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PHILIPPINES ORT COUNTRY
ASSESSMENT REPORT

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EXECUTIVE SUMMARY

Diarrheal diseases are a major public health problem in the Philippines. Estimates based on survey data suggest that there are eight to ten million diarrheal cases annually that receive medical attention and up to 25 million cases that do not appear on reported health statistics. Diarrhea is second only to pneumonia among the leading causes of infant mortality and is first or second among the leading causes of morbidity. Furthermore, 30 to 50% of all hospital pediatric beds are occupied by patients suffering from diarrheal disease. The most effective and efficient clinical management intervention for diarrheal diseases has proven to be oral rehydration therapy. Other interventions, such as intravenous solutions, anti-diarrheal medications and antibiotics are expensive, less effective, sometimes medically contraindicated, and require access to typically unavailable hospital facilities.

The Government of the Philippines/Ministry of Health targeted the institutionalization of Oral Rehydration Therapy as a national health priority in the Five-Year 1983-1987 Plan. Philippine experience with oral rehydration actually began two decades earlier with clinical research at San Lazaro Hospital, and later, field studies in Bacolod City. Subsequently, the Ministry of Health established a National Control of Diarrheal Diseases (CDD) Committee and Task Force to plan, coordinate, implement, and evaluate CDD activities. The Task Force lacks full-time staff and relies on volunteered time of its members to hold periodic meetings overseeing the CDD Program. The CDD Program is under the umbrella of Primary Health Care and focuses on oral rehydration as a prime entry point for developing primary health care implementation mechanisms.

The Ministry of Health efforts to promote ORT include:

- Production of Oresol, an oral rehydration solution that is distributed at no-cost to the public through MOH facilities;
- Short training courses designed to familiarize a large number of government health workers to ORT technology;
- Development of training curriculum, materials, and posters to support training courses; and
- Improvement of disease reporting system to capture more of the actual incidence of diarrhea morbidity and mortality.

The private sector has responded to rising demand for oral rehydration solutions with the marketing of five separate commercial products. However, these products do not yet conform to WHO standards for sodium and glucose concentration levels. Total production of commercial ORS products is less than 10% of the GOP's Oresol production. Retail prices for ORS products are high though accounting for only 10% or 72 million pesos of the total anti-diarrheal medication sales in 1983. Field studies have demonstrated that early use of homemade solutions can play an important role in preventing dehydration. They can thus be seen as a reasonable first step before resorting to Oresol and other packaged products.

Recommendations developed in this assessment reinforce and are consistent with the Ministry's well-defined primary health care policies and ORT strategies. Priority activities requiring donor support address the goals of:

- Increasing access to an appropriate oral rehydration product through commercialization of production and distribution
- Increasing utilization of oral rehydration through the use of a comprehensive training and promotion strategy
- Strengthening the institutional capability of the Ministry of Health to promote use of oral rehydration through the establishment of a special ORT Secretariat.

COMMERCIALIZATION

Widespread availability of an acceptable oral rehydration solution is a constraining factor preventing further expansion of ORT in the Philippines. The Ministry of Health policy to distribute a no-cost product incurs large operating costs and creates diseconomies of scale with increased production. Commercial production capability is clearly demonstrated by the current products already available. Recommended incentives to encourage private sector production of an appropriate ORS include:

1. Ministry of Health establish a production agreement with commercial firm(s) guaranteeing purchase of oral rehydration product in declining quantities over several years with the understanding that:
 - an increasing percentage of total product demand would be met by commercial production
 - the MOH will phase out its own production of Oresol
 - the MOH would purchase at cost-price any excess product if sales fall short of expected levels.
2. Ministry of Health standardize composition, packaging, labeling, and presentation of oral rehydration solutions.
3. Ministry of Health add Oresol to the generic drug list released for bidding to pharmaceutical firms.
4. Funding made available for marketing and strategy studies to further promote private sector involvement.

PROMOTION

Expanding utilization of oral rehydration requires a comprehensive promotion strategy targeted to medical professionals, particularly pediatricians, para-professionals, and the lay public. Professional promotion must be oriented to the use of ORT as a clinical management technique for diarrheal disease. It is recommended that a National Rehydration Training and Research Center be established within the present structures of San Lazaro Hospital.

At a minimum, a formal full-time one month course should be offered, with opportunities available to do clinical trials and related operational research. As it is envisioned, course graduates would be responsible for establishing ORT demonstration units in each province and retraining all provincial health staff. The costs of disseminating publications, newsletters, and meetings should be underwritten. Donor funding should also support promotions targeted to paraprofessionals and the lay public for mass media, printing and distribution of training materials, and inter-ministerial collaborative efforts.

INSTITUTIONAL DEVELOPMENT

The establishment of an ORT Secretariat directly under the Minister, with its own staff and a modest budget, is essential to assure the Government's capability to plan and coordinate its health services delivery and regulatory functions, obtain additional resources from donor agencies and assist in the monitoring and evaluation of an expanded national ORT program.

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ANALYSIS OF ORAL REHYDRATION IN THE PHILIPPINES

BACKGROUND AND SITUATION ANALYSIS

A. NATIONAL DIARRHEAL DISEASE PICTURE

In the Philippines, as in other developing countries, diarrhea is a major public health problem. Diarrhea is now the fourth leading cause of mortality and second only to pneumonia among the leading causes of infant mortality. Furthermore, diarrhea is ranked as first or second leading cause of morbidity on reported health institution statistics. In pediatric hospitals, diarrhea cases diagnosed on admission, occupy 30-50% of pediatric beds. In 1983, 17,000 deaths reported to the MCH were attributed to diarrhea and over 1.2 million cases were treated in health units. Both of these figures substantially under estimate the actual situation. Field studies in Bacolod, Cavite and Iloilo have found that each child under 5 years of age suffered at least one episode of diarrhea severe enough to require treatment. If diarrheal episodes treated at home are included in the statistics, an additional 3 to 5 episodes per child occurred. Thus, 8 to 10 million cases require medical treatment each year and up to 25 million cases are treated at home without the benefit of medical attention.

The prevailing treatment regimen for most sick children is intravenous fluid therapy as well as other medications which together claim a substantial proportion of hospital expenditures. Thus, diarrhea remains

a major cause of mortality in the young and a major drain on the financial resources of private and traditional health services.

B. GOVERNMENT PROGRAMS, POLICIES AND PLANS FOR ORT

During the last four years Oral Rehydration Therapy (ORT) has become the official Ministry of Health policy for the treatment and reduction of diarrheal disease mortality in the Philippines. Administrative support has taken the form of circulars to all Ministry of Health departments, outlining the strategy of ORT. In addition, the Ministry produces and provides a no-cost ORT product, Oresol, for use in the public health system to combat dehydration from diarrheal diseases. It is noteworthy that ORT has appeared in each annual health plan as a major portion of the Ministry of Health strategy to improve the health of the population and to provide health for all Filipinos by the year 2000. As such, CDD is a central component of the Ministry's Primary Health Care initiative. The primary health care goals have consistently identified diarrheal disease as a targeted intervention. ORT as the most appropriate, cost-effective means of managing diarrheal diseases is conceived as an entry point for the development of primary health care delivery mechanisms.

Philippine experience with oral rehydration began with clinical studies on cholera patients at San Lazaro Hospital in the early 1960s. These studies by Philips, his NAMRU staff, and Filipino collaborators were the first attempt to examine oral rehydration as a treatment and eventually

led to the development of an appropriate ORS formulation. Early field studies of oral rehydration and childhood diarrhea were carried out in the early and mid 70s in Bacolod City. An international study group together with Filipino co-workers demonstrated the effectiveness of ORT at the community level. Results of these studies showed (1) a reduced need for hospitalized rehydration and (2) an improvement in the nutritional status of children who were suffering from chronic diarrhea. Following this demonstration, the Government of the Philippines created in 1978 a National Committee which was supplemented in 1981 by Ministry Order No. 82, May 14, 1981, establishing the Task Force for Control of Diarrheal Disease (CDD) mandated to:

1. Assist in the planning, programming, implementation, monitoring and evaluation of the diarrheal disease control program
2. Provide technical support to the National Committee and the field health services
3. Participate in the formulation, coordination, and conduct of research/studies related to diarrheal disease

The Task Force is a 17 member group comprised of representatives from the Bureau of Health Services, Disease Intelligence Center, Planning Service, National Nutrition Service, Bureau of Quarantine, Office of Health Education and Personnel Training, Office of the Minister, Bureau of Medical Services, and the Bureau of Research and Laboratories . Among their accomplishments, the Task Force developed detailed operational plans with objectives that were incorporated into the Five Year Health

Plan (1983-1987). Attention is directed to CDD priority as it is the first program listed under the heading "Support to Primary Health Care" in the plan document. The Task force has also provided technical assistance at the regional and provincial levels, implementation of CDD objectives, and monitored the progress of program efforts. An estimated budgetary requirement of 5.3 million pesos rising to 6.7 million pesos was proposed (Annex #1). No detailed budget was provided in the plan and no specific budgetary allocation for ORT activities has been forthcoming.

In 1975 the Bureau of Research and Laboratories of the Ministry of Health began mass production and no-cost distribution of an oral rehydration solution called ORESOL. ORESOL conforms to the WHO standard formulation. Production has increased annually from 0.6 million in 1979 to 3.1 million in 1981, 4.7 million in 1982, and reaching 5.1 million in 1983. The direct cost is estimated to be ₱1.17 per package. (See Annex #5). High production costs reflect the cost of importing all the raw materials, which are U.S. Pharmaceutical (USP) grade. The product is packaged in a foil, double section sachet with anhydrous glucose on one side and the salts on the other. This separation reduces deterioration, extends shelf-life, and thereby provides a very stable product. Semi-automated packaging on an assembly line assures that labor costs do not exceed 15% of the total production cost. See Annex #2 for a breakdown of present production costs.

Oresol is distributed directly from the Central Ministry in Manila to the health regions, and the provinces and rural health units are responsible

for providing Oresol to barangay health stations, boticas sa barangay and barangay health workers. From 1975 to 1984, distribution to the regions was the responsibility of the Bureau of Research and Laboratories. Recently, the Ministry's supply section took over the distribution of Oresol and is now disbursing it with the other Ministry of Health drugs. Distribution costs therefore are underwritten by the central budget allocation for the distribution of other drugs. In some cases, distribution costs must be borne by regional offices which often are hardpressed to accept the freight charges associated with Oresol supply. It is not clear to what extent freight costs pose a financial barrier to sufficient Oresol supply in the region. Further information may be necessary to interpret the routine cost allocation procedures.

Training

The MOH launched a national training/orientation campaign in 1980 designed to educate MOH health professionals to the concept of oral rehydration and Oresol use. The one day training sessions covered topics of what diarrhea is, the need to treat and prevent it, management of acute diarrhea and simple measures to prevent diarrhea using the primary health care approach. Under the direction of the Task Force, 41 regional trainers and 30 Metro-Manila hospital and MOH personnel participated in the training orientation. These trainees were expected to ECHO their training information to the MOH personnel at the Regional level who in an iterative fashion were to ECHO to provincial, municipal, and barangay

personnel. Evaluation of these training sessions has not yet been done. The MOH is considering an evaluation study to be done sometime next year.

A field inventory with a standard evaluation protocol was developed by members of the Task Force and used in six regions in mid 1981. The objectives of the survey were to evaluate the status of the ORT Program, to obtain baseline data essential to the planning of future ORT program efforts, and to estimate the impact of ORT on diarrheal disease mortality and IV use.

The results of the field study were disseminated in the context of a series of Regional Consultive Seminar/Workshops held in late 1981. All 12 regions participated with a total of 932 people involved. The interactive sessions were used to elicit field experiences in the implementation of CDD/ORT activities, focus on problems and constraints encountered, and to develop policies, implementing guidelines and action plans to strengthen CDD/ORT program implementation.

The Regional Consultive Seminar/Workshops consistently reported ongoing difficulties in introducing and institutionalizing ORD in hospital settings. As a result, another set of training activities began in 1982 with the national Clinical Management Seminar Workshop. A core group of 38 Regional Hospital and 31 Metro Manila Hospital representatives were trained as ORT trainers. The 69 people trained 711 regional hospital personnel. Regional Hospital staff "ECHO"ed the seminar/workshop training to the other hospital staff in the region. In order to fully

promote ORT dissemination, regional hospital staff were to implement ORT at their own hospitals prior to ECHOing ORT strategies.

Funding for these training activities has been provided in part through WHO assistance. A continuing program constraint is the availability of ORT training materials. A detailed Manual on the Management and Prevention of Diarrhea and curriculum guides were developed, though printing costs restricted the number of copies produced.

Overall, the MOH professional training efforts have attempted to reach a large number of people and briefly expose them to ORT technology. While these efforts have produced a widespread awareness of ORT, physicians' use and promotion of ORT is less than optimal. This situation indicates a need for more intensive professional training to ORT in the clinical management of diarrhea.

Mass Media

Efforts to promote ORT to the lay public have been undertaken by the IEC section of the Ministry of Health. They produced two posters describing the use of Oresol. The poster has written and diagrammatic instructions for the mixing and use of Oresol. Approximately 2,000 posters were printed for use in RHUs and hospitals. On account of the limited number of copies and the orientation of the poster to literate workers who use it as an ancillary teaching tool, a mass audience was not effectively reached.

The MOH, with assistance from Kabalikat/PATH, launched another kind of instructional effort to guide mothers in the use of Oresol. They designed a one page flyer to be distributed in conjunction with the Oresol product. A million copies of the flyer have been produced for distribution. In addition to the flyer, a brochure for rural health workers was tested, designed and printed and recently, a Manual for Physicians was produced though it is not yet widely distributed.

Surveillance of Diarrheal Diseases

The routine morbidity and mortality reporting system provides a glimpse of the overall disease picture. Surveillance information is collected from several sources. Under CDD Task Force direction, a special reporting system has been developed to provide information on the number of diarrhea cases seen, the number treated with Oresol, the number of diarrheal deaths, and the stock of Oresol. According to Ministry Order #52, 1980 and MO #91, 1981 these forms are collected and compiled at the municipal, provincial, and regional level with cumulative data forwarded to the next higher level. Regional reports arrive in Manila on a quarterly or semi-annual basis. Compilation of these reports is used to generate the annual report. Ministry Order 80-A 1981 provided for a by-weekly telegraphic report of diarrhea cases and deaths to the Disease Information Center. However, budgetary limitations have made this extremely erratic and generally useless. It is advisable to abandon this as part of the routine reporting system.

Hospital mortality reports continue to provide an important source of information to gauge the impact of the ORT program. While mortality figures are underestimated, recent trends show that mortality is decreasing, particularly for diarrhea-related deaths among infants and young children. According to reported death statistics in 1978 enteritis and other diarrheal diseases, account for 10.9% of all deaths in this age group.

The trends observed in the annual reports indicate an apparent increase in the number of diarrheal disease cases and an increasing use of ORS. The higher number of reported cases is less likely due to an increasing incidence of disease and more likely related to better case finding and reporting of diarrheal disease. Cases reported to the CDD Task Force are now twice the number reported in routine, monthly morbidity reports. The continuing high prevalence of diarrheal disease reported in both service statistics and periodic health surveys, indicates that diarrhea remains a major health problem.

An in-depth sample survey evaluation of CDD/ORT in the Philippines is planned for September. The evaluation is a collaborative effort of WHO, UNICEF and other donors with the Ministry of Health. This evaluation will provide a highly objective view of the overall accomplishments and coverage of the CDD/ORT program.

