply commitment to biological and pharmaceutical customers for a quantity of 30 million devices annually.
6. Procurement by Acacia of the necessary capital production equipment to supply the initial market.

Collaborating Institutions

World Health Organization, Human Reproduction Programme; Acacia Laboratories; AMREF, Kenya

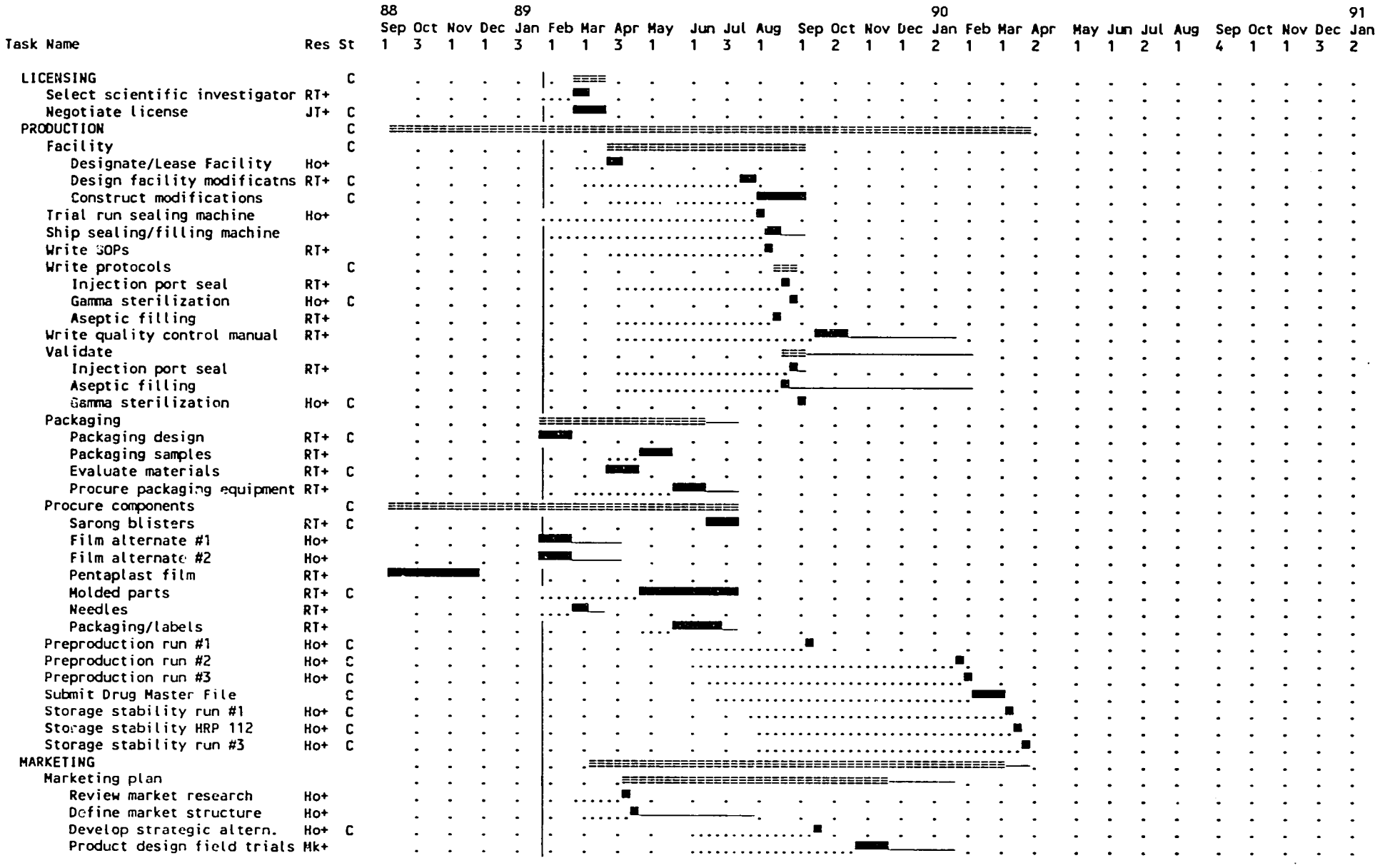
A.I.D. Mission Involvement

Future field trials for tetanus toxoid administration are anticipated in Kenya.

Expenditures to Date: $ 336,123

Future Expenditures Expected Through June 1989: $ 41,741

Schedule Name : SafeTject Development/Licensing Plan
Responsible : Ron Thomas
As-of Date : 23-Jan-89 Schedule File : C:\TL3\DATA\SAFETJEC



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   Develop prospect list       Ho+  C
Execute marketing plan
   Publish scientific paper(s)
   Negotiate supply agreemt(s) Ho+  C
   Sign supply agreement #1    Ho+  C
   Sign supply agreement #2    Ho+  C
   Sign supply agreement #3    Ho+  C
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Detail Task      ===== Summary Task     M   Milestone
(Started)        ==### (Started)        >>> Conflict
(Slack)          ###-- (Slack)          ..  Resource delay
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TIME LINE Gantt Chart Report, Strip 1

Nonreusable Hypodermic Needle

This technology is covered by a confidentiality agreement. The report on the technology can be reviewed after a confidentiality agreement has been signed. The report and the agreement will be available from Gretchen Shively at the TAP meeting on February 1, 1989.

CONFIDENTIAL
Subject to Confidential Disclosure Agreement
Dated April 8, 1987

Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 95,371

Nonreusable Hypodermic Needle

A small device added to disposable needles which renders them unusable after one filling and injection cycle.

Product Description

A small plastic insert is added to a modified standard needle hub or syringe nozzle assembly. The insert swells after contact with aqueous solutions, blocking the fluid pathway. Once swollen, the insert remains swollen and cannot be reshrunk, so reuse of the needle or a one-piece needle/syringe is impossible.

-- Proprietary --

Stage of Product at Inception of A.I.D. Funding

The Johns Hopkins University Applied Physics Laboratory (JHU/APL) applied for a patent for this device in February 1987. Hand-fabricated prototypes of the device were demonstrated to the National Institute of Drug Abuse and the World Health Organization in 1987. A subgrant was signed with JHU/APL in August 1988. Under this agreement, JHU/APL will carry out the development, scale-up, and preliminary licensing activities for this product.

Current Status

Appropriate materials have been identified and preparations are under way for production of the first prototypes to be manufactured rather than hand fabricated. These advanced prototypes will be available by the end of February 1989. A limited number of hand-fabricated prototypes are now available for demonstration. Research on alternate materials, production techniques, use requirements, and product configuration is ongoing.

Rationale

In order to guarantee that disposable injection systems will only be used once, both the syringe and needle must passively become inoperable after a single use. WHO/EPI has proposed the use of fixed needles to achieve this goal. However, fixed needles on all standard syringes for uses other than immunization may increase production and distribution costs due to the large number of syringe/needle size combinations. Another approach is to design hypodermic needles and syringes that are independently self-destroying. Other projects under HealthTech (e.g., SyringeLOCK™) deal with the autodestruction of syringes. This project offers a potential means of guaranteeing single use of separate disposable needles.

Separate single-use syringes and needles would maintain the present arrangement for general medical applications where flexibility of needle size relative to syringe size is essential. This maintenance of the status quo in disposable injection systems will ensure wider application of the devices, resulting in increased economies of scale and lower unit costs.

Performance Specifications

The device should:

- Allow an interval between filling and blockage of the fluid path that is long enough to permit injection, but not so long as to allow a second injection.
- Permit use with liquid or prefilled lyophilized vaccines.
- Require little or no retraining of health care personnel.
- Not swell under humid environmental conditions.
- Require only minimal changes in tooling or production techniques for manufacture.
- Not add to the cost of standard disposable needles by more than 10%.
- Require minimal training.

Progress to Date

A first candidate "hydrogel" plastics material, polyethylene oxide (PEO), has been selected and obtained. PEO has good biocompatibility and has been approved by the USFDA as a food additive. The specific compound chosen for the first prototypes is available in the National Formulary grade, allowing it to be used in drug delivery systems.

The swelling dynamics and extrudability of PEO have been well researched at the University of Maryland under subcontract to JHU/APL. Molding dies have been produced for the extrusion of inserts. Inserts have been made in several different shapes in order to evaluate the effect of the wetted surface area on the swelling time. Material and dies have

been provided to a co-investigator, ATC International, for experimental processing. Prototypes with these new inserts should be available by mid-February 1989.

Several approaches for trapping the insert within the needle hub in a manner that eliminates tampering have been examined. These approaches will permit minimal changes in manufacturing techniques currently used for detachable needles. One approach utilizes an adapter which would fit between the needle hub and syringe, requiring an additional small molded part. A second approach would be to fit the insert within the small conical void between the tip of the syringe nozzle and the inside of the needle hub where the needle opens into the hub. If the second approach is pursued, a small perforated disc of stainless steel will be used to lock the insert in this small "headroom" space.

Future Plans

A broad investigation of additional hydrogel materials for the insert will be conducted. This will ensure that the optimal material for the insert is chosen. Key functional questions are the swelling rates of various materials and the irreversibility of the insert when in the swollen condition.

The JHU School of Hygiene and Public Health will carry out a study using traditional disposable needles to establish the average and range of time needed to administer liquid and lyophilized vaccines. These data will be used to fix the operational window of time for filling and injection prior to blocking.

When molded prototypes are available in quantity, tests will determine drug compatibility, shelf life, and acceptance by health care personnel. Additional development to optimize the configuration will follow. At the end of this project, 200 prototypes will be available for further testing; preproduction planning for the pilot production of 10,000 units will be complete.

Title/Licensing Status

A U.S. patent on the JHU/APL nonreusable injection syringe/needle was granted to the inventor on November 1, 1988, and has been assigned to The Johns Hopkins University Applied Physics Laboratory.

Collaborating Institutions

JHU/APL will carry out development activities. WHO/EPI is expected to carry out field trials.

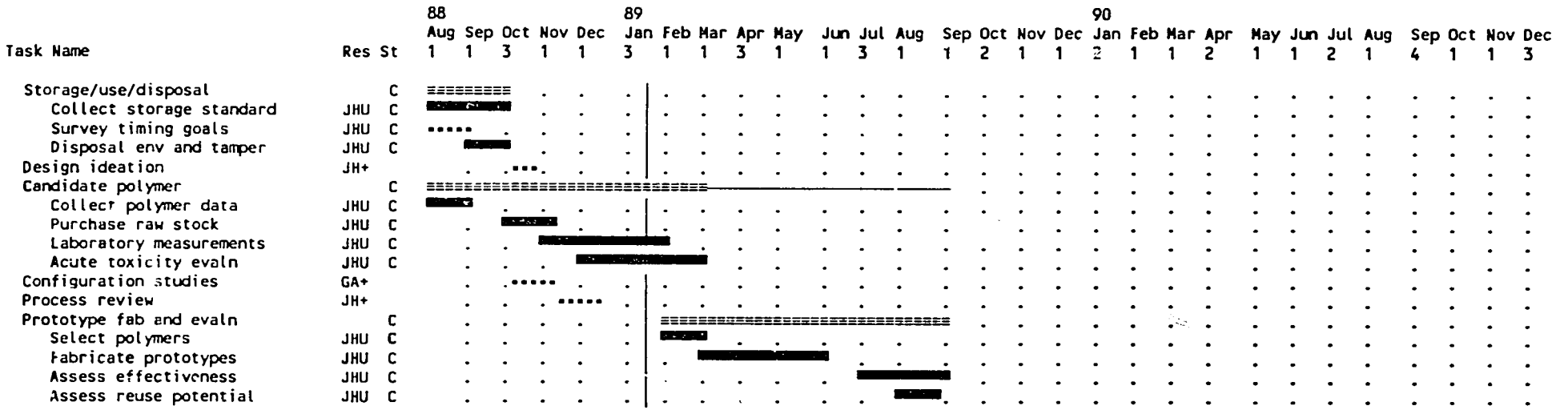
A.I.D. Mission Involvement

Field trials to be determined.

Expenditures to Date: $ 4,326

Future Expenditures Expected Through June 1989: $ 91,045

Schedule Name : Nonreusable Hypodermic Needle
Responsible : Glenn Austin
As-of Date : 23-Jan-89 Schedule File : C:\TL3\DATA\JHU-APL



Detail Task ===== Summary Task M Milestone
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Scale: 1 week per character

TIME LINE Gantt Chart Report, Strip 1

THE JOHNS HOPKINS UNIVERSITY
APPLIED PHYSICS LABORATORY

Johns Hopkins Road, Laurel, Maryland 20707-6099
Telephone: (301) 953-5000 and 792-5000

RECEIVED DEC 21 1988

ATD-RL-88-124
JJW-88-030
December 14, 1988

Program for Appropriate Technology in Health (PATH)
4 Nickerson Street
Seattle, Washington 98109-1699

Attention: Mr. Glenn D. Austin

Subject: Progress Report No. 1, October 1 through December 1, 1988, "Development of the JHU Nonreusable Injection Syringe/Needle".

Enclosure: Progress Report No. 1, October 1 through December 1, 1988 "Development of the JHU Nonreusable Injection Syringe/Needle".

Sir:

In accordance with the Technical Program Plan for the "Development of the JHU Nonreusable Injection Syringe/Needle" the first Technical Progress Report for the period October 1, 1988 through December 1, 1988 is submitted herewith. Five copies are enclosed for your distribution.

Should more copies be required, or if you have any questions or comments, please feel free to contact me at the following number (301) 953-5000, extension 7402.

Very truly yours,

John J. Wozniak

John J. Wozniak
Principal Investigator

External Distribution:

Dr. Kam Leong, JHU School of Medicine
Dr. Neal Halsey, JHU School of Hygiene and Public Health

THE JOHNS HOPKINS UNIVERSITY
APPLIED PHYSICS LABORATORY
LAUREL MARYLAND

Enclosure 1 to
ATD-RL-88-124
JJW-88-030

Progress Report No. 1, October 1 through December 1, 1988
"Development of the JHU Nonreusable Injection Syringe/Needle".

During this reporting period, work began on forming inserts for the single-use syringe by extrusion. The prime candidate hydrogel for extrusion is polyethylene oxide (PEO). Experimentation carried out at the University of Maryland under subcontract to APL in 1984, had shown that extrusion was possible, without additives, using PEO with a molecular weight (MW) of 200,000. Consequently, the baseline for experimental extrusion of inserts is at this MW. Polyethylene oxide, under the Union Carbide Corporation trade name POLYOX, was ordered and the materials were received during the last week of November. The polymer resin was purchased in the National Formulary grade. This recently approved grading enables PEO to be used in the manufacture of certain pharmaceutical, drugs, and drug delivery systems.

