

Oral Rehydration Solution for Acute Diarrhea Prevents Subsequent Unscheduled Follow-up Visits

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ABSTRACT. *Background.* Oral rehydration solutions (ORS) for the treatment of acute diarrhea remain an underutilized therapy in the United States, despite multiple clinical trials confirming their efficacy and safety. Economic barriers to their use have been identified.

Objective. To determine whether providing ORS to patients at the time of their office visit for acute diarrhea can increase ORS utilization and reduce unscheduled follow-up visits.

Design. Randomized, controlled clinical trial.

Setting. Seven health centers of a large health maintenance organization.

Participants. Children ($N = 479$) 0 to 60 months of age with acute diarrhea (at least three watery or loose stools in the previous 24 hours for ≤ 7 days).

Intervention. Prescription for 2 quarts of ORS filled for free at on-site pharmacy plus written instructions versus written instructions alone.

Primary Outcome Measures. Self-reported use of ORS; unscheduled follow-up visits in office, urgent care, and/or emergency department setting.

Results. Subjects in the intervention group were significantly more likely to use ORS after the initial office visit (85% vs 71%; RR: 1.19; 95% CI: 1.08–1.32). Of the standard treatment group subjects, 40 (17.3%) sought unscheduled follow-up care for diarrhea versus 27 (10.9%) of the intervention group subjects (RR: 0.63; 95% CI: 0.40–0.99). Subjects seeking unscheduled follow-up care tended to younger (15.7 vs 19.4 months old), have more stools (7.1 vs 6.2 stools), and more vomiting episodes (4.1 vs 3.0) in the 24 hours before initial evaluation than those not seeking unscheduled follow-up care. Multivariate analysis showed that randomization to the intervention group was associated with a 25% reduction in unscheduled follow-up visits for acute diarrhea.

Conclusions. Providing ORS to families at the time of their office visit for acute diarrhea is associated with a significant increase in ORS use and substantially reduces the need for unscheduled follow-up visits. Health maintenance organizations should consider routine provision of

ORS to children presenting with acute diarrhea. *Pediatrics* 1999;104(3). URL: <http://www.pediatrics.org/cgi/content/full/104/3/e29>; diarrhea, oral rehydration solutions, practice-based research, dehydration, vomiting.

ABBREVIATIONS. ORS, oral rehydration solution; IV, intravenous; ED, emergency department; HMO, health maintenance organization.

One of the most important medical advances of the 20th century has been the development of oral rehydration solutions (ORS) for the treatment of diarrheal diseases.¹ Case management of diarrhea in the United States and other industrialized countries, however, continues to rely heavily on intravenous (IV) rehydration, with a concomitant underutilization of appropriate oral fluids.² This tendency to use IV rather than oral fluids is unfortunate, because proper use of ORS is safer, more physiologic, less painful, and less expensive than use of IV fluids.^{3,4} In addition, ORS is preferred to other, physiologically inappropriate fluids; the high osmolality of fruit juices and carbonated beverages may actually worsen gastrointestinal fluid losses, and such fluids often do not contain adequate sodium.⁵

Efforts to increase the utilization of appropriate oral fluids for the treatment of diarrhea have included the establishment of the National Oral Rehydration Therapy Project and the release of treatment guidelines by both the American Academy of Pediatrics⁶ and the US Centers for Disease Control and Prevention.⁷ None of these measures, however, addresses what may be a prime barrier to the use of ORS: the substantial out-of-pocket expense incurred by its use. Pedialyte (Ross Laboratories, Columbus, OH), the most widely used ORS in the United States, costs \$5 to \$6 per liter. Adequate replacement of excess stool losses in a child with moderate diarrhea therefore could cost \$10 to \$12 per day of illness. Even prepaid medical plans, which tend to seek cost-effective medical therapies, do not routinely include ORS as a patient benefit, nor is reimbursement made to parents or physicians for such expenses.⁸

These economic factors may contribute to the administration of inappropriate fluids such as juices or inadequate amounts of commercially available ORS. Meyers and colleagues⁹ have reported a case in which a parent's inability to purchase commercial ORS contributed to the death of a 9-month-old infant

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from rotavirus diarrhea. We hypothesized that providing ORS directly to the family at the time of their health center visit for an episode of acute diarrhea would result in higher utilization rates of ORS, better case management of diarrhea, and reduced need for unscheduled emergency department (ED) and health center visits.

