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DIARRHOEAL DISEASES CONTROL PROGRAMME

INTERVENTIONS FOR THE CONTROL OF DIARRHOEAL DISEASES AMONG YOUNG CHILDREN:
IMPROVING LACTATION

by

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SUMMARY

The effect of improving lactation on diarrhoea morbidity and mortality is analysed and interventions to increase the quantity or quality of breast milk are reviewed. It is not known whether the breast-fed children of mothers with enhanced lactation (defined in terms of quantity and/or quality) have lower diarrhoea morbidity or mortality rates than breast-fed children of similar mothers with inferior lactation. Although poor maternal nutrition may lead to a deterioration in milk output and quality, attempts to improve lactation by maternal supplementation have not achieved any sizeable increase in milk output, though some improvement in milk quality has been observed. Interventions that facilitate early post-partum contact and feeding on demand, or increase maternal confidence, are likely to increase milk output. On the basis of currently available information, the improvement of lactation by maternal dietary supplementation is not a promising primary intervention for national diarrhoeal diseases control programmes. The improvement of lactation by feeding on demand and allaying maternal anxiety may be a useful supporting intervention in combination with the promotion of breast-feeding. More prospective studies are required into breast-milk intake, growth, and diarrhoea in exclusively breast-fed infants under 6 months of age.

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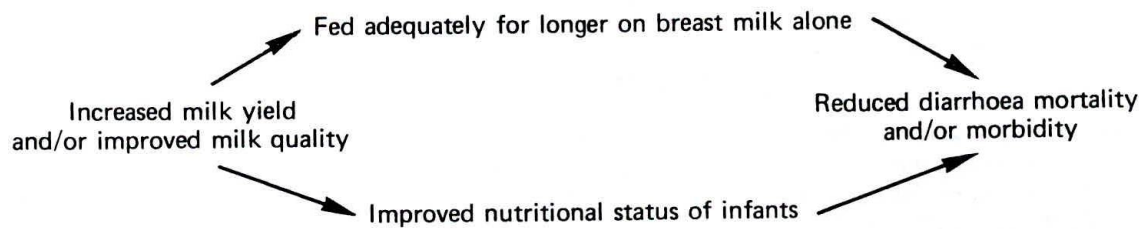
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INTRODUCTION

This paper is the sixth in a series of reviews of potential interventions for the control of diarrhoeal diseases among young children in developing countries (1, 16-20). In the second review in the series, data were presented showing that infants with a poor nutritional status are predisposed to more severe and longer-lasting diarrhoea and to higher case-fatality rates (16). In the third review, exclusively breast-fed infants were shown to be better protected against diarrhoea than partially breast-fed or non-breast-fed infants, and it was concluded that the promotion of breast-feeding can be expected to decrease diarrhoea morbidity and mortality rates substantially in the first 6 months of life (19). In this review, we examine whether improving the quantity or quality of breast milk, as distinct from the promotion of breast-feeding, could be an effective intervention for reducing diarrhoeal diseases among young children. If milk output could be improved in certain situations, infants might be adequately fed for a longer period on breast milk alone. Improving milk output or milk quality in certain situations might also improve the nutritional status of breast-fed infants. The possible relationships are schematically represented below:



The separation of interventions directed towards increasing breast-feeding prevalence and those directed towards improving lactation is desirable since the former are concerned with maternal behaviour and the decision to breast-feed or not, whereas the latter are concerned with physiological performance and the capacity of mothers to produce breast milk.

EFFECTIVENESS

If improving lactation is to be effective as a diarrhoeal disease control strategy, it must be true that:

either

a considerable proportion of diarrhoea morbidity or mortality in young children in developing countries is due to inadequate breast-milk quantity or quality

hypothesis
1

and

programmes aimed at improving maternal nutritional status or breast-feeding practice can improve breast-milk quantity or quality

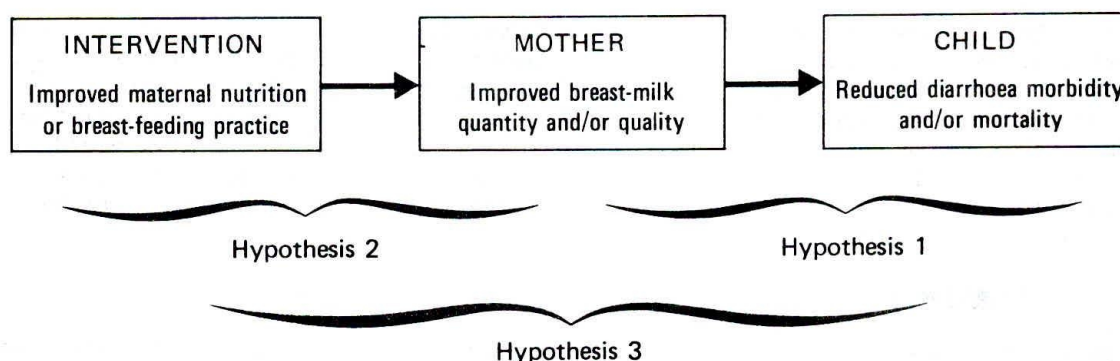
hypothesis
2

or

programmes aimed at improving maternal nutritional status or breast-feeding practice can reduce diarrhoea morbidity or mortality in young children

hypothesis
3

There is a considerable amount of literature bearing on hypothesis 2, but little is known of hypothesis 1, and almost nothing of hypothesis 3. The effectiveness of improving lactation as an intervention to reduce diarrhoea morbidity or mortality would be suggested by a demonstration either of the correctness of hypotheses 1 and 2 or of the correctness of hypothesis 3. This is schematically represented in the following diagram:



The evidence for and against these hypotheses is examined below.

Hypothesis 1: A considerable proportion of diarrhoea morbidity or mortality in young children in developing countries is due to inadequate breast-milk quantity or quality

The adequacy of lactation is assessed by determining the quantity and quality of breast milk produced in 24 hours, or by measuring the growth of the recipient infant. Both methods present problems because there are technical difficulties in measuring milk yields and milk composition, and factors other than milk supply may affect infant growth. Both methods necessitate a reference standard, and appropriate standards for developing countries have not yet been agreed upon (65).

Adequacy of lactation in developing countries: breast-milk quantity

Average milk yields are generally reported to be lower in developing countries than in developed countries. In well-nourished women the average daily production of breast milk is commonly stated to be 850 ml. This figure originated in 1950 as an estimate based on studies in New Zealand and the USA in which 68 measurements were made in 19 mothers at different stages of lactation (22). Milk yields in these 19 mothers ranged from 250 to 1500 ml/day, and it was tentatively assumed that 850 ml represented the average daily output during the first 6 months of lactation. Thus, although this figure is sometimes used as a reference for the adequacy of lactation, it was never intended as such. Since 1950, further lactation studies have been undertaken in developed countries, the results of which indicate that when milk output is at its peak, around the 3rd or 4th month, the average daily volume is usually 750-800 ml (73). Volumes within this range may therefore be considered to represent the average peak yield of well-nourished, healthy mothers. In communities with poor living conditions and a lower plane of maternal nutrition, average peak yields are usually below this range. In 20 studies in developing countries, average peak milk yields in the first 6 months of lactation ranged from 400-730 ml/day (35, 73, 76).

In most studies breast-milk consumption has been measured by test-weighing the infant before and after each feed. This is extremely difficult in traditional societies because of the high frequency of feeding. In some studies, in order to facilitate the measurements, infants who usually were fed on demand have been changed to scheduled feeds, with possible

adverse effects on milk output. Furthermore, the measurements themselves, or their location, may cause the mother anxiety and adversely affect milk output. In Senegal and Sweden, for example, daily milk output was reduced by 160 ml and 210 ml respectively when measurements were made in unfamiliar surroundings (61, 5). It is therefore possible that the volumes reported in some studies could be underestimates. Furthermore, the infant may not consume all that is produced, and therefore measurements based on test-weighing may underestimate milk production.

Notwithstanding the methodological difficulties, it is generally agreed that the average breast-milk output is usually somewhat less in poorly nourished communities (35, 59, 73). This view is strengthened by data from Egypt, where a difference in mean output of 195 ml/day was found between healthy and malnourished mothers (30), and by data from The Gambia (48), Kenya (67), and Zaire (69) where a 35-40% decrease in milk yield (200-300 ml) occurred when food stocks were low. Within-study comparisons such as these are more likely to identify true differences, whereas between-study comparisons may be unreliable if differing methodologies have been used.

Adequacy of lactation in developing countries: breast-milk quality

Comparisons of breast-milk quality present methodological problems since the composition of breast milk changes considerably during a single feed. For example, hind-milk may contain 4-5 times as much fat as fore-milk. Breast-milk composition also varies with the time from parturition, the time of day, the feeding frequency, and the sampling method (manual expression or breast pump). Cross-cultural comparisons of breast-milk quality are therefore difficult to interpret, especially with regard to fat and energy contents.

Lactose is regarded as the most stable constituent of breast milk and the protein concentration is also generally regarded as being constant among communities (35, 59, 73). The fat content of breast milk appears less stable and investigators in Botswana (74), East Africa (10), India (12, 25), Pakistan (66) and Papua New Guinea (2) have reported substantially lower fat concentrations compared with developed countries, while in The Gambia significant seasonal differences in fat content have been observed (73). In Brazil, however, fat concentrations were unaffected by maternal malnutrition (41). The vitamin content of breast milk is known to be affected by maternal diet, and there have been reports of lower concentrations of vitamin A (23), several of the B vitamins (4, 35), and vitamin C (74) in the milk of under-privileged mothers. Very little is known about the mineral content of breast milk in developing countries but low concentrations of zinc and copper have been found in milk from poor Indian women, 1-3 months post-partum (54).