Two extrusion dies were fabricated using the Laboratory's Charilles Roboform Electrical Discharge machine (EDM). One of the dies is configured to produce a six-pointed star and the other an eight-tooth gear for the cross-sectional shape of the extruded PEO. The purpose of these shape differences is to alter the wetted area thereby affecting syringe timing.

Both the POLYOX and the dies were turned over to ATC International to begin experimental processing. The first of these extruded inserts should be available for testing in mid-December.

Two approaches have been examined for trapping the insert within the needle hub portion for syringes with detachable needles. In both approaches the guidance being followed is to incorporate the insert in a manner which would not affect, or affect minimally, the manufacturing techniques currently used for detachable needles.

The first approach uses an adapter which would be bonded to the hub of a traditional detachable needle after adding the insert. The needle with adapter would be mated to a Luer lock type syringe to eliminate accidental separation of the needle following use. Prototype adapters have been machined from stock materials and are available for testing when extruded inserts become available.

The second approach being considered would shape the insert to fit within the headroom (the small conical void between the tip of the syringe nozzle and the beginning of the cannula when the needle is attached to the syringe). A small stainless steel retainer, dome-shaped to ensure one-way motion, would be pressed into the needle hub to prevent tampering with the insert.

A meeting was held at Terumo Medical Corporation, Elkton, Maryland in early November. The JHU insert approach for a nonreusable syringe was presented and Terumo's production engineers offered advice regarding large scale manufacture.

A U.S. patent has been granted for the JHU nonreusable injection syringe/needle. The patent was granted on November 1, 1988 and has been assigned the patent number 4,781,683.

During the month of December work will begin on a broad investigation of possible hydrogels for the insert. The goal of this effort is to insure that alternative polymers are available for testing and that the optimal polymer is chosen for the insert material.

The syringe timing study is also planned for the month of December. The JHU School of Hygiene and Public Health will begin its study using traditional disposable needles to establish the average and range of time needed to administer liquid and lyophilized vaccines. These data are required to tailor the operational window of time for the single use syringe.

As of October 31, 1988, the latest available fiscal report, the project has expended Four Thousand, Three Hundred and Twenty-six Dollars ($4326.00).

HealthTech
Subproject Summary
January 1989

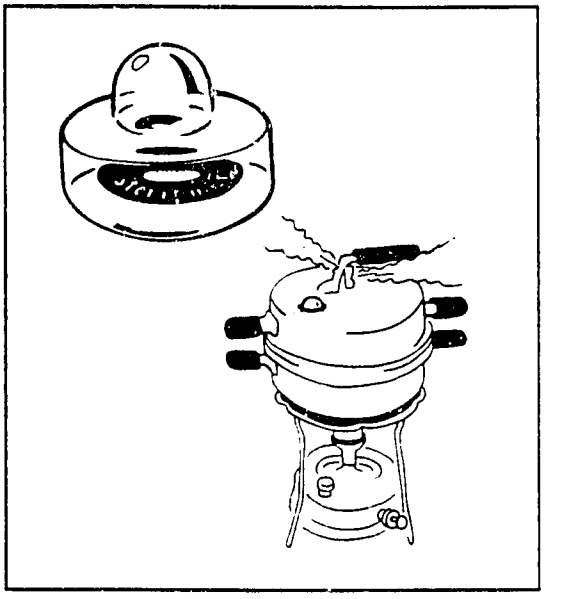
Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 53,807

STERItimer™

Heat-exposure monitor for steam sterilizers that indicates adequate sterilization by a color change

Product Description

STERItimer is a plastic, shallow, inverted mushroom-shaped device that is approximately 7.5 cm in diameter and 2 cm deep. It is affixed inside a steam sterilizer on the underside of the lid. A viewing lens penetrates the lid to allow monitoring. A disk of heat-sensitive material is embedded in the monitor and is black when the sterilizer is being heated. The disk changes to green after 20 minutes of steam release from the sterilizer, in response to heat conducted through the plastic body of the STERItimer over time.



Stage of Product at Inception of A.I.D. Funding

The technology for time/heat color indicators was licensed to PATH in June 1985 based on a 1979 patent from Robert Parker Developments, Inc., Alamo, California. At the inception of HealthTech funding, numerous prototypes had been constructed and evaluated by PATH personnel. Key prototypes were documented by drawings and engineering notes in April 1986 and again in March 1987.

Current Status

Under HealthTech, PATH is now laboratory testing six prototypes, with a single feature varied in each. After several repeats, data will be evaluated to determine the next prototype configuration.

Current prototypes are relatively easy to read and consistent in performance. The color of the monitor changes from black to "full" green an average of 21 minutes from the time of steady steam release from the relief valve, as per WHO specifications.

Rationale

Immunization is a key component of child survival. The risk of transmitting infection by use of improperly sterilized syringes and needles is of increasing concern, especially in areas of high incidence of hepatitis B and AIDS.

Syringes and needles used for vaccination must be sterile to avoid transmission of blood-borne diseases. EPI currently relies principally on sterilizable plastic syringes and reusable needles. These are disinfected between uses, either by open-pot boiling or through the use of a modified pressure cooker. Syringes, needles, and pressure cooker sterilizers are distributed around the world by UNICEF. Disinfection procedures are under the control of the individual health centers or outreach teams. There are many instances where these procedures are not properly carried out due to lack of knowledge, shortage of equipment, lack of fuel, or carelessness on the part of the health care worker.

WHO/EPI has identified the need for a simple indicator device that would attach to the pressure cookers and show clearly when the contents have been exposed to the appropriate sterilizing temperature for 20 minutes. Based on its experience with thermochromic materials in the PATHtimer® and AQUAtimer®, PATH is developing the STERItimer to be retrofit on sterilizers now in use and to be mounted on new sterilizers before shipment.

Performance Specifications

The device should:

- Provide a clearly discernible signal 22 ±2 minutes from the time of steady release of steam from the pressure release valve (20 minutes at 120°C).
- Be compatible with all EPI models of steam sterilizers.
- Be readable under a wide range of light conditions.
- Be reusable for the life of the steam sterilizer, and withstand at least 400 heating and cooling cycles.
- Be reusable within one hour of use.
- Be suitable for retrofit or attachment at the sterilizer factory.
- Cost less than US$10.00 to retrofit existing sterilizer.
- Add less than US$4.00 to the cost of sterilizer manufacture.
- Be durable in tropical climates.
- Require minimal training.

Progress to Date

Dozens of designs have been constructed and tested by PATH. Most prototypes mounted on the outside of the sterilizers have provided uneven performance. This is due to the devices' vulnerability to ambient environmental conditions such as air movement. The sterilizer lid provides an inconsistent heat path to the plastic device, also contributing to unacceptable performance variations. Recently a new approach was undertaken that solves the problem of ambient condition effect. The entire STERItimer device, except for a small viewing and light-conducting "lens-stem," has been relocated inside the sterilizer and insulated from the lid. Tests of the new configuration show a significant reduction in ambient condition effect. During several tests when ambient temperature was varied by as much as 20°C, the resulting shift in time of indication was less than two minutes.

Tests on the device have proven to be problematic. Particularly difficult is the measurement and notation of dozens of data points of temperature, pressure, monitor color, and time within one or two seconds. PATH is obtaining improved data collection equipment which should eliminate this difficulty. Additional errors have been introduced due to sterilizer leaks. The effect of very small leaks on internal temperature has provided some useful operational information which will be reported to WHO/EPI.

New test protocols have been designed, and higher-temperature indicator crystals (the color changing component of the monitor) have been formulated and obtained. In addition, several new prototyping methods have been tried in order to identify the fastest and most consistent method.

Future Plans

Testing and design iteration will continue until an optimal configuration is found. Variations in mounting, crystal location, lens shape, and overall shape and size will be explored before the final calculations are made to determine the exact size of the first field test model.

Several questions remain regarding the optimal functional balance of the final product and should be answered in the next round of testing. These include: the effects of light source on apparent transition color, the effects of heat source on boiling times, environmental effects on boiling and indication times, and space allocation in a fully loaded sterilizer.

Once successful laboratory tests have been completed, an optimal design will be reproduced in 20 to 40 prototypes for extended field and lab tests. A controlled field evaluation will be carried out in Indonesia in order to determine functionality in the field as well as any environmental effects. Training and instructional materials will be developed for wide-scale WHO/EPI and UNICEF field tests. Fatigue tests will be conducted to determine the maximum number of heating/cooling cycles over which the device can sustain accuracy

and readability. Results of field and fatigue tests will be analyzed to determine any necessary changes to the design. Changes will be incorporated and retested.

Wide-scale tests will be conducted on 100 prototypes based on a final design configuration. Studies will be conducted to determine the best method of retrofit of STERItimer monitors on sterilizer units already in the field.

Title/Licensing Status

Relevant patents are owned by Robert Parker Developments, Inc., Alamo, California, and licensed to PATH for developing world use. A royalty of 6%, based on the ex-factory price, is due to Robert Parker Developments for any units sold.

Collaborating Institutions

WHO/EPI originally suggested development of this technology and has shown continued interest in it.

A.I.D. Mission Involvement

Approval for design-stage field tests will be requested from the Indonesia Mission.

Expenditures to Date: $ 9,534

Future Expenditures Expected Through June 1989: $ 44,273

Schedule Name : STERItimer Steam Sterilizer Indicator
Responsible : Glenn Austin
As-of Date : 24-Jan-89 Schedule File : C:\TL3\DATA\STERITMR

Attaches to top of pressure-cooker-type sterilizer

Task Name	Res	St	86 Apr 1	Jun 2	Aug 1	Oct 1	Nov 3	87 Jan 2	Mar 2	May 1	Jul 1	Sep 1	Oct 1	Dec 1	88 Feb 1	Apr 1	Jun 1	Aug 1	Sep 1	Nov 1	89 Jan 3	Mar 1	May 1	Jul 3	Sep 1	Nov 1	90 Jan 2	Mar 1	May 1	Jun 1	Aug 1	Oct 1	Dec 3	91 Fe 1
Design & produce prototype	MF		▪▪▪▪▪▪▪▪▪▪▪▪																															
Demonstrate feasibility/WHO	MF					▪▪▪																												
Discuss design w/p.c. mfrs	MF					▪▪▪▪▪▪▪																												
Fabricate dome & metal core	KMa							▪▪▪▪																										
Prototype cores assembled	KMa								▪▪																									
Test Prestige ptype core	KMa								▪▪																									
Redesign; retrofit model	KMa								▪▪▪▪▪▪																									
Locate alternate adhesives	KMa								▪▪▪▪▪▪▪▪▪																									
HealthTech subproj. approvl	MF															▪																		
Procure 8 sterilizers	GA+																		▪▪▪▪															
Construct retrofit ptypes	GA+																		▪▪▪▪▪▪															
Test retrofit prototypes	KM+																		▪▪▪															
Test/refinement cycle	GA+	C																				▪▪▪▪▪												
Limited field tests																							▪▪▪▪											
Final design document	GA																							▪▪▪										
Build 100 units/assemble 20	GA+	C																					▪▪▪▪▪											
On-site test (Indonesia)	VT	C																						▪▪▪										
Fatigue testing (20 units)	KM+																							▪▪▪▪▪▪▪▪										
Develop training/instr mtl	TE	C																						▪▪▪										
Identify manufacturer	CMc																								▪▪▪▪▪▪▪▪									
WHO/EPI validity test (40)	MF	C																							▪▪▪▪▪▪▪▪									

▪▪▪▪ Detail Task ≡≡≡≡≡ Summary Task M Milestone
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▪▪▪— (Slack) ≡≡≡— (Slack) ..▪▪▪ Resource delay

---------- Scale: 2 weeks per character ----------

TIME LINE Gantt Chart Report, Strip 1

HealthTech
Subproject Summary
January 1989

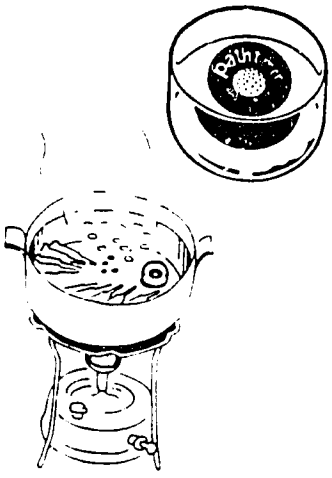
Type: B ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 23,616

PATHtimer[R]

A reusable plastic sensor that indicates when water has boiled sufficiently to disinfect medical instruments

Product Description

PATHtimer is a plastic device embedded with a disk of heat-sensitive material. This disk is black at room temperature and changes to green after 20 minutes in boiling water. When placed with instruments in boiling water, PATHtimer indicates when instruments have been boiled long enough to ensure proper disinfection. PATHtimer is lightweight and reusable, with an expected life span of 600 cycles.



Stage of Product at Inception of A.I.D. Funding

Several advanced prototypes have been constructed and dimensional specifications have been defined, addressing the issue of heat dispersion during the manufacturing and curing process.

Current Status

PATHtimer is now in the scale-up phase of development. Two manufacturers for production of PATHtimer have been identified. Coordination and fine-tuning of the production is occurring and production-type units are available for field evaluation or introductory activities. Units have been procured by UNICEF and WHO/EPI. One of the manufacturers has made several hundred production-type units that have undergone laboratory and quality assurance testing. The other potential manufacturer is experimenting with manufacturing processes before production-type units are made.

Rationale

Many rural health care workers and traditional birth attendants (TBAs) depend on open-pot boiling for disinfection of medical equipment such as needles, syringes, and obstetric tools. Most of these personnel were trained to boil items for at least 20 minutes. In the case of health care workers, their busy schedules and frequent fuel shortages make careful observance of the recommended boiling time difficult. In the case of TBAs, nonliteracy and lack of watches compound the problem of fuel shortage. The frequency and potential seriousness of the infections that can be transmitted in immunization programs or midwifery practices led to the development of the PATHtimer 20-minute and six-minute boiling time indicators.

The 20-minute PATHtimer is intended for use with medical instruments in programs following the current WHO recommendation of 20 minutes of boiling. The six-minute version was designed initially for drinking water disinfection, but would be available for other uses in programs wishing to test its effectiveness for instrument disinfection.

Many governments and international agencies are especially anxious now to minimize the risks of infection associated with contaminated medical instruments, particularly the needles and syringes on which the EPI programs depend so heavily. PATHtimers represent convenient, cost-effective tools for reinforcing the need for thorough disinfection and for enabling health care workers and TBAs to carry it out. Since major shifts in training or practices are not required, it is anticipated that wide-scale introduction can be initiated relatively quickly after field assessment.

