CEREAL BASED ORAL REHYDRATION SOLUTION AND THE COMMERCIAL PRIVATE SECTOR

CONFERENCE PROCEEDINGS
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LIST OF ABBREVIATIONS

A.I.D.	Agency for International Development
CARE	Cooperative for American Relief Everywhere
CBORS	Cereal based oral rehydration solution
CDD	Control of Diarrheal Disease
FHI	Family Health International
GORS	Glucose based oral rehydration solution
ICDDR,B	International Center for Diarrheal Disease Research, Bangladesh
ICHF	International Child Health Foundation
JHU	Johns Hopkins University
MSH	Management Sciences for Health
ORS	Oral Rehydration Solution
PATH	Program for Appropriate Technology in Health
PSI	Population Services International
PRITECH	Technologies for Primary Health Care
UNICEF	United Nations Children's Fund
WHO	World Health Organization

PREFACE

On March 27, 1992, PRITECH sponsored a one-day meeting entitled *Cereal-Based ORS and the Private Sector.* Participants included officials from WHO, UNICEF, and A.I.D as well as diarrheal disease experts and marketing specialists from public health organizations such as Population Services International, CARE, Management Sciences for Health, and Program for Appropriate Technology in Health. (A complete list of participants can be found in Appendix 8.)

PRITECH convened this meeting in order to review the status of ORS products within developing country markets and to develop recommendations for the approach PRITECH should take in regard to the arrival of commercial (CBORS) products in these markets. Morning presentations on commercialization of ORS products and CBORS were followed in the afternoon by discussion and the development of recommendations. The day's proceedings are summarized in the following pages.

INTRODUCTION

PRITECH Project Director Glenn Patterson and PRITECH Project Officer Alfred Bartlett provided the framework for the day's discussion in their opening remarks. These remarks are summarized below.

Why a meeting on cereal-based oral rehydration solution (CBORS) and the commercial private sector? While the vast majority of A.I.D.-supported activities have and will continue to support the government sector, it has become increasingly apparent that mobilization of the resources of the private sector is critical in order to reach public health objectives successfully. The interest in private health services from public health professionals is a recognition that in most populations the private sector already provides a significant share of health care, even for poor families. As we increase the interaction with the private sector, we need to keep our eye on a main goal of public health: improving access to and use of preventive and curative health services. Understanding the appropriate roles for private health care service providers in a national public health program is a new and complicated topic; no single discipline has all of the needed answers. Therefore, this meeting of experts with a broad variety of experiences was called to develop ideas about how best to encourage useful private sector effort.

While the main focus of PRITECH's programs has been and will continue to be on the public sector, PRITECH has taken some first steps towards interacting with the private sector. The PRITECH approach has been to act as a catalyst, encouraging the involvement of the private sector and fostering cooperation between private and public sectors in the area of oral rehydration therapy. In order to improve PRITECH's involvement with the private sector, PRITECH seeks guidance about the approach it should take in regards to a new oral rehydration product: CBORS. We hope that this meeting will provide recommendations and advice to guide PRITECH as it continues its dialogue with private sector firms. More broadly, the results of this meeting, and the results of PRITECH's efforts, will assist A.I.D. as it tries to assess the opportunities for encouraging the private sector to help achieve public health objectives.

PRESENTATIONS

What follows are summaries of the five presentations. These were based on background papers which can be found in their complete form in the appendices. Each presentation was followed by a question and answer period. Those discussions are summarized here as well.

CEREAL BASED ORAL REHYDRATION THERAPY FOR DEHYDRATING DIARRHEA: POSSIBLE OPTIONS

Dr. David Sack, Medical Officer, PRITECH

CBORS developed as a response to lack of glucose or sucrose in the home. Cereals are available in more households, and studies have determined that they can be substituted for the sugars and are, in some cases, better. Conclusions from clinical studies include the following findings: CBORS is safe, due to lower osmolality and wider latitude in mixing amounts; CBORS is as efficacious as glucose oral rehydration solutions (GORS) in rehydrating patients with dehydration due to diarrhea; in cholera and cholera-like illness CBORS is often more efficacious than GORS, as determined by lower stool output. However, nutritional benefits of CBORS are unknown - it should be noted that the increased calorie density relative to GORS does not approach the caloric requirement for children. Further studies are needed to compare food plus GORS to food plus CBORS, and to determine the effect of CBORS and GORS on appetite/anorexia.

DISCUSSION

Is CBORS appropriate for use with very young children who are either at risk of glucose malabsorption or who are breastfeeding?

In WHO studies of three special populations (children 0-5 months, severely malnourished children, and children with high glucose malabsorption), CBORS was shown to be as acceptable as GORS.

Has the efficacy of homemade CBORS been compared with sugar salt solution (SSS)?

No studies have been done on this subject; hypothetically CBORS would be superior because of the wider range of error allowed for a "safe" solution.

ORS COMPOSITION: A WHO PERSPECTIVE

Dr. Nathaniel Pierce, World Health Organization

At least three approaches to improving the efficacy of ORS solution have been identified:

- Give standard GORS solution with frequent feedings of a cereal-based diet;
- Reduce the glucose and sodium content of ORS;
- Replace glucose in GORS with 50g of precooked rice powder.

The first two options listed are recommended by WHO and UNICEF although they have not been adequately or completely implemented. Comparative advantages and disadvantages of each option were reviewed in detail, and can be found in Background Paper #6.

Studies comparing CBORS with GORS have shown greatest effect of CBORS on children and adults with cholera, with 36% stool reduction in the first 24 hours. In children with non-cholera diarrhea, stool reduction averaged 18%. However, children in this study were not fed according to WHO guidelines, which may have exaggerated the difference between GORS- and CBORS-related stool reduction. One study of children with severe, life-threatening, non-cholera diarrhea compared feeding accompanied by GORS and feeding accompanied by CBORS. No difference in outcome was observed within the first 24 hours or during the total duration of illness. Another study looked at the efficacy of "low-osmolarity GORS" in children with severe, life-threatening diarrhea. Preliminary results indicate that low-osmolarity GORS may lead to reduced stool output, although the population studied may have had unusually high prevalence of glucose malabsorption. These results will need to be confirmed in other child populations before a final determination on this issue can be made.

In summary, it has not been firmly established that any of these approaches is significantly more efficacious than standard GORS therapy for children with acute non-cholera diarrhea, and no alternative approach appears superior to GORS plus feeding. Studies to more precisely define the efficacy of these approaches in comparison with standard GORS are underway and will be completed by mid-1993.

DISCUSSION

Will individual caretakers implement recommendations fully enough so that clinical results would be replicated in the community setting? Will this concern will be addressed in future studies? Shouldn't all recommendations consider the implications of constraints on caretaker behavior (such as time) in order to be effective?

WHO focuses on improving treatment at the health facility level, where current practices of health workers and health worker communications with caretakers with regard to correct feeding and rehydration needs to be improved. Therefore, although studies of community behavior are needed, WHO trials focus on ORS use at health facilities.

Isn't it difficult to package CBORS so that the ingredients remain properly mixed?

The assumption that mixing CBORS is difficult because of the different densities of the ingredients was refuted by a description of Galactina's solution to the problem: The cereal is cooked and salt is added *before* the mixture is dried. Mixing of dry ingredients, whether GORS or CBORS, is generally perceived to be problematic.

What was the data on failure rates for orally administered ORS in the comparative studies cited during the presentation? High failure rates are important variables to be considered.

Failure rate data will not be available until the studies are fully analyzed and published.

PRITECH'S INVOLVEMENT IN THE PRIVATE SECTOR

Mr. Camille Saade, Marketing Specialist, PRITECH

PRITECH works with the commercial private sector to complement its CDD public health efforts, to increase ORS availability/access/use, to promote the ORT message, and to help prevent/reduce diarrhea incidence through promotion of breastfeeding and handwashing. PRITECH seeks to form partnerships between the private and public sector, and limits its own role to that of catalyst and marketing consultant. The goal of these efforts is sustainability of CDD efforts. Data from Honduras illustrate that, traditionally, the top 9% of the socioeconomic "pyramid" are served primarily by the private sector, while the bottom 20% are served by the Ministry of Health. The collaborative aim between the public and private sectors can be to reach the 71% segment of the population which is in the socioeconomic middle, and is not targeted currently by either the public or the private sector.

Profitability has been a main driving force for the commercial private sector, as heavy promotion of high-profit antidiarrheals demonstrates. Traditionally, ORS products

occupy only a small share of the diarrheal products market in most countries, whereas motility inhibitors, intestinal adsorbents, antibacterials and other antidiarrheals control the greatest share of the market. Nevertheless, concerns about corporate image and social responsibility seem to motivate private companies sufficiently to invest in marketing ORS products. In order to make ORS profitable, however, a very high volume of sales is needed to compensate for the low profit margin. In some countries constraints such as government taxes on raw materials and limits on distribution exist. A detailed explanation of the PRITECH strategy was presented, and is discussed in Background Paper #1.

DISCUSSION

Has the impact of commercial private sector activities related to CDD been monitored and/or evaluated?

Although no results are available to date, PRITECH expects to have results from Pakistan soon. It is extremely difficult to measure the separate influences of the public sector and the commercial private sector on community and individual behavior. However, outcomes such as sales levels and ORS availability in retail outlets can be measured.

In Pakistan, government procurement of ORS is declining and private sector distribution of ORS is increasing. Are different segments of the population being reached by these different sources? In particular, are the neediest people being reached by the commercial private sector?

Historically, the public sector has targeted its efforts toward the lowest groups on the socioeconomic scale, while the commercial private sector has focused on the middle and upper end of the scale. In response to PRITECH's interventions, the private sector has recognized the market potential of lower socioeconomic groups, and has responded by attempting to reach these groups by making some commercial products available in rural areas where government facilities are scarce. No studies looking at this issue with respect to ORS have been done.

What is the proper role of the commercial private sector? Is the intent to shift part of the public health burden from the public sector to the commercial private sector? Or do we wish to expand the existing public sector distribution system by adding the strength of the commercial private sector to the public sector? Or do we wish to do both?

PRITECH primary objective in Pakistan was to complement the public sector. If this resulted in some shifting of the burden, that would be an added benefit.

ORS AND THE COMMERCIAL MARKETPLACE IN DEVELOPING COUNTRIES

Dr. William Jansen, Assistant Director, Technical Division, PRITECH

ORS was developed to meet the needs of the public sector, which is not the usual way a product is developed. The generic, public sector, low-profit, "low-tech" image of ORS has adversely affected both producers' and prescribers' willingness to promote it.

Within the commercial marketplace, well-established antidiarrheal products are the main competition to commercial ORS products. One of their main strengths is their claim to stop or reduce diarrhea, thereby meeting a major consumer demand. Low retail price and non-medical image of ORS further hinders ORS marketability. However, use of commercial distribution channels can increase considerably the availability of and access to ORS products.

DISCUSSION

How does working with the private sector serve public health objectives? There are three possibilities:

- *Expand private sector activities to target the lowest socioeconomic groups;*
- *Let the commercial private sector take on part of public sector health activities to relieve the burden, and to allow the public sector to focus on the most underserved people;*
- *Make rehydration instead of other inappropriate treatments the desired treatment at all levels of the population.*

Data from Honduras show that, even though the private sector reaches the top 9% of the population while the public sector reaches the bottom 20%, a very large middle segment of the population remains underserved. One should not expect that any company will normally target the poorest segments. However, companies may be persuaded to use innovative strategies to reach lower-income people than they normally would. In addition, campaigns targeted at higher socioeconomic levels also have an impact on attitudes and behaviors of other segments of the population.

Why is GORS being presented as a commercial failure when we know that there are 450 ORS producers in the world today compared to none ten years ago, and when PRITECH effort in Pakistan has been so successful? In addition, several companies have successfully overcome numerous constraints outlined above and will continue to do so with help from PRITECH and other public health organizations.

GORS is not a commercial failure, but we should not underestimate the deleterious effect of identified constraints on GORS appeal.

THE ARRIVAL OF CBORS PRODUCTS: A MARKET ANALYSIS

Dr. William Jansen, Assistant Director, Technical Division, PRITECH

Companies perceive CBORS to have the following advantages:

- CBORS represents a "new" technology;
- It is free of public sector definitions, therefore allowing a company to define its product image and enabling greater latitude over price setting;
- CBORS can be viewed as a replacement for restricted antidiarrheals because it appeals to consumer demand to reduce diarrhea;
- It gives companies the opportunity to expand their existing ORS-product line.

Constraints to CBORS include technical limitations in production and need for new specific marketing expertise.

DISCUSSION

Will the marketing of CBORS as a "new and improved" ORS product degrade the image of GORS?

While this is of concern, in the case of Pakistan, Wilson's added a CBORS product to its GORS products in order to expand its product line. This demonstrates the basic marketing principle that if a product is added to an existing product line, overall sales increase.

It seems that the focus on public health is being submerged in marketing issues. For example, will greater price flexibility and thus higher prices exclude some consumers? In addition, is it a mistake to increase dependency on yet another "magic" product instead of promoting continued fluids and feeding?

It is imperative for public health officials to understand the marketing perspective although we may not, agree with it. A goal of any public health effort is to improve caretaker behavior, and the commercial private sector offers an avenue to this end which should not be ignored. In addition, the commercial private sector may already be reaching a large portion of the population, including those of low socioeconomic status, as evidenced by the significant amount of money spent by Pakistani families on high-priced diarrhea products. Working with the commercial private sector allows public health officials to improve the messages and services reaching consumers.

Given that polypharmacy is the rule in many countries, won't the addition of a new product simply result in continued polypharmacy?

While not all undesirable products will be replaced, the market share of "good" products can be increased. In addition, government regulations have far more impact on dangerous polypharmacy than the introduction of new products. For example, the Pakistan government has banned the antidiarrheal/antibacterial combination of drugs, which has substantially reduced the market share of that category of diarrhea products.

DEBATE

What follows are the main points of debate that were discussed during the afternoon. One side is presented first, followed by the opposing view. The four main points of agreement are listed in the conclusions. The two main products which resulted from the debate are presented separately in the following sections of the report.

THE NEED FOR GUIDELINES

Point:

WHO has been conducting research on CBORS, which will be completed in mid-1993. Until these data have been analyzed it may be premature to create and promote a set of guidelines regarding CBORS. The research may reveal that another solution, such as low-osmolarity ORS, is more effective. WHO is not in a position to issue any such guidelines.

Lack of guidelines should not prevent the use of CBORS in cholera treatment centers where medical personnel have the expertise to prepare and administer the product, as is clearly shown by the example of ICDDR,B.

Counterpoint:

WHO studies have shown that CBORS reduces stool output by 37% for cholera patients. However, in the absence of guidelines, CBORS has not become the standard treatment for cholera. (One notable exception is the ICDDR,B.) In general, cholera treatment centers do not know if preparing CBORS for their cholera patients is an approved procedure or not.

Irrespective of public sector positions, some companies have started producing CBORS. Due to market factors already discussed, this occurrence will probably continue. Without guidelines, public health officials have few tools to advise companies on the issues related to inappropriate marketing and production. For example, Wilson's of Pakistan recently launched their first CBORS product. While PRITECH staff knew of this product, they did not know how to guide the company. The presentation of this new product raises several potential issues, including a package picture that presents a bowl of CBORS, which may be interpreted to look like soup. This may have an undesirable result if it were to lead to a reduction in feeding during diarrhea.

Guidelines are needed which outline the formula, or the range of ingredient amounts within which a safe and effective formula can be made. Guidelines are also needed to prevent companies from making potentially harmful mistakes in production or marketing. These guidelines would be cautionary, as opposed to promotional, in nature.

POTENTIAL IMPACT OF CBORS

Point:

Having one product minimizes confusion and reduces competition. A great deal of time, money and effort has been spent in launching and establishing GORS as *the* diarrhea treatment. This effort has been successful. Even if research identified a better rehydration solution, an argument can be made for only a single solution to be promoted. Promotion of more than one ORS could lead to confusion. For this reason many countries choose to promote a single package size. In addition, there is concern that introduction of a new product may damage the hard won progress of the original product.

Recent research indicates that CBORS is not any more effective than GORS when each is supplemented with food, except with cholera. However, the number of cholera cases compared to the overall number of diarrhea cases is small. If further research confirms these preliminary results, no reason will exist for making the monumental shift from promotion of GORS to CBORS in public sector CDD programs.

Therefore, companies should not be encouraged to adopt new CBORS products. Companies should continue to be encouraged to improve and increase their promotion of standard ORS (GORS).

Counterpoint:

CBORS should not be viewed in opposition to GORS, but mainly in terms of opposition to the antidiarrheals. ORS probably will be a more formidable competitor to the antidiarrheals if the ORS product line is increased. Although in practice CBORS may not be significantly "better" than GORS, companies will be interested in any association between CBORS and reduced stool output. Companies may view this association as a mechanism to achieve greater sales of ORS in general (CBORS in particular) as antidiarrheals are discredited while the consumer demand for products to stop diarrhea continues.

Marketing principles hold that the broader the range of products available, the greater the market will expand. In some countries it is becoming increasingly difficult to interest companies in producing low-cost GORS products (sachets). Companies are already looking for new options and some are expressing interest in CBORS.

In CDD this means that when more types of ORS products (GORS, CBORS, flavored colored etc.) are available, more ORS products will be sold to consumers.

Consensus was reached that not enough is known about the impact of commercial ORS products upon CDD programs and diarrhea case management. Participants agreed that in countries where commercial ORS manufacturing, particularly of CBORS, exists, the public health community should take the opportunity to learn from the experience. A.I.D. reiterated the importance of protecting the hard-won gains of the world-wide GORS effort led by WHO; programs supported by A.I.D. will be appraised carefully to avoid any actions which might damage the GORS program achievement.

CONCLUSIONS

Participants agreed on the following recommendations for PRITECH's involvement in the commercial private sector:

- PRITECH should continue to be involved with the private sector, especially to urge the promotion of GORS and continued feeding during diarrheal episodes.

  Toward this end, PRITECH should strive to replicate its experience with firms and commercial ORS products in Pakistan within other countries where market environments appear favorable.

- PRITECH should not actively promote the adoption of CBORS products by companies. However, PRITECH should engage in a constructive dialogue with firms that decide to manufacture CBORS products in order to provide input which could help minimize any potential negative impacts.

To assist in this process, PRITECH should develop a set of cautionary guidelines to be used when working with companies that decide to produce a CBORS.

- PRITECH should implement research over the next year in countries where commercial CBORS products exist in order to learn about the impact of these products as well as to refine the cautionary guidelines.

RESEARCH QUESTIONS

The following research topics were developed by the group on the premise that, if a CBORS has already appeared on the market, we should use the opportunity to learn more about its impact. It was noted that differentiating between the effects of CBORS commercialization on ORT use from other variables influencing ORT use will be difficult. The issues which emerged from this meeting need to be molded into specific research questions which can then be investigated in a programmatic context. Any PRITECH research effort would focus on categories one through four. The issues in category five are probably best addressed by clinical research which is beyond the scope of PRITECH's mandate.

1. CARETAKER BEHAVIOR:

- Do caretakers know that feeding + fluids is appropriate home management of diarrhea? How does CBORS affect such knowledge (i.e., does it increase this knowledge or interfere with it?)
- Do caretakers understand adequately instructions on CBORS packets?
- Do caretakers confuse CBORS with food? How does the use of CBORS affect feeding?
- How does the addition of CBORS products to available ORS products affect correct treatment of diarrhea? Does a variety of ORS products (including GORS and CBORS) lead to more confusion in the minds of caretakers concerning optimal diarrhea case management in the home?
- How does any commercial ORS product affect home case management of diarrhea?

2. PRIVATE HEALTH-CARE PROVIDER BEHAVIOR:

- How does CBORS affect health-care practitioner case management in health-care facilities? Does the presence of alternative ORS products help reduce the tendency among many private practitioners to prescribe other drugs for diarrhea along with or instead of ORS?

- How does commercial production of CBORS affect the ways companies decide to promote these products by trained pharmaceutical salespeople (also known as "detailing") to private practioners?

3. ORS CONSUMPTION PATTERNS:

- Does CBORS address the consumer's desire to stop the diarrhea?

- How does the presence of a CBORS commercial product affect the use of ORT at home in relation to other antidiarrheals (i.e., does it increase the use of ORS and reduce the use of antidiarrheals)?

