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TRIP REPORT  
INTERNATIONAL SYMPOSIUM ON FOOD-BASED  
ORAL REHYDRATION THERAPY  
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## Background

The International Symposium on Food-based Oral Rehydration Therapy, subtitled, "A Symposium on Improved Oral Rehydration Therapy in Practice in the Home and in the Community," was held November 12-14, 1989 at the Aga Khan University in Karachi. The symposium was organized by the International Child Health Foundation (ICHF) and sponsored by a variety of organizations including: USAID; UNICEF; WHO; the Aga Khan Foundation; Save the Children (USA and UK); John Snow, Inc.; and Gerber Products Company. Approximately 120 participants from 27 countries attended the conference, representing governments, universities, nongovernmental organizations, and industry.

The purpose of the symposium was to review data, mostly clinical, on food-based oral rehydration therapy (FB-ORT)<sup>1</sup> and discuss plans and issues regarding its implementation.

The symposium began with a plenary session that provided an overview of the evidence to date regarding the clinical efficacy of FB-ORT, a synopsis of basic physiology, some programmatic issues, and a description of a manufacturing process for FB-ORT packets. Participants then broke into four smaller groups that met several times to discuss the following topics:

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<sup>1</sup>Much confusion currently exists over proper nomenclature for the type of oral rehydration therapy in which glucose is replaced by another ingredient, usually a foodstuff. For the purpose of this report, it simply will be referred to as food-based ORT, or FB-ORT.

- Group I      Biomedical aspects of ORT
- Group II     Integrating ORT and feeding--the potential of FB-ORT at  
                  the family level
- Group III    Implementing ORT programs at community and district  
                  levels
- Group IV     Strategic planning at the national and global levels

A closing plenary session reviewed findings and recommendations of the working groups.

#### Review of Clinical Data

It was acknowledged at the outset of the plenary session that, despite great increases in availability of ORS packets, ORS usage rates remain low. This was attributed primarily to the fact that ORS does not curtail diarrhea and hence, suffers a lack of acceptance among caretakers, presumably mothers. By contrast, evidence now exists that at least some formulas of FB-ORT are capable of reducing stool volume and duration of diarrheal episodes.

WHO presented a review of 12 randomized clinical trials involving more than 1,100 subjects in which 50-80 grams of rice powder was substituted for the 20 grams of glucose per liter in the standard ORS formula. The review showed several interesting points:

- with rice ORT, the average rate of stool output was reduced by 13%-55% during the first 24 hours relative to glucose ORS;

- rice ORT is an effective rehydrant with disease of any etiology; however, its effect is most pronounced in severe cases such as cholera, where stool output is greatest to begin with;
- the efficacy of rice ORT cannot be replicated by giving glucose ORS along with a diet of rice; and
- in at least some studies, there was a reduction in the range of 12%-33% in the mean duration of diarrhea.

An important point to note about these results is that, given the shortened duration and reduced stool output, it can be said for the first time that ORT helps to "cure" the diarrhea. It was thought that this could be a major factor in improving the acceptability and, ultimately, the use of an ORT relative to antidiarrheals and other medications.

The authors of the review emphasized that the efficacy of rice ORT and/or FB-ORT seen with cholera cases cannot be extrapolated freely to less severe and more common types of watery diarrhea. Also, the safety and efficacy of FB-ORT in severely malnourished children and in infants under three months of age has not yet been established. As a further caveat, it should be noted that the results described above were found with formulas made at the hospital level; the clinical efficacy of rice ORT or FB-ORT has not been confirmed either with home preparations or with manufactured packets of FB-ORT.

A comparison of different ORS formulas investigated to date shows that, despite experiments using certain amino acids (e.g., glycine) and peptides or modified carbohydrates (e.g., maltodextrin), the most effective results have been seen when common foodstuffs were substituted for glucose. Cereals such as rice, wheat, and sorghum have given the best results; plantain ORT is effective only for mild diarrhea. After experimenting with different levels of rice as a substitute in the standard ORS formula, an optimal recipe for one liter of FB-ORT was developed. This recipe consists of:

- 50 grams of cooked rice powder
- 3.5 grams of sodium chloride
- 2.9 grams of sodium citrate
- 1.5 grams of potassium chloride

#### Feasibility of Manufactured Packets of FB-ORT

A process for the manufacture of a packet with the above formula was described by a representative of Galactina, S.A., a Swiss firm retained by WHO/CDD to develop such a process. Because the manufacture of rice ORT utilizes ingredients of diverse particle size, the materials cannot simply be mixed together, as is the case with glucose ORS. Grinding the rice powder to the same particle size as the other components is out of the question because of the extreme hygroscopicity that results. A second relatively common approach, spray-drying, was deemed inappropriate for use with cereals. Instead, drum-drying, a process commonly used in cereal

processing, was adopted. With this technique, ingredients are mixed in an aqueous suspension that is applied to slowly rotating, steam-heated drums for drying.

