Safety and Effectiveness of Homemade and Reconstituted Packet Cereal-based Oral Rehydration Solutions: A Randomized Clinical Trial

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ABSTRACT. Objectives. Parents may be deterred from obtaining commercial oral rehydration solutions (ORS) for their young children with acute diarrheal disease because of its availability and/or cost, especially if they are poor. We conducted a randomized clinical trial to determine 1) whether low-income parents could safely mix and administer cereal-based ORS (CBORS) both from ingredients commonly found in the home and from a premixed packet; 2) whether these CBORS were as effective in maintaining hydration as commercial glucose-based ORS; and 3) whether CBORS were more effective in reducing severity and duration of illness.

Methods. Children 4 to 36 months of age discharged from emergency departments and health centers with acute diarrheal disease were randomized to receive either homemade CBORS, reconstituted packet CBORS, or Pedialyte. A study nurse saw the child at home each day until the illness resolved, and obtained capillary blood for serum sodium at enrollment and at 24 to 48 hours; a sample of CBORS for sodium concentration; stool for pathogen analysis; and daily fluid intake, stool frequency, and weight.

Results. A total of 232 children were enrolled, of whom 203 (88%) completed the study. Two parents (3%) in the homemade CBORS group and one parent (1%) in the packet CBORS group made mixing errors resulting in a high sodium concentration (>100 mEq/L); their children refused the solution and had normal serum sodium values. Mean CBORS sodium concentration for the remainder of the homemade CBORS group was 60 ± 10 mEq/L, and for the packet CBORS group, 54 ± 13. Eighteen children (11%) had abnormal serum sodium values at presentation, which returned to normal in all groups in most cases. Three children (4.5%) in the homemade CBORS group, 4 (6%) in the packet CBORS group, and 1 child (1.4%) in the Pedialyte group failed therapy.

Children refused to take homemade CBORS and packet CBORS (43% and 32%, respectively) more often than Pedialyte (9%), and those in the CBORS groups tended to take less ORS and total fluids. There were no significant differences among the three groups in incidence of daily vomiting or stooling, duration of diarrhea, or weight gain.

Conclusions. CBORS do not offer a clinically significant advantage over glucose-based ORS. Homemade CBORS represent a treatment option in carefully selected cases, but it is not the safest alternative for regular clinical use. Pediatrics 1997;100(5). URL: http://www.pediatrics.org/cgi/content/full/100/5/e3; diarrhea, dehydration, oral rehydration, cereal.

ABBREVIATIONS. ORT, oral rehydration therapy; ORS, oral rehydration solutions; CBORS, cereal-based oral rehydration solutions; CI, confidence interval.

Acute infectious diarrhea is a common illness in young children worldwide and in the United States, where children average between 1.3 and 2.3 episodes per child per year for the first 5 years of life.1 Each year, approximately 1 of 5 children <5 years of age sees a physician for diarrhea, and 1.4% are hospitalized, resulting in >200 000 hospital admissions, or 10.6% of all admissions in this age group.1 It has been estimated that the annual national cost of hospitalization for rotavirus-associated gastroenteritis was $352 million in 1988.2 Some 300 children <5 years of age die in the United States each year because of diarrhea, a rate that has not declined since 1985. These deaths occur primarily in infants and disproportionately among those who are African-American, premature, and living in Southern states and in metropolitan areas.3

Oral rehydration therapy (ORT) is safe, effective, less invasive, and less expensive than intravenous rehydration for the treatment of diarrheal dehydration, and its use in the home early in the course of illness can prevent the development of dehydration.4–8 ORT has been promoted in practice guidelines published by the American Academy of Pediatrics (AAP)9,10 and the Centers for Disease Control and Prevention.11 However, there are economic barriers to the use of ORT for low-income families,12 who may have to pay >$6 per liter in their neighborhood pharmacy for commercial oral rehydration solutions (ORS). Coverage of commercial ORS varies among the state Medicaid programs,13 and one fourth of children in low-income families in the United States have no health insurance coverage at all.14