Performance Specifications

The device should :

- Undergo a clearly discernible color change after 20 minutes in boiling water.
- Not exceed ±1 minute (19 to 21 minutes) in variation in the time of the color change.
- Compensate for differences in altitude; at altitudes above sea level, the color change should occur later than 20 minutes, since at higher altitudes water boils at a lower temperature.
- Have an easily visible color change, even in dimly lit rooms.
- Be durable and reusable, with the ability to withstand hundreds of cycles of use and placement in and out of boiling water.
- Be easy to use, with minimal instructions.

Progress to Date

Following the availability of advanced prototypes and the definition of dimensional specifications, a nationwide solicitation of quotes by casting manufacturers was carried out. Bids were also solicited from developing country manufacturers; however, after review it was determined that the level of technology required to produce PATHtimer is not currently available in developing countries. Establishment of local production will be pursued once demand is established or an improved manufacturing process is available for transfer.

Two potential manufacturers (in Seattle, Washington, and Portland, Oregon) were identified based on cost and quality considerations. These two manufacturers have produced prototype units according to PATH's specifications. One manufacturer has produced several hundred production units and is now investigating building precision molds and producing large volumes.

Laboratory validation of PATHtimer by WHO/EPI was completed in October 1987 in collaboration with an independent Swedish consumer laboratory which evaluated the devices. Based upon this validation, WHO/EPI has ordered 100 units for its use. UNICEF ordered 100 PATHtimers for use by one of its field offices in Afghanistan.

Instructional materials consisting of a one-page brochure with illustrations (colored to show PATHtimer's color change) were developed. Inexpensive packaging options for the PATHtimers were investigated, and PATHtimers are now packaged in plastic bags along with the instructions.

UNICEF has indicated a preliminary interest in including PATHtimer in boiling kits offered through the UNIPAC catalog. It is planned that UNICEF will ultimately purchase PATHtimers directly from the manufacturer of its choice, determined by competitive bidding.

Future Plans

Information will be gathered from field trials and users of PATHtimers, especially from those who have already received the devices. Performance criteria (durability, accuracy, physical integrity) available from different types of health personnel will be of special interest. The acceptability of the PATHtimers will be determined. Field trials of PATHtimer, incorporated into the Safe Birth Program, will be carried out. The selection of field sites will depend on the Safe Birth Program's sites.

Technical assistance and validation of the large-scale production will occur and the quality of the PATHtimers will be continuously monitored. Concurrent with these activities will be the design of a PATHtimer that can perform at altitudes above 7,000 feet. The performance of the current PATHtimer is not reliable at altitudes above 7,000 feet.

Title/Licensing Status

Relevant patents are owned by Robert Parker Developments, Inc., Alamo, California. The technology is licensed to PATH for health and developing country applications. PATH pays royalties equivalent to 8% of the ex-factory cost to Robert Parker Developments. PATH is negotiating a sublicense with Titan Manufacturing Company for manufacture and distribution of PATHtimer.

Collaborating Institutions

The two current manufacturers of PATHtimer are Titan Manufacturing Company (Seattle, Washington) and Jonnie Frame Company (Portland, Oregon).

A.I.D. Mission Involvement

Field activities to be determined.

Expenditures to Date: $ 3,156

Future Expenditures Expected Through June 1989: $ 20,460

Schedule Name : PATHtimer Boiling Indicator
Responsible : Katherine Mack
As-of Date : 24-Jan-89 Schedule File : C:\TL3\DATA\PATHTMR

Reusable indicator for monitoring disinfection

Task Name	Res	St	87 Mar 2	May 1	Jul 1	Sep 1	Oct 1	88 Dec 1	Feb 1	Apr 1	Jun 1	Aug 1	Sep 1	Nov 1	89 Jan 3	Mar 1	May 1	Jul 3	Sep 1	Nov 1	90 Jan 2	Mar 1	May 1	Jun 1	Aug 1	Oct 1	91 Dec 3	Feb 1	Apr 1	May 1	Jul 1	Sep 3	Nov 1
Printing refinements	DO																																
Resolve exotherm problem	DO																																
Embedment: 30 units	DO																																
Lab QA testing	DO																																
Samples to WHO/EPI, MCH; CDC	KMa																																
WHO/EPI lab testing	MF																																
Embedment 200 units	KMa																																
Fatigue testing	KMa																																
Fill UNICEF/WHO orders	KMa																																
Follow-up orders	RW																																
Further QA	KMa																																
Licensing w/ Titan	RW																																
Select field site	VT	C																															
Develop training materials	VT	C																															
Training of field supervisors	DR	C																															
Training of users	DR	C																															
Monitor field use	DR	C																															
Data review/tech. refinemt	KMa	C																															

Detail Task ==== Summary Task M Milestone
(Started) ==== (Started) >>> Conflict
(Slack) ===— (Slack) .. Resource delay
Scale: 2 weeks per character

TIME LINE Gantt Chart Report, Strip 1

HealthTech
Subproject Summary
January 1989

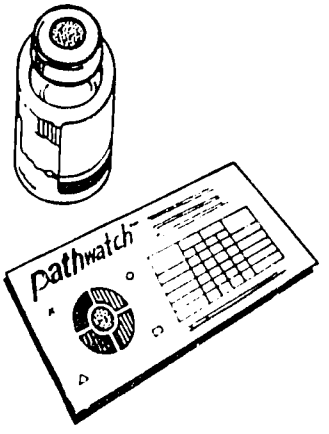
Type: A ; Stage: 3
Budget: Year 1 $ 44,380
Year 2 $ 57,692

PATHwatch™/PATHmarker™ Cold Chain Monitors

Irreversible, color-coded indicators of cumulative heat exposure of vaccines

Product Description

PATHwatch, a label attached to the outside of vaccine boxes, consists of the indicator (a small dot of heat-sensitive ink surrounded by a color reference ring) and a record-keeping table. PATHmarkers are small adhesive dots that are applied to each vaccine vial or ampule at the vaccine manufacturer or the national vaccine storage facility. PATHwatch and PATHmarker contain heat-sensitive ink that changes color from pink to purple to black, becoming black after cumulative heat exposure equivalent to 8 days at 37°C.



Stage of Product at Inception of A.I.D. Funding

Development of PATHmarker began in 1979 using a technology initially developed by Allied Corporation (New Jersey). With support from WHO/EPI, field trials were carried out in ten countries in 1982-84. Based on the results of the field trials, the PATHmarker was refined and the PATHwatch label was developed. After a positive evaluation of the technology by WHO/EPI in 1987, introductory trials in Zambia were initiated with Canadian International Development Agency funding. HealthTech funding covered additional field trial sites and training materials development.

Current Status

Introductory trials are under way in Thailand, and plans have been made to launch a trial in Kenya in January 1989. Preliminary discussions have been held to investigate field trial possibilities and work with a local vaccine manufacturer in Indonesia.

Rationale

The EPI vaccines require careful storage and transport to avoid harmful heat exposures. As vaccines are passed through the lengthy cold chain from the manufacturer to the health worker who finally administers them, it is difficult to monitor accidental heat exposures which may not individually render the vaccine useless but which cumulatively could be significant. Because these exposures do not alter the appearance of the vaccine, they are generally not detectable. As a result, EPI programs have had to adopt very conservative guidelines about vaccine handling and the disposal of vaccines which have received relatively minor heat exposures.

PATH developed PATHwatch (for vaccine cartons) and PATHmarker (for individual vaccine vials) as nonreversible indicators of cumulative heat exposure. These adhesive labels signal potentially harmful heat exposure by a clear-cut color change from pink to black. An intermediate purple color provides a warning when substantial, but not yet potentially harmful, heat exposure has occurred.

Performance Specifications

The monitors should:

- Be small, so they can be used with every vaccine carton and even with every vial.
- Be nonreversible.
- Be inexpensive so they can be used with each vial and can travel to the periphery of the health care system, where most cold chain failures occur.
- Measure cumulative heat exposure (over time) rather than a single heat exposure which exceeds a threshold temperature.
- Require minimal training of health care workers.
- Provide an easily readable, detectable color change.

Progress to Date

Introductory trials have been initiated with government EPI programs in Thailand and Kenya. Introductory trials are designed to provide essential feedback on the training program and on the newer design and production features (the color reference ring, the record-keeping space, the new materials used in the indicators). More broadly, the field assessment will provide valuable information on the actual distribution of vaccines throughout the cold chain, possible cold chain problems, and the potential for improving vaccine stock management (e.g., reducing wastage) through the use of the PATH cold chain monitors. In Thailand, ten provinces in four zones (regions) are participating in the trial. Approximately 22,000 PATHmarkers will be attached to vials of measles vaccine being distributed over a nine-month period. Central and regional level staff were trained in

April 1988, with provincial and peripheral training scheduled for the following two to three months. Actual distribution of vaccine with indicators is now ongoing. In Kenya, a preliminary planning session was held in October 1988 to establish which two districts would participate, to develop a subproject budget, and to plan a training schedule. A return visit for central and district training will take place in January 1989. Preliminary discussions have also been held with government EPI officials and a local vaccine manufacturer in Indonesia regarding attachment of monitors at the time of manufacture and establishment of a field trial.

Future Plans

The trials in Thailand and Kenya will continue for six to nine months as the vaccine with monitors is distributed through the cold chain and data are collected. PATH will assist in the data analysis as needed. The results should enable the respective governments to determine whether or not to proceed with nationwide use of the monitors and, if so, the best strategy for instituting it. If arrangements can be made to work with a vaccine manufacturer in Indonesia, some of the logistical questions about attaching monitors at the manufacturing site can be resolved.

Title/Licensing Status

A patent for the active chemical used in PATHwatch/PATHmarker is owned by Allied Corporation, and is licensed to PATH for use with vaccines in the developing world.

Collaborating Institutions

Field trials are being carried out in collaboration with the Ministry of Public Health in Thailand and the Ministry of Health in Kenya.

A.I.D. Mission Involvement

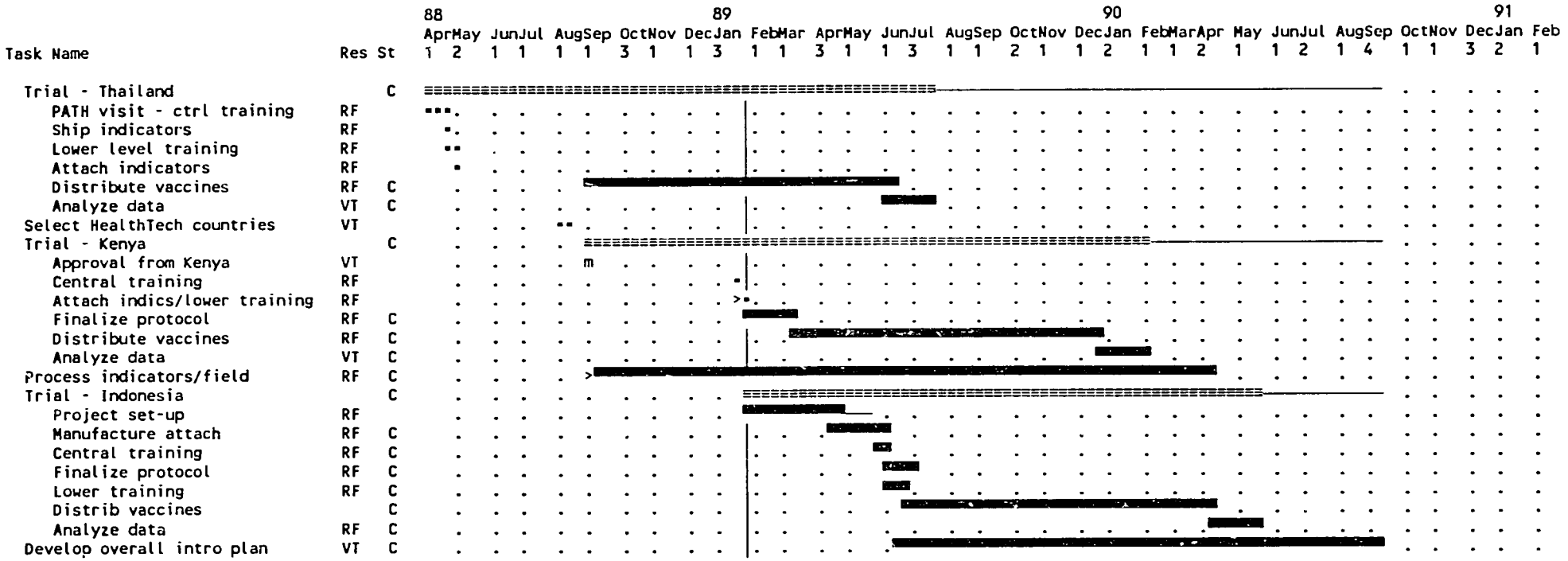
The missions in Indonesia, Kenya, and Thailand are fully informed. The mission in Indonesia may provide some support through funds for country-specific activity.

Expenditures to Date: $ 48,648

Future Expenditures Expected Through June 1989: $ 53,424

Schedule Name : PATHwatch/PATHmarker Cold Chain Monitors
Responsible : Vivien Tsu
As-of Date : 25-Jan-89 Schedule File : C:\TL3\DATA\PWATCH

Time-temperature monitors to help protect vaccines



Detail Task ===== Summary Task M Milestone
(Started) ===== (Started) >>> Conflict
(Slack) ===— (Slack) .. Resource delay

Scale: 6 days per character

TIME LINE Gantt Chart Report, Strip 1

HealthTech
Selection and Screening Activity
January 1989

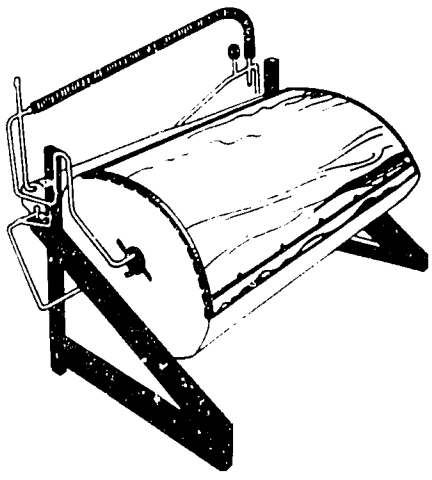
Type: B ; Stage: 1

Solar Refrigerator/Ice Maker

Solar-powered refrigerator and ice maker

Product Description

The Intermittent Solar Ammonia Absorption Cycle ice maker developed by Energy Concepts Company combines the dependability of the ammonia absorption cycle with other proven and highly reliable solar collector technology. The result is a design that incorporates simplicity, reliability, and affordability. This product is designed to be used in remote areas of developing countries where electricity is unavailable or unreliable.