- What is the price sensitivity of CBORS related to how frequently the caretaker needs to purchase it? How does price affect the use of the product by different socioeconomic groups?

- Does commercial production of CBORS affect the ways companies decide to distribute ORS products to rural areas and other underserved geographic areas?

- Who uses CBORS (which consumers, which health-care providers)? For what types of episodes do they use it? How does this change over time?

4. PERFORMANCE OF ORS IN THE MARKET:

- Can commerical CBORS products help reduce the market share currently occupied by antidiarrheals? Can alternative marketing of GORS also help reduce the market share occuped by antidiarrheals? (These options would be more effective in conjunction with regulatory restrictions on antidiarrheals.)

- How does the addition of CBORS to the market affect the use of ORS? Does CBORS displace GORS? Does it displace antidiarrheals?

- Does the presence of a greater number of ORS products (cereal- and glucose-based) increase the total ORS market?

5. CLINICAL PERFORMANCE:

- Is CBORS less likely to be associated with hypernatremia?
- What are the effects of CBORS on anorexia, feeding, and growth? (Does it offer an advantage over GORS?)

PRECAUTIONS FOR COMPANIES INTRODUCING

COMMERCIAL CBORS PRODUCTS

The following cautionary guidelines were developed at the conference for which companies interested in producing CBORS to follow. The aim of these guidelines is to maximize the benefit and minimize the potential harm of companies operating in the ORS field.

- ***CBORS products <u>should</u> be promoted together with continued feeding and breastfeeding.***

  Because of its ingredients, CBORS has the potential of being confused as food by consumers. Such confusion should be avoided since CBORS is not a food, and does not contain sufficient nutrient value to substitute for food or breastmilk. By positioning cereal-based products as a pharmaceutical product rather than a food the risk of confusion with food is minimized.

- ***Cereal-based oral rehydration solution (CBORS) products should <u>not</u> be positioned as food.***

  As with other ORS products, CBORS products should be used by the caretaker along with continued feeding or breastfeeding of the child to optimize diarrheal case treatment and to promote more rapid recovery. Optimal diarrhea case treatment for infants includes continued breastfeeding. Breastfeeding is also an important method for helping to prevent diarrhea.

- ***Companies should <u>not</u> promote CBORS products in terms of improved nutritional benefit over other oral rehydration products.***

  The nutritional value of the cereal or starch in CBORS is minimal and does not replace the need for continued feeding during the diarrheal episode.

- ***CBORS products should <u>not</u> be co-positioned with infant formula products or breastmilk substitutes.***

  Co-positioning or promoting an ORS product along with infant formula products is inappropriate for optimal child health as reliance on infant formula reduces use of breastmilk.

- ***Companies <u>should</u> position CBORS products to compete with existing antidiarrheals in the marketplace.***

  Antidiarrheals and other diarrhea products often have larger market shares than does ORS. Since oral rehydration is the optimal treatment for most diarrheas, ORS is a far better product clinically than antidiarrheal products.

- ***CBORS products should <u>not</u> be co-positioned with antidiarrheals or other irrational diarrhea drugs.***

  Oral rehydration is the best treatment for most diarrheas. Antidiarrheals and other non-ORS diarrhea drugs are useless or even potentially harmful to children with diarrhea. Co-positioning any ORS with antidiarrheal products would detract from optimal diarrhea treatment regimens.

- ***Promotional claims associating CBORS with reducing stool volume or the duration of the diarrheal episode <u>should</u> be avoided.***

  Although recent data suggest that CBORS can reduce stool output among cholera patients (by around 38%) data also indicate that there is no significant stool reduction benefit of CBORS over GORS when GORS is given along with food in non-cholera diarrheas.

- ***CBORS products <u>should</u> <u>not</u> be promoted in a manner which denigrates glucose-ORS products.***

  Oral rehydration is essential for preventing deaths due to dehydration caused by diarrhea. Glucose-based ORS remains the World Health Organization standard for treating diarrhea. For the greatest public health benefit, CBORS products should be introduced in a manner in which the total number of consumers and health practitioners practicing ORT increases (i.e., by adding new segments of the consumer population to the list of ORS users).

- ***Detailing of CBORS products to physicians and pharmacists <u>should</u> highlight that ORT is a more appropriate diarrheal treatment regimen than antidiarrheal products.***

  Information from some countries suggests that private practitioners are often reluctant to prescribe only ORS for diarrhea and, instead prescribe many different anti-diarrheal products at one time. This practice tends to increase the prevalence of antidiarrheals and to slow the growth of ORS sales.

- ***Companies <u>should</u> strive to distribute CBORS products wherever antidiarrheal products are sold.***

  Antidiarrheal products are often well established in the market and enjoy extensive distribution networks. CBORS and other ORS products should be distributed in such a fashion that they are available as an alternative wherever antidiarrheals are sold.

- ***Product-use instructions <u>should</u> limit the period of time for consuming CBORS after mixing to a maximum of 10 hours.***

  After mixing with water, CBORS ferments more quickly than glucose-based ORS. CBORS also provides a rich medium for multiplication of harmful bacteria, posing a risk of additional illness to an already sick child. To reduce the risk of fermentation, product use instructions should clearly state that mixed CBORS ideally be used within a 6 hour period and that once 10 hours has elapsed after mixing, any remaining mixture should be discarded.

- ***Manufacturing and quality control standards for CBORS in all its forms (liquid, granules, powder, etc.) <u>should</u> be the same as those applied to glucose ORS.***

  CBORS is an ingested medicinal product which deserves high standards of production and quality control similar to that utilized in the manufacture of other pharmaceuticals. Production and quality control guidelines exist for glucose ORS, which are good standards to utilize.

- ***Steps <u>should</u> be taken to avoid the chance of infestation of the cereal components of CBORS, both prior to and during production and after packaging (including during the shelf-life of the product).***

  By their nature, cereals and cereal powders are subject to infestation. Good quality control measures should be adopted to avoid infestation (particularly if the product need not be boiled by the consumer before use).

- ***To obtain the optimal efficacy in diarrheal treatment, CBORS products <u>should</u> conform to acceptable limits of ORS composition.***

Although no official standards exist for CBORS formulations, experience with CBORS to date indicate that, for safety and efficacy, CBORS formulations should conform to the following parameters of the solution when prepared according to the instructions given on the package:

Total osmolarity:	200 - 300 mmol/liter
Sodium:	60 - 90 mmol/liter
Potassium:	15 - 25 mmol/liter
Citrate: (or bicarbonate:	8 - 12 :nmol/liter 25 - 35 mmol/liter)
Cereal/powder:	50 g/liter

APPENDIX 1

Background Paper No. 1

SUMMARY OF PRITECH INVOLVEMENT IN THE COMMERCIAL PRIVATE SECTOR

by

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THE PRIVATE SECTOR: A IMPORTANT SOURCE OF HEALTH CARE

Data from developing countries demonstrate that an ever-greater amount of health care is being provided by the private sector. In some countries, the private sector is the health care provider of first choice for most of the population. Data from the Dominican Republic (Bitran, 1989) illustrates this. Bitran found that, of 219,000 individuals in the city of Santo Domingo who sought curative services from health care providers during a two-week recall period, 56% turned to private health care facilities for those services.

In other countries, while public sector outlets constitute the main source of health care for most of the households, the private sector offers health services to a substantial percentage of households. Data from Zaire (Table 1) indicate that public sector health centers represent the health facility of choice for 66% to 72% of the respondents while private dispensaries are the source of choice for 28% to 34%.

TABLE 1

Choice of Health Facility Type
in the Kisantu and Bokoro Regions of Zaire

Type of Facility	Kisantu			Bokoro		
	Kikonka	Kipako	Total	Tolo	Semend-wa	Total
Health Center	68.1%	63.9%	66.1 %	49.4%	86.9%	72.0%
Private Dispensary	31.9%	36.1%	33.9 %	50.6%	13.1%	28.0%
TOTAL	100%	100%	100%	100%	100%	100%

from: REACH, 1989

The private sector can even be an important source of health care among low-income households in developing countries. A 1986 study (Alderman and Gertler, 1988) of low-income urban households in Pakistan found that 73% of the households took pediatric cases to private physicians or chemists (pharmacists). Data from the same study suggest that access to public sector health facilities does not necessarily result in more frequent use of public facilities over private sector sources (Table 2). Some 82% of the low-income households reported availability of public sector health services, but less than 10% utilized those services.

TABLE 2

Utilization of Health Care Facilities
by Low Income Urban Households in Pakistan
(1986 Survey Data)

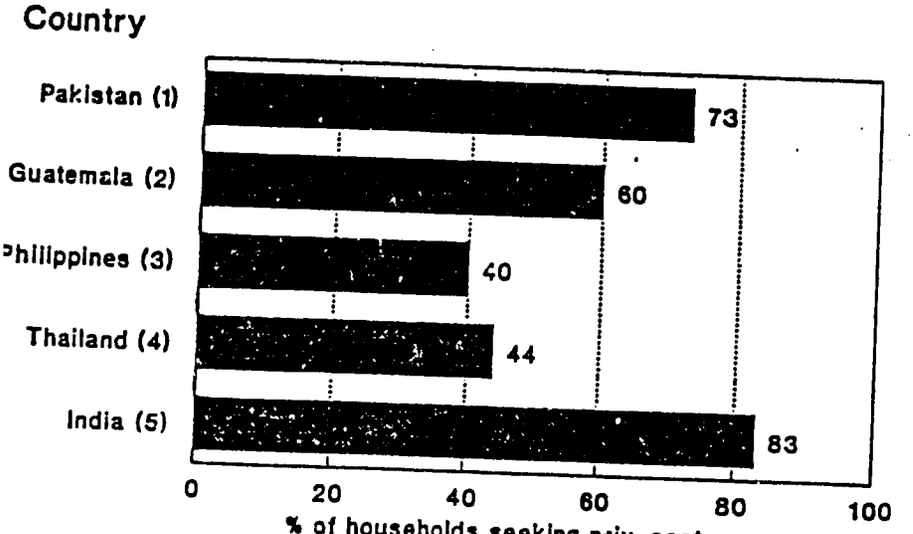
	Type of Facility		
	Government Sector	Private Sector	
		Chemist	Doctor
% of Households Reporting Service Available	82.0	75.9	91.2
% of Households Using Service Conditional on Illness	9.4	16.1	15.9

from: Alderman and Gertler, 1988

For diarrheal case treatment specifically, the private sector is frequently a significant source of care (Figure 1). A KAP study (Indian Market Research Bureau, 1988) of 5,310 women in rural India found that of those who sought treatment for their children with diarrhea, 83.3% consulted a private practitioner while only 7.5% went to a public sector health center. In Guatemala, a survey (Hornik et al., 1989) of more than 9,000 mothers of children (under the age of 5 years) with diarrhea found that the first choice of health care was as follows: public health facilities, (36%), health volunteers (4%), private physicians (33%), and pharmacies or stores (27%). About 60% of Guatemalan mothers, therefore, sought a private sector source of health care for children with diarrhea.

Philippine survey data (Zimicki, 1988) show a similar pattern. Mothers of young children reported that the most common source of advice for diarrheal episodes in their children was the private sector (40%), followed by public sector health personnel (20%), government hospitals (12%), friends and relatives (12%) and traditional healers (9%). A survey of 1,619 mothers in northern Thailand (Varavithya et al., 1989) indicated that, during an episode of diarrhea in their children, 44.3% utilized private sector sources (either by purchasing drugs from stores or consulting private clinics); 46.3% turned to public sector sources (local health centers, hospitals or village health volunteers), while the remaining 9.04% utilized home remedies or consulted traditional healers.

FIGURE 1
Household Use of Private Sector Sources for Treating Diarrhea in Children



1)Alderman & Gertler 2)Hornik et al,1989
3)Zimicki, 1988 4)Varavithya et al, 1989
5)Indian Market Research Bureau, 1988

However, the important role that the private sector already plays in the provision of health care services for diarrheal diseases should be acknowledged and this channel for reaching households utilized in more systematic ways. A place exists for the private sector within CDD efforts because public sector only approaches to CDD are constrained by two basic shortcomings. One is a structural limitation in extending CDD services to the general populace (i.e. coverage). The other is a limitation on long-term sustainability.

PUBLIC SECTOR FOUNDATIONS FOR DIARRHEAL DISEASE CONTROL EFFORTS

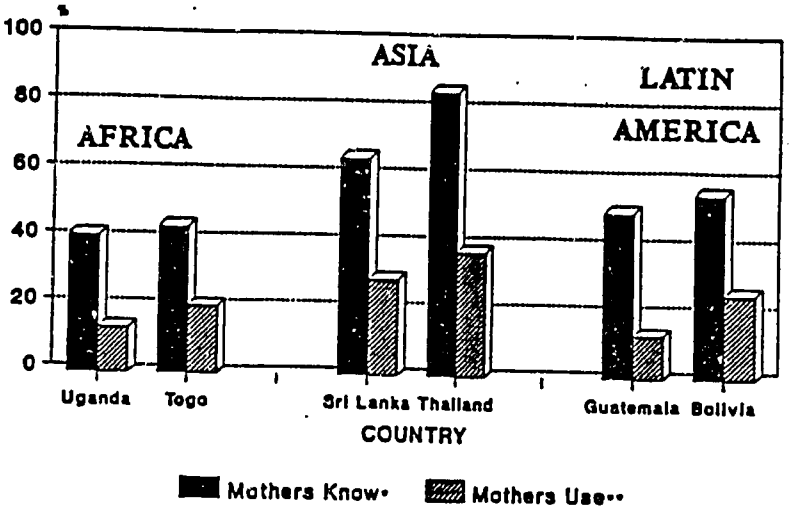
The vast majority of control of diarrheal disease (CDD) activities around the world have been organized within and continue to be implemented by the public sector. That the global CDD effort has been structured in this fashion is not surprising since it followed conventional development models and utilized known, traditional public sector health networks. This public sector approach has realized considerable progress in CDD interventions.

A. Outreach Limitations:

A very disturbing statistic which commonly emerges from developing countries is the consistently low rates of actual and correct use of oral rehydration solution (ORS) in households during diarrheal episodes. Even in countries which enjoy general awareness levels of ORS over 80%, household ORS use rates are often considerably lower (Figure 2). A significant gap between ORS awareness and use clearly has emerged throughout the developing world.

FIGURE 2

ORS KNOWLEDGE AND USE (RURAL)
Comparative Results from DHS I



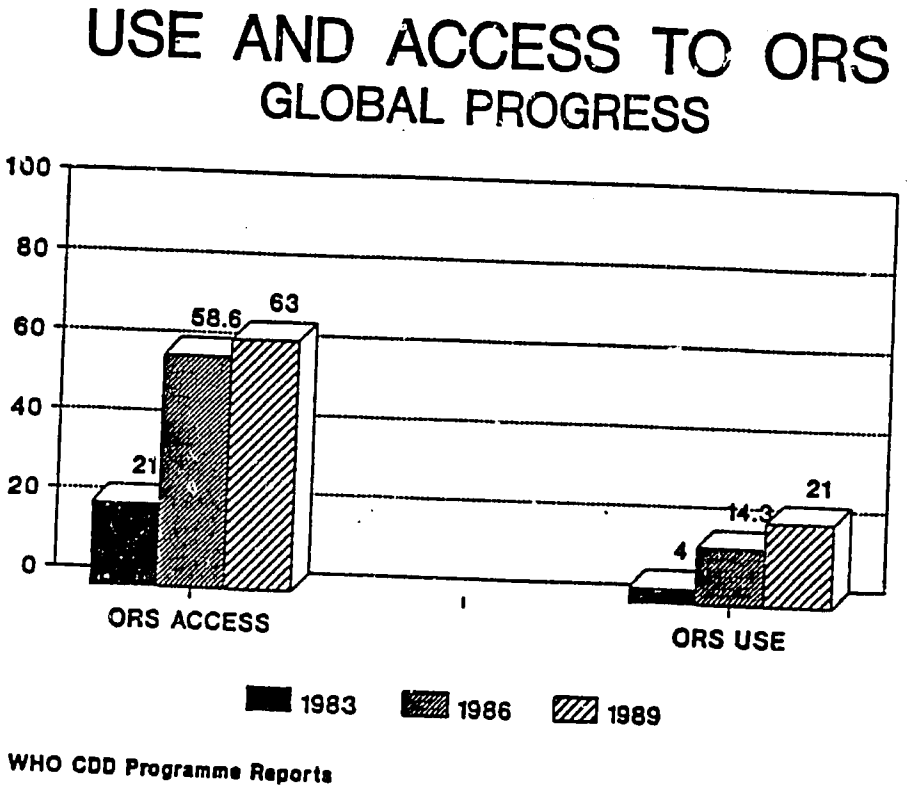
from Bearma et. al., 1991, IRD
** use last 2 wks or recent bowling
*** use for cable last 2 wks

One reason that usage of ORS is low is that current global demand is not fully met by supply. A common limitation of public sector health systems is the regular supply and distribution of needed medical supplies to all health facilities. This is particularly true for facilities at the primary health care level. However, making products readily available to even very small retail outlets represents one of the great strengths of the commercial private sector.

Increasing access to ORS is not the only factor affecting ORS use and the practice of optimal home management of diarrheal episodes among children. Calculations on global access to ORS and its use indicates that use lags considerably behind access (Figure 3). The determinants of the gap between "access" and "use" (as defined in these studies) are not clear. It is possible that the definitrion of access does not represent real access as experienced by families. For example, access might be limited by geographic or social barriers. The quality of public sector services might also be a factor in low usage despite access. Influencing home case management is a complicated and difficult process. The private sector has developed considerable abilities and experience in influencing the behavior of consumers. Perhaps these private sector skills can be useful in improving home management of diarrhea.

Many of the private sector actors in the provision of health care services could be energized to promote oral rehydration therapy, breastfeeding and other diarrheal disease management and prevention practices more widely. The commercial sector, in particular, can be tapped to participate more actively in not only the promotion, distribution and sale of ORS packets, but also the provision of information regarding home management and prevention of diarrheal disease.

FIGURE 3



from WHO CDD Programme Reports

The data presented suggest that an approach which concentrates only on the public sector to deliver CDD services may be limited by the nature of the demand for health care in developing countries as well as by the limitations of adequate service provision by the public sector. To narrow the "usage gap," effort is needed to reach those patients who are commonly served by the private sector.

B. Sustainability Constraints:

Public sector based CDD efforts require regular infusions of financial support from governments and donors. CDD programs that strive to reach 100% of a country's population directly absorb large quantities of financial resources over long periods of time to be fully successful. The strain of sustaining these endeavors over time could be eased considerably if substantial CDD services were undertaken by the private sector on a self-financing, commercial basis.

In several countries, experience has shown that the private commercial sector can provide oral rehydration therapy (ORT) information and ORS products for sale at prices sufficient to provide the seller a profit incentive and yet affordable to significant portions of populations. This has been done with the private sector investing the major part of the finances required to launch ORS distribution, minimizing donor and host country financing.

To date, private commercial sector involvement in the distribution of ORS packets has come primarily from domestic (in-country) manufacturing/distribution firms. The domestic commercial sector in developing countries can be productively tapped further to increase the availability and use of ORS. Participation by multinational manufacturing firms will accelerate expansion of ORT products into developing countries if these firms can be appropriately involved in the global CDD effort.

OBJECTIVES

The goal of PRITECH's activities in commercialization and the private sector is to enlist the marketing capabilities of the commercial sector to help achieve universal access to oral rehydration therapy (ORT) and oral rehydration solutions (ORS), and to help reduce the incidence of diarrhea especially by promotion of hand-washing and breastfeeding. The commercial sector representatives of most interest include pharmaceutical companies, consumer goods manufacturers, and distributors.

The private sector's contribution not only helps in the supply and distribution of ORS; it can also play a complementary role to public sector education efforts. By allocating human and financial resources to promotional - either product specific or general - activities, private agents can help fill the gap between total consumer demand and what is currently provided by the public sector.

To stimulate the private sector in CDD successfully, PRITECH follows a general procedure:

1. Assessment of the current commercial market, including antidiarrheals, and the potential for increased commercial CDD activities.

2. Identification of market opportunities for promising commercial sector initiatives which can realize that potential.

3. Sensitization and stimulation of commercial sector entities for CDD activities, both in terms of market potential and possible contributions to national public health objectives.