C. NON-GOVERNMENTAL EFFORTS

Non-governmental support for oral rehydration has come from both for-profit and non-profit organizations. The efforts described here have come about without direct incentives or financial assistance from the MOH. To date, the government has encouraged neither commercial production/distribution nor homemade solutions, preferring to provide Oresol through its own distribution network for free. Notwithstanding, several products produced and marketed in the Philippines for oral rehydration are now on the market. (See Kabalikat Report, Annex #3.) Unfortunately, none of these products even remotely conform to the WHO/Ministry of Health standard formulation. In addition, the market prices of these products are extremely high, making them generally unavailable to the masses. In 1983, it is estimated that almost 400,000 liters of oral rehydration fluid were sold in the commercial network. This figure includes the leading, product, Pedialyte. Overall sales are reported to be ₱8.5 million or over ₱20 per liter. An indication of the potential market for oral rehydration solutions is the sales figures for anti-diarrheal medications which were ₱60 million in 1982 and precipitously increased to ₱72.5 million in 1983.

In the non-profit arena, a number of efforts have been made to investigate the use of home solutions and home made oral rehydration mixtures. Investigators at the International Institute for Rural Reconstruction (IIRR) in Silang, Cavite have demonstrated that mothers can effectively use a home made solution for early rehydration of their

children. They trained mothers in the use of a Nescafe glass as a measure of water, one pinch of salt and a spoon of sugar. It was reported that hospital admissions in that area have decreased and that the problem of dehydrated children has virtually disappeared. In addition, demand for Oresol has also decreased as mothers have become more self-reliant in preparing their own oral rehydration solutions.

In Iloilo Province, the KABSACA program, funded by the World Bank, has encouraged the use of home made sugar salt solutions through the distribution of a plastic measuring spoon called the "LUKAT" spoon. Acceptance of this approach is yet to be evaluated. The number of diarrhea cases presenting at RHUs and hospitals has decreased and diarrheal deaths have been markedly reduced during the last two years.

Finally, at the Research Institute for Tropical Medicine (RITM) in Alabang, investigators are looking into the effectiveness of traditional healers' home made solutions such as "ahm" and herbal teas.

These experiences suggest that early use of home made solutions can play an important role in preventing dehydration. The use of a homemade solution as a stopgap measure is a reasonable attempt to confront the recurring problems of limited Oresol availability and financial inaccessibility of high-cost ORS commercial products, particularly in areas beyond Metro-Manila.

ANALYSIS OF MAJOR ISSUES

A. PRODUCTION

The critical path in the development of a national ORT program is the availability of an appropriate oral rehydration solution in the market place. Oresol is currently the only such product in the Philippines and yet Oresol can neither be prescribed nor recommended except through MOH facilities. Private doctors can request a small supply of Oresol, but for the most part are unable to obtain or prescribe a safe, electrolyte balanced rehydration solution. With a commercial product, private physicians and private hospitals would find it as easy to prescribe oral rehydration solution as it currently is to prescribe anti-diarrheals and I.V. solutions. A commercial ORS product also would have the advantage of a wider, more accessible distribution network with longer hours and more outlets than the MOH facilities can provide. A major challenge is to encourage a cheap, effective, widely available alternative to ORESOL in the open market. Attention therefore should be focused on both product marketing concerns of formulation, packaging presentation, labeling and distribution, as well as the strategies and incentives to encourage commercial production of an appropriate, low-cost oral rehydration solution. (See Annex #5)

The WHO formula is the standard recommended by the Ministry of Health. Clinical studies have been carried out throughout the world and have generally given satisfactory results with compositions and arranged as

shown in the following table:

| | |
|-----------------------------|---------------|
| Na | 50 - 90 Meq/L |
| K | 20 - 35 Meq/L |
| HCO ₃ or Citrate | 20 - 40 Meq.L |
| Glucose (dextrose) | 2 - 3% |
| or Sucrose | 3 - 4% |

Oresol uses U.S. Pharmaceutical grade glucose, sodium chloride, sodium bicarbonate, potassium chloride, packaged in polyethylene foil. This formulation and packaging provide a shelf life said to be four to five years long. The cost per package is estimated to be ₱1.40 at 1984 prices, excluding overhead and distribution costs.

Commercial products available in the Philippines (see Annex #4) contain a formulation substantially different from WHO recommendations. Coloring, flavoring and other ions and substrates are added to their products. WHO does not recommend the addition of such ingredients. The strongest objection is to ORS being used as a softdrink. There is a potential danger to patients, when it is made attractive in flavor, taste or color, if the product is consumed in quantities beyond that which is needed for rehydration purposes. While there is no evidence for this problem in practice, excessive consumption of salt could result. The addition of these other sugars may also increase the total osmotic activity of the solution to a level substantially above optimal levels. Cautious consideration should be given to limiting the addition of other ingredients and to establishing maximum standards for osmolality.

It would seem reasonable for MOH to establish acceptable formulation standards, through an Administrative Order to FDA, allowing manufacturers to present products that do not excessively deviate from the approved formula. Sodium, in particular, remains a concern among professionals. It is potentially harmful when consumed in quantity without extra liquids beyond the period of rehydration. Regulations should therefore specify acceptable sodium concentration standards.

Acceptable changes to the WHO formula include citrate substitution for sodium bicarbonate and the use of food grade glucose. Bicarbonate in combination with sugar results in a rapid deterioration of the ORS product. One way of managing the chemical problem is to package the sugar separately from bicarbonate as is the case with Oresol. Alternatively, many other countries substitute citrate for bicarbonates. Citrate is an equally effective base in equimolar quantities, does not adversely affect sugar, and seems to provide a more acceptable taste. Citrate costs slightly more than bicarbonate, though savings can be achieved with less expensive polyethylene packaging materials.

U.S. pharmaceutical grade ingredients are now used to make Oresol and accounts for the high price of ingredient materials. Oresol as an oral medication prepared in normal drinking water, is a form of medicinal food. WHO has now considered food grade glucose adequate for ORS production. It is reasonable therefore to accept food grade sodium chloride, sodium bicarbonate, potassium chloride and sodium citrate as well. It is likely that these ingredients could be purchased within the

country at considerable savings.

Finally, studies are now being carried out in a number of countries to investigate the effectiveness of various starches such as rice powder and cassava as a substitute for the sugar base. Starch, with a low osmotic activity, can be incorporated in higher quantities than sugar and thus results in more avid and complete absorption of the ORS. Two published studies have shown a reduction in stool volume and duration of diarrhea with administration of a rice powder-based rehydration fluid. While not yet recommended for wide scale production, consideration should be given to clinical trials of cereal based ORS and to a formulation with starch substrate.

The form of product presentation is an issue closely related to product formulation. The most common presentation for oral rehydration solutions is a sachet packet containing sufficient powder to mix a full liter. The recurring problems of measuring, mixing, and storing the unused portion of a full liter solution are solved by a small quantity presentation. Mixing smaller quantities such as 200 cc to 500 cc. in one glassful provides a convenient measure of fluid to be used for each liquid motion. The disadvantages of a smaller quantity presentation are twofold: the cost of making the smaller package is almost the same as one liter and secondly, there is a tendency to use smaller quantities of ORS with less effective results. Another issue is the divided package which is prone to improper use. People often mix the powder on one side assuming that both sides are the same or attempt to estimate a proportion of the powder to a smaller

volume of liquid. These mixing errors can lead to ingestion of an improper and even dangerous solution.

Commercial presentation of rehydration solutions such as Abbott's Pedialyte have been available for many years. Presentation varies from 8 ounces to 500 cc. No commercial product is marketed as a full liter packet. The price of all products, particularly those pre-mixed in water and presented in a glass container, are substantially above the costs of producing the products and are higher than most people can afford. The high price is thought to be a major impediment to widespread use.

Pre-mixed solutions are popular with the well-to-do and their private pediatricians. Pedialyte, for example, aside from having a composition that considerably varies from WHO recommendations, comes in small quantities at a high price. During our visit to the Abbott company we were assured of their intention to revise the composition of Pedialyte, raising Sodium to 50 or perhaps 75 meq./liter, and reducing glucose from 5% to the recommended 2%. Presented in a 500 cc plastic bottle, it may retail for under P10, making it an attractive and acceptable solution for ORT. Shipping and distribution costs for an ORS product may be a considerable and severe constraint to any liquid presentation.

Notwithstanding, if a liquid presentation for ORT is marketed, standards for water quality should be the same as those used for food products.

Recently, an ORS in tablet form has been developed. Each tablet is dissolved in a glass ranging from 150 to 200 cc. Tablets can be packaged

individually or in a cluster to encourage a sufficient quantity per single purchase. The tablets are self dissolving within 30 seconds and under most trials have proven extremely attractive to the consumer. At a unit cost of 2.2 U.S. cents (F.O.B. U.S.) they are slightly more expensive than the packet. However, their attractiveness and ease of use may well justify the added costs.

The Ministry of Health should establish standards and regulations for labeling all oral rehydration solutions on the market. Standards should be set to require:

- (1) Content labeling to identify powder quantity and resulting concentration when properly mixed. This should include osmolality of properly prepared solution.
- (2) Directions for use clearly written in the local language and supplemented with carefully tested pictures. The recently developed labeling design for Oresol could be a required part of labeling standards for all commercial products.
- (3) Feeding instructions should emphasize the desirability of continued breastfeeding and non-interruption of regular diet with extra food during and after the episode of diarrhea. The improved nutrition status of patients in the Bacolod trial studies are most likely a result of proper advice on feeding rather than solely due to the use of ORS per se. Labeling instructions on some commercial products in the Philippines recommend cessation of food intake. These instructions should be corrected immediately.

- (4) Referral indications to warn of the severity of a diarrheal episode which extends beyond two days or beyond consumption of two liters of ORS. In such a case, medical attention should be sought.
- (5) Expiration date and batch number should be labeled and instructions given to dispose of the mixed fluid after 24 hours.

All labeling and product claims should be subject to review and revision by the Ministry of Health.

The Ministry of Health at this juncture can determine the nature of the Philippines future production capability of ORS. As both a producer and a consumer of this vitally important treatment, the Ministry of Health can determine to what extent production will continue as an MOH prerogative and to what extent as a commercial product. In terms of MOH production of Oresol, alternative options are to:

- (1) Continue present production methods and approaches. A switch to citrate and single pack will allow increased production to 8 million or more per year with the existing facilities. Unit cost will decline slightly.
- (2) Obtain machine production to replace present semi automated operations - This would be expensive, raise production costs, increase susceptibility to operational shut down and make transition to commercial supply difficult.
- (3) Increase production and sell the ORS product on the open market or sell to the Ministry of Health system itself with payment derived

from the Ministry of Health budget, hospital purchases, etc. This option is not yet legally feasible.

The Ministry of Health can also negotiate with commercial pharmaceutical companies to stimulate private sector involvement in ORS production.

Suggested negotiating options include:

- (1) Guarantee MOH purchase in declining quantities over a number of years.
- (2) Require commercial firm to produce and distribute at agreed wholesale cost an increasing quantity of ORS through the commercial market place. If sales fall short of expected level, MOH would agree to buy, at a lesser price, the excess production. This would reduce capital risk to commercial producers.
- (3) A price agreement could stipulate that (1) MOH would buy ORS on a cost plus basis, with the company deriving an agreed upon percentage, and (2) a similar quantity of ORS be sold to the wholesale market place. The commercial price could be somewhat above the price negotiated for the Ministry's quantity purchase agreement. See Table below.

Table: Example Purchase Agreement

MOH buys At ₱1.5, wholesale guarantee sales at ₱2.0 price to inflate with market prices.

| | <u>Year</u> | | | | |
|----------------------------|-------------|------------|------------|------------|-------------|
| | <u>1</u> | <u>2</u> | <u>3</u> | <u>4</u> | <u>5</u> |
| MOH/Sales million packets | 5:1 | 4:2 | 3:3 | 2:4 | 1:5 |
| MOH ₱1.5 | 7.5 | 6.0 | 4.5 | 3.0 | 1.5 |
| Sales at ₱2 | <u>2.0</u> | <u>4.0</u> | <u>6.0</u> | <u>8.0</u> | <u>10.0</u> |
| Total Revenue Million of ₱ | 9.5 | 10.0 | 10.5 | 11 | 11.5 |

- (4) MOH agrees to buy at ₱1.5 any short fall of commercial sales thereby assuring supply of 6 million packets to the public.
- (5) Wholesale price at ₱2 guaranteed for set quantity. Alternative presentation (tablets, liquid), could use same name but be sold at higher price thus encouraging a consistent "product line" ranging from standard (cheapest) one liter packet to tablet to pre-mixed liquid package.
- (6) Composition, packaging, presentation, labeling and control of the Oresol name should be negotiated and contracted by the Ministry. The ORESOL name has become widely known throughout the Philippines - in essence, the MOH has carried out a massive market introduction and promotion of ORS concept. To introduce a new name at this time will be expensive and possibly counter productive. The MOH should consider the use of the ORESOL name a bargaining point provided the commercial firm agrees to use same formulation. This should provide an important "head start" to any marketing effort.
- (7) Open competition for bids to the Ministry's specifications could be placed on the market place. However, it is unlikely that this would result in an adequate response at the present time.

B. PROMOTION

A comprehensive promotion strategy is necessary in order to effectively reach physicians, lay health workers, and the public. The initial

training and product introduction efforts have been highly effective in creating awareness of oral rehydration treatment. This next phase of promotion should aim at institutionalizing the use of ORS in the hospital, the health station, and the household.

Professional promotions should, at a minimum, include intensive training with an emphasis on clinical management practices such as out-patient rehydration, as well as distribution of professional literature and opportunities for professional meetings in order to share new information. A fuller description of suggested activities follows.

(1) Establishment of a National Rehydration Training and Research Center (NRTRC)

The clinical facilities at San Lazaro Hospital could be developed to provide a more formal training setting to be used for health professionals, both in the Philippines and eventually as a regional resource. Several modest modifications to present facilities will be necessary. The present ORT unit should be shifted to the pediatric gastroenterology ward where meningitis cases have recently been vacated. All diarrheal care would then be centralized in one part of the hospital. Standard treatment protocols could be established and basic rehydration and nutritional management maintained.

A formal relationship with the ICDDR, B in Dhaka would provide guidance in the investigation of clinical problems, and training

approaches to develop ORT expertise. The major purpose of the training center is to provide an in-depth training experience and thereby develop specialists in oral rehydration. At a minimum, the center should offer a standard one month course with clear instructional objectives, required reading materials, standard clinical and written presentations, clinical case care, night call, and a final examination. Upon adequate performance in this course, the graduate would earn a recognized certificate signed by the institution and the Minister of Health as a diploma or certificate as an Expert in Rehydration Therapy (ERT).

Funding support should be made available to train one Provincial Rehydration Specialist, probably a pediatrician, to be recruited from existing provincial staff. Once trained and certified in oral rehydration, this doctor would become the provincial resource person for all hospital and health units in the province. A travel allowance should be provided to the specialist to facilitate the demonstration of oral rehydration in all the health units of the province. S/he could also be available to private institutions teaching their staff how to use oral rehydration therapy in the clinical management of diarrhea.

The National Training Center could carry out clinical trials of new oral rehydration composition changes, new anti-diarrheal drugs, therapeutic feeding programs and the like, under controlled conditions. Clinical trials are an added incentive to trainees in

the center and give further support to standardized treatment of all children with gastroenteritis. International collaborative studies could be carried on here as well.