Stage of Product at Inception of A.I.D. Funding

Under Health Link, PATH identified a company in Thailand (Pan Siam Engineering) interested in collaborating with Energy Concepts Company (ECC) of Annapolis, Maryland, on the field testing and local production of the solar ice maker. The two companies have signed an agreement and are collaborating on the design of two units to be used in a field trial.

Current Status

Work on this project has been carried out as a selection and screening activity. In January 1989 a work plan for this project was approved by A.I.D. A prototype unit will be shipped from Annapolis to Thailand in February or March 1989. The first stage of field testing will be carried out by Pan Siam and will assess the technical performance. The second stage of field testing will be organized by PATH and will involve the Thai Government EPI. A solar ice maker will be tested for acceptability in a rural field health center.

Rationale

PATH initiated this project under the Health Link program due to the significant impact on immunization programs which an efficient, economical solar refrigerator could have. Key childhood vaccines are all heat sensitive to some degree, so reliable refrigeration for storing vaccines in rural areas is an essential component of an effective immunization program.

Electricity is often not available on a reliable basis in rural areas. The alternatives are fuel-fired absorption refrigeration (kerosene or bottled gas), solar photovoltaic refrigeration, and solar thermal-powered absorption refrigeration. With kerosene refrigerators, problems are often experienced with the supply and quality of the kerosene or bottled gas. In addition, kerosene and bottled gas are increasingly expensive and, in some cases, have to be imported. Also, the refrigeration systems powered by fuel are reported to be unreliable and inadequate for ice making. Photovoltaic refrigeration systems require storage batteries, are relatively expensive, and are vulnerable to damage. Solar-powered refrigeration based on ammonia absorption has the potential for higher performance, lower operating costs, better reliability, and longer working life.

ECC's unit has the potential to be locally produced for less than $1,000. It has the capacity to produce enough ice for field administration of vaccines and can make additional ice to be used on days when there is not enough sun for ice production. The low initial cost and adequate ice making capacity makes the ECC unit an attractive alternative for remote health centers.

Performance Specifications

The unit should:

- Be capable of making between 15 and 30 kg of ice, or 16 to 24 ice packs (6 7/8" x 4 7/8" x 7/8") in a 24-hour period.
- Maintain the temperature of a freezer at -20°C.
- Maintain the temperature of a three cubic foot refrigerator at 6-10°C.
- Be designed so that an external solar collector can be connected through the wall of a rural health center to a refrigerator/freezer unit located inside.
- Be able to be produced in a developing country with the majority of components available locally.

Progress to Date

Work to date has been carried out by ECC under another A.I.D. grant. Design work is complete and specifications have been agreed upon. A prototype unit has been assembled and is being tested at ECC. Training of Pan Siam engineers has taken place

at ECC. Arrangements have been made to ship a unit to Thailand in February or March 1989. PATH and the Ministry of Public Health in Thailand are discussing the location and arrangements for a field trial to begin in mid 1989.

Future Plans

A product introduction plan for Thailand which will include market demand assessment, local manufacturing capability, distribution, user maintenance, implementation, and control will be prepared. Introduction of the technology to the Thai Government EPI (technology transfer and field testing) will be coordinated by HealthTech.

Title/Licensing Status

Licensing of the rights for local manufacture, assembly, and sale from Energy Concept Company to Pan Siam Engineering is expected to take place after successful completion of the field trials and local assessment phase.

Collaborating Institutions

Energy Concepts Company, Annapolis, Maryland; Pan Siam Engineering, Thailand; Thai Government EPI

A.I.D. Mission Involvement

The A.I.D. Mission in Thailand has been updated on these activities by PATH Thailand staff.

Expenditures to Date: Selection and Screening

Future Expenditures Expected Through June 1989: $ 15,043

HealthTech
Subproject Summary
January 1989

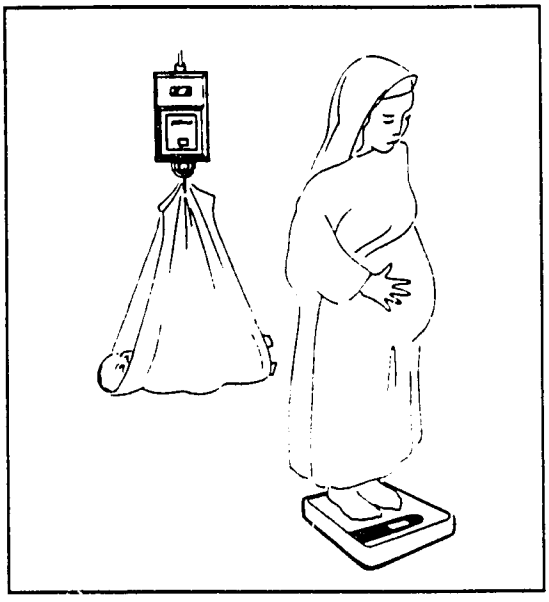
Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 28,864

PATHweigh[R]

Solar-powered electronic scale for growth monitoring of infants, children, and pregnant women

Product Description

The solar-powered PATHweigh scale was developed by Masstech of Australia in both hanging and stand-on versions. A mother or health care worker can stand on the scale and receive the infant in her arms for weighing, as the display can easily be reset to zero after placing a load of any size up to 150 kg on the scale. The digital display, which calibrates the weight in 100-gram increments, averages the weight of a moving load and is easy to read. The case is weatherproofed and sturdy for rugged use.



Stage of Product at Inception of A.I.D. Funding

The principle of this technology was devised by Peter Goodier of Masstech Proprietary Ltd., Oxley Cove, Australia, at the instigation of UNICEF Australia. A development company, Sensor International, Inc., was formed jointly by PATH and Masstech in 1987 in order to obtain financing and oversee the development of the scale. Both WHO and UNICEF provided funding for proof of concept and early development of the sensor.

Current Status

Twenty-six prototype hanging scales and 26 stand-on scales are nearing completion. Although the outside appearance of the case differs from the proposed final design, the inside components are close to the final manufacturing configuration. Thirty of the new prototypes will be made available directly to UNICEF under a separate agreement. The remaining 22 units will be available to HealthTech for laboratory and field evaluation. Direct HealthTech involvement will commence with the purchase of these prototypes.

Rationale

Periodic weighing of young children is a well-accepted technique for assessing adequate growth and nutrition. A variety of scales have been developed for use by health care workers and community members, but none of them successfully meet all the criteria for a good scale for primary health care programs.

A solar-powered, electronic scale has been developed in both hanging and stand-on versions that seems to meet all these criteria. The improved accuracy, portability, and ease of use of these scales should have a significant positive impact on health care workers' willingness and ability to do regular growth monitoring. Carefully monitored field testing should identify any final modifications needed in these technologies before large-scale manufacturing is initiated.

Performance Specifications

The scales should:

- Automatically calibrate the weight.
- Be accurate within 100 grams.
- Freeze the display with a dynamic average.
- Provide an easy-to-read display.
- Operate in a temperature range of 0-45°C.
- Be operable by 2V solar battery.
- Have a rustproof enclosure.
- Withstand brief immersion in water at zero pressure.
- Withstand a drop from one meter onto a concrete floor.
- Be physically robust in a variety of climates.
- Require only limited maintenance.
- Be inexpensive.

Progress to Date

The Sensor PATHweigh is accurate to 100 g, holds its calibration, tares automatically, automatically damps a moving load with its averaging function, has an easy-to-read digital display, and requires little maintenance. Field tests of an earlier version of the hanging scale which were carried out in Indonesia and Bangladesh by PATH in 1986 demonstrated the high acceptability, convenience, and accuracy of the large digital display which damps out the movements of the child, estimates the average weight, and displays a single result.

The hanging scale is portable and lightweight (0.5 kg) and has a capacity of 30 kg. The stand-on scale is also portable and has a capacity of 150 kg. It also has 100 g accuracy, so it offers the unique possibility of weighing a mother, taring her weight, and then weighing her child in her arms. The level of accuracy and reliability make it well suited to maternal weight gain monitoring where small incremental gains must be detected.

Many of the design features of the Sensor PATHweigh were field tested in an earlier strain gauge version of the hanging scale. The new version overcomes the key limitation of the strain gauge scale--dependence on batteries. The unique oscillating sensor has such a low energy requirement that it can be operated directly from a solar cell even under low light conditions.

Intensive efforts have focused on simplifying the suspension mechanism of the stand-on scale, thus reducing its cost. The usual system of mechanical levers and moving fulcrums used in standard platform scales has been replaced by a direct suspension system. This will lower costs and make the scale less vulnerable to shocks. It will also make weight distribution on the scale less susceptible to load placement error. Electronic circuit boards have been completely redesigned to allow for changing environmental conditions. The documentation required for large-scale chip production has been provided to an integrated circuit manufacturer. It is anticipated that the final circuit configuration will also be incorporated into the current prototypes.

Preparation for manufacturing has included identification of a copper-platable aluminum alloy for the load sensing component of the scale. Evaluation of current "super plastic" materials has identified three candidates for injection molding of the enclosure/platform of the stand-on scale. These plastics are relatively new and will permit a previously unrealized level of durability and environmental sealing. Current prototypes utilize cast and machined aluminum enclosures.

Individual components of the current prototypes have been carefully tested for temperature stability and have been exposed to physical stresses expected to be encountered in field use situations. Several components were found to be less than optimal and have been redesigned and refabricated. It is hoped that component testing will eliminate wholesale redesign after the scheduled laboratory and field trials.

Future Plans

Laboratory tests will quantify performance limits such as: the amount of light required to energize the device; the effects of off-center loading and uneven ground; accuracy, durability, and structural integrity. PATH will cooperate with Sensor on the design of the plastic scale enclosure and other components for manufacture. The lead time required for design and tooling for enclosure components is expected to be five months. Trial production will proceed after review of field tests. Several hundred to 1,000 units will be produced in a trial manufacturing run. These units will be available for initial placement in health care centers and for extended field trials.

Field trials will be designed to simulate routine use but with systematic monitoring and data collection occurring throughout. Technical performance according to specifications for accuracy, durability, ruggedness, and reliability will be validated. User acceptability and training requirements will also be evaluated. Field trials are expected to take six to nine months to complete.

Potential field sites for these tests have already been identified. The Aga Khan Health Service in Pakistan has been involved in evaluating the previous version of the hanging scale and is prepared to place new prototypes in a variety of settings within its programs. The A.I.D. Mission in Pakistan has also indicated interest in testing the scales in its rural health center ORT corners. The Safe Birth Program in Malawi has expressed great interest in a stand-on scale for maternal weight gain monitoring in its health centers. Through that project, the role of the stand-on scale as a universal scale for all clinic weighing needs could be evaluated. Ten hanging scales and 10 stand-on scales will be provided for field tests.

Title/Licensing Status

Sensor International, Inc., owner of the technology, was granted a U.S. patent in September 1988, and has filed for patents in Europe, Japan, and other selected Patent Convention Treaty countries, as well as Brazil and China. Sensor International, Inc., is 51% owned by Masstech Proprietary Ltd. and 49% owned by PATH.

Collaborating Institutions

WHO/MCH will review the technology for global application. A WHO/MCH bulletin has been prepared on the Sensor scale (see attachments). UNICEF will carry out field trials in India and at least two other countries. IDRC, the Aga Khan Foundation, and Oxfam have taken an active interest in the PATHweigh program in the past and continue to monitor its progress.

A.I.D. Mission Involvement

The Pakistan and Malawi missions have expressed interest in the project.

Expenditures to Date: $ 500

Future Expenditures Expected Through June 1989: $ 28,364

WHO/Maternal and Child Health

SCALE INFORMATION SHEET

UNICEF

REFERENCE # 8810

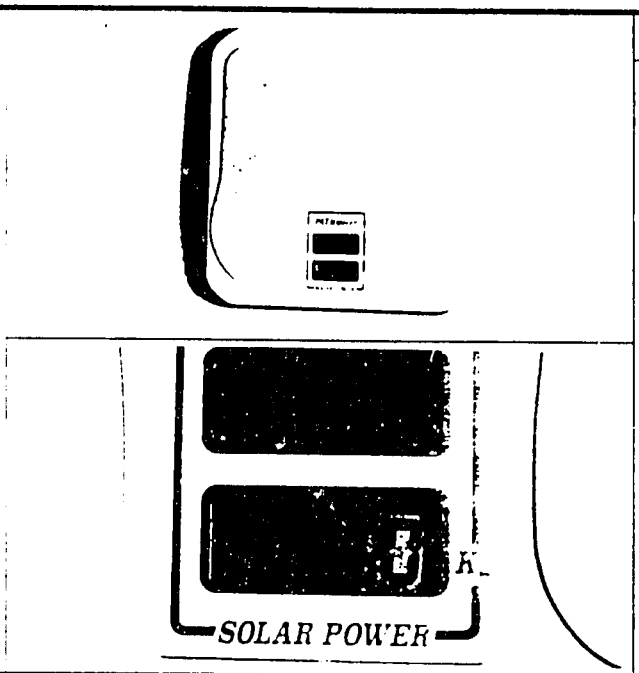
DATE: AUGUST 15, 1988

NAME PATHweigh® Solar Power (Preliminary)

TYPE: Floor/Electronic

SCALES FOR WEIGHING:

- Newborns ☑
- Children ☑
- Pregnant Women ☑



DESCRIPTION

Principle:
Vibrating beam

Accessories:
Pictorial instructions

Dimensions:
28 x 28 x 3 cm

Weight:
2 kg

Other:
Solar powered

CONTROLS, INDICATORS AND ADJUSTMENTS

Zeroing:
Activated by passing foot over the solar cell

Calibration:
Set at factory

Reading:
Digital LCD display indicates weight directly

Locking for Transport:
Power turns off automatically

Other:

PERFORMANCE

Maximum Weight:
140 kg

Smallest Division:
100 g

Maximum Tare: 140 kg

Accuracy/Precision: ±100 g

Damping: Yes

Automatic Features:
Zeroing, taring, damping, on/off

Power Requirements
Solar powered; operates under low fluorescent and incandescent light.

Maintenance Required:
Check calibration annually. Clean solar cell and digital display windows periodically.

OBSERVATIONS FROM THE FIELD

Advantages

Digital readout has good contrast and readibility; readout faces health worker

Easy to transport

Parallax errors are not possible

User has few operations to perform to obtain a weight

Because of the large tare, it is possible for mother or health worker to stand on the scale, adjust the scale to zero and be handed infants for weighing. Infant's weight is read directly.

Method of Use: 1) Pass foot over solar cell briefly and wait for display of 0.00; 2) stand mother on platform; 3) wait a few seconds for the weight to appear; 4) record weight of mother; 5) pass foot over solar cell briefly to return to 0.00; 6) hand baby to mother on scale; 7) record weight of baby.

