

Caregiver oral rehydration solution fluid monitoring charts versus standard care for the management of some dehydration among Kenyan children: a randomized controlled trial

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Background: Diarrhoea is a major cause of child mortality. Although oral rehydration solution (ORS) is an efficacious intervention for correcting dehydration, inadequate monitoring may limit its effectiveness in routine settings. We evaluated the effect of using a caregiver-administered chart to monitor oral fluid therapy on hydration status among children with some dehydration.

Methods: An open-label randomized controlled trial was conducted among children 2–59 months of age. ORS fluid monitoring charts were given to caregivers in the intervention arm to record the hourly intake of ORS. ORS was administered without charting in the control arm. The primary outcome was dehydration defined by the presence of clinical signs of some dehydration, severe dehydration or shock assessed 4 h after initiation of treatment. We also assessed the acceptability of the charts among caregivers.

Results: We evaluated 252 patients for the primary endpoint. Among those who received the intervention, 7/122 (5.7%) were still dehydrated following 4 h of ORS administration vs 20/130 (15.4%) in the control group (risk ratio 0.37 [95% confidence interval 0.16–0.85]). Caregivers in the intervention arm reported positive experiences using the fluid charts.

Conclusions: The use of fluid monitoring charts reduced the frequency of dehydration and was well accepted by caregivers, representing a promising innovation for the management of diarrhoea and dehydration in resource-limited settings.

Keywords: acute diarrhoea, caregiver, children, oral rehydration solution, ORS fluid charts, RCT, some dehydration

Introduction

Acute diarrhoeal disease remains a leading cause of child morbidity and mortality worldwide, accounting for approximately 500 000 annual deaths.¹ In low- and middle-income countries, a high incidence of risk factors such as poor sanitation, vitamin A deficiency and suboptimal breastfeeding contribute to the high burden experienced. The initial step in the management of acute diarrhoea according to the World Health Organization (WHO) Integrated Management of Childhood Illnesses (IMCI) guidelines is classification of the degree of dehydration using clinical signs followed by management based on the level of dehydration (Figure 1).² Poor access to timely, effective and correct treatment with oral rehydration solution (ORS) and zinc are

important factors linked to poor outcomes in resource-limited settings.^{1,3,4}

ORS is a well-established, safe intervention for managing dehydration in children that is promoted by the WHO and the United Nations Children's Fund under the Integrated Global Action Plan for Prevention and Control of Pneumonia and Diarrhoea among the high-impact strategies for child survival.^{4,5} Despite its efficacy (estimated in a recent review to prevent 93% of diarrhoea-related deaths)⁶ and wide availability, mortality and admissions due to complications of diarrhoea remain high.¹ Factors that influence outcomes among patients receiving ORS include the rate of intake, the presence of vomiting and the frequency of diarrhoeal episodes. Interventions to improve monitoring of appropriate intake of ORS are surprisingly lacking.

Clinical signs	Classification	Initial management
<div>All four of<ul style="list-style-type: none">Weak/absent pulseAVPU < ACold hands + temperature gradientCapillary refill > 3 secPLUS:<ul style="list-style-type: none">Sunken eyesSlow skin pinch</div>	Hypovolaemic shock	<i>Admit for emergency IV fluid therapy</i>
<div><ul style="list-style-type: none">Unable to drink or AVPU<APLUS:<ul style="list-style-type: none">Sunken eyesReturn of skin pinch ≥ 2 sec</div>	Severe dehydration	<i>Admit for emergency IV fluid therapy</i>
<div><ul style="list-style-type: none">Able to drink adequately but ≥ 2 of:<ul style="list-style-type: none">Sunken eyesReturn of skin pinch 1–2 secRestlessness / irritability</div>	Some dehydration	<i>Oral rehydration under observation over 4 hours. Reassess for improvement</i>
<div><ul style="list-style-type: none">Diarrhoea with <2 of:<ul style="list-style-type: none">Sunken eyesReturn of skin pinch 1–2 secRestlessness / irritability</div>	No dehydration	<i>Oral rehydration at home</i>

Figure 1. Table showing World Health Organization classification of dehydration due to diarrhoea and the management at each level.