A possible approach to this problem is the promo-
tion by health professionals of ORS prepared from ingredients commonly found in the home, as is done in some programs in poor countries. However, there are concerns that inaccurate measurement of either sugar or salt could produce an ineffective or dangerous mixture, and the safety and effectiveness of homemade ORS in the United States has not been reported. Cereal-based oral rehydration solutions (CBORS) may be prepared from ingredients found in most households, and homemade CBORS should be safer than homemade sugar–salt solutions because of its lower osmolality if prepared with an inappropriately small volume of water. CBORS using rice or other cereals at concentrations of 50 to 80 g/L have been shown to be as effective as glucose-based solutions in restoring and maintaining hydration; in some studies, its use has reduced stool output, shortened the course of diarrheal illness, reduced vomiting, decreased the volume of oral solution needed, and improved weight gain.

To assess the safety and effectiveness of homemade CBORS and CBORS prepared from a packet of premeasured dry ingredients, we conducted a randomized clinical trial. The hypotheses tested were 1) when adequately instructed, parents from a variety of ethnic and educational backgrounds are able to safely prepare and administer CBORS made from ingredients commonly found in the home or reconstituted from a packet of premixed ingredients; 2) CBORS prepared and administered at home are as effective as commercially available glucose-based ORS in maintaining hydration in children with acute diarrheal disease; and 3) CBORS used in the maintenance phase of ORT are more effective than glucose-based ORS in decreasing the incidence of vomiting, number of stools per day, volume of ORS consumed, and duration of diarrhea, and in increasing weight gain.

METHODS

Children presenting to the pediatric emergency departments or primary care clinics of Boston City Hospital and Boston Children’s Hospital or any of seven Boston neighborhood health centers were considered eligible for study if they met the following criteria: 1) age between 4 and 36 months; (2) discharged from treating site with the diagnosis of acute diarrheal disease (defined as the passage of at least one diarrheal stool in the 24 hours before registration) with normal hydration status (in the judgment of the attending physician) by the end of the visit; (3) had had rice introduced to the diet; (4) had a legal guardian available who was fluent in English, Spanish, French, or Haitian Creole, able to follow written instructions, available for home visits, and living within the geographic range of the study; and (5) the attending physician agreed that the child may be included in the study. Children were considered ineligible for study if they 1) presented with diarrhea of >7 days’ duration; 2) had received antibiotics during the 7 days before presentation; 3) were known to have a chronic gastrointestinal or immune disorder; or 4) if the study nurse judged the parent/guardian to be unable to adhere to the protocol instructions. Study nurses were on site at the two emergency departments during peak visit times (usually 2 PM to 10 PM), 7 days per week. They reviewed presenting complaints of all children in the target age range and approached the parent/guardian of those patients whose presenting complaint was consistent with a diagnosis of acute diarrheal disease (ie, diarrhea, vomiting, fever). Potentially eligible patients presenting at participating health centers were identified by health center nursing staff, and a study nurse was contacted to visit the health center and interview the parent. For study participants, the study nurse obtained informed consent, administered a structured questionnaire, and obtained capillary blood for serum sodium assay.

Children were assigned to one of three treatment groups using randomization in blocks of nine subjects each. Group 1 received homemade CBORS, prepared by mixing 2 cups of water, ½ cup of instant baby rice cereal (Gerber Products Co, Fremont, MI), and ¼ level measuring teaspoon of table salt. This mixture was calculated to contain 50 mEq/L sodium, 1 mEq/L potassium, 80 g/L cereal. Group 2 received CBORS, prepared by mixing ingredients from a packet (provided by the Gerber Products Company) with 8 oz of water and containing 60 mEq/L sodium, 15 mEq/L potassium, 48 mEq/L chloride, 25 mEq/L bicarbonate, and 80 g/L cereal. Group 3 received Pedialyte (Abbott Laboratories, Columbus, OH), a commercially available glucose-based ORS (45 mEq/L sodium, 20 mEq/L potassium, 35 mEq/L chloride, 30 mEq/L citrate, and 25 g/L glucose).

