CCM Products

Last Mile Perspectives on ORS, zinc, and cotrimoxazole from CHWs in Malawi and Ethiopia

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SC4CCM Project

The Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood Project is funded by the Bill & Melinda Gates Foundation under grant agreement no. OPP1002868, beginning November 2, 2009. The grant is implemented by JSI Research & Training Institute, Inc. The project aims to demonstrate that supply chain constraints at the community level can be overcome, and that doing so may yield significant improvements in the effectiveness, scale, and impact of CCM. SC4CCM will identify, demonstrate, and institutionalize supply chain management (SCM) practices that improve the availability and use of selected essential health products for treating children under five in community-based programs.

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Abstract

In September and October 2012, the SC4CCM Project conducted focus group discussions with community health workers who have been providing community case management (CCM) services and treatment to children under five in Malawi and Ethiopia. The purpose of the focus groups was to elicit the community health workers' opinions on the suitability of the products they had for their environment – both from a supply chain and client perspective. The products of interest included ORS and zinc for the treatment of diarrhea and cotrimoxazole for the treatment of pneumonia. The facilitators asked CHW participants questions to gather feedback related to the products in use, the ease of management and administration, patient and caregiver/mother acceptability, and ideas for product improvement. This report summarizes the opinions from CHWs in both countries, highlighting areas of agreement and where opinions differed.

Cover photo: SC4CCM Project.



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Acronyms

ACT	Artemisinin-based combination therapy
CCM	community case management
CHW	community health worker
FGD	focus group discussion
HC	health center
HEW	health extension worker
HP	health post
HSA	health surveillance assistant
IMCI	Integrated Management of Childhood Illnesses
KII	key informant interview
LA	artemether/lumefantrine (Malawi)
MAC	Malaria Alert Centre
MOH	Ministry of Health
ORS	oral rehydration salts
SC	supply chain
SC4CCM	Improving Supply Chains for Community Case Management of Pneumonia and Other
	Common Diseases of Childhood project
SCM	supply chain management
SNNPR	Southern Nations, Nationalities, and Peoples' Region

Introduction

The "Improving Supply Chains for Community Case Management of Pneumonia and Other Common Diseases of Childhood" (SC4CCM) project is a five-year project funded by The Bill & Melinda Gates Foundation. Implemented by JSI Research & Training Institute, Inc. (JSI), the project is being implemented in three countries; Malawi, Ethiopia and Rwanda over five years.

Supply Chains for Community Case Management (SC4CCM) is a learning project focused on finding affordable, simple, and sustainable supply chain solutions that address the unique challenges of community health workers. The project goal is to demonstrate that product availability can be significantly improved at the lowest levels of the supply chain, thereby contributing to improved child health in communities. To achieve this goal, the project is testing innovations to generate knowledge that can be put into broader practice for supply chain operations, financing, and advocacy. The project is also learning about the most effective and appropriate products for use at the community level, in order to better advocate for the availability of affordable, pediatric- and supply chain-friendly products to treat children under five for pneumonia, diarrhea, and malaria. As part of the project's interventions, SC4CCM strives to improve understanding and knowledge of the products in use for community case management (CCM), including their perceived strengths and limitations for use at the community level.

In September and October 2012, the SC4CCM Project conducted Focus Group Discussions (FGDs) in Ethiopia and Malawi with Community Health Workers (CHWs) to understand their opinions on and preferences for CCM medicines for the treatment of diarrhea and pneumonia. The impetus for the FGDs was to solicit feedback from CHWs on their experience with CCM products and the suitability of current medicines, including packaging, strength/dose, formulation, and patient acceptability in order to understand the strengths and weaknesses of current products for their particular setting. Given that CCM services are provided at the lowest level of the supply chain there are unique considerations for product packaging - including transportation, storage, and administration. Products need to be well packaged and protected from the elements, both while in transport and wherever the CHWs store them until they see patients, and after they are dispensed to caregivers and children.

In both countries, most CHWs transport products from their resupply point, usually the closest health center (HC), by foot, bicycle, or on the back of an animal (donkey or camel). Therefore, products need to not be too bulky or heavy and be well protected from the elements (rain, heat, humidity). In Ethiopia, products are stored at the health post (HP), a permanent physical structure that is usually well protected from rain and has shelves for storing medicines and health products. In Malawi, CHWs keep their CCM products in a drug box, generally stored in their homes when they are not holding a village clinic or conducting outreach. As homes tend to be grass thatched and have permeable floors and roofs, CHWs have been trained to store their products as best as possible.

"As one of us said earlier, we live in grass thatched houses and we can take care of them by dusting more often" (CHW, Malawi)

"Sometimes our houses have small holes on the iron sheets, there is need to place the box where water cannot drop on it." (CHW, Malawi)

"Yes caring for them it becomes hard because some of us are living in villages that where there are no houses with iron sheets. When you check the villages you could find the house. For example the house I lodged was full of dust I had to ask the

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landlord to put cement on the sitting room only, they understood and did. Now I put my drug box there. But that is very true that some houses are not in good conditions it becomes hard to care for the products." (CHW, Malawi)

Additionally, products need to be suitable for the CCM target beneficiaries – infants and children from two months to five years of age. This is a unique population and the products selected should be appropriate for and acceptable to this age group. The FGDs gathered information from CHWs on their perspectives on the products and any feedback they heard from caregivers about the products they used to treat diarrhea and pneumonia.

CCM Program Background

In Ethiopia, there are over 23,000 Health Extension Workers (HEWs) trained on CCM, with scale up anticipated to 30,000 HEWs. HEWs are a paid cadre of community health workers trained to provide 16 packages of preventive and curative health services. Each kebele or village has a health post where two HEWs are stationed. HEWs manage up to 55 products, including oral rehydration salts (ORS) and zinc for the treatment of diarrhea and cotrimoxazole for the treatment of pneumonia. The HEWs were trained to provide CCM services in 2010 and were provided a training kit at the time of training, with phased distribution of starter kits following, beginning in late 2011 for the first 500 health posts. While HEWs have had ORS prior to the training on CCM and the starter kits, these kits were the first time that most HEWs were receiving zinc and cotrimoxazole tablets. As starter kits for the CCM program are still being distributed, HEWs for the focus group were selected based on distribution date, with the desired experience length being at least three months.