Whether maternal nutrition affects the anti-infective properties of breast milk has received little attention. In The Gambia in the rainy season, substantial decreases in the concentrations of IgA, IgG, C4 component of complement, and lysozyme were found in addition to a decrease in milk volume (50). During this period the prevalence of diarrhoea increased, but this could have been due to factors other than changes in breast-milk composition. In Colombia, significant reductions in the concentrations of colostral IgA, IgG, and C4 component of complement were observed in malnourished mothers (45).

We therefore conclude that, although breast-milk output in developing countries is usually good despite low levels of maternal dietary intake, reductions in daily output of 200-300 ml may occur during periods of acute or chronic maternal undernutrition. Furthermore, poor maternal nutrition may lead to a deterioration in milk quality, primarily in relation to the concentrations of fat and vitamins, and possibly of trace elements, immunoglobulins, and other protective factors. Lipid components in breast milk are believed to have anti-infective properties (36). Deficiencies of certain vitamins and trace elements are known to impair the immune response. It is possible, therefore, that reduced concentrations of specific nutrients and protective factors in the milk of undernourished mothers, compounded by a lower total volume, may adversely affect the nutritional status and immune response of their infants, especially if poor maternal nutrition also resulted in lowered foetal storage of nutrients.

Adequacy of lactation in developing countries: infant growth

In the majority of longitudinal or semilongitudinal surveys of infant growth in developing countries, weight velocity begins to decelerate between 3 and 4 months of age (14, 70) compared with United Kingdom standards (44). In several of these surveys, however, sample sizes were small, birthweight and gestational age are not specified, and it is not usually clear whether the infants were exclusively breast-fed throughout the entire 6-month period. In an effort to provide more reliable data, longitudinal surveys of infant growth have been undertaken recently in Canada (6), Manipur, India (N.C. Luwang, personal communication, 1983), and Jordan (S. Hijazi, personal communication, 1984) of infants who were known to be exclusively breast-fed (that is, no other fluids or foods were consumed, except water in some instances although this was rare among the Indian infants studied). Weight velocity and morbidity were monitored monthly in Canada and fortnightly in India and Jordan, and growth faltering was rigidly defined. Table 1 shows that, in marked contrast to Canadian infants, growth had faltered in 38% of Indian infants before the age of 4 months. In Jordan the prevalence of growth faltering was less than in India, but 15% had faltered before the age of 4 months. In all 3 studies, low birthweight infants were excluded. In the Indian and Jordanian studies the definition of faltering was more severe than in the Canadian study, namely successive fortnightly increments $-2SD$ below the mean increment of North American infants (21). The Indian mothers mostly belonged to the middle socio-economic class, were free from disease, and of parity 3 or less. Infant morbidity data have not yet been reported from India and Jordan, but the preliminary impression is that in both countries faltering was the result of inadequate lactation, rather than infection. In the Canadian study (6) it was found that, among exclusively breast-fed infants, those whose growth faltered had a significantly higher infection-related morbidity rate than those with no faltering. In the majority of these infants, growth failure was detected before clinical infections were observed, and it is therefore reasonable to conclude that an inadequate breast-milk intake caused the growth faltering. These findings are in keeping with the statement issued in 1980 by a United Nations Consultative Group on Maternal and Young Child Nutrition that "In conditions where undernutrition and social deprivation are common, the growth of exclusively breast-fed infants may show signs of faltering before 4 months." (65).

Table 1: Growth faltering among exclusively breast-fed infants^a

Age (months)	Cumulative prevalence of growth faltering (%)		
	Canada ^b n = 36	Jordan ^c n = 87	India ^c n = 84
0-1	0	0	1
1-2	0	1	8
2-3	0	11	13
3-4	0	15	38
4-5	8	29	61
5-6	14	46	85

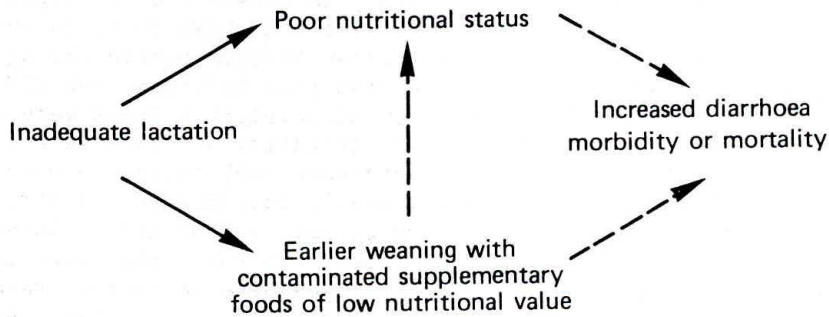
^aCanadian data from Chandra (6), Jordanian data from S. Hijazi (personal communication), and Indian data from N.C. Luwang (personal communication).

^bFaltering taken as body weight <10 th centile of NCHS standard (47).

^cFaltering taken as two successive weight increments $-2SD$ below the mean increment according to Fomon (21) if <4 months of age, or $-2SD$ below the NCHS standard (47) if >4 months of age.

Consequences of inadequate lactation

Poor lactation can be expected to have one of two consequences: either the infant's growth will falter or his mother, perceiving his plight, will provide him with additional food, as for example in The Gambia where mothers whose breast-milk output was below the group mean were observed to introduce supplements earlier than mothers with higher breast-milk yields (71). This second outcome is equally problematic in poor communities since traditional supplementary foods are often of low nutritional value and highly contaminated with diarrhoeal pathogens (3, 58). In these circumstances, inadequate lactation may lead to diarrhoea whether the mother chooses to supplement or not, as shown in the diagram below (broken lines denote a degree of uncertainty).



Direct evidence for this sequence of events is limited. We have located only one prospective study of breast-milk output and diarrhoea. In this study, in The Gambia (71), a significant linear correlation was found between breast-milk output and the age of first diarrhoea-induced weight loss, lower milk yields being associated with earlier diarrhoea. No incidence rates are reported in this study. Lower milk yields were also significantly correlated with earlier weaning and this may be the cause of the earlier onset of severe diarrhoea.

Conclusions concerning hypothesis 1

We can conclude very little about hypothesis 1 from the data reviewed above. Poor maternal nutrition may reduce milk yields and possibly lower milk quality, but we lack information on the prevalence of inadequate breast-milk quantity or quality. We even lack internationally-accepted definitions of adequacy. We know little of the frequency of undernutrition among exclusively breast-fed infants or of the proportion of this undernutrition that may be attributed to inadequate lactation rather than to infection. These gaps in our knowledge are not minor - they represent fundamental questions which require urgent answers. Although inadequate lactation may predispose to diarrhoea, we have no evidence of this except for a single report from The Gambia (71), and this relates to the age of onset of severe diarrhoea, rather than its frequency.

Hypothesis 2: Programmes aimed at improving maternal nutritional status or breast-feeding practice can improve breast-milk quantity or quality

Etiology of inadequate lactation

Breast-milk insufficiency may arise either from inadequate milk synthesis and/or inadequate milk ejection (let-down). Both are under hormonal control, the former by prolactin and the latter by oxytocin. Prolactin and oxytocin are released by separate pathways in response to suckling. Conditioned release of oxytocin may also occur in response to stimuli such as an infant's cry. The milk-ejection reflex can be inhibited by anxiety or physical stress, either by inhibiting oxytocin release or more often by the release of catecholamines which constrict the mammary blood vessels, thus preventing access of oxytocin to the myoepithelial cells. Inhibition is more likely to occur during the early weeks of lactation than later on. Factors which may affect milk synthesis or its ejection, and which may be amenable to short-term intervention, are maternal nutritional status, galactogogues, breast-feeding practices, and the use of contraceptives.

Improving maternal nutritional status

In considering hypothesis 1 we concluded that poor maternal nutrition may reduce milk yields and possibly lower milk quality. Energy and nutrient requirements are increased during pregnancy, and more so during lactation. Dietary intakes, however, may be constrained by poverty, unavailability of food, or intrafamilial food sharing in favour of male members. In some communities, poor maternal nutrition may be longstanding, or may develop during pregnancy and/or lactation. Short birth intervals may exacerbate the problem and a reduction in body weight with increasing parity has been observed in Papua New Guinea (68). Maternal nutrition may also be impaired by infection and an arduous work load. Although better primary health care, family planning, and changes in cultural attitudes towards women may lead to an improvement in their nutritional status, considerable emphasis is currently being given to increasing the dietary intakes of lactating women either by advising them to eat more of the locally available foods or by providing food supplements. "Feed the nursing mother, thereby the infant" is becoming an increasingly popular maxim although the efficacy of this advice has not been adequately tested. Indeed this quotation is derived from an investigation in which only one mother was studied (63). In view of the emphasis being given to the provision of food supplements to lactating women, it is appropriate to consider the effects of such programmes on breast-milk quantity and quality. Only a few evaluations have been undertaken and nearly all are unsatisfactory. Most have not measured consumption of the supplement or the intake of the regular diet. Some are of limited duration or small-scale. The results are conflicting, as shown by the following 6 studies.

In Zaire, 27 lactating mothers received dried skimmed milk (60 kcal (251 kJ) and 6 g protein/day) for one year (33). During the first 3 months of lactation, breast-milk yields of supplemented and unsupplemented mothers averaged 480 ml and 310 ml respectively. However, by the fourth month of lactation, the breast-milk yields of the supplemented mothers had decreased to about 400 ml and were similar to those of unsupplemented mothers. Breast-milk protein concentrations were similar in the first 6 months in both groups but thereafter declined in the unsupplemented group. No decline in protein concentration was observed in the breast milk of supplemented mothers. Consumption of the supplement and regular diet were not measured.

