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Outpatient Use of Oral Rehydration Solutions in Apache Population: Effect of Instructions on Preparation and Contamination

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Summary: Oral Rehydration Solutions (ORS) containing 90 and 50 mmol/L sodium have recently been recommended for use in ambulatory children in the U.S. These solutions are now marketed in powder form by some commercial companies. However, few data are available in the U.S. on the accuracy with which the solutions are mixed at home or on the bacterial contamination that may occur during mixing. We evaluated the effect of various forms of instructions on the occurrence of bacterial contamination and accuracy of mixing ORS at home by mothers of patients who were dispensed the dry ingredients of an ORS containing 90 mmol/L sodium at the U.S. Public Health Service Hospital, Whiteriver, Arizona. Patients were randomized to one of the four following groups: group I (23 patients) was given written instructions for mixing the solution along with a premarked container; group II (22 patients) was given written instructions only; group III (22 patients) was given a premarked container only; and group IV (19 patients) was given neither. All patients were given oral instructions in the preparation of ORS and were asked to refrigerate the reconstituted ORS. We collected samples of ORS at the patient's home 1 day after the clinic visit, to measure their electrolyte content and to identify any bacterial contamination. Mean Na^+ concentrations were significantly lower in the ORS prepared by mothers/guardians in groups that were not given a premarked container [82 ± 13 (II) and 79 ± 21 (IV) mmol/L vs. 88 ± 13 (I) and 92 ± 14 (III) mmol/L; $p < 0.01$]. The frequency of refrigeration was as follows: 89, 75, 74, and 53% for groups I–IV, respectively ($p = 0.15$). The frequency of refrigerated samples with bacterial counts below the threshold of detection in each group was 63% (I), 33% (II), 21% (III), and 12% (IV) ($p = 0.043$). We conclude that when the dry ingredients of ORS are dispensed to ambulatory patients, they should be given a premarked container as well as detailed written and oral instructions.
Key Words: Oral rehydration solutions—Instructions—Premarked container—Bacterial contamination.

The oral rehydration solution (ORS) recommended by the World Health Organization (WHO) has recently been recommended for rehydration of hospitalized and ambulatory children suffering from acute diarrhea, both in developing and developed countries (1). This recommendation was made by a group of scientists with extensive experience in the field of oral rehydration and is based on numerous reported studies which have been conducted in developing countries (2,3), in an American Indian population (4), and in hospitalized patients in the U.S. (5).

In many countries the ingredients of the WHO ORS are dispensed in powder form, with patients being instructed to dissolve the ingredients in an appropriate volume of water. Studies from developing countries have demonstrated that there may

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be a wide variation in electrolyte content of the WHO ORS when it is mixed at home (6,7). It has also been shown that the water used to reconstitute the ORS in these countries is often heavily contaminated with bacteria (8,9) and that bacteria can proliferate (10,11) in the ORS. However, few data are available in the U.S. on the accuracy with which ORS is mixed at home.

The U.S. Public Health Service Hospital located on the Fort Apache Indian Reservation, Whiteriver, Arizona, has been dispensing the WHO ORS to ambulatory patients on the reservation for the past 10 years. From July 1, 1981 to June 30, 1982 we evaluated the effect of providing different forms of instructions and premarked containers on the accuracy (measured by electrolyte and glucose concentrations) with which Apache mothers mixed the ingredients of the WHO ORS, and on the extent of bacterial contamination in these solutions when they were stored at home over a 24-h period.

MATERIALS AND METHODS

The ingredients of the WHO ORS were accurately weighed so that when dissolved in 1 qt (946 ml) of water, a solution that was identical in composition to the WHO solution would be prepared (Na^+, 90 mmol/L; K, 20 mmol/L; Cl, 80 mmol/L; HCO_3, 30 mmol/L; glucose, 111 mmol/L). The powder was dispensed in plastic vials which were labeled as follows: "Dissolve the contents of this vial in one quart of drinking water and mix well." Instructions to use 1-qt containers instead of 1-L containers were given since a number of household commodities are sold on the reservation in quart-size containers and the community is more familiar with this unit of measure.

All patients prescribed the WHO ORS for the treatment of diarrhea by the primary care physician were randomized to one of four groups.

Group I: Oral and Written Instructions and Premarked Container

The mothers/guardians of the patients assigned to this group were given containers that were premarked at the 1-qt level, oral instructions, and a copy of the following written instructions:

E-SOL INSTRUCTIONS

Oral electrolyte solution, also called E-Sol is used to replace water and salts lost in diarrhea. E-Sol is supplied as a powder and must be properly mixed at home. To prepare E-Sol empty all the powder from the container into a quart of clean, fresh drinking water and stir it until all the powder is dissolved. No powder should be left in the bottom of the container. After mixing, store the solution in the refrigerator and throw away any left over after 24 hours. E-Sol is to be given to the baby for 24 hours only. During this time, it is to be alternated with water or tea. Do not give juice, milk, formula, or sweet drinks. If the baby cannot take this solution, or is getting worse, bring the baby to the hospital to be checked.

