A Preliminary Report

Effectiveness of expanded delivery mechanisms/ channels and empowerment of caregivers in improving access of ORS and Zinc in Narok County, Kenya

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1.0 INTRODUCTION

1.1 Background and Problem Statement

Millennium development goal 4 calling for a reduction of child deaths by two thirds by 2015 up from the 1990 levels is unlikely to be achieved in Africa. Pneumonia, diarrhoea and malaria account for more than 50% of deaths of children under five years of age. Africa and Asia account for nearly 90% of child deaths due to pneumonia and diarrhoea, and diarrhoea alone causes about 11% of all child deaths (UNICEF, 2012). In communities with poor hygiene and sanitation practices, young children may suffer over 6 to 10 episodes of diarrhoea per year. In Kenya diarrhoea contributes to over 20% of under five year old child mortality and severe childhood diarrhoea (MOPHS, 2010). This is in spite of childhood diarrhoea being highly amenable to prevention and early management through breastfeeding, good hygiene practices and use of low osmolarity Oral Rehydration Salts (ORS solution) and Zinc supplementation to avoid severe illness and death. A cluster randomized study in Bangladesh reported that children having Zinc supplementation had a shorter duration and lower incidence of diarrhoea than children in the comparison group (Baqui *et al*, 2010). Access to correct information on home management of childhood diarrhoea and to ORS and Zinc at community level remains one of the bottlenecks to effective implementation of this life saving commodities. This problem has its highest impact in hard to reach communities.

According to the Kenya demographic health survey, only 39% of children with diarrhoea received ORS treatment (KNBS *et al*, 2010). Approximately, 80% of mothers knew about ORS. There is erratic supply of ORS in the health facilities and not all children with diarrhoea seek treatment at the health facilities. A decline in use of ORT corners in health facilities is also supported by previous Demographic Health Surveys. Further, although Zinc was introduced for treatment of diarrhoea in 2007 in Kenya, less than 1% of children were receiving Zinc supplements (KNBS *et al*, 2010) - this has however increased to 8% (KNBS *et al*, 2014). Two reasons explain this low usage: Zinc has not been made available at facilities uniformly, and the health personnel may have not been adequately updated on use of Zinc in diarrhoea case management. Problems exist with the supply chain, skills at health facility level, and knowledge and practices in communities.

There is an urgent need for a revamped supply chain system for ORS and Zinc for health facilities and CHVs. Further, mothers and caregivers at the community level need to be empowered to treat children with diarrhoea with ORS and Zinc. The static health facilities are

the main sources of ORS and Zinc in communities in Kenya. Other potential channels of increasing supply of ORS and Zinc at the community level in a revamped supply chain include, local shops and kiosks, the public transport network, local schools, traditional healers and faith based institutions among others. Evidence accumulated from the 70s to today suggest that use of social marketing approaches could play a key role in increasing supplies of ORS and Zinc at community level (Green, 1986; Karen, 1988; Boggs *et al*, 2007). This has to be combined with additional sources of information on use of ORS and Zinc, including local radio stations, print media, local community organisations and groups, and official channels.

This research tested innovative mechanisms of distributing ORS and Zinc and strengthening the capacity of mothers to access and use ORS and Zinc to improve the treatment of children under five years with diarrhoea. The Narok South Sub-County, Narok County was purposively selected based on the challenges experienced in its health service coverage, latrine coverage, access to safe water, and high incidence of childhood diarrhoea. Amref Health Africa implemented this study in collaboration with the Ministry of Health and Micronutrient Initiative. The research study was conducted between January 2013 and February 2015 with financial support by Micronutrient Initiative (MI) and Amref Health Africa.

1.2 Research Question and Objectives

Research Question

Can implementation of an innovative mechanism for increasing mother's access to ORS and Zinc and empowering mothers to use them appropriately, lead to at least a 20% increase in the proportion of children with diarrhoea who receive ORS and Zinc compared to routine programme implementation?

Objectives

Objectives

a) To assess the effect of innovative mechanisms for distributing ORS and Zinc using non-health channels on proportion of children who receive ORS and Zinc compared to routine programme implementation, and;

b) To establish the effect of the intervention on the mother's knowledge, attitudes and practices on diarrhoea treatment

1.3 Narok South Sub-County

Narok South Sub-County has a population of 379,327 including 73,000 children under five years of age. Various ethnic groups are spread across Narok South Sub-County. About 70% of the population is Maasai, about 30% from Kipsigis and other ethnic groups. Administratively, the Narok South Sub-County has 5 divisions, 24 locations and 75 sub-locations. There are 41 health facilities spread across the Sub-County. These facilities are on average more than 10kilometers apart compared to the 5kilometers stated in the policy. The road network is poor. The water sources are inadequate leading to poor hygiene and sanitations resulting in high incidence of diarrhoeal diseases. Livestock keeping is the main economic activity, some areas practicing mixed farming including food crop and horticulture farming. The community health strategy has only partially been implemented in this Sub-County, covering 18 out of 75 community health units (CHUs). The following are the key health indicators: crude birth rate is estimated at 11 per 1,000 live births, population growth rate of 3.6%, infant mortality rate of 52 per 1,000 births, and childhood diarrhoea ranked third top ten diseases.

2.0 METHODOLOGY

2.1 Research design

This is a cluster randomised controlled study (cRCT), which may also be known as cluster randomised trial (Campbell *et al*, 2004), group-randomised trial (Murry *et al*, 2004; Patton *et al*, 2006), or place-randomized trial (Boruch *et al*, 2004). In this design groups of subjects (as opposed to individual subjects) is randomised (Bland, 2004). In this study the sub-location was used as the unit of randomization and subsequently randomly assigned to either the intervention or the control group using stratified random allocation. The investigators chose the cluster randomised control study design as the most suitable because of its rigor and ability to minimize bias in a community based study setting. The health system interventions are difficult to implement at the individual level but the design allows group or community randomisation.

Narok South Sub-County has 75 sub-locations. At the time of study, only 18 sub-locations had fully established CHUs as defined in the government community health strategy. To control for any bias, half of the clusters came from each of the two types of sub-locations – with an established CHU and without an established CHU. The sample of sub-locations for the study was drawn through the following steps:

1. Exclusion of ineligible sub-locations
2. Remaining sub-locations were be categorized by whether they have a CHU or not
3. The sub-locations in each group were then selected using simple random sampling so that each category provides 50% of the total required sample size
4. The total sample size of the clusters and individual interviews was determined using the steps explained in Appendix 1.
5. The selected sub-locations were then randomly allocated to the intervention and comparison groups

Based on the community randomization comparison of two risks (proportions) formula (Hayes and Benett, 1999), 22 clusters and 500 children under five years (in each cluster) were the computed sample size of clusters and children under five years respectively about whom information was solicited during both the baseline and the end-line survey. The described sampling design is illustrated in the diagram shown as Figure 1.

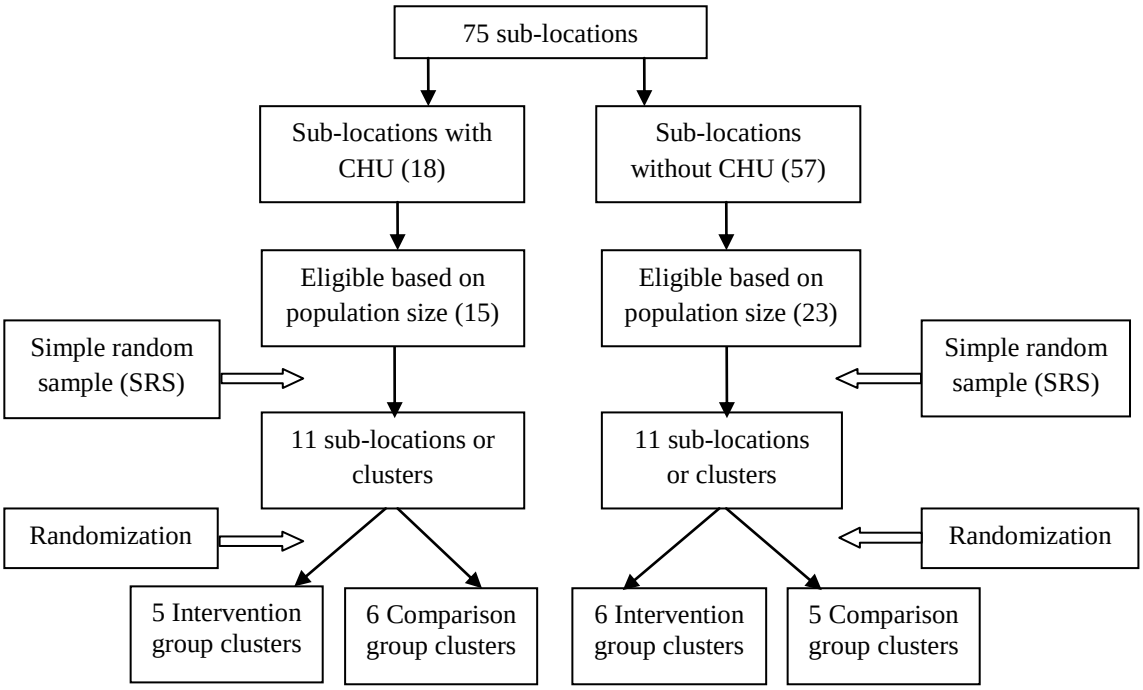

Figure 1: Sampling design for the survey

2.2 Study Population

The primary participants of this study are children under the age of five with or without diarrhoea and their mothers or primary caregivers in clusters selected for inclusion in the study. Also included are health facility workers, community leaders and other informants including school teachers and administrators, private sector business people, religious leaders and traditional healers.