The study nurse assessed the ability of parents assigned to the homemade and packet CBORS groups to correctly identify the household measures used to prepare the solution. Parents were given all materials necessary to prepare and administer the study solution, including measuring utensils and containers for the CBORS groups and Pedialyte for the control group. Instructional leaflets describing how to prepare and administer the study solutions were given along with leaflets describing recommended feeding practice during diarrhea and prevention of transmission of diarrheal disease. Parents were instructed to give the child her/his usual volume of liquids plus an additional volume, which was calculated as 10mL/kg, for each diarrheal stool. They were advised to alternate the study solutions with the child’s other regular liquids, but to avoid sweetened beverages such as juice or soda pop unless diluted with an equal volume of plain water. It was suggested that liquids be given from a bottle or cup, but that if the child vomited the liquid, to give 1 teaspoonful every few minutes until the vomiting ceased. To ensure uniformity of dietary advice, parents were also advised to avoid milk and milk formula, but to continue the child’s usual solids. All educational materials were available in English, Spanish, and French. Parents also received diapers; soy formula; A & D ointment (Moore Medical, New Britain, CT); stickers, marker pens, and plastic bags for labeling and collecting soiled diapers; and a canvas tote bag.

Parents were instructed to save all soiled diapers, mark each diaper with the time of its changing, and record fluid intake on a daily log sheet. A study nurse visited the home each day, beginning on the day after enrollment and continuing until the end of illness, which was defined as passage of a formed stool followed by at least 48 hours with no recurrence of diarrhea. At each visit, the study nurse reviewed the history of liquid intake and stool frequency, performed a clinical assessment of hydration status, and examined the soiled diapers collected since the previous visit. On the first home visit, a sample of CBORS prepared by the parent was collected and assayed for sodium, and stool was obtained for pathogen analysis, which included culture for Salmonella, Shigella, Yersinia, Campylobacter, and Escherichia coli O157:H7; specimens for rotavirus antigen assay were frozen and assayed in batches (Sanofi Diagnostics Pasteur, Chaska, MN). Within 24 to 48 hours after enrollment, a second capillary blood specimen was obtained for serum sodium assay. A mixing failure was defined as CBORS prepared by the parent with a sodium concentration of >100 mEq/L. In all such cases, a repeat test for serum sodium level was obtained, CBORS discontinued, and the parent provided with fluid, and followed up until resolution of diarrhea. If the child appeared to be dehydrated or had other signs of clinical concern, the home visiting nurse referred the child back to her/his original treatment or primary care site. A treatment failure was defined as occurrence of dehydration as assessed by the child’s clinician at any time after enrollment or any child with serum sodium >150 mEq/L at any time after enrollment. These children were removed from the study and given standard clinical care. A study nurse visited families at ~1 week after the end of illness to obtain an interval history and weight. Outcome measures included mixing and treatment failures, occurrence of vomiting, daily frequency and duration of diarrhea, and weight change at end of illness and 1 week later.

Statistical Methods

Proportions were compared using the χ2 statistic. Medians were examined when data distributions were skewed and compared...
RESULTS

Between November 1, 1994 and April 28, 1996, 505 parents whose children appeared to meet the study criteria were invited to participate in the study, of whom 177 (35%) declined and 96 (19%) were found to be ineligible on further examination. A total of 232 children were enrolled, of whom 203 (88%) were followed to an endpoint (end of illness or mixing/treatment failure). Children lost to follow-up (n = 29) and those followed to an endpoint did not differ by demographics, illness history, stool pathogens, or treatment group. Data are presented for the 203 children followed to an endpoint. Demographics of the children are shown in Table 1: mean age was 15 ± 8 months; 38% were Latino (a category which included Puerto Rican [18%], Central American [10%], Dominican [6%], and other Latino [4%]), 30% were African-American, and 10% were Haitian; 87% of children participated in the Special Supplemental Food Program for Women, Infants, and Children. Ninety-seven percent of parents reported the child’s birth weight, 95% had salt, 95% had sugar, and 60% had instant baby rice cereal; 26% had all of the ingredients necessary to prepare homemade CBORS.