RECOMMENDATIONS

- Appropriate for use by outreach clinics, fixed primary health care centers and referral centers

ORDERING INFORMATION

Sources	Reference	Cost
Sensor International, Inc.* *after mid-1989	Floor model	US$40 - $200 (depending on quantity)

WHO/Maternal and Child Health

SCALE INFORMATION SHEET

UNICEF

REFERENCE # 8809

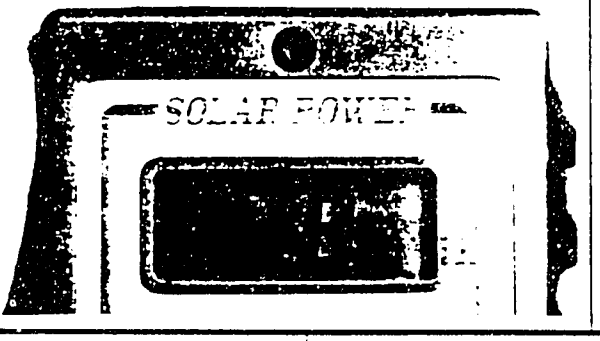
DATE: AUGUST 15, 1988

NAME PATHweigh® Solar Power (Preliminary)

TYPE: Hanging/Electronic

SCALES FOR WEIGHING:

- Newborns ✓
- Children ✓
- Pregnant Women



DESCRIPTION

Principle:
Vibrating beam

Accessories:
Pictorial instructions

Dimensions:
18 x 8 x 2 cm

Weight:
290 grams

Other:
Solar powered

CONTROLS, INDICATORS AND ADJUSTMENTS

Zeroing:
Activated by passing hand over the solar cell

Calibration:
Set at factory

Reading:
Digital LCD display indicates weight directly

Locking for Transport:
Power turns off automatically

Other:

PERFORMANCE

Maximum Weight:
30 kg

Smallest Division:
100 g

Maximum Tare: 30 kg

Accuracy/Precision: ±100 g

Damping: Yes

Automatic Features:
Zeroing, taring, damping, on/off

Power Requirements
Solar powered; operates under low fluorescent and incandescent light.

Maintenance Required:
Check calibration annually. Clean solar cell and digital display windows periodically.

OBSERVATIONS FROM THE FIELD

Advantages

Digital readout has good contrast and readibility

Easy to transport

Parallax errors are not possible

User has few operations to perform to obtain a weight

Disadvantages

Scale must be securely suspended from a supporting beam or tripod; test support structure before use to ensure safety

Method of Use: 1) Suspend scale with display at face level; 2) hang sling or weigh trousers from scale; 3) pass hand over solar cell briefly and wait for display of 0.00; 4) place child in sling; 5) wait a few seconds for the weight to appear; 6) record weight; 7) wait for scale display to return to 0.00, or pass hand over solar cell for display of 0.00.

RECOMMENDATIONS

- Appropriate for use by outreach clinics, fixed primary health care centers and referral centers

ORDERING INFORMATION

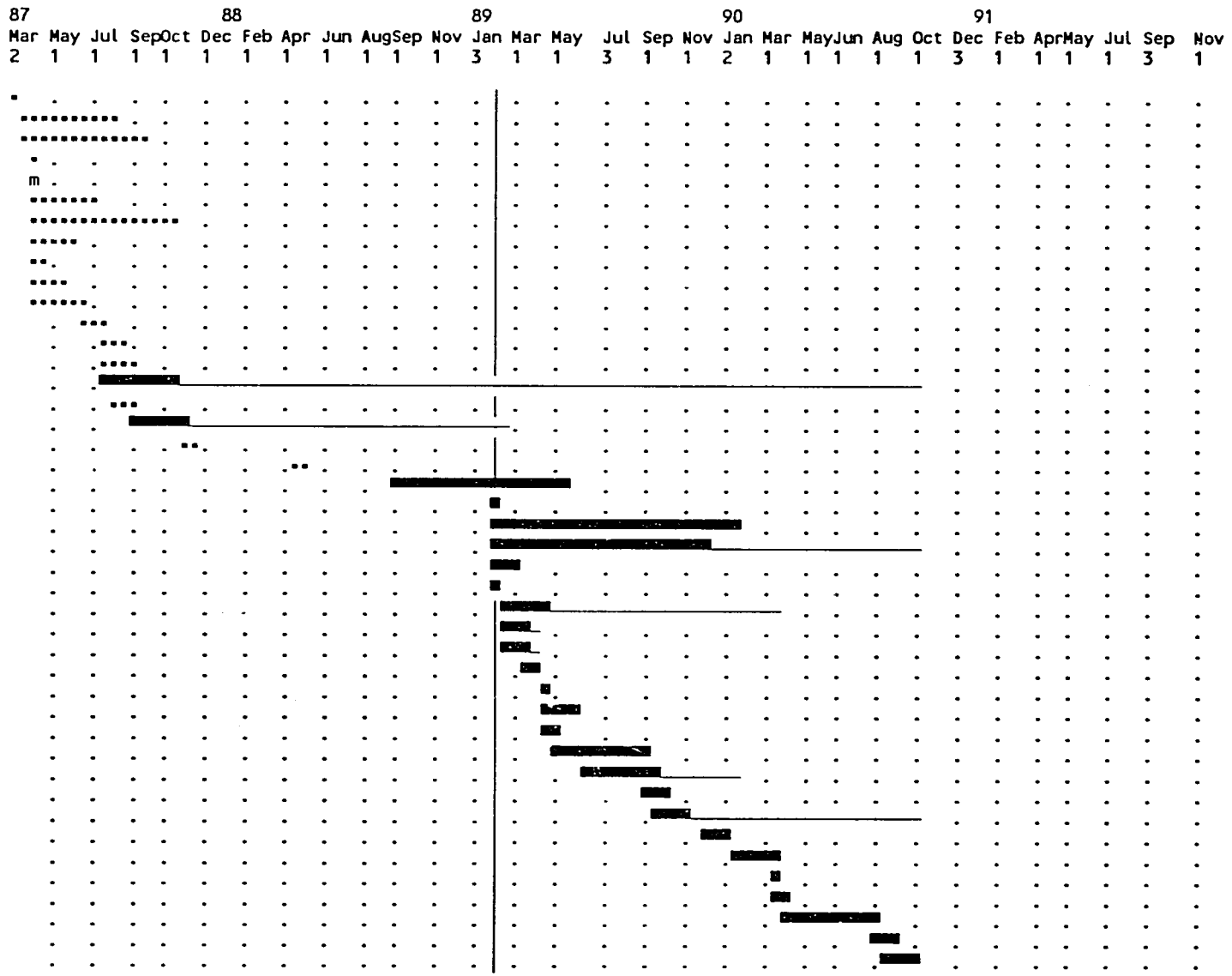
Sources	Reference	Cost
Sensor International, Inc.*	Hanging model	US$20 - $100 (depending on quantity)

*after mid-1989

Schedule Name : Sensor International Weighing Scales/PATHweigh
Responsible : Glenn Austin
As-of Date : 25-Jan-89 Schedule File : C:\TL3\DATA\SIS

Solar-powered hanging & walk-on scales

Task Name	Res	St
Rework sensor; reduce size	PG	
Solar cell sourcing	MF	
LCD +Zstrip sourcing	MF	
Set up machine shop	PG	
SIS agreement signed	PG	
US patent application	JT	
Identify OEM manufacturer	HM	
Design display algorithm	PG	
Hire toolmaker	PG	
Design, build sensor carrier	PG	
Test short sensor	PG	
Comp & select sensor config	PG	
Final. specs w/WHO, UNICEF	MF	
Complete LSI design	PG	
Build sensor; proof press tool	PG	
CAD workup; comp assembly mod	PG	
Masking chip	PG	
Confirm Malawi site	VT	
Confirm Pakistan site	VT	
Masking chip revision	PG+	C
Finalize protocol - Malawi	VT	
Production eng. & tooling	PG+	C
Advanced case design/tooling	MF+	
Hybrid prod./1st batch	PG	
Finalize protocol - Pakistan	VT	
Dvlp trng mat/forms-Malawi	VT	
Dvlp trng mtls, data form-Pak	VT	
Sign subagr. (if nec) - Pak	HM	
Final assembly/field ptypes	PG	
Central training - Pakistan	VT	
Assemble ptypes/other mkts	PG	
Local training - Pakistan	VT	
Field trial - Pakistan	VT	
UNICEF field trials	HM	
Return Pak scales to Sea	VT	
Data analysis/report - Pak	VT	
Final design review	PG+	C
Produce walk-on scales	PG	C
Central training - Malawi	VT	C
Local training - Malawi	VT	C
Field trial - Malawi	VT	C
Return Mal scales to Sea	VT	C
Data analysis/report - Malawi	VT	C



Detail Task ===== Summary Task M Milestone
(Started) ==== (Started) >>> Conflict
(Slack) ==== (Slack) .. Resource delay

Scale: 2 weeks per character

HealthTech
Subproject Summary
January 1989

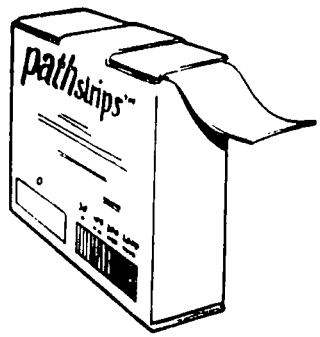
Type: B ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 40,415

PATHstrips™

A low-cost, color-coded test strip for detecting protein in urine

Product Description

PATHstrips are low-cost, ready-to-use dipstrip indicators of proteinuria. They are packaged in a convenient tear-off form which eliminates the need to prepare chemical reagents. To use PATHstrips, a health care worker tears a strip from the box and dips it into a urine sample; then the worker determines protein amounts by comparing the strip color to a color reference chart on the box. The presence of protein in urine (proteinuria) may indicate preeclampsia during pregnancy, urinary schistosomiasis, urinary tract infections, or kidney disease.



Stage of Product at Inception of A.I.D. Funding

PATHstrips were at the manufacturing and introductory stages of development at the inception of the HealthTech project. Prior to HealthTech, concept, feasibility, and development of the simple dipstrips, and laboratory and shelf life studies had been conducted. Preliminary manufacturing procedures were in place. Field testing by traditional birth attendants (TBAs) in Malawi, North Yemen, and Zambia, including use of training and instructional materials developed for PATHstrips, had been completed under other funding sources.

Current Status

The majority of current work on the PATHstrips project is directed towards transfer of the technology for producing the diostrips. Field testing showed that PATHstrips were generally well understood and able to withstand tropical environmental conditions. However, since diagnostics for proteinuria are not always available to both referral centers and TBAs, efforts are under way to identify manufacturers of PATHstrips in developing countries. Preference will be given to a pharmaceutical facility in an African country with a TBA training program and/or a strong system of antenatal care.

Rationale

Hypertensive disorders of pregnancy (HDP) are a leading cause of maternal mortality and fetal death. There are no clear cut signs or symptoms for diagnosing HDP, so urine analysis is critical to determining the need for early intervention. Commercial dipstrips for urinary protein have long been accepted as a convenient and accurate diagnostic for hypertensive disorders of pregnancy (toxemia) and renal disease, and in more recent years for urinary schistosomiasis. Their high cost per test (US$0.10 or more) and the need to import them precluded developing countries from using them routinely for screening.

PATHstrips is based on a color change, has a good shelf life, is suitable for local production, and is expected to cost US$0.01 to US$0.02 per test. WHO/MCH has indicated its interest in helping identify potential local producers because it feels the technology could play an important role in its strategy of identifying high-risk women and targeting services for them.

Since PATHstrips is color coded and requires no mixing of reagents, it can be used by TBAs as well as more highly trained health workers. The dipstrip was tested in PATH's Safe Birth Program, where it was demonstrated that TBAs can carry out the test and that mothers give urine samples without difficulty.

Performance Specifications

The dipstrips should:

- Change color only if protein is present in the urine sample.
- Not change color when dipped in normal urine, which contains only trace amounts of protein.
- Be sensitive to 10 mg/dl albumin and accurate to ±100 mg/dl albumin.
- Provide results within one minute.
- Have a shelf life of at least three years at 23°C and at least one year in tropical environmental conditions.
- Cost less than US$0.05 per test.
- Require minimal training of health workers.

Progress to Date

A pilot manufacturing operation was set up in the PATH laboratory during August 1987 to test the existing manufacturing equipment and identify equipment that needed replacement or redesign. A manufacturing manual has been drafted to aid the technology transfer and serve as a technical reference for the manufacturer. The pilot operation manufactured enough treated paper to make 1,000 rolls of PATHstrips. Labels were redesigned with a

color chart, logo, and instructions to incorporate input from the 1985-1986 field trials in Malawi, North Yemen, and Zambia. The color chart was changed to emphasize the difference between negative and positive results of protein in urine.

Current efforts focus on identifying a manufacturer of PATHstrips in a developing country, preferably in Africa. Proposals from two pharmaceutical companies in Zimbabwe have been solicited. Guidelines to aid in the selection and identification of an appropriate manufacturer have been developed and are being disseminated.

Future Plans

Once a developing world manufacturer for PATHstrips has been identified, a license will be drafted to clarify the terms of the technology transfer, including a guarantee of low price to the public sector and a clause on quality assurance. The technology transfer will take place using the manufacturing manual and a set of custom equipment leading to the establishment of a low-cost production facility. Continuous quality assurance monitoring and introductory activities are anticipated, as well as creation of a distribution network for the dipstrips, perhaps with UNICEF involvement.

PATHstrips are very similar in appearance and behavior to an existing commercial product; it is anticipated that introduction will begin with substitution for the imported product and will rapidly expand from there. Since many TBA training programs are now emphasizing antenatal screening, the dipstrips would fit easily into the curriculum.

Title/Licensing Status

This technology is not under a patent. Nonexclusive licenses are available from PATH on a royalty-free basis.

Collaborating Institutions

None at present.

