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THE A.I.D. DIARRHEAL DISEASE CONTROL STRATECY
(ORAL REHYDRATION THERAPY AND RELATED INTERVENTIONS)

TO THE STAFF OF THE AGENCY FOR INTERNATIONAL DEVELOPMENT:

I wish to underscore my support for continued and increased Agency efforts to promote and expand oral rehydration therapy in A.I.D.-assisted countries. At my request, the attached document was prepared to provide detailed guidance for addressing diarrheal disease control, principally through oral rehydration therapy. It should be used as a tool for discussions with host governments and for program design, implementation and evaluation. It compliments the immunization strategy which I approved last January and the Child Survival Strategy approved in April. It also reflects many of the goals and strategies discussed at the International Conference on Oral Rehydration Therapy (ICORT II) held in Washington in December, 1985.

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DIARRHEAL DISEASE CONTROL STRATEGY

(Oral Rehydration Therapy and Related Intervention)

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DIARRHEAL DISEASE CONTROL STRATEGY
(Oral Rehydration Therapy and Related Interventions)

I. EXECUTIVE SUMMARY

A.I.D.'s health policy emphasizes the "child survival" strategy as the most important means of improving the health status of children in developing countries, and as a basis for building and/or strengthening more comprehensive primary health care systems in time. Control of mortality from diarrheal disease, principally through oral rehydration therapy (ORT), is a major component of this strategy.

In many developing countries as many as one third of all child deaths may be caused by diarrheal diseases and, in some countries, the average child experiences up to 11 episodes each year. Death from dehydrating diarrhea can be prevented in the short-term by the replacement of lost fluids and electrolytes, in most cases by mouth. In the long-term, control of the nutritional impact of diarrhea is equally important and requires adequate feeding during as well as after each episode. Improved water supply and sanitation is also key to long term preventions. Mild to moderate cases can be managed at home, but severe cases may require more intensive therapy by health providers in the health care system. This makes identification of severe dehydration cases and their quick and appropriate treatment critical to survival.

ORT may be simply defined as diarrhea management with appropriate oral fluid, feeding, and referral if necessary. Up to two-thirds of current deaths from diarrhea can be prevented with correct use of this technology.

Prevention of diarrhea (morbidity reduction) can be accomplished through control of the environment (water and sanitation efforts), changes in family behavior (personal hygiene including handwashing, breastfeeding, clean food, feeding during diarrhea), and immunization, especially against measles. Effective linkages between diarrhea control activities, nutrition improvement activities, and environmental efforts can enhance these efforts.

Diarrheal disease control programs should seek widespread acceptance in three stages:

1. Increased Availability - improved access to providers trained in ORT and provided with ORS packets, and improved capability of mothers and other caretakers to offer ORT in the home.

2. Increased Use - higher proportions of providers and mothers, whether in formal health care settings or in the home, using ORT to prevent and/or treat dehydration.

3. Increased Effective Use - including proper preparation, administration of adequate quantities of fluids, appropriate feeding, and referral of serious cases of diarrhea.

Because ORT requires both an effective health system with adequate infrastructure and active participation by family members to succeed, ORT programs can help identify deficiencies in the primary health care system, particularly its outreach component, and can be the mechanism through which system changes are initiated. Thus, support for ORT can, in fact, be the most effective means for building health infrastructure and supporting primary health care.

With ORT as the core of A.I.D.'s diarrhea control efforts, A.I.D.'s goals for children under 5 for 1990 are (1) make ORT available to virtually every child who needs it; and (2) ensure use of ORT in 45 percent of diarrhea episodes.

A.I.D.'s diarrheal disease control strategy has 8 guidelines for development of country-level strategies:

1. Comprehensive programs to maximize effectiveness, including attention to policy dialogue; planning; finance; management; training of health personnel; production, distribution, and sales of ORS; communications and public education; monitoring, supervision, and evaluation; and linkages with preventive measures.

2. Effective case management of diarrhea, emphasizing ORT use both by health personnel and in the home as the core of every diarrheal disease control program. Also a balance between health system, community and home-oriented activities, including an appropriate mix of supply, health manpower training and communication/public education efforts.

3. Nutritional management of diarrhea along with fluid therapy in ORT case management. Also referral of serious cases.

4. A primary target group of children under 2 years of age.

5. Emphasis on program sustainability is planning, and in choosing priorities among competing investments, including enhanced income through sales and fees, recovery and retention of savings from reduced hospital and drug costs, and shifting of program costs to consumers where possible.

6. The private sector as well as the public sector included in diarrheal disease control plans and program activities.

7. Active coordination and collaboration with other donors.

8. Efforts to link ORT activities to nutrition and other PHC programs, and to include activities which have the potential to prevent diarrhea, especially measles immunization and water and sanitation programs.

In addition, the following are critical to successful country program implementation:

1. Countries selected for assistance to maximize the number of deaths prevented for a given investment, based on mortality rates, host country commitment, country size, implementation capacity, existing infrastructure, and the potential for donor collaboration.

2. Policy dialogue to strengthen government commitment, enhance the sustainability of program efforts, and ensure adequate breadth and comprehensiveness of the program.

3. Detailed and realistic planning with achievable country specific targets based on field research.

4. Health manpower training activities including both public and private providers.

5. Strong communications efforts, comprised of adequate predesign research and field testing of messages, continued monitoring and formative evaluation of message receipt and effectiveness, and use of commercial sector firms where appropriate.

6. Continuous availability of ORS packets through local production, if appropriate, commercial sales of ORS, assistance to the drug-purchasing and distribution system, and collaboration between the public and private sectors.

7. Regular and effective supervision as well as information, monitoring, and evaluation activities as the basis for problem identification and informed decision-making.

8. Research to develop new approaches to control diarrhea, to evaluate new ORT formulas, and other new diarrhea therapies, to explore different preventive measures, to carry out ethnographic/anthropological research, and to solve operational problems in country programs.

With these guidelines and program considerations in mind, A.I.D. support will balance efforts aimed at ORT with selective investment in preventive programs, in related PHC infrastructure development (e.g., financial accounting and management, drug purchasing and distribution, health and management information systems), in critical symbiotic programs such as nutrition/growth monitoring and immunization (particularly against measles), in water and sanitation and in targeted basic and operational research.

A.I.D. will encourage long-term planning and, when warranted, will make commitments for five years or more. Where economic conditions demand it, A.I.D. is prepared to finance some recurrent costs for a predetermined time period with concurrent efforts to improve cost savings and a plan for phasing out such support. A.I.D. will support technical assistance in all aspects of diarrhea control, as well as in the dissemination of technical information and field experience.

II. BACKGROUND

The primary goal of A.I.D.'s health program is the reduction of morbidity and mortality in infants and children. With approximately one-third of childhood deaths under age 5 caused by diarrhea, control of diarrheal diseases is a major priority for A.I.D.'s efforts. The Child Survival Strategy and Health Sector Policy emphasize oral rehydration therapy (ORT) as one of the mechanisms to achieve this goal.

In developing countries, acute diarrhea is a leading cause of mortality among children under five years, particularly during the first two years of life when the annual mortality rate from diarrhea is estimated to be 20 per 1,000 children. Worldwide, an estimated five to six million children die from diarrhea annually; 80 percent die before their second birthday. Morbidity from diarrhea is also high. Children in developing countries have from 1.2 to 5.1 attacks of diarrhea annually, with rates in some countries as high as 11 attacks per year.

Some 50 to 80 percent of diarrheal attacks are acute and watery. This type of diarrhea may lead to dehydration, electrolyte imbalance, and death. In these cases death can be prevented by replacing the water and electrolytes lost in the stool. This reverses the dehydration and electrolyte imbalance which have already occurred and prevents further deterioration.

Rehydration fluids can be given intravenously, a technical and expensive process for most developing countries which always requires skilled medical personnel and usually requires hospitalization. With the proper amount of glucose or other absorption stimulating substance added, however, these fluids can be absorbed from the intestine through oral administration, even during diarrhea. In fact, properly administered fluids given by mouth can prevent death from dehydration in all but the severest dehydration -- one to three percent of the cases -- which usually require intravenous treatment.

Diarrhea has a detrimental nutritional impact on the child, usually causing either a failure to gain weight or an actual weight loss. This growth-faltering is related to decreased

food intake due to anorexia or withholding or reduction of food by the mothers (often including a reduction in breastfeeding) perceived to be therapeutic. There may be some decreased absorption of nutrients from the intestine caused by the diarrheal infection which also inhibits weight gain and can be prevented by proper feeding (including breastfeeding) during the diarrhea, and by extra feeding during a "catch-up period" after the episode.

Oral rehydration therapy (ORT) thus includes both the administration of fluids by mouth and appropriate feeding during and after the episode of diarrhea. Both are needed if ORT is to offset the two major morbid effects of diarrhea. The use of ORS, through the treatment of dehydration and restoration of the electrolyte balance, helps to restore an appetite for food.

If ORT is administered in the home by mothers or community health workers, there must be an appropriate referral mechanism for the more severe cases needing intensive treatment. Thus ORT may be simply defined as the management of diarrhea with appropriate fluids, feeding, and referral if necessary.

Where mothers have learned to give appropriate fluids and food at home at the onset of any diarrhea, the proportion of severe diarrheal dehydration cases needing admission and intravenous rehydration at a medical facility has dropped. A variety of solutions such as soups and other starch-containing fluids ("home-available fluids") are currently under study to determine their effectiveness and acceptability. When used in medical facilities, oral rehydration therapy can substantially reduce the need for expensive intravenous fluids; this can produce significant savings for stressed national health budgets. Overall, an estimated two-thirds of deaths from diarrhea might be avoided with correct use of ORT, making it an inexpensive and effective method for reducing mortality.

The infections which cause diarrhea often originate in unsanitary environments and are spread primarily through contaminated water and food. Inappropriate hygienic practices and the increasing substitution of artificial milk for breastfeeding exacerbate the problem. Other viral infections, most notably measles, are also often accompanied or followed by diarrhea.

Prevention of diarrhea -- the reduction of morbidity -- is related to the control of these factors, through improvement of the environment, changing the behaviors of mothers and children, and immunization. The evidence shows that a substantial proportion of diarrheal disease can be effectively prevented when clean water is provided; when mothers and children carry out routine personal hygiene; when breastfeeding begins early, is appropriately maintained, and is followed by appropriate weaning practices; and when

children are adequately immunized, particularly against measles. New vaccines against rotavirus infections and cholera, now in development, may provide additional protection.

Although diarrhea is not more frequent in malnourished children, it is more severe. Duration is prolonged and thus the volume of fluids lost is also increased. A vicious cycle, therefore, is created where diarrhea leads to malnutrition, which in turn leads to increasingly severe diarrhea. Though the dehydration in a child with chronic diarrhea can be corrected with oral therapy, stopping diarrhea is more difficult. Diet appears to have a particularly important role to play; additional research is needed in this area.

It is this relationship, then, which makes feeding during and after diarrhea as important a part of ORT as fluid administration. ORT must be both fluid and feeding. ORT programs may benefit by linking their activities with nutrition programs which make the effects of diarrhea on growth visible to mothers and health workers and motivate them to take action.

Similarly, because of the importance of reducing fecal contamination in the prevention of diarrhea, diarrhea control/ORT programs should also support improved hygiene. ORT and efforts to improve water supply and sanitation are complementary components of an overall strategy for diarrheal disease control; the former focuses on dehydration and reduction of mortality from diarrhea, the latter focuses on the prevention of diarrhea morbidity.

With ORT as the cornerstone of a diarrheal disease control program, the aim of A.I.D. and country programmers should be to increase the percentage of children with acute diarrhea dehydration who are treated with effective ORT. Progress may be measured in the following three dimensions.

1. Availability of ORT is a measure of the likelihood that a child under 5 with diarrhea can be treated with ORT, either in a health facility or at home. Availability has two dimensions. Access to health providers and facilities, currently defined by WHO as the percentage of the target population within reasonable reach of a health provider trained in ORT and having ORS packets (oral rehydration salts). In 1984 33 percent of the population in countries reporting to WHO had access to ORS, while in the A.I.D. emphasis countries,* which make up 77

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* A.I.D.'s Child Survival effort is currently concentrated in the following emphasis countries: Bangladesh, Bolivia, Ecuador, Egypt, Guatemala, Haiti, Honduras, Mali, Morocco, Nepal, Niger, Nigeria, Pakistan, Peru, India, Indonesia, Kenya, Malawi, Senegal, Sudan, Yemen, and Zaire.

percent of the total child population under five in all A.I.D. assisted countries, access ranges from roughly 20 percent to 60 percent, according to WHO/CDD (see Appendix 1). Capability in ORT performance in the home may be defined as the percentage of providers (usually mothers) with necessary knowledge and mastery of ORT skills. Such capability is necessary to enable mothers and other providers to properly manage diarrhea. Capable providers must not only be aware of ORT, but must also have the ability to recognize diarrhea; understand the importance of dehydration; prepare fluid solutions; administer proper volumes; give proper feeding during the episode; recognize when the child needs more intense therapy at a medical facility; and have access to the necessary materials (e.g. sugar and salt) to prepare the oral solutions needed.

