

PRITECH PROCESS EVALUATION OF THE  
PORT COMPONENT OF THE  
PRIMARY HEALTH CARE FINANCING PROJECT

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### List of Abbreviations

ARI	Acute Respiratory Infection
BFAD	Bureau of Food and Drugs
BHS	Barangay Health Station
BHW	Barangay Health Worker
BPS	Biological Production Services
CDD	Control of Diarrheal Disease
CDSS	Country Development Strategy Statement
COA	Commission on Audit
DBM	Department of Budget and Management
DOH	Department of Health
DTU	Diarrhea Training Unit
GMP	Good Manufacturing Practices
GOP	Government of the Philippines
HEALTHCOM	Communications for Child Survival
HMDTS	Health Manpower Development and Training Service
HIS	Health Intelligence Service
IEC	Information, Education and Communication
IFB	Invitation for Bid
IPHO	Integrated Provincial Health Office
IV	Intravenous
KAP	Knowledge, Attitude and Practices
MCH	Maternal and Child Health
MHO	Municipal Health Office
NRTTC	National Rehydration Training and Treatment Center
OER	Oral Electrolyte Replacers
OPHN	Office of Population, Health and Nutrition
ORS	Oral Rehydration Solution
ORT	Oral Rehydration Therapy
PACD	Project Assistance Completion Date
PATH	Program for Appropriate Technology in Health
PHCF	Primary Health Care Financing
PHN	Public Health Nurse
PHO	Provincial Health Office
PIHES	Public Information and Health Education Service
PMS	Program Management Staff
PPS	Philippine Pediatric Society
PRITECH	Technologies in Primary Health Care
RHO	Regional Health Office
RHU	Rural Health Unit
SIMC	Southern Island Medical Center
SS	Supervisory Skills
UNICEF	United Nations International Children Emergency Fund

**USAID**

**United States Agency for International  
Development**

**WHO**

**World Health Organization**

## I. Introduction

### Project Background

In July 1985, USAID/Philippines authorized the Oral Rehydration Therapy (ORT) component of the Primary Health Care Financing (PHCF) Project to increase the utilization of oral rehydration therapy as a primary preventive measure against diarrheal death among infants and young children. The project aims to achieve its objectives by ensuring that a continuous and readily accessible supply of oral rehydration salts is available and that there is an effective demand for their usage. The ORT project is designed to increase ORT utilization through a two-pronged approach which creates demand for ORS products through: 1) training physicians, nurses, midwives and health educators in the public and private sector on the benefits of ORT usage; and 2) information, education and communication campaigns to promote ORT among the public. The commercialization of ORS production and distribution through the private sector will ensure that ORS products are widely available to the public. Commercialization will be promoted by gradually phasing out DOH ORESOL production and its free distribution policy.

Implementation of the ORT component began after the Project Agreement was signed in June 1985. The total budget for the ORT component of the Primary Health Care Financing Project is \$7.3 million. A \$4 million grant was authorized by A.I.D., while the GOP contributed \$3 million for the project to be implemented by the Department of Health (DOH) and the Philippine Pediatric Society (PPS) over a five year period. Of this amount, \$1.9 million (44 percent) is allotted for the establishment of the National Rehydration Training and Treatment Center and the training of health care workers and physicians, \$998,000 (23 percent) for the promotion of ORT to the medical community and public, \$650,000 (15 percent) for ORS commercialization support, \$707,000 (16 percent) for the establishment of the Project Management Staff and \$60,000 (1.3 percent) for evaluation. In 1988, the project's budget was increased by \$300,000 to provide various technical assistance activities through a buy-in from the PRITECH Project. A PRITECH long-term technical advisor will begin working on the project in October 1988.

In 1983, the Primary Health Care Project was initially authorized by USAID as a loan, and in July 1986, the project funds were converted to a grant. In 1986, the possibility of establishing a Department of Health controlled Trust Fund for the disbursement of ORT funds was explored and disapproved by the Department of Budget and Management and the grant was required to go through the regular

appropriations process. According to DOH Financial Services, the conversion from loan to grant was not changed in GOP financial record keeping and USAID project funds continue to be treated as appropriations to DOH and included in the total estimated revenue of the GOP, rather than as grant.

Appropriations are subject to DBM and COA government regulations. The DBM will not disburse additional funds for the project if there is still a balance in DOH accounts. In the past, to obtain additional funds, the DOH has had to completely liquidate the balance of its accounts. At the same time, it has taken DBM up to six months to transfer money from the Treasury to DOH, resulting in delays to financial disbursements. Although USAID has been working to change the project's financial status in GOP records, the issue has not yet been resolved. In May 1988, the Secretary of Health issued a Department Circular stating that funds under the Primary Health Care Financing Project will be treated as regular allotments. USAID and the DOH have been developing alternative financial mechanisms to improve the disbursement of project funds. On September 23, 1988, WHO and USAID signed an agreement for WHO to disburse \$409,807 in USAID project funds for the documentation and revision of Health Intelligence Service forms. It is anticipated that following WHO funding guidelines and procedures will significantly decrease the lead time necessary for funding disbursements for this particular project component.

As of the last quarterly report in June 30, 1988, \$3.062 million in USAID funds had been earmarked for specific project activities, representing 71 percent of the total \$4.3 million obligated for the project. Funds actually committed amounted to \$2.58 million or 60 percent of the total funds obligated. The project budget contains \$650,000 (15 percent of USAID project funds) to support ORS commercialization, of which \$500,000 has been obligated to UNICEF to procure ORS packets. Thus, actual expenditures represented only 21 percent of the project budget. Elapsed time for the project was 36 months from the date of the Project Agreement, representing 66 percent of the total project duration.

The reorganization of the Ministry of Health into the Department of Health in 1986 under President Aquino's new administration contributed to delays in implementing the project, and implementation of project components did not begin until after the reorganization of the DOH was completed. Under Aquino's administrative reform program, the DOH was restructured with an emphasis placed upon integration of program planning at the central level and decentralization for actual program implementation at the

regional, provincial and district levels. District health offices were created in 1986. In each of the 13 regional health offices, there is now a CDD coordinator who has part-time responsibility for coordinating CDD activities.

Management of the national CDD Program is the responsibility of the CDD section of the Maternal and Child Health Service in the DOH. Since 1985, the staff of the central CDD office has been increased from one coordinator and two support staff members to eight staff members to enable the office to respond to the increased demands of the expanded national CDD program. A national CDD Committee directs and coordinates policy functions, and is chaired by the Undersecretary of Public Health Services, and includes the Chief of Maternal and Child Health Service, the CDD Program Coordinator, and the directors of the Biological Production Services (ORESOL Production Unit), Bureau of Research and Laboratories, Nutrition Services, Hospital Operations and Management Service, Environmental Health Services, Health Manpower Development and Training Services, Public Information and Health Education Service, Public Information and Health Education Services, Health Intelligence Service, Research Institute for Tropical Medicine, San Lazaro Rehydration Training Center and representatives from external donor agencies, other government and non-government organizations. The target of the national CDD operational plan for 1988-1992 is to decrease the diarrhea-associated mortality rate by 50 percent (from a 1985 rate of approximately 9/1,000) in children under five years of age.

A CDD/ORT Program Monitoring Staff Secretariat was created in 1986 to coordinate project implementation activities for the ORT Component. While project implementation activities for the ORT component have been undertaken by existing units of the DOH, the Secretariat has the main responsibility for the coordination, management and monitoring of the various activities in the ORT project. Members of the Secretariat have been recruited from existing personnel within the DOH, and supplemented with contract personnel. The DOH is responsible for salaries and recurrent cost of maintaining the PMS, but the PHCF project is funding operational costs such as workshops and conferences, office equipment and supplies, communications and consultant travel.

At USAID, one U.S. Direct Hire has overall responsibility for the PHCF project, and the ORT component of the project is managed by the Mission's Foreign Service National Public Health Advisor.

Since the reorganization of DOH in 1986-87, supervisory skills training courses and clinical management training courses have proceeded on schedule. The National

Rehydration Training and Treatment Center was established at San Lazaro Hospital in Manila and sub-national training centers were established in Cebu and Zamboanga. Scientific meetings on CDD/ORT have been conducted by the PPS in six regions and two issues of a CDD/ORT newsletter have been published and distributed by the PPS. Public promotion strategies are being pilot tested and an ORT radio campaign began on August 15, 1988. An ORT module has been developed for undergraduate medical school and nursing school curriculums. WHO/PRITECH medical education materials are being piloted tested in six medical schools and a memorandum of agreement between USAID and the Association of Philippine Medical Colleges to disseminate educational materials is scheduled to be signed this year.

The PHCF project had an original Project Assistance Completion Date (PACD) of December 31, 1988, which was subsequently amended to December 1989 when the ORT component was added. As of June 30, 1988, the project expenditure total represented 21 percent of total obligated funds, with program time already elapsed at 66 percent.

#### Project Rationale

Acute diarrheal diseases are a major public health problem in the Philippines. Diarrhea has consistently ranked among the leading four causes of morbidity and mortality in children under five years of age. In 1980, the GOP initiated the Philippine CDD Program in the DOH with the objective of reducing diarrheal morbidity and mortality by 50 percent by the end of 1985.

During the first five years of the program, the main activities were the production and distribution of the WHO-formula ORS product, ORESOL. Very little training was undertaken in the first five years of the program, although some clinical training of health personnel was conducted at the regional, provincial and barangay levels.

In 1985, a joint DOH/WHO/UNICEF/USAID review was conducted of the CDD program. The Country Assessment Report identified four major weaknesses in the country program. First, appropriate oral rehydration products were not accessible to the general public, with availability almost exclusively limited to DOH facilities. Second, medical professionals were resistant to promoting ORT usage. Third, there was a lack of public awareness of the merits of ORT. Finally, manpower support within the DOH to manage and coordinate ORT activities was inadequate.

USAID/Philippines developed the ORT component for the Primary Health Care Financing Project in 1985 to strengthen the GOP's Control of Diarrheal Diseases program. The ORT component aims to strengthen national ORT activities by increasing the availability and access to an appropriate ORS product through commercialization of ORS production, a comprehensive training and promotion strategy, including the establishment of a national and sub-national Rehydration Training Centers, clinical training, promotional activities targeted at medical professionals and the public and the strengthening of central management capability in monitoring and evaluation.

In the long run, the goal is to develop an integrated strategy for Maternal and Child Health (MCH) services, integrating the CDD program with other child survival programs. USAID/Philippines' child survival objective is to initiate declines in rates of infant and child morbidity and mortality by (a) improving cost-effectiveness of care through financing schemes and special studies; (b) improving expected value of interventions through better information and more focused programmatic and geographic targeting; (c) improving the use rates of health facilities. The goal of the Primary Health Care Financing Project is to reduce high fertility and infant and early childhood mortality. The ORT component contributes to this goal by reducing diarrhea specific infant and childhood mortality.

In FY 1989, USAID/Philippines is considering a new Integrated MCH component for the Targeted Child Survival Project which builds on the initial success of the ORT initiative. The new project plans to integrate the ORT project with various MCH activities, including health care services related to child growth promotion, child spacing and acute respiratory infections. The project intends to focus on a program of social marketing to build support for an MCH approach to child survival which recognizes the relationship between maternal health, birthweight and ultimate child survival.

## II. Evaluation Plan

Personal interviews, site visits to Regions VII and VIII, and record reviews were the principal methods used. In Manila, the team met with DOH personnel, donor agencies, the Philippine Pediatric Society and other individuals and organizations linked to program activities. Site visits to the regions focused on activities at the regional, provincial, municipal and barangay level. Interviews questionnaires were developed by the evaluation team based on the evaluation scope of work.

The following official documents served as the basis for the evaluation:

- Project Paper
- A Restatement of the Operational Plan
- Implementations Plans
- Memorandum of Agreement between the PPS and the DOH

See Appendix III for a complete list of the documents reviewed.

### III. Findings and Recommendations

#### A. Training

##### Clinical Management Training

The clinical management training as currently being conducted at the National Rehydration Training and Treatment Center (NRTTC) and at the Southern Islands Medical Center (SIMS) has evolved into a very effective, imaginative and well run training course. Currently there are one national and two sub-national centers at various stages of development. Long term plans propose that each region eventually have a regional training center. During 1988, four courses were conducted at both the NRTTC and the SIMC. Courses last for five days with trainees limited to 15 per course. Trainees are limited to this number to allow for a sufficient number of diarrhea cases per trainee. Each trainee is expected to follow three mild, three moderate and three severe cases. One weakness observed was the use of baby bottles to dispense ORS at the NRTTC. This could reinforce bottle feeding and it poses a contamination problem.

Action plans developed by the trainees to be implemented upon their return to their homes are favorably received and supported by District Health Officers. The action plans are a strategy for each trainee to develop district DTUs and to develop a program to clinically train their district colleagues. In cases where there are delays in implementation, it is due to circumstances beyond the control of the trainee, i.e lack of space, lack of acceptance/interest by the hospital administration.

Trainers are utilizing a variety of very innovative training techniques to promote ORT among trainees. These techniques were observed during a field visit to the SIMC in Region VII. The philosophy behind these innovations is that the

trainers do not assume immediate acceptance of ORT on the part of the trainees. To overcome resistance to ORT, the training programs open with an ice breaker that allows trainees to share their previous experiences and express their doubts and concerns regarding ORT. Midway through the clinical course, a debate is conducted between ORT proponents and IV fluid therapy supporters. These are both excellent techniques for convincing doubters about the efficacy of ORT.

The method used to select trainees in Region VII is very effective in combatting resistance to ORS among clinicians. A team composed of the CDD Coordinator and various provincial and district health officers selects as trainees those staff who are most resistant to ORT. In this manner, some of the strongest resisters have become the CDD program's greatest supporters.

The most serious concern regarding clinical training was the poor quality of case management observed in regional, provincial and district hospitals. Although all the diarrhea corners were well-equipped, case management was inconsistent particularly in regard to when to use ORS, for what level of dehydration and proper use of IV solutions. There are a number of possible hypotheses as to why a strong clinical training does not produce better case management among physicians. Physicians at hospitals receive relatively little supervision and it is not the role of the Regional CDD Coordinator to supervise hospitals. The critical mass of trained staff is relatively small in relation to the size of the entire hospital clinical staff. Expecting physicians, who are not formally trained as trainers, to successfully train their colleagues may be an unreasonable expectation. The constraints that physicians face upon their return to their hospitals (pressure from mothers to prescribe something other than ORS, pressure from their colleagues) may be insurmountable for some physicians.

#### RECOMMENDATIONS

Continue opening regional DTUs as scheduled and develop plans for opening DTUs in remaining regions. Assure adequate numbers of well-trained staff. Pair train new staff at national and sub-national centers to assure consistency in the quality of their training. (AID Project Officer, CDD National Committee - ongoing).

Develop and utilize a system for inter-regional pairing of experienced staff with weaker staff in newer programs. The Philippines is replete with qualified, well-trained individuals with extensive experience in CDD. These resources should be utilized to the maximum capacity. These

individuals could be paired for one to two weeks with individuals working in regional where the program has not progressed as fast. (CDD Program Management Team, CDD National Committee - immediate).

Increase follow-up to hospitals at regional, provincial and district levels. (see Supervision).

### Supervisory Skills Training

The program of supervisory skills training courses is excellent! It is planned in a manner responsive to both regional and trainee needs. The implementation is proceeding in a timely manner. Follow-up to the courses in the form of supervision is impressive! One weakness identified is that planning is not integrated with the budgeting process. Concern exists about the availability of funds through full completion of the scheduled courses.

As with the clinical course, a number of very innovative training techniques are being utilized. An ice breaker opens the course allowing participants an opportunity to share their ideas, reservations and experiences regarding ORT. In Region VII, one session on the pathophysiology of diarrhea has been added to the course. This session changes depending on the knowledge level of the trainees (ex. physicians or midwives), but every participant receives a good background in the chemistry of diarrhea.

Each supervisory skills course schedules one evening for a social hour. During this period, trainees are broken into groups and asked to present a skit based on the CDD theme. Their presentations are very reinforcing of the more formalized sessions on prevention, case management, etc.

In both regions VII and VIII, the method for selecting and training course facilitators is very sound. During the SS courses, participative, communicative trainees are identified as potential facilitators. At a later course, they are paired with a strong facilitator to observe and practice facilitation skills. This method has contributed to the development of a strong pool of facilitators allowing adequate rotation among them.

The effect of the Supervisory Skills courses has trickled all the way to the level of the barangay midwife, volunteer health worker and mothers. In Region VIII, although midwives have not yet received the formal SS training, the knowledge of proper oral rehydration therapy has extended to that level through midwives contacts with their nursing supervisors. The midwives' and BHWs' knowledge of oral therapy including proper mixing and prevention messages is

impressive.

#### RECOMMENDATIONS

The implementation of the supervisory skills courses should continue as planned to the midwife level. The program should verify plans during annual planning process and reinforce weak provinces where necessary. (CDD Program Management Team - ongoing).

