

**WORLD HEALTH
ORGANIZATION**



**Regional Office
for the Eastern Mediterranean**

**ORGANISATION MONDIALE
DE LA SANTÉ**

**Bureau régional
pour la Méditerranée orientale**

SCIENTIFIC WORKING GROUP MEETING
ON DIARRHOEAL DISEASE CONTROL
Amman, 11 - 14 June 1979

EM/SC.WG.MTG.DDC./5

1 June 1979

THE EVALUATION OF THE EFFECTIVENESS OF ORAL REHYDRATION
IN ACUTE DIARRHOEA OF CHILDREN UNDER THREE YEARS
OF AGE IN WEST AZERBAIJAN, IRAN*

by

Dr M.A. Barzgar*

Dr S. Ourshano**

Dr J. Nasser Amini***

* Vice-Dean of the School of Medicine University of Rezaieyeh, and
Director of West Azerbaijan project, Iran

** Director, Department Parasitic and Infectious Enteric Diseases,
Ministry of Health and Welfare, Iran

*** Executive Director of Health and Welfare Office of West Azerbaijan,
Iran

N.B. This study was carried out under the auspices of the School of Public
Health and Institute of Public Health Research, University of Teheran,
with the cooperation of the Ministry of Health.

The paper is still (June 1979) in draft form, and further changes may
be made before it is out for publication.

Introduction

West Azerbaijan is one of the 23 provinces of Iran, and is located in North-West part of Iran, with nine districts and 3114 villages scattered in 43660 square kilometers (fig.1). The population of West Azerbaijan is about 1.5 million of which more than 70% live in rural areas. The pattern of morbidity is dominated by infectious and parasitic diseases.

In 1972 a situation analysis of the West Azerbaijan Primary Health Care Project showed that diarrhoea was the most common complaint (22.2%) in children 0-5 years old during summer time, and also that out of 27742 persons of all age groups in the study area who attended health houses (the small health posts of the project) during 1976, 14% in summer and 4.2% in winter attended for diarrhoea. Therefore the Ministry of Health and Welfare, Iran and the School of Public Health, University of Teheran with the assistance of WHO conducted a study in 1977 to evaluate the feasibility and effectiveness of oral rehydration with the WHO-recommended formula of Oral Rehydration Salts (1) in acute diarrhoeal disease in children under three years of age, in these rural areas.

Materials and Methods :

In such a study as this it is important that the service should be easily accessible to the subjects of the study, both in study and control groups. For this reason two similar communities of West Azerbaijan were selected in which a well-accepted primary health care network has been established since 1973. A female local family health worker (Behvarz) is posted in each health house covering between three and six surrounding villages with a total population of about 1500 to 2500, and one male community health worker is attached to each two health houses. In order to facilitate maximum follow-up for this study and control areas, only the villages in which health houses were actually located were selected. The two communities, which later will be called community A or study group and community B or control group, are located 20 kilometers north and south respectively of Oroumieh (capital city of province) and are quite

similar in terms of geographical conditions and socio-economic situation.

After preparation of forms and materials first a knowledge, attitudes and practice study was carried out in 75 families of community A and 107 in community B, and then the instructors of Behvarzan, and then the Behvarzan themselves were trained for this special study in both communities with a strong emphasis on health educational part of program. All children aged 3 to 36 months with diarrhoea were included in the study between 10 May 1977 to 29 September 1977. In both study and control communities a behvarz examined the children with diarrhoea. Stool cultures were not undertaken, but prior experience during the West Azerbaijan's project's situation analysis in 1972 has shown that diarrhoea in most children was not associated with the presence of Shigella or Salmonella in the stools.

In both communities a standard regime of drug treatment was followed, which had been in operation for some time before the study. The children were given per 10 kg. body weight 2.5 ml. of a proprietary syrup. This quantity contained 75 mg. neomycin sulphate, 1 mg of an extract of opium, 0.006 mg of atropine sulphate and 5 mg. of sodium saccharide. This regime was continued from previous practice solely in order that there should be as little change as possible introduced in the treatment of diarrhoea other than the introduction of Oral Rehydration Salts in the study group.