2. Developing Outpatient Rehydration

It is notable that throughout the Philippines, patients presenting themselves to RHU's and government hospitals with a complaint of diarrhea are either provided with a packet of Oresol and sent home or are admitted to the hospital. Virtually no out-patient rehydration takes place. Yet, this has proved the most successful use of ORS in many countries throughout the world. A child with diarrhea, even those mildly or even moderately dehydrated, can be rehydrated by his own mother under medical supervision while remaining in the out-patient department or in the Rural Health Unit. Demonstrations are useful in teaching effective rehydration procedures and assure mothers of their own skills in using the product. Rather than simply giving verbal instructions to mothers on how to mix Oresol, the product should be mixed and the mother should feed her child with the solution under medical supervision. Once rehydrated, the child may be sent home even if diarrhea continues. Out-patient rehydration avoids admission of more than half of the cases to the hospital and assures adequate management of those children sent home.

A demonstration of this out patient treatment should be established at San Lazaro, National Children Hospital, Jose Fabella and other

teaching hospitals. The NRTRC can investigate and document the results of an out-patient rehydration approach. Efforts should also be made to promote out-patient rehydration to the provinces and rural health units.

The oral rehydration corner of the RHUs we observed during this assessment were remarkably sterile. Mothers typically receive a talk but do not have the benefit of a demonstration and it is not known whether they successfully rehydrate their children. Actual rehydration in the center under medical supervision will prove to be far more effective therapeutically and educationally.

3. Professional Literature

The newly developed Physicians Manual on Management and Prevention of Diarrhea should be disseminated to physicians, both public and private throughout the country. Secondly, a regular newsletter should be produced, most likely on a quarterly basis and also distributed to professionals. A newsletter could contain selected articles from Diarrhea Dialogue, Glimpse and other international newsletters, as well as reports on recent Philippine experiences and trials. The Task Force could provide information on the progress of the Philippine Oral Rehydration Program, new policies, new commercial products, results of trials etc.

Considering the demands of producing such a newsletter, publication might be contracted to a group like Kabalikat to assure attractive presentation and timely publication under the guidance of the CDD Task Force.

In addition, WHO and other professional documents on diarrheal disease should be more widely available. Regular WHO publications should be reproduced and available in each provincial or specialist office. A core library should be given to each graduate of the National ORT training and this could be periodically updated through the newsletter. In neighboring Indonesia, a bimonthly publication of diarrhea abstracts is distributed throughout the country. A photocopy service for key articles can be made available. A national diarrheal library should be established, most preferably at the proposed NRTRC at San Lazaro Hospital. The library should have all related WHO publications and guidelines, selected literature from the pediatric, infectious disease and public health publications, and recent books such as Diarrhea and Malnutrition by Chen and Scrimshaw, and the ICORT proceedings. A list of recommended materials can also be obtained from PRITECH.

4. Professional Meetings

The Philippine Pediatric Society and its eight chapters throughout the country have regularly included talks on oral rehydration. However, numerous professional meetings occur without reference to

oral rehydration therapy. Funds should be provided to enable experienced speakers to make presentations at professional meetings and provide up to date information on diarrhea treatment. Commercial promotion of new rehydration products should be encouraged at professional meetings.

There should be consideration of sponsoring a National Diarrheal Disease Meeting at which provincial rehydration experts could present data on their experiences and exchange ideas. Annual meetings have been held in Indonesia for the past 10 years and have been a significant influence on pediatricians and other doctors to encourage the use and study of oral rehydration in their own clinical settings. Such a meeting requires advance announcement, preferably one year or more, to allow time to prepare small clinical studies.

5. Training of Paraprofessionals

In order to support and extend the institutionalization of oral rehydration, paraprofessional promotion is extremely important. Paraprofessionals should be trained in each provincial hospital following standard curriculum guidelines and materials provided by the CDD Task Force. Materials is used here to mean not only written materials in a standard notebook, but also should include a slide sound set on ORT. A slide sound show can be centrally produced and

made widely available at the regional level. In addition, a wall chart depicting therapeutic approaches to ORT such as the one produced by WHO should be provided to each trainee to take back to the health units wherein s/he works.

At the RHU and BHS level, ECHO training could occur. However, this must be supported by the widespread availability of a clear, well-tested brochure, distribution of a wall chart for rehydration direction and an attractive poster promoting the use of ORS. These training materials along with the ECHO approach, familiar in the Philippine setting, should strengthen the use of ORS in the peripheral units.

6. Promotion Beyond the Health Sector

ORT promotion activities should also be encouraged through other ministries particularly those having wide contact with the public. For example, MEC - school curriculum with action lesson plans could be developed for each of the primary and secondary school grades. The curriculum guidelines developed in Iloilo would be a useful starting point. In addition, the Bureau of Agricultural Extension FMT/HMTs could be provided with brochures and a plastic spoon for their own use as well as for field demonstrations. Brochures and posters for other private groups, churches, scouts, etc. should be made available.

Funds for the distribution and production of such materials is a key constraint.

Mass media efforts to inform and educate the lay public are another level of a comprehensive promotion strategy. The Philippines is remarkable for its extensive marketing resources and the sophisticated use of mass media. It is suggested that an experienced marketing firm be engaged to participate in the development of a public promotion strategy. It is critical that product development occurs first and that we be entirely clear about what is being promoted. Presently, the promotion of Oresol to the public is of questionable value since it can be obtained only through the health center. Thus a new product must be consistent with the notion of oral rehydration or perhaps use the Oresol name to assure clarity of promotional messages.

Following the clear identification, naming and presentation of the product, a single critical message should be developed and promoted through widespread use of simple media. The poster is a simple, effective, medium for promoting the concept of oral rehydration. It is recommended as one of the best means to get the idea of an ORS product and name known. Step-by-step instructions on the use of the product is better described on the product label or an attached flyer rather than through a mass media approach. A poster supported by a slogan or jingle repeated frequently on radio and TV is a highly effective, multi-media approach. However, we reiterate the importance of a single message product concept promotion rather than a more

general health education approach in this area. Further efforts are needed to define the most appropriate message to encourage mothers to use ORT and to guide them in the care of severe cases when they should seek appropriate medical attention.

C. MANAGEMENT AND FINANCING ISSUES

Given the range of activities necessary to promote the widespread use of ORT in the Philippines, overall administrative feasibility to manage and finance these efforts must be considered. While the present CDD Task Force has prepared program plans, curriculum outlines, draft policy statements, and annual reports of program accomplishments, there remains a need for a full-time staff to manage the ORT program activities within the Ministry of Health. The program has, fortunately, enjoyed the strong support and guidance of the Minister and, therefore, policy formulation has been generally clear and widely disseminated. It would seem desirable to support the Committee on Diarrheal Diseases and the Task Force with an ORT Secretariat. We suggest that a Secretariat be established with full time professional and support staff under the direct leadership and guidance of the Minister of Health. The purpose is to assure more coherent and consistent coordination of expanded ORT/CDD activities.

An ORT Secretariat could be responsible for establishing an annual plan with targets involving bed use, intravenous use, diarrheal deaths, and coordinate the many issues related to ORS supply, promotion, training, IEC

activities, information system, monitoring feedback and evaluation. Regular meetings on a quarterly basis of regional CDD coordinators could coincide with the regional directors staff meeting, and would assure the translation of national policy planning to regional and provincial levels

The lack of financial resources to effect MOH/ORT plans has crippled efforts to implement the program. A limited term action plan should be established in collaboration between the Ministry of Health, USAID, UNICEF, WHO, KABALIKAT and any other interested parties to implement activities necessary to consolidate and institutionalize the considerable gains already achieved in ORT in the Philippines. Far from establishing a separate vertical program, such a carefully planned program of activities would assure consolidation and institutionalization of oral rehydration throughout the Ministry, and make it a strong component of the basic primary health care implementation strategy. (See Annex #6)

A modest annual budget would provide the central Secretariat with one or two professional staffs and a secretary, adequate travel money to visit regions on a regular basis, and the capability to convene meetings on a quarterly basis in Manila. IEC activities to promote ORT should be budgeted to include professional literature, the proposed newsletter's publication and circulation, brochures, posters, educational materials, and a public media campaign.

Training activities to be funded under such a project would include costs of the National Rehydration Training and Research Center, its operation,

and necessary travel and per diem costs for trainees. Funding could also support provincial level training activities upon completion of the training at the central level, and brief seminars/trainings sessions for rural health and barangay staffs.

Information systems could be strengthened by revising the present reporting forms to include clear denominator information. Further efforts are needed to differentiate the number of RHUs, BHSs or hospitals reporting to the central level. The present form should be revised to record at each level the number of institutions in that area and the number of institutions reporting, as shown below:

| | |
|---------------------|---------------------|
| BHS existing _____ | RHU existing _____ |
| BHS reporting _____ | RHU reporting _____ |

Efforts could be made to retrieve this information on a monthly or at least quarterly basis. Rapid processing, interpretation and feedback could be through newsletters and other reports. Results of commercial sales in each province and region should be reported as well, to indicate progress towards the goal of self-reliance in ORS.

Justification for promoting the expansion of a national ORT program can be based on a financial analysis of the anticipated costs and benefits. The cost of an expanded ORT program appears quite modest when set against the total costs of diarrheal disease. The costs due to diarrheal disease in the Philippines could be measured in terms of bed use, intravenous use, as

well as personal expenditures on anti-diarrheal medications which are estimated to be over 72 million pesos in 1983. In addition, there are labor costs associated with the clinical management of diarrheal disease, particularly with intravenous treatment requiring significantly more nursing time than ORT treatment. An analysis and comparison of these costs will provide an important justification to donor agencies as well as the Ministry to more aggressively expand the ORT program.

The MOH budget should be analyzed to assess the current expenditure on Oresol, centrally purchased drugs, and the percentage of hospital purchases expended on treatment of diarrheal disease. This budget should be scrutinized for possible reallocations to the commercial sector. The funds to purchase Oresol could be derived from the net savings on unnecessary anti-diarrheal drugs and intravenous solutions.

Considerations from the commercial sector's perspective on whether to enter ORS products on the market are assumed to include: the amount of initial capital outlay required, the associated risks on investment return balanced against the protected advantages of a guaranteed Ministry of Health market, and a product concept already known to the public through the extensive and effective MOH marketing of Oresol. A market assessment should indicate potential commercial sales under alternative pricing strategies. The objective of MOH negotiations should be to assure the lowest price possible with the widest distribution to maximize both production and distribution, as well as to minimize out of pocket cost for the consumer. A scenario likely to emerge is of a varied product line

with the packets of ORS targeted to the lower price range market and progressing to tablets and pre-mixed solutions marketed at a higher price range. Estimates of the market demand and relative profitability of alternative product approaches will be necessary.

Because the Ministry of Health is likely to guarantee purchase of ORS from the commercial market place, both the implied risks and capital outlays as well as the cost of indicated market studies should be borne by the commercial sector. Sufficient advantages are afforded to them through a guaranteed market and the marketing advantage provided by the Oresol name-recognition factor. There may, however, be a need for independent market and pricing studies particularly to assure that people in the lowest socioeconomic levels have access to an oral rehydration solution. In this regard, further consideration should be given to the utility of the home made solutions. An evaluation of the Iloilo trial should provide useful insights on acceptability, use, effectiveness, and cost savings.

Financial analysis of the benefits to be accrued from an ORT program should factor in the downstream discounted costs of international loan monies which can be used to initially fund the expanded program efforts. Grant support to this project can be justified on the grounds that it offers a means to develop institutional self-sufficiency and a self-reliant policy for reducing MOH recurring costs through the shifting of production/distribution to the commercial market place.

D. OPERATIONAL RESEARCH ISSUES

While this analysis attempts to be comprehensive, reflecting the current information available, there are a number of areas that require further research. It is recommended that technical assistance be obtained to guide and interpret operational research efforts so that important areas are addressed. Clearly, the operational research should be designed to support commercialization of ORS production, the effective promotion of ORT, and guide program policy decision-making. Suggested areas include:

1. Commercial production and promotion with an emphasis on pricing strategies, market research on consumer demand for ORT, and alternative product presentations.
2. Composition studies to examine shelf life under a variety of packaging and ingredient grades as well as clinical efficacy tests of alternative electrolyte, substrate, nutrient, and flavor combinations.
3. Homemade solutions as a viable alternative; promotion approaches; relative impact on diarrheal deaths; use of Oresol; hospital utilization; and severity of dehydration on admission; evaluations of solution safety; and impact on present practices in response to diarrhea illness.
4. Continuing research into new solutions and agents capable of treating and preventing diarrheal deaths.

RECOMMENDATIONS TO THE MINISTRY OF HEALTH

1. Establish a production agreement with a commercial firm or firms to progressively reduce and eventually replace Ministry of Health production of Oresol. It is expected that an increasing percentage of total product demand would be met by commercial producers, marketed and widely available throughout the country. This initiative will reduce the recurrent costs to the Ministry of Health budget and still reach down to the barangay level. The Ministry guarantees should assure that all purchasing will be in declining quantities over the coming years with arrangements to purchase at cost price excess production if sales fall short of expected levels.

2. Establish a committee to prepare an Administrative Order for the Minister's signature to the Bureau of Food and Drugs outlining standards for composition, packaging, labeling and presentation of oral rehydration solutions in the Philippines. Consideration should be given to encouraging formulations with local ingredients and eliminating requirements for USP quality reagents to allow for substitution with food grade ingredients.

3. Review current Ministry of Health expenditures for stock pharmaceutical product purchases. Products should be evaluated in terms of their therapeutic efficacy and relative priority as reflected in WHO recommended essential drug lists. The reprogramming of drug purchases could result in further funds to purchase Oresol in the commercial market place. Finally,

Oresol should be included on the annual bidding list of generic drugs distributed to commercial pharmaceutical firms.

4. Stimulate further large field trials of home rehydration solutions to monitor the impact on hospitalization, diarrheal deaths, and overall use of Oresol. A home rehydration solution should be recommended as a means to encourage consumption of increased fluid at the onset of diarrhea. A single home solution should be promoted by the MOH. A single glass formula is easier for mothers and would ultimately facilitate transition to a plastic measuring spoon, if the spoons are proven to be a cost effective means of promoting early home rehydration. It is suggested that UNICEF is prepared to substantially develop such home solution field trials. The Ministry of Health could use these results in developing its policy on homemade solutions.

5. Create at San Lazaro Hospital a unified rehydration service combining the present ORT unit and the pediatric gastroenteritis ward in one building. Under the direction of the Minister of Health and Medical Director of the hospital, this unit would comprise a National Rehydration Training and Research Center. The NRTRC would provide formal certificated professional training, as well as carry out appropriate clinical and operational research on rehydration technology for the Philippines. The Center could also be used as a regional resource for the Western Pacific region.

6. Establish an ORT Secretariat, headed by the Minister of Health, to provide the necessary management direction and control to the unified national ORT plan. The existence of a Secretariat, directed by the Minister, would provide a substantial incentive to international donors such as WHO, UNICEF, USAID, and others to fund this national effort which has heretofore existed with ad hoc financial support. This secretariat would be responsible for preparing a detailed implementation plan, receiving and administering funds, overseeing and coordinating support to the national training center, advising other Ministry training activities, preparing media and outreach materials, producing and circulating a professional newsletter, supervising field programs at the regional and provincial level, collecting information and preparing a regular management, technical and financial report. The existence of such a defined management structure in the Ministry would substantially increase the capability of MOH to expand and strengthen the ORT program of the Philippines.