Illness characteristics are shown in Table 2. Parents reported a mean of 6.6 stools in the 24 hours before presentation and 2.2 days with diarrhea before presentation, and 72% reported vomiting. In the judgment of the attending physician, 60% of children were not dehydrated, whereas 34% had mild, 5% moderate, and 0.5% severe dehydration. Stool samples were available for rotavirus assay from 175 children (86%), of whom 47 (27%) had a positive result. A total of 163 specimens (80%) were assayed for bacterial pathogens, of which 5 (3%) were positive for Salmonella and 3 (2%) for Campylobacter. Demographics, illness characteristics, etiology, and degree of dehydration did not vary significantly by treatment group assignment.

When asked whether they had heard of drinks that could be purchased in a store or pharmacy to treat children with diarrhea and/or vomiting, 157 parents (77%) responded that they had, with 151 (96%) naming Pedialyte. A total of 121 parents (60%) reported that they had given their child Pedialyte in the past, and 70 children (36%) were being given Pedialyte at the time of enrollment. There was no difference in history of previous ORS use by treatment group (P = .31). A total of 67% of parents reported that they had a measuring cup in the household, 50% had a measuring spoon set, 97% had salt, 95% had sugar, and 60% had instant baby rice cereal; 26% had all of the ingredients necessary to prepare homemade CBORS.

CBORS Sodium Concentration

The distribution of sodium values in the homemade solutions prepared by study parents is shown in Figure 1. There were two mixing failures in this group (2/66 = 3.0% [one-sided upper limit of 95% CI = 9.2%]). In the first case, the mother mixed a solution with a sodium concentration of 255; she reported that she had not read

**TABLE 1. Sample Demographics (N, %)**

<table>
<thead>
<tr>
<th></th>
<th>Total N = 203</th>
<th>Group 1 (HOMEMADE) n = 66</th>
<th>Group 2 (PACKET) n = 68</th>
<th>Group 3 (PEDELYTE) n = 69</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, months; mean ± SD</strong></td>
<td>15.3 ± 8.2</td>
<td>16.5 ± 7.9</td>
<td>17.5 ± 7.3</td>
<td>15.8 ± 8.8</td>
<td>0.12</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>115 (57)</td>
<td>38 (58)</td>
<td>38 (56)</td>
<td>39 (57)</td>
<td>0.98</td>
</tr>
<tr>
<td>Female</td>
<td>88 (43)</td>
<td>28 (42)</td>
<td>30 (44)</td>
<td>30 (43)</td>
<td></td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Latino</td>
<td>75 (38)</td>
<td>25 (40)</td>
<td>24 (36)</td>
<td>26 (39)</td>
<td>0.73</td>
</tr>
<tr>
<td>African-American</td>
<td>60 (30)</td>
<td>16 (25)</td>
<td>21 (31)</td>
<td>23 (34)</td>
<td></td>
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<tr>
<td>Haitian</td>
<td>19 (10)</td>
<td>9 (14)</td>
<td>6 (9)</td>
<td>4 (6)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>43 (22)</td>
<td>13 (21)</td>
<td>16 (24)</td>
<td>14 (21)</td>
<td></td>
</tr>
<tr>
<td><strong>Maternal age, years; mean ± SD</strong></td>
<td>25.6 ± 6.3</td>
<td>26.5 ± 5.9</td>
<td>24.7 ± 5.8</td>
<td>25.6 ± 7.0</td>
<td>0.25</td>
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<tr>
<td><strong>Maternal education</strong></td>
<td></td>
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<tr>
<td>Less than high school</td>
<td>77 (41)</td>
<td>23 (38)</td>
<td>27 (44)</td>
<td>27 (41)</td>
<td>0.38</td>
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<tr>
<td>High school graduate</td>
<td>70 (37)</td>
<td>19 (32)</td>
<td>24 (39)</td>
<td>27 (41)</td>
<td></td>
</tr>
<tr>
<td>Beyond high school</td>
<td>40 (21)</td>
<td>18 (30)</td>
<td>10 (16)</td>
<td>12 (18)</td>
<td></td>
</tr>
<tr>
<td><strong>Health insurance</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Medicaid</td>
<td>121 (63)</td>
<td>34 (56)</td>
<td>43 (67)</td>
<td>44 (66)</td>
<td></td>
</tr>
<tr>
<td>HMO*</td>
<td>26 (13)</td>
<td>8 (13)</td>
<td>8 (13)</td>
<td>10 (15)</td>
<td>0.61</td>
</tr>
<tr>
<td>None</td>
<td>35 (18)</td>
<td>16 (26)</td>
<td>10 (16)</td>
<td>9 (13)</td>
<td></td>
</tr>
<tr>
<td>Private</td>
<td>7 (4)</td>
<td>3 (5)</td>
<td>2 (3)</td>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>3 (2)</td>
<td>0 (0)</td>
<td>1 (2)</td>
<td>2 (3)</td>
<td></td>
</tr>
<tr>
<td>WIC participation</td>
<td>168 (87)</td>
<td>56 (87)</td>
<td>55 (86)</td>
<td>57 (86)</td>
<td>0.96</td>
</tr>
<tr>
<td>AFDC participation</td>
<td>92 (48)</td>
<td>28 (44)</td>
<td>28 (44)</td>
<td>36 (55)</td>
<td>0.31</td>
</tr>
<tr>
<td>Food stamp participation</td>
<td>94 (49)</td>
<td>30 (46)</td>
<td>24 (44)</td>
<td>36 (55)</td>
<td>0.37</td>
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<td>Child in day care</td>
<td>27 (14)</td>
<td>06 (9)</td>
<td>11 (17)</td>
<td>10 (15)</td>
<td>0.61</td>
</tr>
<tr>
<td>Household has telephone</td>
<td>173 (88)</td>
<td>58 (89)</td>
<td>55 (86)</td>
<td>60 (88)</td>
<td>0.84</td>
</tr>
</tbody>
</table>