All children in both study and control groups were weighed by the behvarz every day during the episode and also six months after the first episode.

The behvarz used a standard list of messages for individual health education of the mothers in both study and control groups. The messages emphasised the need to give plenty of fluids, and on no account to starve or restrict the diet of the child. They also dealt with the causes of diarrhoea and how to prevent it in future, and with the need to bring the child with diarrhoea to the health house as soon as possible and not to wait until it was very ill.

All children were examined daily at the health house or home while ill, and the educational messages were repeated and assistance offered. Clinical symptoms were recorded on special forms and standard criteria for referral were followed. On the first day and therefore not entering the trial, these criteria were: severe dehydration or unconsciousness; high fever; other serious complications. On subsequent days the criteria were the same and also included loss in the last 24 hours of more than 200 grams in a child under 5 kg. body weight, more than 300 grams in a child between 5 and 10 kg., and more than 400 grams in a child over 10 kg. It has to be admitted however that a mother who is anxious and insistent can often persuade a behvarz to refer a child to a doctor if she strongly desires it.

There was very good follow up from day to day to 72 hours of the end of the episode, whichever was the greater, as Table 1 shows.

Only in community A was a glucose - electrolyte mixture used. This mixture, which has been recommended by WHO and is mixed and packaged for UNICEF is called Oral Rehydration Salts (ORS). The composition of each foil package of ORS is:

Sodium chloride	3.5 gramms
Potassium chloride	1.5 gramms
Sodium bicarbonate	2.5 gramms
Glucose (Dextrose)	20.0 gramms

This quantity is to be mixed with approximately one liter of boiled water.

The instruction given by the behvarz for the use of ORS stated that it should be given in addition to other fluids and food, as long as diarrhoea continued.

Primary health care workers in both communities tried to ensure that all children with diarrhoea attended for treatment. The weights of children were measured again six months after each attack. The Behvarzan who weighed the children after six months were unaware of the initial weight, because the files containing the completed special data sheets were collected and taken to the Project central office soon after the child had recovered.

A second knowledge attitudes and practice study was conducted after six months in the same families and with the same respondents as the first (75 families

in community A and 107 in community B). The enquiries were specially concerned with the causes and prevention of diarrhoea and care and feeding of children with diarrhoea, and the findings may be published in detail elsewhere.

Comparability of study and control areas

Table 2 shows the comparison of the two communities (A and B) as regards some socio-economic, sanitary and health characteristics.

The prevalence of breast feeding was high (98%), the same in both communities, and about half of those children who were breast fed were weaned after 24 months.

The manner of seeking care for diarrhoea was the same in the two communities and all of them first consulted behvarzan.

Results :

Table 3 illustrates the characteristics of the two communities as regards diarrhoea among children attending clinic during five months of observation. 336 attacks occurred in 230 children with diarrhoea of community A or 1.46 attacks/per child, and 568 attacks occurred in 344 children of community B or 1.65 attacks/per child. In general, illness were acute and mild to moderate with a similar severity in both communities with these exceptions:

1. The percentage of vomiting associated with diarrhoea in community A was higher (27.3%) than in community B (21.33%). ($0.10 > P > 0.05$)
2. The number of bloody stool in communities A and B was 7 and 2 respectively.
3. The appetites of the patients were better in community A, those with consistently good appetite throughout the episode being 97% in Group A compared with 86% in B. This difference is statistically significant ($P = < 0.01$).

Average consumption of ORS for each child in community A was 2.73 litre, and the mean duration of ORS consumption was 2.2 days.

Table 4 gives data on consumption of oral rehydration fluid per kg. body weight per day by age group. It will be noticed that consumption is highest in the lower age group 3 to 11 months.

Table 5 illustrates consumption per kg. body weight per day in children with one, two, three, four or five episodes. It will be seen that average consumption remains pretty much the same at about 165 ml per kg. body weight per day no matter whether the episode is the first or only one which the child had during the period of the trial or is the second, third or fourth.

Table 6 compares the numbers of children who gained or lost weight or experienced no change throughout the episode. There was little difference between the study and control groups.