METHODS

Study Design

We performed a randomized, controlled clinical trial among infants and young children with acute diarrhea in a large, multi-centered, urban health maintenance organization (HMO). Children 0 to 60 months of age with acute diarrhea (defined as at least three watery or loose stools within the previous 24 hours) were eligible. Patients with persistent diarrhea (defined as diarrhea for >7 days), chronic gastrointestinal disease (eg, inflammatory bowel disease), or symptomatic immunodeficiency states (eg, AIDS) were excluded. Subjects were enrolled at the time of their visit to one of seven health centers of Harvard Pilgrim Health Plan, New England's largest HMO.

Randomization

Because of concerns about patient satisfaction, patients were not randomized on an individual basis. Instead, we randomly assigned by coin toss 2-week blocks of time for each center, during which all subjects would be assigned to either the control or the experimental group. The 2-week period was chosen to take into account seasonal changes in diarrhea disease epidemiology.

Study Intervention

Children with acute diarrhea presenting to the office during the control period (standard treatment group) were provided with written instructions on contemporary diarrhea management, which emphasized appropriate ORS use, early feeding, and preventive measures. Children presenting during the experimental period (intervention group) were given the same written instructions, plus a prescription for 2 quarts of ORS filled at no charge at the health center pharmacy. The ORS contained (per liter) Na 45 mEq, K 20 mEq, Cl 35 mEq, citrate 30 mEq, and glucose 25 g. Two quarts were distributed because children as old as 5 years (or weighing as much as 20 kg) could require as much as 20 to 30 mL/kg/d (ie, 400–600 mL per day) for replacement of stool losses.

Outcomes

The primary study outcome was ORS effectiveness, namely the ability of ORS use to prevent unscheduled follow-up visits after the initial encounter. The following definitions were made a priori: unscheduled office visit, any visit to the health center during usual hours for the same episode of diarrhea not requested by the initial treating physician, physician assistant, or nurse practitioner; and urgent care visit, any visit to the health center after hours for the same episode of diarrhea. We defined any patient with either an unscheduled office or urgent care visit, or with a visit to an ED for the same episode of diarrhea, to have had unscheduled follow-up. Secondary outcomes included ORS utilization (defined by the percent of cases for whom ORS was used after the initial visit), use of physiologically inappropriate fluids such as juices and carbonated beverages, and cost savings.

Data Collection

Demographic and clinical data on study entry were obtained from a self-administered questionnaire filled out by the parent(s) in the waiting room. A standardized clinical data form then was completed by the examining physician or nurse practitioner, confirming the diagnosis of acute diarrhea as well as noting fluid and dietary recommendations. A study nurse contacted the family by telephone ~10 days after the initial visit to obtain information concerning duration of illness, use of ORS and other fluids at home, estimated out of pocket expenses, and occurrence of scheduled or unscheduled follow-up visits. Because all patient encounters, including those to EDs and after-hour urgent care facilities, are registered in a computerized database, the record for all subjects was reviewed for the 10

days after the initial encounter to verify the primary outcomes noted by the study nurse's follow-up telephone call. Median household income data based on ZIP code were obtained from the 1990 US Census (<http://www.census.gov>).

Estimates of Sample Size

The study was designed with sufficient power to detect a 50% reduction in unscheduled follow-up visits. We estimated initially that 8% of patients seen in the ambulatory setting might require this follow-up care. To see a reduction from 8% to 4% of unscheduled follow-up care, with 80% power and two-sided $\alpha = 0.05$, 601 subjects per treatment arm were initially required. After 100 subjects were enrolled, we found an 18% incidence of unscheduled follow-up visits in the control group. With power = 0.80 and $\alpha = 0.05$, a 50% reduction in unscheduled follow-up visits then was found to require 247 subjects per arm. Assuming a loss to follow-up rate of 5%, 260 subjects per arm were required, for a total of 520 study subjects.

Data Entry and Statistical Analysis

Data were entered with the aid of range and logic checks¹⁰ and analyzed with the Statistical Package for the Social Sciences (SPSS for Windows, version 7.0). Categorical data were compared between the two groups using χ^2 analysis or Fisher's exact test. Discrete and continuous data were analyzed with the Mann-Whitney *U* test and Student's *t* testing, when appropriate. Univariate and multiple logistic analyses were performed to relate the occurrence of unscheduled follow-up visits with selected clinical and demographic variables. *P* values <.05 were considered significant.

Ethics

The study protocol was approved by the Children's Hospital Committee on Clinical Investigations, the Massachusetts General Hospital Subcommittee on Human Studies, and the Harvard Pilgrim Health Plan Human Studies Committee.