In India, 15 low-income mothers with habitual protein intakes of about 60 g/day received an additional 280 kcal (1171 kJ) and 30 g protein as skimmed milk daily for the first 6 months of lactation, and 15 similar mothers received a placebo (24). Consumption of the supplement was supervised. Mothers were instructed to continue their usual diets, but despite repeated exhortations it was not possible to prevent some supplemented mothers from eating less of their regular diet. During the six-month period when their infants were exclusively breast-fed, the infants of supplemented mothers gained only 130 g more on

average than control infants. When 6 mothers were hospitalized to facilitate dietary compliance and measurement of breast-milk output, increasing the maternal protein intake from 61 to 99 g/day was accompanied by an increase in average milk yield from 402 to 515 ml/day, and by a decrease in average protein concentration from 1.21 to 1.02 g/100 ml.

In Mexico, 17 mothers received a supplement of partially skimmed milk, vitamins, and minerals throughout pregnancy and lactation (7, 8). Habitual daily intakes in lactation were approximately 2000 kcal (8368 kJ) and 53 g protein and the supplement provided an additional 300 kcal (1255 kJ) and 20 g protein per day. Peak breast-milk output averaged 720 ml in supplemented mothers, compared with 650 ml in control mothers who were matched for physical and socioeconomic characteristics. These higher volumes were also maintained for a longer period, although they were largely offset by a 15-20% decrease in energy and nutrient concentration. Unfortunately, precise information regarding the impact of these changes on infant growth is not available since the infants were themselves supplemented. However, 4 additional cases were studied in which the mother was supplemented but not the infant (7). The mean weight of these 4 infants at 8 months of age was approximately 600 g greater than that of the infants of the 17 unsupplemented mothers. Their heavier weight, however, is probably partly attributable to a heavier birthweight as a result of the pre-natal supplement, and one cannot assume that the weight differential arose as a result of improved lactation.

In Nigeria, the mean breast-milk output of 7 mothers increased from 740 g to 870 g ($p < 0.05$) when they were given an additional 50 g protein per day. There was no significant decrease in the concentration of milk solids (15). During the 2-week supplementation period their infants grew significantly faster and gained on average 200 g more than during the pre-supplementation period when the women ate cassava-based diets containing 50 g protein per day. However, this was a short-term study, the duration of supplementation being only 2 weeks.

In Colombia, generous supplements of enriched bread, dried skimmed milk, and vegetable oil were provided (32). Women were supplemented during the third trimester of pregnancy and during lactation, and a daily supplement of 623 kcal (2607 kJ) and 30 g protein was provided for each family member over one year of age. Pregnant women were allotted 856 kcal (3581 kJ) and 38 g of protein. Consumption of the supplement during lactation was not assessed, but during pregnancy the net increase in energy intake was only 18% of that offered. Breast-milk output was not measured but, during the first 2 months of life, the infants of supplemented mothers gained on average only 45 g more than the infants of unsupplemented mothers.

The effects of pre-natal and post-natal supplementation are currently being investigated in The Gambia (51, 52). The investigation is in two stages. During the first phase of the study the supplement was given during lactation. In the second phase, now under way, supplementation was initiated at the beginning of pregnancy and is continuing during lactation. In the first phase, 130 lactating women were offered groundnut-based biscuits and a vitamin-fortified tea drink, 6 days each week for 12 months. Consumption was supervised and measured. The daily allocation was 950 kcal (3975 kJ) and 35 g protein in the dry season and 1100 kcal (4602 kJ) and 41 g protein in the wet season (52). Over the whole year, the intake of the supplement amounted to 830 kcal (3473 kJ) per day, of which 107 kcal (448 kJ) replaced some of the regular diet. The mean daily energy intake was 2291 kcal (9585 kJ) compared with 1568 kcal (6560 kJ) for 120 unsupplemented lactating mothers. Supplementation had no effect on breast-milk output at any stage of lactation or in any season of the year. The population standard deviation remained the same after supplementation, demonstrating that the supplement had not benefited even the lowest milk producers (51). Supplementation increased the protein concentration of breast milk by approximately 7% at all stages of lactation, but decreased the lactose concentration ($p < 0.01$ in each case). Supplementation did not significantly affect the energy content (51). There was a significant increase in the milk content of thiamin (+40%), riboflavin (+33%), niacin (+43%), and vitamin C (+33%). Maternal supplementation did not prevent the seasonal decrease in IgA, IgG, C4 component of complement, and lysozyme (50).

Although there appears to be evidence that some improvement in lactation was achieved as a result of maternal supplementation in 4 of these studies (India, Mexico, Nigeria, and Zaire), we have been strongly influenced by the Gambian investigation because it has the largest sample size, the most rigorous experimental design, and is the longest in duration. The fact that no increase in milk volume was observed despite a very substantial increase in maternal intake suggests that post-natal supplementation may not be effective in populations where the primary dietary deficit is an inadequate energy intake. Particularly disappointing is the lack of any significant effect on milk output during the wet season when milk yields are known to diminish. One must also consider, however, that during this period women are extremely busy with agricultural activities. It is therefore possible that in the wet season lactating women do not spend as much time nursing their infants as they do at other times of the year. An interesting hypothesis for the lack of effect is that the increased energy intake was utilized by increasing the amount of physical labour undertaken during the busy planting season, although it is possible that at least some of the energy may have been dissipated by a decrease in metabolic efficiency (49). Alternatively, it is possible that the post-partum period is too late to improve milk output and that pregnancy is the more appropriate time when mammary growth is occurring. In rats, pre-natal malnutrition impairs mammary growth and milk production (46).

In the second phase of the Gambian study, preliminary observations indicate that infants of mothers who were supplemented pre- and post-natally are thriving better, although no increase in milk yield has been observed (A.M. Prentice, personal communication, 1983). Morbidity and birthweight data are being analysed which may help to explain this seemingly paradoxical outcome. In this context it is relevant to note that (a) in Guatemala, weight gain during the last trimester of pregnancy was related to the duration of lactation (29); (b) in 5 Chilean studies, a significant association has been demonstrated between birthweight and the prevalence and duration of lactation (40); and (c) there is a positive correlation between birthweight and subsequent milk intake (72). These findings suggest that pre-natal maternal nutrition may affect lactation as well as foetal growth.

The evidence that post-natal food supplementation improves breast-milk quantity is weak. It is possible, however, that the lack of any notable impact may be due to methodological problems, or to a failure to achieve substantial increases in maternal net dietary intake, or to onerous lifestyles which limit the amount of time mothers can spend breast-feeding. It is also possible that the mothers who have been studied were not sufficiently malnourished. This does not mean that lactating women should be excluded from supplementary feeding programmes since the additional food may improve maternal nutrition and be beneficial for any subsequent pregnancy or may increase their feeling of well-being and enable them to take better care of their children. Improving the maternal diet without concurrently introducing some artificial form of contraception may, however, cause a shortening of birth intervals and a rise in birth rate (39). Whether pre-natal supplementation improves lactation remains to be elucidated.

Galactogogues

Many communities regard certain foods or drugs as having galactogogic properties. Precise proof of their pharmacological effects is not available. In an Indian study, 4 substances claimed to promote lactation were investigated but none was found to have any appreciable effect. They were tamarind, cotton-seed, garlic, and 'Leptaden' - an indigenous preparation (24).

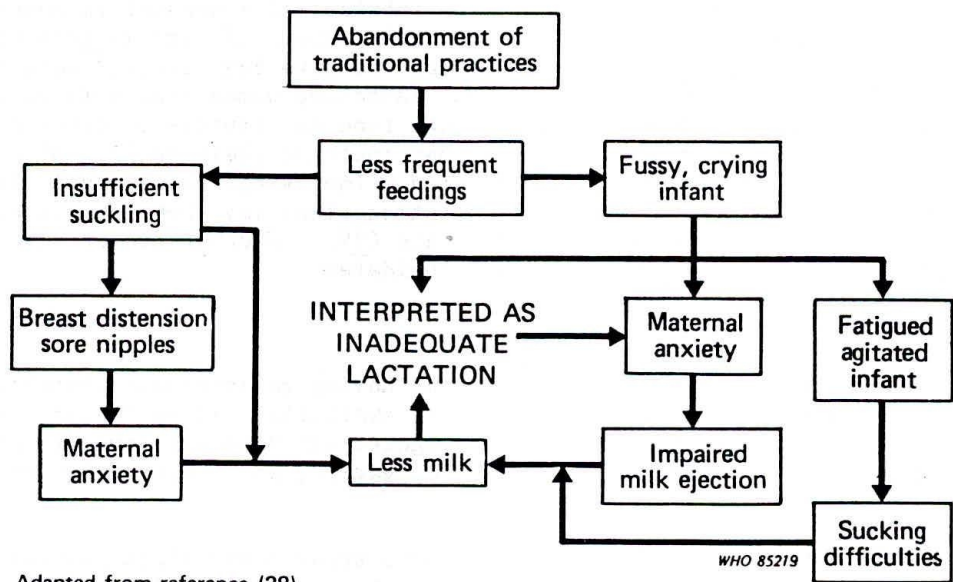
Metoclopramide (38) and sulpiride (77) are dopamine antagonists which increase prolactin release and improve milk yields. Let-down of milk can be induced by giving synthetic oxytocin as a nasal or throat spray (60). However, galactogogues such as these are unlikely to be of any practical use in developing countries.