The literature on efforts to improve the intake of ORS focuses on health workers recording the volume and rate of intake.^{7,8} An example of this is a study done by Doan et al.⁷ at British Columbia Children’s Hospital. The objective of this study was to measure the impact of implementing an oral rehydration clinical pathway using standard nursing assessment forms and instructions on the use of ORS to be initiated and maintained by caregivers. This resulted in a reduced need for intravenous rehydration and a reduction in the length of outpatient visits and hospital admissions.⁷ We found no published studies in which caregivers were involved in charting ORS intake, which would be more practical in low-income countries where the burden of diarrhoea is high and inadequate numbers of health care personnel are unable to provide the monitoring that is required. We hypothesize that a missing link to address sub-optimal use of ORS and poor monitoring is a tool to actively involve caregivers in the management of children receiving ORS. This study may also improve the knowledge and skills of caregivers in the management of diarrhoea and dehydration, which is one of the key community components of the IMCI strategy.² We also hypothesize that the findings of this study may have the potential to reduce unnecessary admissions to hospitals where resources and health care personnel are already constrained.

The purpose of this study was to evaluate the effect of a caregiver-administered fluid monitoring chart on hydration status among children with acute diarrhoea who fulfil the WHO clinical definition of ‘some dehydration’ (equivalent to mild or moderate dehydration).

Materials and methods

Study design

An open-label, parallel group, randomized controlled trial was conducted to compare hydration status after 4 h of ORS administration between children randomized to the use of ORS fluid monitoring charts vs controls. We used in-depth semi-structured interviews to assess the acceptability of ORS fluid monitoring charts by the caregivers.

Study setting

The study was carried out among caregivers and their children in the paediatric outpatient department at Mbagathi District Hospital, Nairobi County, Kenya. Nairobi is the most populous

county, with census projections estimating a population of 4.4 million in 2018, of whom approximately 540 000 are <5 y of age.⁹ Data from the most recent national demographic survey reported literacy rates (defined as attendance of secondary school or higher and ability to read a whole sentence or part of a sentence) of 96.5% among women residing in the county.¹⁰ The study hospital is a busy public district-level health facility that attends to a predominantly low-income population. Approximately 1000 children <5 y of age present with acute diarrhoea each year. The paediatric inpatient bed capacity is 32, with bed occupancy consistently exceeding 100%. The outpatient department is run by two registered paediatric clinical officers, two nurses and one nutritionist per shift. It has an ORS room where children with acute diarrhoea are managed and where monitoring of administration of ORS is done by one nutritionist under the supervision of one nurse.

Sample size determination

In a recent survey done at the study hospital, 30% of children <5 y of age with some dehydration secondary to acute diarrhoea were eventually admitted (unpublished data). A sample size of 134 children per arm would provide 80% power to detect a relative reduction in the proportion of admissions related to some dehydration of 50% at a 5% significance level.

Eligibility criteria

Children 2–59 months of age with acute diarrhoea and some dehydration as defined in the WHO² and Kenya guidelines¹¹ were enrolled in the study after informed consent was obtained from the accompanying caregiver. Caregivers in the study setting are typically the primary guardians (mostly mothers or other close female relatives) who accompany the patient to the hospital seeking treatment. Generally caregivers have little or no knowledge of the correct medical management of dehydration. In this study, caregivers were required to be able to read and write. Children with severe acute malnutrition, dysentery, severe dehydration or shock and children with comorbid conditions requiring inpatient management were excluded from the study.