4. Assistance to commercial firms in the development of ORS marketing plans and facilitation and coordination of these plans with the national public sector CDD programs.

5. Technical assistance in developing a communication strategy, thus ensuring corrections of the ORT message.

6. Monitoring and evaluation of the public health impact of CDD activities undertaken within the private sector.

PRITECH EXPERIENCE

HONDURAS

In Honduras there was a need for a more affordable ORS product in the large private sector to increase accessibility to the product. A PRITECH marketing expert, in 1989, worked with HEALTHCOM to assist one pharmaceutical manufacturer to develop the ORS product the MOH wanted. An introductory marketing plan was developed jointly with the producer in an effort to increase sales and popular access to the product. The marketing approach adopted by the company included a segmented marketing strategy which began with a low-priced, "popular" product to be distributed in urban drug outlets to be followed by a higher-priced brand distributed selectively to pharmacies. The government agreed to continue mass advertising for the MOH produced brand (Litrosol) which would have a beneficial spin-off effect on the demand of the "popular" private sector brand, Hydrosol.

INDONESIA

In Indonesia, the placement of a PRITECH representative has enormously facilitated PRITECH's involvement in the development of Indonesia's ORS production capabilities. Assistance has been provided to several ORS producers regarding identifying of market opportunities, gaining commitment to direct attention and resources to ORS, optimizing market potential, distribution networks and accuracy of health claims. At this time strong interest is being expressed by various ORS producers and potential entrants in the ORS field in branching into the production of cereal based ORS.

JORDAN

In Jordan, PRITECH provided short-term technical assistance in November 1989 which helped a local ORS producer (which was disenchanted with the sales performance of its product) to revitalize its ORS product within the market. This was accomplished by refocusing the company's ORS marketing strategy on physicians and pharmacists, using its main resource: its own detailing force. Now ORS is part of the company's regular detailing program.

KENYA

In Kenya the total estimated market for ORS is 40-50 million packets per year. Due to changing government regulations regarding ORS formula size, half of the ORS producers dropped out of the market in 1990. At this time production is only around five million packets. PRITECH has researched interest and ability among current and ex-ORS producers to produce ORS in the quantities needed. One result of PRITECH's efforts has been the enthusiasm shown by Sterling-

Winthrop for re-entering the ORS market. It is anticipated that their product, Winhydran, will be launched nationally by November, 1992. In addition, PRITECH has been working with Unilever, the major soap producing company in East Africa, to incorporate handwashing messages in their soap promotions.

MALI and NIGER

In Mali and in Niger, ORS was not available outside of public distribution channels. During 1989 and 1990, PRITECH provided training and technical assistance to develop a commercial marketing capacity within the parastatal pharmaceutical companies that produce ORS. This enhanced marketing expertise will allow these parastatals to more effectively place their ORS products within the small but growing private sector. The areas of assistance included marketing planning, distribution, promotion, selling, and merchandizing techniques.

MEXICO

In Mexico PRITECH identified a gap of approximately 45 million sachets between actual sales/ distribution and potential demand. The unsatisfied demand resides mainly in middle and lower income groups. PRITECH is commissioning three market research studies on ORS price sensitivity, knowledge attitudes and practices (KAP) among shopkeepers, and KAP among caretakers with regard to influences on decision making for health product purchases. Already ORS producers have expressed interest in seeing "hard data" that illustrate the business opportunities residing in making ORS more available.

PAKISTAN

In Pakistan, PRITECH found a huge ORS production capacity among seven ORS producers, yet latent demand from households was not being met. Over an eighteen month period, PRITECH helped to develop a national ORS marketing plan (involving all private sector ORS manufacturers) that identified key issues for harnessing both government and private sector resources in a national CDD effort. PRITECH forged a partnership between the government and the private sector that created incentives for outreach distribution and synergistic advertising efforts. The government agreed to step up the generic ORS advertising while the companies, through promotion of their own brands, capitalized on the existing awareness and translated it into product sales. PRITECH stimulated ORS producers to increase their marketing efforts by focusing their attention on identified market opportunities and on ORS market potential.

ZAMBIA

ORS production in Zambia lags behind demand to the amount of approximately five million sachets. In 1991 a beverage company launched a brand of ORS. Being unfamiliar with marketing health products, the company requested and received assistance from PRITECH. A marketing plan was developed jointly, focusing on strategies to utilize their country-wide

consumer-goods distribution network for the distribution of ORS sachets. This distribution network complements nicely the anticipated distribution in pharmacies where two pharmaceutical companies are expecting to compete by the end of 1992. PRITECH is providing additional assistance in the implementation of quality control standards, price setting and product presentation.

Background Paper No. 2

Oral Rehydration Solution (ORS) and the Commercial Marketplace in Developing Countries

by

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1992

I. PUBLIC SECTOR ORIGINS OF ORS

Oral rehydration therapy (ORT) and ORS are innovations which originated within the public health community. ORS, in its various formulations, was primarily developed by public health professionals for use in national control of diarrheal disease (CDD) programs. International institutions, the World Health Organization (WHO) and other donors were involved in testing ORS formulations. The growing understanding about how effective ORT was in reducing diarrheal disease deaths, particularly among children, and the discovery of relatively inexpensive and easily producible ORS formulas combined to ignite a global CDD effort.

Based mainly on research commissioned by the public sector, WHO selected one ORS formulation as a recommended standard for use in national CDD programs around the globe. Ministries of health in developing countries adopted the WHO standard for ORS for use in government health facilities. Throughout the process of "product development" for ORS, manufacturers, pharmaceutical companies and the commercial sector played little or no role.

Once a standard ORS was selected for use in national CDD programs, manufacturers (usually pharmaceutical firms) were then approached to see if they would produce the ORS packets needed by public health facilities and government-operated CDD programs. Prospective manufacturers were given exact ministry of health or donor organization specifications for the ORS product. Such specifications included detailed ingredient formulation, package size, package design, product name, etc. Manufacturers then bid on tenders to supply donor organizations or ministries of health with the amounts of ORS needed to operate public sector CDD programs.

Interested manufacturers normally were not asked to handle ORS product distribution nor to be involved in retail sales to the general public. ORS distribution to health workers and to consumers at the household level was a responsibility largely retained by ministries of health and the CDD program. In many countries, manufacturers simply were asked to produce the ORS (commonly in granulated form and in one liter packets) under periodic tenders and to deliver the tender orders directly to CDD program warehouse facilities.

With public sector assumption of the primary distribution role for ORS, the public sector in several countries became the main supplier of ORS to mothers. In Honduras, for example, a survey (Baume 1987: 10) showed 91.5% of mothers using ORS reported obtaining ORS from public sector sources. Data from Kenya (1990 Kenya Case Management Survey) indicate a similar pattern in which about 88% of mothers reporting ORS use obtained their ORS from a public sector source.

Another important aspect of the government ORS tender process for interested manufacturers was the effort by health planners to keep the unit price of the ORS procured by the public sector as low as possible. Governments and health planners, for example, were not interested in more

attractive packaging if that would raise the unit price of ORS. One reason health planners wanted to keep the unit price low as to reduce the budgetary burden of recurrent annual procurements of ORS for CDD programs.

Another aspect of the desire to keep the price low was the general desire to provide ORS free or at a very low cost to poor families whose children are most at risk of diarrheal disease. The tender/bidding process, consequently, tended to emphasize the need for companies to supply ORS at the lowest price possible so that they would be competitive with other potential suppliers in the eyes of government procurement officials. Over time, experience with large donor-financed tenders for multi-country supply suggested that the unit price for a one liter ORS packet could be expected to range between US$ 0.07 and $ 0.11. Smaller procurements with domestic manufacturers for supplying only one country's CDD program needs might be slightly more expensive.

The result of this general overture by the public sector to private sector manufacturers was that those firms that did respond (and many did not) did so simply to supply government or public sector demand for ORS. For most companies which began manufacturing ORS, the national CDD programs became the main consumers of their ORS production runs. Firms winning ORS tender awards often would set up a production line for ORS only long enough to produce the number of ORS packets required by the tender. When the specified number of ORS packets was reached, ORS production at the firm often stopped. These firms then returned to the production of their regular line of commercial products (which frequently did not include ORS).

Ministries of health (often with donor assistance) took the lead in promoting and "advertising" ORT for use in diarrheal episodes and for familiarizing the public with ORS. In many cases, especially during the initial years of CDD programs when the "image" of ORS was being created, promotion of ORS followed the traditional public health education approach rather than a social marketing approach. These communication efforts often included a message that ORT should be practiced at home during a diarrheal episode in children. Until recently (and still in some countries), the approach to mothers and households often included instructions on how to make a sugar-salt solution (SSS) at home which was almost as effective as the prepackaged ORS product for rehydration.

These communication efforts were very successful in raising public awareness about ORT and ORS. Indeed, household surveys in some developing countries show awareness of ORT to be present in as many as 80% of homes. Another outcome of some of this promotional work was a popular impression that ORS and ORT were simple enough to be prepared or done by the lay person at home and did not require a health professional. Such an impression helped to stimulate an image within private sector quarters that ORS products were simple and, therefore, "low tech."

II. IMPACT OF THE PUBLIC SECTOR ORIGINS OF ORS

Because of the origins of ORS and the way in which ORS was introduced to most developing countries (i.e. through the context of ministries of health), ORS quickly became identified as a generic, public sector product from the viewpoint of many commercial firms and the commercial pharmaceutical market. ORS was not a product developed by commercial firms and most firms felt no identity with the product.

Many firms that produced ORS in the developing world did not have product control over ORS as they would over a regular product in their product line. Firms producing ORS on tender, for example, did not decide brand name, packaging design, package size, market position or retail price like they might with other products. In some instances, ORS product logos were the property or trade marks of the government. Essentially, marketing and distribution decisions (like target consumers, selection of retail outlets, etc.) for ORS in CDD programs were solely in the domain of the public sector. Attempts to mold the image of ORS products in the minds of consumers through mass media were also mainly the domain of the public sector.

Another development was that ORS became viewed as a low priced product. Many countries offered ORS products to consumers for free at government health facilities. Some countries (such as Pakistan or Bangladesh) even placed price ceilings on ORS products distributed through commercial channels. Invariably, the price ceilings were quite low. To private manufacturers, ORS soon was perceived as a product possessing a very low profit potential.

Some companies which attempted to market government sanctioned ORS products through commercial channels encountered yet another phenomenon. Pharmacists, drug sellers and private health practitioners expressed little or no interest in ORS. Salesmen and detailers from a Jordanian ORS manufacturer, for example, reported that some private physicians and pharmacists seemed reluctant to prescribe or provide ORS because they did not wish to charge for something that the patient could get for free or a nominal charge from a government health facility. Private physicians and drug sellers, they suggested, wanted something distinct or "special" to provide patients.

ORS may be viewed as very common or too "ordinary." Some pharmaceutical companies may have decided not to produce ORS in part because they perceive ORS is popularly viewed as simple or non-medical. Past public sector promotional campaigns explaining that mothers can make an acceptable ORS at home with commonly available ingredients certainly would not be an approach taken by manufacturers to boost the use by consumers of its ORS products. Pharmaceutical manufacturers present their product line as "serious" medicines which appeal to health practitioner and consumer alike.

III. ISSUES INFLUENCING THE INTRODUCTION OF COMMERCIAL ORS PRODUCTS

Despite the public sector image ORS has acquired in most developing countries, experience has been gained in attempting to introduce commercial ORS products into the marketplace and commercial distribution channels. PRITECH has actively encouraged private firms to develop commercial ORS products for sale to consumers and to make ORS products widely available through retail outlets (see the Pakistan case study, Forging New Partnerships, Background Paper No. 3). From this experience, several common issues have emerged which companies regularly consider when deciding whether to introduce a commercial ORS product of their own.

Because ORS is viewed by many companies as a product which mainly serves the supply needs of government health system (i.e. the government market), the consumer market potential of ORS products often is not immediately recognized by firms and must be explored. Past public sector demand for ORS products is relatively easily documented and known from the record of government or donor tenders. The potential for consumer demand or pharmacy sales of commercial ORS products frequently must be estimated. Data on the relatively high levels of public awareness of ORT and ORS are often viewed by companies as evidence that the potential for consumer demand for ORS is high as well.

Another factor some firms consider in estimating whether consumer demand is high enough to justify the investment of resources needed to introduce a commercial ORS product is the incidence rates for diarrheal diseases or mean diarrheal episodes per child per year in a country. Combined with information about the total population of children, these data will develop a rough idea of the potential consumer demand for ORS products.

Once the potential size of a consumer market for commercial ORS products is estimated and deemed sufficiently significant, companies must also consider whether they have the means and resources to realize a portion of that total potential market. The means to realize the potential commercial ORS market is usually viewed in terms of creative promotion, attractive product positioning and increasing the availability of commercial ORS products in retail sales outlets. A common way of testing the viability of an approach to realize ORS market potential is simply to try one commercial ORS product and see what happens to sales.

Product retail price is another important consideration. As noted above, ORS is perceived by most companies as being a low price product and a product which, even if distributed through commercial channels, often has low price ceilings set by governments. In Bangladesh, for example, the price ceiling set for ORS products distributed through commercial channels is only US$ 0.09 for a 500 cc packet; in Pakistan, it is US$ 0.17 for a 1 liter packet.

A standard in marketing for virtually any kind of product is that when unit price is low, companies must strive for high volume sales in order to recover costs and allow some profit margin. Indeed, this is the posture that companies take when deciding to introduce a commercial ORS product.

Nevertheless, even when setting an objective of high sales volumes to cope with the factor of low retail prices, commercial ORS prices often remains a problematic marketing issue. Product promotion is essential to stimulate demand for commercial ORS products and normally would be an key ingredient in the effort to achieve market potential identified for any product. Product promotion, however, is expensive and may appear a luxury in a product with a very low retail price.

TABLE 1

Selected Retail Prices for Commercial ORS Products
in Several Developing Countries

Country	Brand/Product	Form	Unit Size	Suggested Retail Price Per Unit (US$)
Pakistan	Orasal	Sachet/Powder	1 liter	0.53
	Peditral	Sachet/Powder	1 liter	0.17
	Rehydrate	Sachet/Powder	1 liter	0.17
Indonesia	Pedialyte	Liquid	400 ml	1.02
	Garam Oralit	Sachet/Powder	1 liter	0.20
Jordan	Aquasal	Sachet/Powder	not available	1.18
	Servidrat	Effervescent Tablets	10 tablets	3.29
	Pedialite	Liquid	240 ml	1.33
Bangladesh	Orasalene	Sachet/Powder	500cc	0.09

Source: IMS data, 1988.

Actually, the high levels of popular awareness of ORT and ORS built by public sector programs often helps respond to some of the promotion vs. low price issues. In the negotiations between public health and commercial entities regarding ORS, the value of "generic marketing" provided by the government has helped induce firms to try ORS production. Pre-existing ORS awareness offers a foundation upon which commercial ORS product promotion can build and thus lessens the total investment the commercial sector might need to devote to promotion to realize the potential of the consumer ORS market.

Companies also consider another factor when contemplating the feasibility of commercial ORS products: that factor can be called "social responsibility" as an aspect of corporate image. Firms usually are concerned about their public image and how governments view them. An

activity which contribute to the achievement of national child survival or public health objectives is a social goal with which corporate management identify and which help enhance corporate image. Making ORS more widely available as part of a national effort to combat a diarrheal diseases, which is a significant cause of death among children, adds a dimension which companies take seriously. It is a dimension, when considering the feasibility of commercial ORS products, which tempers the issue of low profitability.

IV. ORS IN THE COMMERCIAL MARKETPLACE

A. The Competition

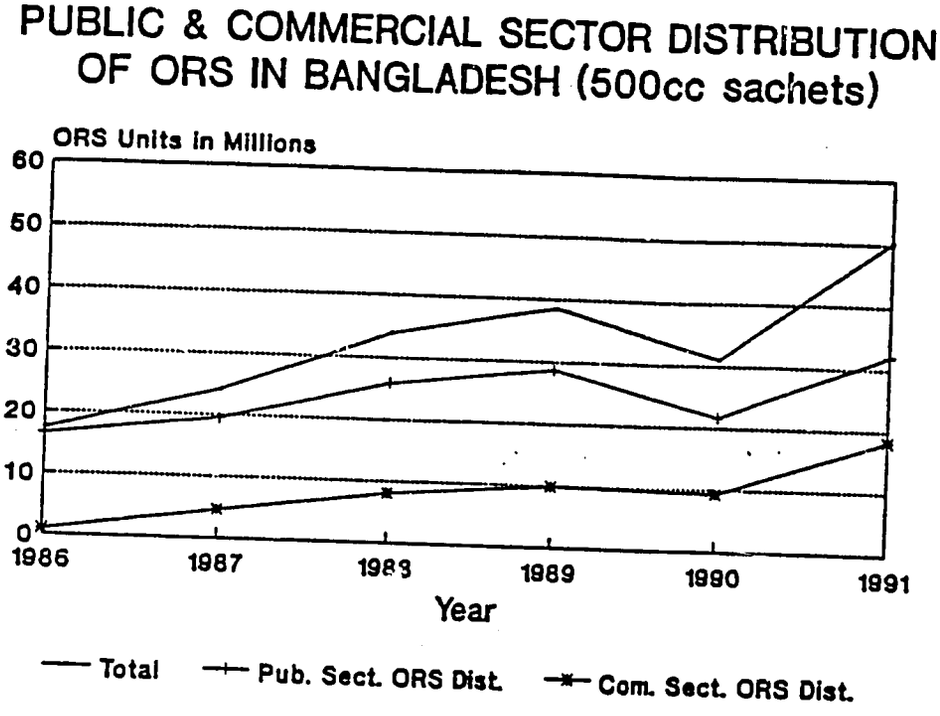
By definition, a commercial product for diarrhea treatment competes with other such products within the marketplace. Therefore, for commercial ORS products the competition is not ORS products distributed through public sector channels. Commercial versions of ORS typically have different packaging and very distinct brand names from the generic ORS (often with government brands or logos). The differences between public sector distribution channels and commercial distribution channels help to separate public sector and private sector ORS products. Companies also normally strive to make their commercial ORS products quite distinct from the generic public sector ORS. Companies usually try to make their commercial ORS products visually different (by color and logo design, for example) to the consumer and may also add coloring or flavoring to help further differentiate their commercial ORS products from generic, public sector ORS.

In fact, available data indicate that the introduction and active distribution of ORS within commercial channels does not hamper public sector ORS distribution and may help to increase the demand for ORS generally. A synergistic relationship can exist which will result in growth in ORS distribution within both the public and commercial sectors. Data from Bangladesh indicate that from 1986 (when commercial ORS distribution began) to 1991 steady increases in ORS distribution occurred in both the public and private sectors (Figure 1).

After the first year that commercial ORS products were introduced in Bangladesh, commercial sector distribution of ORS grew an average of about 46% per year over the four year period, 1987 - 1991. Public sector ORS distribution also grew at an average of 17% per year. The total ORS market (public and private sector distribution combined) nearly tripled from 1986 to the end of 1991.

The main competition to commercial ORS products are the other diarrhea-related products on the shelves of retail outlets. In other words, the arena within which the commercial ORS product must perform is that defined by a consumer's request to a retail worker for a product that will "treat" or "cure" diarrhea, or by the private health practitioner prescriptions for diarrhea. This is the environment within which the commercial ORS product must struggle to survive and within which the "life-giving" sales must be achieved.

FIGURE 1



Data from the Social Marketing Corp. in Bangladesh

The other commercially available products that commercial ORS products appearing in the market of a developing country encountered were antibiotics and antidiarrheals. Such products have long been available in developing country markets.