2. Use is defined as the percentage of diarrheal episodes in children under five which are treated by ORT, either by a provider (community health worker, doctor, etc.) or at home. This has usually been measured by asking a family member whether the child was purposefully given fluids during an episode of diarrhea within the past two weeks. Recent evaluations of ORT programs have shown that simple use is a misleading measure of program success. More detailed questioning of mothers or other caretakers revealed errors made in preparing sugar-salt solution, failure to give adequate quantities of fluid, inappropriate feeding practices, and failure to seek more intensive care when diarrhea persisted and the child began to become dehydrated.

3. Effective use is determined by adequate performance in the four critical aspects of ORT: proper preparation of the replacement fluid, administration of appropriate quantities of fluid, appropriate feeding during and after diarrhea, and appropriate referral either by a health worker or mother to more intensive care for the more seriously ill child, either by a health worker or mother. This should be the ultimate target of ORT programs. Increasing availability, knowledge and use are steps toward effective use.

Universal availability, high, effective use rates, and maximum reduction in diarrhea mortality will likely be best achieved where there is a well-functioning primary health care system, widespread and effective distribution of ORS packets through the drug distribution system, private sector involvement in the program, and effective outreach and communication. Because all of these components need to be functioning effectively, problem areas should be easy to detect and solve in a well-run ORT program. Support for ORT programs is seen as support for primary health care, and can revitalize poorly-functioning health systems, by improving training, supervision, supplies and logistics, and data collection.

Full achievement of targets requires sustained political commitment and substantial mobilization of resources for expansion of this very cost-effective, lifesaving technology. ORT and immunization together serve as the twin engines of the Child Survival Strategy, leading A.I.D.'s efforts to overcome the poverty associated syndrome of malnutrition, disease, unsanitary conditions, closely-spaced births, and lack of maternal education which today causes so many children to die.

III. OBJECTIVES

A.I.D.'s ultimate objectives, in conjunction with host countries and other international donors, include universal availability of ORT, either as ORS packets or home-available solutions, and the appropriate and effective use of ORT for diarrhea.

The explicit A.I.D. ORT targets for 1990 are: (1) make ORT available to virtually every child who needs it; and (2) ensure use of ORT in 45 percent of diarrhea episodes.

Over the life of a diarrheal disease control program, efforts should lead to a reduction in the incidence and severity of diarrhea in the country, and may also lead to a reduction in the prevalence of malnutrition.

IV. GUIDELINES FOR DEVELOPMENT OF COUNTRY-LEVEL STRATEGIES

The guidelines for A.I.D.'s diarrheal disease control program are listed below. These are global considerations, which should be used in developing general international as well as country-specific programming priorities. When A.I.D. is involved in policy dialogue as ORT, or where A.I.D. assistance is sought by countries developing ORT strategies, these principles should be introduced for consideration by the host country.

1. Comprehensive Programs

National diarrheal disease control programs should incorporate all the elements needed for program success. The various components of a national diarrhea program are integrally linked and interdependent. An effective communication program must have a well-functioning medical treatment program in place when parents bring their dehydrated children for treatment. Demand created for the purchase of ORS packets will disappear quickly if packets have not been made widely available. Each component depends on the other. Thus, national programs should assess existing activities and, if necesary, plan action to develop the full range of program components:

policy dialogue; planning; finance; management; training of health personnel, communications and social marketing; production, distribution, and sales of ORS; monitoring, supervision, and evaluation, and research and information dissemination. Each of these elements is discussed in detail in Section V of this strategy entitled Country Program Implementation Considerations.

2. Emphasis on ORT Case Management

Reduced childhood deaths from diarrhea through effective case management either by health personnel or mothers, in health facilities and in the home, should be the core of every diarrheal disease control program. An effective program must ensure both appropriate management of more severely ill cases brought to health facilities and widespread effective use of ORT in the home and community, in order to achieve maximum mortality reduction.

Every child brought to a health facility with diarrhea should receive appropriate treatment from trained personnel. In practice, the majority of such patients should be rehydrated at the clinic itself and also receive a supply of packets for home use. A few will require intravenous fluid therapy, antimicrobial agents, and/or special management of electrolyte status and nutrition, consistent with their clinical status. Training of health personnel in case management, effective supervision and monitoring, and availability of ORS and intravenous solutions where they are needed are essential to this treatment. A major emphasis in programs should be placed on educating parents about why and where they should bring their severely ill children with diarrhea to such trained health personnel.

Also, programs should strive to educate parents and communities about the nutritional consequences of diarrhea as well as early case management in the home using home-available fluids and feeding during diarrhea to prevent dehydration. This should reduce the number of severely dehydrated children who will require treatment at a health facility.

Activities aimed at both the health facility and community levels should ensure quality and avoid the introduction of dangerous procedures through ineffective instruction (i.e., activities should ensure correct mixing of solutions with sodium and sugar concentrations in the safe and effective range, ensure proper feeding during diarrhea, etc.).

An appropriate balance between medical intervention and home-oriented activities should be sought, based on conditions determined in each country. ORT has attracted immense international support both because it is

effective and because its simplicity provides the potential for successful control of diarrhea mortality at the community and home levels. Recent experience, however, has repeatedly demonstrated the difficulty in bringing about correct mixing of solutions at home, correct administration, and correct feeding, despite intensive efforts. Added to these barriers is the realization that more serious cases with a higher likelihood of dying, may require medical intervention with either packaged ORS or intravenous fluids, perhaps even more sophisticated treatment in cases of combined malnutrition and diarrhea. While the administration of fluids at home will reduce the numbers of children needing more intensive care, effective medical care must be available, even though for smaller numbers of cases. For these reasons, through efforts in manpower training, supervision, and logistics improvement, ORT programs should seek to ensure that children needing more intensive and effective treatment than is possible at home can get it.

At the same time, outreach and public education efforts should be supported strongly, incorporating effective monitoring of the results of educational programs and strategies to ensure that mothers have not, in fact, begun to carry out inappropriate practices through incomplete or inaccurate understanding of the process. Recent information indicates that home-available solutions should receive increasing attention, because of the large number of errors in preparing sugar-salt solution. (See Annex VI). Monitoring of the solutions used is strongly recommended, to ensure their safety and effectiveness.

3. Feeding/Referral

ORT case management programs must stress dietary management of diarrhea and appropriate referral of serious cases. Appropriate replacement of fluids and electrolytes lost through diarrhea and vomiting is essential for decreasing diarrhea mortality, the prevention of death from dehydration. Yet the effect of diarrhea on nutrition, producing faltering of growth and an insidious progression toward malnutrition with recurrent episodes, is equally devastating in the long run. Programs should stress efforts to promote proper dietary management of diarrhea in the home and in health facilities along with the promotion of proper fluid management. This should include breastfeeding continuation, feeding during episodes, and extra feeding during recovery. Involving diarrhea patients in other nutrition program activities might be an additional reinforcement.

While fluid replacement in most diarrhea cases can be managed using simple home-available fluids such as starch-containing soups or sugar-salt solution, more serious cases with watery diarrhea or vomiting may require the oral administration of solutions with the complete WHO formula (ORS) to improve absorption, prevent metabolic acidosis[1/] and avoid potassium deficiency[2/] or the administration of intravenous fluid. As these more serious patients are just the ones most likely to die, mortality reduction from a diarrhea program depends on ensuring that this more intensive treatment is both available and used by these patients. This requires educating parents and community-based health workers to recognize the more serious cases of increasing dehydration, and to seek appropriate sources of ORS packets or intravenous treatment. It also requires ensuring that the ORS and IV treatment facilities along with trained health personnel are in place.

4. Primary Target Group

The primary target group should be children under 2 years of age. Mortality and morbidity are highest in this group. During the first two years of life malnutrition secondary to diarrhea is common and can be reduced by effective ORT programs. This is also the primary target group for A.I.D.'s immunization strategy. Children 2, 3, and 4 years of age are important secondary targets.

5. Sustainability/Financing

Programs should emphasize sustainability of ORT and related Child Survival services which they develop. Sustainability depends upon the organizational and managerial strength of a program, on its integration into the primary health care infrastructure, and on its fiscal self-sufficiency. Program plans and assessments should address the question of sustainability directly at the outset of a program, and plans should include mechanisms for gradually increasing the self-sufficiency of assisted programs. (Details of program elements are discussed under Section V.)

1/ Metabolic acidosis is a condition of reduced reserve of alkali in body fluids (for example, as a result of bicarbonate loss in diarrheal stools). The body can compensate to some extent when acidosis occurs. However, if the acidosis is severe and action is not taken to correct it (e.g. by giving bicarbonate or citrate), acidosis can lead to death.

2/ Potassium deficiency can lead to disturbances in the functioning of the kidneys, heart, gastrointestinal tract and muscles. Severe potassium deficiency can be life-threatening.

Economic analysis, financial analysis, and innovation should be included in diarrhea control programs. A.I.D.'s health financing strategy requires that all health sector projects address financing issues in order to better ensure sustainable health programs. Assistance for diarrhea/ORT programs should be provided, as necessary, to analyze program expenditures, identify areas of potential cost reduction or savings (e.g., substitution of ORT for the use of more expensive drugs and intravenous fluids, integration of diarrhea activities with other PHC/Child Survival activities), and study, through operations research and innovative activities, initiatives to shift program costs and activities to the private sector and consumer (e.g. sales of packets, fees for treatment of diarrhea or water consumption).

While it is possible to focus financing efforts on the diarrhea program alone, in most instances such efforts should be part of a larger effort aimed at the whole health sector, including both the public and private sectors. A major target should be to ensure the identification and retention of savings for use in the continuation of the program and in the preventive and promotive primary health care portions of the health system. It may be noted that the savings in hospital, intravenous fluid, and antidiarrheal drug costs from an effective case management program could support the entire expense of most diarrhea control programs if they could be captured and retained. To assist in these activities, A.I.D. is developing a set of uniform cost analysis and accounting procedures.

Finally, to ensure fiscal sustainability, programs should consider steps to gradually shift many program costs to the consumer through such mechanisms as encouraging commercial sector distribution and sales of ORS and the collection of fees from patients who can afford them. In addition, A.I.D. should plan for phasing out our support of recurrent costs by project completion, while recognizing that this will be a long process in some African countries.

6. <u>Public and Private Sector Involvement</u>

The private sector as well as the public sector should be included in planning and program activities. The public sector is responsible for setting national policy, and provides a major proportion of care for the seriously ill and the poor in most A.I.D. supported countries. Therefore, in most cases A.I.D. must initiate its efforts with the Ministry of Health or other similar agency. However, private physicians, pharmacists, and other health care providers, including traditional healers, provide a significant portion of care for children with diarrhea in most countries. Commercial manufacturers

produce and distribute medications widely, often with much better coverage than possible from public sector drug distribution. Commercial advertising firms may be more skilled than government health education units, and commercial mass media may have larger audiences than government stations.

ORT programs must actively seek to include these private sector elements in all aspects of their program efforts. Private providers should be included in MOH training activities. Local private sector manufacturers should be encouraged and, if appropriate, supported in the local production and commercial sales of ORS. Local production of ORS should follow the good manufacture practices and the quality assurance program of the World Health Organization. Sales of packets by both private sector and public facilities can shift much of the recurrent cost of ORS to the consumer. Care must be taken to ensure that the poorest segments of society continue to receive ORS that they can afford. Private providers and sales outlets should be included in monitoring, supervision, and evaluation. Where appropriate, private agencies should generally be used in this multichannel promotion of ORS, ORT, and diarrheal disease control.

PVOs have a special potential role in the provision of complementary services to government programs not otherwise reaching certain portions of the target population, and in the initiation of pilot, innovative, or experimental activities which can serve as demonstration projects for possible replication.

In short, all A.I.D. diarrheal disease control plans should address specifically the current and potential role of the private sector in the country, and the steps to be taken to include those elements in the program being proposed, in addition to planning a comprehensive public sector effort. Policy dialogue should seek to enhance the private sector focus of programs.

7. Donor Coordination

Active coordination and collaboration with other donors should be a part of every program plan. A.I.D. must join with other donors, particularly WHO and UNICEF, in planning regional and individual country programs, sharing investment, commodity and implementation costs, and evaluating progress. A.I.D. should support, with commitment of resources, staff time and leadership, mechanisms to improve the communications necessary for more effective collaboration, not only in programs but also in basic and operational research. Joint efforts to seek policy changes such as the elimination of ineffective antidiarrheal drugs from the national health care system, may be more effective than efforts by A.I.D. alone. To further assist in ensuring collaboration,

budgets submitted for diarrheal disease control projects and other Child Survival related activities should show inputs to the national program from all donors, as well as the A.I.D. contribution.

8. Linkages to Preventive and Primary Health Care Programs

ORT should be complemented by other diarrhea control interventions such as personal hygiene and sanitation as well as linked to nutrition and broader PHC programs. ORT does not equal diarrheal disease control. ORT is a relevant and cost-effective intervention for diarrhea control in all countries, where it prevents the complications of acute diarrhea (dehydration and death) and the nutritional consequences of repeated and/or prolonged diarrhea. It is especially important in those countries where diarrhea mortality rather than morbidity is the main concern.