Table 7 shows the mean weight gain over the first 72 hours of the episode for those in whom the episode lasted that long. Both groups gained in that time, but children in the study group A gained more than the control group B, and the difference is statistically significant for children under one year, and for the children of the eight deaths due to diarrhoea during the study period the one in community A was not in the trial and occurred in hospital. Of the seven deaths in community B, these also had all been referred to a private or public physician and two of the deaths occurred in hospital and five at home.

Table 8 presents the initial weights of children in different age group compared with their weights after six months in both communities. The data are presented by different age groups, and t test and chi-squared tests for significance were applied. As can be seen in this table, the difference between means of weight gained after six months in community A in all age groups are significant with $P < 0.01$ in comparison with community B. It is clear that on the whole the children in the study group gained on the average approximately 400 grams more than the children in the control group in the six months following their first or only episode during the period of the trial.

Table 9 shows that the magnitude of the difference is pretty similar whether the children had one or more episodes. At all age groups in both studies and control group the children with several episodes gained less over the six months after the first or only episode than the children with only one episode, as would be expected; but apparently the difference between the group A and group B in their totalities was not composed mainly of gains in those

children in group A who had had several attacks.

Discussion:

This study was designed for following purposes :

1. To evaluate, in a controlled trial in rural areas of West Azerbaijan, the feasibility and acceptability of oral rehydration with ORS., in children 3-36 months with acute diarrhoeal disease.
2. To evaluate the effectiveness of such rehydration in respect of the following criteria composed between control and intervention villages :
 - a - Speed of rehydration as judged by weight after 24,48 and 72 hours.
 - b - Reduction in proportion of children requiring referral for secondary care.
 - c - Effect on nutritional status (body weight) six months after the episode.
 - d - Change in knowledge, attitude and practice of the parents surveyed before and after the trial.

The following conclusions can be drawn :

(a) This study showed that oral rehydration with ORS in children 3-36 months with gastro-enteritis by primary health care workers (Behvarz) in rural areas of West Azerbaijan was indeed feasible. In terms of acceptability, we had the impression that the solution was not popular, and it is recommended that the addition of some kind of flavouring might make it more acceptable. On the other hand consumption per kg. body weight was in fact slightly higher at 165 ml than 151 ml reported from the similar study in the Philippines (1) so that perhaps our impression was not really correct. It is curious that consumption decreased with age in the same way as in the Philippines study, but unlike that study, consumption did not increase according to whether it was first, second or third episode etc.

(b) The need for referral was not successfully measured. The validity of any results was impaired by a something rather unexpected. The mother, as we have said, could in effect insist on referral. Of the two physicians responsible for the two areas the one in one area was Iranian and the patients naturally felt they could communicate more easily with him, and the other was

foreign. Referral to the Iranian was in general, for all cases adult or children whatever the complaint much more frequent than to the foreign physician (22.4% of all cases in 1976 compared with 13.5%). Because of this distortion, we abandoned any attempt to measure this factor.

(c) Speed of weight gain during the episode is mainly a reflection of speed of rehydration. The more mild, early cases of diarrhoea which are not (yet) dehydrated the less marked will be the difference between the mean weight gains of study and control groups. Nevertheless, there was a difference between mean weight gain in the study and control groups but it was statistically significant only in the case of the children under one year of age.

(d) The most marked difference however is that between the increase in weight of the children of the study and the control groups in the six months which followed their first (or only) episode of diarrhoea. This applied equally to the children with one episode as to children with several. Unlike the Philippines study this study showed a significant difference in this weight gain for children under one year old as well as for those over one.

This is a very difficult result to explain, but since it has been clearly apparent in the Philippines trial, in the unpublished trial carried out in 1975-76 in Turkey at Etimesgut (3) and will be demonstrated in Egyptian trials to be published, it can hardly be accidental. It should compel us to alter somewhat our ideas on the relative importance of defective intake and infection, especially diarrhoeal disease, in the aetiology of protein-calorie malnutrition of early childhood.