A.I.D. Mission Involvement

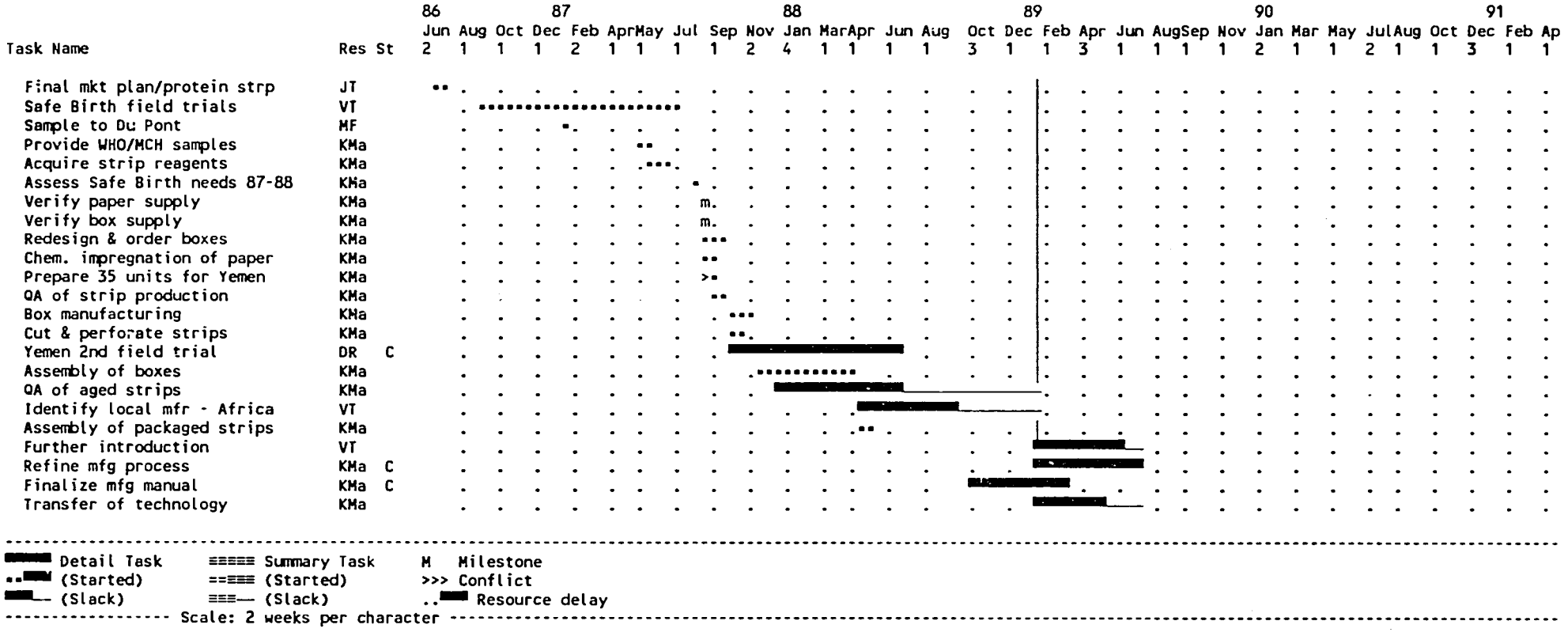
The A.I.D. Mission in Zimbabwe has been briefed on exploratory contacts with the two pharmaceutical companies.

Expenditures to Date: $ 3,024

Future Expenditures Expected Through June 1989: $ 37,391

Schedule Name : PATHstrip
Responsible : Katherine Mack
As-of Date : 24-Jan-89 Schedule File : C:\TL3\DATA\PATHSTRP

Low-cost paper dipstrips to detect protein in urine



Detail Task ==== Summary Task M Milestone
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Scale: 2 weeks per character

TIME LINE Gantt Chart Report, Strip 1

Noninvasive Hematocrit Instrument

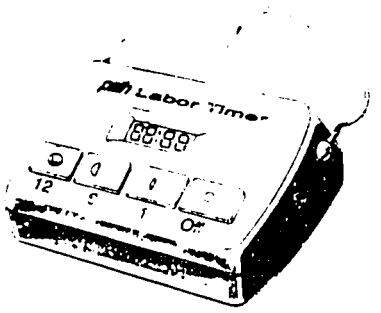
This technology is covered by a confidentiality agreement. The report on the technology can be reviewed after a confidentiality agreement has been signed. The report and the agreement will be available from Gretchen Shively at the TAP meeting on February 1, 1985.

Labor Timer

A simple electronic timer that provides a signal at the end of each stage of labor

Product Description

The Labor Timer is a small electronic "countdown" timer that is used for monitoring the stages of labor. It can be easily set by depressing one of its picture-coded buttons which sets off an audible and visible signal indicating prolonged labor or retained placenta. This signal provides a cue for intervention, referral, or the need for transportation to a clinic setting during the first, second, and third stages of labor.



Stage of Product at Inception of A.I.D. Funding

Concept and performance criteria for the Labor Timer were developed under the Safe Birth Program, a PATH needs assessment and technology introduction program involving focus groups of traditional birth attendants in Malawi, North Yemen, and Zambia.

Current Status

The Labor Timer is undergoing review and feasibility assessment outlined by PATH's selection and screening procedures. Similar devices that could be adapted for use as a Labor Timer are available for demonstration.

Rationale

The stages of labor are timed as a way of discriminating between normal labor and dysfunctional labor which requires intervention. Numerous preventable maternal deaths occur when traditional birth attendants (TBAs), unaccustomed to timekeeping, allow labor to proceed for a prolonged period without taking necessary action. The phases of labor are easily timed; if a phase lasts longer than it should, intervention is indicated. First-stage intervals of 12 hours for primiparous women and six hours for multiparous women are appropriate. If the second stage lasts longer than one hour, the mother risks rupture of the lower uterine segment and the fetus is at risk. If the third stage lasts longer than an hour, this indicates a retained placenta and a high risk of infection or hemorrhage. Although options for intervention are limited, referral to a higher level of health care is often feasible if the decision to do so is not delayed too long. Most labor complications can be corrected if treated in time.

Most TBAs do not own or are unable to use a watch or clock. An individual's sense of time may be limited to the length of the day and night, or the time it takes to cook rice or other staples. Attempts have been made to use hourglass-style timers to aid TBAs, but because of the long time interval involved in the first stage of labor, the lack of an audible signal, and the inability to immediately reset such a timer for the second stage, they have not proven successful.

The Labor Timer would not require the operator to read numbers or "tell time." It would give an immediate audible signal and a symbolic visible signal at the end of a time period. It would also permit instantaneous reset for the onset of each phase of labor. Setting the timer would be as easy as pushing a button coded for first stage *prima*, first stage *multi*, or second (or third) stage.

Performance Specifications

The device should:

- Produce an audible signal, tested to at least 20 meters distance.
- Display the time remaining until zero, and then display an appropriate symbol.
- Be lightweight and compact.
- Have a neck strap so it can be worn by the patient or the TBA.
- Be capable of operating for at least five years on one battery (lithium).
- Display symbols on buttons which have been tested for comprehension by at least 90% of TBAs.
- Count down at preset intervals of twelve hours and one hour.

- Require minimal training.
- Have a unit price of less than US$3.00.

Progress to Date

Early designs of plastic water bags which measured time by the flow of water from one compartment to another proved unworkable in prototype testing. Timed intervals changed with water quality and with multiple uses. It was noted that the timing device had to be very easy to use as the birth process can completely preoccupy the birth attendant.

Sketches, prototypes, and a description of the electronic Labor Timer were presented at the Safe Birth workshop in Zimbabwe in November 1988.

Several commercial timing devices have been examined. After analysis, it was determined that one of the timers could be adapted to operate with three preset times with minimal modification and no new tooling for manufacture of the timer case. Inquiries are being made to locate the manufacturer of this device to ascertain their willingness to manufacture modified timers for this application. If prototypes are produced, they will be tested using the Safe Birth network.

Future Plans

PATH will continue to assess need and demand in this area before proceeding with development work. The relatively large quantity of devices required to achieve a target price of US$1 to US$3 per unit (at least 20,000 units) dictates that demand be guaranteed before proceeding.

Title/Licensing Status

Timers reviewed by PATH carry patent marks. The specific status is unknown.

Collaborating Institutions

IDRC and the Carnegie Corporation have assisted in the needs assessment as part of the Safe Birth Program.

A.I.D. Mission Involvement

Field activities to be determined.

HealthTech
Subproject Summary
January 1989

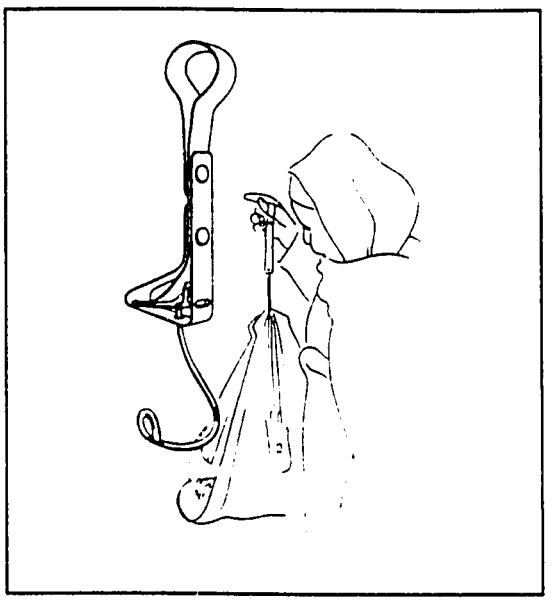
Type: A ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 51,393

BIRTHweigh™

A hand-held, color-coded scale for identifying low birth weight newborns

Product Description

BIRTHweigh is a portable, color-coded spring scale made from a band of stainless steel. A viewing window on the handle reveals a simple yes/no color indicator. The newborn baby is placed in a cloth sling suspended from the scale; any yellow color in the window indicates weight of less than 2,500 grams and the need for special care, while solid blue indicates the baby's weight is normal. BIRTHweigh gives traditional birth attendants and health care workers a simple and accurate way to assess the newborn's weight in the home or at a health center.



Stage of Product at Inception of A.I.D. Funding

BIRTHweigh prototypes were extensively laboratory tested and refined prior to the inception of HealthTech. Initial prototypes were assessed in a large nutritional project in Egypt and refined prototypes were field tested in Malawi, North Yemen, and Zambia. The manufacturing technology was transferred to Malawi. At the inception of HealthTech funding, BIRTHweigh was in the manufacturing and introduction stages of development.

Current Status

BIRTHweigh is currently manufactured in Malawi and is available to countries interested in field testing and introducing the scales into national health programs. Quality assurance and technical assistance for the Malawi manufacturing site is ongoing. For policy and decision makers in countries interested in introducing the BIRTHweigh scale into antenatal health programs, information packets describing BIRTHweigh and the impact of the scales on a country's policies and programs are being prepared and distributed.

Rationale

Low birth weight (LBW) is a well-known indicator of risk for newborns. Since a large majority of infants in developing countries are delivered by nonliterate traditional birth attendants (TBAs) outside of health facilities, PATH developed the BIRTHweigh scale to enable TBAs to identify LBW infants in the home. The scale provides a simple yes/no color indication if the infant is below the international standard of LBW (2,500 grams). Identification of LBW infants can enable health care workers and mothers to provide babies with the special care they need. The scale can provide communities with an epidemiologic tool for assessing need and evaluating interventions.

Many countries have determined that TBAs are and will continue to be important providers of maternal and newborn care. In addition to special training, they need to have appropriate tools. BIRTHweigh is uniquely suited to this need because of its low cost, its potential for local production, and its color-coded, easy-to-read display.

BIRTHweigh has already proven successful and well accepted by TBAs in four countries, and is being field tested in a fifth. Local production has been established in one African country (Malawi). It is anticipated that, after pilot introduction is complete, rapid expansion to a nationwide introduction will be feasible.

Performance Specifications

The device should:

- Be accurate within ±100 grams.
- Be color-coded for use by nonliterates.
- Be lightweight and compact for easy transportation in midwifery kits.
- Be calibrated to a set point of 2,500 grams.
- Have a fixed tare of 100 grams.
- Be durable and accurate for up to five years.
- Suspend a maximum weight of 20 kg.
- Protect the spring from overstretching.
- Be easy to use, with few operations to perform to obtain a weight.
- Be inexpensive for purchase by ministries of health for use by TBAs (less than US$2.00 per scale).
- Require minimal training.

Progress to Date

Technology transfer of the BIRTHweigh manufacturing process to the Polytechnic Institute in Malawi occurred in August 1987. The Polytechnic Institute began producing the scales for regional use in late 1987. To ensure that quality was being maintained during manufacture of the scales, the PATH laboratory conducted quality assurance testing on the first 300 scales; they were found to be satisfactory. Some of these scales are now being used in field trials in Sierra Leone and Somalia.

For the purpose of the introduction activities, a BIRTHweigh introduction packet is being designed. The packet consists of two independent parts. The first part is designed with policy makers and decision makers in mind, and includes background information on BIRTHweigh, a brief summary of the results of the field trials, and an outline of the major policy and programmatic issues that need to be addressed when considering nationwide introduction of BIRTHweigh. The second part of the packet consists of a more detailed introduction plan. It includes a training manual for TBA trainers, a guide for local adaptation of the BIRTHweigh instructional booklet and recording form, a sample of the booklet used in one of the field trials, a training manual outlining the calibration procedure for the BIRTHweigh scales, the pattern for the local manufacture of the BIRTHweigh sling, and a general guide to planning the introduction activities.

Future Plans

The introduction packet will be sent to countries that have expressed an interest in the BIRTHweigh scale as well as to countries that are seen as potential users of the scale. In addition to introduction efforts, efforts are underway to set up local production of the scale in several sites that can serve domestic as well as regional markets. Local production will be established in another country, most likely Egypt or Pakistan. Technical support to the manufacturing sites will be maintained to ensure quality of the scales and replacement of worn equipment.

Title/Licensing Status

BIRTHweigh was developed by PATH without U.S. government funding. No patent has been applied for. The concept and technology are available for nonexclusive licensing on a royalty-free basis.

Collaborating Institutions

Manufacture of the scales is conducted by the Malawi Polytechnic Institute.

A.I.D. Mission Involvement

Mission staff in Malawi and Egypt have been informed of the activities.