In Malawi, CCM is provided by Health Surveillance Assistants (HSAs), a paid cadre of community health workers introduced in 1970s, traditionally for environmental health activities. Since 2008, over 3,000 HSAs located in hard to reach areas have been trained to provide CCM, in addition to other preventive services. HSAs manage up to 19 different commodities, including ORS and zinc for the treatment of diarrhea and cotrimoxazole for the treatment of pneumonia in children under age five. Zinc was introduced to CCM in Malawi in 2010. Most HSAs in Malawi received their first allotment of zinc in late 2010 to early 2011.

Purpose of Focus Group Discussions

The SC4CCM Project undertook focus group discussions in order to better understand the products that CHWs in each country were using and their suitability for distribution to the community level – both from a supply chain perspective and appropriateness for the target clients – children under age five.

Specifically, the purpose of the FGDs was to:

- Understand CHW (and, by proxy, caregiver) preferences for medicines given to children in the community for the treatment of pneumonia and diarrhea in Ethiopia and Malawi. (This includes opinions on medicine presentation, formulations, packaging, and user acceptability).
- Elicit ideas from CHWs on what would improve the medicines they use, both from a patient perspective and from a product management perspective, and understand opportunities and challenges for packaging and formulations at the community level.

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Methodology and Data Analysis

This document is a summary report of focus groups conducted by independent consultants in Ethiopia and Malawi. SC4CCM hired qualitative data specialists in each country and provided them with a semistructured FGD discussion guide to be used with groups of CHWs that the SC4CCM Project helped to select and coordinate. The guide was similar in each country but was adapted to reflect local vocabulary and references. This report, therefore, represents synthesis conducted by SC4CCM based on the final reports, data analysis reports, and transcribed records of the FGDs received from each consultant to compare and contrast findings from the two countries. Quotations from CHWs contained within come from the reports and FGD transcripts.

The FGD guide contained both general and product specific questions aimed at understanding CHW preferences for and opinions on the current packaging, formulation, user acceptability, and opportunities for improvement or change.

Ethiopia

In Ethiopia two qualitative data specialists were hired to conduct FGDs – one consultant for the Amhara region and another consultant for the SNNPR region.

In Amhara, the consultant conducted focus group discussions with HEWs and Key Informant Interviews (KIIs) with health center staff in Mecha and North Achefer woredas. Two focus group discussions were held with 10 HEWs each, with participants selected from 15 health posts. As follow up, key informant interviews were conducted with the health center head and the health center pharmacy department head at the Merawi Health Center in Mecha Woreda and with the health center pharmacy technician and the HEW Supervisor at Liben Health Center in North Achefer Woreda.

The consultant was accompanied to each FGD by a note taker with previous experience conducting FGDs. Data was collected from the FGD and KII participants using the FGD discussion guide. All interviews and focus group discussions were audio-taped, conducted in Amharic language, and transcribed and translated into English. All of the data collected was transcribed and translated materials and field notes were checked for completeness, clarity and consistency. The tape-recorded discussions were translated into English and transcribed verbatim, then thematically analyzed and summarized. Data in the final report was presented in tables and text.

In SNNPR, another consultant was hired based on his experience conducting qualitative research and knowledge of the region. He conducted FGDs in two zones - Hadiya and Gedeo, which included nine and ten HEWs, respectively. HEWs were selected by contact persons in the two zones based on their experience with the CCM program and products. The previously mentioned discussion guide was used for the FGD, while an experienced note-taker recorded comments and observation during the discussions. Two KIIs were conducted with Health Center staff from the same HCs participating in the FGDs from the two zones. Three were pharmacy Technicians and one was a Nurse working in the under-five clinic at the health center.

The study was conducted in Ethiopia from October 14 to October 31, 2012. On average, in both Amhara and SNNPR regions, FGDs lasted for about one hour and fifteen minutes, while the KIIs lasted 30 minutes, on average.

In both regions, upon completion of data collection, the consultants used the analysis framework to identify the main themes. The consultants transcribed the discussions and translated them into English.

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The transcripts were then analyzed according to themes to identify key messages – both areas of general agreement and discordance amongst FGD participants. All data collected including interview tapes, transcribed and translated material and field notes were checked for completeness and submitted to SC4CCM with the final report.

Malawi

In Malawi, SC4CCM contracted the Malaria Alert Centre (MAC) from the Malawi College of Medicine to conduct the FGDs. SC4CCM provided MAC with a semi-structured guide to organize the discussion and ensure that questions of interest about products were addressed and were similar to those questions being asked in Ethiopia. FGDs were conducted with groups of HSAs comprising both female and male participants. The discussions were conducted in both English and Chichewa, recorded onto digital recorders and then transcribed and translated into English for analysis. MAC conducted 6 FGDs comprising of 64 participants total in three districts (Mulanje, Machinga, Nkhata Bay). The three districts were chosen based on the overlap with the supply chain management intervention that SC4CCM has implemented in order to allow for additional questions to be asked about that intervention.

Data was collected by two experienced social scientists hired by MAC. One led the discussion and the other took notes. The FGDs were recorded by audio and later transcribed to English and audited for accuracy. SC4CCM provided input to the content and text analysis of the qualitative data. Qualitative data comprised of field notes and the verbatim transcripts of the FGDs, which MAC compiled into a final report, identifying key themes and messages. The focus groups lasted for about two hours each, but also included questions about project interventions, in addition to the questions about CCM products. The FGDs were conducted between September 26 and October 5, 2012.

Sample

Ethiopia

In Ethiopia, for the product FGDs conducted by SC4CCM, 39 HEWs participated in four FGDs held in two regions (Amhara and SNNPR, including representatives from four woredas). The sample was chosen purposefully based on zones where SC4CCM was already working and length of time that the HEWs have had the CCM products. In the zones selected, HEWs had received their starter kits as part of the second phase of kit distribution (distributed in mid-2012), meaning that most of them had three to six months of experience with the new products – zinc and cotrimoxazole. The project confirmed this by checking the dates of kit receipt with the regional health bureaus, woredas, and health centers. All HEWs in Ethiopia are female so there were no considerations about trying to find a balanced gender representation.

In Amhara, the study health facilities were selected using the purposive sampling criteria mentioned, in consultation with SC4CCM team and woreda health offices. For the KIIs, participants were selected in the HCs that were managing the selected HPs and based on their experience in supporting HEWs with CCM medicines or supervising HEWs. Two focus group discussions were held with HEWs.