2.3 Intervention

In order to achieve the study objectives, the intervention package was designed and covered the following:

1) *Linkage to an ORS and Zinc manufacturer or large distributor:* A linkage was established with COSMOS, a manufacturer of ORS and Zinc. This pharmaceutical company addressed the packaging needs of the study by having the single dose packaging of ORS and Zinc required for treatment of one episode of diarrhoea (2 ORS sachets and 10 tablets of 20mg each of Zinc).
2) *Innovative outlets for ORS and Zinc distribution end points:* The study tested the use of shop and kiosk owners, schools and Faith based organizations as ORS and Zinc co-packs distribution end points from where mothers and caregivers would obtain doses whenever the child were sick from diarrhoea.
    i. *Shop and kiosk owners:* A total of 74 shop and kiosk owners from the 11 intervention clusters were recruited and trained. A purchase price of Kshs 50 per dose (equivalent to 0.5 USD) paid by caregivers included a small profit margin *(of Kshs 10 or 0.1 USD).*
    ii. *Schools:* All schools in the intervention clusters were automatically enrolled and 62 school teachers trained on the use of ORS and Zinc in childhood diarrhoea treatment. Each school was an outlet and had a teacher designated to be responsible for storage and distribution of ORS and Zinc.
    iii. *Faith based institutions – churches and mosques:* 93 FBOs representatives were identified and trained on use of ORS and Zinc in treatment of childhood diarrhoea.

The illustration in Figure 2 summarizes the various sources of ORS and Zinc in any of the study intervention cluster.

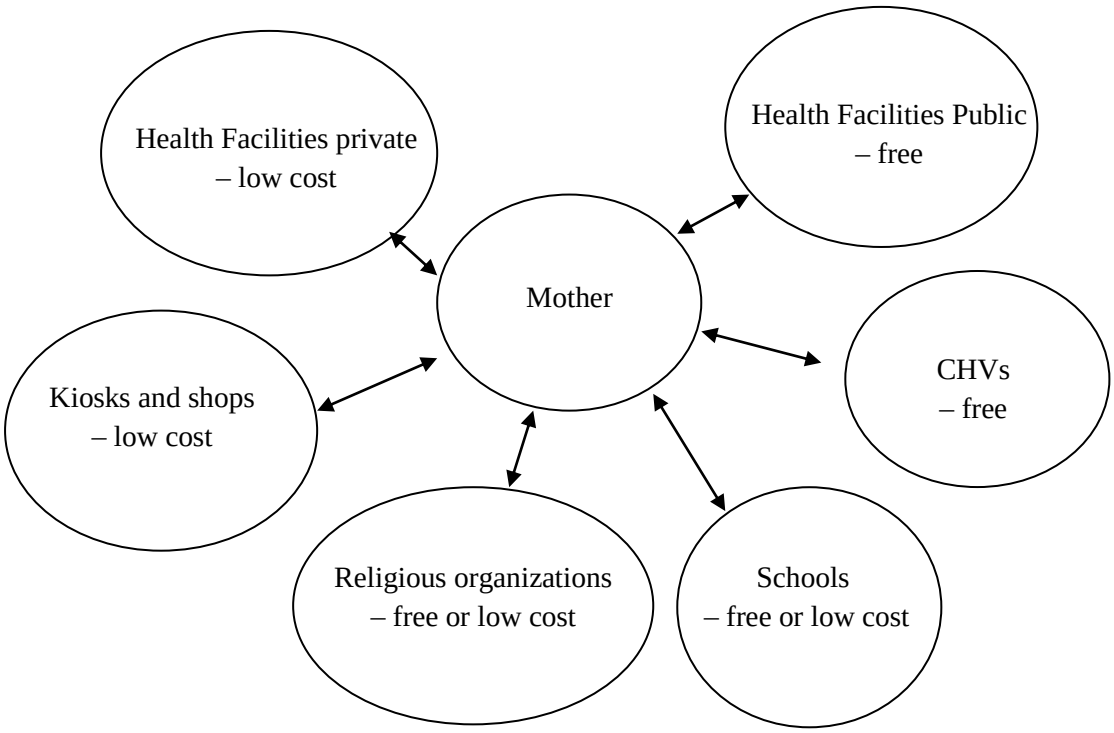

Figure 2: Sources of ORS and Zinc for mothers

3) *Training:* the baseline survey results identified knowledge gaps among different targets that would only be filled through the use of training programmes. A trainer's guide entitled: "Curriculum and Trainers' Guide for Shopkeepers and other community players on use of ORS and Zinc for Management of Diarrhoea in under five year old children within the Community" was developed and piloted during the study intervention period. The training targeted 3 categories/ groups:
    i. *Community Health Extensions Workers*: 9 CHEWs were oriented by the Sub County Health Management Team on the use of ORS and Zinc in diarrhoea treatment. These CHEWs jointly with the project Intervention Research Assistants then carried out training to the shop and kiosk owners, FBOs and teachers using a standard curriculum. The CHEWs also supervised the programme at cluster level.
    ii. *Shop and kiosk owners, FBO representatives, and teachers*: these were trained using the standard curriculum. They were then provided with ORS and Zinc to sell to mothers and caregivers.
    iii. *Mothers and caregivers:* 9,182 mothers and caregivers were trained in the intervention clusters mainly trained to increase the of ORS and Zinc demand side. This was done through well organised training sessions within the community.

4) *Behaviour Change Initiative (BCI) activities:* these included among others the use of model homes, interpersonal communication, edutainment, IEC materials, and use of community-based activities such as market days, religious meetings, chief's baraza, ceremonies etc.

2.4 Implementation process of the intervention package

The implementation process of the intervention package in this study had 8 steps and is summarized in Figure 3.

1. **Identification of the area based on set criteria**: preferably in communities where health facilities are located more than 5 kilometres apart, poor road network, high diarrhoea prevalence, and a range of existing community structures (e.g. churches, schools, markets, manyattas etc).
2. **Development of a clear implementation plan**: an agreed consistent and sustainable supply and demand plan for ORS and Zinc that incorporates the local situation.

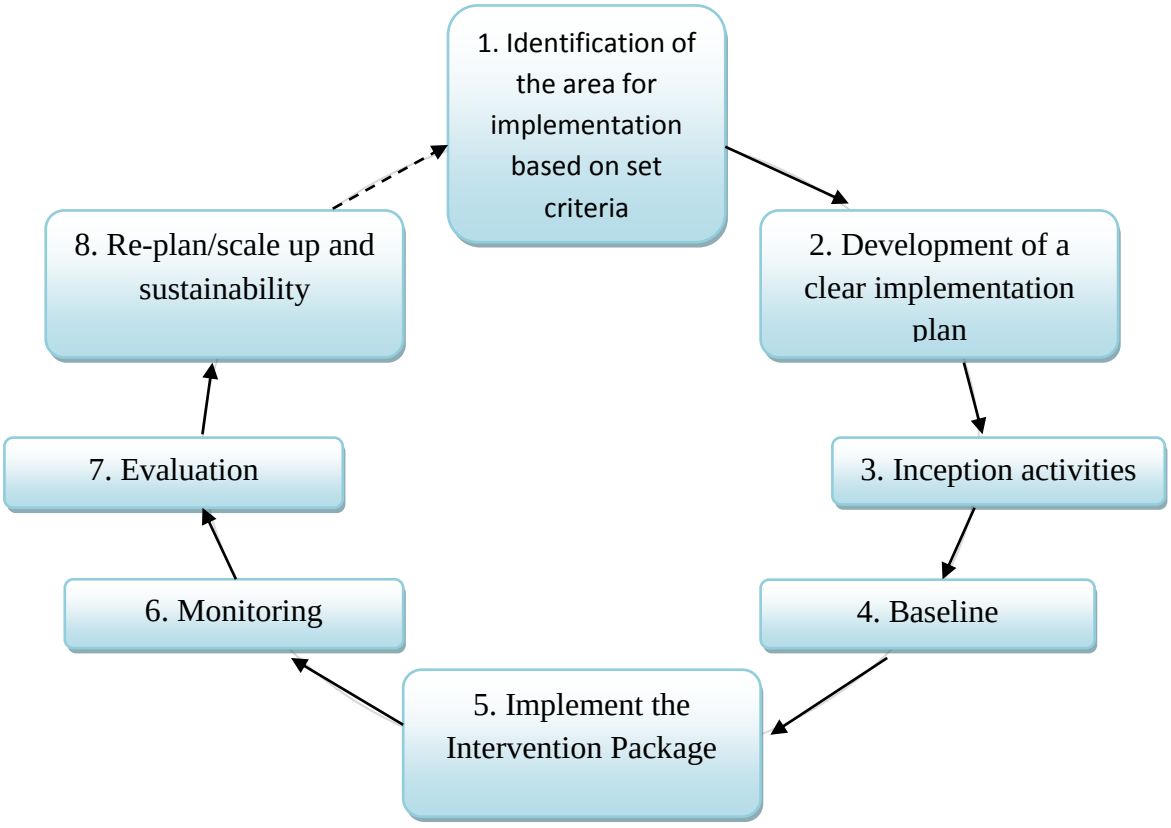

Figure 3: 8 steps for implementing an innovative ORS and Zinc delivery mechanism at community level tested in this study

3. **Inception activities:** including acceptable community entry approaches, stakeholder mapping (community structures), joint community planning, community sensitisation meetings, involvement of relevant County government departments e.g. internal security, Health, Education etc.
4. **Baseline:** conduct a rapid assessment to establish key indicators relevant to diarrhoea and its management in the project area
5. **Implementation of the intervention package:** as described and detail in 2.3
6. **Monitoring**: monitor the implementation activities through monthly supportive supervision, meetings, reports, and quarterly review forums to identify challenges facilitate re-planning.
7. **Evaluation**: should be carried out on the access of ORS and Zinc model preferably at the end of the 12^{th} month of implementing the intervention.
8. **Re-plan/scale up and sustainability:** based on the lessons from the intervention, the team shall re-plan or scale up the model as the cycle starts again in new communities. Sustainability activities should be under the implementation and supervision of the Ministry of health and or development agency operating in the community.

