Formative Research to Develop and Test Messages to Educate Mothers on Zinc Supplementation in Childhood Diarrhea

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ABSTRACT

Background. Zinc is now recommended as part of childhood diarrhea case management but there are concerns regarding treatment duration and perceptions of its use when given with ORT.

Objectives. This study developed and tested messages on zinc supplementation for childhood diarrhea.

Methods. Messages were based on 1) a review of literature and product advertisements, 2) drugstore seller interviews, and 3) focus group discussions (FGDs) among 10 mothers with children six to 59 months old. Subsequent FGDs with 15 mothers consulting at a government hospital helped determine message clarity, comprehension and appeal. A behavioral trial, involving nine mothers whose children had diarrhea, tested recall of and adherence to the messages.

Results: The trial tested three messages—Zinc: 1) strengthens resistance; 2) is a vitamin for the gut; 3) increases the appetite of a child with diarrhea. Seven of nine mothers were able to follow instructions on zinc administration, and demonstrated recall and understanding of these messages. Mothers understood that zinc helps the child with diarrhea, improves appetite, reduces symptoms and hastens recovery, but had concerns regarding the side effects (vomiting), co-morbidities (fever, cough) and consequences of overdose. Standardized counseling cards addressed these concerns. Respondents preferred a simple logo labeled "zinc" with zinc administration instructions on the packaging. Zinc supplementation did not affect ORT use.

Conclusion and Recommendations. Messages sufficiently addressed mothers' concerns on zinc use during childhood diarrhea, with those on zinc improving "resistance" and as a "vitamin for the gut" having the best recall. Results can contribute to zinc's introduction and promotion in the public sector.

Keywords: diarrhea, zinc, oral rehydration therapy, formative research, health communication messages

Introduction

Diarrhea continues to be a leading cause of morbidity among Filipino children.[1] Although dramatic reductions in childhood mortality from diarrhea followed the introduction of oral rehydration therapy (ORT) in the 1980s, a major concern is that ORT does not affect morbidity. Zinc has been found to reduce the duration and severity of diarrhea episodes and to lower incidence for the next two to three months.[2] The World Health Organization (WHO) and United Nations Children's Fund (UNICEF) issued a joint statement in 2004 recommending that children be given 20 mg/day of zinc for 10 to 14 days (10 mg/day for infants below six months of age).[2] The Philippine Department of Health (DOH) released an Administrative Order (AO 2007-0045) mandating the use of zinc supplementation in the treatment of acute watery diarrhea in children. In implementing this policy[a], the following concerns arose: 1) Mothers may discontinue giving zinc prematurely as it needs to be given for 10 to 14 days[b] to get optimum benefit, a duration longer than most acute watery diarrhea episodes, which usually last only two to three days; 2) Mothers may think that giving Zinc is sufficient and replace ORT, thereby undoing several decades of ORT promotion with subsequent consequences on child mortality[c]. As the roles of zinc and ORT in diarrhea case management are different but complementary, zinc should not displace ORT in mothers' understanding and administration of diarrhea treatment.

Messages on giving zinc and ORT have to be thoughtfully constructed to ensure adherence to the recommended regimens for both treatments. This study was undertaken to develop and test messages that were used in a randomized clinical trial (RCT) that investigated the use of zinc and ORT for acute watery childhood diarrhea conducted at the Philippine General Hospital (PGH)[3] as part of a multicenter effort. Results were used to develop a formative research manual[d] for other country sites that participated in the RCT.

Objectives

1. To develop messages on zinc supplementation and ORT use based on the mothers' perspectives
2. To test the effectiveness of the messages with respect to recall, understanding and adherence by mothers of children with diarrhea

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[a]Zinc supplements, usually in syrup or liquid form, are already being prescribed in the private sector, and in selected government units where a supply of the tablets from UNICEF are already available. Source: Micronutrient Supplementation Technical Review, DOH, 2009

[b]Efficacy trials on zinc for childhood diarrhea differed in duration from 10 to 14 days; for this study, 14 days was used.

[c]Oral Rehydration Therapy (ORT) corrects the dehydration that is the usual cause of mortality from diarrhea

[d]Introducing Zinc In A Diarrheal Control Program: A Manual For Conducting Formative Research http://www.izincg.org/pdf/ZINC%20Formative%20Research%20Manual.pdf, accessed July 7, 2009

Methods

This formative research was carried out in three phases from April to December 2002. The phases comprise an iterative process; with each step using what has been learned from the preceding and feeding that information onto the subsequent ones. This process-driven approach makes extensive use of qualitative research methods[e] in order to strengthen or improve the delivery of a program, service or technology. A team of trained and experienced health professionals, supervised by a medical anthropologist with a health background, was responsible for the data collection, processing, analysis and report writing.