Conclusion

Oral rehydration in mild and moderate diarrhoeal diseases of children under three years using Oral Rehydration Salts of the formula developed in South-East-Asia (4) and recommended by WHO and UNICEF is feasible at village level in Iran. It seems to be effective in producing speedier rehydration. It would seem likely to reduce the need for referral to hospital and to reduce

case-fatality, but this is not yet proven and deserves evaluation during wider-scale use. It certainly has a marked effect on nutritional status for at least six months after the episode of diarrhoea so treated, even if it is difficult to explain why, dehydration in acute diarrhoeal disease in young children is one of the major causes of death in Iran and in Asia and North Africa in general. It is also a very important contributor to protein-calorie malnutrition which is in its turn associated with greater frequency and severity of infectious diseases. From the results of this and similar studies, oral rehydration in the manner described seems to offer hope of making a major impact in the short and medium term on both these problems. Therefore these oral rehydration salts should be provided and their use early in the episode encouraged on the widest possible scale and arrangements in respect of supply and distribution, staff training and health education of the public should have a high priority in the health programme of all countries who face this problem.

ACKNOWLEDGEMENT :

We thank Dr N. Fakhar formerly Under Secretary of Public Health, Population and Family Planning, and Dr A.H. Nadim, the Dean of the School of Public Health and Director Institute of Public Health for their support and guidance, and Dr R. Cook, Regional Advisor in MCH, WHO Alexandria, and Dr Y. Watanabe, formerly of the Interregional Cholera Team WHO Geneva, for their valuable assistance.

Last but not least, many thanks to our dear colleagues Miss L. Sayad and Mr I. Pashapur Nikou for their valuable effort for implementing and analysing of all data.

REFERENCES

1. WHO - Prevention and Treatment of Dehydration in Diarrhoeal Disease. A Manual for Use at Primary Level. WHO, Geneva(1976)
2. INTERNATIONAL STUDY GROUP - A positive effect on the nutrition of Philippine children of an oral glucose - electrolyte solution given at home for the treatment of diarrhoea, Bull. Wld. Hlth. Org., 55, 87 - 94. (1977)
3. EGEMEN, A. AND BERTAN, M. - The feasibility study on oral rehydration therapy, Etimesgut, Turkey (cyclostyled document, unpublished, 1976)
4. LANCET (editorial) - oral glucose/electrolyte therapy for acute diarrhoea Lancet 1, 79-80, (1975)

Table I. Follow-up to the end of the period of treatment

	Study Group (A)		Control Group (B)	
	Number	Per cent	Number	Per cent
Complete follow-up	234	79.9%	463	90.6%
Missed one day	35	11.9%	34	6.6%
Missed two days	18	6.1%	11	2.2%
Missed three days	6	2.0%	3	0.6%
TOTAL	293 ===		511 ===	

Table 2

Comparison of the two Communities

Subject of Comparison	Community A (Study)	Community B (Control)
Number of villages	9	12
Population	7292	8462
Number of families	1268	1472
Number of families surveyed in KAP study	75	107
Family size	5.75	5.74
Number of children 3 to 36 months	523 (7.17%)	594 (7.02%)
Families poor or destitute	26.66%	25.26%
History of breast feeding	98%	98%
Families with sanitary latrines	79%	64%
Source of first care for diarrhoea is the Health House	100%	100%

TABLE 3 Diarrhoea episodes in the two communities May to September 1977

	Study Group (A)	Control Group (B)
Number of Children 3 to 36 months who come for treatment of diarrhoea	230	344
Total Number of episodes of diarrhoea	336	568
Number of episodes per child*	1.46	1.65
Number of children with two or more attacks	117	198
Number and percentage of episodes at which children were referred to physician at first visit and did not enter trial	43(12.8%)	58(10.2%)
Number of deaths due to diarrhoea	1	7
Number of child/episodes in the trial	293	511
Mean duration of episodes (days)	3.67	3.69
S.D. of duration of episode	1.62	1.59
Mean delay between onset and first visit to behvarz (days)	1.75	1.46
S.D. of delay between onset and first visit	1.86	1.91
Number and percentage of children with consistently good appetite throughout episodes	285(97.3%)	440(86.1%)
Number & percentage of episodes with vomiting	80(27.3%)	109(21.3%)
Mean duration of vomiting (days)	1.46	1.57
S.D. of duration of vomiting	0.87	1.00
Number of episodes with blood in stool	7	2
Mean consumption of ORS per episode (litres)	2.73	-
S.D. consumption of ORS per episode	1.94	-
Mean duration of ORS consumption (days)	2.3	-
S.D. duration of ORS consumption	1.3	-

* Difference not statistically significant.