In SNNPR, the same purposeful sampling method was used. Nine HEWs from Misha Woreda in the Hadiya zone and 10 HEWs from 10 satellite HPs in Bulle Woreda, Gedeo zone were included in the FGDs. Contacts were made via telephone before departure to the field and instructions given to select the

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most experienced HEWs from the HPs, one from each HP. The KII participants were from the HCs that the HEWs were associated.

Malawi

MAC conducted six FGDs across the three districts (Mulanje, Machinga, Nkhata Bay), two in each district. The SC4CCM team and district staff helped classify trained HSAs as male and female to try to ensure balanced gender representation for the FGDs. Within each group HSAs were further grouped into those living 30km or more from the district hospital, those who lived 15 - 30km away from the hospital and those who lived between 5 and 15km away from the district hospital.

From each group, every 10th HSA on the list was selected. Four participants were invited from the group who lived further than 30km from the district hospital, five participants from the group living 15 – 30km away, and the remaining participants were from the group closest to the district hospital. In total, each FGD had a total of 10-12 participants. The study team used the telephone to reach the selected participants to ask for their consent to be part of the group discussions as well as to confirm participation. All FGDs had a minimum of three female participants except for Nkhata Bay district where there were no female HSAs employed in hard-to-reach areas.

Ethical Considerations

In Ethiopia, permission to conduct the FGDs and interviews was obtained from Regional Health Bureaus, Zonal Health Departments, and Woreda Health Offices before planning began. In Malawi, permission was obtained from the MOH, the IMCI Programme Manager, and district supervisors in the three districts. All FGD participants and KII participants were informed about the purpose, method and anticipated benefits of the study. Participation was entirely voluntary and participants were given the full right to refuse or withdraw at any time during the interview. Informed verbal consent was obtained from all the study participants after describing the study in detail. Participants also consented that their comments could be audio-taped.

Summary of Findings

The following are the recommendations that were clearest from the FGDs, across both countries:

- Provide tablets in the lowest strength needed; splitting tablets is a burden for CHWs and caregivers and manipulation introduces the potential for contamination and inappropriate dosing
- Packaging in the smallest course of treatment using blister packs and sachets is preferred by CHWs to ensure safety, hygiene, and promote easy transport, storage, and dispensing
- CHWs felt that instructions in local language(s) and particularly with pictorial instructions would improve adherence and caregiver ability to properly dispense to children for the remainder of the course of treatment

The following table summarizes the key findings for each product and in general for CHWs in both Malawi and Ethiopia. The findings are discussed in more detail by product and by country in the following sections.

Product	Management/Packaging	User Acceptability	Challenges	CHW Recommendations
CCM drugs- general	 CCM drugs are not difficult to store Tablets in blister strips are preferable to tablets in large bottles 	 Caregivers prefer liquid forms of medicines to tablets – they consider them more effective for children Flavor plays a big role in acceptability of products for children; bitter or salty tasting products are frequently spit out or refused CHWs and caregivers have difficulty with splitting tablets and there is a concern that additional manipulation introduces contamination 	 CHWs lack cutters for tablets Repackaging products introduces potential for contamination Caregivers find it difficult to give tablets to children- Grinding tablets creates drug wastage and potential for contaminations, wastage, and improper dosing Instructions on packaging of CCM drugs is not sufficient CCM drugs don't have pictorial instructions Language of instruction on packages not suitable for caregivers 	 Where liquid forms of products are not possible (or feasible for distribution to CHWs), provide dispersible tablets Provide sufficient, friendly and pictorial instruction using the local language(s) Provide blister strips instead of large bottle packs for tablets Improve the flavor of bitter or salty tasting products

 Table 1 - Summary of CHW Feedback on CCM Products - ORS, zinc, and cotrimoxazole

Product	Management/Packaging	User Acceptability	Challenges	CHW Recommendations
ORS 20.5 mg 1L low osmolarity sachets	 ETHIOPIA: Packaging is protective and easy to store and dispense There are some written instructions, no pictures 1L sachets may be too large for proper demonstration 	 ETHIOPIA: Product is unflavored - children don't like the taste CHWs were concerned that caregivers may not continue giving ORS correctly at home Caregivers do understand the benefits of the product 	 ETHIOPIA: Information on package not clear to parents Heavy to carry from HC to HP if given the full box (1,000 sachets) CHWs were concern about proper administration and use of clean water for mixing 	 ETHIOPIA: Improve the flavor of ORS Provide instructions for use pictorially and in Amharic Consider smaller sachets (0.5L) to reduce wastage and improve ability to mix
	 MALAWI: Packaging is protective and easy to store and dispense Demonstration is straightforward Written instructions, but no pictures 	MALAWI: • Orange flavor is good and easily taken by children; similarity to local orange drink makes it particularly appealing	MALAWI: • CHWs had concerns about caregivers mixing with the appropriate amount of (clean) water and discarding after 24 hours	 MALAWI: Provide instructions in local language and pictorially to improve caregiver ability to recall proper administration Consider smaller sachets (0.5L) to reduce wastage, improve mixing with the right amount of water
Zinc 20mg dispersible Tablets	 ETHIOPIA: Easy to transport, store, and dispense No pictorial instructions on packaging Splitting the blister strips for infants is difficult 	 ETHIOPIA: Flavor and dispersibility are acceptable Caregivers would prefer syrups Caregivers think that a half tablet is an insufficient dose 	 ETHIOPIA: Lack of cutters for zinc tablets at HPs Insufficient information on package CHWs concerned that caregivers did not continue for 10 days 	 ETHIOPIA: Provide zinc in syrup form Provide 10mg dispersible tablets to avoid splitting of 20mg tablets Consider reducing the length of days for zinc to fewer than 5 Provide pictorial and written information on package in Amharic
	 MALAWI: Packaging easy for transport and storage and well protected CHWs complained about splitting blister strips for children under 6 months of age 	 MALAWI: Product dissolves well and tastes sweet Splitting tablets is time consuming and introduces the potential for contamination and improper dosing Strong caregiver preference for syrups 	 MALAWI: Challenges with ensuring the full course (10 days) of treatment is followed Concern that caregivers do not properly split tablets for young infants No pictorial instructions on packaging to help caregivers recall dosing 	 MALAWI: Provide zinc in syrup form Provide 10mg dispersible tablets to avoid splitting 20mg tablets Provide packaging with pictorial and written instructions in the local language Reduce the course of treatment from 10 days