Phase 1: Message Development

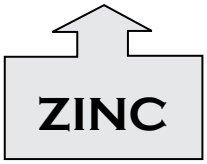
Potential messages were identified from a review of literature on maternal beliefs and practices, treatments, home management and care-seeking behaviors related to childhood diarrhea, and knowledge and use of ORT. Terms and phrases used in advertising for related products were reviewed to ensure that the zinc tablets in this trial would not be associated or confused with an existing product in the local setting. Commercially available zinc formulations for children, which were all found to be liquids or syrups, were examined to determine how they were being marketed, sold and prescribed. Public health messages on childhood diarrhea management, especially those on feeding and ORT use, were likewise reviewed to ensure that there would be no conflicts or inconsistencies with the use of zinc. Focus group discussions (FGDs) with two groups of mothers (n=5 each) with children six to 59 months helped to validate the continued relevance of findings from available literature. Messages were crafted to include one concept or idea per message, adapted to the local setting and screened by the physicians and scientists involved in the RCT for scientific soundness. The message adaptation process considered mothers' understanding of diarrhea and its symptoms, its treatment and management, as well as their perception and concepts of child health and use of medicines including multivitamins and minerals.

Phase 2: Message Testing

To select the most understandable and acceptable messages, three groups of five mothers each were gathered into focus groups. The mothers were recruited from the Out-Patient Department of the Philippine General Hospital and asked to share their experiences with childhood diarrhea. Initially, they were shown single-message cards one at a time to assess comprehension, ease of reading, clarity of links to the zinc treatment, and awareness of similar messages and medicines. Next, with all the cards together on a table, mothers were asked to rank the messages according to their preference and give their reasons for the ranking. They were first asked for the top two messages they preferred, then for a third message that would follow these two. Lastly, they were asked to select a message they would not use at all.

Mothers participating in this focus group were shown the zinc tablet[f] and how it dissolves in a teaspoon of water. They were told that the same formulation would be given to both infants and children. They gave reactions and comments to the tablet's appearance, taste and solubility. Issues and concerns raised by the mothers were discussed with the RCT team to develop standard responses for use during the trial. The issues and responses became the basis for the counseling cards used by the health providers and the research assistants during the trial.

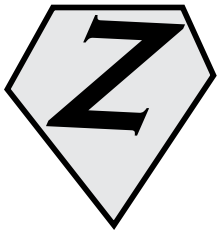
Candidate logos for the zinc packaging (Figure 1) were pre-tested in two separate FGDs, one among mothers and one among midwives in a government health center. They were shown the candidate logos and told that the logos and the messages would be used on the packaging design to be used for a certain drug that will be tested in a government hospital. The actions of the drug were explained to them using the selected messages. They were asked which of the logos they preferred, how they wanted the messages to appear on the label, which messages would go with which logos, and the reasons for their choices.



FOR INCREASED
RESISTANCE
AND APPETITE
OF THE CHILD
WITH DIARRHEA

Candidate logo #1

SUPER ZINC



PAMPAGANA AT PAMPALAKAS
NG RESISTENSYA
NG BATANG MAY DIARRHEA

Candidate logo #2

Pampagana at pampalakas
ng resistensya
ng batang nagtatae

Candidate logo #3

Figure 1. Candidate logos presented to mothers and midwives

[e]The terms "qualitative study" and "formative research" are used interchangeably throughout this report

[f]Sample tablets, manufactured by Nutriset®, were obtained from WHO

Phase 3 : The behavioral trial

The zinc messages were tested on nine mothers, whose children six to 59 months old had acute watery diarrhea, recruited from the Emergency Room of the Philippine General Hospital, the RCT's study site. The RCT's screening and informed consent forms, translated into Filipino, were used in the behavioral trial to simulate trial conditions. The physician on duty prescribed zinc and ORT to eligible children. The nurse research assistant (RA) obtained baseline information that included the child's clinical status, previous consultation and drug use, the mother's perception of the child's condition, and socio-economic indicators. The RA then introduced the zinc tablet to the mother while explaining the actions of zinc using the crafted zinc messages, following a set of guidelines in her delivery based on the formative research findings in phases 1 and 2. She demonstrated the administration of zinc to the mother, while giving instructions for its use at home. After administration of this first dose of zinc, each mother was instructed to observe her child for at least ten minutes. A full-course packet of tablets was given to the mother to give to her child at home.

