

Lessons learned in a pilot introduction of zinc treatment for childhood diarrhea in Bougouni District, Mali

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Acronyms

ACT	Artemisinin Combination Therapy
ALRI	Acute Lower Respiratory Infections
ARI	Acute Respiratory Infection
BCC	Behavior Change Communication
CDD	WHO Control of Diarrhea Diseases program
CHW	Community Health Worker
IMCI	Integrated Management of Childhood Illness
MOH	Ministry of Health
NGO	Non-governmental organization
ORS	Oral Rehydration Salts or Solution
ORT	Oral Rehydration Therapy
SSS	Sugar Salt Solution
WHO	World Health Organization
UNICEF	United Nations Children's Fund

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Introduction

This document reports the lessons learned in a pilot introduction study of zinc treatment for childhood diarrhea in the Bougouni district in southern Mali that took place between April 2003 and October 2004. The overall objective of the pilot study was to identify operational issues that arise when introducing this new intervention. The impact and feasibility of the intervention on a larger scale will be assessed in a subsequent phase of research starting in May 2005. This report is written for program planners and managers who are considering introducing zinc treatment for diarrhea into existing child health and nutrition interventions in rural Africa. The content of the report discusses some of the key lessons learned during the course of the pilot study and offers conclusions and recommendations for future zinc programs. The USAID Micronutrient Program(MOST) website (http://www.mostproject.org/whatsnew.htm) provides additional documents and references related to the introduction of zinc treatment.

The treatment in question is a 14-day course of dispersible zinc tablets, during and following an episode of diarrhea. The recommended regimen consists of one 20 mg tablet per day for children of age 6 months or older and half a tablet, or 10 mg per day, for children less than 6 months. Tablets come in a 14-count blister pack and can be taken directly by mouth or dissolved in water or breast milk and given with a spoon. There is an abundance of evidence for the effectiveness of zinc treatment in reducing morbidity and mortality associated with diarrhea, and formal guidelines for its use have already been established. Briefly, meta-analysis of previous trials has demonstrated that 10 to 14 days of zinc treatment is associated with decreased severity and duration of diarrhea, leading to decreased overall under-five mortality (Bhutta, Bird et al. 2000). Based on these findings, WHO and UNICEF currently recommend incorporating zinc into the treatment all young children suffering from diarrhea (WHO/UNICEF 2004). Finally, WHO and UNICEF recommend that Oral Rehydration Salts (ORS) be administered along with the zinc to prevent or treat dehydration, so programs generally choose to integrate the promotion of ORS sachets with zinc.

During the study, zinc was distributed in two health zones of Bougouni district through community health centers (equivalent to health posts or dispensaries in other African countries) and a village drug kit system set in place by Save the Children USA. In an intervention designed to bring primary health care closer to the village level, Save the Children USA, along with local partners, has instituted a series of village drug kits (caisses pharmaceutiques) throughout the Sikasso region of southern Mali (including Bougouni district) in villages with limited access to a health center. These kits are wooden cabinets stocked with eight products including antimalarials and ORS and are maintained in a household within the community. A community member called the village drug kit manager, or gérant de la caisse pharmaceutique, staffs the kit and functions in the same role as community health workers (CHWs) or depot holders in other countries. From this point on in the text, the village drug kit managers will be referred to as CHWs. The drug kits are connected to the health center of their specific health zone where the CHWs come for meetings, trainings, and to re-stock products. Zinc was placed into two community health centers and 18 drug kits in the two pilot health zones.

To date, many Asian countries have expressed considerable interest in the introduction of zinc treatment for diarrhea. In fact, Pakistan, India, Bangladesh and other countries are in the early stages of launching zinc interventions through public and private sector distribution channels. However, this report specifically focuses on zinc interventions in an African context as there are several significant differences between the health systems and the demographic and epidemiologic characteristics of Africa and Asia that can significantly affect how strategies for the introduction of zinc treatment are chosen. These include: 1) availability and marketing of ORS sachets; 2) population densities in rural areas; and 3) levels of malaria transmission. These typical differences are detailed in the following table.

Table 1. Typical differences between Sub-Saharan African and Asian settings for zinc interventions

	Sub-Saharan Africa	South and South-East Asia
Availability of	Typically only available in health	Widely available both through the
ORS sachets	facilities and pharmacies	public sector and also a range of
		private sector providers
Production of	Often imported. If produced	Multiple producers supplying many
ORS sachets	locally, may only be one producer	different flavors and brands aimed at
	producing primarily for use by the	different market segments.
	Ministry of Health.	
Marketing of ORS	Limited or no private sector	Visible marketing and competition
sachets	marketing and limited promotion	between different brands of ORS by
	by the Ministry of Health in most	different ORS producers
	countries	-
Population density	Generally low	Generally high
Malaria	High levels of transmission and	Low levels of transmission and
	malaria-related mortality in most	malaria-related mortality in most
	countries	countries

Objectives and methodology of the pilot study

The aim of this pilot study was to examine all aspects of the intended zinc intervention strategy in order to find areas for improvement and refinement before implementing on a larger scale. The main objectives were to: (1) identify and resolve obstacles to zinc implementation at the district, community, and household level; (2) identify barriers to care-seeking for children with diarrhea; (3) find new and more effective channels of communication for message dissemination; and (4) define additional approaches to decreasing inappropriate use of antibiotics. Furthermore, we were looking at these elements in the context of the village drug kit and community health center distribution mechanisms, and therefore, closely evaluated these as well.

The pilot study employed a multi-faceted approach to data collection. We carried out two cross-sectional population-based household surveys (one before and one 4 months after zinc introduction), followed children with diarrhea receiving zinc at the health centers or village drug kits, and conducted qualitative interviews with stakeholders, such as drug kit managers, health center staff, and caretakers. Intervention implementation was also carefully documented through

direct observation by qualitative interviewers not implicated in the intervention activities. The methods used in each of these components are briefly described below.

<u>Population-based surveys</u>: A list of all the housing compounds in each village located in the two pilot health zones and their approximate size was compiled. Housing compounds were chosen proportional to their size using a systematic sampling scheme. In the sampled compounds, caretakers of children who had been sick in the previous two weeks were interviewed. If there were two or more sick children residing in the compound, the interviewer drew the name of one of the children lottery-style. When compounds were encountered where there was no sick child or the caretaker did not consent, the interviewer was instructed to exit the compound through the primary entrance and proceed to the compound closest to his or her right. The surveys gathered data on: (1) treatment practices for dia rrhea, including use of ORS, antibiotics, and zinc; (2) careseeking both from health facilities and alternate providers; (3) perceptions of drug kits; and (4) knowledge and compliance with zinc treatment as a result of exposure to messages. A total of 352 surveys at baseline and 351 final surveys were carried out.

Household follow-up of children receiving zinc: A sub-sample of children who received zinc from community health centers or CHWs was followed. Household visits occurred on days 3 and 14 after receiving the zinc treatment. The purpose of these surveys was to describe administration of zinc, describe purchasing patterns, evaluate compliance, assess attitudes and caregiver satisfaction, and check for adverse outcomes or side effects of zinc such as vomiting, convulsions or death. A total of 123 cases were followed-up in their homes—21 children from the community health centers and 102 children from CHWs.

Qualitative interviews: A three person qualitative team carried out semi-structured interviews, a focus group, and direct observations of various intervention activities. The heads of each community health center (chef du poste medical) in each of the health zones were interviewed concerning the introduction of zinc treatment for the management of diarrhea. Twenty-eight (28) interviews with the CHWs managing village drug kits were carried out with regards to the overall implementation of the intervention, such as training, supervision, community promotion, etc., the use of zinc, ORS and SSS in the management of diarrhea, and the operational aspects of the CHW system, such as motivation, restocking, and cost recovery mechanisms. A series of semi-structured interviews were conducted with mothers, fathers, and other caretakers of young children regarding care seeking and home management for childhood diarrhea, knowledge and perceptions of the zinc intervention activities, knowledge and perceptions of the village drug kit system, and financial access to zinc and other medications. Interviewees were selected to include both families using zinc and those not using zinc (and/or ORS) in the sample. A total of 37 parents or caretakers were interviewed; 28 that had used zinc treatment and nine that had not. In order to allow for further contextualization and interpretation of the data obtained from the baseline survey, the qualitative team conducted a focus group with the seven quantitative interviewers and two supervisors who had carried out the population surveys.

<u>Intervention documentation</u>: The same qualitative team, carried out direct observation and careful documentation of three initial training sessions and one refresher training of the CHWs. They also observed 13 community meetings during which zinc and the prevention and appropriate management of childhood diarrhea were promoted by project supervisors. At least one secondary interview with a participant was conducted directly after these meetings to gather

information about perceptions of the meeting, perceptions of the zinc intervention, and further details about diarrhea management in the community. Direct observations (n=16) of consultations for children's diarrhea took place in the health facilities among three health providers. Information about children treated for diarrhea was also collected and compiled from registers in the community health centers and CHW records (notebooks).

This report presents data selectively to illustrate different issues encountered in implementation of this intervention. Because the data were collected at various times during the project, using various methods, after the title of each data table or figure, the following information is included: (1) data collection method, (2) population included in the denominator, and (3) timing of data collection.

Advocacy at the national, regional and district levels

Advocacy with stakeholders in the Ministry of Health, NGOs and other child health and nutrition organizations is a necessary element of any intervention to introduce zinc treatment in order to build or renew commitments to control of diarrheal diseases and malnutrition, have zinc treatment accepted and formally registered with national authorities, and commit policymakers to planning for large-scale adoption and promotion of zinc treatment in local health systems. There is a three-fold rationale which needs to be considered by programs when introducing zinc treatment for diarrhea; it centers on zinc's benefits to management of childhood illness, childhood nutrition, and the promotion of rational drug use. This is further explained in the table below.