Encourage Regional CDD Coordinators to be innovative and flexible with training. Their familiarity with the modules and the local situation should be tapped so that the courses can more effectively respond to local needs.

An effort to strengthen exposure to proper case management during the training should be made. An excellent video on ORT case management recently produced under the auspices of PRITECH by Dr. Jon Rohde should be incorporated into all the courses. All Regional DTUs should be equipped with video equipment. (CDD Program Management Team - immediate).

#### Philippine Pediatric Society

The Philippine Pediatric Society (PPS), during the first year of its formal agreement with the DOH to promote ORT among medical professionals, has made impressive progress.

To date eleven scientific meetings have been held in six regions reaching nearly 400 pediatricians in the first year. The scientific meetings include lectures, discussions and hands-on case management. The success or failure of this activity is a direct reflection of the enthusiasm and strength of regional and provincial chapters of the PPS. Although the national chapter organizes these meetings making general announcements, etc, the local chapters are responsible for managing the meetings. This includes making all physical arrangements, communicating with presenters and participants and preparing reports of the scientific meetings.

Of the eleven meetings held, two have had international speakers. The remainder have had reknowned pediatricians from within the Philippines. Participants were asked to evaluate these meetings beginning in August 1988. Currently, there is no mechanism to assess whether the scientific meetings are affecting the way physicians are managing diarrhea cases.

The ORT Newsletter has had two issues with 5,000 copies printed each quarter. The PPS will meets its original target of four issues in the first year as two more issues

are planned for September/October and November/December. The newsletter is distributed through the membership of the PPS (1200), to the participants of the Scientific Meetings and the remaining copies are sent to members of the Philippine Medical Association. Each issue costs 39,000 pesos to print. The PPS has requested additional funding so as to double the number of copies printed each quarter. Distribution among its own members has been problematic. Some officers of the PPS chapter in Cebu have yet to receive the second edition. The DOH and the PPS have discussed pooling distribution resources which would greatly increase the number of people receiving the newsletter. Although the DOH reviews the newsletter before printing, there have been cases of technically inaccurate information. In the second issue, the WHO formula for ORS was incorrectly given.

The distance study courses will be inaugurated following the printing of the new edition of "Acute Diarrheas: Their Management and Prevention". This is expected to take place by December, 1988.

The PPS should be commended for its efforts and success in requiring all hospitals with pediatric residency training programs to have a functional ORT unit. This policy will be enforced by the Hospital Accreditation Board of the PPS. The DOH has expressed their interest in helping private hospitals develop DTUs.

#### RECOMMENDATIONS

Encourage and expand the activities of the Philippine Pediatric Society. (USAID Project Officer).

PPS should conduct its own KAP survey of private practitioner to provide baseline data of physicians behaviors when treating diarrhea patients. This would serve as a tool for later evaluation of the impact of PPS activities. (PPS - immediate).

Improve and increase the administrative support provided to the PPS. The operation should be computerized and a full-time mid-to-high level manager should be employed to administer the current program and oversee future expansion. (USAID with PPS)

The PPS should be identifying ways to sustain these current activities.

#### B. Information, Education and Communications (IEC)

PIHES field staff (health educator) activities have supported a broad CDD focus for the program, using

traditional methods of interpersonal communication and limited print materials. PIHES (the Public Information and Health Education Service of the DOH) has identified the important elements of a national IEC strategy for diarrheal disease control which include interpersonal communications, print materials, and mass media, but a detailed plan has not been developed. Their actual activities, aside from recent Healthcom assistance, have focused on involvement with traditional means of communication. They have supported a broad spectrum of activities in the CDD program through active involvement in clinical and supervisory skills training, conducting the training in the prevention of diarrhea and leading clinical management trainees in role plays to improve counseling of mothers. The health education capability at the implementation level will be strengthened by the recent designation of district level health educators (public health nurses) whom regional PIHES staff will train.

There appears to exist no national plan or budget for the production of print materials to support program activities. PIHES staff at the central and regional level expressed frustration with a lack of support for production of print materials to strengthen their interpersonal communications in public facilities. They have produced limited materials to date which includes a leaflet prepared in collaboration with Kabalikat and some dialect translations of WHO materials on prevention (Region VII--produced using provincial funds).

#### HEALTHCOM

The HEALTHCOM Project is assisting the Department of Health in the conduct of communication support for the CDD and EPI programs. It launched a successful 90 day campaign in the Metro Manila Region February to May 1988 to encourage mothers to bring their children for measles vaccination. The CDD communication program was launched on August 15. The first phase of the program is scheduled to run for approximately one year in Regions VI, VII, and X. There are two modules in this phase. The first module identifies dehydration as the primary concern with diarrhea and promotes home fluids and continued feeding as the appropriate home management practice. It will be aired in all three regions -- VI, VII and X. The second module will promote a specific product for use during diarrhea - ORESOL for Regions VI and VII and a specific home fluid for Region X.

In preparation for the implementation of the communication program, HEALTHCOM has undertaken research studies on the

following: mothers' knowledge-attitude and practice (KAP) regarding diarrhea management; problems in the preparation and mixing of ORS solutions; feeding practices; home fluids used (Region X) comprehension and recall of the radio and TV spots on diarrhea and dehydration; concept tests for positioning ORESOL in the mother's mind. In addition, HEALTHCOM has undertaken research on the private sector physicians diarrhea prescription practices and a market study on the growth of the ORS market from 1985-1987.

In light of available ORS use rate information, the HEALTHCOM program goal of commercialization by developing a private sector demand for Oresol is well-founded. Recent surveys conducted for the CDD Program and HEALTHCOM estimate the current ORS use rate at only 6 per cent of all cases of diarrhea. Among those surveyed in the communications pilot regions, 18 and 26 percent said they would consult government health services in the case of diarrhea. The remainder, and vast majority, utilize the private sector or remain outside the formal health system. The communications campaign in Regions VI and VII has targeted this sector to increase the market for Oresol.

HEALTHCOM's mandate to institutionalize DOH capabilities in I.E.C. is relevant and important to long-term sustainability. Existing PIHES staff has little experience with the kind of media campaign on which private sector demand creation will largely depend. The role of HEALTHCOM in providing technical guidance to PIHES, both at the national level (planning and management of IEC activities) and in the three pilot regions, is an appropriate one that can enhance program sustainability through the transfer of important skills and knowledge about communications techniques and strategies. Their mandate to assist PIHES with the development of a long-term strategy (see HEALTHCOM Implementation Plan) is important as a first step in the integration of current traditional health communications activities with the more sophisticated media campaign that is planned for ORESOL commercialization. Though preliminary planning was carried out during a HEALTHCOM workshop in August, 1987, the details of a long term strategy describing the complete integration of IEC activities with PIHES or of a long term strategy for HEALTHCOM's media campaign have not been identified.

If these strategies exist, the goals, objectives, and long-term plans have not been clearly articulated to key players. Field visits and feedback from central office personnel have raised concerns after one year of program operation that HEALTHCOM is not adequately coordinating and communicating with national and regional DOH staff. This may in part be due to two factors: 1) HEALTHCOM has had a

very busy year, conducting numerous baseline surveys in the pilot areas and trying to meet deadlines for the media campaign and 2) at the same time, PIHES experienced a change in leadership in the middle of the busiest period which has diluted its ability to focus on Healthcom activities.

The communication program in the three pilot regions is regarded by high level health planners as an important strength of the CDD program, but is not clearly understood in the regions where it is being implemented. Key health educators and CDD program managers in one of the pilot regions were unclear as to the medium and long-term plans for the communications campaign. The details of the current media campaign (messages and time slots) reached the region after the radio spots had begun. Personnel at the national, regional, and provincial levels have expressed a desire to better understand both the long range media activities and their inter-relationship with the use of print materials and interpersonal communications.

There has been little opportunity for field personnel to review and discuss HEALTHCOM plans. The programmed sales conferences to brief health workers about the media messages have been delayed pending resolution of problems with the advertising agency. The CDD pilot regional coordinator for Region VII has not yet received an orientation as to her role. It was explained to the team that this was pending the hiring of a Region X coordinator. Unfortunately, the delay appears to have hampered the effectiveness of the Region VII coordinator. Many national and field personnel expressed a concern that they have little or no information on the follow-on to the first phase of the campaign.

Although HEALTHCOM has been following the technical review procedure developed by the DOH, the mechanism is not functioning satisfactorily.<sup>1</sup> Despite having followed this procedure, the messages which are currently on the air contain technical inaccuracies which adequate technical review should have detected. (ex: "breastfeeding shortens the duration of diarrhea"; "withholding food from a child with diarrhea is sure death"). Personnel in Region VII

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<sup>1</sup>HEALTHCOM has been directed to observe the following technical clearance procedure by Undersecretary Mario Taguiwalo and PIHES Director, Dr. Manuel M. Dayrit: the project is first to obtain clearance/comments from the Regional Directors of the test market regions, and the Maternal and Child Health Service and then get approval from the Department of Health Executive Committee. Dr. Dayrit has further stipulated that the technical clearance would be given by the DOH and not by any external agency.

expressed concern that some of the message content ("Did you know?" series) contradicts health education messages given in health facilities (ex: contradictory messages regarding the use of tea as a home fluid for children with diarrhea). Staff at the national level feel their input was sought too late and in an untimely manner for it to be incorporated into the messages.

#### RECOMMENDATIONS

HEALTHCOM and PIHES staff should work together to develop a detailed long-term CDD IEC strategy. This should be a priority activity with responsibilities clearly defined. The recent appointment of a Chief of Planning for PIHES should facilitate the achievement of a comprehensive strategy. The completed strategy should clearly explain the links among key IEC activities--media, print and interpersonal, and should justify the balance of those activities within the context of program objectives. Upon completion, the strategy should be widely disseminated at the national and field levels. (HEALTHCOM, PIHES - immediate).

The technical review clearance procedure should be reassessed. Messages should be presented for technical review in a timely manner to allow for feedback and necessary adjustment. To guarantee thoughtful review, reviewers should be required to put their responses in writing. An external technical advisory body should be developed to provide technical input, however final approval for messages should rest with the DOH. (National CDD Committee - immediate).

PIHES should utilize the national CDD Committee as a forum for keeping collaborators abreast of current and planned Healthcom activities. This requires that PIHES attend these meetings regularly with the same person representing them at each meeting. This would provide continuity and help strengthen communication between PIHES and HEALTHCOM. (PIHES - ongoing)

Improve communications with field staff in pilot regions. PIHES should exert its leadership in assuring clear and timely communications on all HEALTHCOM activities. Field staff in the pilot regions require clarification of the HEALTHCOM-PIHES relationship, the role of the regional CDD pilot project coordinator, and the objectives/rationale of all components of the communications strategy. HEALTHCOM personnel should visit each of the pilot regions prior to the next phase of the campaign. (HEALTHCOM, PIHES - 4th quarter 88, ongoing)

### C. ORS Demand, Supply and Distribution

The following section reviews ORS demand, supply and distribution in the public and private sectors of the Philippines.

#### PUBLIC SECTOR -- Findings

Demand. There is a wide disparity between projected demand and actual use of ORS, called ORESOL, in the public sector. As computed by the DOH at the national level, the amount of ORS required in 1987 for programs in all regions was slightly more than 9 million one-liter packets. While more than 2.3 million packets were delivered to the regions through the public sector distribution system of the DOH, only 1.7 million packets were actually dispensed to clients who frequented health facilities. Given the total number of diarrheal cases expected in 1987 (22 million),<sup>2</sup> the ORS use rate was only 2.2 percent for the year. (See appendices X and XI.)

Data on ORS use for the first six months of 1988 confirm the 1987 trend and suggest that actual use only slightly resembles expected (hypothetical) demand. (See appendices XII and XIII that present data on Region VIII.)

While inefficiencies in distribution may contribute to the low use rates for ORS, especially in the public sector, there is a growing awareness that the methodology used to estimate total projected demand may be producing unreasonably high estimates of the expected number of diarrheal cases. Until September of 1988, the DOH calculated total demand as follows:

- . 70% of the population has access to public health services
- . 30% of the population actually use public health services
- . 14.5% of the population is under five
- . There is an average of 2.8 bouts of diarrhea per child per year.

Aware that the annual use rates of ORS in public health

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<sup>2</sup>The DOH estimation methodology assumes that 40 packets of ORESOL are required for every 100 diarrhea cases, i.e., 22,810,940 (cases) divided by 100 times 40 equals 9,124,776 (packets).

facilities remain very low and are having an adverse effect on the morale of program staff, and that estimates of public health facilities use may be too high, in spite of promotional and training efforts, the DOH has begun to review and refine the methodology for estimating total demand.<sup>3</sup>

Supply. The supply of ORESOL produced by the Biological Production Services (BPS) at Alabang is less than sufficient to meet public sector program needs. In addition, the product manufactured by BPS does not comply with WHO specifications on production and quality assurance.

Although the DOH production facility at Alabang has an estimated annual production capacity of 5.2 million one-liter packets of ORESOL, average annual production over the last two years has been less than 2.5 million packets.<sup>4</sup> In October of 1987, when the DOH recognized that the level of production would be less than expected and far below the total national requirement (9 million one-liter packets), 2 million packets of ORS were procured under competitive tender from Pascual Laboratories, a private sector pharmaceutical firm.

While the current production level at BPS is less than the rated capacity, and inadequate and inconsistent supply may contribute to low use in public health service facilities, the most serious concerns are that the production system at BPS is not in compliance with international guidelines for pharmaceutical production and that the ORS produced does not

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<sup>3</sup>Recent data collected by the HealthCom Project in Regions VI and VII suggest that only 12-14% of the population actually use public health services. According to the HealthCom surveys, a significant and increasing percentage of the population treats diarrhea at home and does not frequent any type of health service. In 1987, for example, approximately 40% of the population surveyed treated the diarrhea "at home." By May of 1988, the percentage treating "at home" had increased to 60% or more.

<sup>4</sup>The theoretical production capacity is derived by multiplying the estimated daily production target (20,000 packets) times the annual number of work days (260). [20,000 packets x 260 work days = 5.2 million packets annually.] BPS has never achieved this target. A review of the production records indicates that only 2.6 million packets were produced in 1986 and that 2.3 million were produced in 1987.

Until mid-1988, ORESOL production was housed at the DOH. Production was only recently transferred to Alabang. The shut-down at one location and transfer to another unquestionably had an impact on the government's ability to achieve maximum annual capacity.

meet WHO specifications.

As currently configured, the production area at BPS is not properly designed or equipped to produce ORS according to Good Manufacturing Practices (GMPs) for Pharmaceuticals (See Appendix XVII, "Good Practices in the Manufacture and Quality Control of Drugs"). For example, to be in compliance with GMPs, plant operations must be designed to ensure that there is no "back-tracking" of the product during the course of production. As currently produced, the raw material used at BPS goes through the filling and sealing area before reaching the mixing area. This practice contravenes GMPs and is only one example of the many that could be cited to show that the plant is not in compliance.

The fact that the ORS produced is not a homogeneous mixture of sugar and salts, as specified in the WHO guidelines, is of far greater significance. As currently produced, the pre-formed poly-foil packets are first filled with 40 grams of sucrose and then topped off with 7.9 grams of mixed salts (sodium chloride - 3.5g, potassium chloride - 1.5g, and trisodium citrate - 2.9g). Since the packet sent to the field does not contain a homogeneous mixture, there is some likelihood that the solution prepared will have an improper electrolyte balance unless those mixing the ORESOL empty the entire contents of the packet in one liter of water. This is of particular concern because there have been some reports that mothers are not emptying the total contents of the packet in a liter of water.

Distribution. The current distribution practices of the DOH result in over-supply or non-availability of ORS. Warehousing conditions are inadequate and record-keeping systems are unsystematic and idiosyncratic. ORS (ORESOL), like other pharmaceuticals, is pushed through the health system from the "top-down." The Supply Officer at each level assigns the next level down the amount allocated by the responsible CDD officer and instructs the responsible public health official to pick-up the allocation. The system relies on the integrity and ability of the Supply Officer operating at each level to see that stock is picked up, distributed and kept current.

However, at the lowest levels of the health system (Rural Health Units and Barangay Health Units), public health employees often do not have access to the transportation needed to convey the ORS to the service point. In addition, the allocations are only infrequently reviewed in light of the actual use rates of ORS. As a result, there is over-supply of ORS in some regions and at some levels, e.g., region, district, and under-supply or stock-outs in other

areas. (See appendix XIV.)<sup>5</sup>

Warehousing at all levels of the health system is inadequate, and the conditions in which ORS is stored are very poor. Warehouses generally do not have air-conditioning or humidity control, and the cartons of ORS are most often found on the floor, rather than on pallets. The items stored in warehouses are often found without stock cards.