Table 4. ORS Consumption per kg. body weight per day in
different age group

Age group	No.	Mean Lit	S.D. Lit	Range / liter
3 - 11 m	130	0.196	0.08	0.024 - 0.490
12 - 23 m	127	0.144	0.07	0.017 - 0.403
24 - 35 m	36	0.118	0.05	0.010 - 0.207

Table 5. ORS Consumption per kg/per day according to number of the episode

No Attack	No.	Mean Lit	S.D. Lit	Range / Liter
1	208	0.168	0.084	0.017 - 0.490
2	66	0.152	0.064	0.010 - 0.333
3	13	0.170	0.065	0.073 - 0.277
4	5	0.209	0.048	0.055 - 0.178
5	1	0.164	-	-

TABLE 6. Weight Change Over 72 Hours From Beginning of Treatment

Age Group	No. of episodes in which children gained weight		No. of episodes in which children lost weight		No. of episodes in which there was no change in weight		TOTAL	
	A	B	A	B	A	B	A	B
3 - 11 m.	35	67	6	15	8	30	49	112
12 - 23	34	66	16	9	7	12	57	87
24 - 35	7	21	5	14	2	9	14	44
Total	76	154	27	38	17	51	120	243

chi-squared = 4.106
P = NS

* The reason why only 120 out of 336 episodes in group A (35.7 per cent) and 243 out of 568 episodes in group B (42.8 per cent) are featured in this table is that only that number of episodes continued 72 hours or more. The rest dropped out before, almost all of them because they no longer had any diarrhoeal illness.

TABLE 7. Mean Weight Change Across the First 72 Hours of the Episode

Age Group	No. of children		Mean Weight Change Over 72 Hours		S.D.of Weight Change		Significance of Difference P =
	A	B	A	B	A	B	
3 - 11 m.	49	112	119	33	199	121	P= < 0.01
12 - 23 m.	57	87	102	64	207	128	N.S.
24 - 35 m.	14	44	26	10	105	123	N.S.
Total	120	243	100	40	195	125	P= < 0.01

TABLE 8: Weight Gain In Six Months After The First (or the Only) Attack Of Diarrhoea

AGE GROUP	No. of Children		Total First Weights (KG)		Total Weights (kg) after 6 months		Weight Gains (KG)				Significance of the Difference between the means P:
							A		B		
	A	B	A	B	A	B	Mean	S.D.	Mean	S.D.	
3 - 5 months	26	51	144	226	213	337	2.64	0.79	1.98	0.74	$P < 0.01$
6 - 11 m.	51	61	357	443	458	535	1.93	0.77	1.51	0.63	$P < 0.01$
12 - 17 m.	51	57	440	471	525	553	1.67	0.66	1.43	0.68	$0.10 > P > 0.05$
18 - 23 m.	37	44	351	438	407	490	1.53	0.47	1.19	0.61	$P < 0.01$
24 - 29 m.	14	29	145	303	174	357	2.02	0.51	1.19	0.59	$P < 0.01$
30 - 35 m	10	14	115	155	126	173	1.14	0.82	1.26	0.69	N.S.

TABLE 9: Weight Gain in kilograms in the six months following the first or only episode in children with one episode and more than one episode

Age Group	Children With One Episode							Children With More Than One Episode						
	A			B				A			B			
	No.	Mean	S.D.	No.	Mean	S.D.		No.	Mean	S.D.	No.	Mean	S.D.	
3 - 11 months	36	2.57	0.91	63	1.81	0.70	P<0.01	80	2.04	0.65	103	1.63	0.71	P<0.01
12 - 23 months	62	1.69	0.53	57	1.42	0.63	0.03 P>0.01	53	1.68	0.63	103	1.26	0.53	P<0.01
24 - 35 months	15	1.77	0.69	26	1.30	0.68	0.05 P>0.02	20	1.52	0.73	53	1.05	0.59	P<0.01