Randomization procedure

Patients and their caregivers were randomly assigned in a 1:1 ratio to the use of caregiver ORS fluid monitoring charts vs standard care (no charts). Randomization was carried out by an independent statistician using a computer-generated allocation sequence in variable block sizes of 6–10 per block. Allocation was concealed by sequentially numbered sealed opaque envelopes that were opened only after patients and their caregivers had satisfied all the enrolment criteria for the study, including provision of written informed consent.

Study procedures

All children 2–59 months of age presenting with acute diarrhoea were screened for eligibility daily by the study team between 08:00 and 22:00 h and those whose caregivers consented were consecutively enrolled in the study. Sociodemographic data

were obtained by interview, and clinical attributes determined by history and physical examination for all subjects. Those enrolled were then randomized to receive the ORS fluid monitoring chart (intervention arm) or standard care (control arm). Instructions were provided to caregivers in both study arms on the use of ORS for the management of some dehydration, including the volume and rate of administration of ORS, in line with WHO and national guidelines (Supplementary Figure 1).^{2,11} This constituted administration of ORS at a volume of 75 ml/kg over a 4 h period given as frequent sips from a cup (children ≥2 y of age) or by cup and spoon (children <2 y of age) (Supplementary Figure 1).^{2,11} Following 4 h of treatment, subjects in both arms were reassessed by an experienced clinician independent of the study team for signs of dehydration and reclassified as per the WHO classification for dehydration (Figure 1).^{2,11} Appropriate management, including the decision for hospitalization, was then instituted.

Intervention (caregiver ORS fluid monitoring chart)

Caregivers in the intervention arm received further instructions on how to complete the ORS fluid monitoring chart (Figure 2). The chart was formulated based on the concept of other established clinical feeding charts and modified to provide for the assessment and monitoring of ORS administration in the outpatient setting by a lay caregiver. The chart captures the volume of fluid required, the actual amount given to the child and the frequency of vomiting and diarrhoea on an hourly basis. In the event that the child did not meet the fluid intake requirement for that hour, the caregiver was required to increase fluid intake to make up for the deficit in order to catch up and achieve the required volume in the stipulated 4 h. Semi-structured in-depth interviews consisting of open-ended questions were carried out on a subset of caregivers in the intervention arm to assess the acceptability of the ORS fluid monitoring charts. These caregivers were recruited by purposive sampling to represent 10% of the sample size. Respondents were selected during periods when the patient numbers in the outpatient department were relatively low. We also avoided selecting caregivers who appeared outwardly distressed as to facilitate the collection of detailed and objective responses.

Outcome variables

The primary outcome variable was the frequency of dehydration following 4 h of treatment with ORS. We also assessed the acceptability of ORS fluid monitoring charts, which was broadly categorized into positive or negative caregiver responses.

Data analysis

Primary analyses were by intention to treat. Data on baseline characteristics were summarized by study arm. The statistical tests used were χ^2 or Fisher's exact test for categorical variables and Mann–Whitney U test for continuous variables. The proportion of children dehydrated after 4 h and the level of dehydration (shock, severe dehydration, some dehydration) were compared between the intervention and control arms. Risk ratios (RRs) with

Patient's Number

001

Age (months)

4

Sex

M

F

Current weight (kg)


6.3kg

Date

14. Nov. 2014

Instructions

470 ml ORS over 4 hours
(120 ml ORS each hour)



Time

Sunken eyes

Skin pinch (sec)

Irritability

Inability to drink

Consciousness level

Weak pulses

Capillary refill time (sec)

Cold peripheries

0 Hr

☒

N

1

☒

N

☐

Y

☒

☒

V

P

U

☐

Y

☒

2

☐

Y

☒

4 Hr

☐

y

☒

0

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N

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Y

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☒

V

P

U

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Y

☒

2

☐

Y

☒

Hydration status at 4 hours

☒ No dehydration

☐ Some dehydration

☐ Severe dehydration

Clinical outcome

☐ Admitted

☒ Discharged

Time in hours (since initial review)	Amount of ORS to be given (ml)	Amount of ORS given (ml)	Amount of ORS remaining (ml)	Number of episodes of vomiting	Number of bowel motions
0	120	120	0	0	2
1	120	110	10	0	0
2	130	130	0	1	1
3	120	120	0	0	0