Improving breast-feeding practices

Suckling stimulates prolactin and oxytocin release, thus frequent suckling facilitates the early establishment and maintenance of a good milk flow. Demand feeding is therefore preferable to scheduled feeding. Feeding on demand requires that the mother and infant

should be in close physical proximity. In transitional and Westernized societies, hospital routines which separate the mother from her newborn infant, which delay breast-feeding, which offer water or supplementary milk feeds, or which sedate the mother are not conducive to feeding on demand and can adversely affect the initiation of lactation; they may also give rise to anxiety, which inhibits milk-ejection. In Sweden, skin-to-skin contact and suckling immediately after delivery was associated with a two-fold increase in the proportion of mothers who were breast-feeding at 3 months (13). Rooming-in (allowing mother and newborn infant to be in the same room) has been suggested to increase the feeling of motherhood, resulting in a more positive attitude to breast-feeding (53) as well as facilitating feeding on demand. The use of pacifiers is contrary to the concept of feeding on demand. Changes in breast-feeding practice that increase the number of feedings are likely to increase the quantity of milk produced. In traditional societies, feeding on demand in the early post-partum period is the norm and the young infant spends most of the day and night in close bodily contact with his mother. For older infants, however, feeding on demand may be less frequently honoured since the infant may be left with a caretaker whilst the mother works. In India and Kenya, physical separation starts at about 6 months of age (9, 67). Interventions that enable mothers to spend more time with their infants (by easing their work burdens, for example) may help to maintain a high frequency of feeding and improve breast-milk output. Maternal attitudes are important and can affect the adequacy of lactation. This is illustrated by data from India, where exclusively breast-fed male infants were better nourished than exclusively breast-fed female infants (11). The difference in lactation performance was attributed to greater motivation when mothers had male infants.

In traditional societies, the birth attendant plays an important role, imparting the skills of breast-feeding and providing physical help and emotional support (55). Urbanized mothers often lack this form of traditional assistance. Support and guidance is further reduced by the shift from 'extended' to 'nuclear' families. Abandonment of traditional practices may interfere with the almost continuous nursing of the infant and may provoke actual or perceived milk insufficiency as depicted below:



The formation of breast-feeding mothers' support groups may assist in dispelling 'crises of confidence', and the guidance provided by such groups may improve lactation, as has been observed in slum-dwelling mothers in Brazil (D.B. Jelliffe, personal communication, 1983).

Use of contraceptives

The use of oral contraceptives to space pregnancies may lower maternal blood concentrations of folic acid, pyridoxine, riboflavin, and vitamin C. Breast-milk levels of pyridoxine have been found to be significantly lower in long-term users of oral contraceptives (56). Combined oral contraceptives that contain as little as 30 µg of oestrogen can decrease milk volume by as much as 40% if introduced early in lactation (27, 34, 57, 64, 75). Conversely, 17α-progestogen derivatives given alone (mini pills or intramuscular Depo-Provera) may increase milk volume (26, 37, 78). Intrauterine devices also appear to stimulate lactation, possibly by mechanical action provoking a neuroendocrine reflex that increases prolactin output (26, 43) but the evidence is not very strong and recent research suggests an increased risk of uterine perforation when intrauterine devices are used in the post-partum period (31). Where oestrogen-containing oral contraceptives are used, changing the type of contraceptive may improve breast-milk output.

Conclusions on hypothesis 2

Dietary supplementation studies have not been successful in increasing breast-milk output except where habitual protein intakes have been about 50 g per day. All studies present methodological problems which make evaluation difficult, and in only one study was a substantial net increase in maternal energy intake achieved. In this study, in The Gambia, even substantial supplementation did not increase milk output, although milk quality was improved. Interventions that facilitate early post-partum contact and feeding on demand, or increase maternal confidence, are likely to increase milk output, especially in transitional societies. Family planning programmes should consider the effects of oestrogen-containing oral contraceptives on lactating women.

Hypothesis 3: Programmes aimed at improving maternal nutritional status or breast-feeding practice can reduce diarrhoea morbidity or mortality in young children

We have located only one study in which the diarrhoea rates of exclusively breast-fed infants whose mothers have participated in programmes to improve lactation have been compared with diarrhoea rates in other exclusively breast-fed infants (62). In this study in a poor urban district of Manaus, Brazil, where zinc deficiency is prevalent, 37 mothers received 15 mg of zinc daily and 28 mothers received a placebo. Supplementation was started in the first week post-partum and families were visited daily. During the first 5 months of life, when all the infants were exclusively breast-fed, 30% of infants of supplemented mothers had diarrhoea in contrast to 57% of control infants. The difference in diarrhoea morbidity was significant for male infants ($p < 0.05$) but not for female infants. In Puriscal, Costa Rica, changes in hospital routine were associated with a decrease in neonatal diarrhoea morbidity and mortality (42). The changes in hospital routine included early post-partum contact and suckling, rooming-in, and advice on breast-feeding. These changes were associated with an increase in the prevalence and duration of breast-feeding. Whether this increase simply reflected a change in maternal attitudes towards breast-feeding or resulted from improved breast-milk output is not known. There is, however, a physiological mechanism for the latter since more frequent suckling could have enhanced milk synthesis, and the extra attention and advice could have improved maternal confidence and assisted milk ejection.

We have no other data to support or negate hypothesis 3. We have almost no data on hypothesis 1, and only very inadequate data on hypothesis 2. We can therefore make no theoretical calculations on the possible impact of improving lactation on diarrhoea rates.

CONCLUSIONS

There is evidence to suggest that poor maternal nutrition leads to a deterioration in milk output and milk quality and, in The Gambia, lower milk yields were associated with earlier weaning and earlier onset of severe diarrhoea. Attempts to improve lactation by post-natal dietary supplementation, however, have not achieved any sizeable increase in milk output, although some improvement in milk composition has been achieved, mainly in vitamin content. In a zinc-deficient population in Brazil, post-natal maternal zinc supplementation reduced diarrhoea morbidity rates in early infancy. Although there is no proof that the reduction in diarrhoea was due to improved lactation, there seems to be no alternative mechanism since all the infants were exclusively breast-fed.

Pre-natal dietary supplementation may prove to be a more promising intervention to increase milk output than post-natal supplementation. Pre-natal supplementation, however, is subject to the high costs and logistic complexities of all supplementary feeding programmes (16). In addition, its effect on diarrhoea through increasing birthweight (1) may be greater than its effect on diarrhoea through improving milk output or milk quality.

Interventions that change hospital routines to permit early post-partum contact and feeding on demand may improve breast-milk output. Interventions which seek to maintain feeding on demand in the home environment (keeping mother and infant in close proximity both day and night, and discouraging use of pacifiers and supplementary feeds of water), or provide support and guidance, are likely to improve breast-milk output. These interventions may also have a positive effect on maternal attitudes towards breast-feeding, and their effect on diarrhoea through increasing the prevalence of breast-fed infants (19) may be greater than their effect on diarrhoea through improving breast-milk output.

In conclusion, on the basis of data currently available, the improvement of lactation by maternal dietary supplementation is not a promising primary intervention for national diarrhoeal diseases control programmes. The improvement of lactation by allowing feeding on demand and allaying maternal anxiety may be considered a supporting intervention in combination with the promotion of breast-feeding - an intervention that may have considerable impact on diarrhoea morbidity and mortality in the first 6 months of life.

This review has highlighted several areas of ignorance that require further research. More prospective studies of milk output, and of growth and morbidity in exclusively breast-fed infants are required to determine the prevalence of inadequate lactation in different countries and in different socioeconomic groups. Several factors may reduce milk output, including maternal undernutrition, anxiety, and work burdens that limit the time available for breast-feeding. The relative importance of these causal factors should be examined in communities reporting low milk yields. A greater understanding of the relationship between growth faltering and diarrhoea is required, particularly as regards any effect that mild or moderate faltering may have on the frequency, duration, or severity of diarrhoea. In zinc-deficient populations, further investigation is warranted of the effect of maternal zinc supplementation on milk quality and diarrhoea.

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W.H.O. ORAL REHYDRATION CENTRE

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W.H.O. ORAL REHYDRATION CENTRE

Vanivilas Children's Hospital

Bangalore

The O.R.T. Center was started in Vani Vilas Children's Hospital in December 1985 with aid from W.H.O.

OBJECTIVES OF THE CENTER :

1. Service to the patients - prevention and management of dehydration.
2. Training of medical, para-medical, Anganwadi, Voluntary Health workers.
3. Health Education of the parents - prevention of Gastro Enteritis, dehydration.
4. Research programme - conducting trial on use different of types of oral rehydration solution.
5. Growth monitoring of the patients on follow-up.
6. Health Education regarding immunization and infant nutrition so that integrated services are available in a single visit.

INFRASTRUCTURE

We have about 30 beds for diarrhoea manned by two Post Graduates, 5 interneers, 4 staff nurses and 2 helpers supervised by Lecturer, Asst. Prof., Professors and Superintendent.

O R S : Packets of 1 L and 5 L are prepared by Post Graduates Salts are being supplied in bulk by the stores of Vani Vilas Hospital.

TYPES OF O.R.S.

- O.R.S.
- Super O.R.S.
- Citrate based ORS
- Glycine based O.R.S.

Different solutions are prepared in bulk of 5-20 liters depending upon the demand and distributed to the patients, according to the requirements.

Children who are admitted to the ward are assessed as mild, moderate and severe as per the case proforma. Child with mild, moderate dehydration are given different ORS at random.

IV fluids are given to the children with severe dehydration until the correction of deficit therapy i.e., 4-6 hours, later as soon as the child starts taking orally, ORS is given to the child.

These patients are kept for 24-72 hours and discharged as soon as they make recovery. Stool samples are subjected to microscopic examination and culture, routinely.