Table 2. The three-fold rationale for zinc treatment for diarrhea

1. Diarrhea case management: Promoting an effective treatment for diarrhea (zinc) together with ORS can lead to higher rates of both zinc and ORS use, and a significant reduction in diarrhea-related morbidity and mortality. Introduction of zinc treatment together with the new low-osmolarity formulation of ORS can help reinvigorate diarrhea prevention and control efforts.

- **2. Nutrition**: Zinc supplementation during diarrhea episodes is a way of delivering this micronutrient to one of the groups most in need--young children with diarrhea. It is a partial alternative to daily zinc supplements or food fortification where such interventions are not feasible. Diarrhea is common enough that zinc-deficient children may end up receiving several courses of treatment per year, significantly increasing their zinc intake and thus improving their immune function.
- 3. Rational drug use: Parents want an effective treatment for diarrhea. Many parents have not been impressed with ORS, because while it replaces fluids, it does not stop the diarrhea. Therefore, they often seek out antibiotics (cotrimoxazole, tetracycline) or metronidazole (Flagyl), mainly from the private sector. Parents can be convinced to give zinc instead of antimicrobials for uncomplicated diarrhea, consequently decreasing inappropriate antimicrobial use, and thereby possibly slowing the spread of antimicrobial resistance.

In Mali, we have involved key policy-makers and stakeholders in all phases of the zinc research process. Mali's largely decentralized health system makes the collaboration of the Bougouni district chief medical officer and referral hospital staff vital to all our research and intervention activities. First, individual meetings were held with government representatives, partnering NGOs, and bilateral and multilateral organizations such as USAID and WHO before the start of pilot project activities. Then, stakeholders were asked to participate in a large dissemination meeting at the end of the formative phase of the research and before the start of

the pilot. Presentations during this meeting included: (1) the rationale for using zinc and the supporting research; (2) the current policies for diarrhea management in Mali; (3) the findings of the formative research; and (4) the plans for the pilot and larger interventions.

Following the meeting, a pilot committee was created comprised of professors, researchers, and ethics committee members from the University of Bamako, Faculty of Medicine, along with Ministry of Health officials and other partners. The pilot committee held meetings approximately every three months, during which the project team would provide an update of research and intervention activities, as well as discuss problems encountered and the steps taken to resolve them. Pilot committee members also participated in a field visit to view the project firsthand, talk with CHWs and caretakers, and offer feedback to the research team. Many concerns and questions have been raised by pilot committee members and other stakeholders during the introduction of zinc; Annex 2 provides a list of the more commonly asked questions.

Conclusions & Recommendations: Advocacy

- ❖ The introduction of zinc treatment can impact diarrhea management, childhood nutrition, and rational drug use; therefore, advocacy efforts need to target the policymakers and program planners concerned with all of these issues and engage them in a zinc-related dialogue.
- ❖ A pilot committee is an effective strategy to involve diverse stakeholders and policy makers in the integration of zinc into routine policies and programs.

Coverage of zinc treatment at the community level

The pilot study revealed a number of issues associated with achieving a high level of coverage of zinc treatment among children with diarrhea. These include maintaining a continuous supply for providers, and creating and sustaining a demand for zinc in the community through promotion and positioning in relation to competing diarrhea treatments.

Continued zinc supply

An on-going challenge in maintaining adequate coverage of the target population is ensuring a continued supply of zinc tablets at all levels of distribution. The zinc tablets used in the study were procured by WHO from the Nutriset company based in France. Once in-country, the zinc packages are stored at the District Drug Warehouse at the referral hospital in Bougouni until requested by the community health centers. Prior to the start of the intervention, 180 packets (an estimated 2 months supply) were given to each health center, while CHWs operating drug kits received an initial supply of 36 packets post-training. Each CHW was then responsible for restocking his/her drug supply from the health center drug storeroom. This supply chain for zinc was largely effective during the brief period of the pilot introduction; however, the system is especially vulnerable to stock-outs at the drug kit level and stock-outs of ORS packets did occur. CHWs often find it difficult to re-stock drug kits due to the financial and time costs of making a trip to the health center. CHWs may wait until more than one medication in their kit has run out before re-stocking. In some cases, further difficulties resulted when the CHWs sold medications to community members on credit.

Community promotion of zinc treatment

The promotion of zinc treatment for the pilot intervention was done primarily through village meetings and individual counseling provided by CHWs and the head nurses at health centers. A large number of CHWs also reported promoting zinc treatment at community events such as baptisms, marriages, funerals, and religious holidays; they also mentioned promoting zinc treatment in informal discussions with friends and village chiefs. The community-based promotion of zinc was well received; however, it was only conducted in those villages with a village drug kit and did not include all the villages in the health zone covered by the health center. In the final household surve y conducted four months after the introduction of zinc, 59% (81/137) of caretakers of sick children who lived in villages with a drug kit had knowledge of zinc, however, only 28% (99/351) of caretakers interviewed in *all* the villages of the two health zones had any knowledge zinc. While social marketing of zinc for diarrhea has been employed in other countries, large-scale promotion has not yet been carried out in Mali, partially because for the pilot intervention, zinc introduction was restricted to a very limited geographic area. Also, access to mass media in the rural areas of Mali is much more limited than in other contexts.

Competing sources of diarrhea treatments

Many caretakers do not procure medicines for their children from the formal health system (community health centers or village drug kits) which can also negatively impact coverage. In Mali, many drugs and treatments are purchased through the private sector—namely in village markets alongside food and other products or from ambulatory vendors. This phenomenon was examined closely in the pilot study and it was found that the purchase of drugs from unauthorized sources was especially pronounced in the home treatment of childhood diarrhea. Despite the increased coverage that might have been achieved through this distribution mechanism, the decision was made to not make zinc available privately in the pilot study for the following reasons: (1) many of the vendors are without a fixed place of work, (2) some of the vendors are children, (3) it is difficult to monitor side effects and outcomes of zinc treatment when working with informal sector providers as is required at this stage of zinc introduction, and (4) it is difficult to assure quality of the product, as the sources of medications in the informal sector have not yet been determined. In addition, very few private outlets or vendors are sanctioned by the government. However, distribution of zinc through the private sector is currently being utilized in some Asian countries and it merits further examination and discussion in the African context.

Conclusions & Recommendations: Coverage

- ❖ Stock-outs of zinc (and other essential medications) can greatly affect the coverage of the intervention at the community level. Steps should be taken to ensure that CHWs are able to procure medications at the community level with minimal financial and time inputs. For example, we found that in some cases in Mali, CHWs were required to purchase a consultation ticket (approximately \$1.00) from the health facility in order to purchase medications for restocking. The waiver of such fees should be negotiated with health officials in order to facilitate restocking at the community level.
- ❖ Community meetings served as an effective way of promoting zinc in villages where CHWs were active. However, other types of zinc promotion in the community, especially in zones where CHWs are not active, are needed. In addition to the possibility of a large-scale marketing campaign, other opportunities for promotion of zinc as a new treatment may include vaccination days at the health center, antenatal visits, and the "stratégie avancée" outreach activities which take place in the villages. Other suggestions, given by CHWs and project staff, for other types of community-based promotion within the Malian context include: (1) plays created by theatre groups, (2) drumming and/or dancing with the zinc messages, (3) messages about zinc broadcast during village special events, (4) information passed on in schools so that students pass the information to their parents, (5) skits developed and performed by school students in the villages.
- ❖ In order to improve accessibility and coverage, distribution systems might involve private providers and/or vendors in the future. Because zinc is a micronutrient with no chance of evolving resistance and has very few documented side effects, obtaining government approval for such an approach may be less complicated than efforts to gain permission for distributing antimicrobials (such as antimalarials) in the private sector.

Financial access to zinc treatment

Financial access to zinc, as well as other health-related services and treatments, is a complex issue in this setting. In order for caretakers to consider zinc as an affordable option in diarrhea treatment, a number of factors need to be addressed. These include: the price of the zinc treatment, the total costs of improved diarrhea management, costs when the child presents with symptoms in addition to diarrhea, and gender roles in decision making..

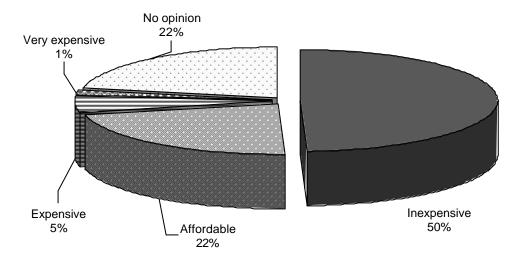
Pricing of zinc treatment

The formal health system in Mali is based on the Bamako Initiative (Knippenberg, Alihonou et al. 1997; Gilson, Kalyalya et al. 2000; Ridde 2003) and uses revolving drug funds for local cost recovery. At the community health center, villagers are charged consultation fees and also need to pay separately to fill any prescriptions obtained. Profits earned at the health center are used to pay staff salaries, for upkeep of the center and equipment, and to restock supplies and medications. CHWs (village drug kit managers), while offering their services for free, still must charge for medications in order to cover costs such as transportation to replenish their stocks. Any additional revenues from the drug kits are split between the CHW and village oversight committees as reinforcement and reward for their hard work.

These factors, combined with a consideration of what would be affordable for this population—especially with the recommended additional purchase of 2 ORS sachets—guided pricing decisions. For the pilot study, zinc was given to the referral hospital depot at no charge by Save the Children and WHO. The referral hospital then sold each zinc blister packet to the health center for 50 francs CFA (~\$0.09US); the health centers sold each blister package to the drug kits for 75 francs CFA (~\$0.14US). At the health centers and the drug kits, zinc packages were sold to patients for 100 francs CFA (~\$0.19US). Therefore, with each zinc sale, the health center collected profits of approximately \$0.09US, and the village committee overseeing the drug kits collected about \$0.05US.