During the 10-minute observation period, a second RA conducted the exit interview outside the consultation area to determine the extent to which the mothers remembered the messages. The mothers were asked: 1) the kind of medicine they were given and what it was for; 2) how it should be prepared; 3) for how long should it be given; and 4) for questions and concerns they may have about the medicine.

Two follow-ups were conducted: 1) within Day 3 to 5 after recruitment, when information on child's status, any subsequent medical consultation and drug use, food and fluid intake since consultation, zinc adherence and perceptions, giving or sharing of the zinc tablet with another child and respondent's reactions about being included in the study was obtained; and 2) within Day 13 to 15, when the same information, except for the sharing of zinc tablets and mothers' reactions, was recorded. In addition, mother's perception of the child's condition after completion of the zinc therapy and how much she would be willing to pay for the zinc tablets were determined.

Since the behavioral trial followed the procedures of the clinical trial as prescribed in the RCT protocol, it also served as an opportunity to field-test the data collection instruments and procedures, and to detect any operational problems during screening, recruitment and follow-up of patients. Results were discussed with the members of the RCT team. Zinc messages were refined. Additional issues raised by the mothers together with standard responses were added to the counseling cards. The RCT's study protocol, which included the formative research component, was reviewed and approved by the Philippine General Hospital's Research Implementation and Development Office (RIDO).

Results

Phase 1: Message Development

The desired outputs were messages that would have both a scientifically sound basis and "marketable appeal." The following issues were considered in message development: 1) the message should motivate the mother to give zinc in the recommended dose and treatment duration; 2) zinc should not be over-promoted to stop or cure diarrhea or treat dehydration–the message should not raise unrealistic expectations similar to the experience with ORT promotion, where the initial marketing approach failed because the people expected an anti-diarrheal drug to harden the stool, a function ORT was not meant for[4]; and 3) the message should be appropriate regardless of the day or time treatment is started. Messages with a temporal factor such as "to make the illness less severe" (acute watery diarrheas usually decrease in severity with time) or shorten its course may not be appropriate as it would not be possible to standardize diarrhea duration at recruitment. In response to mothers' concerns from the initial FGDs, the zinc messages had to address the following questions: What is zinc for? What is it not for? Why does it have to be taken for so long (14 days)? What happens if it is taken for less than 14 days? Why should it be taken with but for a longer period than ORT?

Prior to the study, zinc was being marketed as a component of multivitamins and of some dairy products. At that time, it was already available as single agent (zinc alone) preparations in liquid form for children. Several ideas from the review of literature and of advertisements were considered to answer the question "What is zinc for?" – Should zinc be promoted for its harm reduction ability, i.e., protection against serious diarrhea and recurrent episodes, a prominent concern of mothers? Would it be better to say that zinc gives strength to a child who is weak from diarrhea? Could zinc be marketed to have some purifying effect, based on the belief that diarrhea occurs because of impurities in the body and zinc was needed to get rid of these impurities? Should the message say that zinc could give back what was lost during diarrhea (like nutrients, appetite and activity)?

The initial round of FGDs provided additional information relevant to message development: 1) mothers were concerned about the diarrhea becoming prolonged, worsening or changing to a more serious form; 2) they would go to a health practitioner or seek a second health provider if the child did not show any signs of improvement after a day of home treatment or after the initial consultation; 3) messages on the preventive action of zinc could be attractive to mothers; 4) there were concerns regarding feeding and appetite during the diarrhea episode; and 5) there was a fear of the consequences of diarrhea such as dehydration, loss of weight and loss of appetite.

Clinical trials on zinc supplementation showed that it led to less severe diarrhea, fewer loose stools and shorter duration of the episode.[2] These are the same attributes of a diarrhea treatment that mothers who participated in the FGDs would like to have. One of the potential messages, therefore, could focus on the harm reduction that zinc provides, by describing it as a medicine that "could prevent the diarrhea from becoming worse."

With mothers worrying about the feeding and appetite of their sick child, the idea of promoting zinc to address the child's appetite seemed a potentially good message. *Magandang/maganang kumain* ("good appetite," "eats heartily") was reported one of the main criteria of a healthy body among urban Filipino respondents.[5] Mothers believed that during diarrhea a child's stomach and digestive system were "weak"; hence their home management included dietary changes such as giving of soft foods like *am* ("rice water") and *lugao* ("rice gruel").[4,5] A medicine addressing these problems – weak digestion, loss of appetite – could have a good chance of being accepted by mothers.