In most cases, the systems in place to document the distribution of the ORS appear to be peculiar to the habits of the responsible Supply Officer. On the basis of a brief review of distribution records, there is no uniform system in place for documenting goods ordered, received or dispatched. Each Supply Officer appears to have his or her unique system for recording receipt and dispatch of goods. For example, one Supply Officer in Region VIII recorded the name of the person who picked-up the ORS allocated but never documented the name of the province to which the ORS was sent.

#### PUBLIC SECTOR -- Recommendations

1. Demand. The DOH should continue to review and refine the methodology for estimating total public sector demand for ORS. The DOH is already aware that actual use in the public sector only slightly resembles hypothetical demand. Continued review and refinement of the demand estimates are required to ensure that reasonable program targets are set and met. (Office of the Chief of Staff.)

2. Supply. The DOH should carefully review all options to ensuring a readily available supply of ORESOL of acceptable quality. The DOH should determine whether resources should be made available to renovate the production facility at BPS and bring all operations into compliance with GMPs and WHO specifications for ORS, or whether operations should be phased out. In course of conducting this review the DOH should analyze the overall needs of Alabang and assess the priority of ORESOL production among those needs.

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<sup>5</sup>While no stock-outs were observed during the field visits to Regions VII and VIII, there was ample evidence of over-supply. At several BHUs in Region VIII, for example, the stock on hand could meet program needs for more than 12 months. Since most of this ORESOL is due to expire in November 1988 the Regions are awaiting instructions from the DOH in Manila on the proper disposition and/or use of the existing stock.

To upgrade the BPS and bring the facility into compliance with GMPs for pharmaceuticals the Government may have to invest a significant amount of capital (approximately US \$250,000).<sup>6</sup> The wisdom of making this investment needs to be assessed in light of the mandate of the BPS and the absence of a significant cost difference between the public sector unit cost and the private sector price per packet.

The BPS was established to produce vaccines needed in the Philippines; it was not founded to produce pharmaceuticals. Given the BPS' immediate need to upgrade vaccine production capability and the limited resources available, it is questionable whether scarce resources should be diverted to pharmaceutical production, especially when the Philippines has a pharmaceutical industry that is well-developed and capable of producing the quantity of ORS needed to meet the needs of the public sector.

DOH staff frequently assert that the ORS produced at BPS is significantly less expensive than the private sector packet. A review of 1987 cost and price data do not substantiate this conclusion. The current cost of a packet of ORS produced by BPS is 2.00 pesos. The unit price paid by the DOH for the 2 million packets provided by Pascual Laboratories was 2.15 pesos, only 7% more than the cost of a BPS packet.

The cost breakdown, provided by the staff of BPS, is as follows:

<u>Item</u>	<u>Cost in Pesos (1987)</u>
pre-formed packet	.43
sodium chloride (3.5g)	.10
trisodium citrate dihydrate (2.9g)	.19
potassium chloride (1.5g)	.09
sucrose (40.0g)	.52
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total direct cost/material	1.33
labor and other cost	.67
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total cost of ORESOL/packet	2.00*

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<sup>6</sup>This figure is a very imprecise estimate of the cost of renovating and equipping the plant at BPS. Major renovations are required to meet GMPs. (See Appendix XVIII for an Estimate of the Costs Associated with Renovating BPS.)

It was not possible to obtain complete information on the Pascual product. Data on raw material and packaging material were made available.

<u>Item</u>	<u>Cost in Pesos (1987)</u>
sodium chloride (3.5g)	.02
potassium chloride (1.5g)	.07
trisodium citrate dihydrate (2.9g)	.13
glucose anhydrous (20.0g)	.42
polyfoil laminate packaging	.26
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cost of materials	.90

The cost data presented below are assumptions based on experience with ORS production in other countries. Since this information has not been reviewed by Pascual Laboratories, the percentages are speculative.

<u>Item</u>	<u>Cost in Pesos (1987)</u>
production and quality assurance (40% x .90)	.37
general and administrative (30% of total production cost - 30% x 1.27)	.38
gross margin (30% of total cost - 30% x 1.64)	.50
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total cost of ORESOL/packet	2.15*

\*(1 Peso = US \$0.11)

It should also be noted that the products are not equivalent in terms of content and presentation. The major difference is the substitution, in the DOH ORESOL, of 40 grams of sucrose for 20 grams of anhydrous glucose. Also, the Pascual ORESOL fully complied with the WHO specifications while the DOH product does not.

The DOH appears reluctant to phase out ORESOL production at BPS and to procure the necessary supplies from private sector pharmaceutical firms. There is some concern that private firms will "gouge" the government. The government might address this concern and determine whether private sector firms are interested in providing the ORS required to meet public sector demand at prices the government is willing to pay would by offering a tender for ORS over a multi-year period. If the DOH feels that the prices and conditions proposed by the private firms in response to an Invitation For Bid (IFB) are unacceptable, the government

can proceed to upgrade facilities and conditions at BPS. If the terms are deemed reasonable, the DOH can phase out production as the contractor selected makes ORS available. (Office of the Chief of Staff, December 1988.)

3. Distribution. Supply Officers and responsible CDD Program Coordinators should take actual ORS use-rates into account when allocating ORS. To avoid over-supply and stock-outs of ORS it is imperative that allocations be reviewed in terms of the actual ORS use rates. Until adjustments can be made in the allocation system and a pull system can be implemented, the DOH should place a buffer stock at each level of the health system, e.g., 20,000 packets at the Region, 10,000 packets at the Province and 5,000 packets at the District. To the extent possible, the amount of the buffer should be defined by use rates. The DOH should also consider providing a transportation allowance to health workers at the district and Barangay levels to ensure that ORS is available at the periphery of the system, where it is most needed.

Finally, the DOH should review current warehousing and distribution practices and recommend the development and implementation of appropriate logistic and management systems that can ensure a fresh, adequate and regular supply of ORS, as well as other essential commodities. (National CDD Committee, Office of Procurement and Logistics, and PRITECH, January 1989)

#### PRIVATE SECTOR -- Findings

Demand. Private sector demand for Oral Electrolyte Replacers (OER), ORS-type products, has increased steadily over the period 1985-88. In 1985 there were five commercial brands of ORS in the Philippine market, although only two were distributed nationally. Pedialyte, first introduced in 1973, had 75% of the market and sales of 9.8 million pesos. Glucolyte of Pascual Laboratories had the bulk of the remaining market. In 1986, seven products were on the market and sales reached 14.9 million pesos. An additional product entered the market in 1987 and sales increased by more than 50% (22 million pesos). By the end of 1988 nine rehydrant products are expected to be available in the commercial sector and sales are expected to surpass 30 million pesos.

The price per liter for the products currently available ranges from 7 pesos (ORS Servipharm of Ciba-Geigy) to 70 pesos (Pedialyte of Abbott), and presentations come in

either liquid or powder form. Pedialyte continues to dominate the market and has increased its market share (85%). In the period 1985-1988, the total liter equivalents of ORS-type products sold, including Pedialyte, went from 330,000 to more than 1 million.<sup>7</sup>

Since the commercial firms do not appear to have altered their promotional campaigns radically over the past three years,<sup>8</sup> the large annual increases in sales would seem to be the result of the clinical training and promotional activities associated with the national CDD program. Based on a review of doctors' prescriptions, conducted by IMS in the Metro Manila area, there are indications that oral rehydration products are increasingly prescribed, especially by physicians with 0 to 5 years of clinical practice. As the CDD program continues to train health services professionals in other regions the trend observed in Manila should begin to appear in other cities and regions. The private pharmaceutical firms have obviously benefited, in the form of increased product sales, from the efforts of the national CDD program.

With the enactment of the Generics Law (September 13, 1988), some firms are concerned that their products will have to be modified and that sales projections will have to be revised. One firm, initially interested in entering the oral rehydrant market, has recently decided to withdraw.

Supply. Private Sector firms have the capacity and capability to produce the ORS required to meet public and private sector requirements. While most commercial oral rehydrant products do not conform to the WHO formula,<sup>9</sup> (see appendixs XV and XVI) all the local producers appear to have the capability and capacity to manufacture a product that complies with WHO specifications. Pascual Laboratories, for

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<sup>7</sup>The IMS report prepared for the HealthCom Project notes that "oral electrolyte replacers demonstrate a steady increasing growth rate in sales, an increase of +3%, +11%, and +23% for the years 1985, 1986 and 1987, respectively." p. 11.

<sup>8</sup>Oral rehydrant products are promoted mainly through medical representatives who use all of the following techniques: sales literature, sample donations to physicians and clinics, special sales promotions. Traditionally, pharmaceutical firms also sponsor selected scientific seminars and conferences.

<sup>9</sup>Servipharm ORS and Pedialyte 90 are the exceptions.

example, has the capacity to produce 15 million one-liter packets annually and delivered 2 million packets of ORESOL under a contract with the government. In general, the local, private sector pharmaceutical firms have excellent facilities and equipment, well-trained staff and produce in compliance with GMPs as monitored by the Philippine Bureau of Food and Drugs (BFAD).

Distribution. Private sector pharmaceutical firms take a limited and traditional approach to product distribution. Oral rehydrant products are distributed through a limited group of distributors who market their products to pharmacies, private clinics and hospitals, as well as individual physicians. Most pharmaceutical firms have their own marketing groups, or distribute their products through drug wholesalers or independent pharmaceutical marketing groups. While these mechanisms are capable of placing oral rehydrant products in rural pharmacies, none of the existing pharmaceutical distributors focuses on placing essential drugs in commercial outlets selling consumer products, e.g., sari-sari stores. (It remains to be determined whether the Philippine regulatory authorities allow ORS to be marketed as an over-the-counter product.)

#### PRIVATE SECTOR -- Recommendations

1. Supply. The DOH should consider defining ORESOL (WHO formula) as the generic oral rehydrant product. Since the DOH is anxious to make ORESOL, the WHO formula ORS, as widely available as possible, generic ORS should reflect the WHO formula. Once the government makes a decision and issues a ruling, the pharmaceutical firms will have to decide whether to (a) comply, (b) stop producing their product or (c) ask the government to issue an exemption that will allow them to continue to manufacture their product. Private firms may well argue strenuously that the government should issue exemptions that will allow them to continue to market products that are already well placed in the market and widely understood and used by prescribers and consumers. If the government rigorously applies the law and decides that generic ORS will follow the WHO formula, it is likely that firms already in the market will adjust their formulae and attempt to retain their market share. It is doubtful that the firms will want to surrender lucrative markets.<sup>10</sup> In effect, prompt government action should actually increase the availability of WHO formula ORS and foster the

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<sup>10</sup>Glucolyte, for example, is Pascual Laboratories second largest selling product.

commercial objectives of the national CDD program. (Office of the Chief of Staff, immediately.)

It is noteworthy that Pedialyte, in spite of the cost, is almost one-third of the total ORS market (public and private) in the Philippines. The fact that the market for Pedialyte is large and growing suggests that a readily usable product is preferred by mothers and that unit cost may not be the controlling issue. The success of Pedialyte in the Philippines, and in several other markets, should perhaps prompt public health officials to re-think a policy that currently insists that ORS should be marketed for the lowest possible price. It is well documented that price often conveys value. Initiating a series of pricing studies may produce results suggesting that higher priced products have a greater value, and are more frequently purchased and used. (DOH, HealthCom and PRITECH, May-June 1989)

2. Distribution. A study on the knowledge, attitude and practices (KAP) of pharmacists toward the use of ORS should be conducted. The results of the study should be used to develop a strategy for increasing ORS purchase and proper use. IMS data available to the HealthCom Project indicate that some physicians are increasingly prescribing oral rehydrants over anti-diarrheals. However, the same data suggest that some pharmacists are dispensing anti-diarrheals rather than or in addition to the rehydrants. Since the private pharmacists appear to be a bottleneck to increasing ORS use, especially in the large urban areas, a program similar to that developed by and for the Philippine Pediatric Society should be defined and implemented for the professional pharmacy societies. (PRITECH, March-April 1989.)

3. Distribution. Commercial distributors capable of reaching rural consumers should be identified and encouraged to market ORS. To ensure that consumers have the widest possible access to ORS, firms that market consumer products in the rural areas of the Philippines need to be involved in the campaign for the control of diarrheal diseases. Traditional pharmaceutical marketing is limited in approach and very expensive. Ethical pharmaceutical firms are most often trying to motivate prescribers to carry and dispense their products. It is firms that market basic "health and beauty aids" that have the most experience in promoting and distributing products to consumers. Marketing groups with this experience need to be approached and involved. In the context of working with a marketing firm, it will be important to develop an effective marketing approach and to determine distribution cost and the selling price for ORS. (PRITECH, April-May 1989.)

## **D. Program Management and Administration**

### **1. Organizational Structure**

The main responsibility for Control of Diarrhea Diseases activities within the central office of the Department of Health lies with the CDD/ARI Division of the Maternal and Child Health Service. The MCH Service is one of ten services under the Office for Public Health Services.

The National Rehydration Treatment and Training Center (NRTTC) of San Lazaro Hospital, The Public Information and Health Education Service (PIHES), the Biological Production Service (BPS) which produces Oresol, the Procurement and Distribution Services, and the Health Manpower Development and Training Service (HMDTS) provide major support for CDD activities. Further support is received from the Health Intelligence Service (HIS), Finance Service and other services of the DOH. See Appendix IVa for a DOH organizational chart.

#### **a. National CDD Committee**

The Philippines program for CDD receives its policy direction and technical guidelines on case management and strategies for diarrhea prevention from the National CDD Committee. In addition to reviewing and recommending policies, projects and directional plans related to CDD the National CDD Committee is the coordinating body charged with monitoring and orchestrating the program components. The Committee is made up of representatives from the Department of Health, private sector health care providers, and donor agencies active in the CDD program. The Committee is chaired by the Undersecretary for Public Health Services, with the Chief of the MCH Service serving as vice-chairman and the CDD Program Coordinator of the MCH Service serving as secretary. The CDD program staff of the MCH Service serve as the Secretariat for the National CDD Committee and are responsible for the documentation and support needs of the Committee. The National CDD Committee was reorganized and its present membership and mandate established in May 1988. See Appendix V for Department Order No. 143-Bs., 1988.

#### **b. CDD/ARI Division of the MCH Service**

The CDD/ARI Division is one of three divisions of the MCH Service. See Appendix IVb for an organizational chart of the MCH Service. The CDD program staff of the Division are responsible for the day to day operations of the CDD

program.

c. CDD Program Management Team

The CDD Program Management Team (formerly known as the CDD Management Working Group) is charged with operational problem solving and decision making for the CDD program, and for raising policy issues with the National CDD Committee. The membership of the Program Management Team has been changed from that of the Working Group as stated in the December 1987 revised Operational Plan.

The present membership of the CDD Program Management Team is:

CDD/ARI Division Chief, Chairman  
CDD Program Coordinator  
MS II  
MS I  
WHO Representative  
PRITECH Representative

The Chief of the MCH Service serves as an ad-hoc advisor to the Program Management Team.

d. The PHCFP Project Management Staff (PMS)

The Project Management Staff (PMS) is a Primary Health Care Financing Project (PHCFP) funded entity charged with monitoring the progress of the various components of the PHCFP. One of these components is the CDD component. The PMS reports to the Executive Committee of the DOH. In addition to monitoring the progress of the Projects, the PMS acts as a link between the implementing units and the support services of the DOH (e.g., Finance Office).

The organizational structure for management of the national CDD program and the ORT component of the Primary Health Care Financing Project exists, but is not being fully and effectively utilized at the present time. There remains a degree of confusion over the roles, responsibilities and lines of communication and authority among the various program elements at the National level. Some specific findings follow.

The National CDD Committee is not living up to its full potential. Prior to its reorganization in May 1988, the National CDD Committee had not met regularly to provide the CDD program with the direction and coordination it requires. With the May reorganization the DOH began to move to strengthen the functioning of the Committee. The Committee has met three times since the reorganization, and is

scheduled to meet again in October. However, the press of resolving accumulated CDD issues has delayed the Committee leadership in its attempt to organize the necessary sub-committees and enable the Committee to function in a proactive manner. The Committee membership of 18 members is rather large. This combined with the fact that at each meeting there are a number of observers and invited guests and that some agencies send more than one representative may be making the committee unwieldy.

The CDD Unit of the CDD/ARI Division is strong in the technical area, but relatively weak in its administrative function. The DOH, recognizing that the CDD was short staffed relative to its assigned task, has increased the staffing of the Division. However, it is not clear that the present staffing level is sufficient for the administrative workload and/or that the staff have the background to fulfill the administrative function at the required level.

The mandate of the CDD Program Management Team is not well defined. There is no written statement of the membership and mandate of the CDD Program Management Team. The description given in Section D.1.c. of this report is derived from the statements of various DOH officials.