Yet an ORT program alone is insufficient as a diarrheal disease control program. Additional program elements are needed to achieve maximum mortality reduction and to affect diarrhea morbidity (incidence) significantly. A.I.D. should accompany ORT efforts with investments in appropriate nutrition interventions. Special emphasis should be given to breastfeeding promotion efforts, because of its ability to provide fluid, nutrition and immune protection to the child, and to improved weaning practices, especially improved hygiene of weaning foods. Linkages to food supplementation programs may allow increased nutritional intake for a child with chronic diarrhea and malnutrition.

Active attention should also be paid to appropriate hygiene interventions, including improved maintenance, utilization and financing of water supply and sanitation, as well as education in personal and domestic hygiene.

Immunization against measles has been shown to reduce mortality from diarrhea. Diarrheal disease control programs should make every effort to ensure that national immunization efforts (EPI) include measles immunization.

Operationally, then, A.I.D. project plans for child survival should address specific activities designed to link programs for diarrheal disease control with immunization, nutrition and supplementary feeding, and water and sanitation. These linkages should be phased in over time and should be expanded according to the management capabilty.

Efforts to strengthen medical care, logistics, supervision, reporting and finance are essential to the success of ORT programs. Such efforts can also be an effective means of improving these elements in the whole primary care system. Technical assistance and any necessary additional support should be planned accordingly.

V. COUNTRY PROGRAM IMPLEMENTATION CONSIDERATIONS

Based upon the above guiding principles the following considerations should be heeded in planning and implementing diarrheal disease control programs.

1. Country Selection for Investment

The decision to invest A.I.D. resources in ORT in a particular country should be based on a number of factors. Within the guidelines of the Child Survival Strategy, the following factors will determine priorities for investment in a diarrhea control/ORT program for emphasis and non-emphasis countries, and the relative priority of ORT in emphasis countries:

- High infant and child mortality and a high proportion of deaths due to diarrhea.

- Host country commitment to establish an effective diarrheal disease control unit in its Health Ministry, to make supportive policy changes, and to commit indigenous resources to the enterprise.

- Population size and density. Investment for project startup, administration, and technical assistance would have maximum quantitative impact on child survival in a larger population with high infant and diarrheal mortality rates.

- Host country program implementation capacity and existing infrastructure. Efforts will not be limited to countries with a well-established primary and secondary health care system or a well-managed Ministry of Health that can facilitate program success, but will also include countries, such as those in the Sahel, where existing facilities are meager and investment in diarrheal disease control, as in immunization, can serve to build health infrastructure.

- Collaborative interest by other donors such as WHO, UNICEF, and PVOs in a diarrheal disease program. Such collaborative support would enhance the results obtained for each A.I.D. dollar spent.

2. Policy Dialogue

Policy dialogue between donors and host country governments should occur both at the strategic and program planning levels. It is important to keep in mind that many problems which handicap diarrhea control programs can be resolved through effective policy dialogue with government officials.

At the strategic planning level, the dialogue should first aim at steps to enhance government commitment to the program, dealing with broad issues such as: the extent to which ORT will be actively promoted and endorsed among decision-makers and among leaders in the medical and pharmaceutical communities; ministerial-level decisions on making foreign exchange available to purchase raw materials and packaging supplies for local production of ORS; establishment of WHO-consistent national norms for pharmaceutical quality control; resolution of counterpart funding issues; and political and financial determinations about distribution of free packets or support of market pricing. Special efforts should be made to seek the elimination of ineffective antidiarrheal medications and the restriction of costly ineffective antibiotics in the government health system, and if possible in the private sector as well.

Second, policy dialogue should seek to bring about steps to ensure long-term program sustainability, such as planning for cost recovery, willingness to consider consumer support for services, and involvement of the commercial sector.

At the operational level, dialogue should seek to ensure that the program activities include health care providers and institutions outside the public sector, such as private practitioners, midwives, and private voluntary organizations, and that the program includes all the components necessary for a successful effort (training, logistics, communication and public education, integration into the primary health care system, supervision, evaluation, etc.). Operational policies regarding diarrhea case treatment, drug ordering, reporting forms, supervision activities, and numerous other areas can be dealt with through policy dialogue leading to change from the top down much more efficiently than through isolated, non-reinforced educational efforts.

3. Planning

Detailed, realistic planning should be emphasized and supported. Detailed, realistic planning and target setting of national diarrheal disease control programs are essential to long-term success and the avoidance of implementation problems. Planning should be based on an objective assessment of the current situation, including such matters as the availability of health care, the supply of sugar and salt, the economic status of the health care system, and the role of the private sector, including PVOs, in health care delivery. The subsequent planning should be both strategic and operational, defining approaches and identifying resource requirements as well as setting specific targets, activities, and schedules.

A.I.D. can contribute at both planning levels by helping to assure that all participants and their inputs are included in the planning process and the plans which result. A.I.D. will support the provision of technical assistance to ensure that plans are realistic and achievable within the managerial capacity of the MOH (or other implementing agency), are adequately detailed, and include all necessary components and activities. Specific targets must be established individually for each country, based on adequate epidemiological and health service data which report current status and progress in achieving ORT availability and use, as well as changes in diarrhea mortality and morbidity. In the interest of integration into the PHC infrastructure, A.I.D. should avoid ad hoc projects with short timeframes. Planning should emphasize coherent, long-term programs in diarrhea control which may lead to a broader strengthening of the PHC system, with adequate monitoring, supervision, and logistical support. Diarrhea is a continuing, daily problem not well addressed by sporadic campaign approaches, and requires competent health care facilities to provide backup intravenous therapy for severe dehydration, in addition to ORT activities in the home. A public education ORT campaign thus can never suffice alone.

Finally, plans must emphasize the coordination and timing of program activities. Demand must not be created with an effective mass media program, for example, before the logistics system is ready to provide ORS packets, and the health personnel have been trained to provide service effectively.

4. Health Manpower Training

Health Manpower Training should include public and private providers, and should be followed by supervision. A.I.D. should assure provision of health personnel training in diarrhea case management. Such training should usually emphasize physician training because of the central role of doctors in running the health system and directing health care teams, but should also include nurses and paraprofessionals, who often are the ones actually administering ORT in health facilities and educating mothers. Training should also be provided for pharmacists and pharmacy dispensers, important sources of ORS in many countries, and other less formal providers -- traditional midwives, influential community members, and others -- as appropriate in each country.

Health provider training should include not only the usual training activities for doctors and other personnel already in practice, but also efforts to improve professional, preservice education. Together with WHO/CDD, A.I.D. recognizes the role of effective clinical experience in ORT during medical school training as the

foundation for later utilization of ORT in practice. Consequently, A.I.D. supports the priority given to establishing a well-functioning ORT training unit in the teaching hospital(s) of medical schools in all countries where diarrhea control projects are located, and will consider providing support for developing or improving such units where appropriate.

Diarrhea case-management training programs should not only be aimed at health personnel already in government service but also at individuals in private practice.

ORT/diarrhea training plans should be coordinated with plans for other child survival/PHC training, recognizing both the cost-benefits of integrating training activities and the potential loss of training impact by doing so.

Training plans and programs should include not only the usual training course but also the supervision, monitoring and follow-up education activities which are essential to produce implementation of the lessons learned and lasting behavioral change in the trainee.

5. Communication and Social Marketing

A strong and continuing communications and social marketing component is necessary to bring about widespread public acceptance and message consistency. A.I.D. will support comprehensive approaches to communication, including both direct interpersonal channels and mass media, to promote and sustain the correct case-management actions during diarrhea, and the practices which will prevent diarrhea.

Outreach should be emphasized in ORT programs. Since the families of children at highest risk of disease and death are often the least likely to take advantage of services or new methods, interventions should include mechanisms to identify such families and actively incorporate them into program activities. To attain this goal, systems of communication should be established to effectively reach all peripheral health workers and families. The initial thrust of such outreach should be with basic information. Subsequent efforts of reinforcement and correction of misinformation will ensure that appropriate information is translated into practice. Recent experience proves that properly designed communication can bring about behavior change.

The most successful ORT communications programs to date have shared some important fundamental characteristics: a) they were marked by strong audience orientation; b) they focused on a few action-oriented messages; c) they employed intensive promotion; and d) they were part of a comprehensive program using personal channels such as health workers, mass media channels, and printed

materials -- all designed to mutually reinforce each other. In addition, most of those successful ORT communications programs included: a) extensive use of formative evaluation and monitoring; b) systematic desig and testing of educational materials prior to use; and c simplicity, consistency, and repetition of messages used in health personnel training, interpersonal health education activities, and mass media channels.

The resources and expertise needed for market research and predesign field studies, production and placement of messages, monitoring and evaluation, and coordination with other ORT program activities may be beyond the current management as well as technical capabilities of many MOH CDD or health education units. Technical assistance is often needed in this area, and can be provided through the HealthCom or PRITECH projects (S&T/H). USAID should also assess the potential for contracting with local commercial advertising or social science research firms for these activities.

The impact of mass promotion campaigns has proven to be particularly short-lived. Successful communication requires ongoing reinforcement. National plans and A.I.D. programs should recognize the need for continuation of such efforts if long-term change is to be maintained.

6. <u>ORS Production and Distribution</u>

Efforts to improve the supply and distribution of ORS packets throughout the country should be given high priority. The aim of a diarrhea control program should be to assure ongoing availability of ORS packets down to the level of the health care system determined in the national plan (health center or village health worker), and to encourage availability through private and commercial channels as well. Local production of ORS may be desirable, although it may not always be practical due to insufficient economies of scale and lack of adequate quality control. The decision to stimulate or support local production, as opposed to importation, can be derived from four basic questions about: 1) the number of ORS packets required annually; 2) the presence of manufacturing capabilities in the country (public or private) with adequate experience and competence of personnel, and modern concepts of quality control; 3) the appropriateness of imported packets with regard to language or diagrams used on the label or the availability of a standardized container in the country; and 4) the country's desire to produce ORS.

Quality control is particularly important; even minor differences in certain constituents of the formula can produce a dangerous and potentially fatal ORS solution. All packets, whether produced locally or imported, should

-- ----ed by standard techniques in a statistically reliable fashion to ensure adherence with safety and quality standards. These procedures should include certification of raw ingredients, process validation during production, and final product testing. Good Manufacturing Practices should be followed in the production of ORS (see WHO/CDL/SER/85.8). Outside verification of test results are essential for quality control programs.

A.I.D. and other donor agencies can best support local production by providing technical assistance, funding public promotion of ORS (as free advertising for a commercial manufacturer), and by purchasing packets locally for donation at the national or even regional levels, provided quality control meets U.S. and WHO standards. A single packet size, determined usually on the basis of the most commonly available container for mixing ORS, should be standardized for a country, whether packets are imported or produced locally.

Technical assistance to public drug purchasing and distribution systems can aid development of essential-drug lists which will discourage the purchase of expensive unnecessary drugs. Efforts should aim to eliminate the distribution of ineffective antidiarrheal drugs through the government health system, and if possible, to limit their distribution through other channel. Assistance may be needed to establish effective inventory and reordering systems which will avoid stockouts and will be more responsive to demand changes. ORS distribution might provide the initial impetus for efforts which will improve the drug system for the entire health network.

Finally, ministeries and private manufacturers can be assisted to develop mechanisms of mutual collaboration and support, including reporting on ORS sales and movement, subsidies for commercial prices, government supported advertising (social marketing), and market research, which will have the ultimate result of increasing ORS availability throughout the country.

A.I.D. policy encourages the sale of packets. In the early stages of most national ORT programs, packets are often provided free to clients, to create familiarity and generate demand before assigning any cost to consumers. However, once demand is created, there is reason to believe that many consumers, even at lower economic levels, can and would pay at least a small price for ORS. This can reduce the recurrent costs of ORS packets for the health delivery system, adding to the savings realized in hospital and drug/IV costs. Measures to support commercial sales of ORS can shift not only the cost burden but also the task of distribution to the private sector, which may be more able to respond to demand, and may have greater coverage in remote areas. Policy dialogue may also encourage sales of ORS by public sector facilities.

7. Management and Information Systems, incuding Evaluation

Management, especially Supervision, Monitoring, and Evaluation should be emphasized. National diarrheal disease control programs, with multiple components and operating at all levels of the health sector and the community, demand substantial management and coordination capability. Strengthening the program's organization and management, including generous technical assistance, therefore deserves major A.I.D. attention in most countries. Where existing program management is weak, it may be necessary to initiate activities with only a few of the needed program components while management assistance is provided.

Accordingly, support should be provided to establish or strengthen a central diarrheal disease control unit with sufficient full-time personnel to manage the complex efforts necessary for program success. Some separation and differentiation of the diarrhea program from other primary health care activities, can be useful in raising national consciousness about diarrheal disease control, and the complexities of implementing, managing, and coordinating the multiple efforts needed for a successful ORT program. Full-time personnel are required at the central level in essentially all countries, and at regional or provincial levels in some larger countries. At the same time, integration of ORT and other diarrhea-related interventions into primary health care activities at the peripheral health center and village levels should be the eventual goal.

Supervision, monitoring, and evaluation are critical components of program management, particularly since behavioral change in both providers and consumers is the target of the program. Supervision is essential to reinforcing the lessons given in training programs as well as to ensuring accurate and effective use of ORT by health care providers. Programs should define supervisory activities and design reporting forms with this in mind, assessing in particular the effectiveness of providers in conveying needed information about ORT to mothers, as well as other case management activities.