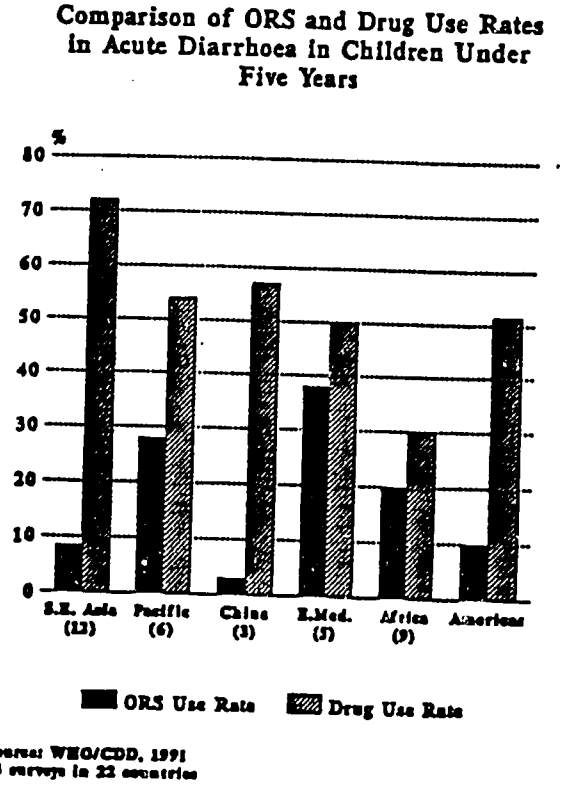
In many ways, these antibiotic and antidiarrheal products represent an established competition having powerful marketing advantages in developing countries. Antidiarrheals are typically positioned as, and have achieved an image of, "serious" medicines for the treatment of diarrhea. They have experienced no efforts to explain how they can be made at home or substituted with home-made alternatives. They usually have medicinal sounding brand names which adds to the pharmaceutical stature of the products. As such, they have the image of being a more serious medical product of pharmaceutical specialists (not in the manufacture domain of the lay-person) [illegible] as being something with efficacy and prestige that a health professional (pharmacist or [illegible]cian) could provide to a concerned mother.

[illegible]s the various regions of the globe, a comparison of ORS and drug use during diarrheal [illegible]es in children shows a clear pattern of advantage for pharmaceutical products other than (Figure 2). In a recent study (Berih, et al., 1989) of pharmacy dispensing practices in [illegible]n, only 4.8% of the pharmacists recommended ORS alone for an infant with diarrhea, while

61.9% of them recommended treatment with antibiotics alone. Another study in Mexico (Gutierrez et al., 1988) indicated that private family physicians prescribed antibiotics in 70.4 - 82.1% of diarrhea cases, while prescribing ORS only between 32 to 35.1% of the time.

Data from Indonesia (Quick et al., 1988) indicated that even in public sector facilities, reliance on non-ORS pharmaceutical products for treating diarrhea cases was common. The study showed that in the treatment of 4,060 diarrhea cases in four health centers, antibiotics were prescribed more than twice as often as ORS. The same data indicated prescription practices which resulted in multiple drugs being applied to a diarrhea case; on average, a child under the age of five years received four different drugs.

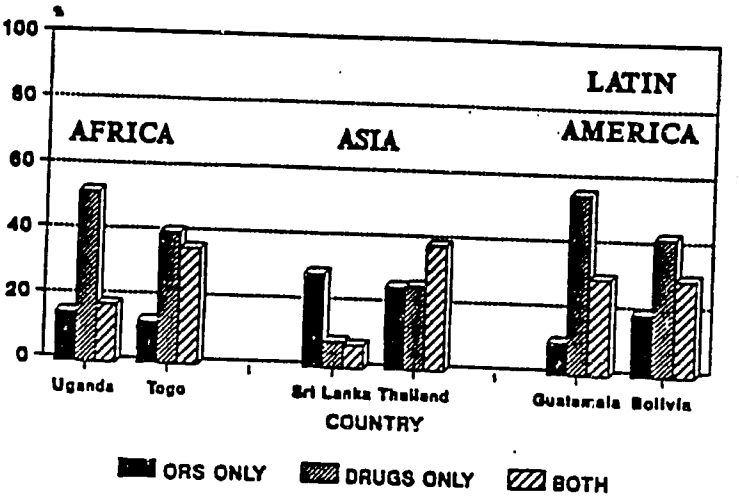
FIGURE 2



Polypharmacy in prescribing for diarrhea cases is certainly not unique to Indonesia. Figure 3 illustrates this practice is commonly found in other countries as well. These data show the extent to which antibiotics and antidiarrheals are established in many countries. It is clear that non-ORS pharmaceuticals enjoy a popularity with large numbers of health practitioners in developing countries. Furthermore, prescribing multiple antidiarrheal products for a single diarrheal episode is common -- a pattern which certainly helps the sales of antibiotics and antidiarrheals.

FIGURE 3

ORS AND DRUG USE*
Comparative Results from DHS I



from Boerma et. al., 1991, IRD
* * called with diarrhea last 2 wks

Another factor which enhances the market position of the antidiarrheal products is the consumer demand to stop the diarrhea, or at least to reduce its volume. Mothers and caretakers seek to stop diarrhea and that therefore the consumer demand for products or health care which offer to do so is high. Private health practitioners are aware of that demand, which helps to explain the prescription behavior noted above. Antidiarrheal products are marketed to meet that consumer demand and, hence, play on this popular appeal to help boost sales.

In addition, commercial antibiotics and antidiarrheal products are commonly sold at a retail price level considerably higher than ORS, but which consumers seem willing to pay. The potential profit margin differential between antidiarrheal products and ORS, therefore, is advantageous to commercial antibiotics and antidiarrheals. The profit differential is present at various points in the product sales/prescription chain: the retailer, the wholesaler, the private health practitioner and the manufacturer.

Another advantage consumer antidiarrheal products have is that manufacturers have much more control and flexibility in deciding the course of product life than is the case with ORS. Most antidiarrheals are the results of internal, corporate product development processes. As a result, the formulation, package design, brand name, and product image are all variables over which the manufacturers have the majority control. Setting of retail prices for antidiarrheal products also does not typically fall under the same types of price control constraints. Even countries have pharmaceutical price controls in place, these controls are usually based on a formula which allows a production cost, which can be increased, and a percentage profit margin above cost allotted to the manufacturer. Greater freedom to respond flexibly to market forces is valued by commercial firms.

TABLE 2

Total Diarrhea-Related Products/Brands Available in the Commercial Market of Selected Developing Countries (1988-1990 market data)

Type of Product	Indonesia		Jordan		Philippines		Mexico		Pakistan	
	#	%	#	%	#	%	#	%	#	%
Antidiarr-heals/ Antibiotics	108	86.4	11	45.8	36	53.7	66	65.3	82	78
Motility Inhibitors	11	8.8	6	25	6	8.9	7	6.9	5	4.6
Intestinal Adsorbents	4	3.2	2	8.4	15	22.5	15	14.9	13	11.9
ORS	2	1.6	5	20.8	10	14.9	13	12.9	6	5.5
Total Different Products/ Brands	125	100		0	67	100	101	100	109	100

Source. MS Data, 1988-1989.

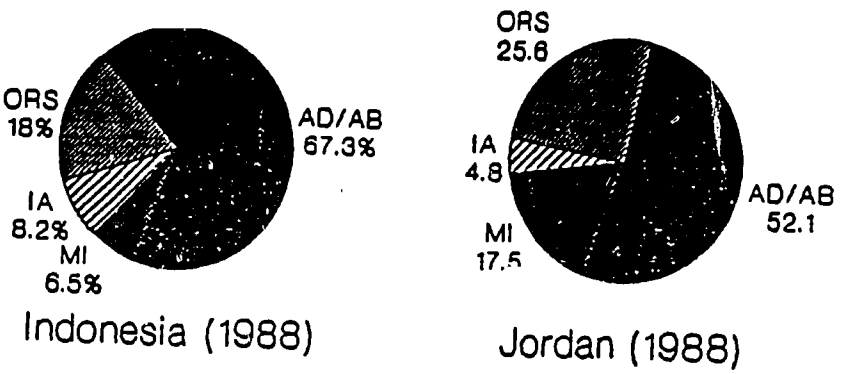
B. Typical Profiles of the Commercial Diarrheal Product Market

Data from a variety of developing countries indicate that ORS products certainly do not dominate the commercial diarrheal product marketplace. The commercial market for diarrheal products is measured by several variables. One of these is the range and diversity of commercial diarrheal products on the market (Table 2).

The variety of products or brands in a given category of diarrheal product is one indication of corporate interest and market demand. The information in Table 2 clearly indicates that antidiarrheals/antibiotics have captured the bulk of market interest in the four countries listed. Although not always at the bottom, the ORS category consistently ranks low.

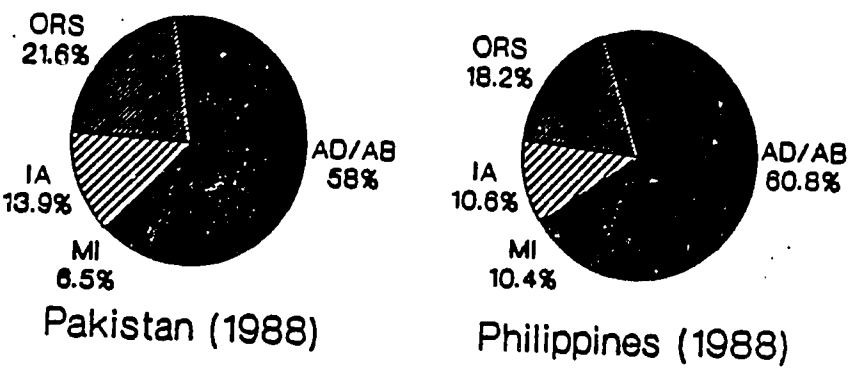
FIGURE 4

DIARRHEAL DRUG MARKET SHARE BY UNIT SALES IN INDONESIA AND JORDAN



Source: IMS data, 1988.

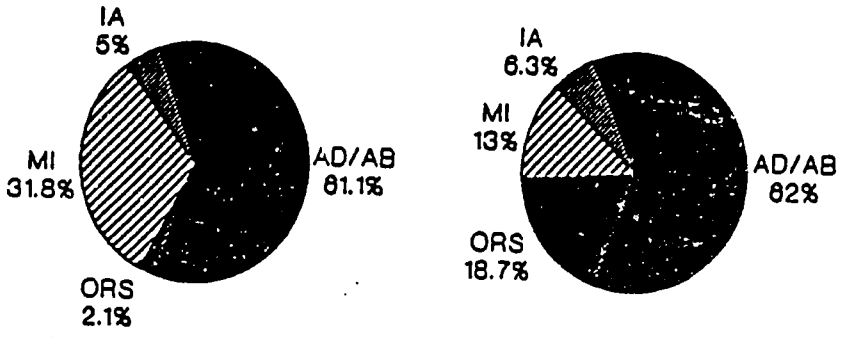
DIARRHEAL DRUG MARKET SHARE BY UNIT SALES IN PAKISTAN AND THE PHILIPPINES



Source: IMS data, 1988.

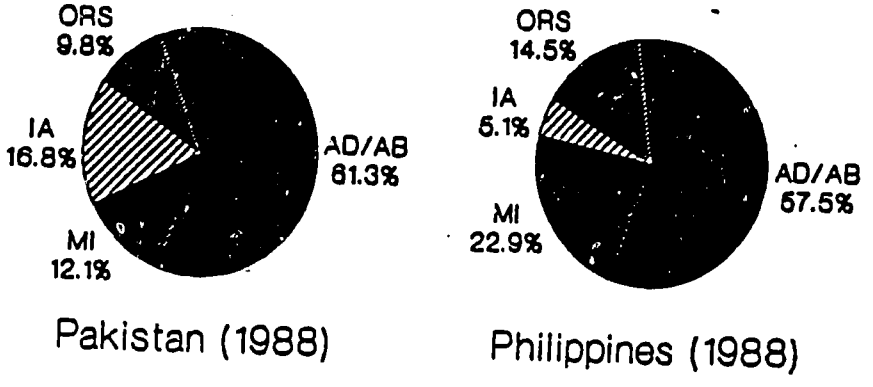
FIGURE 5

DIARRHEAL DRUG MARKET SHARE BY SALES VALUE IN INDONESIA AND JORDAN



Source: IMS data, 1988.

DIARRHEAL DRUG MARKET SHARE BY SALES VALUE IN PAKISTAN AND THE PHILIPPINES



Source: IMS data, 1988.

Another commonly utilized measure of product performance in the commercial marketplace is total market share by unit sales (Figure 4). This statistic provides some measure of what portion of the total unit sales volume is represented by a product or product category. Figure 4 provides data on market share by unit sales for the same four countries. Again, the antidiarrheals/ antibiotic category consumes, by far, the major portion of sales volumes in the diarrheal drug market. ORS consistently places second.

Measuring shares of total unit sales, however, can be misleading since retail price varies and one unit sale of a high price product can be equal in value to several unit sales of a low price product. Monitoring market share by monetary sales value is also important. When this is done for the same four countries, the product category of antidiarrheals/antibiotics once more emerges predominant (Figure 5). Motility inhibitor products take second place in Indonesia and the Philippines. With the exception of Jordan, ORS products again drop to lower place positions,.

V. LESSONS LEARNED TO DATE FROM THE COMMERCIAL ORS EXPERIENCE

The experience of ORS production and the introduction of commercial ORS products is sufficient to draw a few conclusions.

First, it is possible to utilize commercial sector distribution channels to increase the availability of and access to ORS within developing countries. The experience of several manufacturers in Pakistan and the work of the Social Marketing Corporation in Bangladesh (which reports that it now reaches 100,000 retail outlets countrywide with its Orasalene ORS product) demonstrate the outreach potential of commercially distributed ORS products.

Nevertheless, the majority of the ORS produced globally continues to be manufactured for the public sector market and not for the commercial market. ORS generally carries a public sector legacy which did not commonly include the manufacture of commercial ORS product versions for use in the consumer market.

Before becoming interested in commercial ORS products, companies have had to contend with the public sector generic image that ORS normally possesses and recognize the potential for a substantial consumer ORS market. Some firms recognize such a potential as great enough to warrant their attention; others do not.

Companies typically seek ways to make their products unique or distinct. This is particularly true for over the counter pharmaceutical products in which some technical edge (the classic "new and improved" pattern) can be used to advantage against the competition and win the allegiance of the consumer. The simple, non-medical image ORS has acquired hampers the ability of commercial ORS products to employ this marketing technique. Some manufacturers of commercial ORS products have attempted to counter this constraint by adding color and flavorings to the ORS ingredients.

Prescription practices of private health professionals in many developing countries continue to favor antibiotics and antidiarrheals over ORS products. Informal reports from some representatives of pharmaceutical company detail sales forces suggest that these prescription practices are in part due to the simple, non-medical image of ORS. Diarrheal prescription behavior by private health care professionals may well be influenced by product image (the more medicinal and technically "advanced" the better) and by their own perceptions of what patients expect (i.e. specialized drugs and stopping the diarrhea).

Current market profiles for commercial diarrheal products indicate that commercial ORS products face stiff competition from antidiarrheals, antibiotics, motility inhibitors and intestinal adsorbents. Many of these products already hold established positions within the marketplaces of developing countries.

Deciding to produce an ORS product often brings with it government controls over that product. Such controls may bring dictates such as limiting production to a 1 liter size only; limiting ingredient formulation to a certain standard only; and limitations for retail price. These controls may be interpreted by some firms as limiting the product flexibility they normally like to see to adapt to changing market pressures.

The continuing low retail price allowed for commercial ORS products constitutes a very real marketing constraint. Conventional marketing guidelines for setting prices for consumer products instruct that prices should do more than just cover production and packaging costs. Distribution costs, product promotion costs, wholesaler and retailer margins as well as profit to the manufacturer must be calculated. In addition, price-setting must take into account the price of competing products as well as what price levels may do to product image in the minds of consumers. Retail price selection for other consumer products also commonly considers the question of product quality implied by price (i.e. the higher the price, the better the quality; the lower the price, the lower the quality).

ORS products distributed commercially are also viewed by many governments as not serving the public health objective of trying to reach the poorest households that are most at risk of children dying from diarrheal disease. Price is often perceived by health planners to be a barrier to ORS use by the poor. This is a primary reason for price controls that strive to keep ORS products very inexpensive. The setting of retail prices for commercial ORS products, therefore, has not followed conventional marketing guidelines.

Consequently, the greatest potential for making ORS products commercially viable in this low-profit environment is to achieve high volume unit sales. Achieving such high volume sales is not likely in many developing countries if retail sales are limited to pharmacies and drug seller outlets. Higher volume unit sales might be possible if consumer ORS products were distributed and made available as a over-the-counter products in consumer goods shops that sell common, every-day products like matches, soap or aspirin.

In some locations like Bangladesh, with low consumer buying power and very low retail price ceilings set by the government for commercial ORS products, widespread commercial distribution of ORS products may only be possible through government or donor subsidies. The US$ 0.09 retail price for Orasalene does not cover the costs of production, distribution and promotion, and to continue handling this ORS product at this price the Social Marketing Corporation receives external support.

Lastly, one real element of consumer demand for diarrheal products is the desire of mothers or caretakers to stop or shorten the episode of diarrhea in children. Suppliers of commercial antidiarrheal products try, in part, meet that consumer demand. Indeed, stopping diarrhea is a major criterion of consumers in their assessment of the efficacy of diarrheal products. ORS products, to date, have been unable to meet this aspect of consumer demand. Attempts have been made to educate the consumer that ORS is effective and that they should not expect nor demand that diarrhea episodes be stopped. Nevertheless, the consumer demand to stop or shorten diarrhea episodes still appears to be a significant market force in many developing as well as more developed countries.

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PRITECH thanks staff members Scott Endsley and Anita Sherman for contribution of graphs.

Background Paper No. 3

FORGING NEW PARTNERSHIPS:

MOBILIZING THE COMMERCIAL SECTOR FOR ORS MARKETING IN PAKISTAN

by

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1991

I. INTRODUCTION

A. THE PUBLIC HEALTH PROBLEM

About one in every ten children born in developing countries dies of diarrhea before the age of five--some 4 million children per year. In Pakistan, diarrhea remains the major killer of children, accounting for almost one-third of the 700,000 deaths annually among children under five. The government estimates that since 1984 mortality due to diarrhea declined from 300,000 to 200,000 deaths per year. Children in Pakistan, however, still suffer from an estimated 90 million episodes of diarrhea every year. Thus, even with progress in the fight against diarrheal disease, diarrhea remains a major public health problem in Pakistan.

B. ORAL REHYDRATION THERAPY

Most diarrheal deaths result from dehydration--losses of water and electrolytes beyond what the body can tolerate. These deaths are largely preventable. The cornerstone of most diarrhea program efforts is effective prevention and treatment of dehydration, emphasizing oral rehydration therapy (ORT)--the administration of rehydrating fluids by mouth, which can be easily implemented in homes and health facilities.

ORT, as defined by the Government of Pakistan, consists of fluid replacement, continued breast feeding, and feeding. Fluids such as rice water, or oral rehydration salts (ORS), considered a home fluid in Pakistan, can be used to prevent or correct dehydration. ORS is a prepackaged mixture of salt, glucose, and various electrolytes that can be readily mixed with water.

Effective treatment also calls for continued feeding during and after diarrheal episodes to prevent the child from becoming malnourished. Breast feeding in particular is encouraged because breast milk provides immunological benefits against infection and is among the most nutritious foods for babies with diarrhea. In addition, feeding - particularly starches - along with ORS has been shown to decrease stool output.

C. THE STATUS OF ORS DISTRIBUTION: ASSESSING THE CONSTRAINTS

1. Public Sector Activities

The National Control of Diarrheal Diseases (CDD) Program in Pakistan, as in most countries, was established as a public sector initiative to address an important public health issue. Efforts to promote ORT awareness and provide ORT services were focused upon public sector intervention channels. Distributing

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ORS nationally and making ORS accessible to the general population in need were objectives designed to be achieved primarily through public sector facilities. The role of the private sector in obtaining these ORS objectives was largely limited to producing, through government tenders, the ORS needed by the public sector. The commercially produced ORS was sold to the government CDD program for distribution (free of charge) to health practitioners and the public.

The national CDD program realized considerable success in raising awareness about ORS. Progress was also made in bringing ORT in general use throughout government facilities. The National CDD program distributed free ORS packets to parents in government health facilities and, through its outreach and mobile immunization teams, to parents in villages throughout Pakistan.

However, such public sector-based distribution models are largely dependent upon a constant or increasing level of budgetary support. If available public financial resources shrink, distribution and supply can suffer. Indeed, due to budgetary cuts, procurement of ORS by the CDD program decreased from over 21 million packets in 1987 to 6 million in 1988, 3.4 million in 1989 and about 10 million in 1990. The government plans to procure about 10 million packets of ORS for the next five years. Although some provinces have begun purchasing ORS, the quantity of ORS the government can make available to the public at no cost is not enough to meet the need.