Missing values not included. Percentages may not add up to 100% because of rounding.
* An undetermined number of patients enrolled in HMOs were also Medicaid recipients.
the directions when preparing the study mixture, nor did she remember which spoon she had used to measure the salt. When asked by the study nurse to prepare the solution again, the mother replied that she had given away both the instructions and measuring materials. In the second case, the father had received the enrollment instructions, but the mother had prepared the solution; the mixture sample had a sodium concentration of 191 mEq/L. Both children were reported to have refused the solution, and both were found to have normal serum sodium values. The mean solution sodium concentration for the remainder of the group was 54 mEq/L. Five parents mixed solutions with low sodium concentration (ranging from 10 to 37 mEq/L). In one case, the initial serum sodium concentration was 148 mEq/L, and follow-up was 140 mEq/L after administration of a solution with 32 mEq/L sodium. In the other four cases, initial and follow-up serum sodium values were normal. None of these children failed treatment.

The distribution of sodium concentrations in the premixed packet group is shown in Figure 2. There was one mixing failure in this group (1/68 = 1.5% [one-sided upper limit of 95% CI = 6.8%]). The mother reported that the child’s father had added salt to the mixture to improve its taste because the child was refusing to drink it. The solution sample had a sodium concentration of 138 mEq/L, the child was reported to have refused the solution, and his follow-up serum sodium value was normal. One other parent reported adding sugar to the mixture to improve its taste. The mean solution sodium concentration for the remainder of the group was 60 mEq/L. Two parents mixed solutions with low sodium concentration (both were 23); in both cases, initial and follow-up serum sodium values were normal. None of these children failed treatment.

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**Serum Sodium Concentration**

Mean serum sodium concentration was 139 ± 3.0 mEq/L at enrollment and 139 ± 2.5 mEq/L at 24 to 48 hours' follow-up, and did not differ significantly by treatment group. Considering all children with enrollment and follow-up serum sodium determinations (N = 169), 18 patients (11%) had abnormal serum sodium values at enrollment. In all of these cases, serum sodium was determined for study purposes and not because it was considered indicated by the examining physician. Their follow-up sodium values returned to normal in 89% of cases (Fig 3).