A message that includes both therapeutic and preventive actions of zinc, thereby ensuring the child's full recovery from diarrhea, was suggested. This would not only highlight the effect that the child could get well completely within a shorter time but could also make the child as strong as, or even stronger than, he was before he got sick. This message could justify zinc's prolonged therapy, with the explanation that full recovery could be attained only with the completion of the therapy.

Having a separate message to differentiate zinc's action

from that of oral rehydration therapy was also considered. The idea of "twin medicines" (*kambal na gamot*), a concept already applied to the treatment of pneumonia[5, 6] (antibiotics + antipyretic), with zinc and ORT as the "twins." However, with data from the FGD indicating that most mothers already understood the need for rehydration and ORT during diarrhea, the team decided not to use a main message on oral rehydration or use of ORT. There was, in addition, concern that "twinning of medicines" might give the idea that zinc and ORT should be "given together" and therefore "stopped together," thereby affecting adherence to the 14-day zinc course. Some team members felt that it may be more appropriate to develop supporting messages, rather than main messages[g], to emphasize what zinc could not do (treat dehydration) and to reinforce ORT use on a case to case basis.

From these considerations, the following main actions of zinc were selected on which the potential messages could be based:

1. Zinc prevents diarrhea from becoming worse.
2. Zinc prevents future episodes of diarrhea.
3. Zinc increases a child's appetite during diarrhea.
4. Zinc ensures the child's full recovery from diarrhea.

These actions address the expectations of mothers from a medicine for diarrhea but do not indicate or promise that zinc could cure or stop diarrhea; nor do these imply that zinc could treat dehydration. These actions likewise do not guarantee anything that zinc could not do (harden the stool, for instance).

Five (5) messages based on zinc's four (4) main actions are shown in Table 1.

Table 1. Locally adapted messages

Main Action or Effect of Zinc	Adapted Message	Translation of the adapted message
1. Zinc prevents the diarrhea from becoming worse	Gamot para hindi lumala ang pagtatae ng bata.	Message # 1 Drug to prevent the diarrhea from becoming serious
2. Zinc prevents future episodes of diarrhea.	Gamot para maiwasan ang muling pagtatae ng bata.	Message # 2 Drug to prevent the child from getting sick again of diarrhea.
3. Zinc increases appetite	Gamot na pampagana pag nagtatae o gumagaling sa pagtatae ang bata.	Message # 3 Drug that increases the appetite of a child with diarrhea or just getting well of diarrhea
4. Zinc ensures the child's full recovery from diarrhea.	1) Gamot pampatibay ng resistensya ng batang nagtatae.	Message # 4 Drug that strengthens the resistance of a child with diarrhea
	2) Bitamina para sa tiyan ng batang nagtatae.	Message # 5 A vitamin for the gut of a child with diarrhea

We describe the rationale and process for arriving at these messages.

1. Zinc prevents the diarrhea from becoming worse.

The FGD findings showed that mothers were aware that diarrhea could develop into a more serious form despite initial management. The appeal of this message is that zinc would be able to address mothers' fear of the consequences of diarrhea. This message would not be mistaken for other messages usually accompanying anti-diarrheal drugs whose usual selling point is their ability to stop diarrhea; hence, zinc's identification with such drugs would be minimized.

2. Zinc prevents future episodes of diarrhea.

Although none of the mothers participating in the FGDs had a child who experienced recurrent diarrhea, there was awareness that this can happen among children. According to them, dirty feeding bottles and utensils caused this "coming back" of diarrhea. Even if recurrent diarrhea was perceived to be a rare event among them, the thought that this drug could prevent that occurrence could be a motivation for adherence, particularly to the 10- to 14- day zinc course.

3. Zinc increases the child's appetite

Food intake is a major concern of mothers when their children are sick with diarrhea. A number of diarrhea symptoms given by the mothers were related to the stomach and digestion like *kumukulo ang tiyan* ("stomach has boiling sound"), *sumasakit ang tiyan* ("stomachache"), *kinakabagan* ("gas pain"), and *hindi natunawan* ("indigestion")[6] which they think could all lead to loss of appetite. There is a belief[6] that the stomach needs time to recover and take in the foods a child usually eats; hence, dietary management included shifting to soft foods or preparations believed to be easier to digest.

Promoting zinc as a drug to increase the child's appetite during diarrhea could be an attractive message to mothers. Most multivitamins for children available in the local market were also being promoted as appetite enhancers but the uniqueness of this message was in its being identified with something that is to be given during diarrhea. Unlike the commercial multivitamins that are marketed for daily maintenance intake (which could be expensive for a poor family), zinc would only be given for a definite period of time. The adapted message further qualified that zinc should be given to the child while still sick of and/or recovering from diarrhea. Concerns regarding zinc therapy's duration could also be positively reinforced by this message.