FB-ORT manufactured by this process had a shelf life of 24 months when packaged in polyfoil laminate; use of a paper foil yielded a shorter shelf life. Very little preservative effect was gained by using an antioxidant.

Notable features about this manufacturing process include that it requires water of strictly specified quality. This is also true for the raw materials, especially the rice powder. Galactina uses its own rice powder product. Because the resulting product is an ideal medium for bacterial growth, it is essential that stringent microbiological controls be in effect throughout the manufacturing process as well as in finished product testing. Perhaps the most significant aspect of FB-ORT packet production is that it involves food processing, not pharmaceutical, technology. This has implications both for technology transfer and for marketing vis à vis glucose ORS.

The finished packets are prepared either by adding the ingredients to water at 37°C or by boiling in water for an unspecified time. Boiling decreases the viscosity, thereby making it suitable for use with bottle feeding (as Galactina pointed out).

### Program Issues

The conference-organizing committee clearly recognized that a great number of unanswered questions exist regarding implementation of FB-ORT. A broad range of program issues pertaining to FB-ORT were discussed both in the plenary sessions and in the group meetings. The issues that received the most attention included the potential impact of FB-ORT on infant feeding practices, and program management concerns regarding the introduction of this new technology into existing CDD programs. A thorough yet concise overview of these concerns from the point of view of the program manager was presented during the plenary session by John Rohde, Senior Advisor at UNICEF/India. A copy of his paper is attached (see Appendix 1).

We attended Groups II and III, in which the following topics were discussed.

#### **Group II - Integrating ORT and Feeding**

Issues of both the physiological efficacy of FB-ORT as well as the feasibility of program implementation were considered. The discussions focused on a range of outcomes of the therapy itself, the impact of hydration, duration of illness, nutritional status, and ability of the family and the community to deal with diarrhea in children.

Several questions were raised regarding the integration of ORT, feeding, and the potential for promoting FB-ORT at the family level. An overview of some of these questions follows:

1. What evidence do we have that digestible food (e.g., boiled rice, yoghurt, boiled potato) plus standard ORS is equivalent to rice-powder ORS? How are recommendations for FB-ORT likely to affect the total nutritional intake? How can FB-ORT be linked to traditional diarrheal diets?
2. What does it cost and how much time is required of a mother to give ORS and feed a sick child in the course of all her other work?
3. How difficult is it to learn mixing instructions and to give the various FB-ORTs? What are the costs of teaching (effectively) on a wide scale? Can mass communications be used to teach all the approaches to ORT?
4. How much integration is required of the home-based approach with the training of the medical establishment?
5. How should a child with malnutrition be identified? How should such a child be managed for an episode of diarrhea? And how should the child be followed with FB-ORT?
6. What are the existing methods for food processing in the home; at the community level?

7. Recommendations for home-based ORT and FB-ORT may be confused with nutritional recommendations for weaning diets. What are the differences? Can a diarrheal episode be used as an opportunity to teach appropriate weaning diets?

Issues regarding health communication were also discussed. Several of the discussion points are listed below:

- Each health intervention has its own communication needs.
- Audience research is indispensable to select appropriate strategies, test materials, and monitor effectiveness.
- Communication channels must be integrated to maximize their particular strengths.
- Face-to-face communication provides personal reinforcement not easily achieved by other channels.
- Education by itself is not enough to sustain behavior.
- Behavior change requires continuity of resources and support.

The discussion also focused on problems to be solved and opportunities. Outstanding issues included the following:

- Identification of starchy foods to select as a local basis for ORT; availability, effectiveness, acceptability, and cost must be considered.
- Assessment of home-preparation requirements such as availability and costs of fuel and effort required for cooking.
- Discovery of the particular cultural practices that may facilitate adoption and instruction.
- Learning the cultural or familial context that predisposes some children to more serious illness and to less meticulous care.
- Identification of educational channels that can convey the correct measurement of salts and water and the timely administration of adequate volumes of ORS to patients.
- Investigation of the possibility of involving commercial marketing techniques to improve access to and proper use of FB-ORT.
- Further optimization of ORT solutions by exploring the kinds and amounts of proteins that are best.
- Use of widespread commitment to standard ORS products in order to hasten the application and use of improved solutions.

### **Group III - Program Management at the Local and District Level**

Discussion in Group III centered around identifying the objectives of using FB-ORT and developing a strategy to introduce a range of case-management options for use by different levels of health workers. Program managers from several countries presented examples of various treatment options from their experiences to date. These included: the use of sugar salt solution and a special weaning food in Nigeria; the successful introduction of a wheat-based ORT in a rural population in Ethiopia; a field trial of a cereal-based ORT in Kenya; and the extremely favorable results and high acceptability of rice ORT as shown in field trials in Pakistan and Bangladesh.