The above written instructions were read and explained to the mothers/guardians by the pharmacist.

Group II: Oral and Written Instructions

This group was given oral and written instructions identical to group I; however, no containers were provided.

Group III: Oral Instructions and a Container

This group received premarked containers; however, no written instructions were given. Oral instructions identical to those given the other groups were given by the pharmacist.

Group IV: Oral Instructions Only

This group was not given containers or written instructions; however, they received oral instructions identical to those given the other groups.

Mothers/guardians were informed that a study was being conducted to evaluate the mixing of the ORS and that they would be visited the following day to collect a sample of the ORS. Written informed consents were not obtained; however, only those who gave oral consent were visited by a field worker. The day after the ORS was dispensed, a visit was made to obtain information concerning the source of water used for the ORS and the storage of the solution. A 10-ml sample of the ORS was collected in a sterile container and transported to the laboratory in ice packs for analysis.

One aliquot of the ORS sample was used to measure the sodium, potassium, and glucose concentrations using Instrumentation Laboratory Flame Photometer 643. The second aliquot was serially diluted in increments of 10 until a $1:10^6$ dilution was obtained. One-hundred microlitres of each dilution

was plated onto McConkey plates and incubated for 24 h.

RESULTS

The WHO ORS was dispensed for 154 patients (Table 1) who were clinically assessed to have <5% dehydration. Thirty-seven were randomized to each of groups I, II, and III, and 43 to group IV. All the mothers/guardians to whom ORS was dispensed were literate, and home conditions as determined by field workers were comparable for the four study groups. Samples of ORS were available for analysis from only 86 (56%) patients. Among the other 68 patients, 13 (8%) did not use the solution because the child's diarrhea improved, and 55 (36%) were not home at the time of the visit by the field worker. The mean sodium, potassium, and glucose values in the four groups are shown in Table 1. The ORS from the two groups given a container had a mean sodium value closer to the expected sodium value (90 mmol/L) than the two groups that were not given containers (Table 1). These differences were not observed in the two groups that were given written instructions compared with the other two groups.

Three patients had mixed ORS sodium concentrations that were considered to be unacceptably high (>119 mmol/L) or low (<30 mmol/L) (Table 2). All three patients were seen at the hospital 48 h after the initial visit and were found to be asymptomatic. There were no significant differences among the groups in the mean potassium or glucose values.

The *Escherichia coli* growth in the ORS samples after 1 day of storage is shown in Table 3. There were no statistical differences in the number of patients in each group who refrigerated the ORS. The proportion of refrigerated ORS samples that had <10 colonies/ml of *E. coli* decreased significantly from group I to group IV ($p = 0.043$). The mean colony count of *E. coli* in the refrigerated samples of ORS was also lowest in group I. There were too few nonrefrigerated ORS samples to permit statistical analysis.

DISCUSSION

The findings in the present study of the Apache population suggest the following: (a) ORS is reconstituted with greater accuracy if a container is provided; (b) the incidence of bacterial contamination in the ORS is reduced if careful written and oral instructions are given along with a premarked container; and (c) providing premarked containers did not prevent the occurrence of potentially dangerous sodium concentrations in two of 44 reconstituted ORS samples.

In spite of the considerable experience with the use of WHO ORS for ambulatory and hospitalized patients with diarrhea, there is still concern about the possibility of mothers mixing ORS inaccurately when the powder form is dispensed (1–5). Public health workers have suggested different methods for improving the accuracy of mixing ORS at home.

TABLE 1. *Number of oral rehydration solution samples analyzed and mean laboratory values*

	Group I	Group II	Group III	Group IV
No. of patients randomized	37	37	37	43
No. that did not mix ingredients	3 (8%)	4 (11%)	2 (5%)	4 (9%)
No. of samples collected	23 (62%)	22 (59%)	22 (59%)	19 (44%)
Sodium (mmol/L)	88 ± 13[a]	82 ± 13	92 ± 14	79 ± 21
Potassium (mmol/L)	20 ± 3	19 ± 3	21 ± 4	19 ± 6
Glucose[b] (g/L)	20.0 ± 3.7	19.6 ± 4.3	19.3 ± 3.6	18.6 ± 5.6

Groups: I, oral and written instructions and container; II, oral and written instructions; III, oral instructions and container; IV, oral instructions only. Differences in sodium concentrations significant between groups I and III compared with groups II and IV ($t = 2.70$, $df = 81$, $p < 0.01$).