Monitoring the implementation and progress of a national program requires the regular collection, analysis, and presentation of relevant information about all the components of the program (items 5-9 of this section). Supervision of health sector personnel case management is one mechanism for collection of such information. Programs should establish an information system which gathers both health and management information, from households as well as from health facilities. The use of sentinel health facilities[3/] (to

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3/ Sentinel health facilities are specially-designated sites for collecting disease statistics and other program information on a regular basis. The facilities must see sufficient numbers of cases and should be chosen on the basis of their interest and capacity to collect complete and accurate data.

gather needed data dependably from routine clinical activities) and recurrent limited household surveys are two recommended methods to ensure that both target levels are being covered, in addition to routine reporting of diarrhea related statistics by treatment units.

Evaluation of national programs should be coordinated with WHO/CDD, UNICEF, and other appropriate organizations to ensure that standard techniques are being used and that data are comparable with those from other countries. Formative evaluation, carried out periodically during a project, should lead to program adjustments.

Indicators used for these activities should be chosen carefully relative to program targets, so as to be representative, useful, measurable, and feasible to collect at reasonable cost. Incorporating such indicators into existing information and reporting systems should be coordinated with other donors, so that such systems do not become overburdened and unworkable. With the need for both field-level management and internationally comparable data in mind, A.I.D. has developed, in cooperation with other organizations, standardized indicators to measure the progress of its programs and projects (Appendix II). These indicators should be employed in ORT programs, as they permit the measurement of availability (access and capability), use and effective use.

Lastly, none of this information will be useful if it is not fed back, simply and quickly, to supervisors and workers at each level, and used in making program decisions. USAID should monitor programs to ensure that feedback and timely use of data in decision-making is taking place; otherwise, monitoring activities incur needless expense and do not contribute to effective program management.

8. Research and Information Dissemination

Research and information dissemination are important for strengthening technological resources and making them available widely. A.I.D. will support research in a number of areas related to diarrheal disease control, ranging from basic studies to improve the effectiveness and actual appropriateness of the ORS solution, development of vaccines against organisms causing diarrhea, and examination of nutritional aspects of diarrhea and the pathogenesis of persistent diarrhea, to applied or operational studies concerning etheographical/anthropological/behavioral aspects of diarrhea control programs and ORT, communication techniques, feeding during diarrhea, and other program implementation problems both at the local or country level and at regional and international levels. Research priorities will include preventive measures to control diarrhea. Small research projects should also be considered in country programs as a means for involving key physician leaders in the program.

A.I.D. will also support the dissemination of technical information about diarrhea, both through information centers and bulletins (national level as well as international), and through national, regional, and international workshops.

VI. IMPLICATIONS FOR A.I.D. SUPPORT

First, A.I.D. support in the area of diarrhea control will be devoted primarily to ORT as the most immediately effective means of reducing acute and long-term mortality from diarrhea. A.I.D. will also provide some support for diarrhea prevention, particularly in water and sanitation; personal hygiene education; new vaccine development, including a vaccine against rotavirus and cholera; and extension of coverage of children by measles vaccine. The integration of nutrition activities with ORT activities, especially feeding during and after diarrhea and linkages with growth monitoring activities, will receive high priority. Support will also be given for operational research and research on knowledge, attitudes, and practices related to diarrhea. Recognizing that resources made available to support ORT can also contribute to strengthening the basic health care infrastructure, A.I.D. will increase its support for efforts to integrate ORT programs with other basic primary health care activities.

Second, A.I.D. will make long-term commitments. The degree of change required, and the continuous promotional input needed to generate lasting adoption of ORT as the mother's basic response to diarrhea, require many projects to be planned for five years or more. Furthermore, since many countries currently lack the economic ability to support many of the costs of diarrhea control programs, A.I.D. recognizes the possibility that long-term support may be required if programs are to be not only initiated but sustained during times of economic hardship.

Third, the Agency is prepared to finance recurring operating costs for a predetermined time period, with cost and financing analysis, monitoring and phasing-out as an integrated part of program planning and implementation.

Finally, a substantial amount of ORT technical expertise will be needed in communication, logistics, health care financing, management, training and education of health personnel, community development, epidemiology, health planning, and clinical care. A.I.D. will continue its support for such technical assistance.

In order to implement this strategy, A.I.D. has prepared the following concrete steps for strengthening and expanding diarrheal disease control activities, as adequate staff and resources allow.

1. Develop plans and programs with host countries to carry out diarrheal disease control activities with a special emphasis on child survival priority countries. Policy dialogue will be encouraged in countries where diarrheal diseases are a major problem but not a high priority for the host government (e.g., several African countries).

2. Increase the overall funding levels for support of diarrheal disease control activities. A.I.D. funding has increased substantially since 1983, when total expenditures were approximately $12.8 million. This level increased to $18.6 in 1984 and exceeded $45 million in 1985. As appropriate, the level of funding will continue to increase in future years.

3. Launch an ORT/diarrheal disease control project in FY 87/88 to follow the PRITECH contract and provide long-term in-country technical assistance in diarrheal disease control to A.I.D. assisted countries. This project will provide valuable resources to nonemphasis countries as well as to child survival emphasis countries. The Agency will continue to support the Combatting Childhood Communicable Disease Project (CCCD) and its work in diarrheal disease control in Africa.

4. Promote the appropriate use of the private sector in diarrheal disease programs. This may include training of PVO staffs, development of social marketing approaches, assistance in alternative financing schemes, and loans to private companies for the production of ORS.

5. Assist in the production of oral rehydration salts. As a long-term goal, A.I.D. will assist appropriate countries in the local production of ORS. Technical assistance, loans, and quality control guidelines will be available for local private companies interested in production. For those countries not ready for local production, A.I.D. plans to develop a consolidated centralized procurement system which will ensure quality control, and reduce the time of delivery and overall cost of packets. A.I.D. will inform missions of guidelines for quality control at local and the central levels.

6. Maintain and strengthen the overall capacity of A.I.D. to access high-level technical expertise in diarrheal disease control activities. As appropriate, A.I.D. will support the training of key professionals in the area of diarrheal disease control.

7. Increase overall understanding of the role of communication and social marketing in the acceptance and use of ORT by health providers and mothers. The Agency will continue to fund health communication efforts and seek ways to increase their long-term institutionalization within the host country.

8. Continue to support both applied and operational research in an attempt to develop new approaches and better delivery systems for controlling diarrheal diseases. A.I.D. will strengthen its data collection system and evaluation methodology in order to ascertain the impact of its services and to improve its approaches.

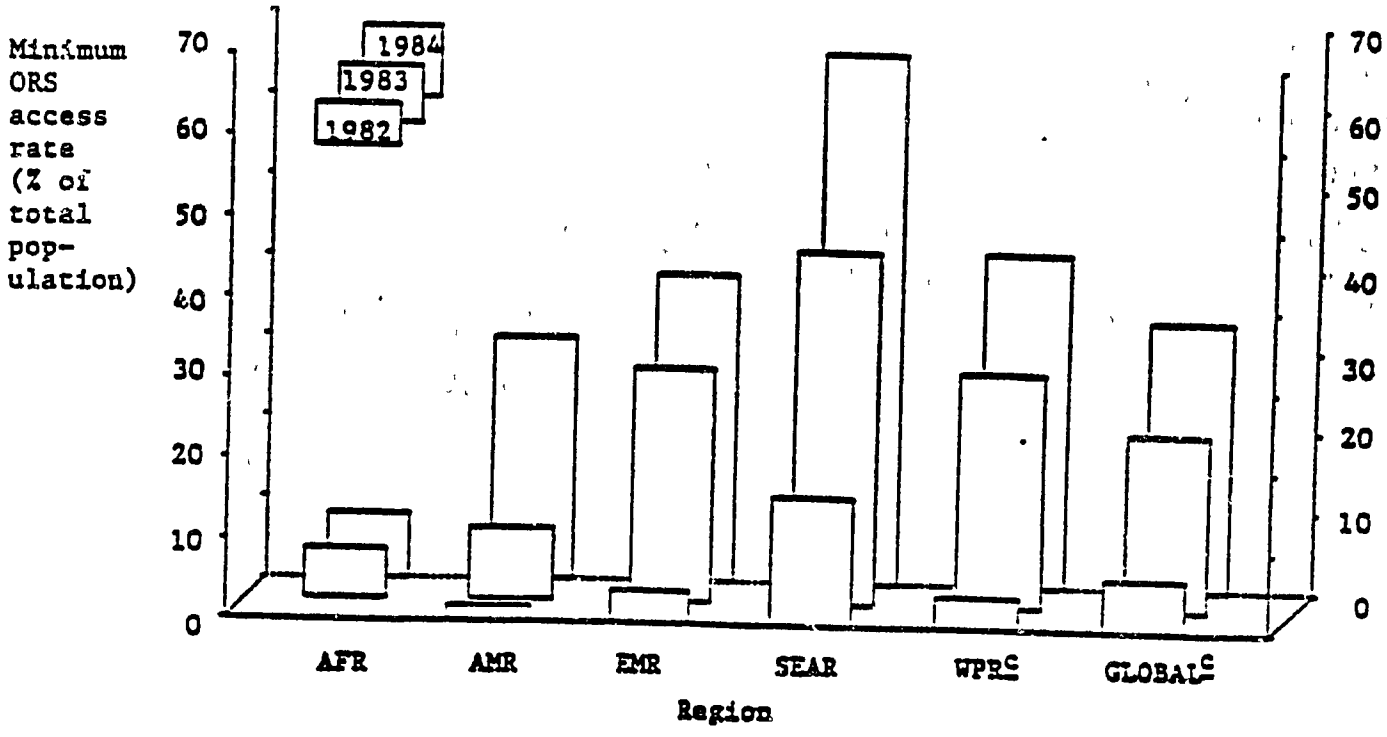
9. Conduct a variety of dissemination activities to make information on diarrheal disease control more widely available. These will include regional and subregional workshops and support for newsletters concerning aspects of diarrheal disease control.

10. Cooperate with multilateral organizations, such as WHO and UNICEF, and other bilateral organizations in support of diarrheal disease control programs. A.I.D. will continue to support the Peace Corps for training and project development in this area.

11. Strengthen overall efforts linking ORT with other proven diarrheal disease control activities such as nutrition, measles immunization, water and sanitation, and personal hygiene. Seek to target the most potentially effective activities in these areas to maximize their impact on diarrheal disease control.

APPENDIX I

ESTIMATED MINIMUM ORS ACCESS RATE[a] 1982 -1984, BY REGION*



Number of countries from which data were available

1982	0	14	13	4	3	34
1983	38[b]	9	15	10	9	78[b]
1984	14	18	9	10	8	59

[a] Proportion of population with reasonable access to a provider of ORS who is trained in its use. Numerators have been calculated assuming no access in those countries for which no data were available. Data were drawn from a variety of sources.

[b] In 1983 access estimates for AFR were based entirely on ORS supply and distribution records. In all other regions and/or years additional information was available.

[c] Excluding China.

* WHO/CDD/TAG/86.2. Fifth Programme Report, 1984-85.

AFR (Africa): Algeria, Angola, Benin, Botswana, Burundi, Cameroon, Central African Rep., Chad, Congo, Ethiopia, Gabon, Gambia, Ghana, Guinea Bissau, Ivory Coast, Kenya Madagascar, Malawi, Mali, Mauritania, Niger, Sao Tome & Principe, Senegal, Seychelles, Sierra Leone, Swaziland, Togo, Uganda, United Rep. of Tanzania, Zaire, Zimbabwe.

AMR (Americas): continued on next page.

AMR (Americas): Argentina, Belize, Bolivia, Brazil, Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, El Salvador, Haiti, Honduras, Jamaica, Mexico, Nicaragua, Panama, Paraguay, Peru, Surinamu, Uruguay, Venezuela.

EMR (Eastern Mediterranean Region): Afghanistan, Democratic Yemen, Djibouti, Egypt, Gaza Strip, Iran, Iraq, Jordan, Kuwait, Oman, Pakistan, Saudi Arabia, Somalia, Sudan, Syrian Arab Rep., Tunisia, United Arab Emirates, Yemen.

EUR (Europe): Turkey.

SEAR (South East Asia): Bangladesh, Bhutan, Burma , India, Indonesia, Maldives, Mongolia, Nepal, Sri Lanka, Thailand.

WPR (Western Pacific Region): China, Democratic Kampuchea, Fiji, Guam, Kiribati, Lao People's Democratic Republic, Malaysia, Papua New Guinea, Philippines, Samoa, Solomon Islands, Tonga, Vanuatu, Viet Nam.