RECOMMENDATIONS FOR DONOR PARTICIPATION IN A NATIONAL ORT PROGRAM

1. Support market and strategy studies as needed to encourage private production. (private studies)
2. Support studies on alternative packaging, ingredients, shelf life, etc. (MOH, Bureau of Research, FDA)
3. Support necessary "capital subsidy" for production to start. (Not MOH)
4. Support media promotion for combined MOH - commercial product. Includes market research, media design/testing, production and distribution, air time, etc.
5. Support National Rehydration Training and Research Center (NRTRC) - establishment, operations and training grants (one per province) (ICDDR, training of trainers)
6. Support professional promotion
 - Publication/libraries
 - Newsletter
 - Meetings
7. Support MOH Training
 - Courses including educational materials, wall chart, etc.
 - Brochures, poster, etc.
 - Slide-sound show

8. Support involvement of other Ministries.

MEC curriculum materials - development/production

BAEx or other agricultural training materials

9. Support Operational Research Projects

Composition/other clinical studies

Home made solutions and aids to their use (i.e. measuring spoons)

10. Support to Central MOH Task Force

Field travel budget

Materials production (policy papers, reports)

Information System Development and Reports

Evaluation of CDD

11. Technical Assistance needs (PRITECH, Local)

Financial Analysis - Costs of diarrhea - Savings and benefits of ORT

Clinical Training and Clinical Research (NRTRC)

(PRITECH, ICDDR, B, NAMRU, WHO)

Media - Product promotion (distinct from Health Education)

ORS Production (PRITECH - WHO/PATH)

ANNEXES

ANNEX 1

ACTIVITIES AND TARGETS OF CDD PROGRAM FROM THE GOP
FIVE-YEAR HEALTH PLAN, 1983-1987

| <u>Activities</u> | <u>Targets</u> | | | | |
|---|----------------|-------------|-------------|-------------|-----------------------------|
| | <u>1983</u> | <u>1984</u> | <u>1985</u> | <u>1986</u> | <u>1987</u> |
| Production of Oresol packets | 5585519 | 601492 | 642745 | 6827963 | 6843620 |
| Establishment of distribution system for Oresol in: | | | | | |
| - Barangay Health Stations | 6,250 | 6,617 | 6,985 | 6,985 | 7,353 |
| - Rural Health Units | 1,692 | 1,791 | 1,891 | 1,891 | 1,991 |
| - Government Hospitals | 406 | 456 | 481 | 481 | 507 |
| - Botica sa Barangay | 33,937 | 35,933 | 37,930 | 37,930 | 39,926 |
| Promotion of Oral Rehydration Therapy to all health workers (regular) involved in the program | 49,558 | 52,473 | 55,388 | 55,388 | 58,303 Health Workers |
| Orientation of Village Workers on ORT | 33,937 | 35,933 | 37,930 | 37,930 | 39,926 VHW |
| Provision of vailable packets (stock) of Oresol to all Botica Sa Barangay - | 5,882 | 6,250 | 6,618 | 6,985 | 7,353 BSB |
| Production/distribution of appropriate IEC materials for different levels of service - | | | | | |
| Leaflets | 549,276 | 711,695 | 719,345 | 824,188 | 867,566 |
| Flash Cards | 28,446 | 8,162 | - | - | - |
| Establishment of monitoring/feedback mechanism - | | | | | |
| PHOs and CHOs | 106 | 113 | 120 | 126 | 133 |
| Conduct of an annula evaluation on the utilization and impact of ORT | 1 | 1 | 1 | 1 | 1 |
| Research and Development | | | | | |
| Estimated Budgetary Requirement | | | | | |
| Hospitals - | ₱3625000 | ₱3922500 | ₱4249750 | ₱4609925 | ₱5006217 |
| General Service | 2700000 | 2700000 | 1700000 | 1700000 | 1700000 |

ANNEX II
OST ESTIMATE OF PRODUCING 5.1 MILLION
PACKS OF ORESOL

ANNEX 2
COST ESTIMATE OF PRODUCTS 5,100,000 PACKS OF ORESOL

| I. <u>MATERIALS</u> | <u>COST/UNIT</u> | <u>QTY./MONTH</u> | <u>QTY./QUARTER</u> | <u>QTY./ANNUM</u> | <u>COST/PKT.</u> | <u>TOTAL COST</u> |
|---|------------------|-------------------|---------------------|-------------------|------------------|-----------------------|
| 1. Glucose, USP, 30 kgs./bag (20 grams/pkt. = 20 kgs./1000 pkt.) | P 23.50/kg | 8340 kgs. | 25,200 kgs. | 100,800 kgs. | .464 | 2,368,800.00 |
| 2. Sodium, Chloride, USP to/kgs. (3.5 grams/pkt. = 3.5 kgs./1000 pkt.) | 22.00/kg. | 1500 kgs. | 4,500 kgs. | 18,000 kgs. | .077 | 396,000.00 |
| 3. Sodium Bicarbonate, USP 25 kgs. (2.5 grams/pkt. = 1.5 kgs./1000 pkt.) | 6.50/kg. | 1050 kgs. | 3,150 kgs. | 12,500 kgs. | .016 | 81,900.00 |
| 4. Potassium Chloride, USP 50 kgs. (1.5 grams/pkt. = 1.5 kgs./100 pkt.) | 26.50 kg. | 650 kgs. | 1,950 kgs. | 7,800 kgs. | .040 | 206,700.00 |
| 5. Polyfoil Packets | .198/pc. | 425,000 pcs. | 1,275 kgs. | 5,100,000 pcs. | .198 | 1,009,800.00 |
| 6. Carton Boxes | 6.00/set | 850 set | 2,550/set | 10,200 set | .012 | 61,200.00 |
| 7. Gummed Tape (16 box/roll) | 28.00/roll | 53 rolls | 159/roll | 638 roll | .0035 | 17,860.00 |
| 8. Plastic bag (4 pcs./1000) | .40/cps. | 1,670 pcs. | 5,000 pcs. | 20,000 pcs. | .0015 | <u>8,000.00</u> |
| | | | | Grand Total | | <u>P 4,150,264.00</u> |

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ANNEX 3

A SITUATION ANALYSIS ON ORAL REHYDRATION SOLUTION IN THE PHILIPPINES

(October 1983)

- I. Introduction
- II. Methodology
 - A. Pantry Check
 - 1. sampling
 - 2. project sites
 - B. Data Analysis
- III. Respondents' Profile
- IV. Findings and Analysis
 - A. The Government Sector
 - B. The Commercial Sector
- V. Conclusions and Recommendations
- VI. Appendices
 - A. Copies of Questionnaires
 - 1. Government
 - 2. Drugstore

A Situation Analysis on
Oral Rehydration Solutions
In the Philippines
(October, 1983)

I. Introduction

Oral rehydration therapy (ORT) is fast gaining popularity throughout the developing countries because of its having revolutionized the management of diarrheal dehydration. In the Philippines today, the Ministry of Health (MOH) has adopted oral rehydration therapy as a nationwide program with its goal of cutting infant mortality rate by 50%. It is being promoted among physicians, health workers and mothers at both the hospital level as well as the rural health unit/barangay health station level. Many problems still prohibit the success of the program such as the complicated two-sided packaging, the difficulty in accurate measurement of 1 liter, proper dosage, unconvinced doctors, traditional thinking mothers and a limited distribution system. Crucial to the attainment of the goals of such a program is its availability to the millions of children from the deprived lower income group. This can only be achieved if every available channel will become involved in the promotion of oral rehydration therapy, including the private sector. Not only the rural health units of the MOH should be tapped as distribution and promotion channels, but also private establishments such as drugstores, sari-sari stores, supermarkets. In this way, ORT could become the means to save the lives of their infants who suffer from diarrheal disease.

This study hopes to do an overview study of ORS in the Philippines, the various products available, the extent to which they are available and any problems that may be experienced with regards acquisition or availability. This study will deal with two components: the government sector and the private sector. More specifically it aims to achieve the following objectives:

1. to determine the present availability and condition of stock of ORS products both government and private;
2. to describe the distribution network of the ORS products;
3. to determine the acceptability of ORS products to users;
4. to establish the peak and non-peak seasons in the usage of ORS products;
5. to identify problems in the availability, distribution and use of ORS products.

II. Methodology

A. Pantry Check

A quick pantry check was done among the government and private distribution outlets of ORS products. A separate questionnaire was formulated for the government and commercial sector respondents. The questionnaire for the government product ORESOL focused on present availability, condition, usage, distribution scheme, product acceptability.

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The questionnaire for the private sector centered on product availability, price, average monthly sales, product distribution, whether over the counter brand or strictly by prescription, or any consumer's comments about the product.

Ministry of Health officials were also interviewed to obtain figures on production volume, quantity distributed to various regions and some production and raw materials procurement costs.

1. Sampling

A sample of 25 respondents per region was interviewed for the pantry check. This was divided into 30% drugstores and 70% government health centers since there are more health centers throughout the country than drugstores. Thus, the 7 drugstores (30% of 25 respondents) were chosen randomly while the 18 health centers (70% of 25 respondents) interviewed were the same health centers randomly chosen for the growth chart situationer. Metro Manila was also included in the study with 10 drugstore respondents and 10 government health centers. The total number of respondents was 121. (See respondents' Profile for breakdown.)

2. Project Site

As this project was planned to piggyback on the schedule and site for the Situation Analysis on Growth Charts in the Philippines, the areas for both projects are the same. The study was conducted in four regions: Regions I, V, VI and X. Because of the limited time, only one or two provinces from each region were selected namely: Benguet and La Union from Region I, Albay and Camarines Sur from Region V, Iloilo from Region VI, and Misamis Oriental and Bukidnon from Region X. Municipalities and subsequent barangays were chosen from the province following a pattern of one being nearer the city, one being further away, and one being in between.

The National Capital Region or Metro Manila was also included as part of the project sites.

B. Data Analysis

The information gathered was collated and qualitatively analyzed. Data from the 5 areas were descriptively compared to show the various ORS products available, their distribution network, and any common problems. Based on these findings a situation analysis of oral rehydration solutions was drawn up. Recommendations were devised from the data presented.

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III. Respondents' Profile

Following is a description of the respondents interviewed by region.
(See page 3a & b).

IV. Findings and Analysis

A. The Government Sector

Based on interviews with Ministry of Health officials at the Central office, the targeted production of ORESOL for 1983 is 6 million sachets. Production is done by quarter where again, a targeted 1.5 million sachets are produced.

So far, at the end of the third quarter of 1983, a total of 4,112,500 sachets have been produced. Following is a breakdown of actual amounts produced this year per quarter:

| | |
|-------------|------------------|
| 1st quarter | 1,397,500 |
| 2nd quarter | 1,572,500 |
| 3rd quarter | 1,142,500 |
| | <u>4,112,500</u> |

Distribution per region is based upon estimated requirements made by each regional office. The table below shows the various amounts distributed to each region:

TABLE 1. DISTRIBUTION OF ORESOL SACHETS PER SAMPLE REGION

| Quarter \ Region | Metro Manila | Region I | Region V | Region VI | Region X | Total |
|--------------------|---------------|----------------|----------------|----------------|----------------|------------------|
| First Quarter '83 | 26,500 | 175,000 | 120,000 | 145,000 | 200,000 | 666,500 |
| Second Quarter '83 | 26,000 | 140,000 | 120,000 | 140,000 | 160,000 | 586,000 |
| Third Quarter '83 | 24,000 | 70,000 | 60,000 | 110,000 | 80,000 | 344,000 |
| Total | 76,500 | 385,000 | 300,000 | 395,000 | 440,000 | 1,596,500 |

These above figures are from the Central Office in Manila. Realities in the field are described in the following findings.

1. Present Availability

ORESOL is generally (47%) available in all regions although in low quantities, in some areas (11%) it is out of stock.

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ORESOL SITUATIONER
Respondents' Profile

| Region Type of Respondents | Rural Health Unit | Barangay Health Station | Barangay Nutrition Scholars | Provincial District Hospitals | Botica sa Barangay | Commercial Drugstores |
|--|-----------------------|-------------------------|-----------------------------|-------------------------------|--------------------|-----------------------|
| National Capital Region | | 7 | | 3 | | 10 |
| Region I La Union Total = 1 San Fernando Benguet Total Baguio City La Trinidad Tublay Tuba | 1 2 | 3 5 3 | | 1 2 1 | | 7 |
| Region V Albay Total = 16 Daraga Camalig Guinobatan Legaspi Camarines Sur Total = 2 Naga City Canaman | 1 2 1 1 | 7 5 1 | | | | 4 4 |
| Region VI Iloilo Total = 17 Iloilo City Leganes Dueñas San Enrique Zarraga Passi | 2 1 1 1 2 | 1 1 2 1 | 1 1 | 1 1 | 1 | 3 3 |

SP

| Region | Type of Respondents | Rural Health Unit | Barangay Health Stations | Barangay Nutrition Scholars | Provincial/District Hospitals | Botica sa Barangay | Commercial Drugstores |
|----------|-----------------------------|-------------------|--------------------------|-----------------------------|-------------------------------|--------------------|-----------------------|
| Region X | | | | | | | |
| | Misamis Oriental Total = 11 | | | | | | |
| | Cagayan de Oro City | | 3 | 1 | | | 5 |
| | Opol | | 1 | 1 | | | |
| | El Salvador | | 1 | 1 | | | |
| | Villanueva | 1 | | | | | 2 |
| | Tagdoan | 1 | | | | | 1 |
| | Bukidnon Total = 7 | | | | | | |
| | Sumilao | 1 | | | | | 2 |
| | Impasug-ong | 1 | 1 | | | | |
| | Manolo Fortich | | 2 | 2 | | | |

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TABLE 2. AVAILABILITY OF ORESOL BY REGION

| Stock Available | Manila n=10 | Region I n=18 | Region V n=18 | Region VI n=17 | Region X n=18 | Total n=81 | % |
|-----------------|------------------|------------------|------------------|-------------------|------------------|---------------|-----|
| out of stock | 2 ^{20%} | 1 | 2 | 4 | 4 | 13 | 11 |
| less than 50 | 5 ^{50%} | 9 | 10 | 6 | 8 | 38 | 47 |
| 50 - 99 | 2 | 3 | 2 | 3 | - | 10 | 12 |
| 100 - 149 | 1 | 1 | - | - | 2 | 4 | 5 |
| 150 - 199 | - | - | - | - | - | 0 | 0 |
| 200 - 249 | - | - | - | - | 1 | 1 | 1 |
| 250 - 299 | - | - | - | - | 1 | 1 | 1 |
| 300 - 500 | - | - | - | 1 | - | 1 | 1 |
| more than 500 | - | 4 | 4 | 3 | 2 | 13 | 15 |
| Total | 10 | 18 | 18 | 17 | 18 | 81 | 100 |

2. Supply

However, inspite of its general availability, there is often a lack of supply at the barangay health station level. The table below describes the duration in which 52% of the respondents are without any supply of ORESOL. Twenty two (22%) percent of the respondents are left with no supply for more than a month, a relatively long span of time especially if during the diarrhea peak season. Prescribed anti-diarrheals are then resorted to causing a contradictory policy to and a let down in the campaign for promoting oral rehydration and doing away with anti-diarrheals. This will also cause further confusion among mother users as to what ORESOL is a remedy for - whether to stop diarrhea or to control dehydration due to diarrhea. Mothers will tend to equate ORESOL in the same category as anti-diarrheals. It seems that even to midwives and the other healthworkers, the non-need for anti-diarrheals is still not fully understood and supported.