Product	Management/Packaging	User Acceptability	Challenges	CHW Recommendations
Cotrimoxazole 120mg Tablets	 ETHIOPIA: Usually supplied as 10 tablet strips; some CHWs reported having large bottles of 100 tabs No problems with transport, storage, and dispensing (with blister strips) No pictorial information on packages 	 ETHIOPIA: No side effects reported Mixed reports of dispersible and non-dispersible product in use Syrup form preferred by caregivers Strips preferred to loose tablets for dispensing Tablets difficult for children and tastes bitter (especially when non-dispersible tablets were reported) 	 ETHIOPIA: Takes time to dissolve Dissolving/grinding tablets at home is difficult for caregivers and introduces potential for contamination Counting tablets from large bottle packages subjects them to contamination at HP and at caregiver/child's home 	 ETHIOPIA: Introduce syrup form Alternatively, ensure (easily) dispersible tablets in strips are provided Provide instructions for caregivers pictorially and in Amharic
Cotrimoxazole 480mg Tablets	 MALAWI: Large bottles of 500 or 1,000 tablets were difficult to transport and store Repackaging for dispensing is time consuming 	 MALAWI: Caregivers would prefer syrups Taste is bitter and the tablets were difficult for children to take – frequently spit out Splitting tablets introduces the potential for contamination and incorrect dosing Blister packs are seen more favorably (and as more effective) by caregivers Caregivers appreciate the effectiveness of the product 	MALAWI: • CHWs concerned that caregivers would not correctly split tablets at home and that repackaging and manipulation by caregivers provided many opportunities for contamination	 MALAWI: Provide cotrimoxazole as syrup, especially for infants and young children Provide tablets in lower strengths to avoid splitting of tablets Provide cotrimoxazole in blister packs in a single course of treatment for easier/more hygienic dispensing Improve taste to reduce spitting out of tablets

Product Specific Findings: ORS

Product Specifications

<u>Ethiopia</u> Product: ORS – 20.5mg 1L low osmolarity sachets, un-flavored

<u>Malawi</u> Product: ORS – 20.5mg 1L low osmolarity sachets, orange-flavored



ORS sachets from Ethiopia (left); Orange-flavored ORS sachets from Malawi (right)

In Malawi and Ethiopia, CHWs use a similar ORS product; the biggest difference is that HEWs in Ethiopia have unflavored ORS, while HSAs in Malawi have orange-flavored ORS.

Management and Administration

When asked about the ability to manage and administer ORS, CHWs in both countries said that they liked the sachets and thought they were easy to transport, manage, and store. They felt that the sachets were well protected from the elements and easy to dispense to patients. The only complaints were about the size of the boxes that the sachets come in – some HEWs in Ethiopia were given boxes of 1,000 sachets which they said were too heavy to transport on a donkey or horseback with their other products.

Some CHWs in both countries mentioned that they had challenges with demonstrating how to prepare the ORS to caregivers if they didn't have a 1 Liter jug. Several said they frequently use a coke bottle (or other smaller but widely available type of bottle) to demonstrate and that this was more appropriate because households do not always have 1 L jugs.

Child/caregiver acceptability

Caregivers in both countries were familiar with ORS and considered it effective treatment for diarrhea. Child acceptability of ORS was an area where there were large differences between countries, due to flavor.

In Malawi, HSAs reported that children drank the ORS mixture easily as it was sweet and resembled a popular local drink called Sobo. However, in Ethiopia, where the product is unflavored, caregivers refer to it as "English salt" and HEWs reported that infants and children did not usually like it due to its salty and bitter taste. As one HEW said, the children say it tastes like tears. Only some children seemed able to drink it willingly.

"Mothers locally know it well and call it 'yengliz chew' (English salt) and like it for the treatment of diarrhea." (HEW, Ethiopia)

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Challenges with adherence/follow up

In both countries the ORS provided for the CCM program has only written instructions in English. CHWs are concerned that this affects proper use as caregiver recall of how to prepare may be limited. CHWs also raised concerns about contamination. CHWs explain to caregivers to boil water from wells and then cool before mixing with ORS, if it is not from a known safe water source, but many felt unsure about whether caregivers actually follow this recommendation.

The CHWs also shared reports of misuse from both countries. These included using an insufficient amount of water (even after proper demonstration), giving just ORS to children (not mixed with liquids), and mixing with other liquids (not water).

CHWs were also concerned with wastage. They said that they instruct caregivers to discard the mixed ORS after 24 hours, but mothers complain that much is thrown away/wasted because their children do not drink the full amount within that time period. Alternatively, CHWs were concerned that caregivers kept the mixed solution for longer than 24 hours so as not to waste it.

CHW recommendations

- Suggestions for improvements from CHWs were to decrease the sachet size to 0.5 L to reduce wastage. This would also make it easier to mix in locally available containers.
- CHWs also suggested that package information be provided in the local language and with pictorial information for the low literacy populations that they frequently serve.
- In Ethiopia, all HEWs thought the flavor should be sweeter and the taste improved to increase child acceptance.

Product Specific Findings: Zinc

Product Specifications

<u>Ethiopia</u>

- Product: Zinc 20mg dispersible tablets in 10 tab blister packs (HEWs trained on zinc in 2010)
- Guidelines:
 1 tab/day for 10 days for children > 6 months
 ½ tab/day for 10 days for children < 6 months

<u>Malawi</u>

- Product: Zinc 20mg dispersible tablets in 10 tab blister packs (introduced to HSAs in 2011)
- Guidelines: 1 tab/day for 10 days for children > 6 months ¹/₂ tab/day for 10 days for children 2-6 months



Dispersible zinc tablets from Ethiopia



Dispersible zinc tablets from Malawi

The products used in Malawi and Ethiopia for CCM are similar, as are the treatment guidelines. In both countries CHWs were asked about their knowledge of ORS and zinc. They were all largely familiar with the products and could explain why ORS and zinc should be given together. They were clear on how to administer both and could cite the individual importance of each. They said that they explain this to caregivers every time a child is classified with diarrhea. When asked about their knowledge of zinc (and particularly why ORS and zinc are given together) CHWs were generally well informed and able to articulate the reasons why they should be given together and the distinct mechanisms of action.