APPENDIX II

JULY 15, 1986

INDICATORS FOR ORT

	TIER ONE	TIER TWO	SPECIAL STUDIES (TIER THREE)
INPUTS	Life of project budget for ORT/ORS activities ($ and %) Current year AID-financed obligations No. ORS packets imported and locally produced by the project, by size Cost per packet to the project Price per packet charged to the consumer	TIER 1 plus following:	TIER 1 and TIER 2 plus following:
OUTPUTS	No. health workers trained through project activities to teach ORT by type of worker Total no. of health workers in project area by type of worker		
EFFECTIVENESS	No. and type of service units and distribution points for ORS packets in project area No. and type of service units and distribution points in project area with ORS packets in inventory No. and type of service units and distribution points in project area with ORS packets in inventory and a trained person available Total number of service units and distribution points in project area	No. and % health workers demonstrating/reporting general and special knowledge/competence re ORT No. and % individuals demonstrating/reporting general knowledge/competence re ORT No. and % children under 60 mos. ever given ORT No. and % children under 60 mos. given ORT during last diarrhea episode occuring within previous two weeks (includes measures of effective use)	Cost per treated episode Cost per death averted Observational studies of effective use of ORT
IMPACT			Mortality rate, 0-12 and 13-59 mos. Mortality due to (or associated with) severe dehydration among children 0-12 and 13-59 mos.

APPENDIX III

TYPE OF ORT FLUIDS

INGREDIENTS	ORS	Super-ORS	Sugar-Salt	Home-Available Fluids
Salt (NaCl)	yes	yes	yes	yes
Potassium	yes	yes	no	sometimes (and usually in low concentrations)
Bicarbonate or Citrate	yes	yes	no	no
Agent(s) to enhance sodium absorption	yes (Glucose or Sucrose)	yes (Glucose plus amino acid (glycine); or starch and protein, e.g., rice powder)1/	yes (Sucrose)	yes (food starches and proteins)

1/ these and other possible agents are under investigation.

APPENDIX IV

Composition of oral rehydration salts

Oral Rehydration Salts (ORS) is the non-proprietary name for a balanced glucose-electrolyte mixture, first used in 1969 and approved, recommended, and distributed by UNICEF and WHO as a drug for the treatment of clinical dehydration throughout the world. In 1984, another mixture containing trisodium citrate instead of sodium hydrogen carbonate (sodium bicarbonate) was developed with the aim of improving the stability of ORS in hot and humid climates. Both compositions are now included in the WHO-recommended list of essential drugs[6] as "Replacement solution".

For convenience, the two mixtures are referred to throughout this manual simply as "ORS-bicarbonate" and "ORS-citrate". They have the following compositions, to be dissolved in 1000 ml of drinking water:

%	ORS-bicarbonate	grams/litre
12.73	Sodium chloride	3.5
9.09	Sodium bicarbonate (sodium hydrogen carbonate)	2.5
5.45	Potassium chloride	1.5
72.73	Glucose anhydrous	20.0
100.00	Total	27.5 g

%	ORS-citrate	grams/litre
12.55	Sodium chloride	3.5
10.39	Trisodium citrate, dihydrate	2.9
5.38	Potassium chloride	1.5
71.68	Glucose, anhydrous	20.0
100.00	Total	27.9

ANNEX 7-A

APPENDIX V

A. GOOD PRACTICES IN THE MANUFACTURE AND QUALITY CONTROL OF DRUGS [1]

1. General considerations

In the manufacture of drugs, overall control is essential to ensure that the consumer receives drugs of high quality. Haphazard operations cannot be permitted in the manufacture of substances that may be necessary to save life or to restore or preserve health

Difficulties will undoubtedly arise in establishing the necessary criteria for the manufacture of drugs that will meet established specifications and that can therefore be used with confidence Recommended practices for the manufacture of drugs of desired quality are set forth below Adherence to these practices, complementing the various control tests followed from the beginning to the end of the manufacturing cycle, will contribute substantially to the manufacture of consistently uniform batches of high-quality drugs

The manufacturer must assume responsibility for the quality of the drugs he produces. He alone can avoid mistakes and prevent mishaps by exercising adequate care in both his manufacturing and control procedures

The good practices outlined below should be considered as general guides; whenever necessary, they may be adapted to meet individual needs, provided the established standards of drug quality are still achieved [2] They are intended to apply to the manufacturing processes (including packaging and labelling) used in the production of drugs in their finished dosage forms

Sometimes it occurs that several firms cooperate in the production (including packaging and labelling) of the finished dosage forms of drugs. It may also occur that a finished, packed, and labelled drug is repacked and/or relabelled, giving it a new designation. It should be pointed out that since such procedures constitute part of a manufacturing operation, they should be subject to the relevant requirements proposed below.

The requirements set forth herein are intended to apply primarily to preparations for human administration However, equal attention should be given to quality in the manufacture of veterinary preparations.

2. Definitions

For the purposes of this document, the following definitions are adopted:

Drug. Any substance or mixture of substances that is manufactured, sold, offered for sale, or represented for use in (1) the treatment, mitigation, prevention, or diagnosis of disease, an abnormal physical state, or the symptoms thereof in man or animal; or (2) the restoration, correction, or modification of organic functions in man or animal.

Manufacturing All operations involved in the production of a drug, including processing, compounding, formulating, filling, packaging, and labelling.

Starting materials. All substances, whether active or inactive or whether they remain unchanged or become altered, that are employed in the manufacture of drugs.

Batch. A quantity of any drug produced during a given cycle of manufacture. The essence of a manufacturing batch is its homogeneity.

Batch number. A designation (in numbers and/or letters) that identifies the batch and that permits the production history of the batch, including all stages of manufacture and control, to be traced and reviewed.

Quarantine. The status of a material that is set apart and that is not available for use until released.

Quality control All measures designed to ensure the output of uniform batches of drugs that conform to established specifications of identity, strength, purity, and other characteristics.

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[1] Official Records of the World Health Organization, No. 226, 1975, Annex 12

[2] Additional recommendations specifically applicable to biological products are set forth in a number of sets of Requirements for Biological Substances adopted by the WHO Expert Committee on Biological Standardization and other WHO expert groups and published in the WHO Technical Report Series

ANNEX 7-B

"Half-finished" product. Any material or mixture of materials that must undergo further manufacture.

3. Personnel

Experts responsible for supervising the manufacture and quality control of drugs should possess the qualifications of scientific education and practical experience required by national legislation. Their education should include the study of an appropriate combination of (*a*) chemistry (analytical chemistry, biochemistry, etc.); (*b*) chemical engineering; (*c*) microbiology, (*d*) pharmaceutical sciences and technology; (*e*) pharmacology and toxicology; (*f*) physiology and histology; and (*g*) other related sciences. They should also have adequate practical experience in the manufacture and quality control of drugs In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control of drugs.

Such experts should preferably not have any interests outside the manufacturer's organization that (*a*) prevent or restrict their devoting the necessary time to their assigned responsibilities or (*b*) may be considered to entail a conflict of financial interest. Finally, they should be given full authority and the facilities necessary to carry out their duties effectively.

In addition to the experts noted above, an adequate number of technically trained personnel should be available to carry out the manufacturing and quality control operations in accordance with established procedures and specifications. All personnel should be motivated towards the establishment and maintenance of high-quality standards.

4. Premises

4.1 *General*

Drugs should be manufactured, processed, packaged, labelled, and tested in premises that are suitable for these purposes.

In determining the suitability of premises regard should be paid to:

(1) the compatibility of other manufacturing operations that may be carried out in the same or adjacent premises,

(2) the adequacy of the working space, which should allow orderly and logical placement of equipment and materials so as to (*a*) minimize the risk of confusion between different drugs or their components, (*b*) control the possibility of cross-contamination by other drugs or substances, and (*c*) minimize the risk of omission of any manufacturing or control step,

(3) those physical aspects of the premises that could affect the quality and safety of products buildings should be so designed and constructed as to prevent the entry of animals and insects, interior surfaces (walls, floors and ceilings) should be smooth and free from cracks, should not shed particulate matter, and should permit easy cleaning and if necessary disinfection;

(4) lighting, heating and ventilation and, if necessary, air conditioning required to maintain a satisfactory temperature and relative humidity that will not adversely affect the drug during manufacture and storage, nor the accuracy and functioning of laboratory instruments.

4.2 *Storage areas*

The suitability of storage areas cannot be strictly specified in a manner that meets all possible contingencies. However, the following principles should be observed:

(1) storage areas should provide adequate space, suitable lighting, and should be arranged and equipped to allow dry, clean, and orderly placement of stored materials and products, whenever necessary under controlled conditions of temperature and humidity;

(2) such areas should provide for suitable and effective separation of quarantined and other materials and products;

(3) special and segregated areas should be available for storage of:

(*a*) substances presenting special risks of fire and explosion;

(*b*) highly toxic, narcotic, and other dangerous drugs (these areas should be adequately protected against theft);

(*c*) rejected and recalled materials and products.

4.3 *Special*

For special purposes, such as the manufacture of drugs that are intended to be sterile but cannot be sterilized in their final containers, separate enclosed areas, specifically designed for the purpose, should be provided. These areas should be entered through an

air-lock and should be essentially dust-free and ventilated with an air supply through bacteria-retaining filters giving a pressure higher than in adjacent areas. Such filters should be checked for performance on installation and periodically thereafter. All surfaces in manufacturing areas should be designed to facilitate cleaning and disinfection

Routine microbe counts of the air in the areas described above should be carried out before and during manufacturing operations. The results of such counts should be checked against established standards, and adequate records of the counts should be maintained.

For the manufacture of drugs that can be sterilized in their final containers, the requirements given above are considered essential, with the exception of mandatory sterilization of air supplies The design of areas used for this purpose should preclude the possibility that products intended for sterilization could be mixed with, or taken to be, products already sterilized. This may conveniently be effected by the use of double-ended sterilization apparatus opening into separate and non-communicating areas.

5. Equipment

Manufacturing equipment should be designed, placed, and maintained in such a way as to:

(1) be suitable for its intended use;

(2) facilitate thorough cleaning wherever necessary;

(3) minimize any contamination of drugs and their containers during manufacture; and

(4) minimize the risk of confusion or the omission of a processing step such as filtration or sterilization.

Operating conditions within an apparatus used to sterilize products should be monitored by means of recording devices, which should be initially calibrated and checked at approved intervals by approved methods Suitable standard[illegible] microbiological indicators may be used to demonstrate the adequacy of the sterilization process.

Manufacturing equipment and utensils should be thoroughly cleaned and, when necessary, sterilized, and should be maintained in accordance with specific written directions When indicated, all equipment should be disassembled and thoroughly cleaned, to preclude the carry-over of drug residues from previous operations Adequate records of such procedures should be maintained

Equipment used for aseptic filling should be checked at suitable intervals by microbiological methods.[1] Weighing and measuring equipment used in production and quality control should be calibrated and checked at suitable intervals by appropriate methods. Adequate records of such tests should be maintained.

6. Sanitation

Manufacturing premises should be maintained in accordance with the sanitary standards issued by the appropriate health authority. They should be clean and free from accumulated waste, orderly, and free from vermin. A written sanitation programme should be available, indicating

(1) areas to be cleaned, and cleaning intervals;

(2) cleaning procedures to be followed and, if necessary, equipment and materials to be used for cleaning; and

(3) personnel assigned to and responsible for cleaning operations.

Eating, smoking, and unhygienic practices should not be permitted in manufacturing areas.

Sufficient, clean, well-ventilated toilet facilities, including facilities for hand-washing and rooms for changing clothes, should be available near working areas for the use of manufacturing personnel.

7. Starting materials

An inventory should be made of all starting materials to be used at any stage in the manufacture of drugs, and records should be kept of the supplier, the origin (if possible), date of receipt, date of analysis, date of release by the quality control department, and their subsequent use in manufacture.

All such materials must be:

(1) identified, and their containers examined for damage;

(2) properly stored in quarantine;

(3) properly sampled by the quality control department;

[1] This may be accomplished by conducting normal filling operations using suitable sterile liquid bacteriological media or other media suitable for dry powder filling, as the case may be, taking into consideration the risks of microbiological contamination of the equipment

(4) tested for compliance with requirements (all materials should be marked to indicate that they are undergoing testing); and

(5) released from quarantine by the quality control department by means of written instructions.

Starting materials that are accepted or approved should be properly and conspicuously labelled as such, and should then be transferred, if necessary, to areas designated for the storage of such materials

All rejected starting materials should be conspicuously identified as such, and should be destroyed or returned to the supplier as soon as possible.

8. Manufacturing operations

Manufacturing operations and controls should be carried out under the supervision of experts, as specified in section 3.

8.1 *Cleanliness*

Before any manufacturing operation is begun, a check should be made to ensure that all apparatus and equipment to be used in the operation has been cleaned and/or sterilized (see section 5)

8.2 *Equipment and containers*

The contents of all vessels and containers used in manufacture and storage between manufacturing stages must be identified by conspicuously placed and clearly legible labels, bearing the name and/or identification code of the processed materials and the necessary batch identification data Similar labels should be attached to mechanical manufacturing equipment during its operation.

8.3 *Precautions against contamination and confusion (mix-up)*

All manufacturing operations should be confined to separate areas intended for such purposes, with complete equipment used exclusively in those areas, or measures should be taken to ensure that neither cross-contamination nor confusion (mix-up) can occur [1]

In manufacturing areas, clean working garments should be worn over, or in place of, street clothing.

The manufacture of drugs intended to be sterile should be performed in areas specially designed and constructed, as indicated in section 4.3. Whenever the different operations are not physically separated, and there is a possibility that unsterilized and sterilized products might be confused, all containers of batches of products for sterilization should bear a clear indication of whether or not their contents have been sterilized.