RESULTS

Evaluable Subjects

From December 1993 to May 1997, 522 subjects were enrolled in the trial. Telephone follow-up was obtained for 494 (95%). The outcomes of the remaining 5% were determined solely by review of the computerized database. Forty-three subjects were ineligible and therefore were withdrawn from the final analysis: 7 were older than 60 months of age; 20 had fewer than three stools in the previous 24 hours; 15 had been enrolled in the trial during a previous bout of diarrhea; and 1 had diarrhea for >7 days before enrollment. Therefore, the final cohort consisted of 479 subjects.

Group Characteristics (Table 1)

On admission to the study, there were no significant differences between the groups in terms of age, sex, duration of illness, frequency of stools, or vomiting. In both groups, 41% of subjects reported using a commercial form of ORS before enrollment. Parent age, employment history, education level, and racial background also were comparable between the groups. Evaluation by the clinician showed that subjects in both groups had similar hydration status on presentation and that both groups had a comparable prevalence of intercurrent illnesses such as respiratory infections or otitis media. The majority of subjects in both groups were considered well enough to be discharged from the office without requiring a follow-up telephone call or appointment for the episode of diarrhea. More subjects in the intervention group received recommendations for ORS than did subjects in the standard group (98% vs 93%; *P* < .002).

TABLE 1. Characteristics on Study Entry

	Standard Treatment (n = 231)	Intervention Group (n = 248)	P Value
Clinical data on presentation			
Age, mo (SD)	19.4 (13.9)	18.5 (13.8)	.49
No. male	132/231 (57%)	152/248 (61%)	.36
Days of diarrhea (SD)	3.2 (1.7)	3.1 (1.7)	.51
Stools in previous 24 h (SD)	6.2 (3.3)	6.4 (3.5)	.42
Vomiting	116/226 (51%)	136/247 (55%)	.42
Breastfed	23/230 (10%)	22/247 (9%)	.92
Used ORS before visit*	94/231 (41%)	101/248 (41%)	.96
Demographic data			
Parent age (SD)	32.8 (6.1)	32.2 (5.8)	.34
Employed outside home	140/225 (62%)	168/245 (69%)	.15
No. children at home (SD)	1.8 (1.0)	1.8 (1.2)	.92
Race (n)	n = 227	n = 243	.41
Alaskan Native	4	1	
Asian	15	12	
African-American	30	44	
Hispanic	29	36	
White	136	138	
Other	13	12	
Subjects attending day care center or preschool	37/229 (16%)	50/246 (20%)	.24
Parents with college degree or higher	117/226 (52%)	117/240 (49%)	.51
Median income for ZIP code (SD)	\$38 698 (10,384)	\$38 958 (10,513)	.80
Clinician assessment			
Normal hydration	177/222 (80%)	189/241 (78%)	.73
No other concurrent illness	156/224 (70%)	148/240 (62%)	.07
No specific follow-up recommended	180/223 (81%)	182/238 (76%)	.27
Recommended ORS use	159/171 (93%)	204/209 (98%)	.002

* ORS was defined as any commercially available oral electrolyte solution designed for fluid replacement in acute diarrhea.

Outcomes

Forty (17.3%) subjects in the standard treatment group sought unscheduled follow-up care for diarrhea versus 27 (10.9%) in the intervention group (RR: 0.63; 95% CI: 0.40–0.99; *P* = .05). The number of patients with unscheduled office visits for diarrhea were 22/231 (9.5%) in the control group versus 15/248 (6.0%) in the intervention group (*P* = .15); those with urgent care or ED visits totaled 22/231 (9.5%) versus 18/248 (7.3%) (*P* = .37). Four subjects were hospitalized after their initial office visit, 2 from the standard group and 2 from the intervention group (Table 2).

The proportion of patients reporting use of ORS at home after the initial office encounter was significantly higher in the intervention group (85% vs 71%; RR: 1.19; 95% CI: 1.08–1.32; *P* < .001). The maximum daily volume and the number of days ORS was used were not different between the groups. No significant differences were found between the groups for the following fluid and dietary practices: use of breast milk, diluted milk or formula, full-strength milk or formula, sports drinks, fruit juices, water, or carbonated beverages. The use of prescription or over-the-counter medicines was infrequent (0%–1% for prochlorperazine, antemotility agents, and

promethazine) and did not differ between the groups.

Out-of-pocket medical expenses (ORS, diapers, other over-the-counter supplies) were \$8.57 (SD: 15.7) in the control group and \$7.75 (SD: 8.52) in the intervention group. In the control group, 65/216 (30.1%) parents reported missing some work because of their child’s illness, versus 83/236 (35.2%) in the intervention group (*P* = .49).