HEALTH EDUCATION

In the afternoon, mothers are taught about the signs of dehydration and method of prevention of diarrhoea.

Prevention of dehydration and nutritional care of the child and immunization advise are also given.

Stress is laid on breast feeding, usual food, during the attack of diarrhoea.

So far, we have trained nearly 500 medical students, 60 post graduates, 300 medical officers, 100 practitioners, 50 B.Sc. nursing students, and Anganwadi workers, nearly 5000 mothers and 120 voluntary health workers.

Table 1:

Diarrhoea still continues to be a major problem in developing countries, it is taking the big share in the admission to Children's Hospital. In our Institute 23.5% of the beds are taken away by diarrhoea.

Of the 2206 admitted between 86 Jan. to 86 December 69 children

died. The mortality rate due to diarrhoea was 3.12%. The mortality was attributable to higher number of admissions due to cholera in the last year (51).

More importantly, as our hospital being a referral hospital, many patients will be in a serious state by the time they reach the hospital. Thirdly many children were (156) malnourished and lastly the associated respiratory infections were responsible for the high mortality.

M : F ratio was 2 : 3

As the table implies diarrhoea is more common in pre-school children 74.4%. 28.73% of the attacks seen in 6-12 months age. Only 13.5% were in school going children.

SEVERITY OF DEHYDRATION

40.79% of the children were mildly dehydrated when they were admitted. 45.55% of the children were moderately dehydrated, only 13.65% of the children were severely dehydrated indicating that if proper care is taken in the earlier stages this incidence of severe dehydration can be reduced.

Majority of the children were given ORS alone (73.48%) IV fluids were given in 26.52% of the children. Prior to the institution of the ORT, all these children used to receive IV fluids. Hence excessive spending of hospital budget on IV fluids and drugs is being reduced. Moreover the difficulties of IV fluids therapy like over hydration, Thrombophlebitis, dys-electrolytemia which were common in the earlier days, are being circumvented. Hence ORT is giving relief to the hospital budget, less injurious to the children and cost effective with no side effects, we have not come across a single child with hypernatremia.

ORT not only reduced the budgetary provisions of the hospital, also reduced the duration of hospital stay. This is definitely helpful to the patients as it is known that hospitalisation of the children leads to lot of inconveniences to the patients as well as financial desarray of the low income families.

Majority of the patients (81.15%) were discharged within 72 hours after the admission.

CLINICAL DIAGNOSIS:

Diarrhoea : Incidence of acute G.E. was 75.65%, 6.95% had bacillary dysentery, cholera was in 2.35%. Amebiasis and giardiasis was diagnosed in 0.45%, 2.53% respectively.

ASSOCIATED ILLNESS :

PEM was noted in 6.98%, of these majority were grade III and IV mal-nourished. 3.94% had respiratory infection like LRI and branchopneumonia.

It is of interest to note that incidence of secondary lactose was very low. It was 0.49%.

Antibiotics were used in 195 cases (7.9%). Metronidazole in 66 cases (3%). Drugs like, antisecretory drugs viz. Loperamide and Demulcents like Kaolin and Pectin were not used. Usage of drugs were discouraged. Parenteral antibiotics were given for children with associated respiratory infections.

PATTERN OF SPECTRUM OF ORGANISMS:

Of the 500 specimen, sent for culture and sensitivity, 263, yielded E.coli-52.6%, in 158 children normal commensals were grown. Shigella was isolated in 17(3.4%) cholera was isolated in 22 (4.4%) and 43 specimens did not yield any growth.

ANALYSIS OF DEATHS:

Of the total deaths, 14 deaths (20.3%) took place within 24 hours and 2.75% deaths occurred in 24-36 hours after the admission. This indicate, 42.05% deaths could be preventable as the majority of deaths are due to severe dehydration (43.5%). Associated illness like PEM & Gr. III, IV (40.6%), LRI (8.7%) were other contributing factors for the mortality. 4 deaths occurred due to dysentery (5.8%) 44.85% deaths occurred in the age group of 1-3 years.

Jan. 1986 to December 1986

Total Number of admissions to G.E. ward	2206
Total number deaths	69
Percentage of deaths	3.12

Sex Ratio:

	Nos.	%
Males	1309	(59.33)
Females	897	(40.67)

Age group :

2 - 6 months	194	(8.79%)
6-12 months	634	(28.73%)
1-3 years	814	(36.89%)
3-5 years	269	(12.19%)
more than 5 years	295	(13.37%)

Dehydration :

Mild	900	(40.79%)
Moderate	1005	(45.55%)
Severe	301	(13.64%)

Culture sent : 500

	Nos	%
E. Coli	263	52.6
Commensals	158	31.6
No growth	43	8.6
Shigella	17	3.4
Salmonella	1	0.2
Protens	4	0.4
Paracolons	7	1.4
Klebsiella	8	1.6
Vibrio cholera	22	4.4
Staph aureus	2	0.4

Rehydration :

ORS/Super ORS alone	1621 (73.48%)
ORS + IV fluids	585 (26.52%)

Number of days of hospital stay (duration of hospital stay)

Less than 24 hours	13.60%
One day	30.8%
2 - 3 days	37.39%
More than 3 days	18.3%

Clinical diagnosis :

Acute G.E.	75.63%
Chr. G.E.	4.53%
Dysentery	6.93%
Amoebiasis	0.45%
Giardiasis	2.53%
Cholera	2.35%
Helminthiasis	5.57%
Sec. Lactose intolerance	0.49

Associated illness

PEM	6.98%
LRI	3.94%
Post measles	0.86%

Drugs used :

Antibiotics	195 (7.93%)
Metronidazole	66

	1983	1984	1985	1986
No. of admissions	1934	2076	2077	2206
Mortality	171	132	102	69
Percentage	8.8%	6.3%	4.9%	3.12%
Change		-25%	-50%	-63.5%

This table shows the effect of ORT on the mortality due to G.E. After the initiation of ORT programme in Vani Vilas Children's Hospital the mortality has come down by 63.5%. This clearly indicate the efficacy of ORT in the management of acute diarrhoea in infants.

EFFECT OF O.R.T. AND HOSPITAL MANAGEMENT

This brief note indicates the usefulness of O.R.T. in the management of diarrhoeal disorders in children and its cost effectiveness and how it gives a relief to the hospital **budget**.

1. Use of IV fluids

	Before O.R.T. (1985)	After O.R.T. (1986)
5% Glucose	469	189
5% Glucosesaline	722	31
Normal saline	222	25
Ringer lactate	892	43
Isolate P	2922	238
Total	5227	586 (bottles)

This clearly shows that the utilisation of IV fluids has been grossly reduced (90%) with IV fluids alone, we could save Rs. 50,000/- per year, in the hospital budget.

2. Drugs:	1985	1986
Garamycin	232 (vials)	52 (vials)
Ampicillin	652	31 "
	884	83

This table implies that use of antibiotics has been minimised to large extent. After the initiation of ORT programme we are not giving any antibiotics for children with watery loose motions. Nowadays antibiotics are restricted to children with dysentery only. This has reduced the morbidity secondary to the drugs. We could be able to change the attitude of the parents on the role of drugs. Emphasis has been shifted to oral fluids and continued feeding.

3. Duration of stay

	1985	1986
Less than 12 hours	2.1%	13.6%
12-24 hours	11%	30.8%

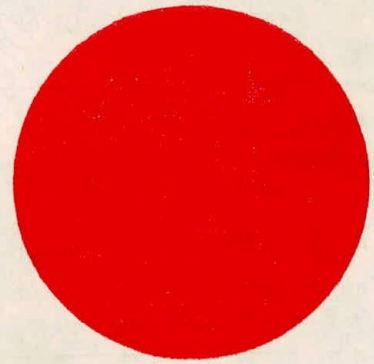
The duration of stay in the hospital is being reduced quite remarkably. Two effects have been felt by us, firstly the load on the hospital staff is being reduced, because of this, we could focus our attention on children with chronic diarrhoea. Secondly, mothers are also feeling happy, because the routine in the house has not been affected, is not coming in the way of earning their livelihood, and also they can manage the children at home.

4. No. of admissions:

Though the number of admissions to diarrhoea ward is not affected almost equal. At this point, we want to emphasise the fact that nearly 1465 children who were kept under observation and also some children who have been disposed in the out-patient to follow plan A were not included in the admissions. This was not possible in the past because we used to admit all these children who come for one or two episodes of watery motions.

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medico friend circle bulletin



MAY 1988

Return of the Liquid Lost

This is a letter to ask your assistance in gathering information to help evolve a more integrated, decentralized, effective, 'people-centred' approach to oral rehydration therapy (ORT).

As you know, in the last five years there has been massive international promotion of ORT. Indeed UNICEF and USAID now consider ORT and immunization to be the twin engines of the "Child Survival Revolution." But whereas immunization has met with modest success in many countries, there is a general consensus (by WHO, UNICEF, and others) that the impact of large scale ORT interventions (with a few notable exceptions) has been **disappointing**.

Serious re-evaluation of ORT strategy is needed. It is important that non-governmental groups, popular organisations and the ultimate users of ORT, be key participants in this re-evaluation process.

ORT, like other health and development technologies, has far reaching political implications. Any such technology can be promoted in ways that are either "people empowering" or "people debilitating" in terms of helping to overcome or perpetuate the underlying social causes of poor health.

The "Child Survival Revolution," has often been compared to the "Green Revolution." In retrospect, the Green Revolution, although *technologically sound* insofar as it increased total food production, in many countries proved to be *socio-politically impoverishing* since it was implemented in ways that widened the gap between rich and poor and left more landless powerless

hungry families than ever before. It would be tragic if the "Child Survival Revolution," for failure to confront the crucial conflicts of interest that we all know exist, were also to further entrench the social injustices and inequities that perpetuate poverty and poor health.