Research was conducted prior to and during the pilot study to evaluate whether pricing would be a barrier to zinc use. In the qualitative data, most mothers interviewed said they found zinc affordable. However, some of the interviewed mothers who did not ultimately seek care for their child's diarrhea stated that the primary reason was due to a lack of funds. One mother, when asked why she had never visited the village drug kit, stated that it was because she did not have any money. She went on to say, "When I find the money, I will go." In the final household survey, caretakers who reported knowing the price of zinc were asked their opinion concerning its cost. Figure 1 presents these results; while most caretakers found the treatment affordable, price remained a barrier for certain caretakers.

Figure 1. Perceptions of the cost of zinc treatment Data collection method: Cross-sectional survey with caretakers of sick children Population (n): 77 caretakers who had heard of zinc and knew the cost Timing of data collection: September 2004, 4 months after zinc introduction



Costs incurred by families

The addition of zinc to ORS therapy for the management of both non-dysenteric and dysenteric diarrhea has been shown to be a more cost-effective intervention than the use of ORS alone (Robberstad, Strand et al. 2004). Zinc and copper, in addition to ORS therapy, for acute diarrhea were also associated with reduced treatment costs in a hospitalized population in India (Patel, Dhande et al. 2003). Current thinking is that zinc should be promoted as a money-saving

form of treatment for families of children with diarrhea. The rationale behind this putative cost savings element is that zinc is a more effective treatment for uncomplicated diarrhea than antibiotics, so the child gets better faster and there is less need to purchase additional medicines, or pay for hospitalization, when the child fails to recover. Additionally, the incidence of diarrhea is lower in the months following the treatment with zinc, so there are fewer episodes of diarrhea that require the family to purchase treatment.

However, in very resource poor settings, such as Mali, families rarely treat childhood diarrhea outside the household, although they may purchase a few pills or capsules from private vendors at a very minimal charge. Consequently, even though the introduction of zinc will bring better diarrhea management practices and better health outcomes, individual families in these settings may be spending far more on treating childhood diarrhea than they were previously mainly due to the encouragement of a more appropriate and complete courses of treatment. The pilot intervention made a simultaneous effort to improve management and referral of cases of childhood diarrhea, incorporating WHO/UNICEF guidelines into the intervention strategy. Therefore, zinc sales were accompanied by the promotion of ORS sachets and health workers were trained to emphasize referral to greater health facilities for children with danger signs. For caretakers, referral implies further consultation fees. While the price of zinc itself was relatively low, these ancillary expenses drove up the total cost of treatment significantly. Prior to this study, diarrhea prevention and control efforts were sporadic at best. Caretakers' standard treatment for simple diarrhea had come to be home fluids supplemented by a few antibiotic pills, frequently tetracycline, purchased at the market (commonly called *kunbléni* in Bambara). Home fluids carry little to no cost and marketplace antibiotics are generally sold at 10 – 15 francs CFA (\$0.02-\$0.03) per pill. The general costs incurred by families of children with diarrhea both before and after the introduction of zinc treatment are summarized in Table 3.

The fact that marketplace medications are sold on a pill-by-pill basis makes them very attractive to caretakers with limited resources, and stiff competition to the medications sold at drug kits and health centers. Within the formal system, health center staff and CHWs are required to sell the full dose of each treatment. Many parents expressed their preference on having the flexibility of only purchasing as much or as little medication as they could afford. A CHW in the Zantiébougou health zone explained the issue as follows:

"The difficulty that we have is the fact that certain people bring only 10 francs or 15 francs in order to buy medications. If you tell them that you cannot sell them just 10 or 15 francs worth of medication, they get angry and say that even though there is a drug kit, they still cannot get medications.....or, as people are used to buying *yalayalafura* [general term for drugs sold in the market or by ambulatory vendors] where there are products for 10 to 15 francs, they may think that it is the same thing [as medicines from the drug kit]." (PV824FB1)

Presenting	Prior to zinc introduction		After zinc introduction	
symptoms of the child	Typical treatments	Cost	Typical treatments	Cost
1. Uncomplicated diarrhea	Home fluids plus a couple of antibiotic tablets from the market	50 Fr	2 ORS sachets (200 Fr) 14 Zinc tablets (100 Fr)	300 Fr
2. Complicated diarrhea	Home fluids plus a couple of antibiotic tablets from the market	50 Fr	Referral to health center 2 ORS sachets (200 Fr) 14 Zinc tablets (100 Fr) Consultation fee at health center (500 Fr)	800 Fr
3. Fever/chills and uncomplicated diarrhea	Antimalarial	15 Fr	Antimalarial (15 Fr) 2 ORS sachets (200 Fr) 14 Zinc tablets (100 Fr)	315 Fr

Table 3. Increased costs incurred by families when zinc treatment is introduced

Costs when multiple treatments are prescribed (or recommended)

The presence of other symptoms, especially fever, further complicates the treatment regimen and in turn, elevates costs. Currently in Africa, malaria receives much attention and, in practice, this means that any child presenting with fever automatically receives antimalarial treatment. Previously, health workers often only prescribed or recommended the antimalarial, in spite of other symptoms, such as diarrhea. After the introduction of zinc treatment in the pilot area, three treatments (ORS sachet, zinc and antimalarial) are now prescribed or recommended for children with fever and diarrhea; the costs are shown in Table 3.

As indicated above, a child presenting with fever/chills and diarrhea may be prescribed an antimalarial, ORS sachets and zinc tablets. On occasion, parents state that theyonly have enough funds to purchase one of the medications, or are able to purchase one now and the others later. The study team and pilot committee are still discussing what should be the recommendations on this matter. However, in situations such as this, where parents cannot afford all the recommended treatments, the cost recovery system may need to be reexamined and subsidies considered in order to reach all families equitably.

Gender and decisions about purchase of diarrhea treatments

When making decisions about child health in this setting, gender roles were found to be an important consideration. While mothers are typically the primary caretakers of children, once financial costs become involved, responsibility turns to the father. Table 4 shows how in the Bougouni district fathers/husbands were more likely to have purchased the zinc treatment than mothers (37%), while an additional 29% of mothers obtained the money for the zinc purchase from their husbands. Qualitative interviews with mothers and fathers affirmed the fundamental role of the fathers in the purchase of zinc and other treatment decisions, such as following referral recommendations. It was also indicated that fathers often play a critical role in the administration of medications; either administering it themselves or reminding their wives about the dosing instructions given by the CHW. Furthermore, CHWs reported having at times by-passed reluctant mothers and approaching fathers in order to convince them of the need to purchase zinc treatment. The following is a typical response given when CHWs were asked

"what do you do when the mother does not have enough money to pay for the recommended treatments?"

"If the mother cannot buy them [the treatments], it is up to you to go and see the father of the child to talk to him and explain the seriousness of the illness and the importance of the treatment for the child......Some [fathers] purchase the treatment, but others, even if they want to purchase it, they do not have the money and cannot." (ZNB_GC901FM1)

The same division of responsibility by gender was not seen in the promotion of ORS. Increasing foods and fluids do not necessarily require financial payments, unless ORS sachets are purchased outside of the home. Therefore, decisions of feeding and fluids remain the mother's responsibility. Because men and women are both involved in management of childhood diarrhea, an intervention promoting improved (i.e., ORS and zinc) management needs to target all community members, but provide different types of information to men and women.

Table 4. Roles of household members in the purchase of zinc treatment Data collection method: Follow-up survey in household with caretakers of children receiving zinc Population (n): 123 caretakers whose children received zinc from CHWs or health facilities **Timing of data collection:** 4-12 weeks after the official introduction of zinc treatment

Mother/caretaker bought the zinc treatment	32 (26%)
Husband purchased the zinc treatment	45 (37%)
Mother searched for money to purchase zinc treatment by:	
asking husband for money to purchase zinc	36 (29%)
asking another family member for money to purchase zinc	5 (4%)
asking another person for money to purchase zinc	4 (3%)
selling goods (shea butter*)	1 (1%)

^{*}a product used in both cooking and beauty products. Women collect the shea fruit from the areas surrounding villages; they then employ a lengthy and complex processing method in order to produce the shea butter.

Credit mechanisms for healthcare costs

In the area of the pilot study, a formalized credit mechanism for healthcare costs currently does not exist. Certain caretakers reported informal borrowing of funds from family members, neighbors, friends, and village associations when absolutely necessary. Such loans were repaid as soon as the borrower was able. CHWs also reported giving certain villagers short-term loans (typically 1 – 2 days to one week), even though defaults could jeopardize the functioning of the kit by creating gaps in the revolving drug fund. In general, managers said that they only gave out loans to those in whom theyheld confidence of repayment and no interest was charged. For example, one CHW reported that if a borrower had defaulted on a previous loan, "we will not be giving him credit for a second time." Also, women were judged to be more reliable than men in reimbursing loans. This is because, "if a woman owes credit, she will be ashamed if her debt is exposed in the presence of another woman, or anyone." Women cited selling goods at the market or asking a family member for funds as means of repaying loans. (GC019SK1)

In searching for methods of enforcing re-payment, CHWs described approaching the village drug kit surveillance committee to impress upon debtors—and all villagers—that

medications in the drug kit belong to the community as a whole. They have suggested that further community education on this point will help decrease defaults and further promote the functionality of the kit. Another recourse for recuperating drug kit loans involved working with the local cotton associations—taking the loan payment from the sale after the harvest. In certain villages, the cotton association, or *ton*, itself served as the lending source. The CHW from one of these villages explained that:

"For those who do not have the financial means to take their child to the health center [after referral] and has the will to go, since there is a *ton* in this village, we go see the managers in order to request credit so that the parent will be able to care for his child at the health center. This is done in the presence of the child's father and he is given the money directly." (GC019SK1)

Rarely were loans needed exclusively for zinc, as the treatment cost was relatively low; however, credit mechanisms became a factor when zinc treatment was coupled with other prescriptions.