The discussion was marked by strongly differing views regarding which options were acceptable at all; these forcefully held opinions seemed to epitomize the diversity of the target populations for FB-ORT and highlighted the extreme complexity of devising a master plan for FB-ORT implementation. For example, some discussants felt that packaged FB-ORT could be a practical and effective replacement or adjunct for the current glucose ORS packets. The packets could be distributed either in government clinics or more likely in commercial outlets, where they would compete with harmful antidiarrheals and antibiotics. Others felt the very manufacture of FB-ORT packets represented the worst in mystifying a home-based therapy, creating both needless dependence on a manufactured product and a situation in which price-gouging would no doubt occur. No resolution was achieved on this point, which characterized both the

differing perspectives and differing experiences of the discussion-group members.

Another key point which generated controversy but no resolution was that of facility-based case management. If a mother brings a moderately-to-severely dehydrated child to a clinic, what should the child be given for therapy? Debate ensued over the relative efficacy of glucose ORS packets versus sugar-salt solution. Only as a side note was the possibility raised of administering FB-ORT to the child along with instructions to the parent for its preparation. This suggestion was dismissed by the facilitators as impractical because many health centers were thought to lack the capability to prepare or maintain a cooking pot of FB-ORT on a routine basis. This contention raises enormous questions--"a health educator's nightmare," as one health educator put it--about providing caregivers with instructions for using FB-ORT.

Despite the ongoing debate within this group, some common themes could be detected. First, there was repeated, if tacit, acknowledgement that a single implementation plan for FB-ORT appropriate to all situations would be nearly impossible to devise, and if such a plan were devised, it would probably be of limited utility. Second, the need for more research as to implementation strategies for FB-ORT was apparent throughout the discussion. Third, the importance of proper feeding, especially breastfeeding, prior to and during disease was cited as the single most important factor in attacking the root of the problem of diarrhea and dehydration. Fourth, the lack of agreement among ORT experts during this

discussion strongly indicated that clarification of messages and approaches regarding the use of FB-ORT would be required before they could be communicated to mothers who were to give care.

### Recommendations and Conclusions

Representatives from the four discussion groups presented preliminary recommendations. These will be published by the ICHF within the next few months, along with a list of participants. Because of the substantial overlap among the groups, a single synopsis of the recommendations follows:

1. A committee should be organized to develop functional nomenclature for the type of therapy discussed during this conference. Currently, confusion exists among designations such as food-based ORS, FB-ORT, cereal-based ORT, nonglucose ORS, and other names.
2. As promising as the clinical data supporting FB-ORT now appear, it is premature to adopt a policy to use FB-ORT on a national or international level. Far more research into the operational aspects of implementing FB-ORT is needed before comprehensive strategies can be developed that are congruent with those of existing CDD programs. In addition, there is the fear that if FB-ORT is adopted on paper, commercial products will be put on the market before a proper role for them is delineated.

3. Breastfeeding and appropriate weaning foods must continue to be stressed as a first line of defense against diarrhea and dehydration. The priority of nutrition should not be overlooked in all the enthusiasm for FB-ORT.
4. Additional clinical study is needed to determine the safety and efficacy of FB-ORT in malnourished infants and in those under the age of four months.
5. Additional field and operational research is urgently needed in several areas, including:
  - potentially harmful confusion between the use of FB-ORT and feeding and nutrition;
  - cultural perceptions and the acceptability of FB-ORT;
  - appropriate and effective techniques for promoting FB-ORT;
  - a comparison of glucose ORS and FB-ORT under field conditions;
  - the use of homemade versus prepackaged FB-ORT; and
  - the possibility of manufacturing FB-ORT either by an automated procedure or as a cottage industry.

It is expected that multicenter trials or multiple studies on several of the above topics will be needed.

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## Appendix 1

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FOOD-BASED ORT - MANAGEMENT CONSIDERATIONS

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Introduction

Invited to discuss implementation issues related to food-based ORT, I have initially identified an array of questions in an attempt to illustrate the important considerations which must go into programming use of FB-ORT. My purpose is to identify a line of inquiry which will lead to productive discussions and a more comprehensive community-based approach to programme development than has generally characterized earlier efforts in the field of diarrhoeal disease control. These are questions that any national decision-maker will want to have answered clearly before he can proceed to include FB-ORT in a national programme. Though I will share with you my own response to many of these issues, I will contend it is your own careful consideration of the issues and options which will best guide programme decisions.