Moderator: "Is it possible to give zinc and ORS together and why"?

"It's because zinc plays her part and so does ORS" (HSA, Malawi)

"Zinc is like a mineral salt and it helps the child not to open bowels and it also helps to build the child's immunity to help the child to not have diarrhea for some time, whilst ORS helps to hydrate the body and targeting on diarrhea and its even recommended on the manual that zinc should be given side by side with ORS" (HSA, Malawi)

In general, the CHWs felt that they were able to spend more time explaining the medicines to caregivers than providers at health facilities. This is because at health centers, medicines are usually given through the dispensary window; whereas at village clinics (Malawi) and health posts (Ethiopia) CHWs sit with caregivers and explain and demonstrate proper product use and ensure that the children take the first dose while the CHWs are observing.

Management and Administration

From a transport and management perspective, CHWs in both countries found the current product packaging to be ideal. Zinc was packaged well, protected from the elements, and not too bulky or heavy.

In general, CHWs reported that zinc was easy to dispense to most patients. However, for infants under six months CHWS in both countries complained about splitting the blister packs and the tablets to prepare a treatment course of 5 tablets of zinc. The first challenge was splitting the strips of 10 tablets, as many CHWs did not have scissors or a sharp knife to cut the blister packs. This sometimes resulted in unequal tears or opening tablets in the blisters and having them fall to the ground.

The second challenge with this is splitting the individual tablets to make a half tablet. CHWs reported not having tablet splitters or knives and having to do this with their hands. Most CHWs said that they demonstrated how to split the tablets with the first dose and gave the remaining half tablet in paper to the care giver to take home for the next dose. This raised several concerns for the CHWs about how caregivers would prepare and administer future doses. They were worried about contamination – due to the lack of knives or splitters in many homes, caregivers would have to use their hands or other tools, which could result in the introduction of contaminants. Another concern was proper dosing – if tablets are crushed while split or split unevenly this could lead to over- or under- dosing. They were also concerned that caregivers would not be comfortable splitting tablets so would either give whole tablet or would not give the product at all to their infants.

CHWs reported that caregivers expressed concern that the split tablets were not even an effective dose – that the half tablets were too small to cure a child. In Ethiopia, HEWs reported that many caregivers ask *'yichi litadnew new?'* - isn't this tablet too small to cure the child? (about the split tablets).

Child/caregiver acceptability

Reports from CHWs on zinc were largely positive. They felt that as a relatively new product zinc was well accepted by caregivers and children. Reports indicated that it tastes sweet and dissolved well, so children generally take it without resistance.

"There are no challenges giving the zinc, it is packed well, it dissolves well too." (HSA, Malawi)

However, CHWs reported that preferences from caregivers were overwhelmingly for syrups. Caregivers seemed to think that syrups were more effective for treating children. Caregivers thought that their children (generally less than two years) were too young for tablets, even after the CHW demonstrated how to dissolve the zinc tablets in liquid. In some instances, CHWs also indicated a preference for syrups, though this ran counter to their feelings that the dispersible tablets were easy to transport (whereas syrups would be heavy and bulky).

CHWs wanted pictorial instructions on the packaging so that caregivers, especially those with low literacy skills, would remember when to give to children and how to prepare the dispersible tablets. CHWs felt that with a 10 day course of treatment it was too long for caregivers to remember without additional instructions.

"Caregivers think it's difficult for their children to take medication of 10 days. So they stop giving zinc after 3 days." (HEW, Ethiopia)

"It is easy for children to take zinc. It is sweet." (HSA, Malawi)

Challenges with adherence/follow up

Challenges with adherence to zinc were reported from CHWs in both countries. Both HSAs and HEWs were concerned that a 10 day course of treatment would not be followed. They reported that caregivers often stopped giving the product when the child starts feeling better.

CHWs said that they try to address this by explaining the benefits of the full course and, where possible, following up with households, especially those that seemed to struggle during the examination. Follow up is not always possible given their other responsibilities, so in Malawi they also use volunteer CHWs for follow up.

Another concern that was reported is that caregivers tend to keep leftover products for other children. Therefore, if a child with diarrhea is better after three days they would stop the zinc treatment and keep the rest of the treatment course until another child in the household was sick (or that same child became sick again). Since CCM services and treatment are free, CHWs try to avoid this by encouraging mothers to bring the other child as needed for their own medication. But there is a general acceptance that beyond stressing the importance of completing the course of treatment and follow up in a few cases they cannot control what caregivers do at home. They try to address this through targeted follow up visits.

"In our communities we are able to assess our community members and we know who needs help and those are the ones we follow-up and help them accordingly, especially typically the villagers with no school, we are forced to follow them up..." (HSA, Malawi)

"To be practical we do not only do follow-ups to all children we try to choose those that had difficulties in understanding how to administer the drugs, our catchment areas are too big to followup every child." (HSA, Malawi)

CHW recommendations

- In both countries CHWs felt that zinc should come in syrup form and this echoed strong sentiments from caregivers that syrups were superior pediatric treatment than tablets. However, this was not evaluated in the context of product management/transport and earlier agreement that for these purposes tablets in blister packs are preferable.
- CHWs also recommended decreasing the number of days for treatment to increase adherence and reduce the burden on caregivers/patients.
- CHWs also felt that the use of local language and pictorial instructions on the packaging would improve ability to explain zinc to caregivers and increase adherence/ proper use for a course of treatment.
- Given the challenges with splitting blister packs and individual tablets for children less than six months of age, CHWs said they would prefer 10mg tablets to avoid splitting blister packs and tablets for younger children.

Product Specific Findings: Cotrimoxazole

Product Specifications

<u>Ethiopia</u>

Product:

Cotrimoxazole 120mg dispersible tablets packaged in strips of 10 tablets*

Guidelines:

2 months to 12 months – 2 tablets 2 times per day for 5 days (20 tablets per course of treatment)

1 to 5 years – 3 tablets 2 times per day for 5 days (30 tablets per course of treatment)



Cotrimoxazole 120mg tablets from Ethiopia

* There were reports of both dispersible and non-dispersible tablets in use during FGDs; there were also some reports of HEWs receiving the products in bottles of 100 tablets. This discrepancy is likely because the first shipment of cotrimoxazole to Ethiopia for CCM was non-dispersible tablets in larger bottles, but later shipments included the dispersible product in blister strips of 10 tablets.