Conclusions & Recommendations: Financial access to zinc treatment

- ❖ In health systems where cost recovery mechanisms are in place, the price of zinc must be carefully chosen. Pricing choices must take into account the need of the health system to sustain itself while also attempting to make the zinc treatment within the financial reach of as many families as possible. The question of how best to ensure financial access to zinc treatment for the poorest families in such contexts remains unresolved.
- ❖ In order to reduce financial barriers, zinc might be provided free of charge, especially when multiple medications are prescribed. However, offering zinc free of charge raises questions of sustainability, since there may be no system in place to continue the supply once project funds are discontinued. Providing only zinc treatment for free in areas with cost recovery mechanisms in place might have unintended consequences, such as families replacing other indicated medications that are not free with zinc.
- ❖ To address issues of financial access when multiple treatments are recommended, subsidies or a restructuring of the cost recovery system must be considered. One approach might be to package drugs together for certain combinations of symptoms and charge the same amount, regardless of the contents of the packet. This type of approach would provide some subsidy to the families required to purchase multiple treatments, while allowing for some cost recovery to sustain the system.
- ❖ In the case of southern Mali, utilization of zinc treatment results in families spending more on diarrhea treatment than they are accustomed. In such contexts, promotion of zinc treatment, along with ORS therapy, should focus on zinc as an effective means of stopping diarrhea quickly, rather than its cost-savings benefits. Such promotion may also discourage locally-available antibiotics as an unnecessary purchase in the treatment of simple diarrhea.
- An intervention promoting improved management of diarrhea (i.e., ORS and zinc) in contexts similar to southern Mali needs to target men as well as women with different types of information about diarrhea case management. Messages promoting zinc as a highly effective medication for diarrhea might be especially directed to men, while messages for women might concentrate on appropriate home management practice.
- ❖ Credit mechanisms, by providing loans for health care expenses, may be able to ameliorate some issues of financial access. However, the question remains as to what sources in the community are able to make credit available; health centers and drug kits have shown themselves to be unviable options for lending funds beyond a certain level. One option, recently explored in an operations research project conducted in the same area, links a system of credit for health care costs to each village's cotton producer association. As the vast majority of the population in this area grows cotton as a means of income, most community members are affiliated with the cotton associations and would therefore, have access to credit.

Correct administration of zinc

Complete and correct administration of zinc to children with diarrhea is a multi-step process, which involves the correct prescription or treatment recommendations and counseling at the level of the health facility or CHW. Parents must then administer the zinc appropriately to their sick children.

Prescribing and counseling by health workers

The dosing of the zinc regimen is relatively simple and the majority of health center staff and CHWs participating in the pilot had little trouble recommending and selling correct doses. The household follow-up survey (n=123) showed that 96% of children who had received zinc treatment were prescribed the correct dose; further details on prescribing practices are presented in Table 5. Furthermore, direct observations of consultations at the health centers revealed that in two of the incorrect cases, it was the same nurse's aide who gave children over 6 months only seven tablets instead of 14—until instructed otherwise. Counseling regarding the administration of zinc treatment was also adequate. In the follow-up surveys, over 90% of caretakers reported that the CHWs and health center staff sufficiently explained the quantity of zinc needed, the length of time for treatment, and the various methods for administering the zinc tablets (i.e., directly, or dissolving them in water or breast milk). However, we found that counseling on danger signs of diarrhea was poor, with fewer than 25% of caretakers reporting that they had been informed by the CHW or health center personnel on danger signs.

Table 5. Reported prescribing practices in health centers and drug kits Data collection method: Follow-up survey in household with caretakers of children receiving zinc Population (n): 123 caretakers whose children received zinc from CHWs or health facilities Timing of data collection: 4-12 weeks after the official introduction of zinc treatment

	Children	Children 7-60	All	
	0-6 months	months	Children	
	n=12	n=111	n=123	
Prescribed/Sold Correct Dose	10 (83%)	108 (97%)	118 (96%)	
Prescribed/Sold Incorrect Dose	2* (17%)	3** (3%)	5 (4%)	
*2 shildren given 14 tablets: 1 eace at health center and 1 eace at village drug kit				

^{*2} children given 14 tablets; 1 case at health center and 1 case at village drug kit
**2 children given 7 tablets at health center and 1 child given 28 tablets at village drug kit

One of the difficulties encountered with zinc treatment obtained at the drug kits is that caretakers sometimes purchase medications without first having the CHW actually see and assess the sick child. Parents will come to the drug kit and demand the medications that they want. This occurrence can lead to incorrect dosages and/or incorrect medications given to the sick child. It also does not allow the CHW to assess for danger signs, possibly missing children that require referral.

Administration of zinc treatment in the home

Most of the mothers found that dissolving the zinc tablet in a small amount of water and giving it the child in a spoon was the most effective manner of administration. All methods reported in the household follow-up survey are presented below in Table 6. Problems with administration of the zinc treatment were relatively uncommon. Vomiting and the child refusing the tablets were mentioned by a very small percentage of caretakers.

Table 6. Ways that zinc was administered to children

Data collection method: Follow-up survey in household with caretakers of children receiving zinc **Population (n):** 123 caretakers whose children received zinc from CHWs or health facilities **Timing of data collection:** 4 - 12 weeks after the official introduction of zinc treatment

Method of administration* (reported few times to always)	All children 0-60 months n=123 (%)
Dissolve tablet in spoon with few drops of water	117 (95%)
Dissolve tablet in spoon with a few drops of breast milk	5 (4%)
Put the tablet directly in the child's mouth	2 (2%)

^{*}not mutually exclusive

In this study, the recommended dose was 14 days of treatment of 20mg per day for 10 days for children over 6 months and 10mg per day for children 0-6 months. We also defined the minimum dose as 10 or more days of treatment of the same dosage, which is the minimum dose recommended by the WHO (WHO/UNICEF 2004). Adherence to the full 14-day regimen during the pilot was high and dosing was generally appropriate (Table 7). About two-thirds of children received the dose of zinc exactly as recommended for 14 days. In addition, over 90% of children followed received at least the minimum recommended dose of zinc. Those cases who only received the minimum dose rather than the recommended quantity either stopped administering zinc on day 12 or 13, or skipped 1 – 2 days during the 2 week period. In two cases of children under 6 months, they were prescribed and received a full tablet (20mg) per day instead of the recommended ½ of a tablet (10 mg). Children that did not even achieve the minimum treatment either had their treatment stopped after a few days, or were children over 6 months who received only half of a tablet per day. While overall adherence was to our expectations, we are not unaware of the study effect—by visiting households interviewers likely increased the level of compliance.

Table 7. Administration of a full 14-day full course of zinc treatment adherence in the home during the pilot study

Data collection method: Follow-up survey in household with caretakers of children receiving zinc **Population (n):** 123 caretakers whose children received zinc from CHWs or health facilities **Timing of data collection:** 4-12 weeks after the official introduction of zinc treatment

	Children	Children 7-60	All
	0-6 months	months	Children
	n=12	n=111	n=123
Administered as recommended	8 (67%)	71 (64%)	79 (64%)
Administered minimum dose	12 (100%)	100 (90%)	112 (91%)

Conclusions & Recommendations: Correct administration of zinc

- ❖ Zinc regimens were prescribed with few errors. Counseling provided about administration of zinc regimens was also adequate; however, because of commonly observed deficiencies, counseling on danger signs requiring further care should be emphasized and reinforced during CHW trainings.
- ❖ In order to avoid the sale of zinc (or other medications) in the absence of the CHWs seeing and assessing the child, (1) training and supervision activities need to stress to CHWs that they should not sell medications without seeing the child (i.e. drug sales on demand), and (2) community promotion activities need to emphasize the value of the CHW's assessment of sick children and encourage families to take children to the CHW, rather than just demanding to purchase medications.
- Side effects and difficulties with administration were relatively rare, with a few mothers reporting vomiting.
- ❖ Over half of the children received the recommended dose of zinc treatment (14 days) and the great majority received the minimum dose (10 days). These results were obtained when the 14 day regimen was recommended; it is not known what the levels of compliance would be achieved when a 10 day regimen is recommended.

Community perceptions and acceptance of zinc

Community reaction to zinc was largely positive. Community members expressed appreciation for the packaging, the taste of the tablets, and the outcomes seen in their children post-administration. Favorable reactions to the zinc tablets often included comments upon the sterile and attractive packaging—a phenomenon observed with other pre-packaged drugs (Kilian, Tindyebwa et al. 2003). Some parents felt that the packaging too closely resembled paracetamol available in local markets, which may prove confusing for certain consumers. Some parents credited the ease in administering the treatment to children to the sweet taste. Others found the appearance of the white tablets to be appealing and clean In general, parents expressed a strong willingness to purchase zinc to treat their child's diarrhea.

The majority of mothers interviewed (in semi-structured interviews) also reacted very positively to the effect of the zinc treatment, stating that their child's diarrhea was resolved in only a few days after purchasing the zinc. In the final survey, 96% of caretakers who reported administering zinc (52 cases) stated that they were satisfied with the treatment. The 2 cases who were not satisfied said that their children were not totally cured by the zinc. Mothers who administered zinc to their children were not only content with the cessation of the diarrhea, they particularly noted the increase in the child's appetite and the return of normal activity levels. For example, one mother stated:

"Before I gave the zinc to my child, he could not go two weeks without having diarrhea. Every time I gave him the medications, the diarrhea would stop for a few days and then start again. But with the zinc it was different, the child took the zinc and he is relieved...he plays a lot as you can see, he eats and breastfeeds without stopping." (PE803FM1)

She also noted that the child easily swallowed the diluted tablets, with no vomiting, and the diarrhea ended after three days, although she continued administering the full course of zinc.