Products that undergo sterile operations should be protected from contamination by using methods such as laminar-flow techniques, and by ensuring that personnel wear clean, sterile gowns, head coverings, masks, rubber gloves, and shoe coverings Before dressing and entering sterile areas, personnel must wash their hands with a suitable disinfectant.

All dust-producing operations involving highly potent substances, particularly antibiotics, should be conducted in confined areas that are provided with adequate exhaust systems or that are maintained under appropriate pressure, so as to prevent cross-contamination. Adequate precautions should be taken to prevent the recirculation of contaminated air.

8.4 *Manufacturing personnel*

No person known to be affected with a disease in a communicable form, or to be the carrier of such a disease, and no person with open lesions on the exposed surface of the body, should be engaged in the manufacture of drugs. Manufacturing personnel should undergo periodic health checks. In order to prevent any impairment of health caused by the handling of hazardous or potent materials, manufacturing personnel should, whenever necessary, wear protective clothing, shoes, headgear, dust masks, etc., and such protective clothing should remain in the area in which it is used In some instances, it may be necessary to have restrictions on the movement of personnel to and/or from special working areas.

8.5 *Documents relating to manufacturing procedures*

Documents [2] relating to manufacturing procedures should be prepared for each drug under the direct supervision of experts (see section 3) who have the

[1] The simultaneous manufacture, in adjacent areas that are not physically separated, of drugs that are similar in appearance should be avoided

[2] Such documents should not be handwritten nor contain handwritten amendments or comments When necessary they should be rewritten and all outdated instructions withdrawn, to avoid the possibility of re-use They should be suitable for copying in a manner that avoids any possibility of a transcription error

necessary authority. They should contain at least the following information for each drug:

(1) its name and dosage form;

(2) a description or identification of the final container(s), packaging material(s), and labels and, where applicable, of the closure(s) to be used;

(3) the identity, quantity, and quality of each starting material to be used, irrespective of whether or not it appears in the finished drug (the permissible excess ("overage") that may be included in a formulated batch should be indicated);

(4) the theoretical yields to be expected from the formulation at different stages of manufacture and the permissible yield limits,

(5) detailed instructions for, and precautions to be taken in, manufacture and storage of the drug and of "half-finished" products, and

(6) a description of all necessary quality control tests and analyses to be carried out during each stage of manufacture, including the designation of persons or departments responsible for or charged with the execution of such tests and analyses.

8.6 *Batch manufacturing records*

Manufacturing records must provide a complete account of the manufacturing history of each batch of a drug, showing that it has been manufactured, tested, and analysed in accordance with the manufacturing procedures and written instructions described in section 8.5 A separate batch manufacturing record should be prepared for each batch of drug produced, and should include the following information.

(1) name and dosage form,

(2) date of manufacture;

(3) batch identification,

(4) complete formulation of the batch (see section 8.5 (3));

(5) the batch number (or analytical control number) of each component used in the formulation;

(6) the actual yield obtained at different stages of manufacture of the batch as compared with the theoretical yield (see section 8.5 (4)),

(7) a duly signed record of each step followed, precautions taken, and special observations made throughout the manufacture of the batch,

(8) a record of all in-process controls followed and of the results obtained,

(9) a specimen of the actual coded label used,

(10) identification of packaging materials, containers, and, where applicable, closures used,

(11) signature of the expert responsible for the manufacturing operations, and the date of his signature;

(12) an analytical report showing whether the batch complies with the prescribed specifications for the drug, dated and duly signed by the responsible expert;

(13) a record of the decision regarding the release or rejection of the batch by the quality control department (see section 10.1 (5)); and

(14) if the batch is rejected, a record of its disposal or utilization.

8.7 *Maintenance of batch manufacturing records*

For reference purposes, all batch manufacturing records should be retained for a specified period.

9. Labelling and packaging

Labelling and packaging materials, including leaflets, should be stored and handled in such a way as to ensure that labels, packaging materials and leaflets relating to different products do not become intermixed. Access to such materials should be restricted to authorized personnel.

Prior to packaging and labelling of a given batch of a drug, the manufacturing and control records specified in section 8 6 should show that the batch has been duly tested, approved, and released by the responsible quality control expert. Prior to being issued, all labels for containers, cartons, and boxes and all circulars, inserts, leaflets, etc, should be examined and released as satisfactory for use by the designated person(s) (see section 10 1 (4))

To prevent packaging and labelling errors a known number of labelling and packaging units should be issued and, if required, coded Such issuance should be made against a written, signed request that indicates the quantity and types required

Upon completion of the packaging and labelling operation, a comparison should be made between the number of labelling and packaging units issued and the number of items labelled and packaged plus the number of units not used All coded unused units should be destroyed. Any significant or unusual discrepancy in the numbers should be carefully investigated

All finished drugs should be identified by labelling that should bear, clearly indicated, at least the following information

(1) the name of the drug;

(2) a list of the active ingredients, showing the amount of each present, and a statement of the net contents, e.g, number of dosage units, weight or volume,

(3) the batch number assigned by the manufacturer;

(4) the expiry date, if required (see section 10.1 (8));

(5) any special storage conditions or handling precautions that may be necessary;

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(6) directions for use, and warnings and precautions that may be necessary; and

(7) the name and address of the manufacturer or the person responsible for placing the drug on the market.

10. The quality control system

10.1 *Quality control department*

Every manufacturing establishment must have a quality control department supervised by a suitably qualified expert directly responsible to management but independent of other departments The quality control department should control all starting materials, monitor the quality aspects of manufacturing operations, and control the quality and stability of drugs.

The quality control department should have the following principal duties:

(1) to prepare detailed instructions, in writing, for carrying out each test and analysis;

(2) to release or reject each batch of starting material;

(3) to release or reject "half-finished" products, if necessary;

(4) to release or reject packaging and labelling materials and the final containers in which drugs are to be placed;

(5) to release or reject each batch of finished drug that is ready for distribution;

(6) to evaluate the adequacy of the conditions under which starting materials, "half-finished" products, and finished drugs are stored;

(7) to evaluate the quality and stability of finished drugs and, when necessary, of starting materials and "half-finished" products;

(8) to establish expiry dates and shelf-life specifications on the basis of stability tests related to storage conditions,

(9) to establish, and when necessary revise, control procedures and specifications; and

(10) to be responsible for the examination of returned drugs, to determine whether such drugs should be released, reprocessed, or destroyed Adequate records of the disposition of such drugs should be maintained

In order to fulfil its responsibilities, the quality control department should take samples (e.g., of starting materials and finished drugs), according to established procedures The samples should be properly labelled, and portions should be kept for future reference

The quality control department should maintain adequate analytical records concerning the examination of all samples taken Such records should incl de

(*a*) the result of every test performed, including observations and calculations, relating to compliance with the established specifications;

(*b*) the source of the specifications used;

(*c*) the signature(s) of the person(s) who performed the quality control procedures; and

(*d*) a final review, the decision taken, and a dated endorsement by a duly authorized expert.

10.2 *Quality control laboratory*

The quality control department should have a laboratory available to it. The laboratory should:

(1) be adequately staffed and fully equipped for performing all quality control tests and analyses required during and after manufacture;[1]

(2) be supervised by a qualified expert (see section 3)

11. Self-inspection

In order to maintain strict adherence to all manufacturing procedures and prescribed controls, it may be advisable for a firm to designate an expert or a team of experts to conduct regularly scheduled inspections of its overall manufacturing and control operations.

However, this should not be taken to mean that any firm that exercises self-inspection should be exempt from the official inspections required by the laws and regulations of the country in which it is located.

12. Distribution records

Adequate records should be maintained of the distribution of a finished batch of a drug in order to facilitate prompt and complete recall of the batch if necessary.

13. Complaints and reports of adverse reactions

Reports of injuries or adverse reactions resulting from the use of a drug should be forwarded to the appropriate authorities Complaints regarding the quality of a drug, including any change in its physical characteristics, must be thoroughly investigated. If they prove well-founded, appropriate measures must be taken as soon as possible. The measures taken should be recorded and filed with the original complaint

[1] If animal tests are necessary, the animals should be given adequate quarters and care (for further information, see WHO Technical Report Series No 323, 1966, pp 14, 16) The use of outside independent laboratories may be advisable for specialized and complex analytical and biological procedures that require the use of costly equipment and that can be performed only by technicians with specialized training Such laboratories should be adequately staffed and fully equipped to perform

APPENDIX VI

ORAL REHYDRATION THERAPY FOR TREATMENT OF DIARRHOEA IN THE HOME

The approach to early home treatment of diarrhoea varies widely and is influenced by many factors, including cultural attitudes and practices, and socioeconomic status. For example, antidiarrhoeal drugs and antimicrobials are commonly used by persons with higher incomes, while those with lower incomes more often rely on folk remedies which often include different types of liquids available in the home (e.g., cereal gruels, herbal teas).

The effectiveness and safety of Oral Rehydration Salts (ORS) solution* for the treatment of dehydration due to diarrhoea both in health facilities and at the community level has been well documented (1, 2, 3). That ORS can be used successfully to maintain normal hydration status in the vast majority of cases following the treatment of dehydration suggests that it should also be effective for early use at home to prevent dehydration. However, as ORS is not necessary for early home therapy in most cases, and is currently available to only one-third of the people living in the developing world (4), other approaches to the preparation of oral rehydration solutions in the home for use early in diarrhoea have been sought. These generally involve the education of mothers to give fluids that are either normally available at home or can be prepared with ingredients at hand. These fluids can be grouped into the following categories:

- Sugar-salt solution (SSS)
- Food-based solutions
- Commercial beverages and other fluids.

This paper reviews the information available on the use of these solutions and provides recommendations for selection of a solution by national Diarrhoeal Diseases Control (CDD) programmes. The paper does not discuss information available on the use of ORS which, as indicated above, is viewed primarily as a solution for the treatment of dehydration.

1. SUGAR-SALT SOLUTION (SSS)

Salt water was used in treatment of cholera patients as early as 1834 in the UK (5). In the late 1940s/early 1950s a carbohydrate (e.g., glucose) was added to oral salt solutions being used to treat diarrhoea, to improve their taste and to provide calories (6, 7). It was in the mid-1960s that glucose-mediated sodium absorption in the intestine was first described and subsequently found to remain largely intact during diarrhoea (8, 9, 10). Because of its carrier function, there is universal agreement that glucose (or a disaccharide or polysaccharide that yields glucose when hydrolysed) should be included in any oral rehydration solution. Sucrose (table sugar) has been widely used as a practical and effective source of glucose.

1.1 Effectiveness of SSS

SSS can correct adequately the fluid volume deficits due to non-cholera diarrhoea in

*ORS solution contains (in grams per litre): sodium chloride 3.5, trisodium citrate, dihydrate 2.9 or sodium bicarbonate 2.5, potassium chloride 1.5, and glucose 20.0.

children and adults (11) though it is inadequate for the correction of accompanying hypokalaemia and corrects acidosis slowly. SSS is also inadequate for the treatment of dehydration and replacement of electrolyte losses in cholera (12). That it may be effective in preventing most cases of dehydration is suggested by its ability to correct fluid volume deficits in non-cholera diarrhoea. However, no studies have directly addressed this question. When SSS was used by village health workers in Egypt (13) and India (14, 15) for primary treatment of diarrhoea, diarrhoea-associated mortality rates declined significantly. However, in the Egyptian study ORS packets were available free from health facilities and health workers or at subsidized prices from shops and pharmacies; and in the Indian study, a pharmacy-prepared mixture containing sodium and potassium chloride, to which sodium bicarbonate and sugar were added at home, was available for those with marked dehydration. In addition, in both studies, repeated home visits undoubtedly led to earlier recognition of diarrhoea cases. Thus, it is not certain whether the fall in mortality rates in these studies was due to the use of SSS at home to prevent dehydration and/or treat mildly dehydrated cases, the use of ORS in more severely dehydrated cases, or the repeated home visits by health workers, or a combination of these.

1.2 Composition of SSS

Assuming that SSS is effective in preventing dehydration, it would be useful to have data on the optimum concentrations of the sugar (glucose or sucrose) and salt (sodium). In a recent study, Santosham et al. (16) demonstrated that solutions containing 30, 50, and 90 mmol/l of sodium were equally safe and effective in treating diarrhoea cases with no or mild dehydration. Snyder et al. (17) compared serum sodium concentrations in children receiving ORS or a labon (salt)-gur (molasses) solution (see section 1.4) containing 90 mmol/l of sodium for primary treatment of diarrhoea in a community-based study in Matlab, Bangladesh, and found very low rates of electrolyte abnormalities in both groups. This type of information led WHO and UNICEF to recommend that home-made oral fluids should have sodium and glucose concentrations of 50-100 mmol/l (18). The lower limit was considered to be the minimum concentration required to prevent most cases of dehydration and to treat mildly dehydrated cases, and the upper limit was felt to be at the highest level of safety.

1.3 Preparation of SSS

In 1972, Church (19) recognized the need for a simple method to enable mothers to prepare SSS at home. He recommended mixing two "thumb and 2-finger pinches" of salt and one "4-finger scoop" of sugar in a pint of water which gives a solution containing 34 mmol/l of sodium and 175 mmol/l of glucose. Since then, many other recipes have been proposed, along with various simple measuring instruments (e.g., teaspoons, bottle caps). Table 1 lists some of these recipes and indicates their sodium and glucose concentrations*. Many of the recipes are outside the 50-100 mmol/l range. About one-third of the recipes include a recommendation to add lemon or orange juice, coconut water, or potassium chloride tablets (as a source of potassium) or baking soda (as a source of bicarbonate). Similar data have recently been tabulated for solutions used in 11 African countries (20).