TABLE 3. DURATION OF ORESOL UNAVAILABILITY (OUT OF STOCK) BY REGION

| Frequency of Unavailability | Manila n=10 | Reg. I n=18 | Reg. V n=18 | Reg. VI n=17 | Reg. X n=18 | Total n=81 | % |
|--|----------------|----------------|----------------|-----------------|----------------|---------------|-----|
| never out of stock in past year (1983) | 2 | 9 | 10 | 11 | 7 | 39 | 48 |
| out of stock for less than 1 week | - | 1 | 2 | - | - | 3 | 4 |
| 1 week to 2 weeks | - | 7 | 4 | - | - | 11 | 14 |
| 2 weeks to 3 weeks | - | - | 1 | - | - | 1 | 1 |
| 3 weeks to 4 weeks | 3 | 1 | - | - | 5 | 9 | 11 |
| more than 1 month | 5 | - | 1 | 6 | 6 | 18 | 22 |
| Total | 10 | 18 | 18 | 17 | 18 | 81 | 100 |

It is only Iloilo that does not seem to have any real shortage of ORESOL (only 5 out of 17 said that they had experienced an out of stock situation). Moreover, in a few areas, there was more than enough supply.

3. Stock Conditions

Problems in the condition of stock is evident with a large 40% of respondents claiming poor condition due to packages with holes having been eaten by cockroaches, ants, rats and other small animals; sachets becoming wet, packaging sometimes getting unstuck or torn open. Storage, because of these complaints, also becomes a problem, especially at the RHU level where a larger supply is usually delivered. Storage compartments used were cardboard boxes, cabinets and large cans which they claimed to be a better storage method.

TABLE 4. FREQUENCY DISTRIBUTION OF ORESOL STOCK CONDITION BY REGION

| Condition of Stock | Manila n=10 | Reg. I n=18 | Reg. V n=18 | Reg. VI n=17 | Reg. X n=18 | Total n=81 | % |
|-------------------------------------|----------------|----------------|----------------|-----------------|----------------|---------------|----|
| Good condition | 7 | 4 | 10 | 10 | 15 | 46 | 57 |
| Poor condition | 3 | 14 | 8 | 8 | 3 | 36 | 44 |
| Wet | 2 | 2 | 2 | 7 | - | 13 | 19 |
| Eaten by insects/ small animals | 2 | 8 | 4 | 3 | 2 | 19 | 21 |
| Packaging torn/ unstuck/deformed | 3 | 4 | 2 | - | 2 | 11 | 14 |
| Others | 1 | - | - | - | - | 1 | 1 |

Note: There were multiple answers.

4. ORESOL Demands

Forty five percent (45%) of the respondents use less than 30 packs a quarter. This large number decreases by half during peak diarrhea season, and becomes more dispersed and distributed to the other average ranges (e.g. 17% who use 31-60 sachets a quarter increases to 33% during peak season). Also the larger average ranges show more responses in the peak season rather than non-peak. It should be noted, however, that this may not be reliable data due to the existing system of recording ORESOL usage.

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Diarrhea season was generally found to vary slightly in each region although most often occurring during the fruit months of April and May, and during the rainy months of July, August and September. Quite contradictory to this is the distribution breakdown of the MOH Bureau of Research and Laboratories (see Table 1) which shows a downward trend wherein quarters 2 and 3 receive less ORESOL than quarter 1. This, perhaps, further explains the low supply of ORESOL at the RHU/BHS level and the frequent shortage. Moreover, it is only Region VI that received a relatively large number of sachets which accounts for the over supply or adequate supply evident in municipalities and barangays in the province of Iloilo.

TABLE 5. FREQUENCY DISTRIBUTION OF QUARTERLY AVERAGE OF ORESOL DISPENSED WITHIN 1983 NON-PEAK DIARRHEA SEASON BY REGION

| Quarterly Average | Manila n=10 | Reg. I n=18 | Reg. V n=18 | Reg. VI n=17 | Reg. X n=18 | Total n=81 | % |
|-------------------|----------------|----------------|----------------|-----------------|----------------|---------------|-----|
| less than 30 | 5 | 9 | 14 | 4 | 13 | 45 | 56 |
| 31 - 60 | 2 | 5 | 1 | 5 | 4 | 17 | 21 |
| 61 - 90 | 2 | - | - | - | - | 2 | 2 |
| 91- 120 | 1 | - | - | 4 | - | 5 | 6 |
| 121 - 150 | - | 2 | - | - | - | 2 | 2 |
| 151 - 180 | - | 1 | - | 4 | - | 5 | 6 |
| 181 - 240 | - | - | - | - | 1 | 1 | 1 |
| 241 - 300 | - | - | - | - | - | 0 | 0 |
| 301 - 500 | - | 1 | - | - | - | 1 | 1 |
| 501 - 700 | - | - | 3 | - | - | 3 | 5 |
| Total | 10 | 18 | 18 | 17 | 18 | 81 | 100 |

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TABLE 6. FREQUENCY DISTRIBUTION OF QUARTERLY AVERAGE OF ORESOL DISPENSED WITHIN 1983 PEAK DIARRHEA SEASON

| Quarterly Average | Manila n=10 | Reg. I n=18 | Reg. V n=18 | Reg. VI n=17 | Reg. X n=18 | Total n=81 | % |
|-------------------|----------------|----------------|----------------|-----------------|----------------|---------------|-----|
| less than 30 | 3 | 2 | 7 | - | 5 | 17 | 21 |
| 31 - 60 | 3 | 8 | 7 | 3 | 6 | 27 | 33 |
| 61 - 90 | 1 | 2 | 1 | - | 2 | 6 | 7 |
| 91 - 120 | - | - | - | 3 | 2 | 5 | 6 |
| 121 - 150 | - | - | - | - | 1 | 1 | 1 |
| 151 - 180 | 1 | 1 | - | 2 | 2 | 6 | 7 |
| 181 - 240 | - | - | - | - | - | 0 | 0 |
| 241 - 270 | - | 1 | - | 9 | - | 10 | 12 |
| 271 - 300 | - | - | - | - | - | 0 | 0 |
| 301 - 500 | - | 2 | - | - | - | 2 | 3 |
| 501 - 700 | - | - | - | 1 | - | 1 | 1 |
| 701 - 900 | - | 2 | - | - | - | 2 | 3 |
| 901 - 1100 | - | - | - | - | - | 0 | 0 |
| 1101 - 1300 | - | - | 3 | - | - | 3 | 3 |
| no records | 2 | - | - | - | - | 2 | 3 |
| Total | 10 | 18 | 18 | 17 | 18 | 81 | 100 |

5. Distribution

It was found that there is no clear, regular and systematic distribution scheme that is followed in any of the regions, including Metro Manila. Conflicting responses were given when asked how many sachets were given and how frequent. The Rural Health Unit would say one thing and the Barangay Health Station, another. Sometimes quota systems would be used (e.g. in Iloilo). A majority though, claimed that replenishment would depend on balance of stock in BHS as well as in RHU. So if a BHS had only 5 sachets left for the month, the midwife could request for more if the RHU still had some left. The system seemed to be very informal and loose.

A monthly form is used to keep track of diarrheal cases at the BHS level and the quantities of ORESOL dispensed. This is sometimes used for replenishment requests. In the process of going over and comparing the numerical data, discrepancies were evident in that the figures did not always tally. It was also discovered that health workers do not fully understand the importance of the form nor the manner in which it should be filled out. Some feel that it is a means for checking that they are doing their job of distributing ORESOL. Hence, they make sure that the number of diarrhea patients and the ORESOL dispensed tally so as to show that all patients were given ORESOL. The record then becomes useless as a means of counting the number of diarrhea cases in that barangay as well as a basis for deciding whether ORESOL in her station is adequate or not. The form itself is very confusing

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and repetitive. In fact, 2 or 3 forms are being used, all with several different variables making a consolidated report very difficult to arrive at. Very often there is a lack of these forms and incomplete improvisations have to be resorted to.

6. Acceptability

It was revealed that taste is a major problem in the success of the promotion campaign for ORESOL. Seventy percent (70%) of the respondents complained of their patients (young children) not wanting to drink the solution and either had to be forced to drink or had to have sugar or some other beverage (softdrink, coconut juice, etc.) added to the mixture. When asked how they respond to such complaints, respondents said that they themselves advised to dilute it with 7-up or coke, or to add more sugar. This shows that midwives and paramedics themselves are not clear as to the non-effectiveness of a diluted solution and do not realize that this is equivalent to not using ORESOL at all. The common feeling was that infants (children below 2) will usually drink it down without too much trouble but toddlers and those of schooling age know better and refuse to drink the solution.

Form received much better reactions from the mothers' viewpoint. They are now able to mix the solution correctly because of the demonstrations that the midwife and paramedic performs to help explain the process. A few remarks however should be noted such as suggestions for a smaller sized pack since infants usually cannot finish the 1 liter sachet in one day. Moreover, if we relate these comments to the large number of respondents who had problems in their stock condition, the need for a better form of ORESOL becomes more urgent.

On the whole mothers recognize the effectiveness of ORESOL in diarrhea cases. This makes the product acceptable despite its taste and form problems.

TABLE 7. FREQUENCY DISTRIBUTION OF TASTE AND FORM
ACCEPTABILITY OF ORESOL BY REGION

| Response | Taste | | | | | | Form | | | | | | | |
|---------------------------|--------|-----------|-----------|------------|-----------|-------|------|--------|-----------|-----------|------------|-----------|-------|-----|
| | Manila | Reg. I | Reg. V | Reg. VI | Reg. X | Total | % | Manila | Reg. I | Reg. V | Reg. VI | Reg. X | Total | % |
| Yes, it is acceptable | 5 | - | 2 | 8 | 9 | 24 | 30 | 8 | 13 | 13 | 15 | 18 | 67 | 83 |
| Not, it is not acceptable | 5 | 18 | 16 | 9 | 9 | 57 | 70 | 2 | 5 | 5 | 2 | - | 14 | 17 |
| Total | 10 | 18 | 18 | 17 | 18 | 81 | 100 | 10 | 18 | 18 | 17 | 18 | 81 | 100 |

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7. Distribution to Mothers

As can be seen in Table 8, ORESOL is mainly distributed to mothers when they come to the clinic for diagnosis. It is also given out to households when the midwife/health workers go out to the field. In these cases, two to three packs are usually handed out to families with children under 5 years so that it is ready for immediate home use. Only 44% of the respondents claimed this as one means since most have stopped this procedure after having experienced that the 2-3 packs given the family is later found eaten up by insects, etc. or just forgotten about and left decaying. Many respondents also reported that a large portion of mothers who have used ORESOL before or who have heard it advertised over the radio voluntarily come and ask for it at the health center. A few BHS/RHUs provide a small supply (less than 10) at their local Botica sa Barangay if any. But this is usually done on a very irregular basis - if any stock is left over at the end of the month.

Another point that was raised was the unavailability of ORESOL at drugstores and other outlets since the BHS and RHU are closed at 4 and midwives are not usually in after 12 pm (they go on field in the afternoons).

TABLE 8. MEANS OF ORESOL DISTRIBUTION TO MOTHERS BY REGION

| Means of ORESOL Distribution to Mothers | Manila n=10 | Reg. I n=18 | Reg. V n=18 | Reg. VI n=17 | Reg. X n=18 | Total n=81 | % |
|--|----------------|----------------|----------------|-----------------|----------------|---------------|----|
| when they come to clinic for diagnosis | 5 | 8 | 18 | 17 | 14 | 62 | 77 |
| in home placement upon mothers' request at health center | - | 7 | 13 | 13 | 13 | 36 | 44 |
| botica sa barangay | 2 | 6 | 1 | 3 | - | 12 | 15 |
| others (e.g. w/barangay capt. or unit leaders) | - | - | - | - | - | 0 | 0 |
| | | | | | | 164* | |

* Multiple responses

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8. Respondents' Comments and Suggestions

The general consensus that was arrived at was that ORESOL has been proven effective. The main concern, though, was an improvement in taste. Suggestions revolved around changes in form to one that is premixed and less cumbersome to mix, improving the package to avoid insects, etc., making sachet size smaller so that it is not wasteful. A few respondents suggested a more intensive educational campaign to help mothers understand that ORESOL is not to stop diarrhea but to help control dehydration. One midwife even brought up the idea of using ORESOL for those who perspire a lot and work in the fields.

B. ORS Commercial Sector

The local Philippine commercial sector has not yet fully recognized the impact oral rehydration products can have on diarrhea cases, the second leading cause for morbidity. To date, only five products have been put into the market: Pedialyte, Isolyte, Glucolyte, Kristalyte and Dioralyte. These five products are not always available at city, provincial, or municipal level drugstores as we shall see in the succeeding "pantry check" findings.

TABLE 9. ORS PRODUCTS AVAILABLE IN COMMERCIAL DRUGSTORES BY REGION

| Product Brand | Manila n=10 | Region I n=7 | Region V n=8 | Region VI n=6 | Region X n=10 | Total n=41 | % |
|---------------|----------------|-----------------|-----------------|------------------|------------------|---------------|----|
| Pedialyte | 7 | 7 | 8 | 6 | 10 | 38 | 93 |
| Glucolyte | 7 | 3 | 5 | 2 | 2 | 19 | 46 |
| Isolyte | 4 | - | 4 | 1 | 3 | 12 | 29 |
| Kristalyte | 4 | 1 | - | 4 | 1 | 10 | 24 |
| Dioralyte | 2 | - | 2 | 1 | 2 | 7 | 17 |

Table 9 indicates where these five ORS products are available at the time of the interviews. Pedialyte can be found in all drugstores interviewed, although low in or out of stock. Pedialyte's popularity can probably be explained by its being a pre-mixed solution. This facilitates easy and sanitary preparation and administration of the product unlike the other powder sachets which call for exact measurements and boiled or clean drinking water. These are very difficult to achieve in rural or low income families where literacy is low, measurement containers are unavailable and the need for boiled, clean water is not understood. Also its composition, according to doctors, is more appropriate for infants (children below 2 years) having a lower sodium content than other brands, especially the government product ORESOL. This will ensure that the child does not go into a state of hypernatraemia. Another factor that can explain Pedialyte's popularity is its more pleasant taste, due to the higher glucose content. It becomes more acceptable to children.

1. Pedialyte

Pedialyte stands as the number one oral rehydration solution (ORS) product in the market today. It is carried by drugstores in the remote municipalities of Misamis Oriental. Pedialyte is a premixed solution manufactured by Abbott Laboratories. It comes in two sizes, 500 ml and 240 ml, in two containers, a plastic bottle with resealable cap and a glass bottle with accompanying nipple. The

newer glass bottle with nipple container is only available in the city drugstores interviewed (ie. Baguio, Iloilo, Legaspi) except for those in Mindanao where the plastic one is used.

TABLE 10. PRICE OF PEDIALYTE PER UNIT BY REGION

| Price | Manila n=10 | Region I n=7 | Region V n=8 | Region VI n=6 | Region X n=10 | Total n=41 | % |
|------------------|----------------|-----------------|-----------------|------------------|------------------|---------------|-----|
| less than ₱13.00 | - | - | - | - | 1 | 1 | 2 |
| ₱13.00 - ₱13.50 | - | - | - | - | - | 0 | 0 |
| ₱13.55 - ₱14.00 | - | - | - | - | 1 | 1 | 2 |
| ₱14.05 - ₱14.50 | 1 | - | - | - | 1 | 2 | 5 |
| ₱14.55 - ₱15.00 | - | 2 | 3 | 1 | - | 6 | 15 |
| ₱15.05 - ₱15.50 | 4 | 2 | 1 | 2 | - | 9 | 22 |
| ₱15.55 - ₱16.00 | 3 | 2 | - | - | 1 | 6 | 15 |
| ₱16.05 - ₱16.50 | - | 1 | 4 | 2 | - | 7 | 17 |
| ₱16.55 - ₱17.00 | 1 | - | - | - | 1 | 2 | 5 |
| ₱17.05 - ₱17.50 | 1 | - | - | - | 3 | 4 | 10 |
| ₱17.55 - ₱18.00 | - | - | - | 1 | 1 | 2 | 5 |
| more than ₱18.00 | - | - | - | - | 1 | 1 | 2 |
| Total | 10 | 7 | 8 | 6 | 10 | 41 | 100 |

Pedialyte is the most expensive brand on the market with prices varying by about 50 centavos depending on how far it is from the supply and how large is the demand for it. The mode is between 14.55 and 16.50 in Metro Manila, Benguet, Albay, and Iloilo but for Mindanao is between 16.55 to 18.