<u>Malawi</u>

Product:

Cotrimoxazole 480mg tablets, generally distributed to HSAs in bottles of 500 or 1,000 tablets

Guidelines:

2 months – 12 months - 1/2 tablet 2 times per day for 5 days (5 tablets per course of treatment) 1 to 5 years – 1 tablet 2 times per day for 5 days (10 tablets per course of treatment)



Cotrimoxazole 480mg tablets from Malawi

Given the differences in the products in use for the treatment of pneumonia, the feedback from CHWs in each country will be discussed separately.

Cotrimoxazole: Ethiopia

Management and Administration

HEWs in Ethiopia reported that the packaging of cotrimoxazole is generally in blister strip form and thus is good for safe transportation from the health center to health post. HEWs also did not report having any problems storing this packaging at the health post. There was some conflicting information about pack size – some HEWs reported receiving tablets in bottles of 100 tablets, rather than blister strips. There were also conflicting reports on dispersibility; HEWs in one region reported having dispersible tablets while others reported having non-dispersible tablets. Further investigation showed that this is likely due to the fact that the first shipment of cotrimoxazole 120mg tablets to Ethiopia for CCM were not dispersible and packaged in bottles of 100 tablets, whereas later shipments (and planned future shipments) are

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dispersible tablets in blister strips of 10 tablets.

HEWs that had the larger bottles of tablets reported that dispensing and counting tablets from large bottles was much more likely to introduce contamination, both during dispensing at the health post and as the caregiver transported and stored the tablets at home, as the HEWs rarely had pill bags for dispensing.

Child/caregiver acceptability

The mix of dispersible and non-dispersible tablets led to conflicting reports on child and caregiver acceptability. Those that had non-dispersible tablets said that it was very difficult to give the medicine to children, especially younger children. HEWs were concerned that as caregivers ground up tablets to mix them with food or liquids to give to smaller children, contaminants may be introduced, or the full dose could be compromised. Even for HEWs that had dispersible tablets they complained that they took a long time to dissolve. There were a few reports, though not unanimous or widespread, that the pills tasted bitter. As with the zinc tablets, there was a strong preference amongst caregivers for syrups, even from those HEWs who had the dispersible tablets.

Challenges with adherence/follow up

HEWs were concerned that there was no pictorial information on packages. However, they did not feel that this impacted their ability to explain the product to caregivers, as it was straightforward. Their concerns were mostly about recall after the caregiver returned home and continued to dose the product in the following days of the treatment course. HEWs felt that improved information on the packaging, both in the local language (Amharic) and pictorial instructions, would improve caregiver adherence and ensure proper continuation of the treatment at home.

"They may or may not remember what we tell them orally. Therefore, we write the information on a piece of carton and give them so that they can read if they are able to read or for other children at home can read it for them." (HEW, Ethiopia)

"It is better to have a pictorial explanation; it would be easier for us to explain and easier for parents." (HEW, Ethiopia)

"The information on the package is not sufficient. It is better if pictorial explanation is added." (HEW, Ethiopia)

HEWs felt that the slow to dissolve tablets (or non-dispersible) were a challenge for caregivers at home, and efforts taken by caregivers to facilitate/speed this process only increased the probability that the medicine would be exposed to contaminants.

Further, those that received the tablets in larger bottles were very concerned with maintaining the integrity of the tablets after repackaging them.

"I can give the strip straight away. But for [the other], I've to open the bottle, count the required tablets... prepare my own paper bag and give it. Therefore, the strip is preferable." (HEW, Ethiopia)

"The strip is preferable .For example, if caregivers place the counted tablets on a wet surface, it will automatically get damaged, and the strip does not." (HEW, Ethiopia)

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HEWs had not received any reports of side effect since the cotrimoxazole tablets were introduced.

CHW recommendations

- While there was generally a strong recommendation for syrups, HEWs also suggested that improved dispersible tablets, where the time of dissolving was reduced, could help improve the product.
- Where HEWs had received larger bottles of tablets, requests for the blister strips was strong.
- For all products, improved packaging information in Amharic and with pictorial information was suggested.

Cotrimoxazole: Malawi

Management and Administration:

Based on experience with other products, HSAs agreed generally that products that were available in blister strips and sachets (generally as individual courses of treatment) are preferable. Except in rare instances, HSAs reported that the cotrimoxazole 480mg tablets they receive were in bottles of 500 or 1,000 tablets. HSAs reported that these bottles were heavy and bulky to transport. Some reported that their quantities were doled out from these larger bottles and issued to them as 200 or 300 loose tablets, for which they were asked to find a suitable container for storage.

This bulk packaging also means that HSAs have to repackage the tablets to give to caregivers, usually with materials they find available, like strips of paper, as pill bags were rarely available. They also reported repackaging the cotrimoxazole in some of the empty cartons they have from the ACTs (referred to locally as LA) or caregivers tying the pills into their clothing to transport home.

"Cotrimoxazole does give us problems because we have to put it in pill bags and if we do not have pill bags as they are not readily available, we are forced to put in LA [Coartem] empty packs and we still have difficulties." (HSA, Malawi)

"When pill bags are available it becomes easier for you just write on them how they should be taking the course as compared to when you have improvised a paper." (HSA, Malawi)

"We try our best finding a paper to wrap them so that they are protected." (HSA, Malawi)

"LA [Coartem] cartons have a certain paper which was made at the manufacturers and we use that when there are no pill bags. We use that, as they are clean." (HSA, Malawi)

"Other caregivers will tie in her wrapper and she forgets and wash together." (HSA, Malawi)

Given the numbers of clients they see, the large bottles of tablets lasted each HSA for several months, but HSAs felt that the length of time, number of contacts, and exposure to the elements with the open bottle likely introduced contamination and wastage as tablets were counted out for each course of treatment. If they had received them in secondary packaging (i.e. 200 or 300 loose tablets in another tin) the tablets at the bottom were frequently crushed and counted as their losses/wastage.

"On a negative note, cotrimoxazole, because it is counted to us maybe one gets 200...300...500 (group response) out of 1000 and they are counted by hands, it's not hygienic, we are also asked to look for empty tins/bottles to keep the drugs. It is better for me to get the full tin of 1000 tablets and

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keep it clean and safe." (HSA, Malawi)

HSAs also complained about the amount of time it took to count out tablets for dispensing to individual patients.