Figure 2. ORS caregiver fluid monitoring chart. A simple chart containing columns for recording the amount of ORS to be given, amount of ORS given, amount of ORS remaining and the number of episodes of vomiting and diarrhoea. It also has a section for the clinician to record the clinical signs before and after treatment.

accompanying 95% confidence intervals (CIs) were computed. A continuity correction of 0.5 was added to each cell in the analysis of outcomes with zero events.¹² To assess the acceptability of the caregiver ORS fluid monitoring charts, information extracted from the Dictaphone was transcribed and grouped into themes for analysis. Stata version 13.0 (StataCorp, College Station, TX, USA) was used for all quantitative analyses.

Results

Description of study subjects

Between 22 July 2014 and 15 January 2015, of the 318 patients assessed for eligibility, 268 were enrolled, of which 134 were randomized to each arm. Sixteen patients (12 in the ORS fluid monitoring chart arm and 4 in the standard care arm) withdrew from the study due to time constraints and opted to continue with ORS administration at home. The remaining 252 patients

(122 in the fluid chart arm and 130 in the standard care arm) were assessed for the primary endpoint (Figure 3).

Baseline characteristics were comparable between the two groups. The median age for the study participants was 12 months (interquartile range [IQR] 8–18 months) in the fluid chart arm and 12 months (IQR 8–15 months) in the standard care arm. Male children comprised 149/268 (55.6%) of the patients recruited, 70/134 (52.2%) in the fluid chart arm vs 79/134 (59%) in the standard care arm (Table 1).

A total of 95/134 (70.9%) caregivers in the fluid chart arm compared with 80/134 (59.7%) in the standard care arm had completed secondary level education and above (p=0.06). Receipt of primary preventive measures and treatment administered prior to seeking care at the hospital were comparable between the two study arms: 14/89 (15.7%) children in the intervention group vs 12/85 (14.1%) controls had received more than one dose of rotavirus vaccine. Of those who had received prior antiemetic treatment, 11/134 (8.2%) were in the intervention arm vs 10/134 (7.5%) controls. We also noted that 37/134