The number of Pedialyte available at the time of the interviews was surprisingly low. Stocks seemed to be unavailable, particularly in Iloilo. The following table will further depict the situation.

TABLE 11. QUANTITY OF PEDIALYTE AVAILABLE BY REGION

| Quantity | Manila n=10 | Region I n=7 | Region V n=8 | Region VI n=6 | Region X n=10 |
|----------------------|----------------|-----------------|-----------------|------------------|------------------|
| none, no stock | 3 | 3 | 5 | 6 | - |
| less than 11 bottles | 4 | 2 | 1 | - | 7 |
| 11-20 bottles | 1 | 2 | 1 | - | 2 |
| 21-30 bottles | - | - | - | - | 1 |
| more than 30 bottles | 2 | - | 1 | - | - |
| Total | 10 | 7 | 8 | 6 | 10 |

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It was found that the smaller drugstores in the municipal areas carry a smaller quantity of pedialyte. This is mainly because of the high cost of Pedialyte being beyond the capital available to the drugstore owner and also, because the demand there is also less. Available data on the average number of pedialyte sold in one month vary from about 3 to 6 bottles in small drugstores and over 100 bottles in the larger city-based drugstores, especially those who service hospitals.

TABLE 12. CONSUMER BRAND PREFERENCE OF ORS PRODUCTS

| Item | Manila n=10 | Region I n=7 | Region V n=8 | Region VI n=6 | Region X n=10 |
|------------------------------|---------------------|-----------------|-----------------|------------------|------------------|
| Largest selling Brand | Pedialyte | Pedialyte | Pedialyte | Pedialyte | Pedialyte |
| Second Largest Selling Brand | Glucolyte | Glucolyte | Glucolyte | Kristalyte | Isolyte |
| Lowest Selling Brand | Isolyte & Dioralyte | Kristalyte | Dioralyte | Isolyte | Kristalyte |

In spite of its being the most expensive product, it is apparent that Pedialyte is the number one selling ORS brand throughout the sample regions, although presently low or out of stock in most areas interviewed. According to respondents, doctors' prescriptions are usually made out for Pedialyte and once mothers have used it, Pedialyte then becomes an over-the-counter brand.

New stock is usually replenished on an irregular basis, depending on the sales the previous week and the demand. Answers vary from a weekly replenishment to an annually replenishment with a majority of respondents stating a weekly, monthly, or bi-monthly replenishment.

The product is usually supplied by Metro Drug (44%). Other distributors are the individual middlemen, Abbott Laboratories, Squibb, Pascual Laboratory, etc.

Pedialyte is normally available in Metro Manila, Regions I, V and X although in low quantities at the moment. Iloilo has no present stock of Pedialyte. This is due to there being none available from their suppliers. A few drugstores have attempted to use the various other less popular brands (ie. dioralyte, kristalyte, isolyte), but have stopped doing so due to the low, erratic demand for the product.

A few (3 respondents) commented on Pedialyte not being as acceptable in taste as Kristalyte which comes in orange flavor. Infants are not able to tolerate Pedialyte at times.

2. Glucolyte

Glucolyte is an ORS product that comes in powder sachet form. It is manufactured by the Pascual Laboratories and distributed by Pharex Inc. It is available in 1 sachet size, 240 ml. Probably because of its cheaper price than the other powder sachets not to mention pre-mixed solutions, it is the second most popular or best selling brand in 3 sample sites: Metro Manila, Regions I and V.

TABLE 13
PRICE OF GLUCOLYTE PER SACHET BY REGION

| PRICE | MANILA N=10 | REG. I N=7 | REG. V N=8 | REG. VI N=6 | REG. X N=10 | TOTAL N=41 | % |
|---|----------------|---------------|---------------|----------------|----------------|---------------|-----|
| LESS THAN ₱3.00 | 1 | 2 | 4 | - | - | 7 | 17 |
| ₱3.05 - ₱3.50 | 4 | 2 | 2 | - | 1 | 9 | 22 |
| ₱3.55 - ₱4.00 | - | - | - | 1 | 1 | 2 | 5 |
| ₱4.05 - ₱4.50 | 2 | - | - | - | - | 2 | 5 |
| ₱4.55 - ₱5.00 | - | - | - | - | - | 0 | 0 |
| ₱5.05 - ₱5.50 | - | - | - | - | - | 0 | 0 |
| NOT APPLICABLE (DOES NOT CARRY THE BRAND) | 3 | 3 | 2 | 5 | 8 | 21 | 51 |
| TOTAL | 10 | 7 | 8 | 6 | 10 | 41 | 100 |

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TABLE 14. PERCENTAGE DISTRIBUTION OF ORS
COMMERCIAL PRODUCT IN POWDER
SACHET PRICE COMPARISON IN 5
REGIONS

| Price / Products By Region | Glucolyte n=41 | Kristalyte n=41 | Dioralyte n=41 |
|----------------------------------|-------------------|--------------------|-------------------|
| less than ₱3.00 | 17% | 2% | 0% |
| ₱3. - ₱3.50 | 22% | 2% | 5% |
| ₱3.55 - ₱4.00 (for 250 ml) | 5% | 2.5% | 7% |
| ₱3.55 - ₱4.00 (for 500 ml) | | 2.5% | |
| ₱4.05 - ₱4.50 (for 250 ml) | 5% | 2.5% | 5% |
| ₱4.05 - ₱4.50 (for 500 ml) | 0 | 2.5% | 0 |
| ₱4.55 - ₱5.00 | 0 | 0 | 0 |
| ₱5.05 - ₱5.50 | 0 | 0 | 0 |
| ₱5.55 - ₱6.00 (for 500 ml) | 0 | 8% | 0 |
| more than ₱6.00 (for 500 ml) | 0 | 2% | 0 |
| does not carry the brand | 51% | 76% | 83% |
| Total | 100% | 100% | 100% |

A mixture of small and big drugstores carry glucolyte although in small quantity, generally less than 30 sachets, with an average monthly sale of 15-20 sachets.

Distributors vary, United Laboratory for Region X, VI, Pharex, Albay Pharmaceutical Inc. and individual middlemen for Regions V and Pharez and individual middlemen for Region I and Baxter Inheider and Pharex in Metro Manila.

Replenishment of supply is irregular varying from weekly to a quarterly supply depending on balance of stock. A few respondents remarked that they had experienced a lack of supply but this was mainly due to an irregular delivery on the part of the suppliers.

Glucolyte is mainly on over-the-counter drug.

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3. Isolyte

Isolyte is a premixed ORS solution. It comes in two sizes, 240 ml and 500 ml. It is the third best selling ORS product. It is much cheaper than Pedialyte, the ORS product it mainly competes with, and yet it has not become as popular. This is probably because it is not as well known among doctors who must prescribe the medicine before it can be bought. It is shown in Table 9 ORS Products available in Commercial Drugstores by Region, that Region I area did not seem to have any Isolyte available. This means the premixed ORS market was totally controlled by Pedialyte.

TABLE 15
PRICE OF ISOLYTE PER UNIT BY REGION

| PRICE | MANILA N=10 | REG. I N=7 | REG. V N=8 | REG. VI N=6 | REG. X N=10 | TOTAL N=41 | % |
|---|----------------|---------------|---------------|----------------|----------------|---------------|-----|
| LESS THAN ₱13.00 | - | - | 4 | - | - | 4 | 10 |
| ₱13.00 - ₱13.50 | - | - | 1 | - | - | 1 | 2 |
| ₱13.55 - ₱14.00 | - | - | - | - | 1 | 1 | 2 |
| ₱14.05 - ₱14.50 | 1 | - | - | - | 1 | 2 | 5 |
| ₱14.55 - ₱15.00 | - | - | - | - | - | 0 | 0 |
| ₱15.05 - ₱15.50 | - | - | - | - | - | 0 | 0 |
| ₱15.55 - ₱16.00 | 2 | - | - | - | - | 2 | 5 |
| ₱16.05 - ₱16.50 | - | - | - | - | - | 0 | 0 |
| ₱16.55 - ₱17.00 | - | - | - | - | 1 | 1 | 2 |
| ₱17.05 - ₱17.50 | 1 | - | - | - | - | 1 | 2 |
| NOT APPLICABLE (DOES NOT CARRY THE BRAND) | 6 | 7 | 3 | 6 | 7 | 29 | 72 |
| TOTAL | 10 | 7 | 8 | 6 | 10 | 41 | 100 |

The prices of Isolyte per region vary widely and does not seem to depend on the region's proximity to Metro Manila because even Manila has rather high prices and Mindanao has even lower prices.

Quantity available at present seems to be 15 to 20 bottles with an average monthly sale of 12 bottles. Isolyte is ordered from Metro Drug in Region X, AHS in Region VI, Baxter Inhelder Inc. in Region V and Pharex in Metro Manila. Replenishment is irregular and depends on the number of sales the previous month and balance of stock.

Isolyte is also mainly an over the counter drug and is usually always available. It is only in Bicol that 2 respondents mentioned that they were told no supply was available in Manila.

4. Kristalyte

Kristalyte is an orange flavored ORS product manufactured by Squibb. It is often a preferred product precisely because of its flavor. A few mothers say their children prefer it even to Pedialyte.

TABLE 16
PRICE OF KRISTALYTE PER SACHET BY REGION

| PRICE | MANILA N=10 | REG. I N=7 | REG. V N=8 | REG. VI N=6 | REG. X N=10 | TOTAL N=41 | % |
|---|----------------|---------------|---------------|----------------|----------------|---------------|-----|
| FOR 250 ML: | | | | | | | |
| LESS THAN ₱3.00 | 1 | - | - | - | - | 1 | 2 |
| ₱3.05 - ₱3.50 | - | - | - | 1 | - | 1 | 2 |
| FOR 500 ML: | | | | | | | |
| ₱3.55 - ₱4.00 | 1 | 1 | - | - | - | 2 | 5 |
| ₱4.05 - ₱4.50 | - | - | - | 1 | 1 | 2 | 5 |
| ₱4.55 - ₱5.00 | - | - | - | - | - | 0 | 0 |
| ₱5.05 - ₱5.50 | - | - | - | - | - | 0 | 0 |
| ₱5.55 - ₱6.00 | 2 | - | - | 1 | - | 3 | 9 |
| MORE THAN ₱6.00 | - | - | - | 1 | - | 1 | 2 |
| NOT APPLICABLE (DOES NOT CARRY THE BRAND) | 6 | 6 | 8 | 2 | 9 | 31 | 76 |
| TOTAL | 10 | 7 | 8 | 6 | 10 | 41 | 100 |

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The price of Kristalyte is higher than Glucolyte and cheaper than Dioralyte. Stock available is generally about 10-15 at the time of interview with an average monthly sale of the same amount. Distribution and replenishment is through Squibb on an irregular basis depending on stock balances. It is mainly an over the counter drug and sometimes unavailable at the distributors end.

5. Dioralyte

Dioralyte is the most expensive ORS product in powder form which probably explains its being the least selling brand. Prices range from P3.00 to P4.50 with the higher prices found in Metro Manila and Cagayan de Oro City.

TABLE 17
PRICE OF DIORALYTE PER SACHET BY REGION

| PRICE | MANILA N=10 | REG. I N=7 | REG. V N=8 | REG. VI N=6 | REG. X N=10 | TOTAL N=41 | % |
|---|----------------|---------------|---------------|----------------|----------------|---------------|-----|
| LESS THAN P 3.00 | - | - | - | - | - | 0 | 0 |
| P3.00 - P3.50 | 1 | - | 1 | - | - | 2 | 5 |
| P3.55 - P4.00 | - | - | 1 | 1 | 1 | 3 | 7 |
| P4.05 - P4.50 | 1 | - | - | - | 1 | 2 | 5 |
| P4.55 - P5.00 | - | - | - | - | - | 0 | 0 |
| NOT APPLICABLE (DOES NOT CARRY THE BRAND) | 8 | 7 | 6 | 5 | 8 | 34 | 83 |
| TOTAL | 10 | 7 | 8 | 6 | 8 | 41 | 100 |

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Stock presently available is about 10-15 sachets but none sold in Region I sample drugstores. Average monthly sales range from 5-10 and stock is replenished irregularly depending upon balance of stock and previous demand. Its distributor is Metro Drug in all regions and if not found available in their store, it is due to the slow and erratic sale of the product upon which their re-ordering depends. It is an over the counter drug.

V. Conclusions and Recommendations

The promotion of ORESOL throughout the country seems to be very extensive and is well known at the barangay level by midwives and paramedical workers. It is recognized as a "miracle drug" that is cheap and can control dehydration due to diarrhea in a simple and home-based manner. However, several problems are evident in the campaign towards the use of ORESOL. First of all, a more defined system must be developed to cope with the demands of the users. The replenishment supply of ORESOL seems to breakdown somewhere along the distribution channel. At the central office level, hundreds of thousands are sent every quarter to the regional offices, yet at the barangay outlets a serious shortage can be seen. To aid in this improved delivery network, a simpler and more concise feedback must be formulated. A form that is well understood must be drawn up to show actual and accurate figures of diarrhea cases and ORESOL dispensed. Volunteer healthworkers, midwives, nurses and other medical personnel should fully understand this feedback system as not one to check on their performance but rather to monitor the distribution of ORESOL.

More clear cut policies should be made as to the role of anti-diarrheals in the case of non-availability of ORESOL, what to advise in cases where patients refuse to drink the solution so that front liner medical personnel will more consistently assist in the promotion of ORESOL. Training on these points should be more rigid.

Problems in stock condition that were mentioned called for packaging and form improvement. A better package would solve such problems as its being eaten by small insects and animals, its becoming unstuck, spilling the contents and thus becoming moist. A different form would also solve these problems as well as contaminated water, wrong measurements of 1 liter, difficulties in opening a 2 sided package. A premixed solution is still preferred as the easiest to prepare and most sanitary ORS form. Other suggestions were a smaller package for the salts so that the 1 liter is not wasted and measurement containers (e.g. one drinking glass, coffee or others) could be easier to find.

Taste was the agreed on concern as needing much improvement. In spite of its effectivity, children, particularly those between 2 and 6 refused to drink the salty-sweet solution. More effort should be exerted in the task of adding flavor into the mixture like the commercial brands

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(i.e. Kristalyte) and in determining how it would affect the effectiveness.

The Philippine ORS commercial products seems to have situated themselves in the midst of the ORS scene with the aim of making the most profit. The most outstanding finding in this commercial situationer is the exhorbitant prices they are sold at. One liter sachet of ORESOL was found to cost approximately ₱1.00, half of which is spent in imported glucose (i.e. ₱25/kg of glucose from Japan). These commercial products, costing about the same sell for at least 3 times this cost. The Pedialyte phenomenon, sometimes costing up to as much as ₱17 and still being the preferred brand in many cases, can be explained. Aside from its being in a premixed form, it also has the support of pediatricians and family doctors both government and private. This is where the physician's role is crucial in the ORS campaign. Doctors must be more convinced of the advantages of ORESOL.