4. Zinc ensures the child's full recovery from diarrhea

Both of the messages related to this action centered around *resistensya* ("resistance"), a popular health-related concept in the Philippines, and used by a number of related product advertisements. *Resistensya* implies a range of constructs including strength, absence of illness, ability to ward-off infections ("resistance" to infections), and being well enough to prevent serious illness. It could also describe a person's constitution like when a child is referred to as *malakas ang resistensya* ("having a strong resistance") which could mean he is not sickly, can easily fight off diseases (or some adverse condition), can bounce back to health more quickly, or is just generally strong and healthy. In contrast, someone with "*mahinang resistensya*" (weak resistance) would be more vulnerable to illness and take longer to recover from it.

The first message for this action – "Drug that strengthens the resistance of a child with diarrhea" – was built around the concept that the drug could make the child more fit to fight the illness and ensure recovery.

The second message – "Vitamins for the gut" – was considered by the study team to be a highly acceptable message for the mothers given their concern for recovery of the gut given the high marketability of vitamins. Zinc, while technically a mineral, was promoted as a vitamin since local concepts of medicines did not distinguish vitamins from minerals.[6] Baseline FGDs also indicate that the term "zinc" was associated with materials used in making metal basins, perhaps related to some understanding of what a mineral is.

[g] Main messages had to be given to each and every mother/caregiver, while supporting messages could be given if needed.

Vitamins are perceived to stimulate appetite and strengthen the body and are popular in the Philippines.[6] A whole range of vitamins and minerals (multivitamin preparations) are available in the local market and are heavily advertised. Their selling points were focused on the presence of nutrients or *sustansya* and capacity to enhance appetite, growth and, of course, resistance. One advertisement seen for a pediatric multivitamin was *Batang malusog, batang magana* ("A healthy child, a child with good appetite"). The term "vitamins," therefore, had become synonymous with anything that could give these beneficial effects. Vitamins, moreover, were already understood and accepted as a medicine that could be taken not only during periods of illness but also during healthy or normal conditions and for prolonged periods.

The Philippine Index of Medical Specialties (MIMS), a catalogue of pharmaceutical products used by health professionals, contains numerous multivitamin and mineral brands for infants and children. At least four of these brands were identified, at the time of the study, to contain zinc, with one (Robovites Multivitamins with Zinc®) claiming to have zinc as a major component. Z-Vita® which contained 82 mg Zinc gluconate per 5 mL syrup was specifically indicated for zinc deficiency in addition to "improvement of appetite," "weight gain" and "resistance to infection." Some infant formulas and follow-on milks contained zinc. An advertising phrase for one such brand was *resistensya-builder* ("one that builds up resistance"), once again demonstrating the appeal of this concept.

The choice of the message "Vitamins for the gut" was also, in part, informed by experiences with tuberculosis (TB) medication. *Mahina ang baga* ("weak lungs") is a common euphemism for TB in layman's terms and some anti-TB drugs are perceived to "strengthen the lungs" (*pampalakas ng baga*) when these were prescribed by doctors.[5] They were consequently perceived as "vitamins for the lungs" based on the logic that the treatment of a weakness would be to take vitamins that strengthen. So prevalent is TB and the appeal of vitamins that anti-TB drugs are even consumed to prevent TB when a person gets even a slight perception of having "weakness of the lungs".[7] "Vitamins for the gut" builds on this acceptance among mothers that a medicine like zinc could "strengthen the child's stomach" within the context of a diarrheal illness. Moreover, the fact that vitamins were understood to be taken on a daily maintenance dose over long periods of time could further help adherence to the duration of zinc therapy.

Phase 2: Testing the adapted messages

Message Preferences. A total of 15 mothers, recruited from the Out-Patient Department of the PGH, participated in three message-testing FGDs. They were in their 20s and 30s, with some high school education, had at least one child less than five years old, and had brought their child for consultation for various reasons including diarrhea, respiratory infection and follow-up. Mothers participating in this exercise had diarrhea management practices similar to those gathered from the literature review and the Phase 1 FGDs.

Table 2 summarizes the mothers' reactions to the individual messages.