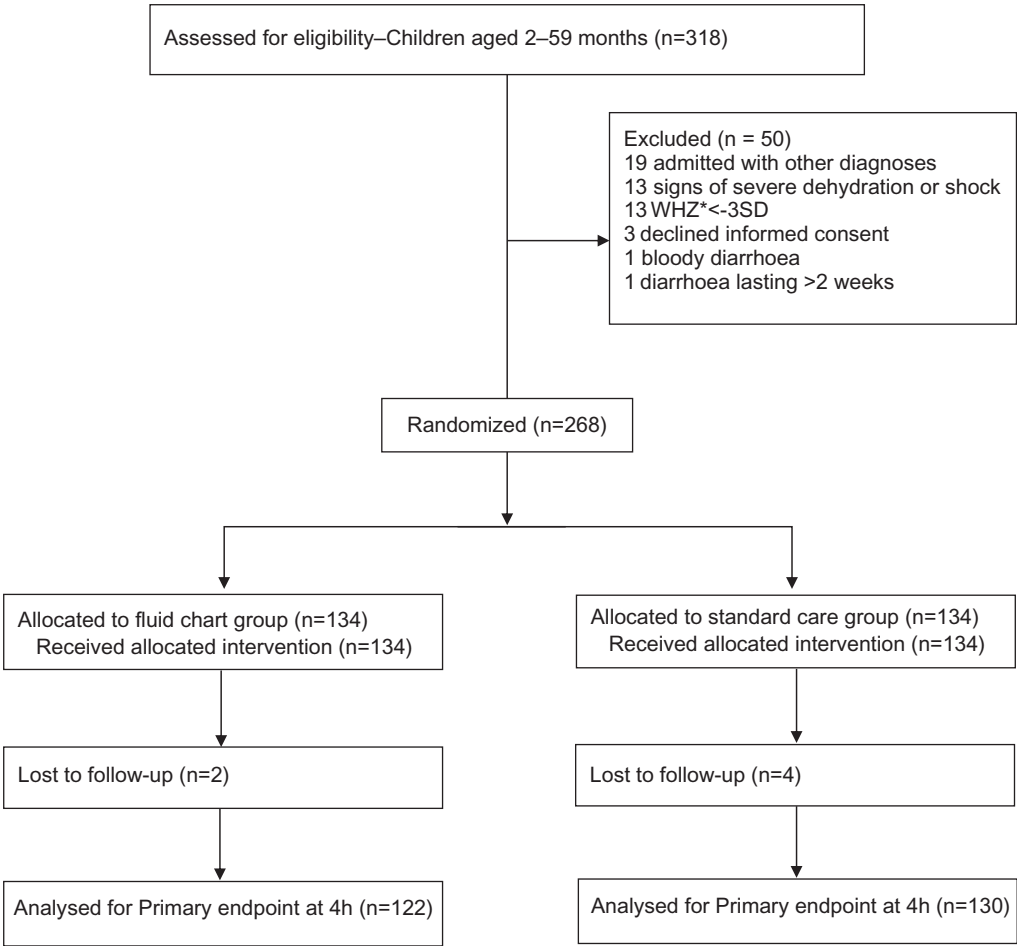


Figure 3. Flow chart showing participant selection with exclusions on case criteria. Of the 318 patients assessed for eligibility, 50 were excluded because they did not meet the inclusion criteria. These eligibility criteria included children 2–59 months of age with acute diarrhoea and some dehydration as defined in the WHO and Kenya guidelines as well as informed consent from the caregivers. The caregivers were also required to be able to read and write. It also highlights patients lost to follow-up who voluntarily left the study due to time constraints and who opted to continue with ORS administration at home.

(27.6%) participants in the intervention arm vs 39/134 (29.1%) controls had received antibiotics for treatment and that 36/134 (26.9%) children in the intervention arm vs 40/134 (29.9%) controls had received zinc sulphate (Table 1).

Risk of dehydration comparing intervention and control groups

Overall 27/252 (10.7%) patients recruited were admitted for further care. In the intervention arm 7/122 (5.7%) children were dehydrated compared with 20/130 (15.4%) in the control arm (0.37 [95% CI 0.16–0.85], $p=0.01$) (Table 2).

A total of 7/122 (5.7%) patients were classified as having severe dehydration at 4 h compared with 7/130 (5.4%) in the standard care group (RR 1.07 [95% CI 0.38–2.95], $p=0.90$). No patients were classified as having some dehydration at 4 h in the fluid chart group compared with 13/130 in the standard care group (10%) (RR 0.04 [95% CI 0.00–0.66], $p=0.02$) (Table 2). No patients had shock following 4 h of treatment (Table 2).

We tested the sensitivity of the results under alternative assumptions of differential loss to follow-up. Under the first assumption, all those who were lost to follow-up remained dehydrated after 4 h of treatment and therefore required hospitalization. Although the direction of effect remained in favour of the intervention group, the effect estimate was not statistically significant (RR 0.79 [95% CI 0.46–1.38]). Under the assumption that all of those lost to follow-up recovered after 4 h of treatment, the effect was consistent with the observed outcome (RR 0.35 [95% CI 0.15–0.80]) (Table 3).