The PHCFP Project Management Staff (PMS) has only recently begun to fulfill its role vis a vis the CDD component of the PHCF Project, and this role is not clearly understood. The DOH CDD program was started a number of years prior to the launching of the PHCF Project. The PMS, which was itself only recently established, therefore concentrated its efforts on other project components which were new and required special assistance to become operational. The PMS has not yet given directions on reporting requirements and formats to the CDD Division. This is due in part to the fact that the CDD Division was initially so under-staffed that there was little hope of its completing the required Project reports. What role, if any, PMS should be playing with the Philippines Pediatric Society project activities has not been defined.

The linkages between CDD and other services and organizations such as PIHES, HEALTHCOM, Logistics, PPS etc. are not working as well as they should. The team found certain instances where coordination among the various program components was lacking indicating that the issues had not been addressed and/or resolved either in the National CDD Committee or through direct contact between the parties involved.

#### RECOMMENDATIONS

The National CDD Committee should push ahead with its plan to strengthen the functioning of the Committee. The Committee should establish its sub-committees and instruct them and the Committee Secretariat on the need to do complete staff work in order to facilitate the proceedings of the Committee. The Committee should strongly urge all services and agencies to send the same representative to each meeting to allow for continuity of discussion. The Committee should take care to deal with only those matters which cannot be better handled by the CDD Unit and its Program Management Team. The Committee should set a calendar for frequent meetings, probably monthly, until such time as it has completed its organizational strengthening and resolved the backlog of CDD issues. Meetings should be held on a regular schedule, e.g., the first Tuesday of each month.

The leadership of the Committee should establish a trial period such as six months or six consecutive meetings after which it will determine whether the membership of the Committee is too large for the efficient conduct of business. If the membership is too large it should be divided into core members who are to attend all meetings and complementary members who will attend only when their input is required for a specific topic. (National CDD Committee-Continuing)

The MCHS should conduct an analysis of the administrative workload of the CDD Unit and determine the staffing needs and training needs of the administrative staff. Arrangement should be made to provide for any staff or staff training needs identified in the assessment. (CDD National Committee - January, 1988)

Roles and channels of communication should be clarified between the National CDD Committee, the CDD Program Management Team and the PMS. (National CDD Committee)

The PMS should provide the CDD Unit with the directions and formats for any PHCFP reporting requirements and train the administrative staff in completion of the reports. (PMS - January 1989)

The National CDD Committee should continue in its efforts to coordinate the activities of the services and organizations involved in CDD. (National CDD Committee-Continuing)

## 2. Operations

### a. Planning

Planning is one of the strengths of the CDD program. The

planning process involves a systematic review of information available from reports, surveys, and informal feedback from which the national staff prepares a comprehensive plan of program goals and activities for the following year. The five-year plan produced by the CDD program in 1987, "A Restatement of the Operational Plan, 1988-1992", will be used as a model to strengthen planning in other DOH programs.

Review of CDD implementation plans is conducted regularly at each level of the health system. This review process includes regular feedback through a series of meetings held throughout the year:

- semi-annual consultative workshop for regional CDD Coordinators
- meetings of national CDD Committee and of CDD Program Management Team
- monthly staff meetings at regional, provincial and district level
- quarterly consultative meetings for provincial staff at the region
- weekly and monthly staff conferences at RHUs
- monthly meetings of regional directors with the Central Office

In addition to strengthening the planning and review process, these meetings provide a useful forum for sharing successful innovations with other regions and provinces. For example, during the March 1988 Consultative Workshop, Region VII presented the results of supervisory skills courses given for their mid-level managers--an idea which proved very successful. Since that meetings, seven more regions have held the courses for mid-level managers and the idea has been institutionalized.

However, while the planning process is well-organized and adhered to, the methodology for setting targets poses a problem. Very low rates of success against targets, even in regions with well-organized services and high numbers trained, have raised concerns as to the validity of the variables used to calculate national targets.

Current targets clearly jeopardize the ability of the program to demonstrate success. Survey results and the national census respectively, seem to support the use of 2.8

episodes of diarrhea per child per year, with a target population of children under five equal to 14.5 percent of the total population. However, field personnel believe the rates for the population with access to health services and for service coverage of cases of diarrhea are unrealistic.

Additional confusion about targets arises from the fact that the midwives calculate their own targets during the supervisory skills course (Targets module), using locally generated figures or survey results. These targets differ from those they ultimately use for monitoring which are passed down from the national level. Locally generated targets may be used only if they are more ambitious than those from the national level.

Instructions for measuring one litre for the preparation of Oresol cause confusion and inaccuracies. Health workers, in part due to uncertainty about the availability of specific measures in the home, are promulgating the use of at least five different measures for one litre. In some cases these are highly inaccurate (the family-size Coke bottle in Region VIII holds 769 ml. rather than one litre). The addition of a third size of Nescafe glass to the market has created much confusion. As health workers have discovered that the recommended medium-size glass is not the same size as before, some have independently adjusted the measuring instructions. (some recommend four glasses filled to the brim, others five and a half to the line, instead of the five to the line previously promoted). The serious problems surrounding measurement appear to be widespread enough to mandate rethinking of the upcoming campaign messages regarding Oresol preparation.

The Central Office has recently demonstrated its willingness to negotiate more realistic targets as the need becomes clear. In response to feedback from the field, the Central Office will propose new targets for discussion by CDD Coordinators, which would lower the estimated access to health services (population within five kms. of trained personnel) from 70 to 60 per cent and reduce ORT coverage rates (by public health facilities) from 30 to 15 per cent. The latter should be attainable, based on information from a recent survey which estimated that only 12-14 per cent of diarrhea cases are seen by public practitioners. The same survey found that 35 per cent of cases are seen by private practitioners and 50 per cent are cared for outside the formal health system. These figures have implications for planning and monitoring future interventions in the non-public health sector. Training targets for the CDD program have also been recently clarified, based on a reassessment of the specific field personnel who should receive clinical training in ORT.

## RECOMMENDATIONS

The program needs to ascertain the feasibility of achieving the targets set for field performance. A survey should be conducted to look at the validity of each variable in the target formulas. This should be done in both urban and rural settings. Particular emphasis should be placed on the following variables: estimated population with access to a public facility with trained personnel, estimated number of diarrhea cases, and use of public facilities for treatment of diarrhea and dehydration.

The program manager should also examine whether the current strategy needs to be modified to reach the approximately 50 percent of the population that traditionally does not seek treatment by private or public practitioners (particularly those beyond the reach of the media campaign). If volunteer health workers or midwives are to actively pursue proper case management in the home (with home fluids or Oresol), then the program will require an indicator for regularly monitoring their effectiveness. (CDD Program Management Team, fourth quarter 1988)

Using information from the above study, service targets used to monitor achievements of BHWs, midwives, and public health nurses, according to rural or urban location of the health facility should be recalculated. The same use rates used for these calculations should be applied to the "Targets" module of the supervisory skills course. National program targets for the purpose of final evaluation are based on statistics which reflect a national average (from nationwide surveys) and need not change. (CDD Program Management Team - second quarter 1989)

In light of new information (and the introduction of a new Nescafe glass) since the study in Region X, the DOH should conduct a new study to identify an appropriate nationally available container for measuring one litre. Since the container study in Region X was conducted, there has been a great deal of new information and Nescafe has introduced a new size glass which has increased confusion regarding ORS measurement. Both of these warrant a new study. If findings indicate no clear choice for a national standard measure, the program management should investigate options for commercial production of a standard Oresol measure that could be linked to a promotional campaign by the producer (ex: prior to the Oresol promotion phase of the Healthcom campaign, a glass could be produced by a local soft drink company with Oresol printed on one side and product advertising on the other that is given free when a specified number of bottle caps is redeemed).

## **b. Monitoring and Evaluation**

The CDD Program accords high priority to continuous monitoring and evaluation of program progress through a combination of supervision, routine data collection, regular reports, and special studies.

### **Supervision:**

Regions visited have excellent systems for supervision of field personnel. Supervisors working in a team approach, as with the District Coordinating Team observed in Regions VII and VIII, contribute to the effective integration of child survival activities at the implementation level. Supervisors make appropriate use of supervisory visits for on-the-job training (midwives in Region VIII who had not yet followed the supervisory skills course were well-informed on ORT); improving health worker morale such as in Region VIII where midwives are annually given cash awards for excellent service. (as with midwives unable to meet nationally established service targets in spite of good outreach); and review of field results to strengthen future planning (interviews with mothers, review of statistics). The supervisory log which is filled out by the supervisor and maintained at the center encourages active involvement in the supervisory process by the supervisee and facilitates good supervisor-supervisee relations.

Guidelines for supervision emphasize quantitative rather than qualitative review. A number of supervisory checklists are in use in the field. Information solicited varies from an inventory of equipment and supplies, record books filled in and achievement of targets, to some notions of case management. The latter information was found on only one form and discussion of quality of case management was limited. Though the checklists themselves do not encourage quality control, the supervisors seen demonstrated very good supervisory skills, contributing to the high level of morale among field workers. This may be a result of the supervisory skills courses.

Supervision of case management in hospital ORT units appears practically non-existent. Physicians and nurses who return from the clinical management training do not receive the same regular supervision and follow-up as the nurses and midwives who have followed the supervisory skills course. The public health nurse supervisor or CDD Coordinator is not in a position to supervise hospital case management by a physician. The senior nurse might supervise other nurses in an ORT unit, but only if she has received clinical training herself.

Some public and private hospital ORT units have instituted the use of a patient treatment form such as that found in the WHO DTU managers book or in the medical education modules. This serves as a reminder of standard protocol for proper case management and can be reviewed by the District Chief of Hospital or visiting supervisor for follow-up assessment of the effectiveness of clinical training. (Whether it is currently used for this purpose is not clear).

Supervision of the regional level program by national program staff is weak. National CDD program staff travel to the regions mostly to help with training programs. Given small numbers of staff and a plethora of training programs during the peak diarrhea season, national staff have been unable to make regular supervisory visits to the regions. Instead they gather information on program problems and progress from reports, consultative workshops, and regional directors' meetings. This leads to gaps in knowledge about innovations in some regions and makes identification of problems in slower regions difficult.

#### Health Information Systems:

Personnel at every level acknowledge an overabundance of forms for information collection and redundancy of information collected. The proliferation of forms is particularly evident at the level of the program implementors where midwives fill out as many as 53 different quarterly, monthly, and weekly report forms for all programs--a situation which seriously cuts into more important service delivery time. In response to this situation, the H.I.S., with financial assistance from USAID, is in the process of overhauling and simplifying the reporting forms. The field-tested comprehensive form is being presented to program managers late in September, 1988.

The CDD Program appears to be collecting only the minimum necessary information through routine data. The form used by the CDD program, in contrast to those of most programs, is a concise and clear single-page form. The new streamlined HIS form has maintained all the information found on the CDD form, with the exception of stock reporting.

CDD program information is regularly consolidated and visually well-depicted on graphs and other wall charts for easy interpretation. For the CDD and other programs, health workers down to the Barangay Health Station produce excellent charts and graphs of program activities.

The extent of actual analysis of the information in

programming terms is inconsistent from one region to another.

#### Surveys:

The program has made appropriate use of surveys to gather baseline data for monitoring and eventual impact evaluation. The Healthcom Project has made a significant contribution through numerous baseline surveys of consumer and health worker practices. (See Appendix VII for a list of surveys to date.)

As a complement to existing baseline data and/or for special needs, this paper contains recommendations for additional studies that should be completed during the life of the Project. (Refer to Appendix VIII)

The program has a clear plan for ongoing and impact evaluation utilizing the WHO Comprehensive Review format (Diarrhea Morbidity, Mortality, and Treatment Practices Survey, Health Facility and Manpower Survey, Supplemental Data).

#### RECOMMENDATIONS

Supervisory checklists developed at the consultative workshops for regions should be reviewed to insure that case management and qualitative factors are being emphasized. The regions have developed their own supervisory checklists at past consultative workshops. The checklists should emphasize the quality of case management rather than quantitative targets. These should be pretested in one of the stronger regions and revised in accordance with feedback in time to present a final version to CDD Coordinators at the March Consultative Workshop. (CDD Program Management Team - Nov. 88-March 89).

Supervision of case management in hospital ORT units should be strengthened. The District chief of Hospital should work with the senior nurse and resident physician in charge of the ORT unit to assure regular supervision of nurses and other physicians in the unit. To the extent possible, a member of the clinical training team should visit each trainee within three months of the training to verify follow-through with action plans and that quality case management is occurring. The chief of the training unit should report to the Central Office on findings during follow-up, with recommendations for adjustments in training and/or supervision. Regular CDD supervisors should assure supervision of non-clinical aspects (ex. supplies, unit organization and general program management). (Clinical Management Training Team, District Chiefs of Hospital -

ongoing)

PPS should develop a plan for follow-up and verification of good case management in private hospitals. This will serve primarily as a mechanism to evaluate the effectiveness of seminars and distance training. (PPS - as soon as possible)

Supervision of the region by national staff should be strengthened. National CDD staff should schedule priority visits, during periods with less rigorous training schedules, to regions where progress has been slowest. Days can be added on to travel for training courses to look at innovations in successful regions and provide encouragement for excellent work. The CDD staff should provide the national monitoring team for comprehensive maternal and child health care with specific issues to be addressed during their supervisory visits. (CDD staff - ongoing)

CDD staff should support efforts to reduce duplication of data collected as well as the overall volume of forms and statistics. Identify mechanism for tracking ORS supply and utilization information once the new HIS form is applied in all regions. (See ORS Demand, Supply and Distribution.) (CDD staff with HIS and Procurement and Logistics Service)

The supervisory skills course for nurse supervisors should emphasize good analysis and application of data collected for planning and monitoring activities. (SSC trainers)

The CDD Program should conduct a Comprehensive Review for evaluation as planned. (CDD staff with WHO - Dec. 1990)

### c. Implementation

AID/Manila's inability to procure locally-produced ORS has contributed to delays in project implementation. Some AID/Manila personnel believe that mission interpretation of AID/W guidelines relating to the procurement of locally-produced oral rehydration salts (ORS) has delayed project implementation. Since the objective of the ORT component of the Primary Health Care Financing Project was to increase the use of ORT, program activities have emphasized the training of service providers (public and private), the creation of a demand for ORT services among consumers, and the provision of a readily available supply of ORS in both the public and private sectors. As originally designed, the project assumed that availability of and access to an adequate supply of ORS were indispensable to achieving sustained impact, and US \$750,000 was budgeted to purchase ORS.

Subsequent to the signing of the Project Agreement events forced AID/Manila to delay plans to procure locally-produced ORS. First, a change in national government took place in early 1986 and several months passed before the new leadership of the DOH was able to focus attention on the implementation of the project, specifically the procurement of ORS. Second, in April and June of 1986 AID/W issued new guidelines pertaining to the procurement of ORS.<sup>11</sup>

While designed to facilitate ORS procurement and project implementation, and give AID Missions clear guidance on what should be done to avoid unfortunate incidents similar to what occurred in Peru from taking place in other countries, in the Philippines the guidelines had the opposite effect. Indeed, although the pertinent cables (State 126991/April 24, 1986 and State 182858/June 11, 1986) contained language allowing local missions considerable latitude in procuring locally-produced ORS AID/Manila procurement and legal staff argued that AID funds could not be used to procure ORS without the explicit involvement and endorsement of the USFDA.

The language of the cables could substantiate the interpretation of key staff of AID/Manila, although it is clear from the actions of other AID/Missions (e.g., Dhaka, Cairo) that AID funds are being used to procure locally produced ORS, provided certain guidelines are followed. Although these guidelines do not appear to be explicitly stated in any document(s), actions taken by AID Missions in the countries where AID funds are being used to procure locally-produced ORS would suggest that the following conditions are in effect before procurement takes place.

The local pharmaceutical manufacturer must follow Good Manufacturing Practices (CGMPs) in the course of

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<sup>11</sup>AID/W issued the new guidelines in response to an incident in Peru where several children were reported to have died after being treated with ORS procured by AID/Lima and manufactured by a US-based supplier.

<sup>12</sup>For example, State 182858 clearly states AID projects proposing to procure ORS outside of the U.S. must take on the responsibility of evaluating the integrity and capability of the designated testing laboratory in order to be certain it can provide quality assurance for this commodity. AID/W does recognize that when procuring outside the U.S. there may be some other technical aspect of specs which, in USAID's judgement, require adaption to local conditions to assure achievement of project objectives."

producing ORS.

The ORS produced must be in conformity with the WHO formula (ORS-citrate or ORS-bicarbonate) and manufactured according to the specifications set forth in the WHO publication "Oral Rehydration Salts: Planning, Establishment and Operation of Production Facilities" (WHO/CDD/SER/85.8).

The facilities of the pharmaceutical manufacturer and the batch records on the ORS produced must be inspected and approved by the national pharmaceutical regulatory authority (the equivalent of the USFDA, e.g., BFAD in the Philippines).

The national government must affirm in writing that AID would be "held harmless" in the event that locally-produced ORS, procured with AID funds, were not in compliance with the WHO specifications.