Mothers preferred the messages on resistance (message #4) and vitamins (message #5). The resistance message was a consistent choice during the three FGDs – 10 out of 15 mothers considered this message their first two preferred messages. While the message on vitamins was chosen only by one of five mothers during the first FGD, six of 10 mothers chose it during the subsequent sessions. A third possible message, message #3 (appetite), was selected by five mothers among their first two and one chose this as her third message. Another possible third message is Message #1, with seven of 15 mothers considering this their third message and two choosing this as their first two. Table 3 has the breakdown of these results.

Table 2. Highlights of mothers' reaction towards the five messages

No (#)	Message	Mothers' Reactions
1	Drug to prevent the diarrhea from becoming worse	1. like a "first aid" for diarrhea 2. similar to Oresol – so that the child's condition will not get serious 3. an early treatment for diarrhea; will result in diarrhea being cured 4. will buy this right away so that there is no need to buy other drugs 5. like an antibiotic
2	Drug to prevent the child from getting sick again of diarrhea	1. may be difficult to make the child drink it 2. no drug to prevent diarrhea because a child normally gets sick with it 3. if child has no diarrhea, it may be hard to give it to him
3	Drug that increases the appetite of a child with diarrhea	1. Drug is multi-acting 2. drug found interesting; one mother would look again at the label if she would encounter this 3. different, halo or "mixture" because it is not only a drug for diarrhea but can also act as a vitamin 4. a child with diarrhea definitely needs this
4	Drug that strengthens the resistance of a child with diarrhea	1. Drug acts more directly to the problem 2. no need to shift medicines; more economical 3. action is more "direct" 4. a solution to a mother's problem regarding medication, but raised concern about its possible price (was perceived to be expensive) 5. actions similar to fruits, like apple 6. similar to vitamins
5	Vitamins for the gut	1. will definitely try it 2. probably good for a child with a weak digestive system; frequent diarrhea could be prevented 3. can improve a child's stool movement 4. may just be a duplication of effects of a multivitamin 5. may not be cost-effective because action is on the stomach only

The following messages, therefore, were chosen as the final messages for the behavioral trial based on the results of the message preference exercise:

- Zinc strengthens the resistance of a child with diarrhea.
- Zinc is a vitamin for the gut of a child with diarrhea.
- Zinc increases the appetite of a child with diarrhea.

Zinc tablet characteristics. Upon seeing the size of the zinc tablet, some mothers expressed concern at giving the tablets

Table 3. Message Preference of 15 mothers

Message	No. of mothers who preferred message as first or second message n=15	No of mothers who chose message as a third option n=15	No of mothers who would not choose this message n=15
1. Drug to prevent the diarrhea from becoming worse	2	7	3
2. Drug to prevent the child from getting sick again of diarrhea	3	3	3
3. Drug that increases the appetite of a child with diarrhea	5	1	1
4. Drug that strengthens the resistance of a child with diarrhea	10	1	0
5. Vitamins for the gut	7	0	4

to infants and very young children. One of them asked if there is a syrup preparation for infants. Another mother asked if it could be dissolved. She said she usually dissolves an Aspilet® (for fever) in juice, administers it through a dropper and once dissolved, the child would usually have no problems taking the medicine. When the mothers were shown how easily the tablet dissolves in water, they were convinced that it would not be very difficult to give to a child, regardless of age. The extra preparation time needed to dissolve zinc was not seen as a problem as this was a practice frequently resorted to by mothers when giving medicines.

Taste is considered important. Aspilet®, for instance, comes in many flavors and children are observed to take to them just like candies. Mothers said that a medicine's taste should not be bitter. They usually taste the medicine first so they would know what to do to make the child take it. For example, if a medicine is bitter, one mother said she would give a little sugar immediately after the child took the medicine. Vomiting occurs when a child doesn't like the taste of the medicine.

When the mothers were allowed to taste the dissolved solution, they found the taste pleasant, in fact a little too sweet. One mother raised the concern of a child getting overdosed because children may like it too much.

Zinc with ORS. The mothers knew about dehydration resulting from diarrhea and had an understanding of how rehydration worked. They were aware of oral rehydration salt (ORS) preparations including Oresol being distributed in public health facilities and those commercially available like Pedialyte® and Hydrite®. They understood that the action of an oral rehydration salt solution was different from the action or effect/s of a drug. In fact, their choices of potential zinc messages further reflected this distinction. However, it was decided to develop support messages on ORT as part of the counseling cards in order to emphasize that ORT is in itself an effective and necessary treatment for diarrhea and should not be withheld even when giving zinc. Similarly, the support messages should also reiterate that zinc should still be continued even if dehydration has already resolved.