As a CDD Programme Manager, I must be consistently mindful of the programme goals and objectives:

1. First and foremost, a reduction in deaths, with particular attention to reduction in death due to acute dehydration;
2. Improved nutritional state, or reduction in nutritional effects of diarrhoea;
3. Reduction in diarrhoea incidence, and reduced severity.
4. Reduction in costs both to the programme and to the patient and society;
5. Self-reliance.

I would wish to examine the implications for the acceptance of FB-ORT on each of these major objectives. I also will recognize a hierarchy of priorities in the order given.

1. Present technologies are perfectly adequate for dealing with dehydration and reduction in dehydration related deaths. But I will seek means to achieve higher use rates, earlier in each episode with adequate quantities of properly mixed solutions. In short, can FB-ORT help achieve higher rates of correct use?

2. Nutritional problems are, however, the major challenge to the programme. Can FB-ORT substantially improve nutritional outcome of diarrhoea episodes? Or, at least reduce the number of episodes most detrimental to nutritional state? Of even greater concern, will it diminish the credibility and impact of efforts to improve feeding during and after diarrhoea?
3. Overall CDD costs are modest and could be best reduced by elimination of useless drugs. Can FB-ORS replace demand for drugs by doctor or the public?
4. Self-reliance in ORS production is important in many country considerations. Can I make FB-ORS? At what cost to the programme? the public?

A critical series of questions, many of which are yet unanswered, need at least tentative and thoughtful consideration. Indeed, my first draft of this presentation was to list of some 60 questions, the answers to most of which were yet unknown, at best, educated guesses. Encouraged to offer at least tentative answers, I will first discuss the pros and cons of the four classes of FB-ORT, and then, as a national programme manager, share with you my concerns and best guess decisions regarding the place of these solutions in a national CDD programme. My perspective is clearly biased by two decades of work in South Asia.

First, let us consider what we are discussing as FB-ORT: This table groups them in 4 categories by definition, advantages and disadvantage. (Table 1)

- Let me emphasize, at the outset, that I do not doubt the technical or scientific superiority of FB-ORT over the sugar-based alternatives - the latter lead the field only by the happenstance of seniority - a consideration nonetheless powerful in decisions made in this part of the world!
- Next, I accept FB HAF as clearly acceptable whenever already used - this is not really an issue. But we should not expect great results from the use of traditional Indian FB-ORT. Rice kanji is known and used throughout the sub-continent, but we showed some years ago that water poured from the rice pot has a starch concentration of 0.3 to 1.0 gm percent, clearly a sub-optimal concentration to replace 2% glucose or 5% rice powder.

- As I consider health facility made ORS only an intermediate step in the introduction of the product to the public, I shall, therefore, concentrate my analysis on home-made ORS - in analogy to home-made SSS - and packaged cereal ORS, in the private and public sector systems.

I will address the adaptation of these two options from four perspectives: 1) the medical, analyzing the implied benefits and costs in terms of duration and severity of diarrhoea, safety and efficacy, effects on development of chronic or persistent diarrhoea and competition with the use of other drugs; 2) nutrition issues, which are my priority, with concerns for improving growth, effect on food intake, the nutritive value of the ORT itself, and the overall nutritional impact of diarrhoea with or without food-based ORS; 3) the audience, either laypersons or professionals, with cultural, convenience, and consumption concerns; and finally, 4) the national programme involving management decisions affecting policy, training, communications, logistics, cost, and self-reliance. I will conclude with my personal judgement of where and how FB-ORT fits into a national programme in South Asia.

#### 1. Medical expectations

FB-ORS is associated with a reduction in stool output, a reduction in duration and, perhaps, most importantly a reduction in the small but significant percentage of those cases which go on to chronic, or persistent diarrhoea. This is a real and useful effect. Can I use it to assure earlier and more effective use? Will this reduction be perceived by the patients? Can this be made a good selling point in my communications strategy? Surely, doctors will appreciate "proven medical benefit", but can I promote it on the "improved response basis" to profession and public? How strong can I push this? I am worried that the population is not likely to perceive a 25% stool reduction, and if they use it early in the course of illness as I will ask them to do, will it not fail as often as glucose ORS? For we know that failure rates are more related to how early in the course of diarrhoea the medicine is tried, rather than its actual effectiveness. While we want early fluid replacement and rehydration, it is the late-comer drugs which are attributed with turning off the diarrhoea.

I am certainly hopeful that by introducing a modern packaged product that offers improved treatment to the public, that I will be able to effectively reduce the purchase and use of other harmful drugs which

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presently plague the success of my programme. The best way to stop use of inappropriate drugs may well be to promote an alternative: FB-ORS. One added benefit is reduction in the amount of ORS required and, therefore, obvious cost savings in ORS itself.

What is the medical effect of food-based ORS on dysentery? I expect it could be an important adjunct to antibiotics, but we lack data on this. No doubt, as we come to treat chronic diarrhoea, we are recognizing the importance of continued high nutritious feeding. Where does FB-ORS fit into this regimen? I certainly prefer a higher nutrient density.