AID/Manila chose not to follow the course adopted by other AID Missions. After long delays (almost two and one half years), a portion of the funds budgeted for local procurement (US \$500,000) were used to purchase ORS from UNICEF. Some in AID/Manila believe that the absence of clear guidance from AID/W prevented the Mission from moving quickly to purchase a local ORS product and delayed achieving the "commercialization" objective of the project. There is, however, some justification for suggesting that not procuring locally-produced ORS has forced AID/Manila to concentrate on developing and implementing demand-generation initiatives, e.g., training, promotion, etc. These measures have led to increased consumer awareness and consumption and increased private sector production, distribution and sales. In effect, the objectives of the project are being met, albeit in a manner different from that defined in the original project design. (See above Part 3C ORS Demand, Supply and Distribution.)

The decision of AID/Manila not to procure locally-produced ORS is understandable in light of the language of the relevant cables. However, it reflects an incomplete understanding of the role of the USFDA and of the fact that AID Missions can follow different procedures when procuring US-manufactured ORS as opposed to buying locally-produced salts. In spite of the language of the cables, the USFDA does not inspect, approve or certify pharmaceutical manufacturing facilities. The USFDA reviews production methods and batch records for products manufactured within the United States and outside the country only when (a) the products are for import into the US or when (b) a national government specifically invites the agency to inspect

production methods and pays for the services.

In addition, USFDA does not regulate USAID's off-shore procurement. USFDA advises the agency; USAID can decide to accept, modify or ignore the advice. Finally, in the matter of ORS production and quality assurance the USFDA has taken a position that is at variance with the ruling of most national pharmaceutical regulatory authorities. While almost all countries follow the WHO ruling that ORS is a pharmaceutical that should be produced according to Drug GMPs, the USFDA classifies ORS as a medicinal food. In the United States, where WHO-formula ORS is not produced and marketed, oral rehydration salts, e.g., Pedialyte of Abbott-Ross, are manufactured according to production systems different from and, in some respects, less stringent than those in effect for pharmaceuticals.

Given USFDA's approach to classifying ORS, and the fact that the agency does not inspect and cannot regulate the pharmaceutical industry of another country (except in certain cases), there is some merit for arguing that AID/Manila should (a) adopt and follow the WHO position on ORS and (b) follow the guidelines specified above when procuring locally-produced ORS. The private sector pharmaceutical industry in the Philippines is well-established, very sophisticated, and thoroughly familiar with GMPs for pharmaceuticals. Also, BFAD staff are well trained and regularly inspect master batch records and facilities, and review the production methods of the local industry.

### 3. USAID/Project Operations

During the process evaluation, members of the DOH PMS, the USAID project manager and the office chief of the Office of Population, Health and Nutrition were contacted and interviewed on monitoring, implementation, reporting and evaluation procedures.

The USAID Project Officer has played an instrumental role in assuring continuing progress on the project at both the national and regional levels. The ORT component project officer, the Foreign Service National public health adviser at USAID/Philippines, has been instrumental in strengthening communication and linkages between DOH, USAID and PPS. Although the PMS is designated as the principal agency to link communication between USAID and DOH, in practice, the project officer has elicited the support of essential CDD staff at the DOH to ensure progress on the project.

Furthermore, the project officer is actively involved in

implementing and supervising the project at the both the regional and national levels. Indeed, in the CDD pilot region (Region 7), the project officer has been an active participant in facilitating training courses and consultative workshops.

Although the PMS has improved project coordination, the PMS has not clarified its role or played a proactive role in the monitoring process. The PMS was only recently established and still lacks role clarity and established channels of communication with other divisions. Many project transactions still do not pass through the PMS office. In some cases, accounting and budgeting offices are failing to provide PMS with necessary monitoring documents and financial records. As a result, the PMS' role has been limited to documenting existing problems and procedures, rather than playing an active role in facilitating problem solving between the CDD staff, other GOP agencies, financial offices, USAID and the private sector.

The sustainability of the PMS and its functions have not been fully addressed at this point. The PMS is currently only designated to monitor ORT activities for the life of the project.

The project places an emphasis on ORT and other aspects of diarrhea case management, rather than a broad emphasis on CDD. The project is focused on ORT which is limited to mortality reduction, rather than CDD which emphasizes morbidity reduction. The most recent CDD Directional Plan emphasizes morbidity reduction, but promotion of ORT has not been adequately linked to a larger CDD program, which emphasizes the reduction of morbidity from diarrheal diseases through environmental sanitation, maternal and child health, nutrition, surveillance and health education activities.

Numerous private sector medical and pharmaceutical associations are interested in being integrated into the project. USAID has successfully pursued linkages to the private sector through medical professional societies by a memorandum of agreement with the Philippine Pediatric Society and the upcoming memorandum of agreement with the Association of Philippine Medical Colleges. Several other organizations expressed interest in receiving ORT training and IEC materials, including the Society of Family Practitioners, the Cebu Pharmaceutical Association (Region 7) and the Philippine Society of Hospital Pharmacists (Region 7). None of these organizations have previously received ORT training.

The format of the USAID project paper is confusing for

evaluation and monitoring purposes. The organization of the ORT component project paper does not clearly delineate inputs and outputs from the public and private sector. For example, the section on ORT promotion among medical professionals does not distinguish private physicians from physicians in DOH clinics, although their medical practices are very different. Other sections on professional meetings, training and literature do not differentiate the audience that is being targeted.

The project's goals will not be able to be completely implemented by the Project Assistance Completion Date (12/31/89). The change of administrations and the subsequent reorganization of the DOH in 1986 delayed initial progress on the project, and the PACD of December 31, 1989 may not allow adequate time to complete project implementation and effectively monitor and evaluate progress on the project. The failure to obtain a private sector pharmaceutical firm to produce and test market ORESOL has also delayed project implementation. As of June 30, 1988, \$3.412 million in project funds was still in the pipeline.

#### RECOMMENDATIONS

The PMS should assume a more assertive role in project coordination and monitoring, particularly of financial transactions. The PMS' role is to serve as an interface between USAID and the DOH CDD program. While the PMS has documented key problem areas and program linkages, the PMS' authority in the project is still unclear. The PMS should monitor the overall financial disbursements of the project, have an observer role in the National CDD Committee, establish closer linkages with DBM staff and be in the position to assign specific monitoring staff to coordinate and follow-up on project activities. The role of the PMS beyond the life of the project also needs to be addressed. (PMS/DOH with USAID, Immediate and Ongoing)

The project paper should be reorganized, clearly delineating public and private sector inputs. For the purposes of future monitoring and final project evaluation, the project paper and log frame should be reorganized to clearly separate public sector activities from private sector initiatives. (USAID Project Officer, First Quarter of FY 1989)

Linkages should be pursued to link the ORT component to a broader CDD program. Once effective case management has been successfully implemented, a more comprehensive CDD program, focusing on a number of factors, including preventive measures, environmental sanitation, measles, malnutrition and bottlefeeding could be emphasized. Where

case management remains weak, it should remain a priority with the other components added after it has improved. Such a strategy is in keeping with USAID's Country Development Strategy Statement which aims to integrate the ORT component into USAID's larger child survival program. (USAID Project Officer - First Quarter of FY 1989)

USAID should continue strengthening the participation of the private sector through agreements with professional medical and pharmaceutical associations. Given the success of the memorandum of agreement with the PPS, USAID should expand ORT activities to other professional organizations. All organizations contacted during the process evaluation were receptive to receiving training on proper diarrhea management. Pharmaceutical companies are the major suppliers of anti-diarrheals and would especially benefit from ORT training. (USAID Project Officer - immediate and ongoing).

The Project Assistance Completion Date should be extended by one year to December 31, 1990. Given the amount of project funds remaining in the pipeline and the failure to contract with a private sector pharmaceutical firm to produce and test market ORESOL, the PACD should be extended by one year. (USAID Project Officer, First Quarter of FY 1989)

#### 4. Finance

During the process evaluation, finance, budget and accounting officers in all levels of the Department of Health were interviewed. In addition to interviews in the central financial office, regional, provincial and district financial officers were interviewed in Regions 7 and 8.

The process evaluation was not an audit of the Department of Health's financial statements for any period. Accordingly, this report will focus on the process for disbursing funds, rather than the financial data collected from different offices.

The project is well-funded, however, GOP funding requirements have limited the usage of project funds. The project is sufficiently funded at the national and regional levels. Indeed, compared to other child survival programs in the Philippines, CDD has more resources to draw upon than most programs. However, the intricate fund disbursement system of the GOP does not lend itself to the utilization of project funds to their full potential.

Project funds are not being utilized to their full potential in some regions. USAID has developed guidelines on how project funding can be utilized in the regions (both pilot

and regular regions), but the central DOH office has not always transmitted this information to the regional levels.

Guidelines from USAID on the scope of funding for the project have not been fully utilized in Region 7. Project funds can be used only for training in most regions, except for the three pilot regions: 6, 7 and 10. Non-training activities can be funded under the project in these regions, including monitoring and training costs. However, the CDD staff in Region 7 was unclear on the scope of funding available for the project because the new Regional CDD Coordinator had not received guidelines from her predecessor. Start-up and non-recurrent costs for surveys, research, promotional materials, translation of communications materials into local dialects and consultative workshops could be incorporated into the budget. Region VII has also requested assistance in implementing communications and research projects but has received no feedback from the central office.

The DBM/COA requirement that cash advances must be liquidated, before additional funding is committed to DOH has delayed the disbursement of funds for the project. Using the GOP appropriations process for funding the ORT project has created uncertainty and unreasonable delays in release of funds. The use of the appropriations process has added several project limitations (e.g. requirements to undergo COA oversight, required use of GOP per diem rates, etc.). The liquidation of accounts is required by the DBM/COA before additional funding to DOH is committed to the project. The transfer of money from the Treasury to DOH has sometimes taken as long as six months to process from the regional financial offices to the DOH central financial offices to USAID. Liquidation of cash advances has also meant that there are no funds available while additional funds are being processed.

Coordination problems between the programming and financial offices have resulted in the postponement of workshops, CDD staff members advancing personal funds for training per diems and the use of non-project funds for ORT promotion. The programming offices in the regions have not always kept the financial offices informed of their planned activities, resulting in delays to disbursing funds and the postponement of project activities. Currently, all programming and funding advancement are done on an annual basis. Money is advanced from the central financial office to the regional office according to the mutually agreed upon implementation plan. The addition of unprogrammed activities has caused proposed project activities to be delayed. As a result, in Region VII, the budgeting process has driven the training

and program schedule instead of vice versa. Activities have been planned mid-year or added to the original budget, resulting in delays in getting money released. For example, the addition of two consultative workshops for 1988 were delayed in Region VII because funds could not be released from the central office immediately. Although the central Financing Services office estimates that financial transfers to the regions can be completed in three to four working days and that a lead time of two weeks is sufficient for scheduling trainings, in actuality, the confusion on guidelines, combined with changing requirements from DBM and COA, has resulted in delays of several months.

The coordination problems have caused CDD Coordinators at both the national and regional levels to advance money out of their personal funds to cover the first few days of training, and be reimbursed later. Indeed, in one region, the running joke is that to be a member of the CDD staff, applicants must have at least \$80,000 in their bank accounts.

Region VII has used non-project funds for smaller ORT projects because they were unaware that project funds could cover non-training expenses. In Region VII, a provincial health office (PHO) was using provincial funds to develop public information materials in the local dialect because the funds had not been allocated in the regional project budget. Nine Regional offices are responsible for programming provincial budgets. Furthermore, public information materials were being mimeographed into poor copies rather than drawing upon available project funds to produce legible documents.

This process is further complicated because the central CDD office provides copies of its guidelines directly to the CDD regional coordinator, rather than the regional financial office. Information has not always successfully been communicated between the CDD regional coordinator and the regional financial office. In Region VII, the finance office did not find out that a training was going on until the last day of training when vouchers were submitted for payment, creating a crisis situation whenever a training course is scheduled.

The creation of the PMS has improved financial documentation and identified key problem areas in financial management, however, the PMS office is not yet being utilized to its full extent. The PMS has developed flowcharts and a documentation of key problem areas in financial management to educate project implementation personnel both at USAID and the DOH on the process for moving funds for Primary Health Care Financing project activities. However,

financial transactions have only recently begun to pass through the PMS office. In the past, there has been weak coordination between the PMS and DOH financial divisions due to the lack of clarity on the PMS' role and its linkage to other divisions. The PMS was unable to monitor all project disbursements because they were not receiving complete information from the accounting and budget divisions, and were not given adequate authority to enforce monitoring procedures. The coordination between PMS and other divisions has also been sporadic and done on an ad hoc basis, rather than on a routine schedule.

Interpretation of COA/DBM standards and regulations has been inconsistent at the national and regional levels. In June 1988, the DBM issued a department circular, National Budget Circular 391, that USAID funds channeled through the National Treasury could not be used to pay per diems or training allowances higher than what is allowed by the GOP. This created tremendous programming difficulties since the DOH and USAID had agreed on per diem rates ranging from @250 to @500 per day, as compared to the GOP ceiling of @135. Additionally, the DBM circular applied only to USAID. Other donors, such as WHO and UNICEF, who do not channel their assistance through the appropriations process, were allowed to continue paying higher per diem rates for travel and training.

On September 22, 1988, after extensive negotiations between DBM, DOH and the USAID project manager, DBM agreed to reinstate the original USAID per diem rates under the current project, with the advice for the DOH to keep within the local rates for future projects. While it is anticipated that this new circular will solve some of the problems on the funding of training, the circular is subject to the interpretation of the regional financial offices and auditors. Coordination between the regional auditors and financial offices has been weak. The regional financial office in Region VII was unaware of which procedures needed to be complied with and which were merely guidelines. Additionally, regional auditors often vary in their compliance with national regulations, depending on their region.

For example, in Region VII, COA's requirements have frequently been unclear to the regional offices and subject to wide interpretation. Furthermore, COA's mode of communication to Region 7 through radio and phone messages has been criticized as being difficult to understand and record in permanent files.

There is insufficient coordination between the central and regional financial offices. Regional offices have not

always had access to full information from the central office when needed. Guidelines outlining the number of participants, per diem rates per day, DOH/USAID policies, standard rates, allowable budget items or accounts which the money is being taken from are developed and distributed by the national CDD office. However, these guidelines do not arrive at the regional financial offices at the same time as the funding allowances. In Region VII, the financial office had received their funding allowances without accompanying guidelines from the central CDD office. At a recent consultative workshop, the central office agreed to advance funding guidelines directly to regional financial offices, but this has apparently not taken effect yet. While funds are scheduled to arrive two weeks ahead of training, the guidelines for the funds have often arrived as much as two weeks after the training is completed due to the indirect transmittal of the guidelines from the national CDD office through the regional CDD coordinator to the regional financial office. Region VII has also experienced delays in receiving replies from the central office to proposals for consultative workshops, research and IEC initiatives. Some of these delays were caused by the delays in receiving a funding warrant from DBM. To alleviate this problem, Region VII has designated one financial officer to verify that the request dossier is complete and to then accompany the dossier to the central office in Manila.

DOH allowances for training and travel expenses have been inadequate, and have discouraged training efforts and program expansion efforts. The development of community support to sustain the project in the long-run is necessary. The main problems identified in the CDD program at the regional and provincial levels were the lack of funds for midwives to adequately cover travel expenses to their service areas and insufficient vehicles to transport ORT supplies to the districts. Since these are recurrent DOH costs, they cannot be covered under USAID funding of the project. However, the Revised Five-Year Directional Plan of Operations of the CDD in the Philippines emphasizes support to the provincial and district levels, which could include the provision of additional financial support to the regions. Efforts should be made to increase DOH allowances at the lower project implementation level.