Zinc with other foods and fluids for diarrhea. The potential messages preferred by the mothers were not seen to be in conflict with dietary practices during diarrhea. Mothers resorted to soft diet during diarrhea because of their belief that the child's stomach may not be well enough to digest other foods. This belief could, in fact, be highlighted or addressed in a zinc message. Mothers usually give medicines after meals or after milk feeding. They said it is important that there be "food in the stomach" (*may laman ang tiyan*) when one takes medicines. This may not be an issue with the zinc tablet since it could be considered a "vitamin".

Development of the zinc label and logo. The label and packaging of locally available pediatric medicines were examined as part of the formative work's market assessment as the initial step to the development of a logo and design of a label with which to identify zinc.

Vitamins for children were available either in infant drops, syrup or chewable tablets (a preparation for vitamin C was packaged as candy jellies) with most liquids usually placed in bottles. In most cases, the bottles were packaged in a box with the name, indications, dosage with or without a logo. The designs on packages of multivitamins were usually colorful and contained pictures of babies for infant drops and of older children for syrups and tablets. Sometimes, attractive drawings of animals, fruits and other cheerful cartoons were used. One multivitamin preparation had a drawing of a giraffe with a message on enhancing growth.

Pediatric medicines including those for diarrhea (for example, Polymagma® and Humagel®) were either in syrup or suspension form, while some drugs for fever were in flavored and multi-colored tablet form. These were not as attractively packaged as the vitamins, with the label often containing just the brand and generic name, dosage, manufacturer, manufacturing and expiration dates, instructions for use and storage and formulation on the label.

In anticipation of the blister packaging of the trial's zinc tablets, medicines packaged in this way were also examined. Currently available blister packs were usually for adult medicines such as antibiotics and drugs for malaria, TB and common ailments (pain relievers, cough/cold remedies) with the name and dose printed on the front side of the pack while the back side contained the brand and generic names and manufacturer.

In discussions on the logo and labels, mothers said they would like to see the dosage on the label so that in case of confusion, they could ask the doctor for clarification. The 14-day therapy appeared understandable and acceptable to them. They said some drugs, like antibiotics, are usually given for a number of days. Specially if prescribed by a doctor, it was acceptable to give a drug for the specified period, even if the symptoms of a disease were no longer seen.

Initial plans to have a picture of a mother with a baby or a toddler on the label were scrapped after mothers who participated in the FGDs said they did not particularly expect such pictures on the labels of medicine. They said these were usually seen on the packaging of vitamins but not on medicine, more so on medicine given during diarrhea.

A logo was instead suggested, to be placed together with the word "Zinc" for identification and recognition. Several candidate logos adapted from existing print materials were presented to the formative research and RCT teams (Figure 1).

Logo #1 (Figure 1) used the "arrow-up" design to indicate increased resistance and improved appetite. The second logo (Figure 1) was patterned after the Superman shield to indicate protection against diarrhea and other illnesses. Logo #3 (Figure 1) used a circle to represent the shape of a tablet or pill. The messages placed together with the logos were based on the final messages resulting from the message testing exercise.

Two of the logos used the Filipino translations while one was in English. Logo #2 also used the English word "diarrhea" for the illness term.

Mothers preferred Logo #3 because of clarity and simplicity of design. The midwives, especially, did not want to use Logo #2 which was patterned after the "Superman" shield. They said this might give an idea of being "too super" and "over" in effect. Both the mothers and the midwives felt that Filipino[h] should be used on the label and that seeing the word *nagtatae* (Filipino term for diarrhea) would not be offensive.

The final label containing both logo and messages used for the behavioral trial is shown in Figure 2. Since it was not possible for the label to be printed on the blister packaging, for the trial it was decided to put the blister pack in a transparent plastic bag, with the label printed on self-adhesive paper on one side of the bag. This way, mothers could read the messages on one side of the bag and look through the other side to see the blister pack itself.

Phase 3: The Behavioral Trial

A total of 24 patients were screened, 10 patients were eligible and were enrolled in the trial; of these 10, two were siblings, thus a total of nine mothers participated. Seven patients completed this behavioral trial, while three were lost. One mother (the one with two children in the trial) had elementary education, five had high school education, two had college education and one did not have information on education. There were five male and five female children in the trial. The mean age was 16 months, with the youngest at three months and the oldest at 48 months old. Four were firstborns, four were the youngest, one is the sixth out of eight children and one did not have information on birth order. Information on monthly income (in Philippine pesos—Php) was given by six mothers. The mean was Php5,980.22[i] (range from Php1,500 to Php9,000). Two indicated that they rely on an allowance from relatives and two did not have information.