Univariate analysis showed that families of younger subjects, subjects with higher stool frequency, and subjects with more vomiting were more likely to seek unscheduled medical care (Table 3). In addition, the use of ORS before the visit was correlated with unscheduled follow-up care. Parents who assessed their child as being dehydrated, those who cared for their child at home, and those with less formal education were more likely to seek unscheduled follow-up care. Presence of fever, duration of diarrhea, dietary therapy used at home before the visit, parent age, and race were not associated with more frequent unscheduled follow-up care.

Multiple logistic regression analysis was then performed, using the occurrence of unscheduled follow-up visits as the dependent variable. Candidate

TABLE 2. Outcome Data

Patient Outcomes	Standard Treatment (n = 231)	Intervention Group (n = 248)	P Value	RR (95% CIs)	Difference Between Means (95% CIs)
Patients with any unscheduled follow-up	40/231 (17.3%)	27/248 (10.9%)	.05	0.63 (0.40–0.99)	—
Used ORS after initial visit	153/216 (71%)	198/234 (85%)	.001	1.19 (1.08–1.32)	—
Days used ORS after visit (SD)	3.27 (2.1)	3.07 (2.0)	.36	—	0.20 (–0.23–0.64)
Maximum no. of ounces of ORS used per day (SD)	13.4 (11.5)	14.5 (12.8)	.41	—	–1.1 (–3.8–1.57)

TABLE 3. Univariate Analysis of Risk Factors on Study Entry for Unscheduled Follow-up Care

Continuous Variables Mean (SD)	Unscheduled Follow-up (<i>n</i> = 67)	No Unscheduled Follow-up (<i>n</i> = 412)	<i>P</i> Value	Difference Between Means (95% CIs)
Patient age in months (SD)	15.7 (13.7)	19.4 (13.8)	.04	-3.7 (-7.3--0.2)
Stools in previous 24 h (SD)	7.1 (4.0)	6.2 (3.3)	.05	0.9 (0.0-1.8)
Episodes of vomiting in previous 24 h (SD)	4.1 (3.9)	3.0 (2.3)	.02	1.1 (0.2-2.0)
Categorical variables <i>n</i> (%)				RR (95% CI)
Use of ORS before visit	35/67 (52)	143/410 (35)	.006	1.50 (1.15-1.95)
Vomiting before visit	46/66 (70)	206/407 (51)	.004	1.38 (1.14-1.66)
Parent's assessment as dehydrated	17/64 (26)	50/400 (13)	.003	2.13 (1.31-3.44)
Child cared for at home	48/65 (74)	246/410 (60)	.03	1.23 (1.04-1.45)
Parent working outside home	32/64 (50)	276/406 (68)	.005	0.74 (0.57-0.95)
High school diploma or less	37/62 (60)	195/404 (48)	.09	1.24 (0.98-1.55)

variables included those that were significant in the univariate analysis. Because of collinearity, presence or absence of vomiting was entered instead of the number of vomiting episodes. The following independent variables were entered: age, use of ORS before visit, child cared for at home (Y/N), parent's assessment as dehydrated (Y/N), parent with college degree or higher (Y/N), vomiting before visit (Y/N), parent working outside the home (Y/N), and treatment group assignment. As shown in Table 4, the only significant positive risk factors for unscheduled follow-up care in this model were the presence of vomiting on presentation and assessment as dehydrated by parents at first visit. The only significant risk factor associated with reduced need for unscheduled visits was assignment to the intervention group. An OR of 0.75 (95% CI: 0.56-1.00) was noted for this factor, corresponding to a 25% reduction in unscheduled follow-up visits for acute diarrhea.

DISCUSSION

In the setting of 1.5 billion episodes of diarrhea, resulting in 3 to 4 million deaths annually of children younger than age 5,¹¹ the World Health Organization has made ORS one of the cornerstones of its efforts to reduce morbidity and mortality from diarrhea. Multiple clinical trials of ORS have confirmed its safety and efficacy in treating and preventing dehydration and electrolyte disturbances caused by diarrhea.^{12,13} Our trial has confirmed that among ambulatory US children with uncomplicated acute diarrhea, providing ORS to the parents at the time of their initial visit is associated with a significant increase in ORS utilization and reduction in unscheduled follow-up care.

Since diarrheal diseases account for an estimated 2.1 to 3.7 million office visits each year in the United States in children younger than age 5,¹⁴ our findings have significant implications for cost-effective management of these children.¹⁵

Some weaknesses of our study should be acknowledged. Owing to the nature of the intervention, it was an unblinded study; both parents and practitioners were aware of study group assignment. The conduct of the study may have influenced fluid and nutritional prescription practices during all phases of the study, not just in the intervention period. The fact that nearly all enrolling clinicians reported recommending ORS to both groups would tend to confirm this supposition, because previous surveys have suggested that recommendation for ORS use is not universal.⁵ In addition, the frequency of prescription medicine use for acute diarrhea was much less common (0%-1%) than findings from previous surveys have suggested. Finally, our reliance on self-reported use of ORS, in the setting of distributing the ORS at no charge, may have biased this estimate of ORS use.