2.5 Comparison

A comparison group of 11 clusters did not receive any additional inputs to the routine programme. The Sub-County Health Management Team was briefed on actions they may take or information they might give during their routine support and supervision visits. The benefits of proper implementation of the research project to their Sub-County and to the rest of the country were explained and their cooperation sought. During the process of data collection, teams came across individual children with diarrhoea. These children were provided with ORS and Zinc and their caregivers were given information on how it should be used as a one-off treatment without any follow up other than that which may happen within the existing systems of diarrhoea management.

2.6 Outcomes

The primary study outcomes were:

1. Children with diarrhoea are correctly managed by mothers using ORS
2. Children with diarrhoea are correctly managed by mothers using zinc
3. Better knowledge on diarrhoea prevention and management by caregivers

2.7 Data collection and management

Qualitative and quantitative data were collected during the baseline and end-line surveys carried out on the fourth month of the study inception and after 12 months of implementation of the intervention respectively to collect the information required for measurement of the study outcomes. The measurement strategy was exactly the same in the two arms and surveys. In order to minimize measurement bias, the survey teams were independent of the intervention implementation team.

Selecting the Qualitative Sample

The qualitative data collection approaches involved focus group discussions (FGDs) and semi-structured in-depth interviews (IDIs). Purposive sampling was used to select the clusters for inclusion in the FGDs based on: study arm (intervention or control), ethnicity (Maasai or Kipsigis), presence of health facility, and accessibility by road network. There were 8 FGDs conducted (one per sampled cluster) during baseline compared to 7 during end-line (Table 1). The number of clusters was based on the saturation level of new information from the FGDs. At cluster level, convenience sampling was used where the team screened for women with children under five years at household level and invited one willing to participate from each Manyatta. A total of 8-12 women were invited to the cluster FGD. The selection criteria of participants to the FGDs are summarised as: having an under five year old child, willing to participate in the FGD, resident in the cluster for the last five years, and sanctioned by women from the Manyatta to be their representative.

42 key informants during baseline and 15 during end-line were purposively selected based on their roles including the local administrators such as Chiefs/ Assistant Chiefs, in-charges of health facilities, school teachers and religious leaders among others. Availability of these key informants was the main criteria for selection or inclusion in the study. The details for the two categories included in the surveys are summarised in Table 1.

Table 1: Participants of Focus Group Discussions and In-depth Interviews by study arm survey

Category	Intervention		Control	
	Number	Participants	Number	Participants
Baseline				
- FGDs for Mothers with children under five years	4	36	4	38
- In-depth Interviews with HC in-charges, Chiefs, other community leaders	24	24	18	18
End-line				
- FGDs for Mothers with children under five years	4	41	3	32
- In-depth Interviews with HC in-charges, Chiefs, other community leaders	7	7	7	7

Study instruments

Four instruments were used to collect the survey data: the Household Questionnaires for mothers and caregivers, In-depth Interviews (IDIs), Focus Group Discussion (FGD) guides, and Health Facility Assessment Tool.

Training and fieldwork

Research assistants (5) from each cluster were recruited based on a set of qualifications and experience to collect the baseline and end-line household data. An experienced qualitative researcher was identified and engaged in organizing the focus group discussions (FGDs). To ensure that the data in both surveys was collected as per the designed procedure, 6 supervisors from MoH and Amref Health Africa were identified and engaged. They also conducted in-depth interviews from the key informants. The Investigators conducted 3-day training for the recruited research assistants, supervisors, and moderators to guide the training of both survey teams.

The fieldwork for the baseline and end-line surveys was held in April 10-17, 2013 and October 20-27, 2014 respectively. Each of the 22 clusters had 5 local interviewers. For supervision purposes the clusters were organized into 5 field teams each having two supervisors in-charge of 2–4 clusters based on the vastness of the clusters. There were six 4x4 wheel drive vehicles and one was dedicated to the team conducting the FGDs. The poor road

network, vastness of the clusters and the heavy rains were the main challenges experienced during data collection during both the baseline and end-line surveys.

2.8 Data processing and analysis

A data processing team was constituted and trained at the Amref Health Africa Offices after the data collection of both the baseline and end-line survey. Two variables to measure level of knowledge and practices on management of diarrhoea were operationalized as described:

Knowledge score on management of diarrhoea

An overall knowledge score on management of diarrhoea was generated using variables listed as follows;

- When would you say that a child has diarrhoea? (Q34); (Correct answer given=1)
- Do you think Diarrhoea is a Serious Problem? (Q35); (Yes=1)
- What is ORS used for? (Q38); (Correct answer given=1)
- From where can you obtain ORS? (Q39_a); (Health facility=1)
- From where can you obtain ORS? (Q39_b); (CHW=1)
- From where can you obtain ORS? (Q39_d); (Shop=1)
- From where can you obtain ORS? (Q39_e); (Pharmacy=1)
- What is Zinc used for? (Q41); (Correct answer given=1)
- From where can you obtain Zinc? (Q42_a); (Health facility=1)
- From where can you obtain Zinc? (Q42_b); (CHW=1)
- From where can you obtain Zinc? (Q42_d); (Shop=1)
- From where can you obtain Zinc? (Q42_e); (Pharmacy=1)
- When do you seek help or ADVICE for a child with diarrhoea? (Q43); (Immediately the child gets diarrhoea =1)
- Describe how you would normally prepare ORS for a child with diarrhoea; (correct method=1)

The variables were aggregated into a variable called knowledge score on management of diarrhoea. A percentage score was computed based on the maximum attainable score (14). A score of $\geq$50% was considered as adequate knowledge on management of diarrhoea.

Practice score on management of diarrhoea

An overall practice score on management of diarrhoea was generated using variables listed as follows;

- I would like to know how much (*name the child* _____) was given to drink during the diarrhoea (including breast milk) (Q47); (MORE=1)
- During the time (*name the child* _____) had diarrhoea, was he/she given less than usual to eat, about the same amount, more than usual, or nothing to eat? (Q48); (MORE=1)
- During the episode of diarrhoea, was (name the child _____) given to drink any of the following? (Q49); (Fluid from ORS sachet=1)
- During the episode of diarrhoea, was (name the child _____) given to drink any of the following? (Q49); (Homemade fluid=1)
- During the time (name the child _____) had diarrhoea, what did you do about it? (Q50); (Sought care from CHV/ Sought care from Public health facility/ Sought care

from Private clinic/ Bought ORS from shop/kiosk/ Bought zinc from shop/kiosk/ Got ORS from other sources/ Got zinc from other sources = 1)

- How many days after the diarrhoea began did you seek advice? (Q51); (Same day=1)
- Did you also give zinc tablets to the sick child? (Q56); (Yes=1)

The variables were aggregated into a variable called practice score on management of diarrhoea. A percentage score was computed based on the maximum attainable score (7). A score of ≥50% was considered as adequately good knowledge on management of diarrhoea.

The tabulation of the quantitative results was done using descriptive statistics with the chi square being used to establish the association between selected sets of variables at the 95% confidence interval. Change attributable to intervention (effect size) was determined by differencing the proportion of the indicator between intervention and control at end-line adjusting for the difference between intervention and control at baseline. This was achieved using the Difference-in-Differences (DiD) approach. After the field data collection, the qualitative data was transcribed for the fifteen voice-recorded FGDs in both baseline and end-line. The research objectives were used in deriving the themes for thematic coding. The transcriptions were entered into the Nvivo 10 qualitative analysis programme which browsed through them to retrieve segments under each code.

2.9 Ethical Issues

The study proposal was submitted to the Amref Health Africa Ethics and Scientific Committee (ESRC) for ethical approval. It was only after this approval that the study activities got initiated in the field.

2.10 Response rate

During the end-line survey, information was collected for 10,623 children under five years from 6,720 households compared to 10,989 children from 6,683 households in the baseline survey.

3.0 RESULTS

This section provides a summary of the study results in four main sub-sections; the background characteristics, mothers/ caregivers knowledge on diarrhoea management, practices on diarrhoea treatment, and channels and associated preferences for accessing ORS and Zinc.