In this region of Mali, distinctions are made regarding different types of diarrhea based on apparent symptoms or perceived causes. Simple diarrhea, most commonly experienced by children, is referred to as $k\hat{o}n\hat{o}boli$ and is characterized by frequent, loose or watery stools often caused by teething or certain foods. $K\hat{o}n\hat{o}r\hat{o}joli$ means "interior wound" and is a more severe form where blood is found in the stool. And, the most dangerous form of diarrhea is $t\hat{o}g\hat{o}t\hat{o}gonin$, (loosely translated as dysentery) where both blood and pus may be present in the stools, and at times is accompanied by vomiting (Ellis 2004).

In earlier phases of the research, it was noted that the treatments families used often depended on the locally-defined type(s) of diarrhea the child had (Ellis 2004). Accordingly, in the final survey after the introduction of zinc, we asked caretakers their opinions about the efficacy of various treatments for three different types of diarrhea. Figure 2 demonstrates that the majority of caretakers who had heard of zinc reported that it is effective for simple diarrhea (kônôboli), however, its effectiveness was thought to diminish with the increased complexity of the diarrhea cases. In this same figure, a similar pattern is seen with respect to ORS, in which it is perceived to be effective for simple diarrhea, but less so for more severe diarrhea. A locally-available antibiotic, sold in the form of loose tablets and likely to be tetracycline in most cases, kunbléni, is perceived to be about equally effective for all types of diarrhea.

<u>Conclusions & Recommendations: Community perceptions and acceptance of zinc</u>

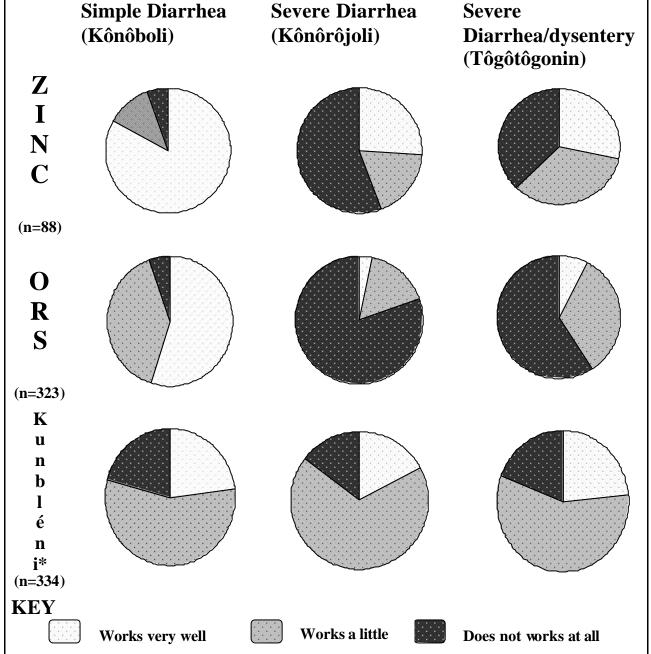
- ❖ Although the association between zinc and appetite has not been definitively established, it was one of the greatest perceived benefits of zinc treatment. Program managers may want to emphasize this aspect in future promotional campaigns.
- ❖ Zinc distributed at the health center was rather plain and can easily be confused with locally available paracetamol. Packaging of zinc needs to be unique and allow mothers to identify it with diarrhea treatment.
- ❖ The utilization of zinc and ORS for *all* types of diarrhea needs to be emphasized in educational and promotional activities. Because the more severe types of diarrhea are often not considered to be sub-types of simple diarrhea, messages need to include all the major, locally-recognized types of diarrhea illness.

Figure 2. Caretakers' perceptions of the effectiveness of zinc, ORS, and antibiotics purchased from the market (kunbléni)

Data collection method: Cross-sectional survey with caretakers of sick children

Population (n): For Zinc pie charts - 88 caretakers reporting knowledge of its efficacy; For ORS pie charts - 323 caretakers reporting knowledge of its efficacy; For Kunbléni pie charts - 334 caretakers reporting knowledge of its efficacy

Timing of data collection: September 2004, 4 months after official introduction of zinc treatment



^{*}An antibiotic capsule, usually tetracycline, available locally in markets and from ambulatory vendors.

Zinc introduction into existing diarrhea interventions

Concerns over replacement of ORS/ORT by zinc

One of the major concerns when introducing zinc into current diarrhea mana gement practices is the potential that caretakers might consider zinc a substitute for ORS or ORT. This possible replacement is a concern for a range of reasons. Zinc is a new product in a "fancy" blister pack and may be a more attractive purchase than an ORS sachet. Parents often prefer to use modern treatments, which generally come in the form of pills or injections, to "cure" the diarrhea (Ellis 2004). Furthermore, in this area of Mali, it has been found that parents understand that ORS and ORT does not cure diarrhea, but rather is used to prevent dehydration. Therefore, if parents only have a limited amount to spend, they may purchase the new, modern zinc product that can cure diarrhea versus a sachet of ORS.

Despite these concerns, current evidence suggests that introducing zinc into the diarrhea management mix may actually improve ORS use, probably through improving appropriate care seeking for diarrhea episodes. A community-based trial in Bangladesh found that introduction of zinc improved the use of ORS (Baqui, Black et al. 2004). The pilot study in Mali was not specifically designed to measure changes in ORS usage. However, preliminary evidence suggests that this limited introduction of zinc did not negatively impact ORS use rates; the proportion of caretakers using ORS for diarrhea in the previous 2 weeks was actually 63% higher 4 months after the introduction of zinc than the proportion using ORS before the introduction of zinc.

Co-Promotion of Zinc and ORT

Because of the potential replacement effect, it is essential that zinc be promoted with some form of ORT, although the best approach to promoting zinc and ORT together is still unclear. In Mali, anyone who purchased zinc was encouraged to purchase ORS sachets; if parents did not or could not purchase the ORS sachets, they were encouraged to prepare Sugar Salt Solution (SSS) in their homes. A co-packaging approach of ORS sachets and zinc is attractive because by design it avoids a potential replacement effect of zinc for ORS and, depending on timing and logistics, can facilitate the co-promotion of the new, low-osmolarity ORS formulation and zinc. However, it increases the price of the package, so that it may be prohibitive for families with limited resources.

WHO and UNICEF recently released a joint statement recommending that the use of zinc and a new, reduced osmolarity formulation of ORS become standard practice in the management of acute diarrhea. This new ORS formulation has been shown to reduce stool output and duration of diarrhea (WHO 2001; WHO/UNICEF 2004). Promoting zinc and the improved ORS formulation together for the same illness may be more efficient and provides an excellent opportunity to promote an improved diarrhea management package, rather than promoting the two treatments separately.

What home fluids to promote: ORS, SSS or other home-available fluids?

In addition to the new ORS formulation, WHO and UNICEF joint statement recommended incorporating zinc into other current management practices, such as increasing

fluids and feeding during diarrhea episodes (WHO/UNICEF 2004). It does not recommend the promotion of SSS, contrary to prior WHO policies. The global change in policy on SSS results from concerns that correct preparation at the household level can be difficult, at times producing solutions with dangerously high concentrations of salt. Nevertheless, in Mali, current national policy still calls for the promotion of SSS if ORS therapy is not possible. Therefore, to be in line with existing MOH policy recommendations, the pilot intervention advised caretakers to prepare SSS if they did not purchase ORS sachets. The Ministry of Health in Mali will soon re-examine its policies regarding diarrhea management. It may reconsider the policy of recommending SSS and modify national policy to instead promote increased feeding and liquids.

<u>Conclusions & Recommendations: Zinc introduction into existing</u> diarrhea interventions

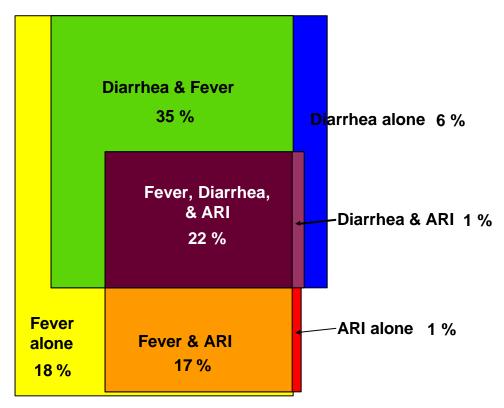
There is a possibility that zinc treatment may replace the use of ORS, as parents may prefer the new, modern-looking tablets to ORS packets. However, because zinc interventions may revitalize appropriate management and care seeking for childhood diarrhea, there is also the potential that zinc introduction can increase ORS utilization rates. Program managers need to carefully plan the promotion of ORS and/or ORT along with zinc so as to positively impact all diarrhea management practices.

Zinc treatment in children with multiple symptoms

Sick children in the community

In this setting, sick children rarely have only one symptom of illness and in fact, most children have multiple symptoms. Figure 3 presents the reported symptoms of children sick within the previous two weeks whose caretakers were interviewed in their homes during the baseline survey. The majority of children reported multiple symptoms (in green, orange, purple, and brown). Fever and diarrhea (in green) was the most frequent combination, with 35% of caretakers reporting these symptoms together. Very few children reported having symptoms of diarrhea alone (blue) or acute respiratory infections (ARI) alone (red). It is possible that some children experienced the reported symptoms successively rather than concurrently, as the data presented here include all symptoms seen during the child's illness of the previous two weeks. Even factoring this in, the information still suggests high rates of multiple symptoms in sick children in their homes. It is also likely representative of the symptom profile of all sick children in the community, as the sample was population-based and sick children were chosen randomly.