Potential difficulties in using the "pinch-and-scoop" method were initially demonstrated in a study (21) in which the mean weight of a pinch of refined salt was recorded as 0.42 g (± 0.12) for mothers in the UK, 0.96 g (± 0.52) for mothers in Trinidad and Tobago, and 2.27 g (± 1.65) for mothers in India (numbers in parentheses are ± S.D.). For the latter group, a pinch of crude salt weighed 1.63 g (± 0.96). In another study in Calcutta, a scoop was found to deliver 15-20 g of sugar and a pinch 0.8-2.7 g of salt (22). In a study in Nepal, about 25% of the solutions had greater than 90 mmol/l of sodium when prepared by the pinch-and-scoop method (23). In contrast, the Bangladesh Rural Advancement Committee (BRAC) has reported a consistently acceptable range of concentrations of sodium (30-100 mmol/l) and glucose (40-178 mmol/l) using the pinch-and-scoop method when training and supervision were intensive, the salaries of trainers were related to the quality of the performance of trainees, and the fluids were prepared in containers provided for mixing (24).

*A. Voight of the Centers for Disease Control, Atlanta, USA, provided many of these recipes.

Recognizing the differences in size of available teaspoons and in the amounts delivere by pinches and scoops, Hendrata (25) designed a double-ended plastic spoon to measure sal and sugar for mixing in a cup (200 ml) of water which yields a concentration of 77 mmol/l o: sodium and 58 mmol/l of glucose. Morley has widely promoted, through the Teaching Aids a: Low Cost (TALC) programme of the Institute of Child Health, London, UK, a similar spoon o: durable plastic, on which are written instructions in nine different languages.

Levine et al. (26) compared in American nurses the pinch-and-scoop, household-spoon, anc double-ended-spoon methods for measuring sugar and salt and found large intra- anc inter-person variability in the first two methods. The double-ended spoon gave the most consistent results. Ransome-Kuti (27) observed that only 34% of 217 Nigerian women could prepare SSS correctly using teaspoons and proposed the use of a simple plastic measuring device which, if manufactured on a large scale, would be inexpensive. Harland et al. (28) found that the osmolality of SSS prepared by 7 Jamaican mothers was more accurate when the double-ended plastic spoon was used than when it was mixed by other hand-mixing methods learnt through health personnel and radio and television messages. In contrast to these results, a study in Mozambique (29) found the pinch-and-scoop to perform better than the double-ended plastic spoon when the sugar and salt were damp and lumpy, making measurement by level spoonsful difficult. Similarly, in a study in Zimbabwe, de Zoysa et al. (30) found more reliable results when SSS solutions were prepared with domestic teaspoons than with the double-ended spoon, although the reason for this could not be identified.

In another study in Vellore, India (31), use of both the pinch-and-scoop method and the double-ended plastic spoon by village health workers resulted in solutions ranging from 25-120 mmol/l of sodium and 25-140 mmol/l of glucose; both of these ranges were felt by the investigators to be acceptable from the point of view of safety and efficacy, though they are wider than those recommended.

In another study in Zimbabwe (32), mothers were taught to prepare SSS by mixing 6 level teaspoons of sugar and half a level teaspoon of salt in 750 ml of water. The results were encouraging in that, after a period of 11-26 days, recall of the method taught was correct 64% of the time and 84% of mothers prepared fluid that had salt and sugar concentrations within the defined range of 30-100 mmol/l of sodium and 50-149 mmol/l of glucose. Eighty-eight per cent of mothers had available a 750-ml bottle, a teaspoon, sugar, and salt. This report registers one of the most satisfactory experiences with the preparation of SSS.

To prevent the use of solutions containing a high salt content, some workers have advised mothers to make sure that SSS does not taste "more salty than tears" (33). However, as the sodium content of tears varies from 108-176 mEq/l (34), this advice may not be appropriate. Its reliability also is doubtful.

1.4 Availability of ingredients and utensils

Although published reports are few, surveys and informal enquiries in some Asian and African countries (e.g., Bangladesh, India, Mali, Nigeria, Senegal) have revealed that non-availability of salt and sugar or mixing utensils (e.g., spoons) can create operational problems in the use of SSS. In a study in Nepal (23), less than 50% of the homes were found to have sugar and any kind of teaspoon. In many countries sugar is expensive, particularly when purchased in small amounts, and its market price and availability vary according to the season. Even when available, the crystal size, degree of refinement, and moisture content of the sugar and salt can cause difficulty in measurement, as mentioned above. In rare cases, impurities have been found in salt and sugar in the market.

Because of its cost and occasional non-availability, alternatives to the usual cane sugar have been sought. For example, "gur" - a crude, brown, lumpy sugar made by concentrating sugar-cane juice - has been promoted in Bangladesh as a replacement for sugar (35). It has a sucrose content which varies from 52 to 81%, a potassium concentration of about 7 mmol/l, and a variable amount of bicarbonate (usually <10 mmol/l). Honey, 70-80% of which is composed of glucose and fructose in about equal proportions, has also been recommended as a substitute for sugar (50 ml yields about 110 mmol/l of glucose) and has been tried in place of glucose in ORS (36). However, it is generally expensive, varies considerably in quality and is not as widely available as is generally thought.

Teaspoons are usually available in the homes of families of middle to high socioeconomic status, though they may vary considerably in size. In poorer homes they may be found less often. However, in one country (Nigeria), mothers are being educated in the national programme to use a widely available plastic 3-ml spoon for preparing SSS (37). The special double-ended plastic spoons recommended by Morley are certainly more practical, but they may be relatively expensive, especially if made locally, and can be misplaced or used for other purposes. In a study in Nepal, the spoons could be found in only 17 of 50 homes two weeks after their free distribution (38). Similar spoons recommended by Hendrata (25) are at present being evaluated in India and the Philippines.

Recommendations on the amount of salt and sugar to be dissolved must be related to the volume of water; unless a widely available container of an appropriate size is identified, it is not possible to formulate a meaningful recommendation for the preparation of SSS. However, this aspect of SSS preparation is often neglected. Studies in Egypt (39) and India (40) have found that even the concentration of ORS solution made from pre-packaged ORS may be inaccurate if a suitable mixing container is not identified. Empty soft drink and beer bottles have frequently been used. In countries where no such container has been identified, some national programmes have provided a standard mixing vessel to one person in each community, who in turn calibrates containers in neighbours' homes.

1.5 Ability of mothers to learn, retain, and use knowledge

Even when the ingredients and utensils are available, preparation of a safe and effective SSS requires that the mother learn the skill and remember it when needed. As noted above, de Zoysa et al. in Zimbabwe (32) recorded satisfaction with the recall performance of mothers 11-26 days after they had received training. However, in a follow-up, nationwide study undertaken two years later, it was found that while 72% of mothers with children having diarrhoea in the past six months were aware of SSS, only 21% could recite the correct formula (41).

Chowdhury, reporting on the BRAC project in Bangladesh mentioned earlier, observed that 89% of the mothers prepared satisfactory SSS by the pinch-and-scoop method six months after instruction (42). In a more recent review of the national CDD activities in Bangladesh, it was found that 59% of episodes of diarrhoea occurring in BRAC programme areas during the previous two weeks were reported by mothers to have been treated with lobun-gur solution as compared with 15% of episodes in non-BRAC areas (43). However, in the most recent evaluation of the BRAC programme, problems in preparing the solution accurately and using it correctly were identified to a "greater extent than ever expected" (44).

In The Gambia (45), mothers were taught through the nationwide Mass Media for Infant Health (MMIH) project to mix SSS using bottle caps and soft drink bottles, to recognize when to take the child for medical care, to continue feeding during diarrhoea, and to adopt hygienic practices to prevent diarrhoea. After two years of intensive educational activities, more than 70% of all mothers could describe the SSS formula. However, while half of all diarrhoea cases were reported to have been treated with properly made SSS at the end of the campaign, only 15% were treated by a family member fully conversant with the clearly defined five-point procedure for mixing and administration. In a follow-up survey done one year later, less than 10% of mothers could recite how to properly mix and administer SSS and only 25% reported using it for the most recent episode of diarrhoea in their children (46).

A six-month campaign similar to that in The Gambia was undertaken in Swaziland to promote the home use of SSS. In an evaluation of the project (47), the proportion of those who reported using SSS during the most recent diarrhoea episode was 36% before the campaign when 47 different formulations were taught; after the campaign, the proportion of users increased to about 48% and, more significantly, more than half of them used one of two different formulations, one of which was taught during the campaign. The percentage of mothers who could describe the formula correctly increased from 8% to 26% after the campaign. About 4% before and 17% after the campaign said that they both used SSS and knew the amounts of sugar, salt, and water of the formula. However, 54% of mothers described formulae with unacceptably high salt concentrations, which appeared to be due to difficulties in understanding the message about adding salt to the solution. An innovative objective

element for evaluation was to look during home-visits for the rehydration kit that had been promoted in the radio message; about 38% of the respondents had heard of the kit, but only 6% reported owning such a kit, and only half of them could show it to an interviewer.

In a more recent community survey conducted in Rwanda, an analysis was made of SSS prepared by mothers following advice received through various health workers. Fifty-four different recipes for preparation of SSS were described by 469 mothers with a child who had diarrhoea during the past month. An analysis of 63 solutions revealed sodium concentrations ranging from 9 to 1057 mmol/l; only 21% had a concentration of 50-99 mmol/l, 9% were less than 50 mmol/l, and the remainder more than 100 mmol/l. Furthermore, it was found that the volume of fluid given by mothers varied from 3 to 325 ml/kg with a mean of only 31 ml/kg (48).

1.6 Summary

From this review it is evident that the different approaches advocated for preparing SSS have met with varying degrees of success, and that the following factors can influence the composition of SSS: availability, size of crystals, and moisture content of the salt and sugar; dexterity in the use of the fingers; size of the spoons and mixing containers; and ability of mothers to learn, retain, and apply the knowledge and skill.

The review has also shown that the education of mothers to prepare and administer properly a reasonably acceptable SSS is a task requiring considerable time and reinforcement. Evidence to date suggests that it is increasingly more difficult for mothers to understand a message on the preparation of SSS, to remember the message, to prepare SSS accurately, and to administer it properly when required.

2. FOOD-BASED SOLUTIONS

Various food-based solutions are traditionally used in many cultures for early home treatment of diarrhoea. However, they have received much less promotion and attention than SSS and consequently there have been far fewer studies of their preparation, use, and effectiveness. The information that is available is summarized below.

In a study in Calcutta (49), mothers were advised to use a traditional SSS (Sarbat), rice water, soaked puffed-rice water, soaked pressed-rice water, green coconut water, or butter-milk for early home therapy. Evaluation carried out monthly over two years amongst a 10% sample of randomly selected homes showed that 75% of families used one of the above-mentioned fluids, 27% sought ORS packets from village-based health workers (compared with 60% in an early study when home therapy was not promoted), and 50% of cases receiving the fluid did not seek further treatment; however, a similar percentage (38%) of cases who did not receive these fluids also did not seek further treatment. In rural Thailand (50), rice water with salt was compared with SSS, tea with salt, and ORS as early home fluids and all four preparations were found to be equally effective in preventing dehydration. However, the number of cases in each group was small. In Khmer refugees (51), an educational campaign to use rice water with salt for early treatment of diarrhoea is reported to have led to a significant decline in the number of diarrhoea cases coming for treatment and with severe dehydration, and in the malnutrition rate (however, no figures were given).

Those searching for alternatives to glucose in a home solution have taken advantage of the fact that the large molecules in rice-starch release glucose gradually, glucose then being absorbed rapidly, so that rice starch can be given in relatively large amounts without risk of inducing an osmotic diarrhoea. Studies in Calcutta and Dhaka have shown that children and adults receiving rice-powder-based ORS for the treatment of dehydration have significantly lower stool volume and ORS requirements than those receiving standard ORS (52). WHO-supported research projects being carried out in six countries, and projects under way at the International Centre for Diarrhoeal Disease Research, Bangladesh, are now evaluating cereals like rice, maize, wheat, millet, and sorghum as a source of glucose. The results of these studies will help to identify cereal-based solutions that are appropriate for home use in areas where such cereals are a basic food.

In fact, some research on the use of starch-based home solutions has already yielded interesting results. In New Delhi, Bhan et al. (53) compared the acceptability of SSS, a solution containing powdered puffed rice with added salt, and moong dal (lentil soup) with

added salt in young children with diarrhoea over a three-month period. They found that 87% of 158 cases used SSS, 50% of 112 cases rice solution, and 34% of 130 cases moong dal. Most of the study population preferred the taste of SSS and mothers' preference for the same was related to the ease of preparation. More recently, Rahman et al. (54) reported the results of a feasibility study in Bangladesh on the use of a home-made rice-salt solution mixed by mothers using 2 handfuls of rice (or 60-70 g of rice powder) and 1 level teaspoonful of salt in a litre of water. After training, which included demonstrations, over a period of two months, weekly home visits were made during a four-month period to collect data on the type of treatment provided and the outcome. One hundred and fifty randomly collected samples were found to have sodium concentrations ranging from 2 to 250 mmol/l, 57% had concentrations of 71-110 mmol/l, and 28% had concentrations of 111-250 mmol/l. When taste was used as the main criterion for assessing salt content, more solutions had sodium concentrations above 120 mmol/l. The difficulties of adding the correct amount of salt to a home solution, even where supervision is extensive, are further substantiated by this study.