The characteristics of the study cohort also may have influenced our results. Enrolled children tended to be older than the peak age for rotavirus infection in the United States, although their stool frequency and other measures of illness severity still suggested that they had significant illness. There was a wide range of racial diversity in the cohort, although parents tended also to be older (mean age: 32 years) and well educated (the majority with college education or higher). Because previous studies have linked young maternal age, nonwhite race, and lower socioeconomic status with poorer outcomes in

TABLE 4. Multivariate Analysis of Factors Associated With Unscheduled Follow-up Care

Variable	OR*	95% CI	<i>P</i> Value
Age (mo)	0.98	0.95-1.01	.16
Use of ORS before visit	1.27	0.94-1.71	.12
Out-of-home day care	1.04	0.73-1.49	.81
Parent's assessment as dehydrated	1.49	1.04-2.13	.03
Parent with college degree or higher	0.86	0.64-1.15	.31
Vomiting on presentation	1.38	1.00-1.89	.05
Parent working outside home	0.79	0.57-1.10	.17
Number of stools in previous 24 h on presentation	1.07	0.99-1.15	.10
Randomized to intervention group	0.75	0.56-1.00	.05

* OR for age and number of stools represent increasing odds of unscheduled visits for each month of age and number of stools in previous 24 hours on presentation, respectively.

Model $\chi^2 = 30.171$; 9 df; *P* = .0004.

ORs < 1.00 indicate reduced unscheduled follow-up care.

diarrheal disease, the inclusion of an older, well educated cohort probably biases toward a negative result in the intervention under study. It may well be that poorer, younger, and less well educated families might be especially well served by the provision of ORS at the time of their acute visit. Unfortunately, the lack of detail in the medical history recorded in the HMO database precluded an estimate of the number of patients seen during the study period who were eligible but were not enrolled in the study.

Despite these potential drawbacks, the trial represents a unique evaluation of a prescription practice intervention to positively influence case management of acute diarrhea and subsequent resource utilization. Although parents in the intervention group reported using ORS more frequently than those in the control group, there was no evidence that families used ORS to the exclusion of other foods and fluids or that they used ORS in inappropriately large volumes or for too many days. Although prescription intervention has been widely used in developing countries,¹⁶ to our knowledge, this is the first instance of its use for diarrhea management in an industrialized country.

We found that patients at highest risk for unscheduled follow-up care were younger children and those with more severe illness (as indicated by higher stool frequency, more vomiting, and/or parent assessment as dehydrated). Use of ORS before the initial office visit also was associated with unscheduled follow-up care, although this likely represents an appreciation by the parent of the severity of illness. On the other hand, certain socioeconomic factors also were associated with more unscheduled follow-up care; children cared for at home were more likely to obtain unscheduled follow-up care, whereas children whose parents worked outside the home were less likely to seek such care. Therefore, our results demonstrate that both physiologic and social variables play a role in determining which children will return for unscheduled follow-up care.

How should our results be interpreted in consideration of the recent development of an effective rotavirus vaccine? The tetravalent vaccine has been shown in studies to significantly reduce hospitalizations and office visits for rotavirus diarrhea,¹⁷ and economic analyses of the vaccine also support its cost-effectiveness.¹⁸ Although rotavirus infection is the most common cause of acute diarrhea in children, other causes of gastroenteritis are increasingly appreciated. Because ORS is effective in replacing fluid and electrolyte losses regardless of the etiology of diarrhea, the routine implementation of a rotavirus vaccine would likely not detract from the effectiveness of systematic distribution of ORS. Furthermore, epidemiologic data would suggest that many of the subjects in our study were not suffering primary rotavirus infection, thus emphasizing the utility of ORS as therapy for acute diarrhea of any etiology.

In this randomized, controlled, practice-based trial, we have shown that providing ORS to parents at the time of the initial visit for their child's acute diarrhea is associated with a significant increase in ORS utilization as well as with a marked reduction in

subsequent unscheduled office visits. Multivariate methods accounting for other factors that may have impacted on unscheduled follow-up care showed that the provision of ORS still resulted in a 25% reduction in unscheduled medical care. Because diarrheal diseases account for a sizable proportion of physician visits in this country, these findings support a significant costs savings as well. HMOs should consider routine provision of ORS to infants and children presenting with acute diarrhea.

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