Figure 3. Reported symptoms of children sick in previous 2 weeks Data collection method: Cross-sectional household survey with caretakers of sick children Population (n): 352 caretakers of children sick within the previous 2 weeks Timing of data collection: April 2004, before the introduction of zinc



Sick children presenting for health care

A similar profile of multiple symptoms is also seen in children who present for care at community health facilities or village drug kits. As shown in table 8, children treated with zinc at the village drug kits were more likely to report diarrhea as their only symptom than those children treated at health facilities. However, very few children who were treated with zinc presented with diarrhea alone in either location and in both cases over 70% of children with diarrhea also have fever, ARI symptoms or both. In reality, it is not surprising to see children with multiple symptoms, as it is common occurrence in Africa. The association of certain childhood illnesses and symptoms, such as malaria parasitemia and dehydrating diarrhea (Ibadin, Airauhi et al. 2000), likely plays a role in this trend and needs be considered.

Table 8. Symptom patterns of children receiving zinc treatment for diarrhea at village drug kits or health centers during zinc pilot study

Data collection method: Follow-up survey in household with caretakers of children receiving zinc Population (n): 123 caretakers whose children received zinc from CHWs or health facilities Timing of data collection: 4-12 weeks after the official introduction of zinc treatment

Symptom complex	Total n=123 (%)	Presenting to Village Drug Kit n=102 (%)	Presenting to Community Health Center n=21 (%)	
Diarrhea only	31 (25%)	28 (27%)	3 (14%)	
Diarrhea + fever	36 (29%)	30 (29%)	6 (27%)	
Diarrhea + ARI*	23 (19%)	17 (17%)	6 (28%)	
Diarrhea + fever + ARI* + fever	33 (26%)	27 (27%)	6 (27%)	
* reported symptoms of cough, raised respiratory rate, respiratory difficulties, chest pain,				

and/or chest in-drawing

Many children in this region are also chronically malnourished; in the most recent DHS survey, 48% and 23% of children surveyed in the Sikasso region were moderately and severely stunted, respectively. Rates of acute malnutrition are also high, with 9.5% and 1.8% of children found to be moderately and severely wasted. {Demographic Health Surveys, 2001 #185}. A recent study, examining malaria drug resistance, which was conducted in health zone adjacent to the pilot area also found very high rates of malnutrition in children enrolled at the health facility (Radigues 2004).

Illness management in children with multiple symptoms

The frequent occurrence of multiple symptoms in sick children presenting for care raises issues of where zinc fits in an integrated management of childhood illness strategy. In fact, the failure to integrate and review the management of multiple symptoms during CHW and health center staff trainings was the largest operational issue encountered by our study team. Community health center staff are nurses who have received IMCI training. CHWs were originally established primarily as community-based distributors of malaria treatment and trained accordingly. Therefore, the training modules developed and implemented at the start of the pilot intervention focused almost exclusively on diarrhea management and did not focus on management of other childhood illnesses, such as malaria. However, during the course of the pilot study, monitoring of health worker registers and follow-up of children treated with zinc in their homes revealed that many of the children presenting with both diarrhea and fever were only sold zinc tablets and ORS sachets—they did not receive chloroquine treatment (the recommended treatment for all cases of fever).

Table 9 presents the treatments given to sick children, in addition to zinc received at health facilities and village drug kits, as reported in household follow-up interviews. The numbers also include those treatments obtained from other venues (such as a private vendor) that were given before or after receiving zinc treatment. For example, in some cases children with fever and diarrhea received chloroquine from another venue before presenting to a village drug kit (CHW) for zinc. A very small proportion (18%) of children with symptoms of diarrhea, fever, and ARI received an antimalarial: children with symptoms of diarrhea and fever were even less likely to receive an antimalarial. Treatment of fever with an antip yretic medication (paracetamol) was equally poor.

Within two weeks of noting the deficiency in management of children who present with fever and diarrhea, day-long meetings were held, in cooperation with the local health authorities, to discuss the issue in-depth. It was decided to provide follow-up "refresher" training to the CHWs. Discussions in this training and subsequent interviews with CHWs revealed that many of them had been working under the misconceptions that the combination of treatments was not necessary. CHWs stated "we did not know that it is necessary to also treat malaria; we believed that diarrhea treatment was sufficient," and questioned whether, "the child could handle two treatments at once." A review of drug kit registers (notebooks) and a second series of interviews after the refresher trainings confirmed that CHWs were managing children presenting with diarrhea and fever much more appropriately.

Table 9. Treatments children received (in addition to zinc) by symptom complex Data collection method: Follow-up survey in household with caretakers of children receiving zinc Population (n): 123 caretakers whose children received zinc from CHWs or health facilities Timing of data collection: 412 weeks after the official introduction of zinc treatment

Reported symptom complex	n	Treatments Received			
		ORS	Antibiotic	Antimalarial	Paracetamol
Diarrhea only	31	15 (48%)	5 (16%)	5 (16%)	3 (10%)
Diarrhea + fever	36	22 (61%)	1 (3%)	3 (8%)	4 (11%)
Diarrhea + ARI*	23	18 (78%)	7 (30%)	7 (30%)	3 (13%)
Diarrhea + AR I* + fever	33	24 (73%)	6 (26%)	6 (18%)	6 (18%)
* reported symptoms of cough, raised respiratory rate, respiratory difficulties, chest pain, and/or chest in- drawing					

There are two distinct issues in the management of children with multiple conditions. The most obvious, discussed above, is to ensure that all of the conditions the child has are adequately treated. A second concern is to how to ensure that all of the required medications are administered correctly to the child, and if not all medications are given, that at least the most important ones are given. There may be need to indicate the relative priority of the different medications if either the parent in unable to purchase all of the medications, or because of the child's condition the parent judges that the child will have difficulty ingesting all of the medications. A child presenting with diarrhea and fever may be prescribed an antimalarial, an antipyretic, zinc and ORS. If a parent indicates that she/he does not have sufficient funds to buy all of these treatments, he/she will likely prioritize and make purchasing decisions according to their individual knowledge and past experience. Therefore, health workers may require more detailed counseling guidelines for explaining the importance of the multiple treatments, as well as how to administer the various medications. Furthermore, consideration should be given to packaging treatments for different combinations of symptoms, and selling them at an affordable price.

In Mali the use of traditional medicines for all illnesses is commonplace. Nonetheless, there is a perception that that there are effective traditional treatments for malaria, but not for diarrhea, which contributes to difficulties surrounding the treatment of diarrhea with fever. Previously, children often received only chloroquine for diarrhea with fever, likely because of strong malaria control campaigns in this area. However, after the introduction of zinc, when questioned in in-depth interviews, many parents prioritized purchase of zinc to treat children with diarrhea and fever. The primary reasons stated for this preference included the perception

that there are effective traditional treatments for malaria, but not for diarrhea and that diarrhea takes away child's strength and, as such, is a more serious illness. As one parent explained:

"Malaria is easier to treat than diarrhea. I would begin by treating the diarrhea. There are many treatments for malaria and traditional medicines, which are effective, but for diarrhea... before, we used *kunbléni* (capsules, often tetracycline), but it is not effective and we mostly use it for *konorojoli* (severe diarrhea). Therefore, even if I could not buy the malaria medications, I could use the traditional medicines for that."

This phenomenon is especially concerning as Mali moves its first-line malaria drug to an artemisinin combination therapy (ACT), artesenate-amodiaquine. If the price of the new ACTs remain relatively high, parents of children with diarrhea and fever may be even more likely to revert to traditional therapies for the fever, while purchasing zinc for diarrhea. And, even though zinc was promoted only for diarrhea in the pilot study, some caretakers still perceived it to be an effective treatment for malaria and/or fever, as shown in table 10.

Table 10. Perceptions of symptoms zinc can treat

Data collection method: Cross-sectional household survey with caretakers of sick children

Population (n): 99 caretakers who had heard of zinc

Timing of data collection: September 2004, 4 months after zinc introduction

Which symptoms can zinc treat?*	n=99
Simple Diarrhea	95%
Dysentery	28%
Severe Diarrhea	31%
Malaria (Sumaya)	20%
Fever (Farigan)	9%
Loss of appetite	12%

^{*}Open-ended question; responses add to more than 100%

Referral of children to facilities

In any community-based intervention, program managers must decide which combination of symptoms should prompt referral to health centers. Some referral guidelines are based on general danger signs, while others involve more complex algorithms or symptom combinations. When making decisions about which illnesses or combination of symptoms should prompt referral to a higher level of care, one of the main considerations is what illnesses community-based providers, or even peripheral community facilities, are authorized to treat.

In Mali, CHWs were expected to refer children with general danger signs, such as convulsions, loss of consciousness, or inability to eat or drink, to health facilities. Because CHWs in Mali are not authorized to use antibiotics, they were also instructed to refer children with signs of Acute Lower Respiratory Infections (ALRI). In the zinc pilot intervention, CHWs were also instructed to refer all children who presented with bloody diarrhea to the community health center, so that these cases could be assessed and prescribed antibiotics if necessary. However, the rate of referral for such cases from the community to health centers was exceptionally weak. According to CHW registers, approximately 4% of children (10/244) had blood in their stools, yet none of these cases were referred. Previous research in this population

found that CHWs often recommended referral, but did not record it in their registers unless they thought parents would comply (Winch, Bagayoko et al. 2003), which could contribute to such poor measure of referral levels.

Another facet of referral that merits further discussions involves the recommended actions a CHW should take before the referral of complex cases. In the pilot study, CHWs were instructed to sell the zinc and any other recommended treatments and then to refer if the child required further care at health facilities. This strategy is commonly used for malaria and pneumonia treatment in the community, because prompt treatment of severe cases of these illnesses is critical. However, concerns were raised that this strategy, especially for diarrhea, could diminish appropriate referral as well as reduce prompt compliance with referral. For example, if a mother receives some treatment, she may decide not to go to the health center, even if the child is referred. An alternate approach would be to simply refer complex cases, without any treatment given before. The obvious disadvantage of this approach is that there is the risk that the sick child receives no treatment because he or she is never taken to the health facility.