Assessment of acceptability of ORS fluid monitoring charts to caregivers

Fifteen caregivers were interviewed for acceptability of ORS fluid charts. A total of 12/15 (80%) caregivers assessed in the fluid chart arm reported that the fluid charts were beneficial, easy to understand and allowed them to participate in the child’s management. The remaining 3/15 (20%) reported that they were

Table 1. Baseline characteristics of study participants

Characteristic	Fluid chart	Standard care	p-Value
Age (months), median (IQR)	12 (8–18)	12 (8–15)	0.51
Female	64/134 (47.8)	55/134 (41.0)	0.27
WHZ < -1 SD ^a	61/134 (45.5)	61/134 (45.5)	1.0
Caregiver's education (secondary and above)	95/134 (70.9)	80/134 (59.7)	0.06
Caregiver's age (y), median (IQR)	26.0 (23–29)	25.5 (23–28)	0.72
Treat domestic drinking water ^b	91/134 (67.9)	92/134 (68.7)	0.90
Exclusively breastfed for first 6 months	79/132 (59.8)	77/133 (57.9)	0.89
Received ≥1 dose of rotavirus vaccine	14/89 (15.7)	12/85 (14.1)	0.77
Duration of diarrhoea (d), median (IQR)	3 (2–4)	3 (2–4)	0.95
History of vomiting	104/134 (77.6)	109/134 (81.3)	0.45
≥1 comorbidity	48/134 (35.8)	50/134 (37.3)	0.80
Prior treatment with ORS for current illness	75/134 (56.0)	77/134 (57.5)	0.81
Prior treatment with antiemetic	11/134 (8.2)	10/134 (7.5)	0.82
Prior treatment with anti-diarrhoeal medication	4/134 (3.0)	2/134 (1.5)	0.41
Prior treatment with antibiotic	37/134 (27.6)	39/134 (29.1)	0.79
Prior treatment with herbal medication	2/134 (1.5)	5/134 (3.7)	0.25
Prior treatment with zinc sulphate	36/134 (26.9)	40/134 (29.9)	0.59
Previous admission due to diarrheal illness	22/134 (16.4)	24/134 (17.9)	0.75
Any prior experience using ORS	91/134 (67.9)	94/134 (70.2)	0.69

Values presented as n/N (%) unless stated otherwise.

^aWHZ: weight-for-height Z score relative to WHO reference growth standards.

^bTreatment of domestic drinking water using any one of a range of possible alternatives, including boiling, chlorine-based solution and activated carbon filter.

Table 2. Risk of dehydration and degree of dehydration at 4 h comparing fluid chart and standard care groups

Outcome	Fluid chart (n=122), n (%)	Standard care (n=130), n (%)	RR (95% CI)	p-Value
Dehydration present at 4 h	7 (5.7)	20 (15.4)	0.37 (0.16–0.85)	0.01
Degree of dehydration				
Shock	0	0	1.07 (0.02–53.27)	0.96
Severe dehydration	7 (5.7)	7 (5.4)	1.07 (0.38–2.95)	0.91
Some dehydration	0	13 (10.0)	0.04 (0.00–0.66)	0.02

Table 3. Sensitivity analysis for risk of hospital admission based on alternative assumptions of differential loss to follow-up

Outcome	Fluid chart, n/N (%)	Standard care, n/N (%)	RR (95% CI)	p-Value
Observed outcome	7/122 (5.7)	20/130 (15.4)	0.37 (0.16–0.85)	0.01
All those LTFU dehydrated at 4 h	19/134 (14.1)	24/134 (17.9)	0.79 (0.46–1.38)	0.41
All those LTFU rehydrated at 4 h	7/134 (5.2)	20/134 (14.9)	0.35 (0.15–0.80)	0.01

LTFU: lost to follow-up.

not beneficial and were time consuming. Among the quotes from the caregivers who were interviewed were:

Caregiver 1: *'It helped me give ORS, to know amount to give and I was able to see my child's progress'.*

Caregiver 2: *'It was well organized, easy to understand, taught me how to give ORS using time and allowed for monitoring'.*

Caregiver 3: *'We should be given the fluid monitoring charts to go home with to use when the child has diarrhoea'.*

Caregiver 4: *'Using the chart was time consuming'.*

Discussion

In this study conducted in a district hospital in Kenya, the use of the caregiver ORS fluid monitoring charts resulted in a 63% reduction in the frequency of dehydration requiring hospitalization in children presenting with acute diarrhoea. This reduction in dehydration is substantial and, if replicable in other settings, is likely to have a significant effect at the population level. In the hospital where the study was conducted, diarrhoea was responsible for approximately 25% of all admissions between September 2011 and August 2013. Based on our findings, it can be postulated that the use of caregiver fluid monitoring charts may result in a 15% reduction in all-cause admissions at this facility.