Child/caregiver acceptability

In general, HSAs in Malawi reported that caregivers were pleased with the effectiveness of cotrimoxazole since it was introduced because it cured their children quickly. However, of all of the products they administered to children, HSAs reported the biggest problems with cotrimoxazole. HSAs reported that the taste was bitter and it was the product that the children were the most likely to spit out, whereas such problems were rarer with well-flavored tablets.

"We are forced to hold the baby down for them to accept cotrim, but with LA [Coartem] because it is sweet and has a flavour, we do not have a problem, children take the solution down their throats without any problems." (HSA, Malawi)

"The main issues when you are dealing with a child you need to be patient, then with the flavours as we have already said because the cotrimoxazole that we are using now is meant for adults. May be if they could be bringing some flavoured cotrim with a bit of sweetness then the problem of giving through the mouth and vomiting might be reduced." (HSA, Malawi)

"At first, children think ORS is bitter, but after taking it, they realise its sweet. But not with cotrimoxazole - when you have just taken it, there is an aftertaste that discourages the children not to continue drinking." (HSA, Malawi)

This raised a concern with HSAs that if caregivers chose to grind up or dissolve the tablets to make them more palatable they could potentially be under- or over-dosing or increasing the risk of contamination by combining with unsafe water or other liquids.

Almost all of the HSAs complained about using an adult formulation and needing to split tablets for younger children. They all said that they usually demonstrate how to split tablets but then send the caregivers home with the full tablets to split at the time they give to the child.

"As for me, cutting the pills is a bulky and tiring job, I just demonstrate to the mother on how to share the tablets in quarter or halves." (HSA, Malawi)

"Me too, I demonstrate how to cut the first tablet and I ask the mother to do likewise (HSA, Malawi)

HSAs were concerned about the risk of contamination that could occur both as they demonstrate tablet splitting and as caregivers split and manipulate tablets at their homes. While they said that they try to emphasize the importance of hygienic practices, they were not confident that these were followed regularly by caregivers.

"It is our observation that some do it without washing hands and you know caregivers are of different interests so when breaking the tablet they make it dirty." (HSA, Malawi)

They were also concerned about ensuring that the split tablets were split evenly to ensure equal dosing.

In one focus group in Malawi, HSAs reported that they had received cotrimoxazole packaged in blister strips rather than the larger bottles/tins. As donors procure some CCM products for specific districts, it is

likely that this was an instance where the products came via donor procurement rather than the government/MOH-issued channels. These HSAs reported a much more positive experience with this packaging, both for their own administration, as well as the caregiver's perception of the medicine.

"From my experience, the colour does help, for example when a caregiver received cotrim from blister packs, I heard her saying, 'but today I have received drugs from a packet' and she appreciated it so much thinking that medication is more powerful than the one wrapped in a paper but it was just the same cotrim in a different package. And the colour also played a role for the mother to accept that she had received good medication." (HSA, Malawi)

Challenges with adherence/follow up

Given the issues with taste, spitting out, and the splitting of tablets, HSAs were concerned with adherence levels. However, they did say that caregivers seemed to understand, in general, how to give the product. They conducted follow up visits when feasible, generally targeting caregivers who they felt were less likely to remember how to administer the treatment to their child.

"For one to know if the mother has followed the full dosage we do follow ups on the third day and we ask to see the empty packs for the different medication received." (HSA, Malawi)

Caregivers expressed a strong preference for syrups, especially for cotrimoxazole that can be difficult to get children to accept. A few HSAs reported that occasionally caregivers seek treatment from other sources and feel that the syrups or other products they receive (or they see their neighbors receive) are superior to the cotrimoxazole they receive from HSAs.

"Even the syrups they play a big role in encouraging caregivers in taking medication and I have seen other caregivers getting jealous that you have given their friends better medication than them, when they are suffering from the same ailment and the other one receives syrup and the other tablets." (HSA, Malawi)

"Yes, just to add on, when a patient at the village clinic receives cotrim and [then] they visit the health facility and receive amoxyl, the caregivers become biased and they believe the medication they receive from the health facility is more powerful than the one from the village clinic." (HSA, Malawi)

CHW recommendations

The HSA recommendations for cotrimoxazole in Malawi included the following:

- Provide cotrimoxazole as a syrup, especially for infants and young children
- Provide cotrimoxazole tablets in lower strengths to avoid splitting tablets
- Provide cotrimoxazole tablets in blister packs
- Improve taste/flavor to increase patient acceptability and reduce spitting out of medicines

During one FGD, the participants mentioned that they were aware that cotrimoxazole 120mg tablets were available at the health center, but not through the CCM program that is specifically focused on pediatric treatment.

"What I am surprised of is the cotrimoxazole that we are using and the one they are dispersing here

at Machinga District Hospital it shows that they already have the ones for children. So what I am surprised of is that we are using what is meant for adults and the way they taught us. Then you have to cut in half." (HSA, Malawi)

General Product Information

In addition to product-specific feedback, CHWs shared some interesting thoughts and experiences on products and perceptions of medicines in the community in general. The color and packaging played a role in perceptions of effectiveness with caregivers. Some products were seen to be more similar to the products dispensed from private clinics and were therefore seen as more effective.

Color and Packaging

In both countries, some CHWs mentioned that color is very important. Colored tablets are considered more effective, whereas white tablets were perceived as less effective and bitter tasting. Further, products that come in blister packs were seen as more effective than loose tablets that were given to clients in strips of paper.

As mentioned previously, there are still widely held beliefs that syrups are more effective for children. Caregivers feel from previous experience that tablets are hard to swallow and that liquid formulations are more suitable for children. The general consensus is that tablets are not appropriate for children under two or three years of age. This was repeated across products and countries despite positive experiences reported with dispersible zinc tablets. The CHWs seemed to want to be able to meet the caregiver requests, though this was not evaluated against the increased burden on storage or transportation that syrups would put on the CHWs. In general, when caregivers requested syrups, CHWs reported that they advise caregivers that with proper administration, all forms of the drugs they have available can cure the child.