[a] Mean ± SD.

[b] Only 22 samples in group I and 20 samples in group II tested.

TABLE 2. *Sodium concentrations in oral rehydration solutions after 24 h of storage*

mmol/L	Group I	Group II	Group III	Group IV
<30	0	0	0	1[c]
30–59	1	1	0	1
60–79	1	5	4	4
80–99	18	13	15	10
100–119	1	1	2	3
>119	1[a]	0	1[b]	0
No. of samples tested	22	20	22	19

See text or Table 1 for description of groups.
[a] 120 mmol/L.
[b] 141 mmol/L.
[c] 11 mmol/L.

These include using mass media to educate the mothers (12) or village workers (6), and dispensing measuring spoons or premarked 1-L plastic bags to aid in mixing the solutions (13).

Cutting and co-workers demonstrated a wide range of sodium concentrations (39–510 mmol/L) when the powder form of the WHO ORS was reconstituted in household containers (7). Our study suggested that mothers/guardians mix the ORS with greater accuracy if graduated containers are provided. As demonstrated in this study, the ORS may be mixed incorrectly even if graduated containers are given. Two of our patients (one in group I and one in group III) produced solutions containing potentially dangerous sodium levels (120 and 141 mmol/L, respectively). Close observations of these two patients did not demonstrate adverse effects from the use of these solutions, which reflects our findings over the last 7 years (since 1976). We have not observed a single case of hypernatremia in more than 1,500 ambulatory patients who received WHO ORS in powder form (14).

It has been shown that in some developing countries ORS is frequently prepared with water heavily contaminated with fecal coliforms (8,9). It has also been demonstrated that, even when the WHO ORS is prepared with distilled water, bacterial contamination may occur, resulting in bacterial proliferation (8,10,11). Watkinson et al. demonstrated that neither the incidence nor the duration of diarrheal illness was prolonged in patients who ingested ORS that was prepared with water contaminated with 10^3/ml of *E. coli* (9). In many developing countries the children are frequently exposed to a high concentration of fecal organisms in food and water. Under these circumstances the benefits of rehydration with contaminated solution outweigh the risk of exposure to the fecal coliforms in the ORS. However, in developed countries such as the U.S. where children are not normally exposed to food or water contaminated with fecal organisms, it would be desirable to use an ORS with minimal or no bacterial contamination. Tap water, which is periodically checked for coliforms by the Indian Health Service, was used to reconstitute the ORS used in this study. Bacterial contamination was not found in the water distributed to this population during the study period. Therefore the bacterial contamination of the ORS in this population probably occurred during preparation and storage.

The most probable explanation for the mothers in group I refrigerating samples more often—thereby producing less contamination of the ORS—is that the provision of written instructions at home

TABLE 3. Escherichia coli *in oral rehydration solution samples after 1 day of storage*

E. coli growth	Group I	Group II	Group III	Group IV
No. of samples tested	18	20	19	15
No. of samples refrigerated[a]	16 (89%)	15 (75%)	14 (74%)	8 (53%)
No. of refrigerated samples[b] with <10 colonies/ml	10 (63%)	5 (33%)	3 (21%)	1 (12%)
Mean colony counts in refrigerated samples[c]	1.0×10^1 (1.01 ± 1.66)[d]	1.6×10^2 (2.20 ± 1.91)	1.1×10^3 (3.05 ± 2.10)	3.4×10^2 (2.51 ± 0.92)

Group descriptions in text and Table 1. Analysis by Newman-Keuls test. Group I < group III, $p < 0.05$. All other comparisons, $p > 0.05$.
[a] $\chi^2 = 5.36$, $p = 0.15$.
[b] $\chi^2 = 8.15$, $p = 0.043$.
[c] $F = 3.08$, $p = 0.036$.
[d] Values in parentheses are $\log_{10}$ colony counts ± 1 SEM.

may have helped to reemphasize the importance of using proper mixing and refrigeration techniques. In illiterate populations, other techniques, such as illustrative pictures, may achieve the same result.

We would like to emphasize that this study was designed to evaluate the optimal method of distributing ORS to the population on the Fort Apache Indian Reservation. These methods may not be appropriate for other geographic areas. The method of distribution of ORS should take into account the cost, feasibility, level of education, and cultural habits of the population. Our study suggests that in literate populations such as ours, when the powder form of ORS is distributed to patients, it is desirable to dispense graduated containers for measuring the water, as well as clearly stated written and oral instructions.

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