In a study at Singapore General Hospital (55), paediatric diarrhoea cases with no or mild dehydration treated with rice water with no added salt were found to have a lower number of stools than cases treated with ORS. This study raises the theoretical possibility that rice gruel without salt may be effective in preventing dehydration and reducing diarrhoea losses by promoting reabsorption of endogenous sodium and water excreted into the bowel during diarrhoea, though whether it would be adequate for children with more than mild diarrhoea is not known. It is interesting to note that rice gruel with a little salt and lemon added to taste has been customarily used by rice-eating populations in many parts of the world as a home remedy for diarrhoea, as have similar fluids or gruels made from fermented maize or cassava in Africa.

Other home fluids which may be useful but have not been well evaluated include home-made soups of vegetables, fish, or chicken. In one study, De Menibus et al. (56) claimed that a soup made from 500 g of carrots and an equal volume of water, which yielded a concentration of about 58.5 mmol/l of sodium (possibly because of added salt), 27 mmol/l of potassium, and 2 g/l of glucides in addition to some protein, fat, dextrine-maltose, and calcium, was as effective as ORS in the treatment of dehydration. This approach with different vegetables and foods deserves more attention.

3. COMMERCIAL BEVERAGES AND OTHER FLUIDS

Non-alcoholic and non-caffeine-containing drinks are often promoted as beneficial for the prevention of dehydration and even for symptomatic relief during diarrhoea. However, the composition of generally available soft drinks and commercial soups and juices (Table 2) indicates that most are unsuitable because of their high osmolality (57). All have a very low sodium content, except for the soups whose concentrations are too high.

Among the fluids listed in Table 2, breast-milk is the most important for young infants because of its unique immunological and nutritive properties. Its low sodium content also makes it an excellent fluid for the prevention of hypernatraemia. Diluted cow's milk is also appropriate in non-breast-fed infants, except in rare cases with clinically apparent lactose intolerance; however, it contains more sodium than breast-milk. Green coconut water (58) contains glucose and potassium, but is expensive and contains very little sodium; its osmolality varies from 255 to 333 mosm/l. Tea without the addition of salt and sugar provides only water and a little potassium and is not likely to be useful in preventing dehydration.

4. Conclusions and Recommendations

4.1 ORS has been proved to be highly effective for the treatment of dehydration. It is very likely also to be effective for the prevention of dehydration, though even if used from the onset of diarrhoea, it would not prevent all cases of dehydration, especially those of cholera-like severity. However, as ORS is not needed to prevent dehydration in most diarrhoea cases and its availability often cannot be assured, alternative solutions for early home therapy to prevent dehydration have been sought.

4.2 Research has been undertaken to identify alternatives to ORS for early home therapy. The possible options are (a) sugar-salt solutions (SSS), or (b) food-based solutions.

4.3 SSS is currently the most widely promoted home-made fluid. As it is reasonably effective in replacing fluid losses in dehydration and is the alternative for the treatment of dehydration when ORS is not available, it should also be effective in preventing most cases of dehydration. However, considerable problems have been associated with its preparation and use, which include the uncertain availability and variable quality of sugar, and at times also of salt, the lack of suitable utensils for measuring the ingredients and water, and, most importantly, the difficulty in educating mothers to learn, retain, and use the skills required for its proper preparation and administration. The errors in preparation have been found to lead to a solution which is often ineffective and/or unsafe.

4.4 There has been much less experience with the systematic promotion and use of food-based solutions for early treatment of diarrhoea. Their potential advantage is that mothers in many areas are familiar with their preparation and the solutions themselves are made from ingredients and with utensils usually available in the home. Examples of traditional fluids that are commonly used in homes and may have a sound physiological basis (i.e., contain acceptable concentrations of starch and sodium - see 4.6) include cereal gruels, and certain soups. Proper and effective use of these solutions also requires training of mothers, particularly if the traditional recipe requires modification - e.g., if more salt than normally used must be added to the solution. Whether there is any difference in the effectiveness of such solutions prepared either in the traditional way or in a modified manner (e.g., with added salt) to make them physiologically more appropriate has still to be determined. Much attention is at present being focused on the use of cereal-based home solutions, but some important questions remain to be answered before their use can be widely recommended. These concern their digestibility in young infants, the problem of their fermentation, the risk of their being confused with weaning foods, and the potential danger that mothers will assume that concurrent feeding during diarrhoea is not required.

4.5 Strategies to prevent dehydration must be a component of all national CDD programmes. However, in the absence of information on the proportion of childhood diarrhoea cases that become dehydrated without the use of any home fluid, and on the effectiveness of various solutions in preventing dehydration, it is not possible to formulate precise global recommendations on a choice of home solution. Countries should select the approach that is safest, most effective, and most practical in their particular circumstances. As a general guide, solutions should be used that are physiologically appropriate (see 4.6), easy to prepare accurately, and for which the ingredients and utensils are widely available. Solutions which require that mothers learn and carry out new instructions for their preparation and use - be they SSS or food-based solutions to which more salt than usual is added - should be recognized as being more difficult to prepare and use accurately. The choice of solution may require operational research and should take into account such factors as the traditional practices for diarrhoea treatment, knowledge or beliefs about the cause of diarrhoea, the composition and availability of common food-based solutions, the availability and cost of salt and especially sugar, the availability of standard measuring utensils, and the ability of the national CDD programme to provide essential training for health workers and ORS supplies to treat cases with dehydration. The WHO Diarrhoeal Diseases Control Programme is currently preparing guidelines to assist countries in selecting the appropriate home solution. Whichever home solution is chosen, no single channel of communication should be used to convey instructions for its preparation and administration; mass media and trained health workers should be used together to educate mothers in the recommended approach.

4.6 In the light of the difficulties of preparing and using home solutions accurately, as reviewed above, it may be appropriate to revise the WHO/UNICEF recommendations for the sodium concentrations of such solutions from a range of 50-100 mmol/l to a range of 30-80 mmol/l, although a solution of up to 100 mmol/l may still be considered safe. In areas where breast-feeding is common, one may wish to recommend the use of solutions at the upper end of this range as the sodium content of breast-milk is very low and its concurrent consumption therefore reduces the risk of hypernatraemia in young infants. In other areas, it may be preferable to recommend solutions with sodium concentrations towards the middle of this range. To ensure maximum absorption of sodium, the glucose concentrations of home

solutions should be 1-1.4 times the sodium concentration. For solutions containing cereal, because of their low osmolality, as a guide one may use up to the maximum concentration compatible with an easy-to-drink solution (this is usually 50 grams/l).

4.7 Whether SSS or a food-based solution is recommended, in many situations the first action that a mother may need to take when diarrhoea occurs is to give the most readily available, unharmful fluid (this will often be breast-milk and may even be water). Breast-feeding of infants during diarrhoea should always be promoted because breast-milk has valuable nutritional and immunological properties, decreases stool volume, and prevents hypernatraemia. To avoid the risk of osmotic diarrhoea, the use of commercial beverages, including commercially-prepared, concentrated fruit juices, should be discouraged.

4.8 No matter what approach to home solutions is chosen, a child cannot be said to have full access to oral rehydration therapy unless this includes access to ORS. Thus, in addition to promoting the use of a home solution, all programmes need to emphasize the distribution of ORS, the training and supervision of health staff to ensure its correct use, and the education of mothers to make them aware of the signs of dehydration that require its use. The goal should be to use home solutions and ORS in sequence and not as alternatives (59).

Table 1: Recommendations for preparation of sugar-salt solutions.

Recommendation numbers [a]	Advised domestic measures:			Concentration: [b] g/l		mmol/l	
	Salt	Cane sugar	Water	Salt	Cane sugar	Sodium	Glucose
7	1 tsp	1 tsp	1 pint	10.0	10	171	29
8	2 tsp	4 tbsp	1 litre	10.0	60	171	175
11	1 tsp	6 tsp	750 ml	6.6	40	113	117
9	1/4 tsp	2 tsp	1 cup	6.3	50	107	146
28	5.3 g	50 g (molasses)	1 litre	5.3	33	91	96
16	3.5 g	40 g	1 litre	3.5	40	90 [c]	111
22	1 tsp	8 tsp (glucose)	1 litre	5.0	80	86	222
1	1 level tsp	4 heaped tsp	1 litre	5.0	28	86	82
6	1 tsp	4 tsp	1 litre	5.0	20	86	58
17	1 level tsp	8 level tsp	1 litre	5.0	40	86	117
26	1 level tsp	6 tsp	1 litre	5.0	30	86	88
4	1/2 tsp	4 tsp	1 pint	5.0	40	86	117
20	1/2 tsp	4 tsp	500 ml	5.0	40	86	117
30	1 tsp (3 ml)	10 tsp (3 ml)	650 ml	4.6	46	79	134
29	0.9 g	4 g	200 ml	4.5	20	77	58
27	3.5 g	30 g	1 litre	3.5	30	60	88
23	1 level bottle top	8 level bottle tops	900 ml	3.3	27	56	79
21	1 tsp	8 tsp (glucose)	1.5 litres	3.3	53	56	147
24	1/2 level tsp	6 level tsp	750 ml	3.3	40	56	117
32	1/3 tsp	4 tsp	580 ml	3.0	35	51	102
3A	tip of tsp	1 level tsp	1 glass	3.0	25	51	73
12A	1/2 tsp	10 tsp or 2 handfuls (4 f) or 50 g	1 litre	2.5	50	43	146
2	1 pinch	2 cubes or	1 cup	2.5	50	43	146
	1 pinch	1 scp (3 f)	1 cup	2.5	125	43	365
15	1/2 tsp	2 level tbsp (or honey)	1 litre	2.5	30	43	88
12B	2 g or 4 pinches (th & 2 f)	10 tsp or 2 handfuls (4 f) or 50 g	1 litre	2.0	50	34	146
13	2 pinches	1 handful (4 f)	1 pint	2.0	50	34	146
31	2 pinches	1 scp (4 f)	1 pint	2.0	60	34	175
25	2 pinches	1 scp (4 f)	1 pint	2.0	60	34	175
33	1/4 tsp	4 tsp	650 ml	1.9	30	33	88
18	2 pinches	2 fistful	1 litre	1.0	50	17	146
3B	1 pinch	1 scp (3 or 4 f)	1 pint	1.0	60	17	175
14	1 pinch	1 scp (4 f)	1 pint	1.0	60	17	175
5	1 pinch	5 cubes or 1 small handful	1/2 litre	1.0	50	17	146
19	1 pinch (3 f)	2 scp (4 f)	500 ml	1.0	120	17	351
10	1 pinch	3 cubes or 3 tip	1 litre	0.5	15	9	44

[a] Sources of recommendations are available from the Diarrhoeal Disease Control Programme, World Health Organization, Geneva

[b] The following calculations have been used to convert recommended domestic measures into concentrations in grams per litre:

1 cube of sugar = 5 g
1 level or unqualified (4-5 ml) teaspoon (tsp) = 5 g
1 tsp (3 ml) = 3 g; tip of tsp = 0.6 g
1 heaped tsp = 7 g
1 tablespoon (tbsp) = 15 g
1 level bottle top = 3 g
1 pinch of salt (3 finger or thumb & 2 finger) = 0.5 g
1 scoop of sugar (scp) (4 finger) = 30 g
1 handful or fistful (small or unqualified) or 3 f scp of sugar = 25 g
1 pint = 500 ml
1 cup or glass = 200 ml

[c] Including Na^+ from added $NaHCO_3$

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Table 2: Sodium and potassium content of fluids often used for home treatment+

Fluid	Concentration (mmol/l)		Osmolality
	Sodium	Potassium	(mOsm/kg H_2O)
Commercial soups (chicken, beef)	114 - 251	2.2 - 17	290 - 507
Commercial juices			
Apple	0.1 - 3.5	24 - 30	654 - 734
Grape	1.3 - 2.8	28 - 32	1167 - 1190
Lemon	9.0 - 10.0	27 - 29	485 - 506
Orange	0.6 - 2.5	41 - 65	542 - 710
Carbonated beverages			
Coca-cola	1.7	0.1	601
Pepsi-cola	1.3	0.1	591
7-Up	5.0 - 5.5	1.0 - 2.0	523 - 548
Canada dry	0.8 - 2.7	0.1 - 1.5	515 - 557
Water			
Tap	0.0 - 1.0	0.0 - 0.5	48 - 50
Coconut*	0.0 - 5.4	32.6 - 53.5	255 - 333
Tea	0.0	5.0	-
Milk			
Breast	7.0	13.0	-
Cow's	22.0	35.0	-

+Table contents taken in part from reference (57)

*Glucose content was found to vary between 100 and 139 mmol/l by the hexokinase method (58)

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