No doubt, for home-made FB-ORS there is greater safety as there is no osmotic danger of this starch substrate as there is with sugar. This added safety must be balanced against the greater danger of contamination and the requirement for producing a fresh batch as frequently as six-hourly. How dangerous is keeping FB-ORS mixed for 12, 18, or even 24 hours?

In balance, I'd like evidence that more people, professionals, and public, will use more FB-ORS earlier and in more adequate quantities than using present G-ORS.

## 2. Nutritional effects

By far, the most important considerations are those of nutrition. A recent community-based study in Matlab (included 3 areas: packets of rice or glucose ORS, and a comparison or control area) has shown substantial improvement in growth of children with 4 or more episodes of diarrhoea per year treated with rice ORS (144 gm/month) compared to glucose ORS (127 gms) and "normal" treatment (110 gms). No special dietary advice was offered. This is a remarkable nutritional result, exceeding the impact of many daily feeding programmes. Indeed, these results seem implausible, but certainly worth verifying. If true in other communities, it offers powerful incentive to introduce rice ORS. Surely, the nutrient density of FB-ORS is greater than glucose ORS, about 180 kcal versus 80 per litre. But studies show that less food-based ORS is required to rehydrate a child and to maintain this hydration, and therefore total calorie intake is only slightly higher. Studies involving 266 children aged 1-5 years showed a reduction of 30-50% in stool output with a comparable reduction in ORS consumption. Calorie intake in the FB-ORS groups was 27 kcal/kg/day versus 19 kcal/kg/day

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from glucose ORS. The difference, though significant statistically, represents a mere 8% of daily requirement for this age group. The caloric density of 18 per 100 cc is a far cry from the 100 calories per 100 cc's which is desirable for food in this age-group. I certainly cannot buy FB-ORS on the basis of additional calories it provides. But I can't either ignore the implied results from the Matlab study.

My biggest and most heavily weighted concern is the effect of FB-ORS on food intake. I have already seen a number of patients who have taken FB-ORS for weeks or months on end, fed by a concerned mother who felt that she was ideally treating her child with chronic diarrhoea - only to present with severe marasmus. In the sub-continent mothers consider many fluids, made from cereal base, as adequate diet for a sick child as it is considered a food. If viewed as a food is it not likely to be given less often than a replacement fluid? People must clearly understand what is fluid and what food using both in adequate quantity. What will be the influence of educational efforts teaching mothers to make FB-ORT on the preparation of weaning foods? Will she feel the diluted gruels (dal water, rice soup, etc.) are proper foods after all? Just as we are searching for methods to increase caloric density in weaning foods, will FB-ORT confuse this message? I hope not, for I could not consider the product if there was any reasonable likelihood that overall food intake would decline by patients using FB-ORS.

I would like in fact to know that food intake increased, as apparently it does with glucose ORS in comparison to nothing (ref. Philippines, Iran, Turkey studies). That is presumably related to earlier return of appetite following repletion of the electrolyte imbalance, replacement of potassium, and adequate base to offset the acidosis. But if patients take less food-based ORS, are they not going to get less potassium and less bicarbonate? Will these deficits actually take longer to replace in these patients? The 17 August Lancet review shows no difference in measured serum electrolyte levels, and I find that very reassuring. Packaged FB-ORS could include trace nutrients important in diarrhoea, such as folate, zinc, and possibly vitamin A, all of which have been implicated as means to reduce diarrhoea duration or recurrence. But, of course, these could be included in any ORS packet.

It is, in the end, my consideration of the nutritional effects of FB-ORS that will be the major determining factor and whether I would include it in my programme.

### 3. Audience considerations

Here, I must define who I wish to use and convince of the efficacy of FB-ORS. Medical doctors may be attracted by the scientific proof of its improved rehydration efficacy and may find it an attractive prescription item even to displace other ineffective anti-diarrhoeal agents. If so, this is a very positive attribute. Of course, doctors are often conservative in adopting new technologies, and that may be a negative factor. But I am reasonably convinced of the ability of detail-men and pharmaceutical companies to convince the profession on this point.

Much of our decision to use FB-ORT should be based on cultural attitudes, perceptions, and expectations of lay audience, the mothers, particularly the poor and illiterate mothers of malnourished children. I'd like to know more about what they expect and perceive in a diarrhoea treatment? What has been their findings with glucose ORS, their satisfactions and unmet expectations? It is entirely possible, they may prefer a rice-based medicinal rehydrating fluid considering it healing, therapeutic, and more fitting with cultural norms. This could easily be determined with relatively few focus group interviews, or depth discussions with mothers coming to a clinic.