The mechanism by which ORS fluid monitoring charts were effective may include involvement of the caregiver in close monitoring and written feedback on the progress towards rehydration of the child. In so doing, the charts mandated caregivers to pay closer attention and give smaller quantities of fluid in shorter time intervals coupled with instructions on increasing fluid intake to make up for deficits. Fluid charts are also likely to have resulted in a closer interaction between health providers and mothers, which is likely to be beneficial. The duty of monitoring fluid intake for sick children in outpatient clinical settings should ideally be the task of a health care worker. In settings experiencing acute health workforce crises, this form of delegation presents an opportunity to free up clinical and nursing time for more specialized duties. In Kenya, the nursing shortage is particularly pronounced, with a ratio of nurses to patients of 49 per 100,000 population compared with 143 nurses per 100,000 population recommended by the WHO.¹³ The fact that sick children presenting to hospitals are generally accompanied by a caregiver provides an innovative, scalable framework for implementation of our findings. While task shifting has been widely described among skilled and semi-skilled health care workers,^{14–18} further research is needed on the effectiveness and safety of this approach when applied to caregivers and other laypersons.

To our knowledge this is the first study that provides evidence that using a simple monitoring tool to promote partnership and involvement of caregivers in their sick children's care can improve the outpatient management of some dehydration. Previous studies have used health care workers to monitor ORS administration with similar effects, including a reduction in admissions and hospital costs.^{7,8} However, these studies were conducted in high-income settings where adequate numbers of health care workers are available for monitoring, which limits generalizability to most resource-limited settings.

We postulate that the effect of the intervention on the outcome would have been even more pronounced if the study was performed at the community level, where clinical guidelines are not available as the standard of care. A possible approach to scaling up the use of the charts may involve integration of the charts within the standard health promotion material provided to caregivers during routine maternal and child health clinics. The potential impact of cascading the intervention to the community level is particularly relevant in settings such as Kenya, where more than 40% of diarrhoea cases do not seek care in health facilities.¹⁰

The reduction in the rates of dehydration requiring hospitalization associated with this study intervention has further potential economic and clinical benefits. An observational study of 172 children 0–35 months of age admitted to a tertiary hospital in Kenya estimated the cost of inpatient care per child with diarrhoea at US\$65.05 to the patient, US\$141.78 to the hospital and US\$165.56 to the society/economy,¹⁹ which markedly exceeds the average outpatient cost of an estimated US\$5 at most district hospitals.

We found a high rate of acceptability for the fluid charts by the caregivers, with the majority reporting that the charts were beneficial, easy to understand and allowed them to see the child's progress. This may be due to the fact that the chart was purposefully designed for lay caregivers with relatively low levels of education. It is important to note, however, that a few caregivers reported that the fluid charts were time consuming, suggesting the need for further work to explore ways to enhance acceptability of the charts.

The strengths of the study include the randomized design, which controlled for both known and unknown confounders. There was weak evidence of a difference in the level of education of the caregivers between the two study groups. We explored potential confounding by this variable on the effect of treatment on the outcome in adjusted analyses. The resulting estimated treatment effect was similar to that observed in the unadjusted analyses (RR 0.37 [95% CI 0.16–0.85]). Literacy in Nairobi is also generally high, exceeding 95% among women in the most recent national demographic survey.¹⁰ The patients in the study received the allocated intervention as assigned and there was also good follow-up for the primary outcome. Assessment of the primary outcome and the decision to admit following reassessment was made by an experienced clinician independent of the study team, thereby mitigating against potential reporting bias. The inclusion of a qualitative aspect to obtain caregivers views on the charts is an additional strength.