3.1 Background characteristics

Characteristics of Respondents

Over 90% of the respondents in both surveys were female with slightly over a half aged below 30 years (Table 2). The residents are predominantly Maasai (70%) with almost half being Protestants. In the end-line more than half (54.4%) of the respondents were house wives compared to 45.6% reported during the baseline.

Table 2: Percentage distribution of selected socio-demographic characteristics of the respondents by survey and study arm

Characteristics	Baseline			End-line		
	Total (n=6,683)	Intervention (n=3,306)	Control (n=3,337)	Total (n=6,720)	Intervention (n=3,144)	Control (n=3,576)
Sex of the respondent						
Male	5.4	4.5	6.4	3.6	2.3	4.7
Female	94.6	95.5	93.6	96.4	97.7	95.3
Relationship to HHH						
Wife	82.5	81.4	83.5	85.7	85.4	86.0
Self	12.3	12.6	12.1	9.6	10.3	9.0
Daughter	3.3	4.1	2.6	2.6	2.8	2.4
Other Relationship	1.9	1.9	1.8	1.1	0.6	1.5
Age of respondent						
Below 20 years	7.7	8.5	7.0	8.0	7.5	8.4
20 – 29	48.5	49.6	47.3	49.9	52.5	47.5
30 – 39	23.7	24.1	23.2	23.6	22.1	25.0
40 - 49	7.2	7.6	6.8	5.3	4.6	5.9
50 years or longer	2.0	2.0	2.1	1.1	1.1	1.1
Don't know	11.0	8.2	13.7	12.0	12.2	11.9
Respondent's Ethnicity						
Maasai	70.5	67.3	73.6	70.0	64.3	75.0
Kipsigis	26.4	29.1	23.7	27.2	31.1	23.7
Kisii	1.4	1.8	1.0	0.8	1.2	0.4
Kikuyu	0.9	0.9	0.9	0.6	0.8	0.5
Others	0.8	0.8	0.7	1.4	2.5	0.4
Religion of the respondent						
Protestant	43.8	47.9	39.8	50.9	55.5	46.9
Traditional African	34.7	30.2	39.2	26.8	25.3	28.1
Catholic	18.2	19.3	17.1	20.3	17.6	22.7
Muslim	0.3	0.3	0.4	0.3	0.3	0.3
None	3.0	2.4	3.6	1.7	1.3	2.0
Main occupation						
Housewife	45.6	43.6	47.6	54.4	42.7	64.7
Farmer	15.1	14.9	15.2	11.3	13.4	9.5
Livestock keeper	14.8	14.1	15.2	9.9	15.0	5.3

Mixed farming	14.2	16.6	11.9	11.0	13.0	9.2
Trader	7.7	7.9	7.6	2.7	2.3	3.1
Salaried	2.0	2.1	1.8	9.9	12.8	7.4
Others	0.6	0.8	0.5	0.8	0.7	0.8

Whereas 55.6% of respondents reported in baseline to have no formal education, a similar high level of 48.2% was noted during the end-line survey (Figure 4).

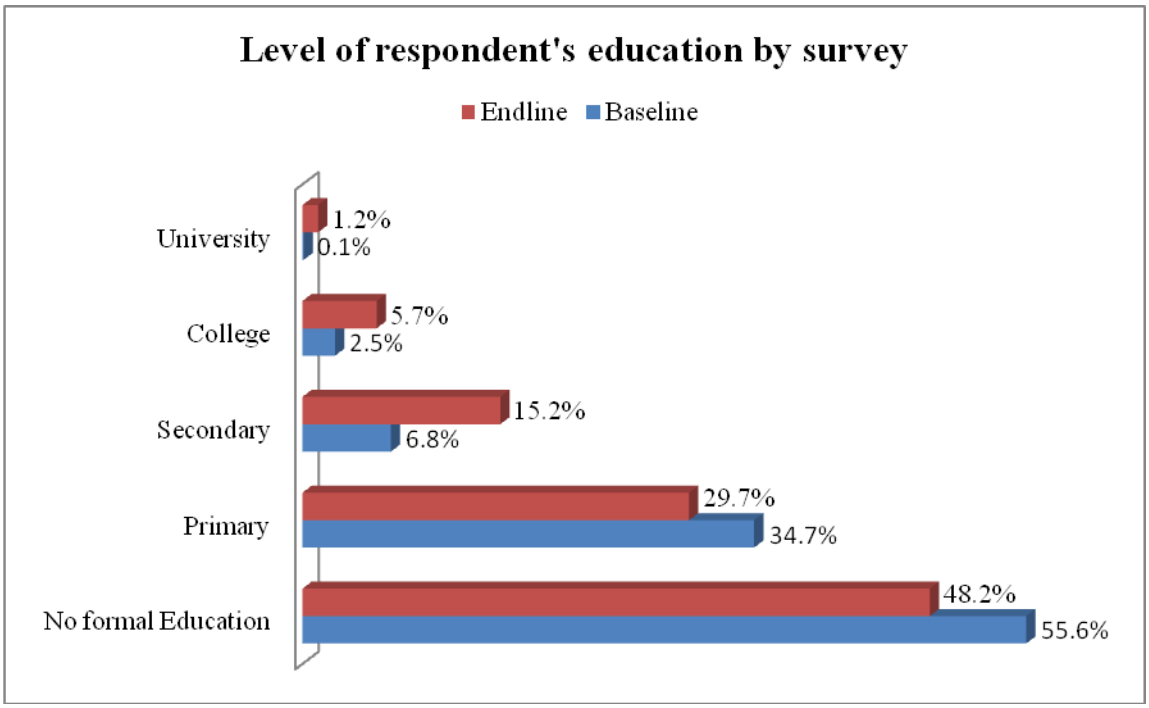

Figure 4: Level of respondent's education by survey

Characteristics of children under five years

In the end-line survey, 6,720 households were visited and information collected for 10,623 children under five years of age compared to 6,683 households and 10,989 children during the baseline survey. Nearly all the respondents in both surveys were reported as the mother of the index child, 93.6% compared to 91.7% in the baseline (Table 3).

Table 3: Percentage distribution of selected socio-demographic characteristics of children by survey and study arm

Characteristics	Baseline			End-line		
	Total (n=10,989)	Intervention (n=5,497)	Control (n=5,492)	Total (n=10,623)	Intervention (n=5,194)	Control (n=5,429)
Children per household						
One	51.6	50.3	52.9	33.4	28.6	38.0
Two	35.1	35.9	34.3	41.3	44.6	38.1

Three	12.5	13.2	11.9	23.2	24.4	22.0
Four or more	0.8	0.6	0.9	2.1	2.4	1.9
Sex of the child						
Male	51.2	52.1	50.3	53.0	51.7	54.3
Female	48.8	47.9	49.7	46.0	47.2	44.9
Not specified	-	-	-	0.9	1.1	0.8
Age of child (in month)						
0 – 6	8.9	9.0	8.9	10.9	11.1	10.6
7 – 12	13.1	12.5	13.7	14.1	13.4	14.7
13 – 24	21.7	21.4	22.0	22.5	21.1	23.8
25 – 36	21.2	20.3	22.0	21.9	21.0	22.8
37 – 48	17.7	18.2	17.2	17.2	17.8	16.5
49 – 60	17.4	18.6	16.2	13.5	15.5	11.5
Relationship to child						
Mother	91.7	92.2	91.2	93.6	95.3	92.0
Father	4.2	3.4	5.1	2.3	1.5	3.0
Sister	1.4	1.4	1.3	1.3	0.8	1.8
Brother	0.5	0.6	0.5	1.0	0.6	1.5
Other	2.2	2.4	1.9	1.7	1.8	1.6

Water, hygiene and sanitation

Drinking Water

There is scarcity of drinking water in the study area. Half (baseline 50.6% vs. 59.9% end-line) of households get drinking water from an improved source during the wet season compared to only 18.6% (baseline) and 27% (end-line) during the dry season. The scarcity of improved drinking water was confirmed during the in-depth interview where a health provider in a public health facility explained that:

> *"people in this community especially when it is dry collect stagnant water used for irrigation and use it for consumption. The health risks are worse as they don't boil it before drinking".*

The return time taken to fetch drinking water was falling between the two surveys as shown in Table 4. The table also shows an increase in the proportion of households that cover their drinking water containers – from 29% at baseline to 37.5% at end-line. However, water treatment remains low and assumed a falling trend during the two surveys (24.1% at baseline vs. 20.2% at end-line).