Of greater concern and difficulty to predict is the consumption of FB-ORS, particularly when it must be made at home. Will it be consumed in adequate quantities and frequency? This relates not only to the perception of its role in treatment, but also the work, difficulty, cost and perceived effort in its production, preparation, and the convenience and acceptance by the child and ease of its administration. Surely, in communities that view rice and rice gruels as medicinal, appropriate and desirable for young children with illness, this will be a strong positive factor.

How difficult is it to teach mothers to make FB-ORT? Recall the difficulty we've had teaching mothers to make SSS. Will preparation of an acceptable solution continue to be an operational obstacle? What is the acceptable range of composition for FB-ORT? Fortunately, in contrast to sugar solutions, there is no osmotic danger of FB-ORT - you can add as much cereal as you like - this is a real advantage of FB-ORS. We need to push for maximum cereal concentrations, but not to the point that it is undrinkable. Hydrolysed rice, using amylase rich flour or, in commercial preparations, pre-cooked and pre-digested, may yet make a high calorie

rehydrating drink. But we still must add salt. Our own studies of mothers adding salt to home fluids in India have resulted in widely ranging concentration with over 30% above 120 meq/litre. Rice fluid tended to be salted even more heavily than sugar water or plain water.

In the warm tropics, will we recommend preparation of a fresh solution for each loose motion, as we do for ORS by the cup or glassful? Will mothers follow this guidance? Consider the experience of BRAC, the largest and most ambitious face-to-face training effort for ORT in the world. Use rates of ladan gur solution have barely risen above 20 per cent in spite of knowledge (exceeding 90 per cent amongst mothers. More recently, BRAC has conducted an experiment where village mothers are taught LGS, rice-based ORS, or both and use rates have been followed. Although the rice-based ORS is usually preferred both by mothers and children, according to taste (long ago proven at ICDDR, B) its use has consistently been less than half of LGS in subsequent diarrhoea episodes. The effort in its preparation is one more impediment to its regular use and acceptance. Are the added benefits of FB-ORT sufficient to offset a lower rate of use or a later introduction as a result of the problems of preparation? I don't think so - not when use rates appear to be a critical impediment to further reduction in dehydration and, perhaps, death. This is a very definite disadvantage and I would want to know how difficult it is to overcome this with persistent health education.

#### 4. Management concerns

My analysis of national CDD programmes over the past decade suggests that a clear unambiguous policy related to even the simplest of issues is of critical importance. Controversy relating to such seemingly simple issues as home solutions, package size and composition, colour, or flavour, indications for use or packets and quantities to be given to patients, have all been critical impediments to establishing a strong programme. Apparent ambiguity, or rapid changes in policy, have been major stumbling blocks to the implementation of the programme. The addition of food-based ORS to existing policy and plans requires a precise unambiguous position for this product at all levels of the plan, including its relationship to the existing products, in the home, in the market place, and in the government health system.

Upon adoption of FB-ORT, my training materials will have to be revised to reflect this new policy, clearly and carefully indoctrinating

all related manpower from the highest to the most peripheral level in the many elements of food-based ORT, its preparation, use, expectations, problems, benefits and potential difficulties, particularly in relationship to glucose ORS. This will require a major effort to avoid confusing staff. My experiences, most of them difficult, in training to use sugar-salt solutions makes me particularly concerned of the difficulties in home-made FB-ORS. Even a change in packet size requires major training efforts. This is not a trivial change.

For the packaged variety I am concerned about shelf-life, storage, spoilage time, uniformity of package size, measuring, diluting, and the effects of non-sterile water, i.e., and the time it takes for this product to become unacceptable for consumption. Included in this is the question of where and how the product will be manufactured, and, if imported, implications related to foreign exchange, supply line, and my eventual self-reliance. I am particularly concerned about the relationship to my existing supplies, production and distribution of glucose-based ORS packets as I consider local production a major logistics accomplishment in my programme.

I am interested in finances, both foreign exchange and local, in the costs to the government as well as to the patient community. I recognize these costs must include materials, time, convenience, and I continue to have considerable concern again for home-made solutions and the cost, not only of materials but also the fuel for cooking and the time taken to prepare FB-ORS. On the other hand, private sector may well make this product a popular and self-financing one, and its profit margins may exceed those of glucose ORS. I would like to look at demand elasticity and cost studies, and to know whether this product might absorb some of the presently excessive costs being expended on other useless or harmful drugs. Can it replace these products?