A more total and coordinated ORS campaign is necessary if our aim is to achieve a more self-reliant mother in basic health care practices. The government promotion of free ORESOL will not continue forever and therefore will need support from the private sector. There is a need for an acceptable and effective product sold at easily afforded prices that can be an alternative to the government product. These must be available at more distribution outlets so that mothers can avail of the product any time. Doctors must become part of the oral rehydration therapy campaign and advise their patients to use various ORS products.

Copies of questionnaires

1. Government
2. Drugstore

7. How is ORESOL distributed to mothers?

_____ When they come to clinic?

_____ In-home placement?

_____ Available in Barangay Health Stations?

8. What are quantities distributed by RHU (Quarterly)?

_____ Directly mothers/patients? _____ Quantity

_____ To BHIS? _____ Quantity

_____ Others? _____ Quantity

9. Any other comments on ORESOL?

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ORS SITUATION ANALYSIS
QUESTIONNAIRE
Commercial Sector

1. What are the ORS products available now? In what quantity?

| Characteristics Brand | Sachet | | | Bottle-indicate whether ^{p=plastic} _{g=glass} | | |
|--------------------------|--------|----------------|--------------------------|--|----------------|---------------------------|
| | Size | Price/ Unit | Total quan. available | Size | Price/ Unit | Total quant. available |
| | | | | | | |

2. Monthly sales of each brand in the past 6 months (no. of sachets and/or bottles sold. Indicate sachet/bottle size) with corresponding monthly sales.

| Month Brand | Jan. | Feb. | Mar. | April | May | June | Total |
|----------------|------|------|------|-------|-----|------|-------|
| | | | | | | | |

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3. Interviewer: Based on #2, determine the average monthly sales in the past 6 months of the following:

| | Brand | Sales | |
|---------------------------------|-------|----------|-------|
| | | Quantity | Price |
| a. largest selling brand | _____ | _____ | _____ |
| b. second largest selling brand | _____ | _____ | _____ |
| c. lowest selling brand | _____ | _____ | _____ |

4. Is there any promotion being undertaken on any of the brands?

_____ Yes Specify brand and type of promo (i.e. giveaways, posters, etc.)
 _____ No

5. Product Distribution

- a. Who is product distributor/brand?
- b. How often are stocks replenished?
- c. How is the required quantity determined?

| Brand | Distributor | Frequency of stock replenishment | Basis for determining quan. required |
|-------|-------------|----------------------------------|--------------------------------------|
| | | | |

6. Are the available ORS brands given over the counter or strictly by prescription only?

| Brand \ Types of distributor | By Prescription | Over the Counter |
|------------------------------|-----------------|------------------|
| | | |

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7. Are the products always available? Explain.

| Brand | Yes | No | Reason/s |
|-------|-----|----|----------|
| | | | |

8. Have you sold other ORS brands before?

_____ Yes

a. What are these brands? _____

b. Why have you stopped selling them?

_____ No

9. Have you received any comments from buyers on any particular brand regarding taste, form, color?

_____ Yes

Please indicate brand and corresponding comment given on it. _____

_____ No

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ANNEX IV
KABALIKAT BRIEFING DOCUMENTS - FORMULATION
OF ORT PRODUCTS SECTION

ANNEX 4

KABALIKAT BRIEFING DOCUMENTS
FORMULATION OF ORT PRODUCTS SECTION

PRODUCT NAME: ORESOL

MANUFACTURER: Ministry of Health
Bureau of Research and Laboratories

FORMULATION:

| | |
|--------------------|---------------|
| Sodium Chloride | 3.50 g |
| Potassium Chloride | 1.50 g |
| Sodium Bicarbonate | 2.50 g |
| Glucose | 20.00 g |
| Sodium | 90 mmol/liter |
| Potassium | 20 |
| Chloride | 80 |
| Bicarbonate | 30 |
| Glucose | 111 |

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PRODUCT NAME: PATH ORS TABLET

MANUFACTURER: PATH INTERNATIONAL

FORMULATION : Each Tablet contains:

| | |
|--------------------|--------|
| Glucose | 3.0 g |
| Sodium Chloride | 0.53 g |
| Sodium Citrate | 0.44 g |
| Potassium Chloride | 0.23 g |

Tablets produce 150 cc solution with following concentrations:

| | |
|-----------|-----------------|
| Glucose | 111 mmol/liter |
| Sodium | 90 mmol/liter |
| Potassium | 20 mmol/liter |
| Chloride | 80 mmol/liter |
| Citrate | 11.4 mmol/liter |

PRODUCT NAME: PEDIALYTE

MANUFACTURER : Ross Laboratories, a division of Abbott
Laboratories, U.S.A.

FORMULATION :

| | |
|-------------------|--------------------|
| Water | Sodium Citrate |
| Dextrose | Citric Acid |
| Potassium Citrate | Magnesium Chloride |
| Sodium Chloride | Calcium Chloride |

One liter provides: (mEq)

| | |
|-----------|-----------|
| Sodium | 30 |
| Potassium | 20 |
| Magnesium | 4 |
| Calcium | 4 |
| Chloride | 30 |
| Citrate | 28 |
| Dextrose | 50 grams. |

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PRODUCT NAME: GLUCOLYTE

MANUFACTURER: Pascual Laboratories, Inc.

FORMULATION:

| | |
|---------------------|---------|
| Sodium Chloride | 0.325 g |
| Sodium Citrate | 0.600 g |
| Potassium Chloride | 0.375 g |
| Magnesium Gluconate | 0.250 g |
| Glucose Anhydrous | 7.500 g |

PRODUCT NAME: DIORALYTE

MANUFACTURER: USV (Phils) Pharmaceutical Corporation

FORMULATION:

Sodium Chloride 0.20 g

Sodium Bicarbonate 0.30 g

Potassium Chloride 0.30 g

Dextrose Monohydrate 8.00g

Dissolve in 200 ml

Sodium 35 mmol/liter

Potassium 20

Chloride 37

Bicarbonate 18

Glucose 222

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PRODUCT NAME: ISOLYTE 0

MANUFACTURER: AHS/Philippines Inc.

FORMULATION : Each 100 ml contains:

| | | | |
|-----------------------------|---------|----------------------------|---------|
| Dextrose Anhydrous, B.P. | 5.0 g | Flavoring Essense (Pure) | |
| Calcium Chloride 2H 0 | 0.030g | Orange Extract | 0.20 ml |
| Magnesium | 0.041 g | Sodium Metabisulfite, B.P. | |
| Potassium Citrate B.P. | 0.227 g | less than | 0.015 g |
| Potassium Chloride B.P. | 0.052 g | Water for injection, | |
| Sodium Chloride B.P. | 0.053 g | B.P. | q.s. |
| Sodium Acid Phosphate, B.P. | 0.078 g | | |
| Sodium Citrate B.P. | 0.098 g | | |

CONCENTRATION OF ELECTROLYTES (mEq/L)

| | | | |
|-----------|----|-----------|----|
| Sodium | 24 | Chloride | 24 |
| Potassium | 28 | Citrate | 31 |
| Calcium | 4 | Phosphate | 5 |
| Magnesium | 4 | | |

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PRODUCT NAME: KRISTALYTE

MANUFACTURER: AHS/Philippines Inc,

FORMULATION : Each 1000 ml of solution supplies:

| | |
|--------------------|---------|
| Sodium Chloride | 0.73 g |
| Potassium Chloride | 1.86 g |
| Trisodium Citrate | 3.80 g |
| Citric Acid* | 1.20 g |
| Dextrose | 18.00 g |
| Sucrose | 18.00 g |

One Liter provides:

| | |
|-----------|-----------|
| Sodium | 51.2 mEq |
| Potassium | 25.0 mEq |
| Chloride | 37.5 mEq |
| Citrate | 38.7 mEq |
| Dextrose | 100.0 mEq |
| Sucrose | 52.0 mEq |

* Citric Acid added for flavor

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ANNEX V

A TECHNICAL REPORT: ORS PRODUCTION
AND DISTRIBUTION IN THE PHILIPPINES

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ANNEX 5

A TECHNICAL REPORT:

ORS PRODUCTION AND DISTRIBUTION IN THE PHILIPPINES

1. ROLE OF THE MINISTRY OF HEALTH

Production

From a modest beginning in 1979, the capacity of the MOH's own ORS production unit has increased to nearly five million one-liter packets of Oresol per year. One shift of 22 workers, some of whom are handicapped, use simple, locally-made machines to mix salts, fill, seal, and pack pre-folded packets.

While this operation has run smoothly and has filled Oresol needs to date, the MOH now is seriously concerned about the relatively high cost of production approximately ₱1.20 excluding overhead, the availability of imported raw materials under recent stringent GOP controls on foreign currency expenditure, and the inability to meet the increased demand for Oresol, projected at 8 to 10 million liters.

That these concerns are justified is beyond question: the production cost is about 30% higher than the current "world" price for one-liter ORS packets paid by agencies such as UNICEF and USAID; all raw materials are imported into the Philippines and potentially subject to severe price inflation and/or import restrictions; and production capacity is indeed limited under the existing scheme, in great measure due to the use of the two-compartment package.



Analysis of these three factors simultaneously suggests the cause and possible solutions to the problems. The change to a divided packet for Oresol shortly after production began was made in order to assure adequate shelf life. Problems with product deterioration have been experienced in most tropical countries when the sodium bicarbonate is mixed with the other ORS ingredients due to the difficulty of removing all moisture before filling the packets and maintaining the integrity of the sealed packets. Separating the salts from the glucose has been found to be a satisfactory solution. The use of expensive pharmaceutical-grade ingredients and heavy duty packaging material was undoubtedly due to the desire to adhere to the original standards set by WHO, which stemmed from the policy that ORS is a drug to be administered under medical guidance. Both these requirements need to be carefully reconsidered in the context of MOH budget constraints, since recent technical developments and worldwide experience with ORS production suggest a number of lower-cost options for Oresol production:

a. Deterioration of ORS is the result of the effects of heat and moisture, on the combination of the base (sodium bicarbonate) and the sugar (glucose). When a single compartment package is used, it is necessary to use anhydrous glucose and all other dry ingredients, and to use packaging material that is impermeable to moisture if the ORS is to be stored under conditions of high ambient humidity. High ambient temperature rapidly accelerates deterioration if moisture remains in or is allowed to enter the packet.

Physical separation of the bicarbonate from the glucose will in itself drastically increase shelf life, and this was the method chosen in the case of Oresol. However, if this two compartment packet were to be retained, it is entirely possible that a much less expensive packaging film could be used without compromising shelf life of the product. Since the present foil laminate now accounts for around 30% of the total cost of Oresol (Table 1), by substituting ordinary polyethylene film costing one-third as much, the cost of a packet of Oresol could be reduced by 20%, although the need for a printed package insert would eliminate some of this savings. The above is only a point of departure and not a recommendation, but it should be mentioned in passing that if a two-part package is retained, mixing the sugar with the sodium and potassium chlorides and isolating the bicarbonate (as opposed to the present package in which the glucose is isolated) would have the two-fold advantage of making the sugar much less useful as a household sweetener, as well as removing the slightly unstable bicarbonate from the highly hygroscopic sodium chloride.

b. The two-part package should be replaced by a single packet for several reasons, not the least of which is cost. To accommodate the vertical seal which divides the two packets, and to provide a flap for easier manual opening of the packet, about 30% more packaging material is required than is used in a standard UNICEF one-liter ORS packet. Opening and filling the two sides requires nearly twice as much labor as would be needed for a single-compartment packet. These facts are well-known to the MOH. The key factor involved in making this change is the certainty of a reduction of the present product shelf life of four-plus years to something lower. The optimal choice of an alternative lower cost method of producing Oresol depends on

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having a good idea of what shelf life is actually required or acceptable, and what shelf life can be expected from each of the alternatives under consideration. Faulty information about either of these will result in higher program costs than otherwise need be sustained, and at worst in setbacks to the program caused by the distribution of deteriorated Oresol. Assessment of the minimum required shelf life will be discussed in connection with the subject of ORS distribution. Actual shelf life of alternate Oresol formulas and packages when not already known through prior experience will have to be determined through laboratory trials prior to adoption of any particular approach.

c. Assuming the adoption of the single-compartment packet, the substitution of sodium citrate for sodium bicarbonate may be safely recommended, although definitive results of efficacy trials are not expected from WHO until later in 1984. This substitution is known to result in greatly improved stability under storage conditions of high heat and humidity. Even though the cost of the citrate per packet will be slightly higher than for bicarbonate, a longer shelf life will result, or alternatively, a shelf life equal to a properly manufactured bicarbonate formulation can be obtained using less expensive packaging material. WHO suggests that a tri-layer foil with a thinner (50M) aluminum layer is acceptable for the standard minimum one year shelf life, but this is only marginally less expensive. A coated paper-polyethylene laminate yields a minimum six month shelf life.

glo

d. A further change which would result in lower product cost is the substitution of ordinary locally-produced sugar (sucrose) for the imported anhydrous glucose. Even though twice the weight of sucrose is then needed, the net cost is half that of the glucose, and represents a significant savings of foreign exchange. This saving is partially offset, however, by the need for more packaging material and the increased cost of shipping the finished ORS due to greater weight and bulk. The sugar would almost certainly have to be dried and perhaps ground before further processing, but since there is little experience with sucrose-based ORS, tests would have to be carried out to arrive at a process and package having adequate shelf life. It may be possible to use a cheaper packaging material such as cellulose or polyethylene, but stability tests with a citrate glucose monohydrate ORS suggest that it may be necessary to use a more impermeable film when anhydrous glucose is replaced by other sugars.

e. A final cost-saving variation is the substitution of locally-produced table salt for pharmaceutical grade. The local salt may require drying, which could be done together with the sugar, in order to reduce moisture to the accepted one percent level before filling and sealing.

f. The replacement or supplementing of the present production set-up with automatic machinery for ORS packet dosing, filling and sealing has been proposed by the MOH as a way of raising the level of production and incidentally reducing problems of employee absenteeism. Some factors influencing the decision to acquire automatic machinery are:

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- Serious problems with powder feeding and machine reliability are likely to be encountered unless an air-conditioned, dehumidified environment is provided, and the powders thoroughly dried.

- The capital investment of roughly \$35,000 for such a machine would be only marginally justified on economic grounds, since replacement of the 11 workers now opening, filling, and sealing packets would result in a savings in wages of only \$86,000 per year, and one or two more skilled operators would have to be retained in addition. If the social costs of disemploying nine workers are considered, the investment becomes even less attractive.

- Acquisition of automatic machinery for ORS production is inconsistent with the MOH's stated desire to get out of the business of producing Oresol in steadily increasing quantities as the CDD program expands. In any event, there is not enough room available in the present facility at San Lazaro for both the manual line and an automatic line, and since the capacity of the typical automatic machine is roughly 5 million per year when operated on a single shift, no production increase would result from this substitution of machinery for the manual production line.

Changing to a single compartment package would be a more practical and quickly-attainable way to increase MOH production to the level of 8 to 10 million packets per year. It is not unreasonable to expect that nearly twice as many single-compartment packets could be opened and filled in the same time now needed to fill a given number of the present packets. One or two more sealing machines could be added, or tooling modified to permit sealing of two packets at a time. If necessary, an extra half shift could be worked. One or two more workers and a larger mixer might be needed to handle the additional blending workload due to the need to mix all the ingredients, rather than only



the small amount of salts as is now done. It will also be advisable to air-condition the mixing room, and to provide a tray drier, if needed, as mentioned previously. A net reduction in unit labor costs between 20% and 40% could be expected from the change to the single package.