Another constraint of the public sector distribution system was the limited effective outreach to the general public. Only 26 to 30 percent of Pakistanis who seek health care actually go to government health facilities. The majority (70 percent) go to the private sector: private physicians, traditional healers, chemists and others who prescribe or provide health services.

2. Commercial Sector Activities

Although some ORS products were sold commercially, most firms perceived the domestic ORS market in Pakistan to be driven mainly by government purchases. The largest part of domestic commercial production of ORS was devoted to supplying government ORS tenders. Most producers maintained their licenses to manufacture ORS simply to enable them to bid on government tenders. Only two of the fourteen firms holding ORS manufacturing licenses actually produced and sold a considerable quantity of ORS.

Commercial firms typically considered the demand for ORS products to rise and fall with the needs of the public sector. Consumer demand for ORS was ill-defined or considered non-existent. Similarly, firms were not convinced ORS could be profitable product.

Aspects of the government regulatory environment surrounding ORS also represented constraints to the commercial sector. One government regulation, for example, required that ORS (like a prescription pharmaceutical product) be sold only through medical stores. Since medical stores are found primarily in urban areas, this restriction essentially limited access to ORS to the 30 to 40 percent of the population that lives in urban areas. The regulation also ruled out extensive commercial distribution channels that reach a wide variety of other retail outlets (such as stores selling general consumer goods like tea, soap, sugar, etc.).

ORS, as a pharmaceutical product in Pakistan, falls under the existing government system for setting retail price ceilings for pharmaceuticals sold commercially. The price ceiling for ORS (Rs. 3.00 or about US$ 0.20 for non-flavored ORS and Rs. 3.75 or around US$ 0.25 for flavored ORS) had not been raised since it was set in 1986. Manufacturers, consequently, considered ORS a "low profit" product and were not interested in further investment in ORS marketing. From their perspective, either the price ceiling had to be lifted or raised or another means of making ORS more profitable had to be found.

Related to the issue of profitability was the cost of ORS production. The foil packaging, commonly used for powdered ORS sachets, typically represents the most costly single raw material in the ORS manufacturing process. Packaging costs, therefore, were a major factor in the ability to realize a financial return from a product with a relatively low retail price. The import duty on the aluminum foil used for ORS packaging increased the cost of the foil to manufacturers by 120 percent. Reducing this element of ORS production costs could make the profitability of ORS more attractive to firms.

D. IDENTIFYING THE OPPORTUNITIES:

Along with a set of constraints, the ORS situation also possessed strengths which suggested opportunities for significant commercial sector contributions to Pakistan's national CDD effort. Three main strengths were identified:

1. Well Developed Commercial Sector

Pakistan's commercial sector has a long history of domestic production of both pharmaceutical and consumer good products. From this tradition, the commercial sector possesses a wide range of production, marketing, distribution, advertising and market research skills. Many different pharmaceutical and consumer goods companies have local production plants and considerable experience in introducing new products within the marketplace. This well-established commercial presence meant that the private

sector possessed entrepreneurial experience and the means to invest its own capital in new product ventures.

2. Sizeable Consumer Market Potential for ORS

Given the total population of Pakistan (around 100 million), any product used commonly in the home theoretically could realize a market large enough to attract the attention of many companies. The potential market for ORS in Pakistan is very large.

On average, a Pakistani child under five years of age is estimated to have five episodes of diarrhea each year. Pakistan has about 18 million children under the age of five, which translates into approximately 90 million diarrheal episodes per year. Assuming two packets of ORS per episode, a total of 180 million packets would be needed to treat all cases of diarrhea in children. Adult use would add significantly to this total.

If consumers would commonly take ORS during diarrheal episodes, then the potential consumer market for ORS in Pakistan theoretically could exceed 180 million packets a year. Such a market size, even when keeping the retail price fixed at the 1986 ceiling level, could exceed a theoretical total sales value of between $36 million and $45 million annually. Although such numbers are largely hypothetical, the important point is that even if only a portion of the potential consumer market is realized, the potential return to companies could be sufficient to attract their investment in ORS marketing.

3. Positive Competitive Environment

Having several firms with licenses to produce ORS represented a valuable resource. One advantage was that these firms together possessed considerable production capacity to meet potential demand within a consumer market for ORS. Fourteen companies had licenses to produce ORS, although only seven were actually doing so.

These seven ORS producers, alone, had a combined production capacity estimated to be between 60 and 100 million packets per year (depending on the number of worker shifts used on the production line). This capacity, of course, was not being fully tapped since total annual production from these producers was only about 18.5 million packets of ORS.

The presence of several ORS manufacturers also offered the ability to develop several competing brands of ORS which could seek to reach differing segments of the consumer population. This would allow normal market forces to work in positioning competing products to reach the broadest spectrum of consumers possible.

Another advantage of the presence of a number of firms was that each company had differing marketing strengths: some excelled at reaching private physicians, while others were better at reaching pharmacists or shopkeepers. Still others specialized in targeting community groups, such as mothers and school children. Companies utilized differing distribution networks which had historically resulted in firms placing their products more successfully in some geographical regions of the country than in others. Involving several companies in meeting the needs of a consumer ORS market could make the ORS products more widely available.

II. THE APPROACH FOR ACTIVATING THE COMMERCIAL SECTOR

Based on the analysis of the existing situation, PRITECH worked closely with USAID and the National CDD program to define a means for the commercial sector to appropriately compliment public sector efforts to achieve national CDD objectives. The purpose was to develop together an approach for effectively involving the commercial sector. All agreed that the approach to the commercial sector should strive to be as self-sustainable as possible.

Several social marketing models existed from international experience for involving the private sector in the achievement of national public health goals. However, many of these were based on annual public sector or donor financing for part or all of the product, promotion and distribution costs. Another aspect of most existing social marketing models was a typical reliance on lead firm with one product line to achieve the desired complimentary public health effect from the commercial sector.

Given the strengths identified in Pakistan's commercial sector, it was determined that a new, alternative approach should be tried. This alternative social marketing model would not offer any public sector or donor financing for product costs; companies would be expected to invest in any new or expanded ORS marketing effort primarily with their own funds. Similarly, it was decided to adopt an approach which encouraged the participation of as many firms as were interested.

A. OVERALL OBJECTIVES:

The general objective was to increase the availability of ORS and use of ORT during diarrheal episodes by utilizing the commercial sector's potential to produce, promote and distribute ORS products widely. More specific objectives included:

- Increasing consumer demand for ORS.

- Increasing the awareness of ORS and the correct use of ORS

within a proper ORT regimen for children within both the general populace and among private health care practitioners.

- Developing the consumer market for ORS products by motivating commercial firms to become more active.

- Increasing the distribution and sales of ORS products by commercial firms.

- Insuring that commercial ORS marketing initiatives are consistent with Pakistan's National Diarrhoea Treatment Policy (which defines ORT as ORS/fluids plus breastfeeding plus feeding).

Some indicators were selected to measure the extent to which these objectives were achieved. One indicator chosen was an increase in ORS prescriptions by private physicians by 25 percent per year for the first two years. Another benchmark selected was an increase in commercial sales of ORS by 15 percent the first year and by 20 percent in the second year of operation.

B. SPECIFIC OBJECTIVES FOR THE COMMERCIAL SECTOR

Given the assessment of the existing commercial role in ORS production, promotion and distribution, specific objectives were set to define some of the desired changes in the commercial sector. These specific objectives included:

- Increase awareness about the consumer market potential of ORS.

- Create a more attractive environment for firms to invest in and undertake more aggressive ORS marketing initiatives.

- Increase commercial production and sales of ORS through the greater commitment of existing production capacity and distribution systems.

- Broaden and expand existing distribution networks for ORS products. Since the existing seven ORS producers were pharmaceutical companies and their distribution networks were mainly limited to pharmaceutical outlets, one objective was to encourage these companies to consider alternative marketing strategies. Particularly for those with other over the counter (OTC) products, these alternatives could include adding new distributors to increase the number of retail outlets carrying their products and the geographical outreach.

- Correctly promote ORT (ORS/fluids + breast milk + food).

Firms producing and marketing ORS should promote ORT as defined by the National CDD program, meaning ORS/fluids plus breast milk plus food.

- Encourage the formation of partnerships which could expand ORS availability in the marketplace. Such partnerships could combine the strengths of ORS producers and other pharmaceutical companies with wide OTC distribution networks and/or consumer companies.

C. STRATEGY FOR ACHIEVING OBJECTIVES

To achieve these various objectives, the basic strategy adopted for this alternative social marketing model was to provide the intermediary functions needed to facilitate cooperation between the public and private sectors. These intermediary functions were essential since the approach to the commercial sector was not premised on the public sector purchasing a set of services or products. Methods to precipitate change had to be different. The means to realize the desired objectives required:

- Continued collaboration with the government to step up and further develop its generic ORT advertising and training of government health personnel.

- Encourage firms to do more to realize the potential of the commercial ORS market.

- Providing information and technical assistance to participating commercial firms to help maximize their marketing capacities.

- Facilitating regular communication between commercial ORS producers, international organizations and the government so that the constraints affecting both the achievement of national CDD goals and the optimal performance of the commercial ORS market are mutually understood.

- Collaborating with the government and ORS producers to change government regulations which: (1) limited the availability of ORS products at the retail level and (2) adversely affected the self-sustainability of wider commercial ORS distribution (such as the increased production cost of ORS due to high import duty on foil).

- Making ORS available to rural Pakistani consumers

through consumer marketing.

III. IMPLEMENTING THE APPROACH

A. CRITERIA FOR SELECTING COLLABORATING COMPANIES

Although the approach adopted called for cooperating with any commercial firm which expressed interest, PRITECH targeted certain companies whose capacities and characteristics showed the greatest promise of achieving the objectives set for the commercial sector. Working closely with the USAID Mission, PRITECH developed criteria for target companies. According to these criteria, participating companies must:

- Have a detailing or sales force making at least 5,000 calls per month to doctors, pharmacists or shops. This meant that the company would be able to reach large numbers of people with ORT messages.
- Present an ORS marketing plan targeted to the company's intended consumers.
- Develop an evaluation plan describing how the company would assess the success of the firm's ORS/ORT promotional activities. Most ORS producers previously used total sales as their main measure of success.
- Agree not to co-position ORS with potentially harmful products such as infant formula, antidiarrheals, etc. This was the most difficult requirement because most ORS producers or companies willing to market ORS also produced antidiarrheal drugs or infant formula.
- Agree to a review of its promotional materials by the National CDD Program, the Ministry of Health, top Pakistani pediatricians, and collaborating international agencies. In order for this to be acceptable, PRITECH guaranteed that this review would take no longer than two weeks.

B. PARTICIPATING COMPANIES

Over the course of implementing the program, a broad spectrum of national and international companies met the selection criteria and decided to participate in the ORT and related efforts. Collaborating firms included both pharmaceutical companies and consumer goods companies. A list of these firms is presented in the table below.

COLLABORATING COMPANIES

Pharmaceutical	Consumer
Searle	Lever Brothers
Wilson's	Milkpak Dairy
Woodward	Pakistan Dairy
Abbott	Chaudhry Dairy
Highnoon	Green's Dairy
	Tetrapak

Each of these companies brought differing and desirable strengths to the effort to realize the commercial sector objectives. For instance, Searle focused on physician detailing and professional seminars and conferences, while Wilson's strength lay with pharmacists and shopkeepers. Woodward has a wide distribution network in the consumer market which can cover up to 70,000 sales outlets. Woodward specializes in programs involving the community, such as baby shows, during which ORS contests are featured. Woodward also plans on promotional efforts which involve school children.

C. PRITECH'S ROLE

The approach adopted was predicated on the government continuing to vigorously implement its CDD program within the public sector and for commercial firms themselves to be the main implementors of ORS marketing interventions. However, PRITECH recognized that the success of this approach required that an environment had to be established which allowed standard business practices to flourish to keep the interest of the private sector. At the same time, furthering the public health objectives of the government and international organization, through collaboration with commercial firms, needed to be assured. The inherent operational differences between public and private sectors common to any country needed to be addressed.

PRITECH's role was to initiate this effort and to act as that needed broker or catalyst to bring together the commercial sector and the government. To build an efficient relationship, PRITECH helped identify common interests and define how one sector could assist the other. Furthermore, PRITECH played a catalytic role among commercial firms to try to start new partnerships. In addition, the program provided motivation and assistance with marketing plans, development and testing of promotional materials and technical information to the collaborating companies.

Some of the specific implementation tools used by PRITECH included the following:

1. Dissemination of Information

One of the needs of the commercial sector was to understand the technical parameters of recommended ORT regimens and technical issues related to ORS application and efficacy. PRITECH provided technical information to all companies interested in marketing ORS. To keep companies up-to-date on the latest technical advances in ORS and ORT, PRITECH sent relevant journal articles, WHO updates and the bi-monthly Technical Literature Update produced by PRITECH/Washington. The program also made available samples of ORS packets and promotional materials from other countries.

2. Marketing Workshops

The National CDD program and PRITECH held marketing workshops and sales training courses for ORS producers and consumer companies. During these workshops, participants (using simulated data to avoid any issues between companies over proprietary sales or distribution information) developed marketing plans for hypothetical ORS products and identified problems which were later discussed with government health officials. Marketing plans developed during these workshops were generic; however, since the data used was very close to Pakistan's, these plans provided companies with blue prints which they could later use to develop company- specific plans.

While companies did not share their marketing plans with others, they readily participated in workshops and requested information from the project. In addition, some companies asked PRITECH to review their ORS marketing plans (these are proprietary, and PRITECH held them in the strictest confidence).

3. Market Research

One attractive feature of the program to commercial firms was an opportunity to better understand the dynamics of the consumer ORS market. This was important both to help firms assess the potential of the consumer ORS market and to assist them in improving the consumer use and market penetration of their ORS products. Not all firms could afford (on the financial return from ORS sales) to invest in the market research needed to gain this understanding of the ORS market.

PRITECH commissioned trade audits (a means to estimate user consumption rates as distinct from total sales figures) and consumer market indices. Data from this research was made available to all interested companies. This enabled all

participating ORS producers to modify and refine their marketing strategies.

4. Technical Assistance

A variety of forms of technical assistance were provided. PRITECH collaborated with companies interested in conducting market research of their own. This collaboration was in the form of technical assistance and did not involve funding. Such technical assistance could help in the design of the market research or in helping to interpret market research results for application to marketing plans. Other technical assistance was offered to firms in the review of promotional materials or product instructions to help insure consistency with national CDD policies. The program also assisted the government and international organizations to consolidate data on commercial ORS production and distribution and, importantly, to comment on how progress in the commercial sector was complementing the public sector CDD program.

5. ORT Promotional Activities

If needed by participating firms, the program could also make matching grants of up to $20,000 per company for ORS detailing and publicity materials for one year. In order to qualify for these matching funds, companies had to agree to follow the National Diarrhoea Treatment Policy and to meet criteria previously described in this paper. This small matching grant was important in Pakistan because there is a regulatory ceiling of 5 percent of revenue which pharmaceutical companies can spend on the promotion of products. Thus, by co-financing promotion of ORS with producers, it was possible to considerably increase ORS promotion by some commercial firms.

Another aspect of the program's work in ORS promotion was trying to insure that all promotional materials were technically appropriate and in line with national CDD policy. Interestingly, most participating companies did not take advantage of the matching grant for ORS promotion, preferring instead to finance ORS promotional activities on their own. PRITECH also provided assistance in the technical review of promotional materials and the integration of promotion within marketing plans.

6. New Product Development

Besides collaborating with the pharmaceutical industry, PRITECH worked with the Pakistan dairy industry in a venture that could significantly increase the availability of ORS. Recognizing that several commercial dairies had more production capacity than was being used, PRITECH and the USAID Mission obtained the services of the Land O'Lakes Company to assist four Pakistani dairies to develop and test a pre-mixed (liquid) ORS

that can be packaged and distributed by producers and marketers of milk products. These dairies produced and tested liquid ORS and various packaging options. The dairies received no financial assistance whatsoever. The only funding involved the technical assistance provided by Land O'Lakes through a sub-contract with PRITECH.

More recently, a partnership between Abbott, a pharmaceutical company, and the dairies is being explored: Abbott would produce ORS and one of the dairies would package it, possibly using Tetrapak packaging (a cardboard-box-like container often used to package juice drinks). Although the technical feasibility of producing and packaging liquid ORS in Pakistan has been established, regulatory issues related to production and packaging outside pharmaceutical facilities remain. Land O' Lakes continues to explore collaboration with dairies in quality control and Tetrapak has played a coordinating and catalytic role. Should liquid ORS ultimately be produced or packaged by one or more dairy, commercially distributed ORS could realize a significant expansion into grocery retail outlets using the dairy distribution system.

D. GOVERNMENT'S ROLE

By late 1988, when this private sector program was launched, the Pakistan government, in collaboration with PRITECH, USAID and other international agencies (such as WHO and UNICEF), progressively prepared the necessary CDD groundwork which was key to the success of the private sector effort. The government's contributions included:

- Promotion of ORT through government health facilities and outreach immunization teams as well as government-sponsored, generic promotion of ORS through the mass media, which created high popular awareness of the product. This awareness was transformed into demand for ORS by the commercial sector.

- Development of a state-of-the-art National Diarrhoea Treatment Policy (see Illustration 1) which promoted ORS as the first line treatment and defined ORT as ORS/fluids plus breast- feeding plus feeding. The policy provided guidelines for the private sector to use in development of promotional materials and training of detail and sales forces.

- Reassessing government regulations which affected the ability of commercial firms to market ORS more widely to consumer and taking steps to modify those regulations if appropriate.

- Development and testing of key messages for illiterate and low literacy parents, the educated public, physicians, paramedics, and pharmacists. These messages were used by the private sector to develop its promotional materials. PRITECH collaborated with the National CDD program in this effort.

- Development and popularization of a national ORT logo. Companies could use this ORT logo in their promotional materials.

- Training of government physicians and paramedics in treatment of diarrhea, which focused on ORT as the first line treatment.

- The Government of Pakistan established ORT units and corners in government health facilities to promote the correct use of ORT, in collaboration with USAID's PRITECH project, funded by USAID's Primary Health Care and Child Survival projects,

- Development and testing of point-of-sale (POS) materials for pharmacies and shops, in collaboration with PRITECH. These materials could be printed and distributed by ORS producers and other interested companies.

E. THE ROLE OF PROFESSIONAL ASSOCIATIONS

Members of the Pakistan Paediatrics Association and the Pakistan Medical Association promoted ORT during their scheduled monthly and annual meetings. In addition, Pakistan's top pediatricians donated their time to conduct diarrhea management training for pediatricians, physicians, and detailmen/salesmen working for ORS producers.

MOTIVATING COMPANIES TO PARTICIPATE

Even if companies met the targeted criteria mentioned above, they did not necessarily decide unaided to participate in the effort. Besides inputs mentioned above, some of the specific methods used to motivate companies to participate included:

1. Profitability/Market Potential

The program had to demonstrate to companies that there was an attractive potential for a commercial ORS market and that this consumer market for ORS products could become sufficiently profitable to warrant their interest. The program also had to demonstrate that it could be helpful in responding to marketing issues raised by the commercial firms themselves.

PRITECH first worked with the commercial sector to identify the potential market for ORS and to develop alternative strategies for increasing demand for the product. PRITECH also worked with ORS producers to develop appropriate mechanisms to obtain a rebate of foil import duties for ORS. Also, in response to other marketing constraints, the National CDD program took the lead in liberalizing the sales of ORS so that it could be sold in all retail outlets in Pakistan. This increased potential retail outlets that could carry the product by 70 percent. The National CDD Program and PRITECH pointed out to the commercial sector that the CDD Program had already created high awareness of ORS and intended to continue doing so. Commercial companies, using creative marketing approaches, could turn this generic awareness into demand for their brands of ORS.

2. Company Image

[illegible] very interested in enhancing the company image. Therefore, PRITECH tried to motivate potential participating firms to become interested in commercial ORS marketing by pointing out that, if they promoted ORT according to the national policy, the company could help achieve a national public health goal. In doing so, the company could improve its image in the eyes of the government, top physicians and, ultimately, the public.