Coartem as a model

In both countries, ACTs (Coartem D) was cited as having color, taste, packaging and consumer information that both CHWs and caregivers liked and felt was effective. The main benefits were:

- Good packaging for transport, storage and dispensing
- Good flavor and dispsersibility meant that it was well accepted by caregivers and children
- Considered effective by caregiver for treatment of fever
- Only three days of treatment
- Good instructions in local language and with detailed pictorials



Coartem as a model for use of local language and pictorial instructions (example from Rwanda)

Coartem was recommended as a model for other products and frequently mentioned by CHWs as the basis for comparison for the other products that they had for children under age five.

"The LA [Coartem] that we give nowadays has a good colour and to add on top of that it has a good taste and when children see that they remember that it's a sweet drug and they do not have any problems they do take." (HSA, Malawi)

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"Yes, on the sweetness, the flavour of LA [Coartem] when compared to cotrim after they are both dissolved, the children have and show some dislike when taking cotrim because it is a bit bitter and if it possible in the future there should make cotrim in syrup form so that it can attract our children to take medication without spitting." (HSA, Malawi)

CHWs said that written instructions in the local language are helpful, but also mentioned the clear pictorial instructions on Coartem as a good model for other products due to variable literacy rates of the populations CHWs serve. HEWs in Ethiopia referenced instructions on the ACTs of the sun and moon and pictures of a mother holding tablets on her hand to represent morning and evening and the corresponding doses as an effective way of communicating the dosing to caregivers.

In general, the CCM program and the products that CHWs have are considered effective and are improving the CHWs' roles and their relationships with the communities they serve. CHWs reported that the fact that the CCM services and treatment are free will continue to improve access through the program, as long as products are available.

However, the products need to be acceptable by infants and children and continuously available to meet program goals of reducing childhood mortality. Related feedback included:

"The availability of CCM products has helped to enhance our relations with caregivers as they trust us to provide the right medication and proper help when a child is sick." (HSA, Malawi)

"Previously, no treatment was provided at HPs for any condition, the focus was only on prevention. But since CCM drugs came, we're treating and saving the lives of children under the age of five years." (HEW, Ethiopia)

"Women are excited when you give them ORS and zinc because it is helping the diarrhoea so that in the future the child does not have similar occurrence of diarrhoea. They also feel good to seem to have taken a lot of products." (HSA, Malawi)

Other interesting comments came from CHWs who felt that the services they offered should not be restricted to children between two months and five years of age. Several mentioned pressure to treat others in their community – children less than two months and older children and adults.

"We would have also covered all children from 0-59 months and not older, hence we just selected a certain range and we are meant to help children. When the program is meant to reduce distance and you are telling the mother to cover a distance for her 6-12 year old children, it can be unfair." (HSA Malawi)

"Previously, children used to die from pneumonia because they're brought to HCs very late. But, now we can treat them at HP. The CCM drugs are very useful to the community here. People in the community even say that it would be good if similar drugs can be brought for adults too and they're willing to pay for it." (HEW, Ethiopia)

However, in general, CHWs felt that the role they were playing was important to increase access to treatment and decrease childhood morbidity.

"As much as we are facing some challenges people are grateful that instead of traveling a long

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distance they are being helped right at home." (HSA, Malawi)

"In my [community] kebele, before the CCM drugs were introduced, there were lots of cases of children with pneumonia. People used to take their children to HCs and private clinics for treatment and paying a lot of money. But, now we've the CCM drugs and we can treat them here. And, when people started to hear information that we can treat them in five days here, more and more people are coming to us today" (HEW, Ethiopia)

Recommendations

The findings from these focus groups, although from a very small sample of CHWs, do provide some insight to common perspectives and opinions of the primary users of CCM products - CHWs and caregivers and their children. The cross-country agreement on issues, especially where similar products were in use, indicates that these may be generalizable to other CCM settings and programs, especially in rural areas where CHWs transport and store their own products. Based on CHW input, the following recommendations stand out for CCM products in general:

- Provide tablets in the lowest strength needed; splitting tablets is a burden for CHWs and caregivers and manipulation introduces the potential for contamination and inappropriate dosing
- Packaging in the smallest course of treatment using blister packs and sachets is preferred by CHWs to ensure safety, hygiene, and promote easy transport, storage, and dispensing
- CHWs felt that instructions in local language(s) and particularly with pictorial instructions would improve adherence and caregiver ability to properly dispense to children for the remainder of the course of treatment, particularly for the lower literacy populations that they frequently serve
- Caregivers have a strong preference for liquids to treat children, especially those under age three; however, dispersible tablets if flavored well and dissolve quickly can be acceptable

For specific products, the following recommendations were the most commonly heard:

ORS –

- Consider providing smaller sachet sizes (0.5 L) to decrease wastage
- Include instructions for use in the local language with pictorial instructions to improve adherence
- Provide locally acceptable/familiar flavors rather than unflavored ORS to improve acceptability

Zinc –

- Provide zinc 10mg dispersible tablets for children in the younger age range (under 6 months) that currently require a half tablet of the 20mg tablets to avoid splitting and manipulation
- Provide instructions for use in the local language with pictorial instructions to improve adherence
- Reduce the length of the course of treatment if possible to improve adherence

Cotrimoxazole -

- Provide pediatric-appropriate strengths/formulations to avoid tablet splitting and manipulation
- Provide products in blister packaging as an individual treatment course to improve dispensing
- Ensure quick dispersibility and well-flavored tablets to improve acceptability with children and caregivers
- Provide instructions for use in the local language with pictorial instructions to improve adherence

As was mentioned in the product sections and product-specific feedback, almost all caregivers and some

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CHWs have a strong preference for syrups for infants and children. Further research is needed to understand the preference for syrups over the dispersible tablets. As dispersible tablets are relatively new to both programs, additional investigation into their acceptability is needed. Further education and explanation about their benefits and ideas to promote them as a syrup alternative may be needed to increase acceptability, both with CHWs and caregivers. From a supply chain perspective, the positive feedback on ease of transport and storage of dispersible tablets needs to be weighed against the preference for syrups, as the bulk and weight of syrups would be an increased burden and may negatively affect product availability, given the transport methods frequently employed to move products to community health workers at the "last mile" of the supply chain.

Much effort and many resources are being invested in implementing and scaling up CCM programs in countries around the globe. The products selected for these programs and their use and acceptability by children and caregivers in the community are critical to these programs' success and impact; therefore ensuring that the products are well matched with the user needs should be an important part of program design and evaluation. Product selection should be revisited regularly to ensure that CHWs and their clients have access to products that are optimal from both a distribution and outcome perspective.

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