Table 4: Percentage accessibility to water source and households' hygiene and sanitation by survey and study arm

Characteristics	Baseline			End-line		
	Total (n=6,683)	Intervention (n=3,306)	Control (n=3,377)	Total (n=6,720)	Intervention (n=3,144)	Control (n=3,576)
Time taken to fetch water						
< 11 minutes	13.6	13.7	13.4	13.7	10.0	16.9
31 - 60 minutes	27.2	24.2	30.2	32.4	33.2	31.6
61 - 120 minutes	17.3	19.4	15.3	14.3	16.3	12.5
>120 minutes	10.5	11.6	9.4	5.2	4.7	5.6
Not specified	-	-	-	0.4	0.5	0.3
Water storage method at HH						
Same fetching container	60.2	54.4	65.8	55.7	50.3	60.5
Covered container	29.0	33.6	24.5	37.5	42.5	33.0
Open container	10.8	12.0	9.6	6.6	6.8	6.4
Others (pot and tank)	0.1	0.1	0.1	0.3	0.4	0.1
Drinking water treated	24.1	29.1	19.1	20.2	23.5	17.3
Boiling	15.8	18.6	13.0	13.1	14.7	11.6
Adding chemical	8.1	10.3	6.0	6.5	7.7	5.5
Others (sieving/ in sun)	0.2	0.3	0.1	0.6	1.1	0.2
Presence of utensils drying rack	65.3	63.9	66.8	75.0	68.0	81.1
Clean compound	50.2	48.4	51.9	62.3	55.6	68.2
Clean dwelling	66.4	63.3	69.5	82.4	76.5	87.6
Sharing sleeping space with animals	49.3	46.7	51.9	36.7	38.1	35.5
Presence of latrine	25.3	25.0	25.6	26.0	29.6	22.9

Household hygiene and sanitation facilities

Overall, three quarters of households in the end-line were found to have a utensils drying rack with the control sites having a higher proportion (81.1%) than the intervention sites with 68% (Table 4). The intervention compounds were cleaner (68.2% versus 55.6%) compared to the control.

The presence or absence of a latrine was analysed by ethnicity with the Maa speaking community having a significantly lower proportion of this important facility – 9.8% at baseline, but this increased to 11.4% at end-line with p value <0.001. An informant during an in-depth interview confirmed the low latrine coverage among the Maasai by explaining that:

"…there were no toilets except only in schools and the health facility".

Figure 3 represents latrine coverage and trends by study arm and ethnic groups during the study period. Whereas the increase in latrine coverage among the Maasai is appreciated, the declined among the other ethnic groups in both study arms is worrying.

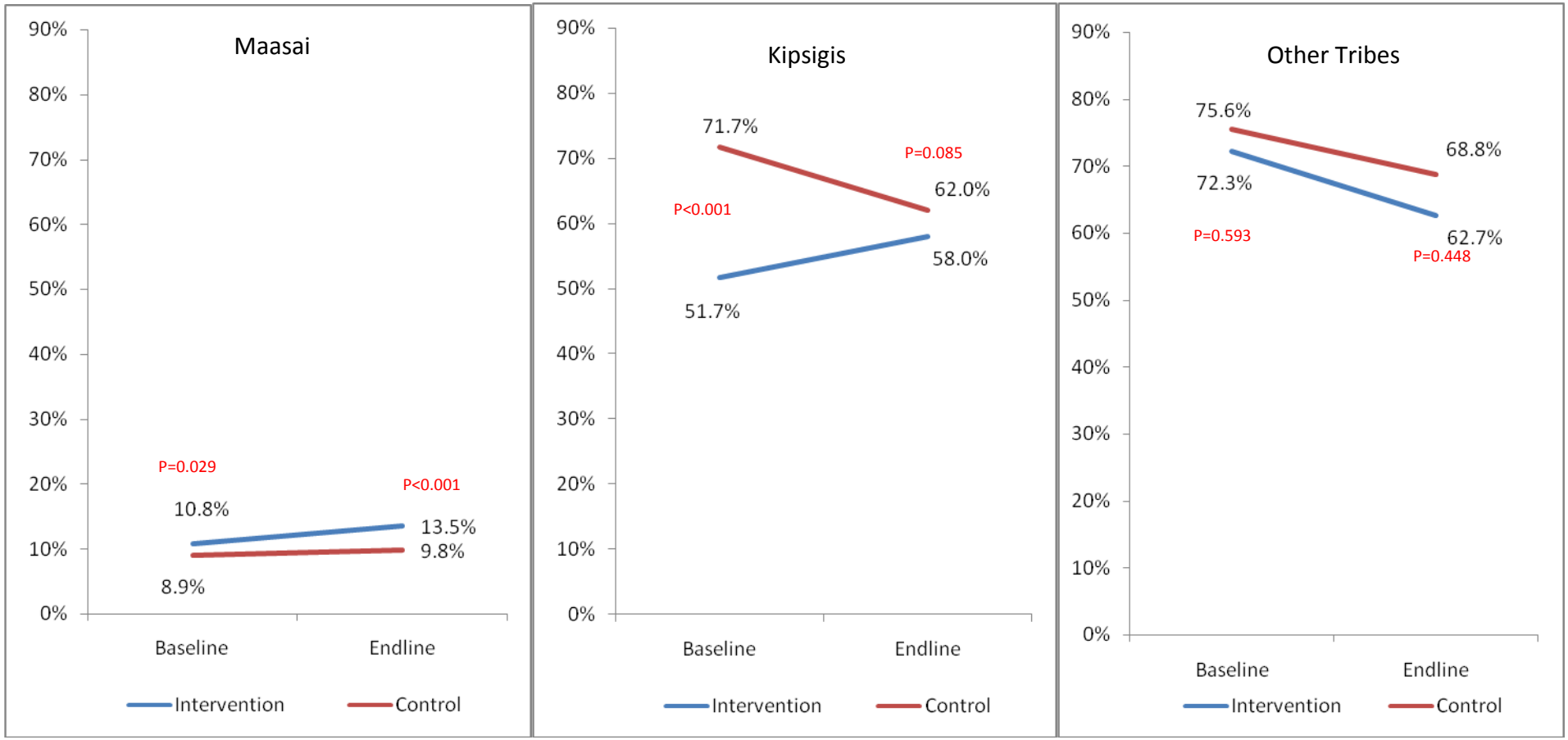

Figure 5: Latrine coverage by study arm and Ethnicity

2.11 Knowledge on prevention and treatment of diarrhoea

Source of knowledge on diarrhoea

At both baseline and end-line, the public health facility was reported as the main source of knowledge on prevention and treatment of diarrhoea was a public health facility. It is however worth noting that at end-line 2 in every 10 respondents (20.8%) in the intervention arm stated having received diarrhoea knowledge from Amref Health Africa, up from zero at baseline (Table 5).

Table 5: Source of knowledge on diarrhoea prevention and treatment by study arm and survey

Characteristics	Baseline			End-line		
	Total (n=6,683)	Intervention (n=3,306)	Control (n=3,377)	Total (n=6,720)	Intervention (n=3,144)	Control (n=3,576)
Public health facility	63.4	63.1	64.4	75.6	74.3	76.8
Family members	25.0	24.3	25.7	22.6	18.4	26.6
Private facility	11.1	8.6	13.5	16.0	13.6	18.3
Herbalist	4.7	4.6	4.7	6.8	2.5	10.8
CHVs	4.2	3.5	5.0	9.3	10.9	7.7
Community training	3.7	4.9	3.7	8.1	11.4	5.0
Others	3.7	6.1	1.4	1.6	1.5	1.7
Radio/Newspaper	3.3	3.5	3.1	12.5	10.3	14.5
Church	1.4	1.3	1.4	4.6	6.4	2.9
Written pamphlet	0.7	0.4	1.1	0.9	0.5	1.3
Amref health Africa	0.02	0.04	0.01	12.6	20.8	4.8
Where one can obtain ORS *(multiple response)*						
Health facility	61.2	65.0	57.5	76.0	78.6	73.6
Pharmacy	4.0	3.7	4.4	15.8	18.2	13.6
Shop	2.7	1.2	4.1	27.6	30.6	25.1
Community Health Volunteers	2.5	1.5	3.6	6.7	7.6	5.9
Traditional practitioner	0.8	0.1	1.5	0.6	0.2	0.9
Friend / Relative	0.4	0.4	0.5	0.7	0.9	0.5

Level of diarrhoea knowledge by study arm and survey

To assess the overall level of knowledge, 14 variables that tested mother/caregiver's knowledge were aggregated into a variable called knowledge score on management of diarrhoea. The variables included knowledge on what diarrhoea is, its causes, transmission, treatment, where to get treatment among others. A percentage score was computed based on the maximum attainable score (14). A score of ≥50% was considered as adequate knowledge on management of diarrhoea.

The difference in the proportion of mothers/ caregivers with adequate knowledge on management of diarrhoea between end-line and baseline within the intervention arm (β=43.7%) was significantly high compared to the same in the control arm (α=30.8%); ($p<0.001$). Increase in the proportion of mothers/ caregivers with adequate knowledge on management of diarrhoea attributable to the intervention (effect size; β-α) was 12.9% (Figure 6).