3. Social Responsibility

Commercial companies do have a sense of social responsibility. Although urging socially responsible behavior in itself does not often result in actual commitment, highlighting a company's sense of social responsibility can be a contributing factor to corporate commitment to ORT. Top-level officials in most companies are sensitive to the fact that their company could save lives of Pakistani children. Detail and sales force can become very committed to ORT, once they realize that they are instrumental in saving lives.

4. Product Appeal

Another task was to convince ORS producers to promote breastfeeding and feeding along with ORS. This promotional approach was not initially appealing to firms because ORS producers feared that the impact of a multi-faceted promotional message would dilute the product's focus. Producers had to realize that co-positioning ORS with breastfeeding and feeding would improve the appeal of their product. PRITECH collected, summarized and disseminated to producers research which indicates that ORS, when given along with breast milk and food (particularly starches), reduces stool output -- and stool reduction, research showed, is one objective the consumer commonly seeks. Efforts toward this end worked. A number of ORS

made entry to the ORS commercial market more attractive to pharmaceutical companies with large OTC distribution systems and consumer companies.

Allowing rebates to commercial firms for import tax on packaging foil used in ORS production. This regulatory change increased the profitability of ORS products to manufacturing firms -- even without changes in government determined price ceilings.

3. An Increase in Commercial Sales of ORS Products

Perhaps the most telling variable indicating a more vibrant ORS market is a sales trend showing dramatic increases for commercial ORS products. For example, total commercial sales of ORS products increased by an impressive 86 percent (from a total of 15 million packets to 26 million packets) in 1990 alone (see Illustration 3)!

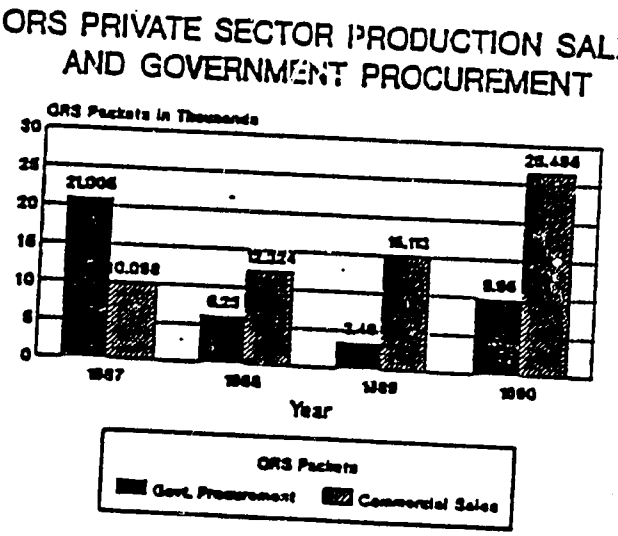

Illustration 3

This striking increase in ORS sales was not typical of the overall market of diarrhea medicines, nor did it happen in the case of any other drug used for diarrhea. On the contrary, from 1989 to 1990 sales of antibacterial drugs declined slightly and motility inhibitors declined by almost 100 percent. This decline, however, was due to the government ban on antimotility drugs in liquid form. Sales of intestinal adsorbents increased very slightly.

Importantly, the market share of ORS in the commercial diarrheal drug market also grew. The ORS share in total units

producers started promoting feeding during diarrhea. Others will soon begin doing so.

IV. RESULTS

A. CHANGES IN THE COMMERCIAL ORS MARKET

Most notably, the program succeeded in significantly stimulating the commercial sector in Pakistan to actively promote, distribute and market ORS products throughout the country. Companies acknowledged the potential of a consumer ORS market and were sufficiently motivated to invest time, effort and resources in developing that potential.

1. Increase in Commercial Sector ORS and ORT Activities

During the process of program implementation, commercial firms already producing ORS products for the commercial market devoted increased production line capacity to these products. Some also introduced new ORS brands. Another aspect of heightened effort was seen in the sales and detail forces and an increase in time devoted to ORS products within their existing product line.

Companies also began complimentary ORT promotional activities in concert with their ORS products. Searle, for example, embraced oral rehydration therapy and produced a promotional booklet entitled, "Searle's Commitment to Oral Rehydration Therapy" (see Illustration 2). This booklet was distributed by Searle's Managing Director to policy makers and leading physicians. Such activities demonstrate that firms were willing to responsibly promote breastfeeding and feeding along with ORS product usage during episodes of diarrhea.

2. Easing of Regulatory Constraints to ORS Market Growth

To realize the potential of the commercial ORS market, regulatory constraints to market growth required attention. The proactive and supportive role of Pakistan's National Control of Diarrhoeal Diseases program and the joint action by ORS producers were critical to the success realized in achieving these regulatory adjustments. PRITECH's role in this matter was to facilitate interaction among the private sector, the government, and the international agencies to modify appropriately this regulatory environment. The modifications achieved were:

Deregulation of ORS sales, previously restricted to pharmacies, to allow over-the-counter transactions in all commercial retail outlets. This change enabled ORS producers to expand their distribution networks and

sold went from 18 percent in 1989 to 29.2 percent in 1990, and the ORS portion of dollar value of total sales went from 9.7 percent in 1989 to 15.5 percent in 1990 (see Illustrations 4 and 5). These data are significant because they indicate that ORS products are becoming more established in the diarrheal drug market.

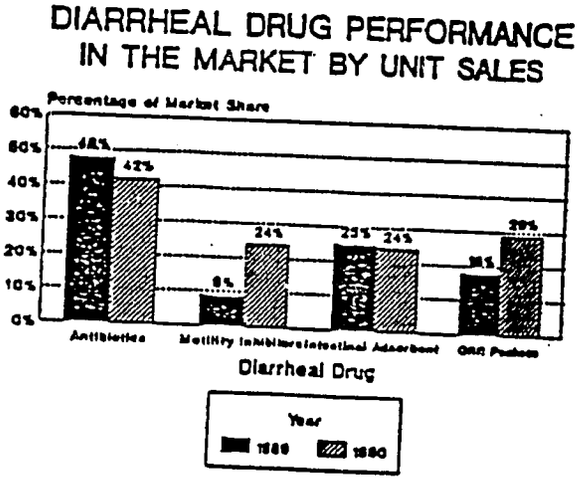

Illustration 4

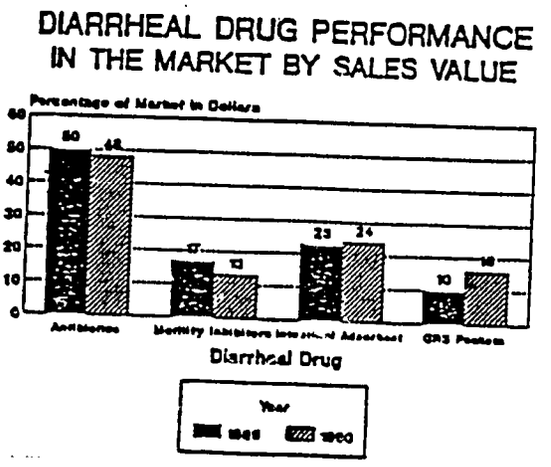

Illustration 5

4. New Companies Entering the Market

A significant indication about the vibrancy of the ORS commercial market is the behavior of firms which did not already have ORS brands on the market. When applying this criterion as well, the commercial ORS market in Pakistan evidences beneficial change. New companies are entering the ORS market.

Companies are also developing and introducing new ORS products. New liquid ORS brands are planned for introduction within the market soon. A rice-based ORS brand was launched in the summer of 1991. In addition, another firm plans to enter the ORS market with a lentil/rice-based ORS product in 1992.

Six consumer goods companies also explored the feasibility of marketing ORS products. However, these companies have not entered the market, primarily because of concerns over the price ceiling on ORS products. Should the price ceiling be lifted, these companies may decide to enter the ORS market.

5. Forging New Partnerships

Four Pakistani dairies/juice producers have experimented with the production of liquid ORS products. These dairies are considering the formation of partnerships with a multinational pharmaceutical company in which the pharmaceutical firm would produce ORS and one or more dairies would package it using the dairies' excess packaging capacity. One attractive benefit of such partnerships is expanding the availability of ORS products through the diary distribution networks to food retail outlets.

In addition, two other firms in Pakistan, Searle and Woodward, have formed a temporary partnership until Woodward's own ORS production facilities are operative. Searle will produce ORS (under a Woodward brand label) which Woodward will market in both pharmaceutical and consumer markets. Although Woodward's ORS brand is a potential competitor because Searle markets its own ORS brand, Searle realizes a benefit because it uses some of its excess manufacturing capacity to produce ORS for Woodward. Furthermore, Searle does not fear loss of its share of the ORS market because it concentrates on pharmaceutical outlets while Woodward's marketing strenth lies in the OTC and consumer-goods outlets. Woodward's extensive distribution network covers about 70,000 retail sales outlets.

B. CHANGES IN THE PROFILE OF NATIONAL ORS DISTRIBUTION

Four years ago, the national profile of ORS distribution in Pakistan showed the government was the major channel for delivering ORS to potential users. The government absorbed about 67% of all domestic ORS production; the balance (33%) flowed through commercial distribution channels (see Illustration 6).

PROFILE OF NATIONAL ORS DISTRIBUTION

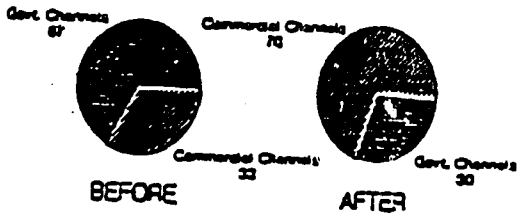

Illustration 6

Now, the situation has reversed. The commercial sector is the predominant channel for getting ORS to the public. Government distribution channels handle less than 30% of ORS produced. Commercial distribution commands over 70% of ORS production.

C. IMPROVED APPLICATION OF OPTIMAL DIARRHEAL DISEASE TREATMENT

In public health terms, the accomplishment which is perhaps the most important and difficult to measure is improved treatment of diarrhea. Nevertheless, the collaborative effort with commercial companies by the PRITECH program did have a positive impact on treatment. Promotional materials by a number of ORS producers now contain ORT (ORS plus breastfeeding plus feeding) and prevention messages in addition to product selling.

One example is Searle's promotional approach for ORS to health practitioners and the general public. Previously, Searle's promotional leaflets for physicians and consumers previously stated inappropriately that no food (only ORS) should be given to children with diarrhea for 24 hours. Now, Searle's promotional materials to the same audience correctly explain the importance of breastfeeding and continued feeding throughout diarrhea. Searle has also developed posters about: prevention of diarrhea; signs for detecting dehydration; and, nutrition during diarrhea.

While the complexities of measuring and attributing mortality reductions to any particular activity are well known, several surrogate indicators give encouragement that the ORS/ORT efforts, mostly public and more recently private, are paying off. Surveillance from major hospitals indicates that most diarrhea pediatric patients have no or mild dehydration. Moderate and severe dehydration cases have decreased considerably.

D. NEW PRIVATE SECTOR INITIATIVES IN DIARRHEAL DISEASE PREVENTION

In addition to making ORS products more widely available through the strengths of the commercial sector, the program determined that these same strengths might also be applied to the broader diarrheal disease issue. Toward this end, efforts were made to interest soap or detergent manufacturers in the public health benefits of soap products, particularly in regard to limiting the transmission of diarrheal disease.

These efforts resulted in Lever Brothers Pakistan, Ltd. deciding to develop a hand-washing promotional campaign in collaboration with PRITECH. Lever now plans to position and market one of its popular soaps products for the prevention of diarrhea. In addition to its on-going advertising efforts, Lever plans to promote its products in Pakistani villages with a fleet of trucks with large screens on the back to show films. Lever

has offered to show ORT and other health-related spots on these mobile vans free of charge. The possibility that Lever Brothers will become a marketer of ORS through its very extensive distribution network continues to be explored.

V. CONCLUSIONS AND LESSONS LEARNED

The attempt to complement the important work of Pakistan's National CDD Program through innovative approaches to the commercial sector succeeded. That the effort was a success is clear since the basic CDD objectives of this pioneering initiative were achieved in a relatively short period of time and to an extent that the national profile of ORS distribution has already been changed favorably: ORS products are now more numerous and much more widely available in the commercial market than ever before. Because commercial firms came forward to invest in the effort and to realize the potential commercial market for ORS, the people of Pakistan now have much greater access to quality ORS products.

A. STIMULATING THE COMMERCIAL SECTOR

The PRITECH program in Pakistan has shown that several intervention mechanisms can be utilized to effectively mobilize commercial sector interest in ORS products and to apply productively market forces to expand the commercial ORS market.

1. Building Upon Public - Private Cooperation

This program in Pakistan would not have been possible without cooperation between government and commercial firms toward common goals. In trying to define those common goals, it was essential to allow differing interests (between government and private sector) to motivate the achievement of that goal. This was possible mainly through constant dialogue and improved communication between the public and private sectors.

One example of the identification of a common goal between the public and private sectors were approaches to consumers (or users of ORT). The government wanted to promote ORT as composite concept (the use of ORS or fluids combined with breast milk or food. Firms manufacturing ORS wanted to respond to consumer demand that ORS use should reduce stool output in addition to rehydrate. Once ORS manufacturers realized that ORS given along with foods would reduce stool output, they began to position their ORS products along with food and promote continued feeding during the use of these products.

PRITECH served as a catalyst or broker for the critical communications between the public and private sectors, helping to identify common goals and to find appropriate mechanisms to

achieve those goals. The government continued to demonstrate a progressive willingness to explore complimentary CDD activities with the private sector. Although commercial firms responded positively to requests to collaborate with the national effort to save children's lives, it was also important to point out to the firms that their participation in the effort would enhance their corporate image in the eyes of the government, prominent physicians and consumers.

2. Understanding the Market Through Assessment

One important element of the success of this program was the careful application of commercial marketing methodology with the knowledge acquired about the unique characteristics of both the pharmaceutical and consumer goods marketplace in Pakistan. Over time, PRITECH assessed the ORS market in Pakistan to determine the potential for commercially marketing ORS products and to identify some of the means to realize that potential. This assessment was used to develop a Pakistan private sector strategy including marketing approaches and plans which were essential for optimally involving the commercial sector. An accurate understanding of the Pakistan market was a critical element in making technical assistance to firms appropriate and valuable to the firms.

3. Factoring Market Size and Profitability

The profitability of commercial ORS products had to be a given accepted by both the public and private sectors. Most commercial firms initially did not consider ORS to be a very profitable product. This perception had to be changed. Reassessing profitability was driven both by encouraging private sector executives about the significant size of potential consumer demand for ORS products and by reducing the costs of production. The data on the rates of diarrheal episodes among Pakistani children and the total number of children in Pakistan helped to convince executives about the potentially large size of the ORS market. Government willingness (discussed below) to rebate certain import taxes for ORS raw materials improved prospects for lessening ORS production costs.

4. Capitalizing Upon Existing Production Capacity

Seven firms were producing ORS at the start of the program. Some of these had excess production capacity. Other firms had the means to produce but did not do so. The commercial sector, therefore, had the means to increase ORS production relatively easily without significant amounts of additional capital needed to increase ORS production. This situation contributed favorably by reducing the opportunity costs for interested firms to participate in the program. Indeed, three additional firms began producing ORS products during the course of the program.

5. Modifying the Regulatory Environment

A critical outgrowth of the cooperative spirit between the public and private sectors were changes in government regulations which constrained the growth of the ORS market. With foresight and flexibility, the government responded to constraining issues identified by commercial firms. The two most significant modifications in government regulations were: permitting the sale of ORS in all retail outlets and allowing firms to receive a rebate of import taxes on packaging foil used in packaging ORS products. These modifications greatly expanded the possibilities for distributing ORS products and made the potential financial return to manufacturers from investing in ORS commercial marketing much more attractive.

6. Fostering Positive Competition

One important mechanism was to expect several different commercial firms with ORS production to participate in the program simultaneously. This approach allowed the principle of competition to help further develop the potential of the general ORS market and to exploit, to the maximum extent possible, differing distribution networks to get ORS to the largest number of consumers quickly. Fostering competition also helped to increase the number of ORS brands available to better serve a wider range of consumers.

On the surface, working with several different firms with competing ORS brands might appear impossible or at best impractical. The competition might not allow cooperation. This issue, PRITECH found, was manageable by honoring the proprietary concerns of specific companies concerning their marketing plans and by identifying common interests of ORS producers around which the various firms could cooperate. These common interests, for example, included the constraints on the commercial ORS market (such as regulatory restriction of ORS sales to pharmaceutical outlets or low ceilings on retail price).

7. Exploring Alternative Distribution Networks

The firms manufacturing ORS in Pakistan are pharmaceutical companies. By the nature of their other product lines, these firms have strong distribution networks for reaching chemist shops or other outlets for pharmaceutical products. Most shops of this sort are in the more urban centers of Pakistan. So, even after manufacturers began their commercial ORS marketing efforts, the availability of the ORS product did have limits.

Therefore, it was important to work with ORS producers to widen their existing distribution networks and to identify additional distribution systems within the commercial arena which could make the ORS product more commonly found in a wide range of

retail outlets. In an effort to maximize ORS distribution and brand variety, PRITECH worked with four diaries and the U.S. firm Land O' Lakes on the development of liquid ORS products which could be distributed by the dairies to grocery and food retail outlets.

8. Using the Commercial Sector for Non-ORS CDD Work

Even if a company is not interested in marketing ORS, it is possible to convince it to contribute to the CDD effort in ways consistent with the company's objectives and product line. For instance, PRITECH initially approached Lever Brothers to ask the company to market ORS. Although the former chairman of the company considered the request, Lever did not agree to this proposal because ORS does not fit within its product line and has a very low ceiling on retail price. However, Lever responded positively to PRITECH's request that Lever position one of its soap products for hand-washing to prevent diarrhea. This appealed to Lever's sense of social responsibility as well as its self interest; positioning one of its soaps to prevent diarrhea could expand Lever's presence in the soap market.

9. Motivating Firms Without Direct Financial Assistance

The key motivating forces for involving the commercial sector in greater ORS marketing efforts did not include the ability of the PRITECH program to finance specific activities undertaken by the participating firms. Even though the program could offer modest matching grants to firms to help in mobilizing their ORS marketing activities, most firms did not use this facility of the program. Participating firms valued the PRITECH program primarily for the technical assistance it offered and the "brokering" role it could play in the interface between the public and private sectors. The services sought most frequently by firms were: facilitating interaction with the government, particularly regarding regulatory matters; technical linkages to national and international CDD efforts; technical guidance on ORT and appropriate ORS promotion; advice on alternative marketing techniques; access to market research data; guidance on the development of product promotional materials; and, assistance in advertising.

B. CONTRIBUTIONS OF THE PUBLIC SECTOR

Throughout the PRITECH program, the achievements and contributions of the Government of Pakistan have been very important and noteworthy. One such achievement is the adoption of a standard national case-management policy (see Illustration 7) for diarrhea. This policy promotes ORS as the first-line treatment in health facilities and as one of the home fluids for home treatment. The policy defines ORT as ORS/fluids plus breastfeeding plus feeding. In addition, the policy provides a

state-of-the-art guideline which can be used by ORS producers to develop promotional materials and train detail and sales force to promote the product.

Furthermore, the government has taken steps to help make the diarrheal drug market become more favorable for ORS products. In 1987, for example, antidiarrheal and antibacterial combinations were banned. The government also stopped purchasing antidiarrheals for use its health facilities. In 1990, all pediatric forms of antimotility drugs were banned.

A very critical government contribution to the program's success was the responsiveness in reviewing regulatory issues affecting commercial ORS marketing and in taking action where appropriate to modify those regulations. Similarly, government CDD communication efforts helped to increase public awareness and demand for ORS. The program found that generic promotion of ORT by the public sector could be supplemented very effectively by brand promotion in the commercial sector.

The government, in its assessment of progress towards national CDD goals, acknowledged the role of the commercial firms. It also appreciates that the national messages about case management and prevention of diarrhea are being disseminated to private health providers whom the government has been unable to reach.

C. A NEW, MORE SUSTAINABLE MODEL FOR SOCIAL MARKETING

PRITECH utilized a new social marketing model in Pakistan for promoting and making public health products more widely available through commercial distribution channels. Unlike most-other models, the PRITECH model did not rely on significant donor financing of product or marketing costs. Nor did it rely on a relationship with one main firm for marketing the public health product.