Two children with abnormal enrollment values and three children with normal enrollment values had a follow-up serum sodium value that was abnormal, but none were in the range defined as treatment failure and all were clinically healthy at follow-up. No child with an abnormal serum sodium value on reevaluation required hospitalization.

**Treatment Failures**

Among children in the homemade CBORS group, there were three treatment failures (4.5%, [one-sided upper limit of 95% CI = 11.3%]); two children were hospitalized. There were four treatment failures in the premixed packet CBORS group (6% [one-sided upper limit of 95% CI = 13%]); two were hospitalized. One child failed treatment in the Pedialyte group (1.4% [one-sided upper limit of 95% CI = 6.7%]) and was hospitalized. These proportions are not significantly different (P = .39).

**Oral Liquid Intake**

Most parents did not maintain complete written records of oral intake as requested, thus, daily recall was relied on to estimate quantitative liquid consumption. In the first 24 hours after enrollment, 43% of the children in the homemade cereal ORS group did not take any of the assigned solution, compared with 32% of those in the packet group and 9% of those in the Pedialyte group (homemade vs packet, P = .3; homemade vs Pedialyte, P = .00003; packet vs Pedialyte, P = .003). This pattern remained consistent on most of the following 5 days of illness. Children who took none of the cereal-based solutions in the first 24 hours were not more likely to have been on Pedialyte at enrollment nor to have had previous experience with Pedialyte. A total of 21% of parents of children taking none of the cereal-based solutions reported that they had not offered the child the study solution. Among children who did not refuse ORS, those in the homemade CBORS group consumed less ORS than those in the Pedialyte group on days 2 and 4 (Table 3). Among all children, those in the homemade CBORS group consumed less total fluid than those in the Pedialyte group on days 2 and 3, and less than those in the packet group on day 2 (Table 4).

At the end of the child’s illness, parents were asked their opinion of the assigned solution. There were no significant differences among the three groups in the proportion of parents who found the smell or consistency of the solution to be unpleasant (8% to 13%), although more parents found the color of the homemade (9%) and the packet (15%) CBORS to be unpleasant compared with those assigned Pedialyte (0%) (P = .0005). Perception of unpleasant qualities was not associated with the child’s not taking the assigned solution, nor was the parents’ perception that the CBORS was too thick to serve (homemade 16%, packet 7%).

**Vomiting, Stool Frequency, Duration of Illness, and Weight Gain**

There were no differences by treatment group assignment in the proportion of children vomiting per day for the first 7 days of illness after enrollment,
which ranged from 17% to 28% on day 1 and declined thereafter, nor in median number of diarrheal stools, which ranged from 1 to 2. There were seven cases of diarrhea persisting >14 days beyond enrollment: three in the homemade group, and two each in the packet and Pedialyte groups. In all these cases, illness resolved in the third week after enrollment. These cases were excluded from analysis of duration of illness. Median duration of diarrheal illness did not differ by treatment group: for children in the homemade CBORS group, 92 hours (10 to 310); for those in the Packet CBORS group, 97 hours (19 to 327); and for those in the Pedialyte group, 92 hours (10 to 310).

Using 80% power with \( \alpha = 0.05 \), and given the sample sizes and SDs observed, we calculated that the smallest detectable difference between group 1 and group 3 was 38 hours, and between group 2 and group 3, 39 hours. To assess potential therapeutic differences among the children with the most severe disease, we repeated this analysis using only the children in the upper tercile of ORS consumption in the first 24 hours and, again, found no significant differences in proportion of children vomiting, stool frequency, or duration of diarrhea. We obtained the same results when we restricted the analysis to those children in the upper tercile of stool frequency on day 1, and again when we restricted analysis to those children who were judged to be dehydrated at presentation.

Between enrollment and end of illness, children gained a median of 0.180 kg (range, −0.125 to 1.83 kg), or 1.8% of enrollment (hydrated) weight, and between end of illness and 1 week follow-up, 0.200 kg (range, −0.55 to 1.54), or 2.0%. There were no differences in weight change among treatment groups.