#### RECOMMENDATIONS

The DOH should clarify to the regions activities that can be included in the scope of funding under the ORT Component of the Primary Health Care Financing Project. A large percentage of project funds have still not been earmarked (29 percent) or committed (40 percent). In the pilot regions, non-training initiatives can be funded under the

project. USAID/DOH should distribute existing policy guidelines clarifying what project funds can be used for and ensure that the guidelines are clear. (DOH with USAID - Fourth quarter 1988)

Budgets should be integrated into the program management process. Budget projections should be jointly prepared by the CDD office and the appropriate financial offices from the outset of program planning. Additionally, regional health offices should provide financial offices with a training schedule on a quarterly basis to allow adequate time in preparing training allowances. A periodic comparison of actual vs. budgeted expenditures would also assist the CDD program in making future budget projections. (CDD Staff at the National and Regional Levels, Immediate and Ongoing)

Training and orientation about CDD program management for financial support staff should be expanded. In the May 1988 consultative workshop, all regional CDD coordinators, financial officers and regional auditors attended an orientation on financial management of the CDD program. Additionally, a special orientation of relevant financial requirements was sponsored by the central CDD office for Region VII. Some financial officers were trained in Region VII, and the training improved the budgeting and disbursement process. This orientation should be expanded to other regions. At the regional level, the CDD staff should hold a one day or half day orientation for the financial and auditing staff on the activities of the CDD program to encourage their cooperation through active participation in the program. (CDD Staff at the National and Regional Levels with DBM, Fourth Quarter 1988)

USAID should consider the possibility of contracting a private firm or centrally funding the project through PRITECH or some other appropriate organization if GOP financing mechanisms cannot be modified during the life of the project. If funding disbursement problems continue, USAID should consider contracting with a private firm to manage the project or consider managing the project through the centrally-funded USAID/Washington PRITECH project. This could be applied only to the ORT component, or possibly, the whole Primary Health Care Financing Project. This alternative was proposed and initiated by USAID/Philippines last year, but negotiations were temporarily tabled on the subject. Managing the project in this manner would reduce USAID/Philippines direct involvement in disputes over per diems, training allowances, etc. (USAID Project Officer, As Needed)

Guidelines on funding procedures should be sent to regional

financial offices, in addition to the Regional CDD Coordinator. To ensure timely and efficient processing of funds, Regional financial offices should receive information directly from the central CDD office, rather than channeling communication through the Regional CDD Coordinator. (CDD Staff at the National and Regional Level with Regional Financial Offices, Fourth Quarter 1988)

The DOH should review travel and training allowances for midwives in the rural health units and transportation allowances for supply delivery. The low priority given to funding transportation of supplies and travel allowances for midwives is in conflict with the DOH's overall strategy to develop community-based programs and decentralize program implementation to the regional, provincial, district and barangay levels. (DOH, Annual Planning Exercise)

The role of PMS in the financial process should be strengthened. Since the reorganization of the DOH and creation of the PMS office has been successfully implemented, efforts should now be channeled to linking the PMS to specific monitoring and review responsibilities, including financial reviews and progress reports. (PMS/DOH with USAID, Immediate and Ongoing)

#### d. Donors

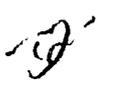
WHO and USAID activities are well coordinated in the CDD program, particularly in the training area. WHO provides the funding for Regional level training and USAID funds the training at the Provincial and District levels. UNICEF plays an important role in CDD at the barangay level. Problems have been identified in the area of information sharing and coordinating other types of activities. Because the mission of donors is to assist and support the activities of the DOH, the DOH should serve as a clearing house for all donor activities.

#### RECOMMENDATIONS

The DOH should use the National CDD Committee meeting as a forum for encouraging all donors active in CDD to exchange information on their planned activities with the DOH.

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PRIMARY HEALTH CARE FINANCING  
ORAL REHYDRATION THERAPY COMPONENT

(492-0371)

PROCESS EVALUATION SCOPE OF WORK

UNITED STATES AGENCY FOR INTERNATIONAL DEVELOPMENT

SEPTEMBER 1988

Outline of Terms of Reference for the Process Evaluation of  
the ORI Component of the Primary Health Care Financing Project  
(492-0371)

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## List of Abbreviations

CDD	Control of Diarrheal Disease
COA	Commission on Audit
DBM	Department of Budget and Management
DOH	Department of Health
GOP	Government of the Philippines
IEC	Information, Education and Communication
NRTC	National Rehydration Training Center
OPHN	Office of Population, Health and Nutrition
ORS	Oral Rehydration Solution
ORT	Oral Rehydration Therapy
PHCF	Primary Health Care Financing
PPS	Philippine Pediatric Society
PHCF	Primary Health Care Financing
PRITECH	Primary Health Care Technology
UNICEF	United Nations International Children Emergency Fund
USAID	United States Agency for International Development
WHO	World Health Organization

## I. PROJECT BACKGROUND

In July 1983, the Mission authorized the Oral Rehydration Therapy (ORT) component of the Primary Health Care Financing (PHCF) Project to increase the utilization of oral rehydration therapy as a primary preventive measure against diarrheal death among infants and young children. The project aims to achieve its objectives by ensuring that a continuous and readily accessible supply of oral rehydration salts is available and that there is an effective demand for their usage. Implementation of the ORT component began after the Project Agreement was signed in June 1985. A \$4 million grant was authorized by A.I.D., while the GOP contributed \$3 million for the project to be implemented by the Department of Health (DOH) and Philippine Pediatric Society (PSS) over a five year period. In 1988, the project's budget was increased by \$300,000 to provide various technical assistance activities through a buy-in from the PRITECH Project. The PHCF project had an original Project Assistance Completion Date (PACD) of December 31, 1988, which was subsequently amended to December 1989 when the ORT component was added. As of June 30, 1988, the project expenditure total represented 21 percent of total obligated funds, with program time already elapsed at 87 percent.

The project aims to increase ORT utilization through a two-pronged approach which creates demand for ORS products through training and information, education and communication campaigns and then assures that there is a steady and continuous supply of ORS products.

## II. PURPOSE OF EVALUATION

The process evaluation has a twofold purpose:

- o To assess the progress of implementation of the ORT Component of the PHCF Project (at the input/output level).
- o To identify problems and recommend measures for improvement.

The process evaluation will review the status of completion of the project elements (e.g., technical assistance, training and procurement) and progress towards achievement of the purpose. Recommendations for final adjustments in project design and lessons learned from the project will also be included in the evaluation.

The mid-project review will determine: (1) whether the GOP/DOH remains fully committed to fulfilling the project's objectives; (2) progress made in the production, procurement, distribution and commercialization of Oral Rehydration Solutions (ORS); (3) the level of ORT promotion among medical professionals; (4) progress made in public promotion of ORT; (5) the level of coordination between the GOP implementing agencies, the Philippine Pediatric Society and A.I.D.; and (6) the appropriateness and extent of training courses.

The mid-project evaluation will also determine whether there needs to be any modification in project design, make recommendations for any necessary project amendments and determine the timing of additional fund releases. It should be possible to determine whether project Conditions Precedent were met in a timely manner, whether Covenants to the Agreement are in compliance, whether proposed contracts are in place and appropriately staffed and whether training programs are operational.

### III. SCOPE OF THE REVIEW

The process evaluation will assess the quality and pace of project implementation. The evaluation will focus on the identification of implementation problems and their respective solutions. The results of this evaluation will serve as the basis for making necessary adjustments in the implementation strategy and plan. The focus of the evaluation will be on: project accomplishments, the status of completion of various project elements, contributions made by the donors and participants, an assessment of the extent to which the project has resolved or is resolving the original problem, recommendations for adjustments in project design, a review of data collection results and a summary of lessons learned from the project. In addition, organizational and management issues will be assessed, the adequacy of the budgetary and financial support and the monitoring and reporting system of the project.

To date, the following activities have been implemented under the project and will be evaluated: (1) the renovation and restoration of a National Rehydration Training Center; (2) CDD/ORT newsletter published and distributed; (3) scientific meetings of CDD/ORT conducted in various parts of the country; (4) revision of a manual for management of acute diarrheas developed; (5) ORT advertising materials for TV and radio developed; (6) supervisory training skills courses and clinical training courses offered; (7) development of ORT module for undergraduate medical curriculum; (8) some procurement of equipment, training supplies and materials; and (9) organization of Program Monitoring Staff Secretariat.

Specifically, the evaluation will assess the responsiveness of the different organizations to the project, as well as units within the DOH, in relation to their mandated roles and objectives. In addition, the evaluation will examine the institutional arrangements and decision-making processes of the project components. The timeliness, adequacy and the structure of budgetary releases will be reviewed to determine their suitability to the project.

IV. KEY EVALUATION ISSUES

The process evaluation will include recommendations based on the results of the evaluation exercise and provide answers to the following questions:

A. PROJECT INPUTS AND OUTPUTS

Questions to determine the extent to which project component activities have been successfully undertaken:

1. ORS Supply: Production, Procurement, Distribution, Commercialization

- o Is ORS commercialization proceeding as planned? If not, what are the major impediments and how can the process be improved?
- o Are there ORS products that are reasonably priced and widely accessible so that a continuous supply of ORS is available nationwide?
- o What progress has the DOH made with plans to phase out its production of Oresol and procure commercial ORS products using its own funds?
- o Does a mechanism for the systematic procurement and distribution of Oresol exist? How effective has this mechanism been to assure that there is an adequate supply of Oresol at the different health facilities?
- o What can be done to accelerate the pace of production, procurement, distribution and commercialization of ORS products?

2. ORT Promotion Among Medical Professionals

- o To what extent is the use of ORS being institutionalized in households, hospitals and health stations?
- a) Establishment of a National Rehydration Center
  - o Has the NRTC been established and thoroughly equipped?
  - o Are training courses being conducted as planned?
  - o To what extent has the NRTC training helped in promoting ORT among doctors and nurses in government and private health facilities?

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o Is the training strategy/methodology, including selection criteria, technically and administratively sound?

o How much on-the-job training is included in the current training programs?

o What administrative problems have been encountered in the conduct of clinical management trainings and to what degree have these problems affected achievement of the project's objectives?

o Is the quality of the training programs current with the latest medical practices? How often are the training courses monitored for quality? Is the training management staff capable of correcting any deficiencies that are discovered?

o Is logistical support being delivered in a timely manner?

o How many physicians have been trained in ORT under the PPS distance study course? How effective is distance training?

b) Dissemination of Professional Literature

o Are scientific information and professional materials being disseminated? What materials are available and who are the recipients?

o How frequent, timely and widely disseminated has the ORT Newsletter been? Who are the recipients of the newsletter?

o Has a suitable library been established at the NRTC containing WHO publications, literature on pediatric infectious diseases and public health publications?

c) Professional Meetings

o How many scientific meetings have been conducted? How widely attended have these been? How relevant and responsive have the speakers and specific topics been?

o Have professional organizations such as the Philippine Pediatric Society, Philippine Medical Association, Academy of Family Physicians and other interested groups exchanged information? What is the status of implementing the revised medical curriculum through these organizations?

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3. Paraprofessional Training (Supervisory Skills Course)

o How appropriate are the training modules and training design in relation to the functions and responsibilities of the participants? How many nurses and midwives have been trained?

o How widely is outpatient rehydration being promoted by Rural Health Units and government hospitals?

o Are logistical needs being fulfilled and are supplies being delivered on time? Is the current delivery system working efficiently? Where are the bottlenecks? What can be done to improve delivery?

o Have evaluations and assessments been conducted on the quality of the training courses? What have been the results? Is the training management staff capable of correcting whatever deficiencies are discovered?

4. Public Promotion of ORT

o Is the IEC component proceeding as planned? Are mass media and promotional campaigns the most effective means to reach households?

o Is a communications/social marketing plan in place? Why have there been delays in implementing public promotion activities?

o Has the work undertaken by the contractors been effective?. Are the activities under this component proceeding in a logical way? What improvements can be made?

5. Program Staff Support

o Has the Program Monitoring Staff for ORT been monitoring project implementation activities as planned?

o Is the staffing/organization of the Program Monitoring Staff sufficient?

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**B. IMPLEMENTATION ARRANGEMENTS**

Questions to assess the coordination between agencies, monitoring and reporting systems of participating agencies:

**Department of Health**

- o Is there a functional organization mechanism within the DOH that has the capability to plan, manage and coordinate the implementation process of the various project activities?
- o Is the proper amount of project monitoring and guidance being provided by DOH?
- o How effective has the CDD Committee been in facilitating project implementation? Are all the involved units providing the required project information and data? Is there adequate staff and logistical support?
- o Have DOH regulations impeded progress on project implementation? If so, how can these impediments be minimized? Has the Central Office been releasing funds to the regions in a timely fashion? Is the Central Office causing avoidable delays in the project by slow responses and/or unreasonable requirements? How can the project implementation process be improved?

**United States Agency for International Development**

- o Is OPHN providing the proper amount of project monitoring guidance?
- o Have USAID regulations impeded project implementation? If so, how can impediments be minimized? Has USAID's involvement in project activities been too intrusive or should it be more comprehensive?
- o Has USAID been releasing funds in a timely fashion? Are there delays which are avoidable such as slow responses and/or unreasonable requirements? How can USAID's role be improved?

**Department of Budget and Management/Commission on Audit**

- o Have DBM and COA regulations impeded project implementation? Can these impediments be minimized?

**Philippine Pediatric Society**

- o Is the "ORT Promotions among Medical Professionals" being implemented in accordance with the memorandum of agreement between DOH and PPS?
- o Are any data being collected from private pediatricians on ORT usage in the private sector?

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All Organizations

- o What is the current inventory of data now being used in the organizations?
- o Are all involved organizations recording and reporting the required project information and data?
- o Are quarterly reports being submitted, consolidated and analyzed by each agency?
- o Is financial data readily available?

C. PROJECT REDESIGN EFFORTS

Questions to determine whether any major changes are necessary in the project design:

- o Should there be any major changes in the project design? If so, what changes are recommended? Are these changes separate from improving the implementation of the current project?
- o Why are some regions more effective than others in promoting the use of Oral Rehydration Therapy? Can these methods be spread to other regions?

V. METHODOLOGY AND PROCEDURES

1. Secondary data will be used primarily to compare actual accomplishments with set targets. Ocular inspection/field visits may be necessary to confirm or validate data gathered.
2. Primary and secondary data will also be used to assess the effectiveness of current monitoring and reporting systems. The evaluation team will review existing documents and conduct interviews with central office and field personnel to identify project implementation problems.
3. The evaluation team will survey program managers and implementors at the different levels of the various organizations.
4. To the extent possible, regions will be categorized according to the degree of inputs they have received under the project.
5. The evaluation team will decide which regions to visit.

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## VI. EXPECTED OUTPUT

The assessment will provide vital information on the different components of the ORT Project which will be used as the basis for changes and revisions on current organizational and operational aspects of the project. An evaluation report outlining the findings will be prepared together with the corresponding recommended measures to improve effectiveness and efficiency of the project.

Each major recommendation should indicate the appropriate organization or individual with whom the responsibility will lie. Recommendations should be stated concisely with reasonable deadlines.

## VII. COMPOSITION OF EVALUATION TEAM

The evaluation team will include six members: four consultants from PRITECH, an A.I.D. representative and a DOH representative. UNICEF and WHO will be participating as observers. The evaluation will begin on September 12, 1988 and will be completed in three weeks.

## VIII. REPORTING REQUIREMENTS

A draft of the evaluation report will be completed by September 30, 1988 and a final version will be completed by October 31, 1988.

The final evaluation will comply with A.I.D./Washington's evaluation format and include:

- o Executive summary stating the development objectives of the activity evaluated, purpose of the evaluation, study method, findings, conclusions, recommendations and lessons learned about the design and implementation of the project.
- o Project Identification Data Sheet
- o Table of Contents
- o Discussion of Report will include (1) the purpose and study questions of the evaluation; (2) the economic, political and social context of the project; (3) team composition and study methods; (4) evidence/findings of the study concerning the evaluation questions; (5) conclusions drawn from the findings; (6) recommendations based on the study finding and conclusions, stated as actions to be taken to improve project performance.
- o Appendixes will include a copy of the evaluation scope of work, most current logical framework, a list of documents consulted, and individuals and agencies contacted. Additional appendixes may include a brief discussion of study methodology and technical topics if necessary.