The PRITECH model operates by utilizing existing commercial market forces to stimulate the interest of firms in making a public health product widely available. A basic objective of the model is to make the environment for marketing the public health product more attractive to firms through: demonstrating potential consumer demand and market size; enhancing the marketing abilities of the firms through technical assistance and market research; performing a brokerage function between the public and private sector; and, if appropriate, attempting to modify regulatory constraints to marketing the public health product.

The Pakistan experience has shown successfully that this new model works. Indeed, commercial distribution and sales of ORS products have risen sharply during the program's implementation. ORS products are more numerous now and are more widely available

than ever before in retail outlets. Impressive as these accomplishments are, there is another aspect of the model which is just as significant: contributions to greater sustainability.

Like other models, the PRITECH model contributes to making national public health initiatives more sustainable by utilizing commercial distribution channels to reach the general public instead of relying only on public sector distribution. In Pakistan, the marketing initiative resulted in the commercial sector replacing the public sector as the main channel of ORS distribution. This accomplishment relieves the government of the burden of financing the direct distribution of most of the ORS available to the public.

However, unlike other models, the PRITECH model relied on participating firms doing the bulk of their own investment for introducing ORS products into the market. Brand ownership, production and marketing decision authority was entirely in the hands of the participating firms. The chances of companies continuing to market ORS products after the PRITECH program ends are high for the following reasons:

- Companies can realize some profit through product sales.

- Product marketing costs are financed by the firms themselves through sales revenues.

- Several firms are involved, ensuring that no one company has a monopoly of the product.

- Competition among the several firms should ensure that each company will present the best possible product at an affordable price.

- Companies made a commitment to ORT through increased investment in machinery, facilities and promotion.

- Trends for total sales of ORS products are on the rise.

- New companies are entering the ORS market, suggesting corporate confidence in future market growth.

- There is recognition that cooperation with national public health policies and goals improved corporate image.

Because of these factors, it is likely that companies will continue promoting ORT and others will join this effort. As long as the government continues its existing policies and regulations, production, distribution and marketing of ORS by the

commercial sector should continue to grow.

PRITECH believes that the achievements realized to date from this new social marketing model can be successfully replicated in other countries. The model would be particularly appropriate in other countries that already have existing ORS production capacity and more than one producer in the market. Although the model was tried only for ORT and ORS products, it could also be applied to other socially beneficial products.

VI. THE ONGOING CHALLENGE

Although the effort to involve the commercial sector more broadly in making ORS more widely available has already produced admirable results, more can still be accomplished.

A significant regulatory issue, from the perspective of the commercial sector, is the retail price ceiling on ORS products. Flexibility in product pricing is a basic premise in commercial marketing and the current price ceiling on ORS products is a constraint to market growth. It is possible that, as long as the price ceiling remains, consumer goods companies will not invest in marketing ORS products.

Another issue is how to stimulate more advertising by commercial firms so that potential consumer demand for ORS can be realized. Currently, pharmaceutical companies are restricted to spending not more than 5 percent of their sales revenues for advertising. This restriction results in limiting firms in the total amount they can invest in demand creation. In this environment, ORS products must compete with other products within any given company for a share of the limited advertising budget. Since ORS is a relatively low profit product, companies, when allocating their advertising budget for various products, tend to place ORS at the bottom of the list. If an exemption to this advertising restriction could be given to ORS, producers may be willing to increase their promotional expenditures for ORS.

An important new development is the arrival of cereal based ORS products on the market. From a marketing perspective, these products offer the advantage of helping to meet consumer demand for interventions during diarrheal episodes which will also reduce stool output. Cereal based ORS may represent a real opportunity to capture further market share from the classic antidiarrheal drugs, the use of which detracts from national CDD objectives. One manufacturer in Pakistan has just recently introduced a new cereal based ORS product (while continuing to produce and market its pre-existing ORS brands). Another producer also has plans to introduce a cereal based ORS.

Another significant development for the future is the interest in pre-mixed, liquid ORS products by diary companies. Having liquid ORS products in the marketplace offers several potential advantages. One is that the use of pre-mixed ORS eliminates historic public health concerns about consumers combining incorrect volumes of water with ORS powder at home. Pre-mixed, liquid ORS products, by production standard, would be the correct formulation. In marketing terms, having liquid ORS products represent a marketing advantage in offering a diverse ORS product line which can more effectively meet the differing needs of varied segments of the consumer population.

The greatest challenge, however, is to ensure availability of ORS to all Pakistani children who need it. This means making ORS available in as many retail sales outlets as possible. This should include even very small shops, such as "karyana" shops in villages where most people live. To accomplish this objective, ORS products will have to be marketed through a still wider range of distribution networks. Entering new distribution networks will require the involvement of consumer goods companies which sell products like tea or matches which typically are available everywhere.

In the future, the private sector ORT initiative should focus on working with the government and consumer companies to find creative ways of making ORS a viable product for consumer goods companies to market, while maintaining the quality control of this product. If ORS is to be made available to all children who need it in a sustainable fashion, it will be the consumer goods companies that will take the product beyond the urban areas to the villages where most Pakistanis live.

APPENDIX 4

Background Paper No. 4

The Arrival of Commercial Cereal-Based Oral Rehydration Solution (CBORS) Products: A Commentary on Market Forces Affecting Corporate Interest in CBORS

by

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1992

I. BACKGROUND

Around the globe, there is growing evidence that corporate interest in cereal based oral rehydration solution (CBORS) products is increasing. This interest has already led to the recent arrival of commercial CBORS products within two developing countries. During the summer of 1991, Wilsons Pharmaceuticals (a Pakistani firm) introduced Cerealyte, a powdered CBORS product which requires heating before use, into the Pakistan market. At about the same time, Unipharm launched Resoral-AR, a liquid CBORS product containing rice powder, within the Guatemalan market. Another Pakistani firm, Highnoon, has been developing a CBORS product composed of a lentil-rice mixture. Highnoon anticipates calling its CBORS product "Oralnu" and is taking steps to introduce Oralnu within the marketplace.

Multinationals and firms based in the developed world are also acting upon this interest in CBORS. In 1990 within the U.S., Mead-Johnson began marketing Ricelyte (a liquid product formulated from rice-syrup extracts). Ricelyte has enjoyed some success in the oral rehydration solution (ORS) market and there may be some interest at Mead-Johnson for introducing Ricelyte within some of the developing countries of Latin America and Asia. Galactina, a Swiss firm, has developed an instant powdered CBORS product which the firm is now registering for use within Switzerland and for export. Galactina representatives anticipate the registration process for their CBORS product to be complete by June 1992. Sandoz, a large multinational pharmaceutical firm, is reported to be in the process of developing a CBORS product as well.

Whatever the decisions of health planners concerning ORS products for use within the public sector, it is clear that some firms are proceeding ahead with CBORS products for introduction within the international marketplace. Why are companies interested in CBORS and why have some already taken steps to produce CBORS products for sale to consumers and private health care practitioners? The answers to these questions lie as much within the interplay of powerful market forces as within the data concerning the clinical efficacy of CBORS. The following discussion identifies some of the market variables which may be driving corporate interest in CBORS products.

II. CBORS CHARACTERISTICS WHICH ARE RESPONSIVE TO MARKET FACTORS

A. A "New" Technology

A series of recent research efforts have been initiated to explore the clinical potentials of perfected CBORS. This CBORS research has involved some well known and very respected figures in the medical research world. CBORS research originated as part of the quest of the scientific community to develop and improve oral rehydration solution technology. The results of this research have prompted legitimate debate within the public health community over just how much better an alternative ORS should be before warranting a change from existing standards within control of diarrheal disease programs. However, this debate does not seem to be a factor in determining corporate interest in CBORS.

Glucose ORS products (mainly for use in government health care systems) represent an older, established technology which has been present in some countries for up to ten years. For some manufacturers, CBORS apparently represents a product which could be marketed as a new ORS technology which is based on some of the latest oral rehydration research. In both over-the-counter and prescription medicines, "new" technological developments represented in new products offer marketing advantages which can be used to attract the attention of consumers and private health care professionals alike.

B. Freedom from Public Sector Glucose ORS Heritage

As noted in Background Paper No. 2 (Oral Rehydration Solution and the Commercial Marketplace in Developing Countries), glucose ORS in many locations has acquired a public sector image and the public sector has played a major role in presenting ORS to the general public. This public sector heritage of glucose ORS meant that when attempts were made to make commercial glucose ORS products more widely available in the marketplace, companies often could not follow standard business practices for product introduction and marketing.

CBORS is not now a product commonly in use by the public sector. Most countries do not have now a set of preconceived standards or ideas about CBORS products: no prescribed formula, no standard package size, and no predetermined concept of what the retail price should be. Therefore, companies adopting CBORS products may perceive they will be able to do so in greater freedom and in a fashion more compatible with standard business practices for consumer products.

C. Undefined Product Image

If kept distinct from glucose ORS, the image of CBORS products has yet to be defined. Companies marketing CBORS products may see opportunities to create their own product image for CBORS and position it accordingly within the marketplace. Most probably, companies are interested in positioning their CBORS products as a "serious" medicine for diarrhea in the hopes of attracting the allegiance of private health practitioner and consumer alike. Some commercial manufacturers apparently perceive that starting a fresh product image with CBORS will allow them to utilize their marketing ingenuity to try to conquer market problems in a fashion that glucose ORS has not enjoyed.

D. Prospects for Greater Price Flexibility

Since CBORS is not standard in most national control of diarrheal disease (CDD) programs, governments may not have the same low retail price expectations for CBORS that they usually do for glucose ORS products. Low returns to manufacturers, wholesalers and retailers for glucose ORS has hampered the financial viability of glucose ORS products and constrained their ability to compete against other considerably more profitable diarrheal drugs. Some manufacturers believe that the retail price for commercial CBORS products may have more flexibility (i.e. be higher) -- particularly if powdered glucose ORS products, with their low retail price ceilings, continue to be offered widely within a country.

Non-ORS antidiarrheal drugs already enjoy relatively high prices which translate into higher returns for drug sellers as well as manufacturers. The average price of single antidiarrheal product, for example, can easily be ten times more than a powdered glucose ORS product in a developing country. To date, there is very little data on and experience with the commercial market value of CBORS products. In the U.S., Mead Johnson's Ricelyte product retails for about $4.00; however, compared with developing country pharmaceutical markets, U.S. pharmaceutical prices are much higher. Rough estimates for an exported CBORS product similar to what Galactina has developed (landed in a developing country, packaged and distributed to the drug seller) place the retail price at around US$ 0.80 - 0.90. Other CBORS products, which utilize a production technology simpler than that of Galactina (as is reported for the product under development at Sandoz) and which may be produced locally, would be expected to have a substantially lower retail price. Even so, the anticipated retail price for a commercial CBORS product would be higher than that of the usual commercial glucose ORS product in powdered form.

E. A Possible Replacement for Banned or Restricted Antidiarrheals

Several countries, such as Pakistan and Indonesia, have taken steps to ban or substantially restrict antidiarrheal products. Many countries, for example, do not include antidiarrheals on their essential drug lists. Increasing criticism about the dangers or ineffectiveness of some non-ORS diarrheal products have also prompted some pharmaceutical manufacturers to remove a few products from markets. Johnson and Johnson, following severe criticism over its Imodium E product in Pakistan, removed the pediatric (liquid) form from markets all over the world.

Looking into the future, some companies apparently see these events as part of an increasing trend which will limit the marketability of antidiarrheal products in the years to come. If the future of antidiarrheal products is questionable because of an environment of growing government restrictions, some companies seem to view CBORS as the type of product which could fill the gap of the "retreating" antidiarrheals.

F. Ability to Appeal to the Consumer Demand to Reduce Diarrhea

Despite general recognition of widespread consumer demand to stop or reduce diarrhea during diarrheal episodes, manufacturers of glucose ORS products have not been able to say anything about the ability of glucose ORS to stop or reduce diarrhea. Ineffective antidiarrheal products and antibiotics have long tried to respond to this consumer demand and have done so with some marketing success.

The availability of data which indicates that CBORS is effective in reducing volume and duration of some forms of diarrhea (especially cholera) has suggested to manufacturers that they could legitimately claim that CBORS products both effectively rehydrate and reduce stool output during a diarrheal episode (a 32% - 36% reduction among patients with cholera and 18% among patients with acute non-cholera diarrhea, according to recent WHO reviews). Such a combination of characteristics, rehydrating and reducing stool output, could provide a product an alluring promotional appeal for both consumers and private health practitioners.

G. Opportunities to Expand ORS Product Lines

In consumer goods industries generally, adding similar products to an existing product line often helps to capture a greater share of an existing consumer market and to help the total market grow. Soap companies, for example, often offer a wide range of soap products possessing different features and abilities. By offering a wide product range, the company has a greater chance to appeal to a greater variety of consumers (and sell more).

For those companies that already manufacture glucose ORS, CBORS may also represent an opportunity to expand their ORS product line. An expanded product line may offer the same benefit to the total ORS market as it does to soap markets. The case of Wilsons

Pharmaceuticals in Pakistan introducing a CBORS product along side their other pre-existing glucose ORS products apparently represents an attempt to follow this marketing strategy. It appears in this instance that the Wilsons CBORS product expanded the company's ORS product line toward the higher price end of the market -- but, with the very low government ceilings on their glucose ORS products, that was the only direction open for expansion.

III. CBORS FACTORS WHICH MAY LIMIT THE INTEREST OF SOME FIRMS

Not all aspects of potential CBORS products offer attractions. There also important business variables associated with CBORS which may deter the interest of some firms.

A. Technical Limitations in Production

Manufacturing CBORS products will require some form of cereal processing. In the case of the Galactina CBORS product, some of the cereal processing techniques required are quite sophisticated and need specialized production machinery. Many pharmaceutical companies, particularly those based in developing countries, do not have cereal processing abilities or capacity in their existing production machinery. The modification of existing production capacity could involve considerable investments in new machinery and staff training. Some firms may be unwilling or unable to make such investments and, thus, decide the prospect of CBORS product manufacture to be unattractive on these grounds.

B. Variations in Product Line

The types of companies which may already have the production equipment and expertise for the cereal processing portion of CBORS are firms which make food products. Such firms, however, do not normally have a pharmaceutical product line. For companies whose history is mainly based on processed food products, contemplating entering the pharmaceutical product arena would represent a major change in their internal definition of corporate mission or business objectives. The pharmaceutical and food markets are normally viewed by firms as being very different business arenas. Food companies may well be uninterested in entering a business arena historically dominated by well established pharmaceutical firms.

IV. CONCLUSION

Several characteristics of CBORS as a product for the treatment of diarrhea respond to pre-existing market forces and have apparently induced some corporations to launch or contemplate commercial CBORS products. Additional characteristics related to CBORS production technology and marketing might actually restrict the entry of some potential private producers into the CBORS field.

Data on the real market performance of commercial CBORS products in developing countries are not yet available and the market experience with such products is still quite short. To understand if the market potential some firms may see in commercial CBORS products is actually realized, market research and assessments will be needed over time.

APPENDIX 5

Background Paper No. 5

ORS Composition:
A World Health Organization Perspective

World Health Organization
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1992

ORS COMPOSITION: A WHO PERSPECTIVE

Introduction

Glucose-based ORS solution is the recommended treatment of most episodes of dehydration caused by diarrhoea; only patients with severe dehydration require initial rehydration intravenously. A single ORS formulation is recommended by WHO and UNICEF. During 1990, ORS equivalent to 400 million litres of solution was produced worldwide. Of this, 270 million litres were produced in 64 developing countries, accounting for 80% of ORS used in developing countries. About 95% of ORS products available in developing countries conform to the composition guidelines of WHO and UNICEF.

The recommended treatment for acute dehydrating diarrhoea includes prompt rehydration with ORS solution, continued breastfeeding and, after rehydration has been achieved, giving other fluids in addition to ORS solution and continuing to feed with an appropriate diet for age. This treatment strategy has been shown to be both safe and highly effective. It does not, however, appreciably reduce diarrhoeal stool output or the duration of diarrhoea, which are results parents and many health workers wish to achieve. An ORS solution that could have this effect might be accepted and used even more readily than the current product.

Approaches to "improving" ORS effectiveness

There are at least three approaches that might improve the efficacy of ORS solution. These are:

Approach	Mechanism
1. Give standard ORS solution with frequent feedings of a cereal-based diet	Provision of additional organic carrier for sodium absorption
2. Reduce glucose and sodium content of ORS	Reduced osmolality
3. Replace glucose in ORS with 50g precooked rice	Additional organic carrier and reduced osmolality

The remainder of this brief paper will consider the apparent advantages and disadvantages of these approaches, the status of research on their relative efficacy, and a proposed approach to reaching a decision as to which, if any, should be promoted as recommended therapy.

Advantages and disadvantages of ORS options

Some of the apparent advantages and disadvantages of these three approaches are summarized below:

1. Give standard ORS solution with a cereal-based diet. This is the treatment currently recommended by WHO/UNICEF. It was not, however, the treatment routinely given in trials that have compared the efficacy of standard ORS solution with that of other ORS formulations. It is possible, therefore, that differences in efficacy observed in those studies might not be seen, or might be of a different magnitude, were this approach used as the standard therapy.

Advantages:

- No change in ORS formula would be required.
- No change in treatment guidelines would be required.

Disadvantages:

- There would be no food-related benefit during rehydration, before feeding was resumed.
- Any benefit attributed to feeding would be lost, or reduced, if an appropriate diet could not be taken after rehydration. This could occur in patients with significant anorexia or repeated vomiting, and in those continuing to require large volumes of ORS solution for many hours, making it difficult to resume normal feeding.
- The benefit would not be available to young infants who should not yet be given solid foods.

2. Reduce the glucose and sodium content of ORS solution. An oral rehydration solution with reduced sodium content has been repeatedly recommended by some paediatricians in developed nations. These paediatricians express concern that the sodium content of WHO/UNICEF ORS solution (90 mmol/l) is too high and risks inducing hypernatraemia, especially during maintenance therapy of infants with viral diarrhoea. In at least one country, Egypt, hypernatraemia is frequently seen in dehydrated infants who present after home therapy with standard ORS solution. The role of ORS in this problem, however, remains controversial. Moreover, if there is a problem, it is as likely to be caused by transient malabsorption of glucose from a slightly hypertonic solution, as by the sodium concentration. Insufficient intake of water or other plain fluids may also play a role.

Advantages:

- A hypotonic solution assures the intake of sufficient free water by patients who may not be given other fluids or breastmilk during therapy, as is recommended by WHO/UNICEF.
- When there is transient, partial glucose malabsorption, a hypotonic solution may reduce stool output by avoiding osmotic diarrhoea.
- The ingredients and appearance of ORS would not change, although ORS composition would be modified; and conversion to

the new formula by production units would be relatively simple. Additionally, the cost of ORS might decrease slightly.

Disadvantages:

- A change in ORS composition would be required.

- The solution may not be as efficient as standard ORS for maintenance of hydration in patients with large continuing losses of stool that has a high sodium concentration; for example, during cholera. This would be reflected as a need for larger volumes of ORS solution.

3. Replace glucose in ORS with 50g of precooked rice powder.

Advantages:

- An appreciable beneficial effect in comparison to standard ORS has been clearly demonstrated for patients with cholera. The benefit, if any, for infants and children with severe non-cholera diarrhoea has not been precisely defined, but is certainly much smaller.

Disadvantages:

- Rice-based ORS would be more costly than glucose-based ORS, probably by about three-fold. This relates to the increased amount of ingredients/litre (50g rice vs. 20g glucose) and the greater cost for packaging, transportation and storage, owing to the greater bulk and weight of rice-based ORS.

- For manufacturing reasons, rice-based ORS would likely be considered a food and be produced by food manufacturers, not drug makers. This would create two problems: (i) a food company would have to be able to produce the product to standards of precision that are far more stringent than those used for foods, and (ii) novel regulations and guidelines would have to be adopted and implemented to allow production by a food company of a therapeutic product and to assure that the product meets required standards for composition. WHO is aware of only one country in which registration of rice-based ORS is currently being attempted: Switzerland.

- Infestation of the packaged product with weevils and related insects could be a problem. This is seen frequently with other packaged cereal products that are produced in developing countries and stored under warm, humid conditions. Should this occur with rice-based ORS, the adverse effects for CDD programmes could be very serious.