Most agree that oral rehydration is an extremely important part of primary health care. But people disagree about how ORT should be promoted and implemented. While the issues debated often seem to be technical or logistic, they often have serious political implications. Some of the issues in the debate are listed below, (in a highly polarized form) according to their main proponents.

Need for wider participation in ORT evaluation and decision making

Most of the formal studies, publications, high-level promotion, and international conferences on ORT have been conducted by large international and national agencies, whose experience and basis tend to favour the strategies in the "top down" column of Chart.

However, there are many small non-governmental and community directed programs that have long term experience in ORT. The experience and biases of these 'grass roots' and 'people-centered' programme tends to favour the 'bottom-up' approach. Also, there is mounting evidence that many 'folk remedies' and traditional forms of diarrhea management may work as well or better (at least in certain circumstances) than the ORS formulas most promoted by the health establishment.

CHART 1 TWO STRATEGIES FOR ORT PROGRAMS

Strategy of health ministries and big international agencies (TOP DOWN)

Strategy of non-governmental field programs, popular organizations and community-based programs (BOTTOM UP)

Programming:

implemented as a separate program, or as part of 'selective primary health care'

integrated into *comprehensive primary health care* (includes the social causes of poor health)

Main type of ORT promoted:

- packets of ORS salts (glucose based)
- standardized formula

- home mix (sugar or cereal based)
- formula adapted to local resources, conditions and beliefs

Main focus and investment:

- on *products*, (manufacture and distribution)
- social marketing
- social mobilization (getting politicians and celebrities to promote it)

- on *education* (through many channels: health posts, schools, etc)
- awareness raising
- community participation (mothers, popular organizations, healers, teachers, children)

Management:

- centralized
- controlled by health sector

- decentralized
- collaboration from other sectors: health, education, communication, popular organizations

Main implementing body:

Health ministry, health posts, health workers

Multisectorial: school system, health system, women's organizations

How it is presented:

as a medicine (to facilitate acceptance and use)

as a food or drink (to demystify and promote understanding of concept)

Annual cost:

- increases every year due to growing demand (for packets)
- or transferred to consumers through commercial sale of packets

fairly constant for first few years, then rapidly declines as educational investment "pays off" and sound ORT practices become "common knowledge"

Evaluation

- safety of ORS method based mainly on content of formula and accuracy of preparing solution

- safety of methods based more on social factors: availability and constraints of supply, peoples habits and attitudes

—indicators of success :

—number of packets distributed

—number of people who know how to mix ORS correctly

—reduction in child mortality

—reliance on hard data, statistics, controlled studies

—indicators of success :

—how many people understand concept and process

—how many people use ORT in a way that seems to work

—impact on children's, families' and community's well-being

—reliance of people's impressions and observations.

Main goal emphasized :

child survival

improved quality of life

Political Strategy : *win government support* by using methods that strengthen and legitimize government and make people dependent on its provisions (government empowering).

win popular support using methods that organize and empower people, and helping them to become less dependent, more self-reliant.

It is time to recognise the credibility of the experience and perspectives of these non-government, people-centered and traditional approaches of the management of children's diarrhea. There are many reports of dramatic reduction in child mortality using home mix ORT sensitively adapted to or building on people's traditions, local resources and constraints. Too often these successful grass roots approaches are not seriously considered by scientists and policy makers because those most intimately involved in community work do not have all the 'baseline data' and, scientifically controlled studies to validate their findings. Yet, the cumulative findings, 'impressions' and success of many community-based endeavors may have greater validity (especially in terms of long range social goals) than the expensive carefully controlled (but no less biased and perhaps no more accurate) studies by the experts.

It is time that those 'on the bottom' be listened to more carefully and that new 'people-centered' models of research be encouraged and recognized for their pragmatic validity.

The controversial and polarized issues of ORT strategy, as they relate both to technical issues of implementation and to societal issues of poverty and power, seem a good place to begin.

We need the help of those of you who represent, work closely with, or feel accountable to the poor majority.

Please send us any reports, information, experiences, anecdotes, program plans, teaching materials and names of other people we should write that you can that could help us document and formulate alternative "people-centered" approaches to ORT. Please also let us know of the problems and obstacles you have encountered, with whatever approaches to ORT you have used or observed.

Areas in which we are Especially Interested in Learning from you about include:

1. Comparison of different approaches: ORS, formula, home mix, cereal based ORT (including soured porridges), etc. (including social, political, economic issues).
2. factors affecting safety (social, logistic, technical, chemical)
3. traditional forms of diarrhea control (e.g. using traditional weaning food as supplementary nutrition during diarrhea episode) how well they work, and why
4. obstacles, problems, conflicts of interest, and reasons for success or failure (opposition from doctors, local authorities, traditional healers, etc.—and ways of overcoming it).
5. effect of ORT strategy on overall health and social goals

6. relative advantages and disadvantages of promoting ORT as medicine' or as food, ways this is done and results.
7. educational methods and materials and comparative results (including experiences in using school teachers, children, women's organization, political groups, nutrition workers, agriculture extension workers, etc. in promotion and implementation)
8. ways to stress importance of adequate fluid intake during and after diarrhea
9. pros and cons of new development strategies applied to ORT-eg. 'social marketing' 'social mobilization', technological fixes', commercialization as compared to more people-centered strategies focusing on participation, cooperative action, awareness raising, and popular organization.
10. implications, successes, difficulties or hardships that have arisen through the commercialization of ORS products (specific examples)
11. examples of 'participatory research'
12. examples of misleading data, statistics or reports
13. ORT as applies to other illnesses than diarrhea (e.g. measles)
14. ideas and suggestions for more effective approaches to ORT (especially in the context of primary health care and social change)

What we hope to do with the information gathered.

We hope to write a booklet to be titled something like : *The Return of Liquid Lost: putting oral rehydration therapy in the people's hands*. The booklet will be in two parts.

Part A *helping people learn about ORT*. Emphasis will be on non-formal education and communication methods that adapt to and build on people local traditions and beliefs. Examples will be included (with your help) from many community programs in different parts of the world.

Part B *The Politics of Oral Rehydration Therapy*. This part will focus on ORT in the larger context of primary health care, and the root causes of poverty, poor health and death from diarrhea. It will explore conflicts of interest and try to give voice to those who are least heard.

This book will be presented in clear, simple language with many examples and illustrations so that field workers, community health workers, and persons with limited formal education can understand underlying issues and the politics of health interventions, so that they can begin to participate in deciding about methods and strategies.

We enclose a summary of a report on diarrhea control in Mozambique. This was written based on my trip in March 1986. I returned to Mozambique in September 1987 to participate with Mozambique's Ministry of Health in planning the educational component of its exciting new 'people-centered' plan for diarrhea control.

Timeline for your input

I would appreciate your response as soon as possible. Please do keep sending me your observations and ideas throughout the next year, as both the development of the Mozambique program and the proposed book will be an ongoing learning process.

The information we are asking you to send us need not be well organized or studiously presented. Even casual observations can be very helpful.

Please help us in helping to formulate and educate the health establishment about more truly "people-centered" approaches to ORT and to promote primary health care as a part of a worldwide struggle for social justice.

We eagerly await your response. As thanks for your help, we will be pleased to send you a complimentary copy of 'The Return of Liquid Lost' when it is published. Thank you.

—David Werner

The Hesperian Foundation,
P.O. Box. 1692, Palo Alto
California 94302, U.S.A.

Summary of report Concerning "Diarrhea Control in Mozambique," based on a visit by David Werner (March 8-15, 1986), as a consultant to the Ministry of Health,

In Mozambique the approach to oral rehydration based on manufactured packets has not significantly reduced child mortality from diarrhea. In the city of Beira, where the ORS packet-producing factory is located, 14% of children under 5 still die of diarrhea—one of the highest diarrhea-related mortalities in the world. Reasons for low ORT effectiveness include: terrorism that hampers factory productivity; inadequate packet supply; the common practice of giving only one packet per case of diarrhea; popular misconceptions; difficulty in supplying packets to outlying areas; inadequate educational component; colonial teaching methods; insufficient consideration of people's beliefs, traditions and home remedies; and inadequate health infrastructure, especially in remote parts of the country.

In one district, Inhambane, the child mortality due to diarrhea is much lower than many other parts of the country. On looking for an explanation, it was found that although oral rehydration packets had been promoted in the area, most mothers continued to use traditional home remedies, which correspond very closely to cereal-based ORS solutions. Research in Bangladesh and elsewhere has shown cereal-based solutions are in many ways superior to sugar-based solutions.

Based on the success of the mothers in Inhambane, and given the unique constraints in Mozam-

bique, a number of possibilities exist for a more appropriate, cost-effective approach to ORT:

- Creation of a Central Committee for Diarrhea Control, authorized to coordinate an *integrated multisectoral approach to diarrhea control and ORT*.

A shift in focus from production to education and from packets to home mix ORS.

Involvement of the school system as the main promoter of home-based ORS, in collaboration with the local women's organization and Party organization, and with support of the mass media.

- A process of 'participatory research' involving school teachers, school children, and mothers in investigating modern and traditional diarrhea management in homes, in order to facilitate study on how best to adapt ORT to different parts of the country.

- Investigation and promotion of different types of home mix, with emphasis on rice powder, maize powder, and other cereal-based mixes, especially for areas where sugar is not available (including possibilities of cereal-based ORS without salt where salt is not available).

- Development of 'people-centered' educational methods and clear, simple, well-illustrated educational materials, for use in schools, health posts, and homes.