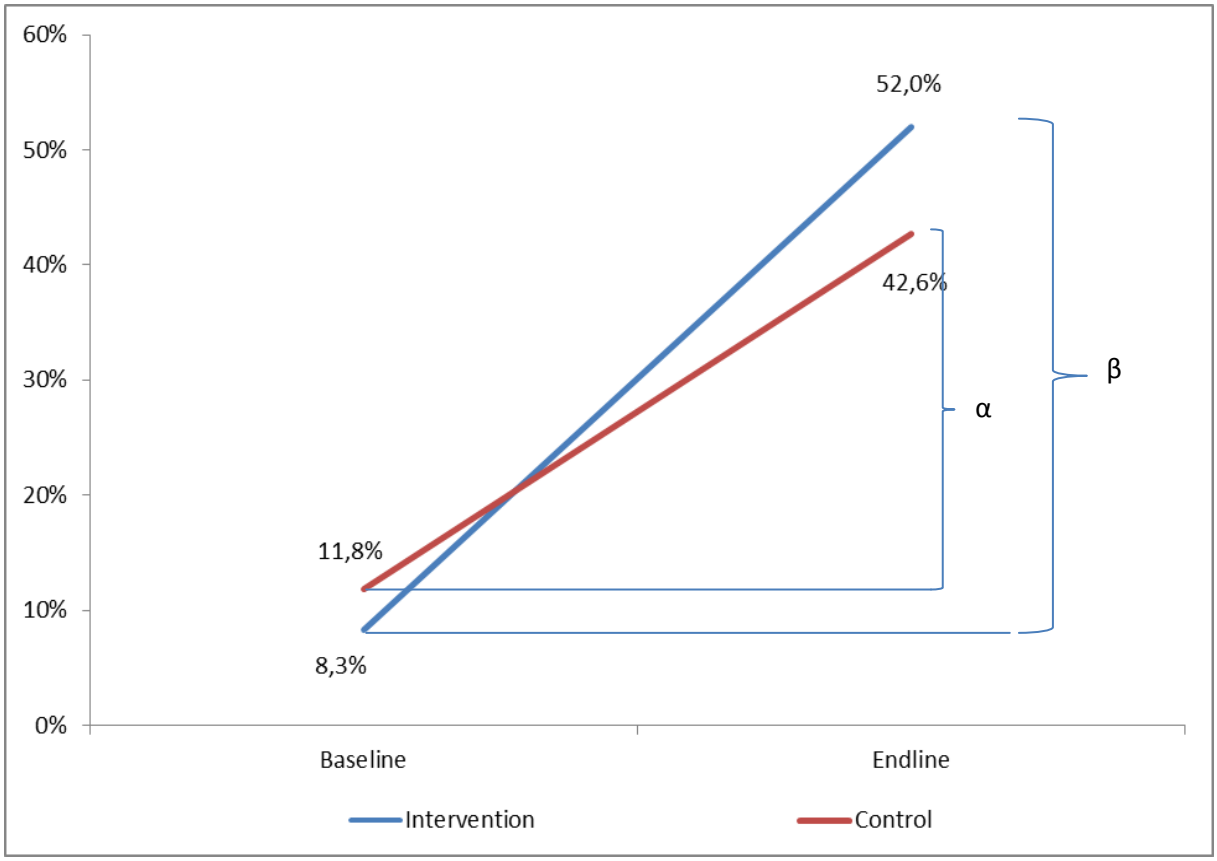

Figure 6: Adequate knowledge on management of diarrhoea among mothers/ caregivers of the children by study arm

2.12 Attitudes towards diarrhoea management

This section is based on the qualitative findings from FGDs and key informants both at baseline and end-line regarding the knowledge on causes of diarrhoea, attitudes towards diarrhoea and practices in management of diarrhoea. Table 6 compares the qualitative responses given at baseline and end-line. The causes and preventive measures of diarrhoea in children seem to be better understood at end-line than at baseline. Whereas traditional herbs

were mentioned as being used in treatment of diarrhoea in both surveys, the use of ORS and Zinc was mentioned during the end-line.

Table 6: A Summary of the Qualitative Findings at both Baseline and End-line

Themes	Baseline	End-line
Causes of Diarrhoea	- Teething in babies - Breastfeeding while pregnant - Engaging in sex while breastfeeding	- Poor hygiene practices: consumption of dirty food and water, not washing hands before eating/ feeding or after visiting latrines - Complication from another existing illness - Teething in babies
Prevention of Diarrhoea	- Use Herbs - Deworming of the children	- Improving on hygiene practices: washing hands before feeding/ eating and after visiting latrines - Construction and use of latrines for human waste disposal - Boiling/ treating drinking water - Provision of safe drinking water in the community - Deworming of the children
Treatment of Diarrhoea	- Traditional medicine (Herbs) - Give alcohol and bitter herbs	- Give mixture of water with sugar/ salt to the child - Use traditional medicine (herbs) - Use ORS and Zinc
Sources of advice	- Laibons - Traditional Birth Attendants	- Herbalist - Health facility - Shops dispensing ORS and Zinc - Old women in the village, e.g. mother in law

2.13 Mother/caregiver practices on diarrhoea management

Prevalence of diarrhoea

Overall, diarrhoea prevalence dropped from 20.4% at baseline to 14.9% at end-line; ($p<0.001$). Figure 7 presents the distribution of children experiencing diarrhoea in the last two weeks by study arm. The difference in occurrence of diarrhoea between end-line and baseline within the intervention arm (β=6.4%) was significantly high compared to the same in the control arm (α=4.6%); ($p<0.001$). Reduction in occurrence of diarrhoea attributable to the intervention (effect size; β-α) was 1.8%.

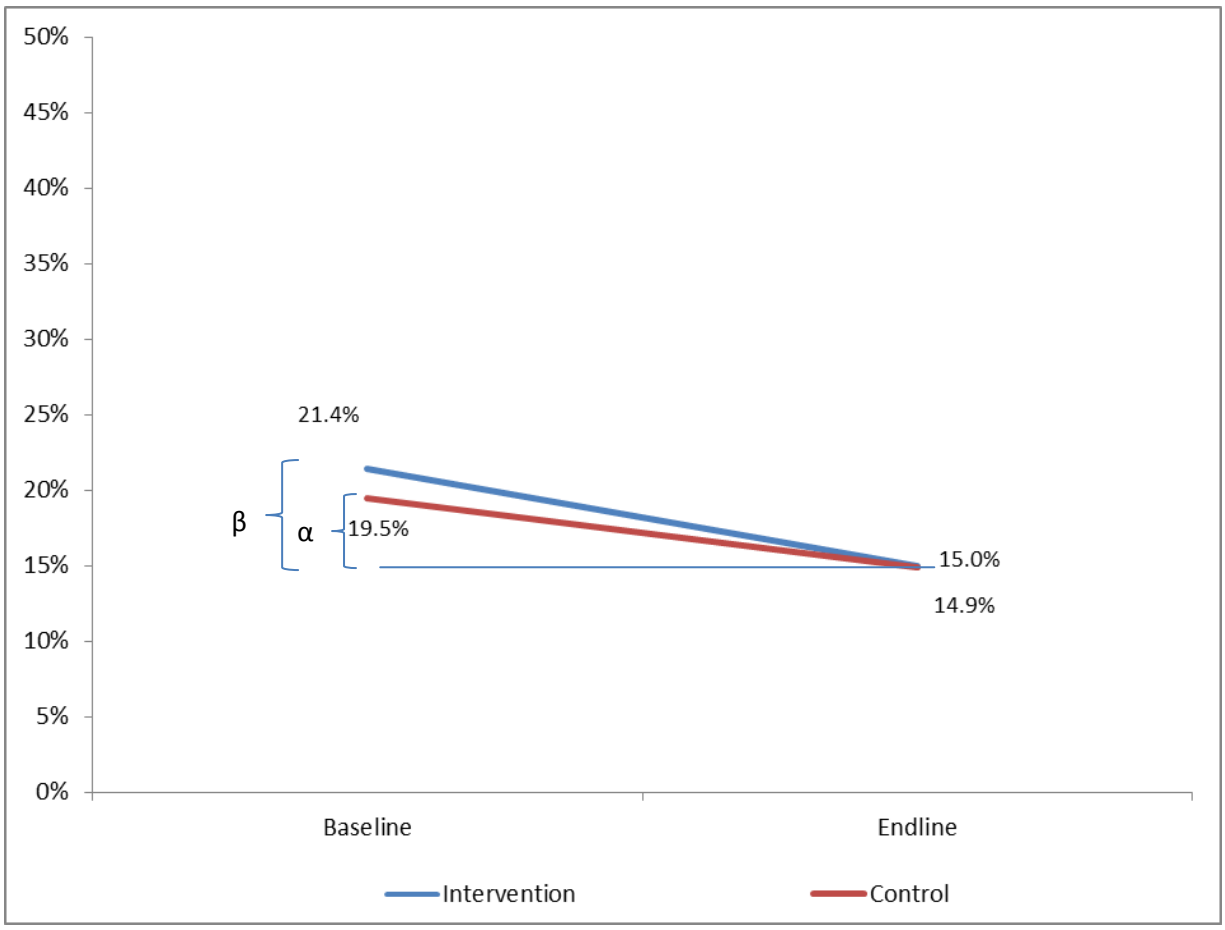

Figure 7: Occurrence of diarrhoea in the last two weeks among children by study arm

Home Management of diarrhoea

Actions taken during diarrhoea

The proportion of children with diarrhoea for who care was not sought dropped from 31% at baseline to 22.3% at end-line survey. A similar drop was experienced at both arms of the study. Whereas majority in both arms of the study sought care from a government health facility, mothers/caregivers from the intervention sites were more likely than those from control sites to have gotten treatment for the episode from a site that was not a government health facility as shown in Table 7.