Finally, I am particularly concerned about my communications strategy. How will I position food-based ORS? Will it be seen in conflict with glucose ORS, or with other rehydrating messages? To whom will I promote it? Remember, in the early years after ORS was developed, there was reluctance of medical professionals to accept even packaged ORS with resulting efforts to introduce it directly to paramedical workers and into the peripheral system. Feeling bypassed, as indeed they were, the medical profession in many countries actually opposed ORS. We must be sure not to make this error again. Support by the medical profession and their involvement in promotion of FB-ORT would be critical to its

acceptance at all levels. But can we then promote it openly to public as well? Without undoing earlier promotion of G-ORS, or food messages? Of greatest concern is its perception as a food, and how I can avoid confusion on this issue? It has taken me a long time to develop a clear, coherent, and publicly understandable set of messages. I am reluctant to confuse the public at this time.

### Conclusion

I would decide to start FB-ORS as exclusively private sector undertaking. Surely, marketing mechanisms, promotion, distribution and sales techniques are well developed, at least in the countries of South Asia, enabling new products to reach a wide market and a high level of distribution in a short time. To leave this product in the private sector seems to me an important introduction strategy.

Packaged FB-ORS might readily find a place in the market and I could rely substantially on the private sector marketing effort to overcome many of the problems which I have brought up in this talk. It could be included as an alternative rehydrating product, akin to packaged ORS, without substantially affecting my policy, my logistics, training, or communications. Private sector could promote its better attributes and, hopefully, contribute to replacement of harmful anti-diarrhoeal drugs. With appropriate marketing position, the community could be positively disposed to both its salutary effects reducing quantity and duration of diarrhoea stool as well as any positive nutritional benefits. I would caution them, however, to be certain that all mothers recognized that it is not a replacement for diet during or after diarrhoea, and that food remains of primary importance both for therapy and recovery. I would hope that the private sector would detail it to doctors who themselves would explain its modern and preferential use to mothers.

While it was being promoted in the private sector, I would conduct a variety of studies in medical units to better define its actual impact on diarrhoea duration, on dysentery, on chronic diarrhoea, and overall, on nutrition. I would conduct field studies with various audiences to better understand cultural perceptions and willingness to consume, and in the event of a successful market introduction and popularity of this product, only then would I consider using packets in any government programme and even later still, introducing the home-made product into my national programme only if field research had proven it feasible and preferable.

The array of considerations which will determine when, how, and at what level I accept the various forms of FB-ORT into the national diarrhoea programme is extremely complex. If my concerns sound conservative, they reflect, perhaps, the 20 years that it has taken to introduce the proven technology of oral rehydration solution G-ORS into wide scale use in developing countries for diarrhoeal disease. Bob Phillips, the Director of the Cholera Research Laboratory in Dhaka, under whom ORS was developed, was opposed to its field trials in 1968 contending that its efficacy had already been proven and scientists should move on to other frontiers and unknown areas of diarrhoeal disease research. Bob's intuition on things scientific and technical was generally insightful and clairvoyant, but on the matter of adapting that technology, making it available to all, he was as naive as the most inexperienced among us.

I am convinced that food-based ORS is of proven medical benefit, it seems likely to be culturally acceptable and often used in a proper and desirable manner, and with some cost and effort it can be managerially, logistically, and financially integrated within the scope of national programmes. I remain uncertain of its effect on nutrition, and finding that the most critical lacking element of my CDD programme, am unwilling to chance a negative effect on feeding. I will encourage the private sector to introduce this product as widely as possible, and, meanwhile, engage in the array of studies needed to answer my most critical questions.

10 November 1989

JER/us

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**PROGRAMME PRIORITIES**

REDUCTION IN DEATHS - DEHYDRATION

IMPROVED NUTRITION

REDUCTION IN INCIDENCE AND SEVERITY

COST REDUCTION

SELF-RELIANCE

FOOD-BASED ORT - OPTIONS

	HAF	FAC-ORS	HOME ORS	PACKET-FBORS
DEFINITION	TRAD. FLUID	FB-ORS	FOOD-SALT	FB-ORS
ADVANTAGE	AVAILABLE, CULTURAL SAFE	INTRODUCTION CORRECT FORMULA CLINICAL	AVAILABLE, CULTURE EFFECTIVENESS USE	APPEAL REPLACE DRUGS DOCTORS USE EFFECT SELF-FINANCE
DISADVANTAGE	TIME COSTS INEFFECTIVE COMPETE ORS	DEPENDENCY	COSTS LOWER USE PREPARATION FOOD USE SHELF LIFE VISCOSITY	COMPETE ORS PRICE SHELF FOOD USE?

ISSUES\_TO\_RESOLVE

- MEDICAL - TECHNICAL/SCIENTIFIC
- NUTRITIONAL - FEEDING/DIET
- SOCIO-CULTURAL - AUDIENCE PERCEPTIONS/  
PREFERENCES
- MANAGERIAL - POLICY/LOGISTICS/MANPOWER

## MEDICAL ISSUES

CLINICAL RESPONSE: STOOL VOLUME, DURATION, CHRONIC;

DOCTORS VS PATIENTS - FAILURE RATES

REDUCE HARMFUL DRUGS: PRESCRIBING, COST, PROMISES, ORS  
QUANTITY

EFFECT ON DYSENTERY, PERSISTENT DIARRHOEA?