<u>Conclusions & Recommendations: Zinc treatment in children with multiple symptoms</u>

- ❖ Sick children commonly have multiple symptoms of illness and health facilities and CHWs must frequently manage children with several illness symptoms. Therefore, community and facility levels providers need to be trained to manage sick children presenting with multiple symptoms. It is not sufficient to give training on manage ment of diarrhea when introducing zinc treatment for diarrhea, training needs also to cover management of common combinations of presenting symptoms such as diarrhea and fever, or diarrhea and cough. Job aids and registers/notebooks for recording symptoms and treatments should be designed with the presentation of multiple symptoms taken into consideration.
- ❖ Steps should be taken to ensure financial access to treatment for children who present with multiple symptoms, such as fever and diarrhea, and may require 4 or more different medications according to guidelines for presumptive treatment in the community. As new drugs are introduced for malaria, diarrhea and pneumonia, policy makers need to examine the costs that will be incurred when different combinations of symptoms are treated, and develop policies for subsidization that will not only make expensive medications such as artemisinin combination therapy affordable, but also promote rational treatment behavior for children with multiple symptoms
- ❖ A large proportion of sick children in populations such as southern Mali also suffer from malnutrition. Approaches to combine zinc interventions with longer-term strategies to improve overall child nutrition need to be explored.
- Referral to health facilities by CHWs for children who require further care is very weak, and parents may not observe referral recommendations, even when correctly counseled by CHWs. Promotion of appropriate referral practices needs to be a two-pronged approach. CHWs need adequate training and support to correctly refer complex cases. Since appropriately referred children often do not reach facilities, strategies also need to focus on facilitating the logistics of referral and sensitizing caretakers and household decision makers about the importance of referral. It may be more effective to aim behavior change communication (BCC) strategies to improve adherence with referral recommendations at men, since they play a large role in household health decision making, especially for decisions which involve significant sums of money.

Promotion of rational drug use

The unnecessary use of antibiotics can contribute to the development of antibiotic resistance (Radyowijati and Haak 2003). Additionally, the purchase of antibiotics when they are not indicated can also burden families with unnecessary costs. Antibiotics, except in the case of cholera and dysentery, do not have a positive effect on the diarrhea episode, and therefore, children with simple diarrhea should not receive antibiotics. Despite this, the use of modern medications—especially those purchased from unauthorized vendors—to treat childhood diarrhea is extremely high in southern Mali. Table 11 presents selected types of treatments given to children who reported diarrhea in the previous two weeks during the baseline survey. Traditional treatments were commonly given (73%); however, treatment with antibiotics was almost as common, with almost 60% of children with diarrhea reportedly receiving some antibiotics. Almost half (49%) of the antibiotics were purchased in the market; with another 13% purchased from unauthorized village vendors. Parents often purchase a few pills at a time at these locations. All the sources of antib iotics given to children are presented in figure 4. Ten (10) percent of caretakers reported purchasing antibiotics from two sources, with the community health center and the market the most common combination of sources in these cases.

Table 11. Types of treatment given to children with diarrhea

Data collection method: Cross-sectional survey with caretakers of sick children

Population (n): 228 caretakers of children sick with diarrhea within the previous 2 weeks

Timing of data collection: April 2004, before the introduction of zinc

•	n=228
Traditional treatment	167 (73.3)
Modern treatment	
ORS	S 25 (11.0)
Antibioti	` '
Antidiarrhoea	6 (2.6)

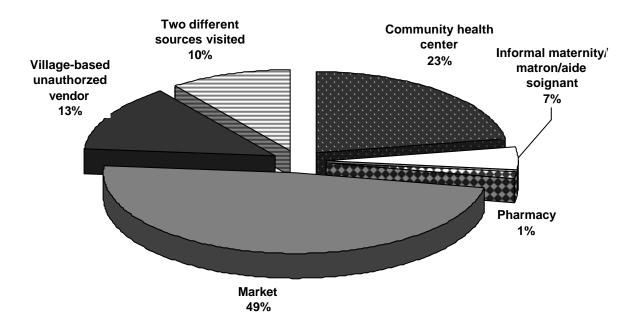
Because within the Malian context it is generally thought that childhood diarrhea is better treated with modern medicines, zinc has been well-accepted and does not necessarily compete greatly with traditional medications. Zinc also has great potential to replace antibiotics as a 'medicine' for diarrhea thus decreasing overall antibiotic use among children. In a recent study in Bangladesh (Baqui, Black et al. 2004), 13% of children with diarrhea living in zinc clusters were being treated with antibiotics for their diarrhea episode as compared to 34% of children with diarrhea living in control clusters (p<0.01). One concern that may deserve further attention is that zinc may not only reduce the rate of inappropriate antibiotic use, but its use may also decrease the rates of antibiotic use for cases of diarrhea which require antimicrobial treatment, such as dysentery.

Figure 4. Locations where antibiotics were purchased

Data collection method: Cross-sectional survey with caretakers of sick children

Population (n): 135 caretakers of children sick with diarrhea within the previous 2 weeks who reported purchase of an antibiotic for illness episode

Timing of data collection: April 2004, before the introduction of zinc



Conclusions & Recommendations: Promotion of rational drug use

- ❖ Use of antibiotics for childhood diarrhea, especially from unauthorized sources, is extremely common in southern Mali. Introduction of zinc has the potential to reduce the inappropriate use of antibiotics for acute diarrhea and accompanying promotional messages should discourage antibiotic use for simple cases of diarrhea.
- ❖ Parents are accustomed to purchasing and administering a few pills or capsules from the market for an episode of diarrhea. The longer term preventative aspects of zinc treatment should be emphasized in promotional activities in order to support the need for a 10 to 14 day treatment regimen; giving zinc for 10 to 14 days both fully treats whatever zinc deficiency the child had when treatment was initiated, and also builds up zinc levels in the body, and is associated with decreased incidence of diarrhea in the 2 or 3 months following a course of zinc treatment (Bhutta, Black et al. 1999; Baqui, Black et al. 2002).

Monitoring and evaluation of zinc introduction

The introduction of zinc requires careful monitoring and evaluation activities. In Mali, at the CHW level, a diarrhea notebook was used to monitor the zinc intervention. It contained columns related to diarrhea, treatments given, referral, and treatment outcomes. The trainings included a component about maintaining the notebooks; the notebooks provided an easy method for supervisors to monitor the performance of the CHWs and coverage of the zinc intervention.

The additional diarrhea notebook added to the responsibilities of the CHWs and some CHWs experienced difficulties, such as keeping notebooks up to date or recording the outcome of the treatment. Some second (back-up) CHWs had difficulty completing notebook entries unassisted, mostly because they often have lower levels of literacy. Overall though, the notebooks did not pose a great problem for the CHWs, and they were a very valuable tool in the routine supervision of the project and monitoring of results and problems. It was through the use of these notebooks that we were able to verify that children with diarrhea and malaria were not receiving appropriate care and take immediate remedial actions.

Annex 3 presents a list of sample indicators for monitoring and evaluating zinc programs. The indicators are based loosely on the evaluation frameworks proposed by Habicht et al and Bryce et al (Habicht, Victora et al. 1999; Bryce, Victora et al. 2004; Victora, Habicht et al. 2004). They are presented in a sequence which approximately follows the chains of events that must occur for the intervention to have an impact. Certain levels must be achieved earlier in the chain (such as availability of zinc) in order to have the desired effects later in the chain (such as improved diarrhea management practices).

This is not intended as a comprehensive list, nor should all the presented indicators necessarily be used in all programs. Obviously the established goals and accompanying activities will differ between programs; evaluation methodologies and key indicators will need to reflect these specific goals and activities. Monitoring and evaluation activities will also depend greatly on the program's available resources and are often determined by the needs of the program managers and financing institutions. For example, indicators for health facility staff and CHWs level are presented together here so as to avoid repetition. However, the need to evaluate each indicator at these different levels will depend on program activities and the requirements of funding agencies. Also, depending on the duration of program activities, periods such as 3 months may need to be extended to 6 months, 1 year, or longer.

Conclusions & Recommendations: Monitoring and evaluation

- ❖ A monitoring and evaluation plan should be an integral part of any programme introducing zinc. The indicators chosen need to reflect the overall program goals and structure. Program managers may consider using some of the sample indicators presented in annex 3.
- ❖ Use of simple notebooks at the community level can be a valuable tool for program supervision and monitoring of difficulties or problems in implementation.

Conclusions

Overall, zinc as a treatment for diarrhea has been well-received in Mali by partner organizations and community members alike. This pilot study provides valuable information about both the difficulties and opportunities associated with the programmatic introduction of zinc treatment in an African setting: the main conclusions are summarized here.

Advocacy with stakeholders in the Ministry of Health, NGOs and other child health and nutrition organizations is a necessary element of any intervention to introduce zinc treatment in order to build or renew commitments to control of diarrheal diseases and malnutrition, have zinc treatment accepted and formally registered with national authorities, and commit policymakers to planning for large-scale adoption and promotion of zinc treatment in local health systems. The introduction of zinc treatment can impact diarrhea management, childhood nutrition, and rational drug use; therefore, advocacy efforts need to target the policymakers and program planners concerned with all of these issues and engage them in a zinc-related dialogue. Advocacy may also be needed in relation to oral rehydration solution. Knowledge about low-osmolarity ORS sachets is still limited. Furthermore, availability of the existing higher-osmolarity formulation of ORS may be limited, and there may have been no recent marketing or health education on ORS in the country. There may be a need to "relaunch" ORS as a health intervention at the same time zinc treatment for diarrhea is introduced.

Limited availability of zinc at the local level may be a major constraint on program effectiveness. Steps should be taken to ensure that both zinc and ORS sachets are readily available in both health facilities and at the community level. In order to improve accessibility and coverage, distribution systems should consider distribution through private providers and/or vendors.