## CONTACTS

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Dr. Corazon Sabolao, CDD Coordinator  
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Mr. Nestor D. Collera, Supply Officer  
Ms. Lucy Ramos, Commission on Audit

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Ms. Anacleta Engalan, Volunteer Health Worker

Mahaong Barangay Health Station

Ms. Caudiosa Lasala, Midwife

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Ms. Susan Man, Chong Hua Hospital, Chapter President  
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Mrs. Elverita Montejo, Midwife

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**Gabi Barangay Health Station**

Ms. Gloria Tura, Midwife

### Appendix III

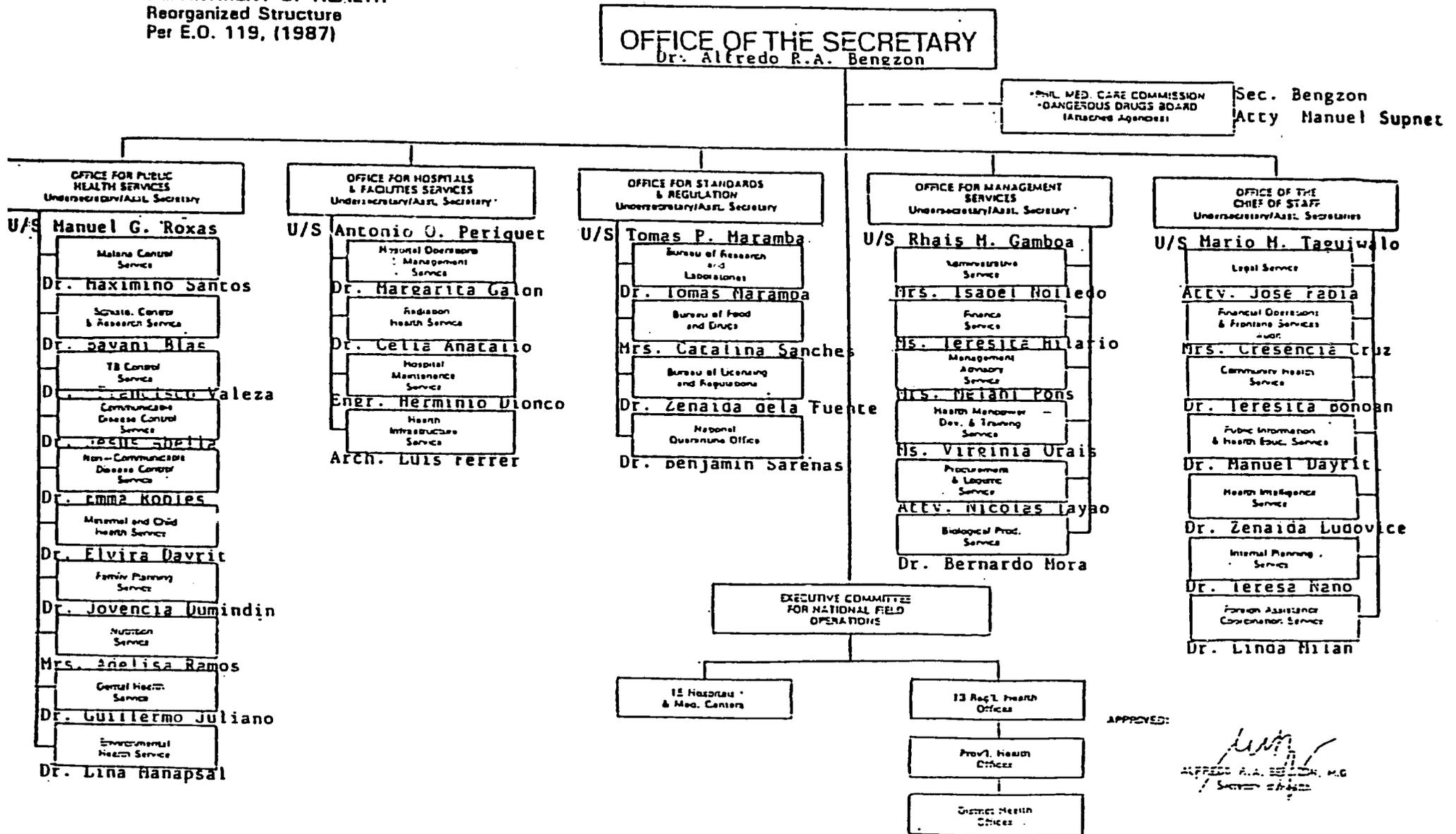
#### Documents Reviewed

1. Philippines ORT Country Assessment Report, PRITECH - May 1988
2. Primary Health Care Financing Project: Oral Rehydration Therapy Component, Project Paper Supplement - March 1985
3. Primary Health Care Financing Project - ORT Component Implementation Plan
4. A Restatement of the Operational Plan for the National Program for the Control of Diarrheal Diseases (1988 - 1992) December 1987
5. Report of the Joint MOH/MMC/WHO Comprehensive Program Review - December 1985
6. USAID Quarterly Report Project Status Reports of the PHC Financing Project - ORT Component - June 1985 - June 1988
7. Memorandum of Agreement, Department of Health and Philippine Pediatrics Association
8. Trip Report, Dr. M.H. Merson 14-21 February 1987
9. Country Development Strategy Statement FY 1988, Philippines - April 1987
10. Assessment of Current Diarrheal Disease Clinical Management Training in the Philippines; Consultant Report, Dr. Mariam Cleason - August 1987
11. Trip Report, Healthcom Project, Philippines, Horznik, Verzosa - August 1987
12. Recommendations on ORT Supply and Distribution Policy Issues in the Philippines; Consultant Report, Steve Fabricant
13. ORT Newsletter, PPS, Volume 1, numbers 1 and 2 - April/July 1988
14. Summary Report, CDD Consultative Workshop - March 1988
15. Healthcom: Philippines, Implementation Plan - March 1988
16. Review of Financial and Other Reporting Forms used at regional, provincial, district levels.
17. DOH Departmental Orders pertaining to CDD Program
18. Regional and provincial annual implementation plans and training plans for 1988 and Progress Reports (Regions VII and VIII)
19. Surveys Conducted for the CDD Program - See Appendix VII

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Appendix IV a.

**DEPARTMENT OF HEALTH**  
Reorganized Structure  
Per E.O. 119, (1987)

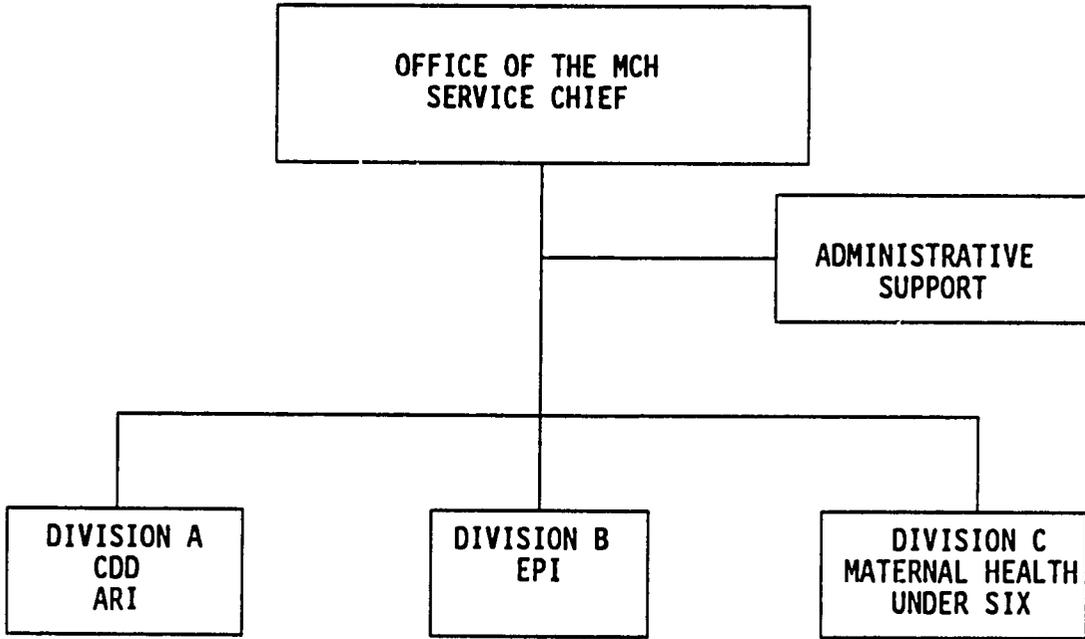


APPROVED:

*[Signature]*  
ALFREDO R.A. BENGZON, M.D.  
SECRETARY

Appendix IV b.

The CDD Program in  
the DOH Organizational Structure





Republic of the Philippines  
Ministry of Health<sup>SO</sup>  
OFFICE OF THE MINISTER  
Manila

May 18, 1988

DEPARTMENT ORDER  
NO. 43-Bs., 1988

SUBJECT: Reorganizing and strengthening the National CDD  
Committee

In order to facilitate the coordinated and efficient implementation of the multipronged approach in the Control of Diarrheal Diseases (CDD), the National CDD Committee created under Ministry Order No. 169-C s. 1984, is hereby reorganized and strengthened.

The following shall compose the National CDD Committee:

- Chairman - Undersecretary for Public Health Services
- Vice-Chairman - Chief, Maternal and Child Health Service
- Secretary - CDD Program Coordinator, Maternal and Child Health Service

Members:

1. Chief, Environmental Health Service
2. Chief, Nutrition Service
3. Chief, Hospital Operations and Management Service
4. Chief, Biologicals Production Service (Oresol Production Unit)
5. Chief, Public Information and Health Education Service
6. Chief, Health Manpower Development & Training Service
7. Chief, Health Intelligence Service
8. Director, Research Institute for Tropical Medicine
9. Director, Bureau of Research and Laboratories
10. Officer-in-Charge of San Lazaro Rehydration Training Center
11. Representative from external donor agencies, other government and non-government organizations

*Logistics*

*Unit, AZID  
WHO, PPS*

The Committee shall be the advisory body that will review and recommend directional plans, broad policies and projects related to CDD. It is delegated as the coordinating body that will monitor and orchestrate the various program components.

The Chairman is authorized to invite representatives from other government agencies, non-government organizations and external assistance agencies who have an interest in CDD activities.

The Committee may also create sub-committees and Ad-Hoc Committees as necessary in the execution of its function.

The National CDD Committee shall meet quarterly or as often as necessary upon recommendation of the Chairman.

The CDD Program Management Staff of the MCH shall serve as the Secretariat of the National CDD Committee and shall be responsible for all documentation and support needs of the Committee.

The Committee is also hereby authorized to request any form of assistance from any agency and unit of the Department of Health and from other agencies with related functions.

This supersedes Ministry Orders No. 193 s. 1980, No. 82, s. 1981 and No. 169-C s. 1984.

  
ALFREDO R. BENGZON, M.D.  
Secretary of Health

Appendix VI

CDD Indicators, Definitions and Measurement Tools

Indicator	Definition	Measurement Tool
ORS Access	% of children under 5 (target population) that live within 5 kilometers or one hour travel time to a trained provider of ORS with adequate supply	DOH/CDD program data
ORT Use	% of all diarrhea episodes in children under 5 treated with ORT. (ORT as used here means the use of ORS to prevent or treat dehydration, proper feeding during the diarrhea episode, and early referral when the condition does not improve).	Standard WHO M/M/T survey
ORS use	as above except refers exclusively to ORS	Standard WHO M/M/T
Proper ORT Use	% of all diarrhea episodes in children under 5 in which: <ul style="list-style-type: none"> <li>a. <u>ORS</u> or a recommended home fluid is proper prepared <u>and</u> properly administered;</li> <li>b. appropriate feeding is carried out during and after the episode; and</li> <li>c. the mother or guardian knows when to seek treatment outside the home</li> </ul>	Special survey
ORS use in public facilities	% of public health facilities in which ORS is available and used to treat diarrhea in children under 5	CDD program management information system (MIS) data
ORS use in private hospitals	% of private hospitals in which ORS is available and used	Sample survey of private hospitals
ORT use among private practitioners	% of private practitioners who administer or prescribe ORS or a recommended home fluid for treating diarrhea in children under 5	Sample survey of private pediatricians

b. Additional Indicators for CDD Monitoring/Evaluations

<u>Indicator</u>	<u>Measurement Tool</u>
Mortality in children under five Diarrhea-associated mortality in Children under five	M/M/T Survey
Diarrhea morbidity (episodes per child per year)	M/M/T Survey
Mothers knowledge of diarrhea prevention measures	KAP
Health practitioner knowledge and practice of ORT - ORS use, breastfeeding and feeding, appropriate use of antibiotics	Health Facilities Survey, KAP
Private sector prescriptions ORS, antidiarrheals	IMS
Private sector sales ORS, antidiarrheals	IMS
Stockouts of ORS	DOH/CDD Program Data
<u>Output Indicators</u>	DOH/CDD Program Data PPS Reports
Courses held, numbers trained public sector, private sector	
Hospital with clinically trained personnel	
Hospitals with ORT Units public, private	
Professional seminars held, attendance	
IEC materials produced, campaigns held	
Newsletters circulated	
Schools with CDD curriculum	

## Appendix VII

### CDD Program Surveys Reviewed

Report of the Joint MOH/WHO/UNICEF/USAID Comprehensive Program Review  
(January - February 1985)

Report on the Joint MOH/MMC/WHO/USAID Comprehensive Program Review  
(December 1985)

ORT/CDD Program Review Supplemental Baseline Data (May 1986)

Pre-Campaign Tracking Study on Diarrhea Management In Regions VI, VII,  
X (December 1987)

Three Year Baseline Market Share Data on the Diarrheal Therapy Market  
1985 - 1987 (April 1988)

Final Report Project Restore, Region VII (June 1988)

Pre-Launch Market Study, Project Hydro Base, Region VI (July 1988)

Pre-Launch Market Study, Project Hydro Base, Region VII (July 1988)

Qualitative Study of Home Made Fluids for Diarrhea, Region X (July 1988)

Project Restore II, Greater Manila (August 1988)

Project Restore IV, Greater Manila (September 1988)

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## Appendix VIII

### Additional Surveys Recommended

1. PPS: KAP survey of private practitioners (baseline)
2. Healthcom, DOH: Container availability survey (decision-making)
3. PRITECH: KAP survey of pharmacists (strategy formulation)
4. COD, DOH: Survey of urban-rural health facility use (decision-making)

Appendix IX

SUPERVISORY SKILLS COURSES  
(through August 1988)

Region	Target	Completed
1	8 provincial, 19 district	1 provincial
2	6 provincial, 13 district	1 provincial
3	11 provincial, 22 district	1 provincial
4	11 provincial, 22 district	1 provincial
5	6 provincial, 14 district	6 provincial
6	9 provincial, 24 district	9 prov 5dist
7	8 provincial, 21 district	8 prov 16dist
8	8 provincial, 15 district	4 provincial
9	6 provincial, 13 district	6 provincial
10	8 provincial, 15 district	8 provincial
11	6 provincial, 16 district	6 provincial
12	6 provincial, 13 district	6 prov 3dist

Appendix X

ORS USE RATE BY REGION, 1987

Region	Expected Total Diarrhea Cases among 0-4 y.o.	Diarrhea Cases seen among 0-4 y.o.	Cases given ORS	ORS Use Rate
I	1,623,885	39,680	36,749	2.3
II	1,049,182	26,328	24,710	2.4
III	2,292,517	54,068	47,936	2.1
IV	2,981,904	50,853	43,095	1.4
V	1,580,634	44,366	40,264	2.5
VI	2,091,922	48,808	39,480	1.9
VII	1,741,328	74,928	69,874	4.0
VIII	1,275,388	30,188	26,509	2.1
IX	1,169,006	40,305	37,177	3.2
X	1,417,240	38,334	32,819	2.3
XI	1,614,581	33,674	28,253	1.7
XII	1,029,736	55,000	45,178	4.4
NCR	2,944,617	41,731	36,213	1.2
PHILS.	22,811,940	572,263	508,577	2.2

Appendix XI

ORS USE AND SUPPLY  
1987

Region	MAXIMUM ORS NEED*	ORS DELIVERED		Cases Given ORS			Packets Used	Packets/Case
		No.	% Max.	0 - 4	5	Total		
I	649,554	140,000	22%	36,749	33,362	70,111	107,450	1.5
II	419,673	140,000	33%	24,710	16,948	41,658	107,003	2.6
III	917,007	140,000	15%	47,936	35,750	83,686	137,603	1.6
IV	1,192,762	262,500	22%	43,095	16,742	59,837	215,000	3.6
V	632,254	290,000	46%	40,264	24,852	65,116	194,325	3
VI	836,769	265,000	32%	39,480	21,742	61,222	259,788	4.2
VII	696,531	310,000	44%	69,874	42,248	112,122	252,000	2.2
VIII	510,155	140,000	27%	26,509	19,845	46,354	98,500	2.1
IX	467,602	140,000	30%	37,177	28,038	65,215	111,973	1.7
X	566,896	152,500	27%	32,819	22,000	54,819	145,905	2.6
XI	645,832	140,000	22%	28,253	19,249	47,502	94,190	2.0
XII	411,894	140,000	34%	45,178	6,305	51,483	121,000	2.4
NCR	1,177,847	55,000	5%	36,213	10,242	46,455	55,000	1.6
PHILS.	9,124,776	2,315,000	25%	508,257	297,323	805,580	1,721,528	2.1
NRTTC		65,300		8,821	4,855	13,676	3,621,265	2.37

\* Maximum need : 40 packets for every 100 diarrhea cases, ( includes allowance for adults).