Expenditures to Date: $ 8,473

Future Expenditures Expected Through June 1989: $ 42,920

Schedule Name : BIRTHweigh
Responsible : Katherine Mack
As-of Date : 24-Jan-89 Schedule File : C:\TL3\DATA\BIRTHWGH

Simple weighing device for risk assessment of newborns

Task Name	Res	St	86 Mar 3	May 1	Jul 1	Sep 2	Nov 3	87 Jan 2	Mar 2	May 1	Jul 1	Sep 1	Nov 2	88 Jan 4	Mar 1	May 2	Jul 1	Sep 1	Nov 1	89 Jan 3	Mar 1	May 1	Jun 1	Aug 1	Oct 2	90 Dec 1	Feb 1	Apr 2	May 1	Jul 2	Sep 4	Nov 1	91 Jan 2
Field trial oral report	VT																																
Production - 30 units	MF																																
Refinement testing	DO																																
Egypt trial written report	VT																																
Send 12 units to WHO/MCH	MF																																
WHO/MCH lab tests	MF																																
Safe Birth field trials	VT																																
Receive WHO test results	MF							m																									
30 BW & 70 slings to Zambia	DR								m																								
Construct 20 [illegible] for WHO/MCH	DO																																
Submit PO - jigs, dies, manual	MF																																
Produce prod. manual & jigs	MF																																
Inspect jig drawings	MF																																
Pilot production, Seattle	MF																																
Technology transfer - Malawi	MF																																
Pick other local mfr sites	VT																																
Yemen 2nd field trial/Safe B.	DR	C																															
Identify 2d site local prod	VT																																
Refine tools & mfr manual	MF																																
Quote replacement equipment	KMa																																
Develop local training mtls	VT	C																															
Train supervisors & TBAs	VT	C																															
Field assessment	VT	C																															
Technology transfer	MF	C																															
QA follow-up	MF	C																															

Detail Task ===== Summary Task M Milestone
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TIME LINE Gantt Chart Report, Strip 1

HealthTech
Subproject Summary
January 1989

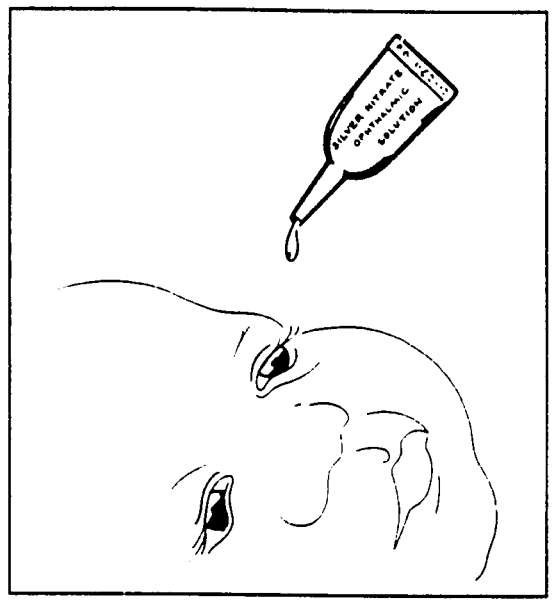
Type: B ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 15,536

Eyedrop Unit-dose Delivery System

Unit-dose package with dispensing capabilities for eyedrops

Product Description

This system is a single-use dispenser for silver nitrate or tetracycline ophthalmic solutions especially for dispensing eyedrops into newborns. It provides long shelf life and stability, well-controlled fluid delivery, and protection against cross-contamination. The current configuration is a polypropylene cone-shaped tube with a twist-off stopper. An individual foil overwrap is tamper resistant and provides a vapor barrier. The plastic vial and overwrap are printed with instructions.



Stage of Product at Inception of A.I.D. Funding

This product, in various forms, has been in trial studies within WHO/MCH since before October 1986. The package configurations currently under consideration have been in production and use by the contract packaging firm of CP Packaging (Jamesburg, New Jersey) for delivery of other fluids for the past six years.

Current Status

Numerous candidate packages currently available from packaging contractors have been identified. The best candidate so far is available at a low cost of below US$0.04 per unit. The contractor has USFDA Class II designation and previous experience with silver nitrate packaging. Final checks are under way to determine which tests of the best configuration are required by USFDA. Samples of the candidate package are available.

Rationale

Purulent conjunctivitis of the newborn caused by *Neisseria gonorrhoeae* is a serious and potentially blinding condition, well-known in most parts of the world. Studies have shown that 30% of babies exposed to infection during birth will develop gonococcal conjunctivitis if a preventive measure is not applied. The incidence of the disease can be reduced to 2% if silver nitrate prophylaxis is used. The disease can be effectively prevented by the installation of silver nitrate drops into the eyes of the newborn child. A preventive approach to this disease has become particularly important in light of the increase in antibiotic-resistant forms of gonorrhea.

The procedure, carried out immediately after birth, consists of cleaning the infant's eyelids and dispensing a 1% silver nitrate solution into the conjunctival sacs. Silver nitrate is inexpensive, and the procedure can be carried out by traditional birth attendants and other community health workers.

Silver nitrate does cause some irritation, and actual damage to the eye has occurred after the application of silver nitrate solution that has become more concentrated through evaporation. Because of this, there is a need for single-dose packaging of silver nitrate, thereby avoiding the continual opening and closing of a bottle in long-term storage. Single-dose packaging should not substantially increase the cost of the intervention, and should allow for effective dispensing of the solution while providing adequate protection from light during shelf storage. Single-dose packaging currently exists in the form of plastic capsules (from France) and wax capsules (USA). However, these are expensive, costing from US$0.08 to US$0.35 per dose. Packaging comparable to the proposed product is approximately US$0.15.

Proper single-dose packaging can eliminate both overconcentration and cross-contamination. The silver nitrate package developed by PATH will eliminate past problems and add the features of excellent fluid delivery characteristics and guaranteed single use.

PATH's target cost is less than US$0.05 complete. This price reduction, combined with a well-tested resistance to vapor loss, should make silver nitrate attractive to health care programs in countries with high incidence of gonococcal *Ophthalmia neonatorum*.

Performance Specifications

The dispenser used for silver nitrate should:

- Have a 0.5 ml capacity
- Dispense solutions or slightly viscous emulsions in controlled drops, without need for the nozzle to touch the eye or surrounding tissue.

- Provide barrier properties which will maintain a 1% concentration of aqueous solution in extreme climatic conditions without exposure to ultraviolet light, vapor loss, oxidation, or tampering.
- Have a nozzle that will not cause damage if it accidentally comes in contact with the eye.
- Discourage or prevent reuse.
- Have a very low cost (less than US$0.05).
- Require minimal training.

Progress to Date

Several dozen manufacturers and contract packagers have been identified and their products evaluated. In early 1988, 200 trial foil package prototypes were produced and placed in lab and field trials under the auspices of WHO/MCH. These packages proved to be vulnerable to leaks and minor vapor loss, and did not deliver an easy-to-administer drop form. A number of other packages were obtained and rejected due to poor sterility documentation, non-USFDA registered facilities or materials, poor fluid drop formation, inadequate vapor barrier properties, or high prices.

A New Jersey manufacturer has been located with a long and well-proven record of packaging pharmaceuticals and an USFDA Class II-rated facility. The package used is of a polypropylene material which carries an USFDA master file and provides extremely sturdy protection against rough shipment and storage conditions. This package also provides a twist/break-off stopper that discourages recapping and reuse. Each unit-dose vial will be coded with an expiration date and lot identification. Individual foil overwraps will provide a vapor barrier and protection against ultraviolet light and environmental exposure. Each overwrap may be printed with instructions, warnings, and full identification of the product.

Future Plans

PATH will order a sufficient quantity of prototypes for laboratory and initial field tests. If laboratory tests for compatibility and stability show the current product configuration to be unacceptable, a second choice from the pool of previously rejected package configurations will be reexamined. If laboratory tests indicate acceptability, PATH will offer 500 to 800 units for inclusion with WHO/MCH field testing now in progress.

The investigation that has been undertaken for eyedrop unit-dose packaging of silver nitrate will be evaluated for possible applications in other unit-dose delivery system packages such as vitamin A and iodized oil.

Title/Licensing Status

This product is a new application of an existing package made by CP Packaging, Jamesburg, New Jersey, for dispensing other fluids. The patent and title status are unknown.

Collaborating Institutions

The following institutions have provided information and may coordinate field tests: WHO/MCH and the International Eye Foundation.

A.I.D. Mission Involvement

Field activities to be determined.

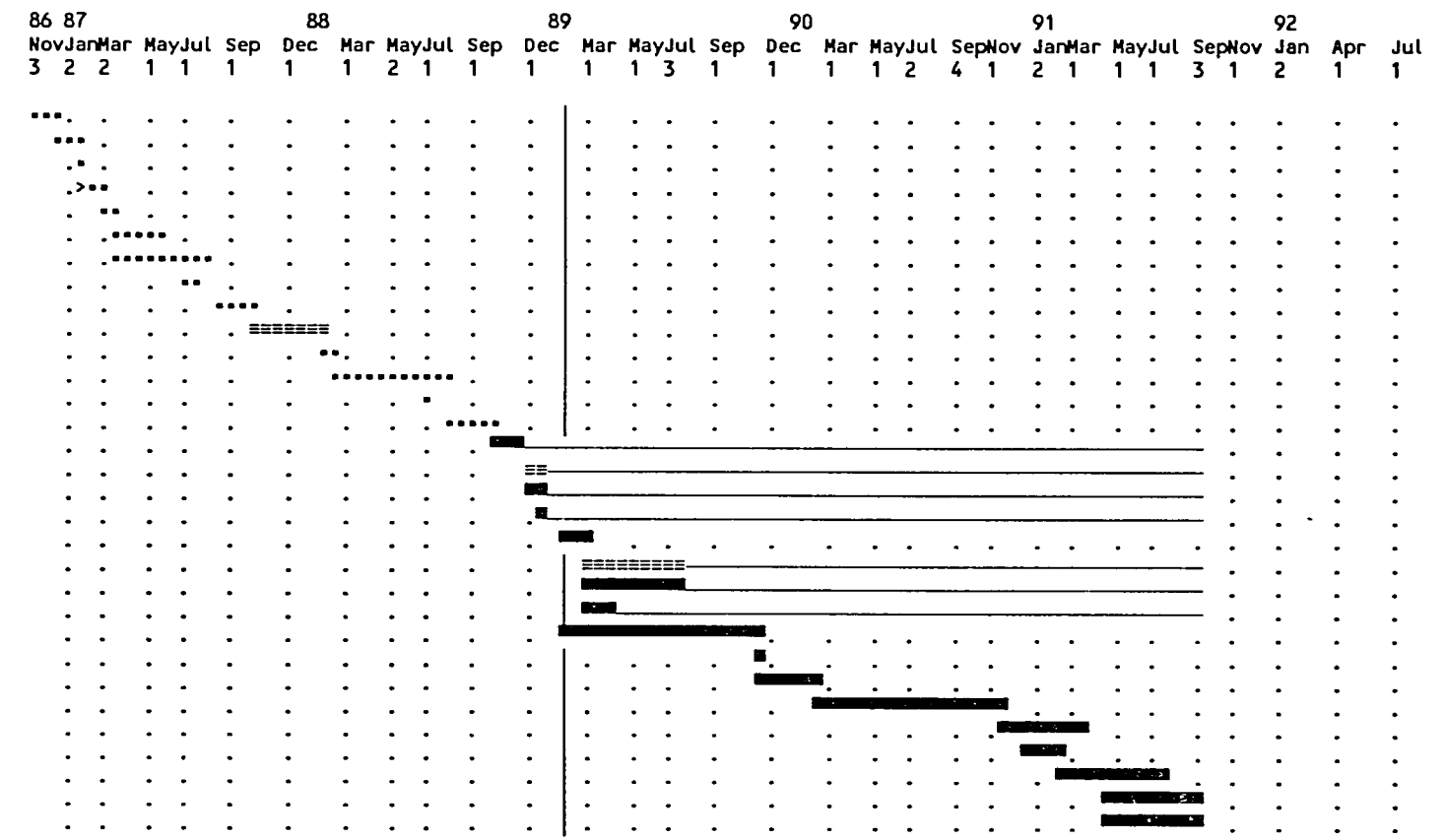
Expenditures to Date: $ 2,530

Future Expenditures Expected Through June 1989: $ 13,006

Schedule Name : Eyedrop Unit Dose Dispensers
Responsible : Glenn Austin
As-of Date : 24-Jan-89 Schedule File : C:\TL3\DATA\EYEDROP

Flexible plastic pouches containing single doses ...
nitrate: for use

Task Name	Res	St
Design to preliminary specs	MF	
Construct 1st prototype	MF	
Lab test 1st prototype	MF	
Reconstruct 1st prototype	MF	
Send samples to WHO/MCH	MF	
WHO/MCH prelim validation	VT	
Shelf test	KMa	
Safe Birth focus group	DR	
Construct improved ptypes	MF	
+ Lab test improved ptype	KMa	
Send WHO/MCH improved smpls		
Shelf test improved ptypes	KMa	
Tests unacceptable		
Review existing products	Li+	
Contact manufacturers	GA+	
Evaluate capabilities	GA	
FDA master file?	GA+	
Pricing comparison		
Order samples		
Lab tests (stability etc.)		
Stability tests	Co+	
Bio-tests	Co+	
Field tests		C
Tests unacceptable		C
Construct new design	RT	C
Shelf test new design	KMa	C
Prelim. fld test/Safe Birth	VT	C
Construct 2000 units	KMa	C
Field test w/ WHO/MCH	VT	C
Develop manufacture manual	MF	C
Identify local mfr site	CMc	C



Detail Task ===== Summary Task M Milestone
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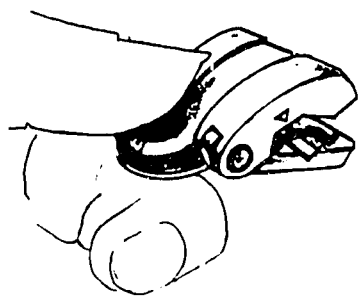
TIME LINE Gantt Chart Report, Strip 1

Umbilical Cord Safety Clamp

A small device which in one motion cuts and clamps the umbilical cord in a clean, safe manner

Product Description

This hand-held clamp cuts and clamps the umbilical cord in one motion. The user simply depresses opposing thumb rests and clamps the device over the umbilical cord. When in the clamped position, the device protects the cut end of the umbilical cord from infection. After use, the knife is embedded in plastic and both it and the unused clamp are disposed of. The applicator may be retained for reuse.



Stage of Product at Inception of A.I.D. Funding

The concept and performance criteria were developed under the Safe Birth Program, a PATH needs assessment and technology introduction program involving focus groups of traditional birth attendants in Malawi, North Yemen, and Zambia.

Current Status

Feasibility studies are under way, based upon concept drawings and descriptions. No prototypes have been produced.

Rationale

Neonatal tetanus is a major cause of newborn fatalities, particularly in countries where cultural practices involve the application of soil, ashes, or dung to the newborn's umbilical cord immediately after birth. Delivery kits supplied to traditional birth attendants usually contain cotton ties and a new razor blade. Instructions specify boiling and sun drying of cloth ties and disinfection of the cutting instrument. Since both the ties and blade may be diverted for purposes other than delivery, sterility and availability are not guaranteed. The ties may be dipped in disinfectant but will not prevent infection at the cord end.

The umbilical cord clamp and cutter components would be provided in sterile packaging and would not be reusable. The clamps would protect the cord end from contamination by their shape. An additional bonus of the pressure cut and clamp action is the release of thromboplastin, a clotting agent in blood, and the promotion of blood vessel contraction.