Table 7: Action taken during diarrhoea by study arm and survey

Characteristics	Baseline				End-line			
	Total n=2,245	Intervention n=1,175	Control n=1,070	P value	Total n=1,588	Interventio n n=777	Control n=811	p value
Action taken during the illness								
Nothing	31.0	33.0	28.8	**<0.001**	22.3	25.4	19.4	**<0.001**
Sought care from GoK HF	38.8	34.0	43.9		47.0	45.3	48.7	
Used home remedy	18.8	24.3	12.7		14.3	11.2	17.3	
Sought care from private clinic	7.6	4.6	10.8		7.1	5.4	8.8	
Bought ORS and Zinc from shop	2.1	2.2	2.0		5.9	9.5	2.3	
Got ORS and Zinc from other sources	0.4	0.3	0.5		0.7	0.6	0.7	
Sought care from CHV	1.5	1.6	1.3		2.7	2.6	2.8	

Fluids and food given to children during diarrhoea

Children with diarrhoea lose a lot of fluids and electrolytes. Actions taken at home by mothers/caregivers are critical in determining the success of treatment. The main aim of diarrhoea treatment is to give the child with diarrhoea increased amounts of appropriate fluids and food. Appropriate homemade fluids include porridge, fresh fruit juices, soup, and do not include any bottled, carbonated or juices with preservatives. These practices varied greatly between the two arms with caregivers in the intervention arm more likely to have given the same or more amount of fluids during the episode, the ones in the control gave much less or somewhat less. However the practices relating to food appears to be similar in both arms as in Table 8.

Table 8: Fluids and food given to children with diarrhoea

Characteristics	Baseline				End-line			
	Total n=2,245	Intervention n = 1,175	Control n = 1,070	P Value	Total n=1588	Intervention n=777	Control n=811	p value
Amount of fluid intake during illness								
Much less	29.7	29.7	29.6	**<0.001**	31.0	26.0	35.8	**<0.001**
Somewhat less	17.1	13.4	22.3		22.8	19.6	25.9	
About the same	18.7	16.7	20.9		18.5	22.5	14.7	
More	29.2	34.9	23.0		24.4	29.0	20.1	
Nothing to drink	3.4	3.6	3.2		1.8	1.9	1.7	
Don't know	1.3	1.7	0.9		1.4	1.0	1.8	
Amount of food intake during illness								
Much less	30.1	32.7	27.2	**<0.001**	34.6	36.7	32.6	**<0.001**
Somewhat less	22.5	21.6	23.6		23.1	22.8	23.4	
About the same	19.8	16.6	23.3		17.1	20.8	13.4	
More	7.6	8.6	6.4		9.3	2.7	15.7	

Nothing	11.8	12.1	11.6		15.6	16.7	14.5	
Don't know	8.2	8.4	7.9		0.3	0.3	0.4	
Child given homemade fluid	34.7	35.7	33.7	0.167	40.5	35.0	45.7	**<0.001**
Child given other fluids	9.7	9.4	10.0	0.544	21.0	13.8	27.9	**<0.001**

Use of ORS and Zinc for diarrhoea management

Analysis of use of ORS and/or Zinc among children experiencing diarrhoea in the last two weeks was done as presented in Figure 8. Between group comparisons revealed that use of ORS and Zinc combined was significantly high in control (7.2%) compared to intervention (3.1%) at baseline; ($p<0.001$). The pattern was different at end-line with a significantly high proportion using ORS and Zinc combined in intervention (38.4%) compared to control (18.7%); ($p<0.001$). Within group comparisons revealed that use of ORS and Zinc combined was significantly high at end-line (18.7%) compared to baseline (7.2%); ($p<0.001$) in control arm (11.5%; denoted as α). A similar pattern was observed in the intervention arm where a significantly high proportion used ORS and Zinc combined at end-line (38.4%); compared to baseline (3.1%); ($p<0.001$), (35.3%; denoted as β).

The difference in use of ORS and Zinc combined between end-line and baseline within the intervention arm (β=35.3%) was significantly high compared to the same in the control arm (α=11.5%); ($p<0.001$). Change in use of ORS and Zinc combined attributable to the intervention (effect size; β-α) was 23.8% as shown in Figure 8.

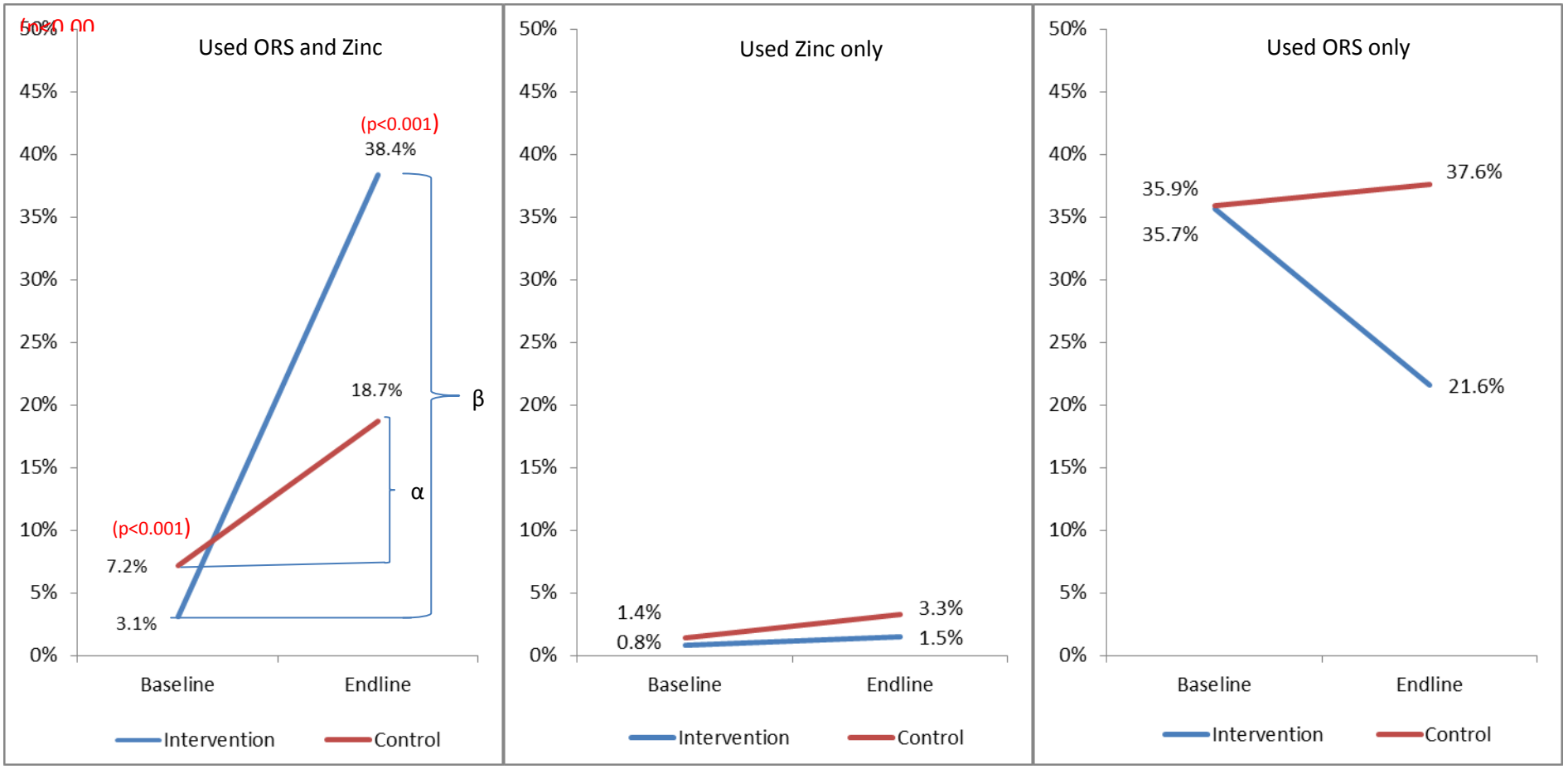

Figure 8: Use of ORS and/or Zinc among children experiencing diarrhoea in the last two weeks by study arm

Level of adequate use of good diarrhoea management practices

To assess mother's/caregiver's overall practice when their children had diarrhoea, 7 practice variables were aggregated into a variable called practice score on management of diarrhoea. These included care seeking, amount of fluids and food given to the child, the treatment provided. A percentage score was computed based on the maximum attainable score (7). A score of $\geq$50% was considered as adequately good level of practice on management of diarrhoea.

The analysis of adequately good practice on management of diarrhoea among mothers/ caregivers of the children by study arm was done as presented in Figure 9. Between group comparisons revealed that the proportion of mothers/ caregivers with adequately good practice on management of diarrhoea was significantly different between control (14.0%) and intervention (8.5%) at baseline; ($p<0.001$). The pattern was similar at end-line with the proportion of mothers/ caregivers with adequately good practice on management of diarrhoea significantly high in intervention (32.4%) compared to control (24.4%); ($p<0.001$). Within group comparisons revealed that the proportion of mothers/ caregivers with adequately good practice on management of diarrhoea was significantly high at end-line (24.4%) compared to baseline (14.0%); ($p<0.001$) in control arm (10.4%; denoted as α). A similar pattern was observed in the intervention arm where a significantly high proportion of mothers/ caregivers with adequately good practice on management of diarrhoea at end-line (32.4%); compared to baseline (8.5%); ($p<0.001$), (23.9%; denoted as β).

The difference in the proportion of mothers/ caregivers with adequately good practice on management of diarrhoea between end-line and baseline within the intervention arm (β=23.9%) was significantly high compared to the same in the control arm (α=10.4%); ($p<0.001$). Change in the proportion of mothers/ caregivers with adequately good practice on management of diarrhoea attributable to the intervention (effect size; β-α) was 13.5%.