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Appendix XII

CDD USE RATE OF SERVICE  
1987 & JAN. - JUNE 1988

120  
↓ (at 6000 75 (83)  
over the pop.  
potential use)

*above - not  
necessarily those  
from CDD-101.*

PROVINCE/CITY	USE RATE '87	USE TARGET '88 (desired)	EXPECTED USE '88	ACTUAL USE JAN. - JUNE '88	USE RATE JAN. - JUNE '88
LEYTE	2.0%	5.2%	10,758	4,145	1.3%
SO. LEYTE	3.7%	7.4%	7,564	2,434	2.4%
BILIRAN	3.3%	6.6%	2,454	791	2.1%
E. SAMAR	4.6%	9.2%	9,996	2,860	2.6%
N. SAMAR	4.1%	8.2%	10,804	3,007	2.3%
SAMAR	3.9%	7.8%	9,318	2,661	2.2%
CALBAYOG CITY	2%	4%	1,278	285	0.9%
ORHOC CITY	1.5%	3%	1,034	342	1%
TACLOBAN CITY	1%	2%	674	195	0.6%
REGION	3.4%	7%	64,512	17,496	1.9%

*120*

Appendix XIII

22. IX. 88

**TARGET POPULATION WITH ACCESS AND O R S  
REQUIREMENTS OF REGION VIII FOR  
1988**

	POPULATION 1988	TARGET POPULATION WITH ACCESS 1988 (6.76 x 1988)	POTENTIAL USE 1988	EXPECTED USE 1988	ORS REQUIRMENT FOR YEAR 1988	REMARKS
LEYTE	1133227	115094	322263	16758	67012	
→ SOUTH LEYTE	559600	76508	102222	7564	10256	
BILIRAN	13 816	13278	37178	2454	3316	
SAHAR	420313	42662	119454	9318	37272	
EASTERN SAHAR	302704	38804	108651	9996	30204	
NORTHERN SAHAR	463629	47058	131762	10804	43216	
CALBAYOG CITY	112400	11409	31949	1278	5112	
ORHOC CITY	121303	12312	37474	1034	4176	
TACLOBAN CITY	113087	12024	33667	674	2606	
REGION	3242839	329148	921614	62670	250600	Tacloban City Medical Center included in the computation for expected use and ORS requirement of the whole region.

NOTE: Use rate of the region for 1987 - 3.4%  
Population of the whole region with access - 70%

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Appendix XIV

Table 3a. ORS DISTRIBUTION PATTERN  
1983

Region	Balance EO 1987	Ave. No. Cases per Month (all ages)	No. of mos. ORS stocks will last	Sent April 1988	Mos. ORS stocks will last (at 2 packet/case)	Should have been sent in April based on pRev. yrs. need	Max. to be sent based on max. need
I	32,550	5,843	28 months	30,000	5.3 mos.	105,174	671,317
II	32,997	3,472	4.7 "	30,000	9.0 "	48,608	20,545
III	2,397	6,974	0.17 "	92,502	6.8 "	157,376	952,150
IV	47,500	4,986	4.7 "	72,500	12.0 "	69,804	1,219,158
V	95,675	5,426	8.8 "	30,000	11.6 "	32,556	681,750
VI	5,212	5,102	0.51 "	403,500	40.0 "	122,448	693,292
VII	235,209	9,344	12.6 "	413,500	35.0 "	74,752	722,105
VIII	41,500	3,363	5.4 "	30,000	9.3 "	54,082	526,627
IX	28,027	5,435	2.6 "	30,000	5.3 "	97,030	87,030
X	6,595	4,568	0.72 "	321,000	35.0 "	109,632	559,261
XI	45,310	3,959	5.8 "	30,000	9.6 "	47,503	671,038
XII	19,002	4,292	2.2 "	30,000	5.7 "	35,800	35,006
NCR	0	6,095	0	65,117	5.0 "	67,092	1,227,972
PHILS	593,472	67,759	4.4 months	1,047,267	7.7 mos.	1,083,168	9,535,310

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Annex XV

Composition of Commercial ORS Products

COMPOSITION	GLUCOLYTE	GASTROLYTE	LYTREN	PEDIALYTE	ORESOL	AQUALYTE	ORS
Glucose	166.6 mmol/l	101	50	139	111	111 (20g)	111 (20g)
Sodium	50	50	50	45	90	50	3.5g (KCL)
Potassium	20	20	25	20	20	20	1.5g (KCL)
Chloride	42	52	40	35	80	50	
Bicarbonate	28	18	--		30	Citrate 34mg	No Citrate 29g
Gluconate	5	--	--				
Magnesium	2.5	--	2				
Calcium						4	
Phosphorus						5	
Food Source							
Price/L	23.09	57.00	50.0	70.00	FREE	P57.00	P 7.00
Indication	Prevention Correction	Prevention	Preven- tion	Prevention	Correc- tion	Preven- tion	Preven- tion
COMPANY	Pascual	Rorer	Mead Johnson	Abbott	MOH	Wyeth Suaco	Ciba- Geigy

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Appendix XVI

MANUFACTURERS OF ORS AND THEIR CORRESPONDING PRODUCT  
BRAND NAME

<u>Manufacturer</u>	<u>Brand Name</u>	<u>Packaging / Content</u>	<u>Retail Price</u>	<u>Contents</u>
1. USV-Armour Metro	* Dioralyte	P/P Powder 200 ML x 3's	₱18.10	1. Sodium 35 MEq. 2. Potassium 20 MEq. 3. Chloride 37 MEq 4. Bicarbonate 18 MEq 5. Dextrose 200 MEq.  Total osmolarity is 310 m osmol per liter
2. Pascual Pharex	Glucolyte	P/P Powder 250 ML	₱ 6.40/p (8/12)	1. Sodium Chloride .325 g 2. Sodium citrate .600 g 3. Potassium chloride .375 g 4. Magnesium gluconate .25g 5. Glucose Anhydrous 7.5 g
3. Astra Zuellig Pharma	* Kalium	P/P Dureles 100's (₱96.90) (no info on content)		1. Potassium chloride .75 g
4. SQUIBB Zuellig Pharma	Kristalyte	P/P Powder for Oral Solution 200 ML, 500 ML		Per 1,000 ML. Reconstituted Solution 1. Sodium 51.2 MEq 2. Potassium 25 MEq 3. Chloride 37.5 MEq 4. Citrate 57.4 MEq 5. Dextrose 100 NOSM 6. Sucrose 52 NOSM 7. Caloric contents 136 KCAL.
5. ABBOTT Metro	Pedialyte	P/P Sterile Solution 500 ML - ₱35.00 250 ML with Nipple	₱32.66 27.20	PER LITER 1. Sodium 45 MEq 2. Potassium 20 MEq 3. Chloride 35 MEq 4. Citrate 30 MEq 5. Dextrose 25g. 6. Calories: 100 PER L.

\*Out of Stock in large drugstores and Botica. (8/12/88)

ps

<u>Manufacturer</u>	<u>Brand Name</u>	<u>Packaging</u>	<u>Retail Price</u>	<u>Contents</u>
6. Abbott Metro	Pedialyte -90	Sterile Solution 500 ML.	₱ 38.00 (8/12)	Per Liter 1. Sodium 90 MEq 2. Potassium 20 MEq 3. Chloride 80 MEq 4. Citrate 30 MEq 5. Dextrose 25g. 6. Calories: 100 Per L.
7. Wyeth Suaco	Aqualyte	Oral Electrolyte solution 1 Liter 250 ML.	₱ 54.20 22.90 (8/12)	1 Liter 1. Sodium 50 MEq 2. Potassium 20 MEq 3. Chloride 50 MEq 4. Citrate 34 MEq 5. Magnesium 4 MEq 6. Calcium 4 MEq 7. Phosphate 5 MEq 8. Glucose 20 MEq 9. Calories 80 MEq 10. Osmolarity 269
8. Servipharm Zuellig Pharma	ORS-Oral Rehydration Salts	P/P sachet for 1 Liter solution	₱ 7.85/p	PER PACKET SOLN. 1. Glucose Anhydrous 20 g 2. Sodium Chloride 3.5 g 3. Trisodium Citrate dihydrate 2.9 g 4. Potassium chloride 1.5 g
9. Mead Johnson Phil.	Lytren Powder	1 Packet 250 ML. SOLN	₱ 12.40	1 liter SOLN. 1. Sodium 50 MEq 2. Potassium 25 MEq 3. Chloride 40 MEq 4. Calcium 4 MEq 5. Magnesium 4 MEq 6. Phosphorous 3.5 MEq 7. Glucose 50 MMOL 8. Calorie Content: 205.6 KCAL.

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<u>Manufacturer</u>	<u>Brand Name</u>	<u>Packaging</u>	<u>Retail Price</u>	<u>Contents</u>
10. Rorer	Gastrolyte	5 Grams	₱11.50/p	1. Sodium Chloride; BP-375 MG 2. Sodium Bicarbonate, BP-300MG 3. Potassium Chloride, BP-300 MG 4. Dextrose Monohydrate, BP-4000 MG

SOURCE: PIMS 1987, The indicated retail prices are the prevailing market prices in drugstores as of August 12, 1988

dp

## A. GOOD PRACTICES IN THE MANUFACTURE AND QUALITY CONTROL OF DRUGS<sup>1</sup>

### 1. General considerations

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

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

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

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

Sometimes it occurs that several firms cooperate in the production (including packaging and labelling) of the finished dosage forms of drugs. It may also occur that a finished, packed, and labelled drug is repacked and/or relabelled, giving it a new designation. It should

be pointed out that since such procedures constitute part of a manufacturing operation, they should be subject to the relevant requirements proposed below.

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

### 2. Definitions

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

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

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

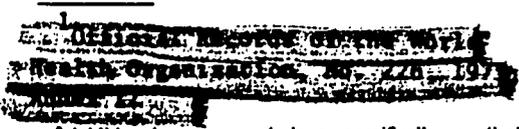
**Starting materials.** All substances, whether active or inactive or whether they remain unchanged or become altered, that are employed in the manufacture of drugs.

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

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

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

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



<sup>1</sup> Additional recommendations specifically applicable to biological products are set forth in a number of sets of Requirements for Biological Substances adopted by the WHO Expert Committee on Biological Standardization and other WHO expert groups and published in the WHO Technical Report Series.

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

### 3. Personnel

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

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

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

### 4. Premises

#### 4.1 General

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

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

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

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

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

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

#### 4.2 Storage areas

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

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

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

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

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

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

(c) rejected and recalled materials and products.

#### 4.3 Special

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

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

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

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

#### 5. Equipment

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

- (1) be suitable for its intended use;
- (2) facilitate thorough cleaning wherever necessary;
- (3) minimize any contamination of drugs and their containers during manufacture; and
- (4) minimize the risk of confusion or the omission of a processing step such as filtration or sterilization.

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

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

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

#### 6. Sanitation

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

- (1) areas to be cleaned, and cleaning intervals;
- (2) cleaning procedures to be followed and, if necessary, equipment and materials to be used for cleaning; and
- (3) personnel assigned to and responsible for cleaning operations.

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

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

#### 7. Starting materials

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

All such materials must be:

- (1) identified, and their containers examined for damage;
- (2) properly stored in quarantine;
- (3) properly sampled by the quality control department;

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

ANNEX 7-D

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

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

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

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

## 8. Manufacturing operations

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

### 8.1 Cleanliness

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

### 8.2 Equipment and containers

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

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

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

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

<sup>1</sup> The simultaneous manufacture, in adjacent areas that are not physically separated, of drugs that are similar in appearance should be avoided.

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

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

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

### 8.4 Manufacturing personnel

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

### 8.5 Documents relating to manufacturing procedures

Documents<sup>1</sup> relating to manufacturing procedures should be prepared for each drug under the direct supervision of experts (see section 3) who have the

<sup>1</sup> Such documents should not be handwritten nor contain handwritten amendments or comments. When necessary they should be rewritten and all outdated instructions withdrawn, to avoid the possibility of re-use. They should be suitable for copying in a manner that avoids any possibility of a transcription error.

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

- (1) its name and dosage form;
- (2) a description or identification of the final container(s), packaging material(s), and labels and, where applicable, of the closure(s) to be used;
- (3) the identity, quantity, and quality of each starting material to be used, irrespective of whether or not it appears in the finished drug (the permissible excess ("overage") that may be included in a formulated batch should be indicated);
- (4) the theoretical yields to be expected from the formulation at different stages of manufacture and the permissible yield limits;
- (5) detailed instructions for, and precautions to be taken in, manufacture and storage of the drug and of "half-finished" products; and
- (6) a description of all necessary quality control tests and analyses to be carried out during each stage of manufacture, including the designation of persons or departments responsible for or charged with the execution of such tests and analyses.

#### 8.6 *Batch manufacturing records*

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

- (1) name and dosage form;
- (2) date of manufacture;
- (3) batch identification;
- (4) complete formulation of the batch (see section 8.5 (3));
- (5) the batch number (or analytical control number) of each component used in the formulation;
- (6) the actual yield obtained at different stages of manufacture of the batch as compared with the theoretical yield (see section 8.5 (4));
- (7) a duly signed record of each step followed, precautions taken, and special observations made throughout the manufacture of the batch;
- (8) a record of all in-process controls followed and of the results obtained;
- (9) a specimen of the actual coded label used;
- (10) identification of packaging materials, containers, and, where applicable, closures used;
- (11) signature of the expert responsible for the manufacturing operations, and the date of his signature;
- (12) an analytical report showing whether the batch complies with the prescribed specifications for

the drug, dated and duly signed by the responsible expert;

- (13) a record of the decision regarding the release or rejection of the batch by the quality control department (see section 10.1 (5)); and
- (14) if the batch is rejected, a record of its disposal or utilization.

#### 8.7 *Maintenance of batch manufacturing records*

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

#### 9. *Labelling and packaging*

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

Prior to packaging and labelling of a given batch of a drug, the manufacturing and control records specified in section 8.6 should show that the batch has been duly tested, approved, and released by the responsible quality control expert. Prior to being issued, all labels for containers, cartons, and boxes and all circulars, inserts, leaflets, etc., should be examined and released as satisfactory for use by the designated person(s) (see section 10.1 (4)).

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

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

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

- (1) the name of the drug;
- (2) a list of the active ingredients, showing the amount of each present, and a statement of the net contents, e.g., number of dosage units, weight or volume;
- (3) the batch number assigned by the manufacturer;
- (4) the expiry date, if required (see section 10.1 (8));
- (5) any special storage conditions or handling precautions that may be necessary;

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- (6) directions for use, and warnings and precautions that may be necessary; and
- (7) the name and address of the manufacturer or the person responsible for placing the drug on the market.

10. The quality control system

10.1 *Quality control department*

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

The quality control department should have the following principal duties:

- (1) to prepare detailed instructions, in writing, for carrying out each test and analysis;
- (2) to release or reject each batch of starting material;
- (3) to release or reject "half-finished" products, if necessary;
- (4) to release or reject packaging and labelling materials and the final containers in which drugs are to be placed;
- (5) to release or reject each batch of finished drug that is ready for distribution;
- (6) to evaluate the adequacy of the conditions under which starting materials, "half-finished" products, and finished drugs are stored;
- (7) to evaluate the quality and stability of finished drugs and, when necessary, of starting materials and "half-finished" products;
- (8) to establish expiry dates and shelf-life specifications on the basis of stability tests related to storage conditions;
- (9) to establish, and when necessary revise, control procedures and specifications; and
- (10) to be responsible for the examination of returned drugs, to determine whether such drugs should be released, reprocessed, or destroyed. Adequate records of the disposition of such drugs should be maintained.

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

The quality control department should maintain adequate analytical records concerning the examination of all samples taken. Such records should include:

- (a) the result of every test performed, including observations and calculations, relating to compliance with the established specifications;
- (b) the source of the specifications used;
- (c) the signature(s) of the person(s) who performed the quality control procedures; and
- (d) a final review, the decision taken, and a dated endorsement by a duly authorized expert.

10.2 *Quality control laboratory*

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

- (1) be adequately staffed and fully equipped for performing all quality control tests and analyses required during and after manufacture;<sup>1</sup>
- (2) be supervised by a qualified expert (see section 3).

11. *Self-inspection*

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

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

12. *Distribution records*

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

13. *Complaints and reports of adverse reactions*

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

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

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Appendix XVIII

Estimate of the Costs Associated with Renovating and  
Equipping the Biological Production Services (BPS)  
to engage in the Manufacture of ORS

Without obtaining quotations from local contractors in the Philippines it is difficult to estimate the costs associated with renovating the space at BPS to produce ORS that complies with international standards. The estimates presented below are based on cost information contained in WHO/CDD/SER/85.8, "Oral Rehydration Salts, Planning, establishment and operation of production facilities," and derived by PRITECH/PATH in the course of equipping ORS production and warehousing facilities in several different developing countries.

	<u>Cost in US\$</u>
1. Renovation of Production Facility and Warehouse (= 7,000 sq.ft.)	
build walls	5,800
tile walls	2,500
install aluminum windows	700
install terrazzo floors	12,900
prepare ceiling	2,100
install ductwork and A/C and dehumidifier	39,600
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subtotal 1	63,600
2. Production Equipment	
automatic sachet packaging machine	65,000
granulating and sieving machine	24,000
tray dryer	18,200
drum hoop mixer	3,500
platform scale	3,300
hand lift truck	4,100
generator	12,500
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subtotal	130,600
(freight/insurance @ 25%)	32,650
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subtotal 2	163,250

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3. Quality Control Equipment <sup>1</sup>	14,500
(freight/insurance @ 25%)	3,625
subtotal 3	18,125
 Total cost of renovation and equipping: (subtotals 1,2, and 3)	 \$244,975

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<sup>1</sup>The following equipment is included in this category: bench scale, analytical balance, portable pH meter, moisture balance, dessicator with vaccuum connector and three-way valve, dessicator without vacuum and dessicator plate.