The estimated effects on production cost of the above possible modifications are summarized below:

TABLE 1

Direct Costs of Oresol Production by the MOH

| <u>Present Cost Breakdown</u> | <u>Per Packet</u> |
|-------------------------------|--------------------------|
| Raw materials | |
| Glucose, anhydrous, USP | P0.45 |
| Sodium chloride, USP | 0.12 |
| Sodium bicarbonate, USP | 0.03 |
| Potassium chloride, USP | <u>0.05</u> |
| | P0.65 |
| Poly-foil-poly packets | 0.42 |
| Outerpack materials | <u>0.04</u> |
| | P0.46 |
| Direct labor | 0.04 ^{1/} |
| Supervision | <u>0.02^{2/}</u> |
| | <u>P0.06</u> |
| | TOTAL <u>P1.17</u> |

1/ This figure differs significantly from existing estimates, and was arrived at by multiplying annual wage of P8,700 by 22 workers and dividing by 5 million.

2/ Assumes two supervisors at P2,000 per month.

(Table 2 follows)

TABLE 2: Estimated Cost and Shelf Life Effects of Possible Modifications to ORS Production

| Modification | Inputs Changed | Estimated Cost change per packet | Net Change per per liter | Effect on Shelf life |
|--|---|----------------------------------|--------------------------|--|
| A) Retain 2-sided packet, use cheaper packing film | Foil to polyethylene film Printed insert | ₱ - 0.28 + 0.05 | ₱ - 0.18 - 0.23 | None |
| B) Retain present formula and foil, use 1-part | 30% less foil 40% less labor | - 0.14 - 0.02 | - 0.16 | Reduced to around one year |
| C) Change to citrate | Higher cost of citrate More citrate needed | + 0.015 + 0.015 | + 0.03 | Increased over situation B |
| D) Citrate used but cheaper packaging film (one-part packet) | 1) thinner gauge aluminum layer 2) paper-poly | - 0.05 - 0.10 | - 0.05 - 0.10 | Minimum one year Minimum six months |
| E) Use food-grade sucrose instead of glucose, poly-foil packaging material | 30% more packaging film needed lower unit cost but 40 gms needed | + 0.14 - 0.24 | - 0.10 | Possible |
| F) As in (E) but use cheaper packaging film | Paper-poly instead of poly-foil | - 0.15 | - 0.15 | Possible further reduction |
| G) Local food-grade salt used in place of NaCl USP | | - 0.08 | - 0.08 | None if dry |
| H) Bulk packing in 2-kg units | Eliminate foil Add bottle | - 0.30 + 0.10 | - 0.20 | None if bottle kept sealed |

NOTE: 1) Care must be used in calculating cost changes when the modifications are combined. Modifications (D) and (F) are mutually exclusive, as are (A) and (B).
 2) Modifications (E) and (G) do not consider the costs involved in the drying possibly needed.
 3) Alternate materials costs: Sugar ₱6 per kg, Sodium Citrate \$1.50/kg, Salt ₱10/kg, 2-liter bottle ₱8.

OP

Thus, selected modifications in ORS production could result in cost savings (which are almost entirely foreign exchange savings) of from ₱0.16 (B alone) to ₱0.51 (B, C, E, F and G).

Table 2 suggests that each cost-saving modification (except A and G) has an associated shelf-life reduction. Not enough is presently known about these to be able to predict resultant shelf-life, so it will be important to determine this through laboratory testing before adopting any particular changes.

In addition to the above, CDD program costs could be further reduced by supplying the larger hospitals with rehydration centers with Oresol packed in bulk containers.

Glucose Availability

A major concern which resulted in the present assessment was the inability of the GOP to provide the MOH with foreign exchange to procure the anhydrous glucose powder which is the major constituent of Oresol. Since it is likely that the problem will persist, some way must be found to assure a reliable supply of raw materials for Oresol in the future. Several options have been examined. The following can be said about these alternatives:

a) Local production of anhydrous glucose:

Since only about a dozen factories in the world make this product, it has been difficult to obtain detailed information on the technique or economics of this process. Available information suggests that while powdered glucose cannot be made from cane syrup or sugar, it can be made from starch derived from corn or cassava, both of which are grown in the Philippines. A minimum of 50,000 tons per year represents the minimum production to make a

plant economically viable, and as far as can be determined, no glucose powder, either anhydrous or monohydrate, is produced in the Philippines. At least one plant is producing starch from cassava and has started to convert the starch to high-grade liquid glucose at a potential rate of 50 tons per day. The technique for converting this into glucose powder is not known to this firm, but they would consider doing it if it were economically sensible, i.e., if a local market exists and the capital investment was within their means.

Whether the desired anhydrous form of glucose powder could be made in such a plant remains to be determined, as does the size of the local market. Glucose powder is used locally (imported) in pharmaceuticals including I.V. solutions, and is marketed as a food supplement, although these probably use the monohydrate form. Further investigations into the industrial processes and the potential local market would have to be made to determine the feasibility of local production of glucose. In any case, a long lead time should be anticipated in connection with this option. A strong case for not pursuing this approach rests on the possibility that ORS based on cereal starches (rather than sugars) may be demonstrated to be clinically superior within several years.

b) Substitution of locally-available products:

Sucrose from sugar cane is manufactured and widely available in the Philippines. The feasibility of using it in ORS in place of glucose (or together with it as in the case of a locally-marketed commercial product, Kristalite) has been discussed already. Although over twice as much has to be used to obtain the same transport effect as 20 grams of glucose, the local price is only a quarter of that of the imported glucose, resulting in a significant saving of foreign exchange. Another conceivable substitution is that of locally-made glucose syrup for powdered glucose in a liquid ORS

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presentation. At ₱7 per kg, it is even more attractive than cane sugar at ₱5 per kg since it can substitute for powdered glucose in a nearly 1:1 ratio by weight.

c) Procurement by the private sector:

Among the benefits likely to be realized by the MOH procurement of Oresol from the private sector is the improved reliability of supply under present economic conditions. The multinational and larger national pharmaceutical manufacturers have made various financial arrangements for guaranteeing a continued supply of imported raw materials. They are unlikely to be willing to supply the MOH with these materials, but their import arrangements would indirectly benefit the MOH if one or more of these companies were to produce Oresol for the CDD program in addition to the commercial market.

d) A final option, clearly the least desirable if self-sufficiency is a goal, is the continued dependence on external donor assistance in the procurement of glucose and other raw materials.

Distribution

Oresol is distributed through the MOH general supply system, along with other drugs and supplies for regional and provincial health facilities. Distribution data for 1983, when 5.1 million packets were produced, is not available. In 1982, 4.7 million were produced, of which 4.4 million were shipped to regions, and 4.1 million were distributed by MOH facilities to patients, barangay health workers, boticas sa barangay, and households. 1.6 million was accounted for by the CDD reporting system, with much of the other presumed use being beyond the reach of the reporting system.

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While the policy of distributing free 2 packets per year to each household has served to stimulate the wide availability and familiarity with Oresol, this implies a requirement of 16 million packets per year for the exclusive use of health facilities, boticas sa barangay, etc. Reconsideration of this goal seems appropriate given the expense and logistic difficulties entailed. More complete usage data from the peripheral levels of the distribution chain should allow a fairly accurate calculation of the actual needed shelf life to be made with attendant cost-saving implications. Promotion of household rehydration with such methods as the plastic 2-sided spoon may be a viable alternative. Until more is known about actual usage patterns it is not possible to evaluate this policy. Lack of Oresol at the barangay level is usually traced back to shortages at higher levels, reflecting the MOH's problem of meeting the demand for the product.

The major problem at the most peripheral levels is accessibility to Oresol supplies - essentially unavailable after official health station hours, unless a botica sa barangay stores is functioning. Commercial availability in sari-sari stores could substantially alleviate this problem.

2. Role of the private sector

The equivalent of some 600,000 liters of ORS are now produced or imported by the private pharmaceutical industry. The most successful product is Pedialyte, a pre-mixed liquid maintenance solution which now costs about ₱18 per 500cc. bottle and is sold mainly in urban pharmacies. Other maintenance solutions are marketed in powder form, but there is no suitable rehydrating ORS now on the market.

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Among 358 registered drug laboratories and contract packagers, the knowhow and production capacity surely exists in sufficient strength to produce more than enough ORS for the Philippines. Although no manufacturer has yet made the serious leap into marketing ORS, many may already be aware that a sizable market exists. The gap between current supply and actual need has been estimated at from 10 to 20 million liters per year. Sales of anti-diarrheal drugs reached ₱72 million in 1983 and have been growing by 20% per year. Commercial ORS represented only ₱8.5 million of these sales. The potential is obviously great. It is probable that the greatest deterrent to the entry of the private sector into the popular-price, mass-distribution ORS market is simply the MOH's increasing success in giving Oresol away for free. If a policy is adopted saying in effect that free distribution of Oresol beyond the MOH health facilities will be phased out over time, the private sector should be motivated to enter the market. In theory, if the market is large enough, several products will be presented and free competition will result in a low prices and wide distribution. However, the needs of the CDD-ORT program might be better met if more control were exercised by the MOH. It is desirable to ensure that inappropriate compositions and presentations are not marketed, that labeling is not confusing or misleading, and that price be kept to a level affordable by the majority of the rural population.

The approaches which seem most likely to stimulate the private sector to market ORS consistent with the MOH's objectives are:

- a) Offer and encourage the use of the name Oresol or a variation. Oresol is almost certainly the most widely recognized product among the rehydrating solutions available.



b) Limit by means of Administrative Order the composition of ORS to that known to be clinically effective and safe for rehydration. Alternative presentations might be encouraged.

c) Offer guaranteed MOH procurement, media promotion, market research data technologies where available, or other incentives to the private sector to encourage for maintaining a low wholesale price and full-scale distribution through existing commercial networks. Imposition of direct price controls should be considered only as a last resort.

d) Encourage the development of a product line which positions differently-priced alternative ORS presentations in a manner intended to capture all socio-economic strata.

Such an approach to the private sector should result in at least one presentation of Oresol being available at drugstores throughout the country at a price from ₱3 to ₱5 per liter packet. The price target for MOH procurement from the private sector should be the actual cost of production including overhead factors if the MOH were to produce the Oresol in some modified form. The present estimates of ₱1.20 to ₱1.40 ignore the MOH's overhead costs.

Some consideration could be given to retaining part of the present production facility to do bulk packing of Oresol for distribution to larger MOH units. In the event of problems with the private sector supplier, this would be an emergency backup for Oresol.

Widest possible distribution of pharmaceutical products generally occurs when a product can be sold outside traditional drug channels. In the Philippines it is necessary for such products as certain vitamins, analgesics, cough syrups, etc. to have approval of the FDA before they can be marketed in supermarkets, boticas sa Kadiwa, sari-sari stores or other consumer outlets. Clearly, it would be in the interest of the CDD program to eventually have

Oresol available in some presentation through these channels. If the pharmaceutical sector cannot be persuaded to enter this market with a low-cost product, an approach to the food industry could be made if the MOH concurs with a non-medicinal classification for ORS. Mass distribution of a low-cost, pre-mixed ORS has never been attempted in any country because a prohibitive product and distribution cost is always presumed. Low cost packaging such as that already used for juices and soft drinks using local food grade ingredients and pasteurization rather than sterilization, should make it possible to produce a pre-mixed solution at very reasonable cost. If distribution could be done by "piggy-backing" ORS onto the beer or soft drink distribution system, the long-sought goal could be achieved.

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ANNEX VI
PROPOSED PHILIPPINE ORT PROGRAM

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PROPOSED PHILIPPINE ORT PROGRAM

MINISTRY OF HEALTH

CDD TASK FORCE - - - - ->
NATIONAL CDD COMMITTEE ->

INTERNATIONAL AGENCIES
WHO, UNICEF, USAID

ORT SECRETARIAT

COMMERCIAL
PRODUCTION AND
MARKETING OF ORS

UNICEF
KABALIKAT
↓
HOME
ORS
SOLUTIONS

WHO U.P.
P.P.
↓
NAT. REHYDRATION
TRAIN. RES. CENT.
SAN LAZARO

NAT. ORT PROGRAM
ANNUAL PLANS
REGIONAL COORD. MEETINGS
TRAINING
IEC FOR ORT
REPORTING/MONITORING
ANNUAL EVALUATION

KABALIKAT
WHO
UNICEF
AID

NATIONAL DIARRHEA
INFO SERVICE
LIBRARY
NEWSLETTER
COPY SERVICE

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ANNEX VII
PERSONS INTERVIEWED

ANNEX 7

PERSONS INTERVIEWED

Ministry of Health

Dr. Jesus C. Azurin, Minister of Health
Dr. Antonio Acosta, Deputy Minister
* Ms. Enriqueta Sullesta, Nursing Program Supervisor
(Coordinator CDD Task Force)
Dr. Virginia Basaca-Sevilla, Director, Bureau of Research and Laboratories
Mrs. Catalina C. Sanchez, Director, Bureau of Food and Drug
Mr. Michael Lopez, Supply
CDD Task Force -
Ms. Marietta Bernaje - IEC
Dr. Zenaida Ludovice - DIC
Ms. Aida Soldevilla - Health Education

Hospitals

San Lazaro

Dr. C. Ranoa, Chief, San Lazaro Hospital
Dr. Fernando, Medical Specialist II, Head of Gastroenterology
Dr. N. Abejar, Medical Specialist I, In-Charge of ORT Unit

Jose Fabella

Dr. C. Firme, Chief, Dr. Jose Fabella Memorial Hospital
Dr. Lantin, Chief of Clinics
Dr. Fernandez, Head of Pediatrics

National Children's Hospital

Dr. C. Agregado, Chief of Hospital

Children's Medical Center

Dr. Fe del Mundo, Director
Dr. Thadeus Evangelista, Chief

Philippine General Hospital

Prof. Perla Santos-Ocampo,

Region 3

Dr. Reyes, Provincial Health Officer
Dr. C. Baltazar,
Ms. Remie Gabriola
Personnel in: RHUs: Bacolor and Sexmoan
District Hospital, Guagua, Pampanga

Philippine Pediatric Society

Dr. Arturo Ludan

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U.P. Medical School

Dr. Alberto Romualdez, Dean

RITM

Dr. M. SanieI

NAMRU

John Cross

IIRR

Dr. Dennis Lebayan and Dr. Lorna Lebayan

Production, Distribution and Marketing

- Mr. Renato Tolentino, Philippine Starch Industrial Corporation
- Mr. William Chua, Simon Enterprises/Sellchem Co.
- Ms. Enriquito Santiago, Nesco Foods Corporation
- * Ms. Tess Abesamis, Asia-West Marketing
- Dr. Eduardo Roberto, Asian Institute of Management
- * Ms. Cecilia Verzosa, Kabalikat ng Pamilyang Pilipino
- Mr. Ben Dy, Ciba-Geigy Co.
- Dr. Samson, United Laboratories, Inc.
- Dr. Willy Torres, United Laboratories, Inc.
- Mr. Aubrey Bout, Abbott Laboratories, Inc.

Donor Agencies

- Mr. Steven Umemoto, UNICEF
- * Ms. Victoria Rialp, UNICEF
- Mr. Rolf Carriere, UNICEF
- * Mr. Gary Presthus, WHO, Program Officer
- Mr. Fritz DeHaan, WHO, Medical Officer
- Ms. Mary Kilgour, USAID/Manila, Deputy Director
- * Mr. John Dumm, USAID/Manila, Chief, Office of Pop., Health & Nutrition
- * Ms. Joy Riggs-Perla, USAID, Project Officer
- * Dr. Rosendo Capul, USAID, Project Officer
- * Ms. Pamela Edison, USAID, Consultant

* Member of Ad-Hoc Advisory Group