Dear Friend,

I note from Ravi Narayan's review of Prof. Bannerji's book "Health and Family Planning Services in India" in mfc bulletin (No. 136) that it has been pointed out that Lok Paksh has priced this book too high. Considering the cost of production, the price cannot be much lower. The effort was to recover the cost by selling it to institutions and then offer heavy discount to those scholars who are interested but who are unable to afford the price. Incidentally, this was precisely the reason why this book was published through Lok Paksh. You will be glad to know that following the commitment of Lok Paksh, it has already made available the book at a discount of 40% to such types of people through Ms. Norma Alvares, c/o Almeida Vaddo, Parra,

Goa, 403501 and Mr. John D'Souza, CED, 3 Suleman Chambers, 4 Battery Street, Bombay 400039. Anybody wishing to get a copy of the book at the subsidized rate is welcome to contact these organizations or Lok Paksh, P. Box 10517, New Delhi 110067 directly.

Disha Banerjee, Manager,
Lok Paksh.

I do share Dr. Morley's concern that it is necessary to use separate standards for boys and girls because boys are slightly heavier than girls at all ages (Dear Friend column, mfcb 138). I have indeed used separate standards for the analysis

(Contd. on p. 8)

✓ Medical Research on Trial

(Contd. from issue No. 139)

Yusuf, Collins and Peto give as an example 24 trials aimed at determining the usefulness of long-term treatment with beta-blockers during the months or years following myocardial infarction. Out of these 24 trials, 21 failed to produce results that were statistically significant by conventional analysis. Yet together, say Yusuf and his colleagues, the aggregated results suggest a statistically significant reduction in the death rate. The individual trials were too small to detect this effect on their own. Such inconclusive results may have discouraged many doctors from using this treatment routinely.

To prevent all the research that has gone into numerous small trials going to waste, it is possible—provided that someone has the motivation and resources to undertake such a mammoth task—to obtain the results, from all the randomised trials of a particular treatment, and look at them together. This is just what Yusuf, Peto and Collins, together with John Lewis, a statistician with ICI Pharmaceuticals, and Peter Sleight, Professor of Cardiovascular Medicine in Oxford, did to find out about the 24 trials of beta-blockers mentioned above. They ended up with data covering about 24,000 patients, analysis of which allowed them to conclude that long-term treatment with beta-blockers reduced the death rate by about 25 per cent.

Systematic overviews of this kind are cumbersome and need careful research. It is particularly important to track down all related studies, not just published ones, for there is a tendency for studies that appear to be unpromising or that are not statistically significant—often confusingly, called “Negative” studies, even though the results may be in favour of treatment—to remain unpublished. A more logical approach is to design and conduct large studies from scratch. Some medical researchers have already successfully adopted this approach: the results from the two largest trials of treatment of overt disease ever completed were published in *The Lancet* earlier this year. One trial collected data from 16027 patients in 245 centres in 14 countries. It showed that treatment with beta-blockers for just a week significantly reduced mortality in the first seven days after a heart attack, and that this benefit persisted for at least a year.

The other “supertrial” investigated the effect of a drug called streptokinase, again in the immediate treatment of patients who had just had a myocardial infarction. Doctors wanted to know if the drug’s ability to dissolve blood clots would reduce the risk of death. This trial involved 11086 patients admitted to 176 of the 200 coronary units in Italy.

The *Lancet* called the organisation of this trial “an unparalleled achievement.” Doctors managed to recruit enough patients within 17 months. The trial showed that patients treated with streptokinase suffered 18 per cent fewer deaths during their stay in hospital, a reduction that was “statistically highly significant”, said *The Lancet*.

Yet organisation is not the only obstacle to setting up such trials. Doctors need to be persuaded to take part. Richard Peto says that collaborators derive no personal gain, such as a published paper under their own name, by taking part. This may be a positive disincentive in a medical career where advancement can depend on amassing a string of publications. As a means of encouragement, the organisers of such trials simplify the administration for collaborators as far as they can. The easier it is for individual doctors, the more likely they are to enter their patients. And the more collaborations there are, the sooner results will be available.

The problems do not end here, however. Many doctors and medical scientists involved in organising trials have been puzzled by recent attacks on their methods. Two news items in *The Guardian* earlier this year carried the headlines: “Doctors keep leukaemia patients in the dark” and “Prostate cancer sufferers being castrated without proper consent, doctor claims.” The doctor in question was Richard Nicholson, deputy director of an organisation called the Institute of Medical Ethics. Nicholson maintains that patients entering these trials are not given enough information to allow them to give fully informed consent to their participation. This argument hinges mainly on the fact that in some trials designed to compare two similar treatments in current use, patients are first randomised and then asked for their consent to the treatment they have been allocated to—and of course if the patient is not happy with the allocated treat-

ment, then s/he does not receive it. But the important point is that patients are eligible to enter the trial only if their doctor is uncertain about what is the best treatment for them.

Take the example of the MRC's trial into the treatment of prostate cancer. This trial is comparing early or late treatment for cancer of the prostate that is too advanced for local treatment to be wholly effective. The trial aims to determine whether more patients survive for longer if orchiectomy (removal of the testes) is carried out as soon as cancer of the prostate is diagnosed or whether it is better to wait until symptoms, such as bone pain, appear as the cancer spreads beyond the prostate. Orchiectomy is an effective treatment because prostate cancer thrives on the hormone testosterone produced by the testes. There are alternatives to orchiectomy—drugs that interfere with the cancer's response to the hormone—but some of these have severe side effects. The drugs also cause the testes to shrivel.

At present, treatment is haphazard. Whether a patient (whose symptoms are such that he would be eligible to enter the MRC's trial) receives early or late treatment either with drugs or by orchiectomy will depend on which hospital he attends, and, perhaps, on which consultant his general practitioner refers him to. Urologists disagree about which treatment is best. The proportions of patients who receive a particular treatment in various parts of the country differ, just as the rates at which different drugs are prescribed following a heart attack vary throughout Europe. Treatment depends not on scientific evaluation but on a surgeon's personal preference, however much that may be founded on good faith and sound, 'clinical judgment'

The treatment of patients entering the trial differs in the following way. By taking part in the trial, their surgeons have admitted that they do not know which is the best treatment in this particular case. Instead of treatment depending on their personal preference, the surgeons will allow the trial's organisers to allocate their patient at random to either early or late orchiectomy. The trial's protocol says. "It is the MRC's view that there is no ethical requirement for informed consent when the consultation in charge of the case is satisfied that each option used in the trial may reasonably be believed to be in the individual patient's best interest." Peto, who is analysing the data for the trial, says: "There

is a necessary parallel between good ethics and good science. If you are certain that a particular treatment works for a particular patient it is only ethical and scientifically interesting to randomise where you are uncertain."

The only difference for the patient is that the treatment he receives is determined at random, rather haphazardly. Yet Nicholson says: "Old men up and down the country are being castrated without their informed consent." Peto takes a different view: "You do ask for consent for the operation. But if you are comparing two treatments, either of which is appropriate, then it is acceptable to allocate the patient to either group at random, and then ask them to join the study." In the case of the prostate cancer trial, he says, it is very difficult to get the idea of uncertainty over. "Post-randomisation consent allows you to explain much better what the patient is in for and of course, they can always refuse the allocated treatment, just as they can in ordinary clinical practice."

Peto believes that the prostate cancer trial will be valuable whatever its result, provided of course that enough patients—at least 2000—enter to make its results informative. For, if the trial finds that there is no material difference in survival between those given late and those given early orchiectomy, then thousands of patients in Britain, and tens of thousands throughout the world, will be spared unnecessary surgery or drugs. If there is a difference, then thousands more men each year may benefit from treatment that will delay the progression of their disease.

Nicholson maintains: "I am no enemy of controlled trials. I think that they are the best ways we have at the moment of increasing and improving medical knowledge. But it is essential that they are entered into trials." He believes that the requirements for consent are greater in research than in "ordinary treatment". Peto disagrees. "I think that what is said to patients in trials should bear a reasonable relationship to what is said outside of trials. I do not see any reasons for double standards." He asks why doctors who are obviously thinking about whether a treatment works should be harassed while others, who pretend a certainty that they are not justified in having, are left in peace. "There is no fuss about what they say to patients in hospitals where they do not bother to enter

(contd. on page 8)

A Decade After Hathi Committee

The Hathi Committee appointed by the Government of India, to study the and suggest measures to improve the drug industry in India, submitted its report more than a decade ago. Hathi Committee Report is still considered both within and outside India, as the most authentic and exhaustive study of the Indian Pharmaceutical Industry. Unfortunately the recommendations of the Hathi Committee were largely neglected in India whereas many other developing countries have already formulated their National Drug Policies in the line of Hathi's recommendations. The new Drug Policy announced by GOI in 1986 gave away more concessions to the foreign sector much against the spirit of the Hathi recommendations. Eventhough the Hathi Committee Report was published in 1975, copies of the report are not available now. Kerala Sastra Sahitya Parishad (KSSP) decided therefore to publish a summary of this report for the benefit of all those who are striving for a people's Drug Policy for our country. The book "A Decade After Hathi Committee" contains apart from the Hathi Committee Report, the recommendations of Pai Committee appointed by the Kerala Government on procurement and supply of drugs and the papers presented by eminent doctors and social scientists at the seminar on the Indian Drug Industry organised by KSSP. The book is to be released on the 24th of May 1988, the third death anniversary of Dr. Olle Hansson the Swedish Paediatric Neurologist who fought against the unethical marketing practices of multinational drug companies. Edited by Dr. B. Ekbal, and priced at Rs. 25/- copies are available from the

Convenor,
Publication Committee,
KSSP, Maravancheri,
Trichur, Kerala.