Sensitivity analyses under the assumption that all children who were lost to follow-up would have ultimately required hospitalization suggested a lack of effect of the intervention. However, we argue that this scenario was unlikely since the main reason for withdrawal was informally determined to be impatience among caregivers who felt their children were not 'sick enough' to require observation in the hospital for 4 h. We feel the true treatment effect was closer to the alternative scenario, whereby all those who withdrew ultimately recovered. It is reassuring to note the direction of effect under both assumptions was consistent with the observed outcome, favouring those who received the intervention.

Limitations of this study include a lack of blinding in determination of outcomes and convenience sampling between 08:00 and 22:00 h, which may exclude sicker patients who tend to present to the hospital at night.²⁰ As the study was carried out in a setting where literacy rates are reported to be greater than 95%, we designed the caregiver ORS fluid monitoring chart in English and specifically for literate caregivers. This may limit generalizability of the tool to low-literacy populations. Possible adaptations for scaling up the implementation of this chart to non-English-speaking caregivers may include translation to local languages or modification to incorporate contextually appropriate pictorial instructions in place of text. Due to the nature of the intervention, it was not possible to blind the study team and caregivers to the use of the fluid monitoring chart. We also note that spilling and vomiting of ORS during administration may have occurred during the study, thus posing a problem in determining the amount of ORS administered with absolute accuracy. However, we opted for this pragmatic approach purposely to mimic real-world settings where the intervention would ultimately be implemented.

Another limitation was potential contamination arising from caregivers in the control group adopting the practices of those in the intervention arm. We attempted to minimize this by restricting the two groups to separate rooms. Further, the effect of crossover of this nature would suggest that the findings observed are an underestimation of the true effect of the intervention. For borderline severe cases that fulfil the clinical definition for some dehydration, the treatment effect associated with use of the charts is likely to be less pronounced since the caregivers would be keen to observe the recommended schedule for fluid administration in a child with visible signs of dehydration regardless of the availability of a monitoring chart. The effectiveness of the chart may therefore be argued to be restricted to children along the milder end of the spectrum of the WHO definition for 'some dehydration'. However, it must also be noted that those with milder forms of illness generally represent the majority of outpatient consultations. Due to limited resources to conduct the study, it was not possible to obtain follow-up data for study participants beyond the primary endpoint (and discharge for those admitted). It is therefore not possible to confidently report on the late outcomes of those who were not hospitalized. As a modest-sized single-centre study, these findings need to be validated in larger trials and in different settings in order to provide high-quality evidence to inform policy decision making.

Overall, however, this study provides useful evidence demonstrating that caregivers can play an important role in the management of childhood diarrhoea in outpatient settings. If implemented alongside other proven interventions, including water sanitation and hygiene (WASH), rotavirus vaccination, vitamin A supplementation, exclusive breastfeeding, community case management and general health systems strengthening, it may contribute towards reducing morbidity and mortality secondary to diarrhoeal disease.

Supplementary data

Supplementary data are available at *International Health* online (<https://academic.oup.com/inthealth>).

Authors' contributions: MK and AA conceived the study. MK, DW, NK, AL and AA participated in the design of the study and the collection and interpretation of data. MK produced the initial draft of the manuscript that was further developed by DW, NK, AL and AA. All authors reviewed and approved the final version of the manuscript.

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Competing interests: None declared.

Ethical approval: The study was conducted after obtaining approval from the Kenyatta National Hospital/University of Nairobi Ethics Research Committee (KNH-ERC/A/160) and Mbagathi District Hospital Ethics Research Committee. Written informed consent was obtained from caregivers prior to enrolment and participants were informed of their right to withdraw from the study at any stage without penalty.

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