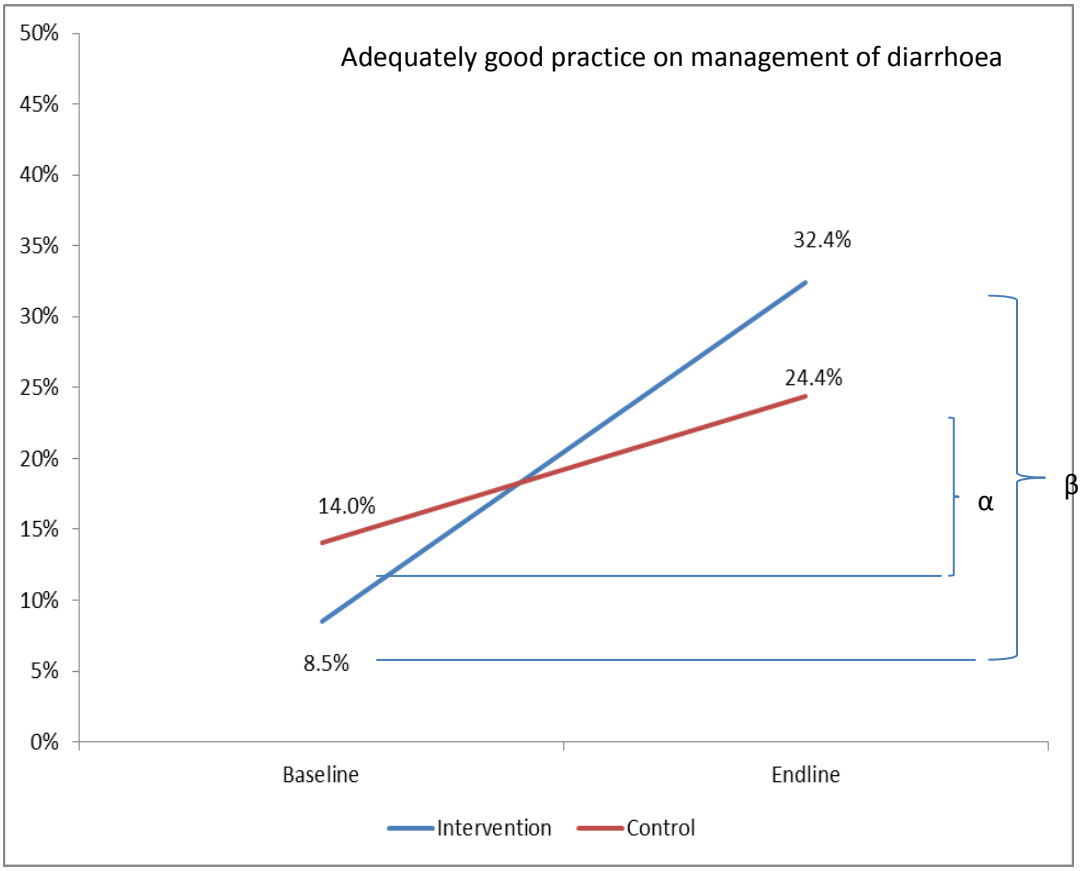

Figure 9: Adequately good practice on management of diarrhoea among mothers/ caregivers of the children by study arm

2.14 Preferred alternative (non-traditional) sources of ORS and Zinc

Preferred sources of ORS and Zinc

In both the baseline and end-line surveys health facility ranked top in preference for ORS and Zinc medicines followed by the shop/ kiosk. It is however worth noting that the preference for public health facilities declined from 66.6% in the intervention arm during the baseline to 51.1% at end-line with a more than twofold surge (from 15.0% to 31.0%) in preference for shop/ kiosk in the intervention arm during the inter-survey period. The private clinics, local school, pharmacy, community health volunteers (CHVs) and churches/ Mosques were also mentioned as shown in Table 9. Others mentioned were the inclusion of home distributors and herbalists.

Table 9: Distribution of preferred sources of ORS and Zinc in management of diarrhoea

Characteristics	Baseline	End-line

	Total (n=1,549)	Intervention (n=787)	Control (n=762)	Total (n=6,720)	Intervention (n=3,144)	Control (n=3,576)
Preferred ORS and Zinc sources						
Health facility	65.3	66.6	64.0	62.0	51.1	71.7
Shop/kiosk	13.9	15.0	12.9	21.6	31.0	13.1
Private clinic	4.8	2.2	7.5	7.4	6.1	8.6
Local school	3.4	2.5	4.2	0.3	0.7	0.0
Pharmacy	2.7	2.8	2.6	2.3	2.4	2.2
CHV	2.1	3.2	0.9	2.6	3.8	1.6
Church/Mosque	1.6	1.7	1.6	0.3	0.7	0.0
Others	6.2	6.1	6.3	3.5	4.2	2.8

Others sources; – home distribution and herbalist

The preference question was paused to the key informants during the in-depth interviews and the FGDs. Most informants stressed that the community would prefer to have the ORS and Zinc availed in Churches, schools, kiosk/shops, and or chiefs' offices as they are closer to the people and are easily accessible. However, they cautioned that this move would only be possible after proper information and training is given on the administration of the medicines to those involved. According to a nursing officer from a health facility:

> *"The shops and churches are closer to the community especially for those living far from the health facilities for example those living in Oljororoi where there are no health facilities and close ones are miles away. Such shops and Churches would be beneficial".*

Willingness to pay for ORS and Zinc co-packs

At baseline, slightly over three quarters (75.6%) of the mothers/ caregivers were willing to pay Kshs 50 for the ORS and Zinc co-packs but this increased to over 80% at end-line as summarized in Table 10.

Table 10: Willingness to buy diarrhoea medicine at Kshs 50 by survey and study arm

Characteristics	Baseline			End-line		
	Total (n=6,683)	Intervention (n=3,306)	Control (n=3,377)	Total (n=6,720)	Intervention (n=3,144)	Control (n=3,576)
Will buy diarrhoea medicine at 50/=						
Yes	75.6	76.4	74.9	83.5	85.8	81.5
No	24.4	23.6	25.1	16.5	14.2	18.5
Amount willing to buy if <50/= (n=2,677)						
None (free)	25.9	26.8	25.1	14.3	17.7	12.1
Ksh 5	2.6	2.3	2.8	1.4	0.4	2.0
Ksh 10	17.0	18.9	15.1	24.0	18.6	27.6
Ksh 15	1.1	1.5	0.8	1.5	0.9	2.0
Ksh 20	37.1	33.4	40.7	29.8	28.7	30.5
Ksh 25	2.0	2.2	1.9	5.1	6.1	4.5
Kshs 30	13.1	13.8	12.5	19.9	23.3	17.6
Kshs 35	0.1	0.1	0.1	0.2	0.4	0.0
Kshs 40	1.1	1.2	1.0	3.8	3.8	3.8

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Appendices

Appendix 1: Sample size determination

The assumptions for determination of sample size in this survey were as follows:

There are two primary outcomes. The first primary outcome is the proportion of children under five years with a reported diarrhoea episode who received ORS as treatment for the correct period. The assumptions for estimating the sample size are:

- *Proportion of children under five years with reported diarrhoea symptoms who received ORS in the comparison arm*. The KDHS (Kenya National Bureau of Statistics *et al*, 2010) prevalence of children under five years who received ORS for diarrhoea is 40% for Rift valley province. We assume that this proportion in comparison sub-locations will be the same (40%).

- *Range of this proportion across clusters in the comparison arm*: It is assumed that the above proportion in different sub-locations lies between 20% and 60% ($\pm$50% of the comparison value).

- Average proportion of children under five years with reported diarrhoea episodes who received ORS in the intervention arm: the intervention is expected to increase the level of utilization of diarrhoea treatment with ORS by at least 20 percentage points to reach a final coverage of 60% or more.

The second primary outcome is the proportion of children under five years with a reported diarrhoea episode who received zinc as treatment for the correct period. The assumptions for estimating the sample size are:

- Proportion of children under five years with reported diarrhoea episodes who received Zinc in the comparison arm. This is estimated at about 10%.

- Range of this proportion across clusters in the comparison arm*:* It is assumed that the above proportion in different sub-locations lies between 5% and 15%.

Number of individuals per cluster: Our unit of randomization is the sub-location which has an average population of 5,000 people. Children under-five years constitute 20% of the population, giving us a population of 1,000 children. With a KDHS reported 2-week prevalence of diarrhoea in children under five years at 17%, the average number of children less than five years with diarrhoea in each cluster is 170. In this sampling design, we have taken an approach that looks at half of the cluster at each survey time, and therefore we will use 85 children with diarrhoea as our target population, which will be achieved by interviewing mothers of 500 children per cluster.

- The power of the survey is set at 90% with a confidence level of 95%

The following community randomization comparison of two risks (proportions) formula by Hayes and Benett 1999 was used to estimate the cluster sample size of the study.

The calculation of sample size of clusters based on these assumptions yields the following: on primary outcome one, 60% coverage with ORS in the intervention arm – 11 clusters per arm, a total of 22, and on primary outcome 2, based on 34% coverage with zinc in the comparison arm – 3 clusters. The study was therefore based on random selection and allocation of 22 clusters, eleven in each arm.