Money is to be sent by MO, DD or cheque
(add Rs. 5 - for Bank charges; postage is free.)

(contd. from p. 5)

presented in the mfc article and have indicated that NCHS standards are preferred because they are available separately for boys and girls (p 3, mfc 136). Regarding Dr. Morley's second point about subtle discrimination against girls in food availability, the possibility cannot be overlooked or wished away. It is however, an extremely difficult area to research, document and measure its incremental impact on nutrition and survival of children.

Leela Visaria, GIAP, Gujarat.

Ratnagiri Drugs Pvt. Ltd., situated at Ratnagiri, a backward district of Maharashtra, is a well planned pharmaceutical manufacturing Unit. A group of like-minded persons intend to manufacture and market essential products in generic form. For doctors who wish to prescribe generic products, availability of such products in prescribable form is not assured. Ratnagiri Drugs Pvt. Ltd. plans to do just that—manufacture generic products in prescribable form. The factory will be inaugurated by Dr. Zafrullah Chowdhry, of Gonashasthra Kendra, Bangladesh on Olle Hansson Day, the 24th of May 1988. All drug activists are welcome. For further information contact Dr. Rane, 2117 Sadashiv Peth, Pune - 411 030.

(contd. from p. 7)

patients into trials. "The really unethical thing is that thousands of patients die because treatments are not evaluated properly."

(concluded)

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No. 3/160/81

12th Jan., 81

DIARRHOEAL DISEASES - THEIR SIGNIFICANCE

1. Diarrhoea is the most common cause of sickness and death among children below three years of age.
2. Repeated attacks of diarrhoea during early childhood precipitate malnutrition which makes the children susceptible to diarrhoea thus setting in a vicious cycle.
3. It is a popular practice to withhold milk and other food from a child suffering from diarrhoea. This is wrong, as a child with diarrhoea requires more fluid and nourishment.
4. Diarrhoeal diseases are caused by a number of pathogenic germs including cholera vibrio and these harmful germs thrive in places where sanitary conditions are poor.

COMMUNITY HEALTH CELL
47/1, (First Floor) St. Marks Road
BANGALORE - 560 001

WHAT HAPPENS IN DIARRHOEA?

There is an enormous loss of water (dehydration) and salts from the body due to vomiting and diarrhoea in these conditions. This loss of water & salts from the body causes various symptoms like intense thirst, restlessness, cold hands & feet, weak pulse, lowering of blood pressure and stoppage of urine; when severe, this condition may lead to death of the patient.

TREATMENT OF DIARRHOEA PRIMARILY MEANS THE TREATMENT OF DEHYDRATION

Replacement of water and salts, which have been lost from the body forms the basis of treatment of all diarrhoeal diseases. This can be done with :

1) ORAL GLUCOSE-SALINE :

It has been shown that oral glucose solution increases the absorption of water & salts in the body. Based on this, a glucose-salt solution has been developed by the Cholera Research Centre, Calcutta. This preparation named as 'CHOROSOL' contains the following ingredients per litre of water :

Sodium chloride (common salt)	- 3.5 grams
Sodium bicarbonate (baking soda)	- 2.5 "
Potassium chloride	- 1.5 "
Glucose	- 20.0 "

The above salts and glucose can be dissolved in one litre of drinking water & then given to patients liberally.

2) INTRAVENOUS SALINE :

A small number of patients with severe dehydration who do not respond to oral glucose-saline or who cannot be given oral fluids because of unconsciousness may require intravenous saline. Treatment with intravenous saline can only be given in hospitals and dispensaries under the supervision of an experienced doctor.

RW

ANTIBIOTICS :

Cases of severe diarrhoea and those passing blood and mucus in the stools may be treated with tetracycline, 2 capsules (500 mg.) 6 hourly in adults and one capsule (or 2 teaspoonfuls of syrup) every 12 hours in children for 2 days. Furazolidone or chloramphenicol can also be used in place of tetracycline.

ASSESSMENT OF DEGREE OF DEHYDRATION :

Patients with watery diarrhoea and vomiting may present with various degrees of dehydration. When mildly dehydrated, a patient may appear almost normal whereas those with severe dehydration may be in comatose (almost unconscious) condition. Therefore, the degree of dehydration must be assessed before initiation of treatment. Certain symptoms and signs help in this assessment.

HOW DEHYDRATED IS THE PATIENT?

<u>Mild</u>	<u>Severe</u>
1. Thirsty	1. Too weak to drink
2. Alert	2. Drowsy or unconscious
3. Radial pulse normal	3. Radial pulse weak or absent
4. Urine flow normal	4. Urine flow reduced or absent
5. Skin elasticity may be reduced	5. Skin elasticity poor

ORAL FLUID THERAPY :

How to make the fluid :

Fixed quantities of salts and glucose as indicated earlier are to be dissolved in one litre of drinking water and should be used within 24 hours. The solution should not be boiled.

How to administer the Fluid : Infants & younger children :

A small quantity of Glucose-salt solution (2-3 teaspoonfuls) should be given by mouth every five minutes to infants and young children. Large quantity of fluid given at a time may result in vomiting. Therefore, fluid should not be given in too large a quantity. But as much as a patient is willing to drink may be given.

Older Children and Adults :

Patients may be instructed to drink as much fluid as they like from a clean glass or cup. A large container with glucose-salt solution may be kept at the bed side.

HOW MUCH FLUID TO BE GIVEN?

In a mild state of dehydration, a child may require about a litre and an adult may require 2-3 litres of oral fluid per day.

In severe cases, however, the requirement may be much more. The fluid should be continued until the diarrhoea stops and dehydration is compensated and the patients look normal.

WHAT HAPPENS WHEN THE PATIENT IS VOMITING?

A patient may sometimes vomit out a part of the oral fluid; however, the rest of the fluid gets rapidly absorbed and once the dehydration is corrected the patient stops vomiting.

ADVANTAGES OF ORAL FLUID THERAPY :

1. The patient need not be hospitalized and can be treated at home by para-medical staff or by the relatives.
2. Oral fluid therapy is cheap and the ingredients are available locally. A packet of CHOROSOL costs about a rupee.
3. The solution can be made with ordinary drinking water. No sterilization is **required**.
4. Storage and transportation cost is minimum. A packet of CHOROSOL can be stored at room temperature for long.

INTRAVENOUS FLUID THERAPY :

Experience at the Infectious Diseases Hospital, Calcutta, has shown that as many as 95% of all cases of gastro-enteritis including cholera can be treated with oral fluid alone. Less than 5% of cases who come with severe dehydration may require intravenous saline to start with, followed by oral glucose-salt solution. However, the number of such severely dehydrated cases can be reduced if oral fluid therapy is given during the early stage of dehydration.

The severely dehydrated cases should be transported to the nearest hospital or dispensary for intravenous rehydration. Oral glucose-saline must be started, however, even before this, and should be continued till the patient reaches the hospital and till such time intravenous therapy could be started.

WHAT INTRAVENOUS FLUIDS ARE TO BE USED?

- 1) RINGER'S LACTATE SOLUTION is the best commercially available solution which can be used for children and adults. However, it is not readily available in most places.
- 2) NORMAL SALINE has been in use at the Infectious Diseases Hospital, Calcutta, for the last few years. Intravenous normal saline alongwith oral glucose-salt solution can be successfully used for the treatment of all degrees of dehydration.

HOW MUCH TO BE GIVEN?

Ringer's lactate or normal saline may be given at a dose of 100 ml./kg. body weight initially during the first 6 hours. Oral glucose-salt solution may also be given liberally.

It is absolutely of no use to given subcutaneous saline and this practice must be stopped.

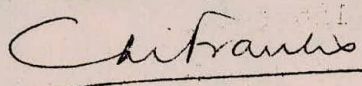
EDUCATING THE MOTHERS IN HOME-CARE

Treatment of a child with diarrhoea should begin at home and therefore, mothers should be educated on the basic principles of home-care. A mother should know that :

- 1) A child who has diarrhoea, should be given as much fluid as he/she will drink. For this purpose, the glucose-salt solution can be prepared by dissolving a packet of 'CHOROSOL' in one litre (2 pints) of drinking water. In case of infants, a teaspoonful of fluid may be given every five minutes until the diarrhoea stops. Large quantity of fluid, if given at a time, may cause vomiting.
- 2) A child with diarrhoea should get his normal food to maintain his nutrition. With-holding milk and other food will make the child weak. If the infant is being breastfed, breastfeeding should be continued.
- 3) A child gets infection through contaminated food or drink and diarrhoea can be prevented by following hygienic practices in child care, particularly in feeding. A child should be given freshly prepared food in clean utensils.
- 4) A child with poor health suffers more often from diarrhoeal diseases. Therefore, the general health of the child should be improved to prevent diarrhoea. The following basic facts should be remembered :
 - a) A child's body is just like a running machine and it needs food (fuel) to keep the machine in running condition. Therefore, a child should not be allowed to starve at any time - in health or in disease.
 - b) A child's body is growing all the time. The child needs food containing the building materials such as proteins (egg, fish, meat, milk, dal, etc.,) as well as energy-giving food (rice, wheat, potato, sugar, etc.,) to build the body.
 - c) It is a common practice to keep a child on barley-water for days when he is sick. This is wrong since barley water is the most inferior food and contains no protein. Enough quantities of simple food stuffs like rice, chapati, and dal can support the normal growth of a child if meat, fish or eggs are not available.

Copy to

1. Interns
2. Staff, Department of Paediatrics
3. Staff, Community Medicine.



D E A N