**DISCUSSION**

Most parents in this low-income and multiethnic sample were able to safely prepare CBORS both from ingredients commonly found in the home and from a premixed packet (97% and 99%, respectively). However, several potentially hazardous mixing errors were made, although in none of these cases was there an adverse clinical outcome. Most other reports of trials of homemade ORS preparation are from poor countries, where wide ranges of accuracy in solution sodium concentration have been found. Few such studies have been reported from industrialized countries; studies from Italy and England have shown a high variability of homemade sugar–salt ORS. The greater accuracy of the parents in our study may be attributable to the fact that they had been instructed personally in solution preparation by a nurse in addition to having received written instructions.

Children were less likely to take the cereal-based than the glucose-based solution. Median ORS and total fluid consumption reported by parents were low for all three study groups; this might reflect inaccurate reporting, because most parents did not adhere to instructions to keep a written record of fluid intake. Nonetheless, treatment failure rates were similarly low for the three treatment groups and within the range of failure rates reported in other trials of outpatient ORT in the United States. The three solutions studied were found to be equally effective in maintaining hydration and correcting both hyponatremia and hypernatremia. We did not find any advantage in treatment outcome among children in the CBORS groups compared with those assigned glucose-based ORS. This may have been attributable to the relative mildness of illness in the children studied. Furthermore, a recent metanalysis has shown no significant reduction in stool output in children with acute, noncholera diarrhea given rice-based ORS. Thus, efforts to prevent the morbidity and mortality of acute diarrheal disease in US children should not be focused primarily on the use of cereal-based as opposed to glucose-based ORS.

Whether using an ORS at the onset of illness is more effective in preventing dehydration than simply increasing the child’s usual fluids is not known; the AAP practice parameter states that ORS is not necessary for the child without dehydration, whereas the Centers for Disease Control and Prevention recommends that “families with infants and small children should be encouraged to keep a supply of ORS at home at all times and use the solution when diarrhea first occurs in the child.” There are no data available to answer this question. It is our clinical impression that the majority of children with
acute gastroenteritis will do well even without ORS, but there are a minority of children who develop severe purging, especially with rotavirus infection, and it is these children who will be most in need of an appropriate ORS to maintain hydration and prevent hyponatremia and hypernatremia. Our data show that homemade CBORS is not the safest alternative, because it carries the risk of potentially dangerous mixing errors even with the most careful supervision, and it is likely that the children most severely affected with dehydrating diarrhea would be most likely to consume, if offered, a mixture erroneously prepared with too much salt. There are circumstances in which homemade CBORS may be considered an option, eg, in the case of a young child with rapid purging whose family is unable to obtain commercial ORS and is in telephone contact with a clinician who has confidence in their ability to prepare the solution correctly.

The packet-reconstituted CBORS was diluted correctly in all cases, although errors in preparation can still be made, especially by the addition of extra ingredients to the ORS (as occurred in two cases in our study), which can also occur with a premixed commercial solution such as Pedialyte. A premixed packet for reconstitution with water may represent the most pragmatic way to ensure that families at highest risk have ORS on hand when the need arises. Such packets could be distributed readily at primary care facilities, although the cost might need to be subsidized to remove the economic barrier standing between poor families and ORT.

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Gluocse-based ORS packets may be obtained from Pharmacia & Upjohn, Kalamzoo, MI 49001 (KaoLectrolyte) and Jianas Brothers Packaging Co, Kansas City, MO (World Health Organization ORS). CBORS packets are available from Cera Products Inc, 8265L Patuxent Range Rd, Jessup, MD 20794 (CeraLyte).
Safety and Effectiveness of Homemade and Reconstituted Packet Cereal-based Oral Rehydration Solutions: A Randomized Clinical Trial
Alan Meyers, Amy Sampson, Richard Saladino, Sujata Dixit, William Adams and Alejandro Mondolfi
*Pediatrics* 1997;100;e3
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