SAFETY: OSMOTIC - PACKET, HOME; STORAGE TIME

CORRECT USE RATE

NUTRITIONAL ISSUES

FB-ORS - EFFECT ON GROWTH?

CALORIC DENSITY - TOTAL ENERGY CONSUMPTION

APPETITE AND ELECTROLYTE BALANCE

FOOD: EFFECT ON DIET DURING-AFTER DIARRHOEA

FOOD INTAKE

AUDIENCE\_ISSUES

MEDICAL: SCIENTIFIC, ALTERNATIVE DRUG,  
PRESTIGE

LAY: EXPECTATIONS, BELIEFS, EXPERIENCE  
WITH ORT - SUGGESTIONS

PREPARATION: INGREDIENTS, FUEL, TIME, SALT,  
VISCOSITY

CONSUMPTION: CHILD ACCEPT, FREQUENCY, QUANTITY

CULTURAL POSITION - CONSUMPTION

## MANAGEMENT ISSUES

- POLICY - CLARITY, CONSISTENCY
- TRAINING - PROFESSIONALS, PARA, PUBLIC
- LOGISTICS - SHELF, POCKET SIZE, WATER QUALITY
- FINANCE - COST, FOREIGN EXCHANGE, SUPPLY LINE
- COMMUNICATIONS - G-ORS, FOOD, MEDICAL VS PUBLIC

| POLICY - COMMUNICATIONS |

## COMPOSITE EVALUATION

<u>MEDICAL</u> :	PROFESSION - PROMISING	+3
	LAY PUBLIC - UNCERTAIN RESULT	+1
<u>NUTRITION</u> :	NUTRIENT IMPACT - UNCERTAIN	±
	COULD REPLACE FOOD	-2
<u>AUDIENCE</u> :	CULTURAL ACCEPTANCE	+2 TO 3
	CONSUMPTION (DEPENDS)	±
<u>MANAGERIAL</u> :	POLICY, TRAINING, LOGISTICS	-1 TO -3
	COMMUNICATIONS	-1 TO +1

J. ROHDE OPINION

FB-HAF

EAC-ORS

PACKET-ORS

HOME\_FB-ORS

LEAVE IT

TRIALS

COMMENCE FB-ORS

FUTURE

PUBLIC - G-ORS

## Appendix 2

PAPERS FOR FBORT SYMPOSIUM

- |      |  |   |
|------|--|---|
| 1.   | <b>Keynote Address</b>   | <b>William B. Greenough, III, M.D.</b><br><b>ICHP and Johns Hopkins University</b>                                    |
| 2.   | <b>Food-based Solutions</b>  | <b>Dr. A. Majid Molla</b><br><b>Aga Khan University</b>   |
| 3.   | <b>Clinic-based Treatment<br/>With Cereal-ORS:<br/>Established Benefits and<br/>Unanswered Questions</b> | <b>Dr. Nathaniel Pierce</b><br><b>Diarrhoeal Diseases Control Programme,</b><br><b>World Health Organization</b>      |
| * 4. | <b>Food-based ORT:<br/>What's in it for me?</b>  | <b>Dr. Jon Rohde</b><br><b>Management Sciences for Health/UNICEF</b>  |
| 5.   | <b>Basic Physiology</b>  | <b>Dr. Michael Field</b><br><b>Columbia University College of Physicians<br/>and Surgeons</b>                         |
| * 6. | <b>Application of Basic<br/>Transport to Improved<br/>Solutions</b>                                      | <b>Dr. Dilip Mahalanabis</b><br><b>International Centre for Diarrhoeal<br/>Disease Research, Bangladesh (ICDDR,B)</b> |
| 7.   | <b>Dietary Therapy for<br/>Childhood Diarrhoea:<br/>Results of Clinical<br/>Trials</b>                   | <b>Dr. Kenneth Brown</b><br><b>University of California/Davis</b>   |
| 8.   | <b>Food Technology and<br/>Manufacturing of ORT</b>  | <b>Mr. Rene Burki</b><br><b>Galactina S.A.</b>  |
| 9.   | <b>Food and Feeding:<br/>The Mother's View</b>   | <b>Dr. Margaret Bentley and<br/>Dr. Elizabeth Herman</b><br><b>Johns Hopkins University</b>                           |
| 10.  | <b>ORT in the Context of<br/>Primary Health</b>  | <b>Professor K.W. Newell</b><br><b>Liverpool School of Tropical Medicine</b>  |
| 11.  | <b>Background Paper</b>  | <i>International Child Health Foundation</i>  |