Performance Specifications

The device would:

- Have a concealed blade with means to permanently incapacitate the blade after use.
- Have clamps on either side of the knife with an [illegible]icator configured to ensure proper placement of the clamp in relation to the abd[illegible]
- Be completely moldable, with no metal parts [illegible]an the blade.
- Have a clamp which remains on the cord stu[illegible] is configured for comfort even when the infant is on its stomach.
- Be very low in cost (less than US$0.03).
- Require minimal training.

Progress to Date

The concept sketch and product description were presented at the Safe Birth workshop in Zimbabwe in November 1988. Participants were very interested; one suggested color-coding the different sections to make it easier to train traditional birth attendants how to use them.

The preliminary design for validation of manufacturability is complete. The preliminary cost analysis is complete; the target cost is thought to be conservative. Obstetricians have been identified who are willing to collaborate in further feasibility investigations.

Future Plans

Evaluations of the cord clamp will be conducted with the aid of several obstetricians. Areas of investigation include the force required to cut the umbilical cord cleanly, and the clamping force and geometry required to clamp the cord successfully. Current practices will be studied and currently used devices will be obtained for analysis.

If feasibility studies continue to show that the device has potential, a "sketch model" will be constructed to illustrate its function and check geometry. After review of the sketch model by medical practitioners, a modular prototype or "breadboard" will be constructed to test specific functional aspects. This prototype will be tried in laboratory conditions and modified as needed. Limited clinical testing will take place on a small number of prototypes created to model all functions of the proposed product. Preproduction prototypes will be produced and tested in a wider clinical program, including the Safe Birth Program. At this time, demand for the product in developing countries will be reassessed.

Upon successful completion of testing of preproduction prototypes, a final design will be documented in drawings and analyzed for structure and dynamics. Tooling (molds) for injection molding will be produced and a first run of molded parts will be hand assembled for field tests.

Title/Licensing Status

Several U.S. patents for similar devices have been identified. It is possible that a license for a device with an existing patent will be necessary to continue development; however, the PATH design is substantially different from patented designs.

Collaborating Institutions

None at present.

A.I.D. Mission Involvement

Field activities to be determined.

Type: C ; Stage: 2
Budget: Year 1 $ 0
Year 2 $ 10,000

Urinary Iodine Dipstick

A simple field test to measure urinary iodine

Product Description

Urinary iodine assessment is the main indicator used for identification and evaluation of iodine deficiency disorders. Until now, this test has required laboratory facilities and trained personnel. The product under development will allow low-level personnel to do rapid field assessment of urinary iodine levels.

-- Drawing unavailable --

Stage of Product at Inception of A.I.D. Funding

Initial research was carried out by Dr. John Dunn at the University of Virginia at Charlottesville. The major technical issues remaining to be resolved are the effect of impurities in the urine, characterization of the color change, and stability of the final product under tropical conditions.

Current Status

The project has been approved by A.I.D. and work has begun on development of a prototype. Dr. Dunn is conducting a feasibility study of the concept under a subcontract with PATH.

Rationale

Over 800 million people live in areas deficient in dietary iodine. Of those, approximately 200 million have a demonstrable iodine deficiency disorder (IDD). IDD includes hypothyroidism, goiter, reproductive failure, and cretinism. Recent studies suggest that, in addition to these easily recognizable disorders, many more children and adults suffer from less obvious mental impairment due to iodine deficiency. IDD programs depend on measurement of urinary iodine in order to target populations and evaluate intervention outcomes. Urinary iodine assessment currently requires laboratory facilities and highly trained personnel. This product would simplify field assessment of urinary iodine.

Performance Specifications

The device should:

- Have a consistent color change despite impurities in urine samples.
- Have a color change that is easily evident upon visual inspection.
- Be stable for at least one year under tropical conditions.
- Be inexpensive.
- Require little training for correct use.

Progress to Date

The subcontract to the University of Virginia was arranged in October 1988. Dr. Dunn and his staff are working on a prototype. An interim report on their progress is due in May 1989.

Future Plans

PATH will assess prototypes when they are available.

Title/Licensing Status

The core technology is the property of Dr. Dunn of the University of Virginia. Preliminary discussions are under way on ways to assure general availability of ensuing products.

Collaborating Institutions

University of Virginia at Charlottesville

A.I.D. Mission Involvement

Field activities to be determined.

Expenditures to Date: $ 4,000

Future Expenditures Expected Through June 1989: $ 6,000

HealthTech
Subproject Summary
January 1989

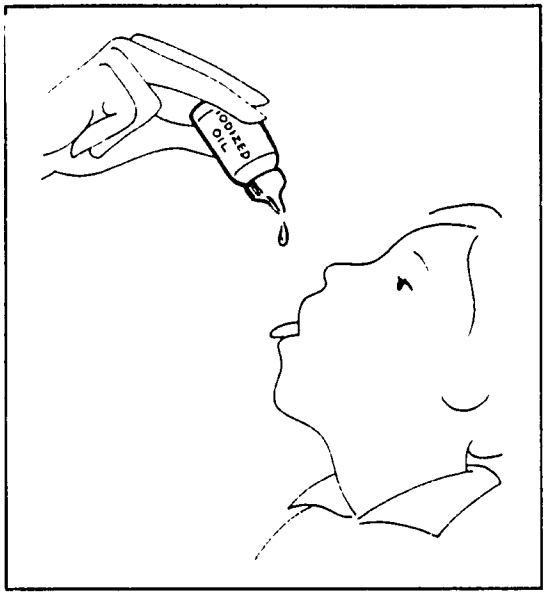
Type: C ; Stage: 4
Budget: Year 1 $ 0
Year 2 $ 22,647

Iodized Oil

Iodized oil is given either orally or by injection to prevent or treat iodine deficiency disorders

Product Description

Iodized oil is a prophylactic or treatment for iodine deficiency. It can be administered as an intramuscular injection or given orally. Oral administration is preferred in most settings and a single oral dose will provide sufficient iodine for up to two years. Iodized oil is the intervention of choice in areas where iodinated salt is not available.



Stage of Product at Inception of A.I.D. Funding

Injectable-grade iodized oil is currently being produced by facilities in France and the People's Republic of China. The government of Indonesia (GOI) is interested in local production of less expensive orally administered oil to decrease the cost of providing oil for Indonesian health programs; the GOI has asked PATH for assistance. PATH has worked with P.T. Kimia Farma, a pharmaceutical firm owned by the GOI, to develop the initial laboratory-scale process for production.

Current Status

Some HealthTech funding has been used to evaluated the feasibility of this product under Selection and Screening Activities. The work plan for the iodized oil project has recently been approved by A.I.D.; work will begin in February 1989.

Rationale

Severe iodine deficiency in pregnant women causes severe, irreversible mental retardation in their offspring; recent studies suggest that these children represent only a small fraction of the infants who suffer from less obvious mental impairment due to this deficiency. Over 18% of the population of Indonesia is estimated to be at risk for iodine deficiency disorders. Iodine deficiency can be easily controlled. The GOI has initiated a program with two foci: iodinated salt and iodized oil. Less expensive oral iodized oil will allow the government to reach more of the population at risk.

Performance Specifications

The oil should be:

- Formulated from a domestic vegetable oil.
- Stable for 12 months without refrigeration.
- Able to pass toxicity tests and any specifications of GOI regulatory agencies.
- Packaged to allow administration with little retraining of health staff.
- Affordable to health programs in developing countries.

Progress to Date

Linkages were established with two research and development centers dedicated to iodized oil technology, the International Council for the Control of Iodine Deficiency Disorders and the Nuclear Medicine Laboratory at Siriraj Hospital, Bangkok, Thailand. The work plan has just been approved and work will begin in February 1989.

Future Plans

A.I.D. funding will be used to help P.T. Kimia Farma do the necessary testing and scale-up of the process. If P.T. Kimia Farma produces iodized oil in excess of Indonesia's needs, the possibility of sales on the international market will be explored.

Title/Licensing Status

P.T. Kimia Farma will apply for necessary local production licensing in Indonesia when scale-up is complete.

Collaborating Institutions

P.T. Kimia Farma; Indonesia Ministry of Health

A.I.D. Mission Involvement

The Indonesia Mission has been informed and is supportive of this effort.

Expenditures to Date: $ 6,798

Future Expenditures Expected Through June 1989: $ 15,849

HealthTech
Selection and Screening Activity
January 1989

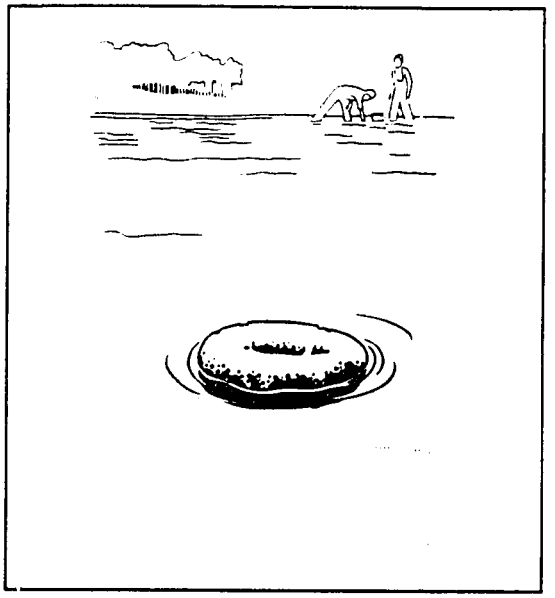
Type: C ; Stage: 1
Budget: Year 1 $ 0
Year 2 $ 18,960

Biological Larvicides

Biological larvicides for use in vector control programs for dengue fever and malaria

Product Description

Bacillus thuringiensis serotype H-14 is a biological larvicide traded under the name VECTOBAC and produced by Abbott Laboratories. VECTOBAC is available in several formulations, including aqueous solutions, granules, and powder. VECTOBAC appears to have strong potential against *aedes aegypti*, the vector of dengue fever. *Bacillus sphaericus*, although not yet commercially available, is a new generation of this product which holds promise for control of the anopheline mosquito, the vector of malaria.



Stage of Product at Inception of A.I.D. Funding

In 1985, PATH undertook a market feasibility study of VECTOBAC in Indonesia and Thailand and determined that a significant urban market existed for using VECTOBAC in the integrated control program for dengue fever. Numerous contacts were made with key figures in both the private and public sectors in order to develop this study.

Current Status

PATH, working with Abbott Laboratories and the Indonesia Ministry of Health, developed protocols for testing the product efficacy of VECTOBAC in two separate laboratories in Indonesia. The tests, which were paid for by Abbot and completed in November 1988, were conducted to support the registration of the product. The outcome of these laboratory evaluations was very positive, showing that VECTOBAC was able to kill the selected mosquito vectors and thus might be applicable in the national vector control program. In January 1989 the work plan was approved. The work to date has been completed as a selection and screening activity.

Rationale

Vector-borne diseases, especially dengue fever and malaria, continue to be a serious health threat in the tropical environment of Indonesia. Special concern is focused on dengue fever because of its high prevalence in over-populated urban areas and the high incidence of death among children who contract the disease. Recent outbreaks in Jakarta and other major urban centers have increased the demand for new preventative measures.

Global research on various biological control agents of disease vectors has intensified during the past decade. However, interest in their actual use in developing world vector control programs has lagged far behind. Biological larvicides are one of the most promising biological control agents. While they have been available for several years from international sources, the multinational companies which produce biological larvicides have not perceived enough of a market in developing world health programs to initiate serous marketing efforts. Despite strong indications of their safety and efficacy, biological larvicides have not had either a marketing effort from abroad or a local proponent, and therefore have not been adapted for use in developing world health programs.

Mosquitoes are becoming resistant to chemical agents such as DDT at the same time that the diseases they carry, such as malaria, are becoming more difficult to treat. These changes, combined with a growing awareness of the environmental danger of chemical approaches, are leading health professionals to advocate an integrated strategy for controlling mosquito-borne diseases. The integrated approach recognizes that there is no single answer to the problem and encourages multiple interventions. These approaches may include both the use of repellents to reduce *aedes aegypti* in locations of greatest need and the use of larvicides.

Performance Specifications

The formulations used to apply biological larvicides should:

- Allow an interval between applications which is short enough be effective but not so short that regular application is inconvenient or expensive.
- Not adversely affect non-target species, i.e., humans and aquatic life.
- Be safe for handling by consumers and untrained household personnel.
- Require minimal or no appliances for application other than those already used by existing vector control methods.
- Be able to be formulated using local carrier materials in the particular country.
- Be stable under tropical conditions.

Progress to Date

Market feasibility studies conducted in 1985 suggested a significant market for VECTOBAC in urban areas. Introduction of the product may be facilitated because of increasingly strong private-sector involvement in vector control practices.

Communications with the Ministry of Health on the subject of VECTOBAC have been actively maintained. The Ministry continues to be keenly interested in the concept of biological larvicides and is seeking any pertinent information or test results on this new technology.

The recent laboratory efficacy tests showed that VECTOBAC is able to eliminate disease-carrying vectors. The active ingredient of VECTOBAC is an endotoxin which is ingested by the larvae and results in rapid disintegration of the larva gut followed by immediate death. Although VECTOBAC is also effective against the black fly, major interest in the product relates to its suitability for mosquito abatement programs, especially those related to the control of *aedes aegypti*, the vector of dengue fever.

The superior safety profile of these products has increased optimism that these biological larvicides will be accepted for community-based health programs.

Future Plans

After registration of VECTOBAC is approved in Indonesia for use as a biological larvicide, PATH will seek to complete the feasibility study of this product by facilitating the start-up of local formulation by a local partner. Opportunities will be sought to design a formulation which is particularly appropriate for Indonesia.

Laboratory tests using *Bacillus sphaericus* are being planned at the special Research Unit for the Biological Control of Disease Carrying Mosquitoes in Semarang, Central Java, to determine the efficacy of this product against the anopheline mosquito, the vector of malaria. PATH will seek to coordinate the confirmatory testing with Dr. Sustiayu, the head of the Biological Control unit, along with providing technical assistance in monitoring and supervising the project.

Title/Licensing Status

Abbott Laboratories owns the patent on VECTOBAC. The laboratory efficacy tests which were completed in November 1988 were conducted to support the official registration of VECTOBAC. It is expected that VECTOBAC will be accepted for registration review by the Indonesian Pesticide Committee in January 1989.

Collaborating Institutions

Abbott Laboratories; Indonesia Ministry of Health

A.I.D. Mission Involvement

The A.I.D. Mission in Jakarta and the Indonesia Ministry of Health have expressed strong interest in PATH's work on biological larvicides.

Expenditures to Date: $ 3,251

Future Expenditures Expected Through June 1989: $ 15,709