- As rice-based ORS has a different appearance and behaves differently in solution (suspension) than standard ORS, a major effort would be required to retrain health workers around the world in its preparation and use.

- In most countries, children treated for diarrhoea at a health facility are given enough ORS packets to continue treatment for two days at home. However, the useful life of rice-based ORS solution before it sours is 8-12 hours, much shorter than for standard ORS solution. This would require either that package size be reduced (and more packets be given) or that larger amounts of unused ORS solution be discarded. Either approach would add to the expense of home treatment.

Research results and research in progress

1. Standard ORS plus a cereal-based diet. This approach has been assessed in a small number of studies, but none has been of fully satisfactory design. Results of at least two studies appear to show no clinical benefit for rice-based ORS in relation to treatment with standard ORS solution and a rice-based diet; another study yielded apparently opposite results. WHO is supporting two large randomized studies to compare the outcome of treatment with standard ORS solution or rice-based ORS solution in children with severe non-cholera diarrhoea who are given a conventional rice-based diet. Results of these studies should be available by mid-1992.

2. ORS with a reduced content of glucose and sodium. One prospective randomized trial has been done comparing three treatments in 61 children less than 18 months of age with severe non-cholera diarrhoea. The treatments were:

Group A - IV rehydration and maintenance for 24 hours, then maintainance therapy with standard ORS solution until diarrhoea stopped.

Group B - Rehydration and maintainance therapy with standard ORS solution until diarrhoea stopped.

Group C - Rehydration and maintainance therapy with diluted ORS solution until diarrhoea stopped. The solution contained (in mmol/l): Na^+, 60; K^+, 13; Cl^-, 53; citrate, 7; total osmolarity was 207 mOsm/l.

Provision of food and other fluids was identical for each group and followed standard WHO guidelines. Their intake, however, was less in Group B owing to the large volumes of ORS solution that were required.

The results showed that diarrhoeal stool output during the first 24 hours and the entire illness, and duration of diarrhoea were reduced by 37%, 37% and 35%, respectively, in children given diluted ORS when compared with those given standard ORS. Results in Groups A and C were similar. The mechanism of the apparently enhanced efficacy of diluted ORS solution is not clear. One possibility is that standard ORS solution evokes osmotic diarrhoea in some children, owing to transient glucose malabsorption. This explanation, however, is speculative. Further studies comparing standard ORS with a low osmolality ORS are underway in four countries and will be completed by mid-1993.

3. Rice-based ORS. Evidence from a number of clinical trials involving more than 1300 subjects shows that treatment with rice-based ORS solution reduces stool output and probably the duration of diarrhoea in comparison to treatment with standard ORS solution. A meta-analysis of these studies showed that the mean reduction in stool volume during the first 24 hours of treatment for children and adults with cholera or cholera-like diarrhoea was 36% and that for infants and young children with severe non-cholera diarrhoea was 18%. Based on additional studies now completed, but not included in the meta-analysis, the latter figure probably overestimates the true difference in efficacy of these therapies. A final analysis of all studies involving infants and children with severe non-cholera diarrhoea (nearly 1000 subjects) will be available in mid-1992.

Proposed process for developing a policy on use of a modified ORS formulation

When all results of the above studies are available, in mid-1993, it should be possible to determine whether any of the three described strategies is appreciably more efficient for treating patients with dehydrating diarrhoea than is standard ORS. The proposal of WHO is that no decisions be taken on this subject until then. At that time, it should be decided whether any change is recommended, bearing in mind: (i) the immense advantages of a single packaged ORS product for use in patients of all ages with diarrhoea of any etiology, and (ii) other considerations, as noted above, that might affect the practical value of these therapies.

Background Paper No. 6

Cereal Based Oral Rehydration Therapy for Dehydrating Diarrhea: Possible Options

by

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1992

ABSTRACT: The use of cereals or starchy staples in oral rehydration fluids add substantially to the efficacy and effectiveness of rehydration fluids prepared only with glucose or sucrose in patients with dehydrating diarrhea. Specific improvements of cereal based oral rehydration therapy (CBORT)[1] (relative to glucose ORT) include a decrease in purging rate and volume, and a shortening of duration of diarrhea in patients with cholera-like diarrhea. The application of CBORT to diarrhea control programs has not occurred because CBORT is not substantially better for patients with milder diarrhea, and because the introduction of CBORT solutions into control programs brings along with it programmatic and logistic questions.

This review examines the physiologic and clinical basis for CBORT and suggests alternative strategies for application of these findings to diarrhea treatment. The key conclusions of this evaluation include the following:

1) Development and marketing of CBORS through the private commercial sector will be appropriate in some countries.

2) The use of CBORT technology is acceptable for the treatment of any diarrhea, either by

   a) using cereal based oral rehydration solution (CBORS)[2] as a rehydration solution, or

   b) feeding of cereals as gruels to children with diarrhea (along with standard ORS);

   In either case appropriate feeding should be given in addition to rehydration solution.

3) Consideration should be given to making CBORS available for use in the treatment of cholera and other severe diarrheal diseases, particularly at cholera centers.

The focus of the present meeting is on issue #1, appropriate development and marketing of CBORS through the commercial sector.

[1]Cereal based oral rehydration (CBORT) refers to the treatment given to dehydrated patients with diarrhea in which a solution containing cereal (e.g. rice) and electrolytes is administered.

[2] Cereal based oral rehydration solution is a specific solution used for rehydration and contains the same electrolytes as the glucose ORS recommended by the WHO, but with 50 grams of cereal in place of the 20 grams of glucose.

BACKGROUND

Clinical studies of cereal based oral rehydration therapy (CBORT) have recently been reviewed by Khin Maung U and Greenough (J Pediat 118: S72-78 and S80-85, 1991) and by a symposium (Cereal Based Oral Rehydration Therapy for Diarrhoea, 12 - 14 November, 1989, The Aga Khan University, Karachi, Pakistan) and by Gore, et al (Brit Med J 304:287-291, 1991). Thus, much is known of the physiologic basis for CBORT, and clinical studies have established its clinical efficacy[3] and its superior efficacy relative to glucose ORS when treating patients with severe dehydration from cholera-like diarrhea.[4] The papers also have examined the potential for implementing programs based on CBORT. Rather than repeating the summaries of these papers, a reprint of the reviews by Khin Maung U and by Gore are enclosed in the appendix.

The important issues raised by the clinical studies include the following:

1. Does CBORT decrease stool outputs in children and adults with severe diarrhea (cholera and cholera-like illness) relative to treatment with glucose ORT?

Studies from Bangladesh and India demonstrated a consistent reduction in stool volumes and reduction in diarrhea duration in cholera and cholera-like patients treated with CBORT. The reduction with CBORT was in the range of 20 to 50% and one study demonstrated a significant decrease in duration of diarrhea. Cereals (or foods) used included rice, wheat, sorghum, millet, potato. Of these, the most data is available for rice, and this cereal appears to be the most consistent in its performance.

2. Does CBORT decrease stool outputs in children and adults with mild to moderate diarrhea (non-cholera illness) relative to treatment with glucose ORT?

In general, differences in purging rates between CBORT and glucose ORT in patients with mild diarrhea have been less or not significant. In one study from Egypt, CBORT was associated with a decrease in purging rates; however, a similar effect was seen with glucose ORS if the children ate food (rice) in addition to receiving rehydration fluid. This suggests that glucose ORS can be improved by feeding a starchy cereal during rehydration. Whether this would occur in cases with cholera is not known.

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[3] Efficacy refers to the demonstrated ability of the drug or intervention to treat a certain condition. In this case, CBORT has been shown to rehydrate patients with dehydration due to diarrhea.

[4] Superior efficacy refers to the decrease in purging rate and duration of diarrhea in patients treated with CBORS in comparison to glucose ORS.

3. **Is there a physiologic basis for the improvement of CBORT over glucose ORT in treatment of patients with severe diarrhea?**

The improvement of CBORT is apparently related to a) lower osmotic load, and possibly to b) additional transport mechanisms (e.g. amino acids) in addition to the glucose-mediated transport. With glucose ORS, glucose molecules are absorbed and carry with them, sodium and water molecules. Therefore, the solution should contain approximately equal concentrations (millimoles) of sodium and glucose. This results in a solution which is slightly hypertonic with respect to plasma and leads to an osmotic penalty which tends to shift fluid from the blood into the lumen. If starch (a poly-glucose) is used as a replacement for glucose, a large number of glucose molecules can be included in the solution, but in a form which is not osmotically active. The glucose molecules are enzymatically cleaved, and are absorbed (along with the sodium) but without a buildup of glucose molecules in the lumen. Thus, the resulting solution is hypotonic, and the osmotic forces tend to pull fluid from the lumen into the blood as would be desirable for a rehydration solution.

Although rice cereal contains protein as well as starch, the role of amino acids as an explanation for the improvement of CBORT is speculative at this point. It is known that certain amino acids, e.g. alanine when added to standard glucose ORS, does improve sodium and water absorption in cholera patients, apparently by providing an additional transport site for absorption of sodium. Whether the addition of these same amino acids would improve a starch based ORT is not known. However, even if proteins were to improve starch-based solutions, it is doubtful that sufficient amounts of protein are available in CBORT to be effective in this regard.

For potential commercial products which could supplement CBORT solutions with specific amino acids, this may be an area for further research and development.

4. **Is there a nutritional benefit from CBORT relative to glucose ORT?**

The nutrient density (calories per liter) of CBORT is greater than glucose ORT (about 200 kcal versus about 80 calories per liter). This is because one normally adds 50 grams of cereal per liter carbohydrate but only 20 grams of glucose. One is limited, in the case of glucose, because increasing the concentration of glucose beyond 20 grams / liter results in an ever greater osmotic load, a decrease in effectiveness of the resulting solution and a risk of hypernatremia. This problem does not occur with cereals and one is limited simply by the viscosity of the solution.

The difference of 120 calories per liter is probably not a significant improvement in terms of the caloric requirements for the child when one considers that the average 1-3 year old child requires approximately 1400 calories per day. For this child to fulfill all daily nutritional requirements, he/she would have to drink between 7 and 18 liters of ORS in a day, which is clearly not feasible or desirable. To make a nutritionally improved solution, one would have to add calorie-dense foods to the diet. Hence, the nutritional aspects of oral rehydration likely relate primarily

to the appetite and the foods which are eaten in addition to the rehydration fluid rather than to calories from the rehydration fluid itself.

Some have suggested that certain fluids, especially those which replace potassium and correct acidosis, are beneficial in improving appetite and strength and decreasing nausea related to the illness. Whether there is any differential effect between CBORT and glucose ORT with respect to appetite is not known.

A differential beneficial effect of CBORT on long term nutrition and growth has been observed in at least one study. If this is confirmed, CBORT might offer additional benefits in addition to improvement in immediate hydration.

5. Are there differences in safety between glucose ORS and CBORS?

When mixed correctly and used appropriately, there appear to be no differences in safety between the two solutions.

For glucose ORS packets or home-made sugar ORT solutions, mixing errors resulting in excessive concentrations of solute has been the primary safety issue. One advantage of packet-based solutions has been the standardization of the solutes in the solution, though errors in the volume of water can also results in a solution with excessive concentrations.

If a packet-based CBORS solution were developed, it should be at least as safe as the glucose ORS solution.

For home-made solutions (e.g. sugar-salt solutions (SSS)) which have more frequently been found to have inappropriately high concentrations of solute, a comparable CBORS may have some advantages, though this is speculative. Reasons for the potential improvement in safety is the decreased osmolality of CBORS solution, and potentially the greater "safe" concentration of sodium. Generally, the upper safe limit for sodium (a proxy for total osmolality) in SSS is thought to about 120 mmoles, since a solution with higher than this level would certainly be considerably hypertonic. On the other hand, a CBORS could have somewhat more sodium (perhaps as high as 150 mmoles) and still have a "safe" total osmolality.

6. What have been the clinical limitations that have prevented the adoption of CBORT?

Though recognized to be at least as efficacious as glucose ORT, and to be better than glucose ORT for cholera-like diarrhea, three questions have predominated.

a. Is the improvement in therapy with CBORT sufficiently great that it will be perceived as better by the patient and family?

b. Since most episodes of diarrhea are mild, and therefore in the category of illness which is not improved by CBORT, is a different formula necessary for the few episodes of severe diarrhea where it will make a difference?

c. Assuming that CBORT is more efficacious, can the same benefits be gained by feeding cereals during rehydration?

The feeling by some health planners is a) that the magnitude of the improvement with CBORT is small in most cases, b) that the proportion of cases which are sufficiently severe to warrant the improved solution is small, and c) that in any case, the benefit of cereal can be realized by feeding. In most cases, this reasoning appears sound; however, there are some problems with it and some gaps in knowledge which need further clarification.

The family perception of whether a given treatment is "working" is not well studied. Only in clinical trials can a comparison of experimental and control groups be made to know which fared better. For the family who does not have a control group with which to compare, the desire is simply that the patient's diarrhea be stopped as soon as possible. Whether a perception of rapid clinical improvement occurs in the case of CBORT is not established with certainty, but would be a crucial outcome to know.

Regarding whether a substantial proportion of cases will benefit from CBORT, the answer depends largely on the denominator of the proportion. While it is true that most episodes (defined as three or more stools per day) would not benefit more from CBORT than from glucose ORT, it is equally true that most episodes are sufficiently mild that they would do well with nearly any fluid, and probably with no fluid. That is, a majority of diarrhea episodes are not life-threatening and will resolve without special treatment. The strategy has been however, to treat all episodes in order to prevent dehydration in the few that may lead to dehydration -- while realizing that most children would not become dehydrated. If one uses "all diarrhea" as the denominator upon which to base recommendations, the data is overwhelmed by background information from children who would have done well no matter what treatment was given.

On the other hand, if one includes in the denominator only cases sufficiently severe to cause dehydration, the conclusion may be considerably different. Among cases with life-threatening dehydration from cholera-like diarrhea and in whom ORT makes the crucial difference, CBORT is clearly more efficacious than glucose ORT.

These findings would suggest that persons who come to cholera treatment centers should have CBORT. If the CBORT were as cheap and as available as glucose ORT, it may be appropriate to use CBORT to treat and prevent dehydration in other settings.

The notion that the benefits of CBORT can be realized by adding cereals to the diet is an attractive one, but still to be proved in the case of cholera-like diarrhea. The finding that glucose ORS can acquire the attributes of CBORS by adding foods goes against our current understanding of the physiologic basis for CBORT's relative superiority since such a solution

would not have a decreased osmolarity. On the other hand, if amino acids (or other substrates) in the cereal accelerated sodium absorption, feeding cereals to patients receiving glucose ORS would be physiologically reasonable.

Additional studies are needed to compare glucose ORS with and without cereal feeding in cholera to determine if such feeding improves net uptake of fluids in a manner comparable to that achieved with CBORS.

7. What are the programmatic implications from the basic physiologic and clinical studies?

There is a scientific basis for the development and utilization of CBORT; however, optimal methods for utilizing these findings still need to be determined. Furthermore, there is still the possibility for future improvements in ORT technology, perhaps by adding other substrates to the solution. Therefore, CBORT should not be considered a fixed or finished product but one with continued potential which will require continued research and development.

With the principles learned, several possibilities exist for using CBORT.

1. In the home, cereals rather than glucose or sucrose, could be used when preparing home-made ORT solutions. This might be especially important in geographic areas where sugar is expensive or in short supply, where rice or other cereal is cheap and available, and especially where similar cereal gruels or soups are already part of the culture. However, physiologically safe ranges of such perspectives must be determined, and methods for teaching the preparation of such home available fluids would need to be developed. Recipes which are part of the folk culture should be examined to determine levels of sodium and osmolality and programs should include warnings about those types of fluids with dangerously high concentrations.

2. In the treatment of severely dehydrated patients (such as those with cholera) CBORS represents a superior rehydration fluid which will decrease purging and potentially shorten hospitalization time. This use may be technically the easiest to implement, since one is dealing with pharmacists, and nurses who should be able to prepare such solutions. However, coordination of hospital solutions with home solutions must be considered so that there is not a perceived inconsistency between treatments given at home and at the hospital.

3. For industry, CBORT offers the opportunity of introducing new products into the market: namely CBORT packets. Such private sector efforts might improve the availability of rehydration fluids, though the entrance of new products through the private sector raises additional concerns which are addressed in a separate, adjoining paper.

CBORS OPTIONS

Research on CBORS has been ongoing for more than ten years and has resulted in numerous reports in the medical literature. At the ICDDR,B a locally prepared CBORS has been the "standard solution" since 1983, and the results from its use have been very favorable. Similarly a commercial product adapted from these concepts (Ricelyte), has been introduced and appears to be commercially successful in the U.S and will likely be introduced in other countries as well. Ignoring the potential for CBORS and avoiding the development of policies whereby the benefits of CBORS can be realized by various diarrhea control programs no longer seems feasible. The introduction of commercial products may overtake "official policy," and development of a strategy for maximally utilizing CBORS in a proactive manner seems more appropriate.

One issue raised by leaving CBORS to the commercial sector is the question of what segments of the consumer population are best served by the marketplace. How adequately do the poorest households utilize commercially supplied products and services? It is possible that the poorest households, who are most likely to benefit from CBORS because of greater risks from diarrheal diseases, may not regularly utilize commercial ORS products due to a lack of disposable income. Consumption patterns of pharmaceutical products with regard to the poorest households is not fully understood.

Some options for taking advantage of CBORS might include:

1. Guide the development and marketing of CBORS solutions in LDC's through various cooperative mechanisms with the private sector, and in a manner sensitive to the objectives of national CDD programs. This is the central objective of the meeting for which this paper has been prepared.

2. Appiy more widely the use of CBORS in facilities which treat large numbers of diarrhea cases and which are apt to see cholera and other severe diarrhea more frequently. At such facilities, the use of CBORS can be encouraged by technology transfer of methods for preparations of CBORS or by commercial preparations of larger size packets for large quantities (for example, 20 liters per packet). This would have special application to larger hospitals and refugee camp situations.

3. Utilize principles of CBORS in recommendations for home available fluids.

4. Fund research to answer crucial questions related to CBORT.

    4.1. Is CBORT perceived by the family to be better than glucose ORT, and if so, why? (Because it stops the diarrhea faster? Because the child regains appetite faster?)

4.2. In severe diarrhea (e.g. cholera), does the addition of cereal foods early in the rehydration phase render glucose ORS equivalent to CBORT in terms of decreasing purging rates?

4.3. Can improvements (e.g. adding amino acids) be made in CBORT to further improve its efficacy?

4.4. Are there groups of children with contraindications for CBORT? Contraindications for glucose are very limited – glucose intolerance for example. These have not been exhaustively considered for CBORT. What is the policy significance of such groups?

4.5. Define the range of acceptable electrolyte concentrations for CBORT solutions. For glucose ORS, this was accomplished at an early stage; however, for CBORT, comparable studies have not been carried out, and it is possible that the acceptable range for sodium is much greater than it is for glucose ORS.

CEREAL BASED ORS AND THE PRIVATE SECTOR
AGENDA
FRIDAY, MARCH 27, 1992

8:00 - 8:50	Arrival of participants Breakfast
9:00 - 9:20	Introduction by facilitator *Steve Reimann* Introduction of participants Announcements, logistics, review of time table Formal opening of meeting by PRITECH Director *Glenn Patterson*
9:20 - 9:30	Review objectives for the morning and for the day
9:30 - 9:55	Presentation by *David Sack, M.D.* (Background Paper #6)
10:00 - 10:25	Presentation by *Nathaniel Pierce, M.* (Background Paper #5)
10:30 - 10:45	Coffee Break
10:45 - 11:10	Presentation by *Camille Saade* (Background Paper #1)
11:15 - 11:40	Presentation by *William Jansen, Ph.D* (Background Paper #2)
11:45 - 12:10	Presentation by *William Jansen, Ph.D.* (Background Paper #4)

CEREAL BASED ORS AND THE PRIVATE SECTOR
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12:15 - 1:15	LUNCH
1:15 - 1:30	Review of influential variables (identified during morning presentations)
1:30 - 1:45	Outline of current situation
1:45 - 3:00	Discussion of implications (plenary)
3:00 - 3:15	Coffee Break
3:15 - 4:00	Development of recommendations (small groups)
4:05 - 4:50	Discussion of recommendations (plenary)
4:50 - 5:00	Closing comments
	Departure of participants

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MARCH 27, 1992

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