Financial access. In resource poor settings, families may rarely treat childhood diarrhea outside the household, although they may purchase a few pills or capsules from private vendors at a very minimal charge. Consequently, even though the introduction of zinc will bring better diarrhea management practices and better health outcomes, individual families in these settings may be spending far more on treating childhood diarrhea than they were previously—mainly due to the encouragement of a more appropriate and complete courses of treatment with both zinc and ORS sachets. Referral implies further consultation fees.

Correct administration and community perceptions. Zinc regimens were prescribed with few errors. Counseling provided about administration of zinc regimens was also adequate; however, because of commonly observed deficiencies, counseling on danger signs requiring further care should be emphasized and reinforced during CHW trainings. Although the association between zinc and appetite has not been definitively established, it was one of the greatest perceived benefits of zinc treatment. Program managers may want to emphasize this aspect in future promotional campaigns. Zinc distributed at the health center was rather plain and can easily be confused with locally available paracetamol. Packaging of zinc needs to be unique and allow mothers to identify it with diarrhea treatment. The utilization of zinc and ORS for all types of diarrhea needs to be emphasized in educational and promotional activities. Because the more severe types of diarrhea are often not considered to be sub-types of simple diarrhea, messages need to include all the major, locally-recognized types of diarrhea illness. Use of antibiotics for childhood diarrhea, especially from unauthorized sources, is extremely common in southern Mali. Introduction of zinc has the potential to reduce the inappropriate use of antibiotics for acute diarrhea and accompanying promotional messages should discourage antibiotic use for simple cases of diarrhea.

Multiple treatments and multiple symptoms. Sick children commonly have multiple symptoms of illness and health facilities and CHWs must frequently manage children with several illness symptoms. Therefore, community and facility levels providers need to be trained

to manage sick children presenting with multiple symptoms. It is not sufficient to give training on management of diarrhea when introducing zinc treatment for diarrhea, training needs also to cover management of common combinations of presenting symptoms such as diarrhea and fever, or diarrhea and cough. Job aids and registers/notebooks for recording symptoms and treatments should be designed with the presentation of multiple symptoms taken into consideration. Health workers may require more detailed counseling guidelines for explaining how to administer multiple medications. Furthermore, consideration should be given to packaging treatments for different combinations of symptoms, and selling them at an affordable price. In order to reduce financial barriers, zinc might be provided free of charge, especially when multiple medications are prescribed. However, offering zinc free of charge raises questions of sustainability. To address issues of financial access when multiple treatments are recommended, subsidies or a restructuring of the cost recovery system must be considered. One approach might be to package drugs together for certain combinations of symptoms and charge the same amount, regardless of the contents of the packet. This type of approach would provide some subsidy to the families required to purchase multiple treatments, while allowing for some cost recovery to sustain the system.

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Annex 2. Questions frequently asked during introduction of zinc treatment for diarrhea

Table 12. Questions and concerns expressed by the pilot committee overseeing the zinc introduction study in Mali and participants in other meetings

1. Nutrition:

- 1. What is the evidence for zinc deficiency in Mali What is the level of deficiency and what are the causes?
- 2. What are the clinical signs of zinc deficiency?
- 3. What are the dietary sources of zinc other than meat?
- 4. Is breastmilk a good source of zinc?
- 5. Is zinc deficiency a criterion for inclusion in the study and/or for treatment of children presenting to a health provider, and if not, why not?
- 6. Is zinc deficiency also a problem in school age children?
- 7. Why not give zinc as a daily supplement, instead of as a treatment for diarrhea?

2. Diarrhea case management:

- 8. Why provide zinc as a treatment separate from ORS? Wouldn't it be simpler for delivery of the intervention to include zinc in the ORS?
- 9. How safe are zinc tablets, and how common is vomiting resulting from ingestion of the tablets?
- 10. Will parents have enough funds to pay for both zinc tablets and ORS sachets? Won't people with limited resources tend to purchase the zinc tablets in place of the ORS sachets, resulting in lower rates of ORS use?
- 11. Is it wise to include zinc in the national list of essential medicines? This may result in the price being fixed at a level too low for it to be a profitable product for the private sector to produce and market.

Annex 3. Suggested sample indicators to monitor the introduction of zinc

					Possible data
	Sample Indicators		Numerator	Dominator	collection method(s)
Provision (Implementation)	1.	Proportion of health facility staff &/or community health workers (CHWs) in program area that are trained in the new diarrhea management protocol	# of health facility staff &/or CHWs in program area that are trained in the new diarrhea management protocol	Total # of health facility staff/CHWs in program area	 Program administrative records Health facility assessment
	2.	Proportion of health facility staff &/or CHWs in program area that have clinical guidelines/job aids/visual aids in place	# of health facility staff &/or CHWs in program area that have clinical guidelines/job aids/visual aids in place	Total # of health facility staff/CHWs in program area	 Program supervision records Health facility assessment
	3.	Proportion of health facility staff/CHWs receiving supervisory visit in past 30 days	# of health facility staff/CHWs reporting supervisory visit in previous 30 days	Total # of health facility staff/CHWs in program area	Program administrative recordsHealth facility assessment
Provision (Availability & Accessibility)	4.	Number of health facilities/CHWs providing zinc + ORS per 100,000 children < 5 years of age in program area	# health facilities/CHWs providing zinc & ORS packets in program area [x (100,000)]	Estimated population of children < 5 years of age in program area	 Program administrative records Health facility assessment Most recent census
	5.	Proportion of children < 5 years of age who live less than 5 km from any zinc + ORS distribution point	# of children < 5 years of age residing in towns or villages within 5 km of health facility or CHW supplying zinc & ORS	Estimated population of children < 5 years of age in program area	Program administrative recordsMost recent census
	6.	Proportion of health facilities/CHWs without stock-out of zinc in the previous 3 months	# of health facilities/CHWs who do not report a gap in stock of zinc in previous 3 months	Total # of health facilities/CHWs in program area	Routine HIS dataHealth facility assessmentSupervisory records
Provision (Quality)	7.	Proportion of health facility staff /CHWs who correctly recommend zinc + ORS to more than 90% of children <5 presenting with diarrhea 3 months after training	# of health facility staff/CHWs who recommend zinc + ORS for a minimum of 90% of children with diarrhea	# health facility staff /CHWs in program area from who data is obtained	 Routine HIS data from records Exit interviews/follow-up interviews Cross-sectional surveys
	8.	Proportion of children < 5 with diarrhea treated at health facilities/by CHWs who receive appropriate treatment for diarrhea according to revised IMCI/C-IMCI norms	# of children <5 with diarrhea treated at health facilities/CHWs who are recorded as receiving/ report correct IMCI treatment	# of children <5 with diarrhea treated at health facilities/ CHWs who are recorded/interviewed	 Routine HIS data from records Exit interviews/follow-up interviews Cross-sectional surveys
	9.	Proportion of caretakers of children < 5 treated with zinc who received counseling about zinc administration &/or ORS preparation and administration	# of caretakers of children <5 treated with zinc who report receiving counseling about zinc administration &/or ORS prep.	# of caretakers of children <5 treated with zinc who are interviewed	Exit interviews/follow-up interviewsCross-sectional surveys

	Sample Indicators	Numerator	Dominator	Possible data collection method(s)
Utilization	10. Number of health facility attendances of children <5 with diarrhe a per 1000 children <5	# of children <5 with diarrhea attending health facility [x (1000)]	# of children < 5 in program area population	Routine HIS data Recent census data
	11. Number of zinc blister packets distributed at health facilities/CHWs	# of zinc blister packets distributed at health facilities/CHWs	1	 Routine HIS data Health facility assessment Administrative records
	12. Average number of zinc blister packets distributed per health facilities/CHWs	# of zinc blister packets distributed at health facilities/CHWs	# of health facilities/CHWs	 Routine HIS data Health facility assessment Administrative records
Coverage	13. Proportion of children < 5 with diarrhea in previous 2 weeks who received the minimum recommended dose (10 tablets) of zinc	# of children <5 with diarrhea in previous 2 weeks whose caretakers report zinc purchase and administration of > 10 tablets of zinc	# of children <5 with diarrhea in previous 2 weeks included in survey	Cross-sectional surveys
	14. Proportion of children < 5 with diarrhea in previous 2 weeks who received zinc & ORS	# of children <5 with diarrhea in previous 2 weeks whose caretakers report zinc & ORS administration	# of children <5 with diarrhea in previous 2 weeks included in survey	Cross-sectional surveys
	15. Proportion of children < 5 with diarrhea in the last 2 weeks who sought treatment from an authorized provider	# of children <5 with diarrhea in previous 2 weeks whose caretakers report seeking care at an authorized provider	# of children <5 with diarrhea in previous 2 weeks included in survey	Cross-sectional surveys
Impact*	16. Change in proportion of children <5 who visited a health facility/CHW for last diarrhea episode*	% of children <5 who visited a health facility/CHW for last diarrhea episode at final survey	% of children <5 who visited a health facility/CHW for last diarrhea episode at baseline survey	Baseline and final cross- sectional surveys
	17. Change in proportion of children <5 who received zinc treatment for last diarrhea episode*	% of children <5 who received zinc treatment for last diarrhea episode at final survey	% of children <5 who received treatment for last diarrhea episode at baseline survey	Baseline and final cross- sectional surveys
	18. Change in proportion of children <5 who received an inappropriate antibiotic for last simple diarrhea episode*	% of children <5 who received ORS therapy for last diarrhea episode at final survey	% of children <5 who received ORS therapy for last diarrhea episode at baseline	Baseline and final cross- sectional surveys

*For impact indicators the calculations are as follows:

Absolute change = [(numerator column) – (denominator column)]

Relative change = [(numerator column/denominator column) - 1]