During the exit interviews, six of the mothers did not regard zinc as an antibiotic; one respondent said it was and another said it was a drug for diarrhea and hence acted like an antibiotic; one mother could not be located for a response. The vitamin message appeared to be quite salient among the respondents as the terms "vitamins" and "resistance" were mentioned by five and two mothers, respectively. One mother said it should be given to a weak child because it can make him strong and better able to "resist" the disease. Four of them said this particular vitamin is especially for the child's stomach. Only one mother mentioned the message on zinc's effect on the appetite during the exit interviews.

Six mothers remembered the instruction of giving one tablet per day, four correctly recalled the 14-day therapy and five remembered to dissolve the tablet in a little water. In some instances, the mothers were specific enough to mention that the drug still needed to be given even after the diarrhea has stopped.

All of the mothers in the trial had never heard of this drug before. One said she heard of zinc to be a component of some milk brands in the market and it was a mineral that could strengthen and stimulate the digestive system. Another one was concerned the drug was not available in stores yet. She was worried her child might be *hiyang*[j] to this drug and it would be hard for her to obtain it.

Issues related to introducing a new drug included the occurrence of side effects (three mothers) and development of allergy (one mother). The fact that it has to be given for 14 days and even after the diarrhea disappeared raised some concerns about overdose. On the other hand, there did not seem to be any problem with regards to the size of the tablet being the same for infants and toddlers.

As anticipated, the possibility of sharing the tablets with another child came up. One mother asked if she could give her other child some of the medicine because she thought he was also having diarrhea. Another mother asked if zinc could be given to an older child while one actually gave her older child a tablet because she said this child's digestive system is weak. Still another asked if the drug could be taken by adults to take advantage of its potential effects.

Only one mother voiced the perception that zinc might have some rehydrating effect. Thinking that zinc was also for treating dehydration, she asked whether to stop zinc, too, along with ORS when the child has been rehydrated.

One question commonly asked was "What will happen after the 14 days? What shall I do after all the tablets have been consumed? Why can I not give it when the child is well and not sick?" Apparently, there was some interest not only about giving zinc during the trial and duration of therapy but also beyond.

The questions and concerns raised by the mothers were all noted down and discussed with the project consultants for the most appropriate responses. These were compiled and became the basis for the counseling cards that served as the health providers' guide in responding to possible queries of mothers and caretakers during the clinical trial.

Development of the Counseling Cards

Aside from the messages, counseling cards were developed. During phases 1 and 2, several issues came up including vomiting, breastfeeding, co-morbidity, overdose from zinc, the 14-day therapy and zinc with ORT. Additional concerns regarding the cost and availability of zinc tablets were raised from phase 3. The investigators of the clinical trial discussed the most appropriate way to address these issues by providing the scientific basis for the responses and considering the local context in which they would be given. These were developed into counseling cards.

Discussion

This formative research component to develop and test the messages with which to explain and introduce zinc helped identify mothers' packaging and labeling preferences and raised issues and concerns related to zinc supplementation such as dosage, mode of administration, side effects, 14-day therapy, and complementation with ORT which were important to mothers.

A key finding was that mothers in this setting have a reasonably good knowledge and understanding of ORT. During the FGDs, the mothers were able to give a sound and accurate basis for the actions of and the rationale behind ORT. This was useful in deciding that a main message on ORT may not be necessary and that a separate ORT message would be developed for the counseling cards as an ancillary message. This helped to focus the main messages on zinc.

The formative research was able to distinguish which among the identified actions of zinc would have the potential for use in the development of interesting, believable and motivating messages. This approach using "effective appeals or motivational statements" has been used in promoting other micronutrients.[8] The development of messages was anchored

[h] Filipino is the national language of the Philippines – it is largely based on Tagalog, the predominant language used on the main island of Luzon

[i] The poverty threshold in the Philippines was P11, 451 in 2000 and P12, 267 in 2003. Source:NSCB website: http://www.nscb.gov.ph

[j] Hiyang is a Filipino folk concept meaning "suited, agreeable, or compatible".

on what was important and relevant to mothers: a) the child's feeding and appetite during illness, more so during diarrhea; b) the diarrhea developing into a more serious form (as implied by their care-seeking behaviors and ability to recognize worsening symptoms); and c) the importance of the child's general health leading to easier recovery from diarrhea. At the same time, these messages were designed not to raise the mothers' expectations of zinc beyond what was known about its scientific effects and actions. The messages were careful to refrain from saying that zinc could treat diarrhea or replace oral rehydration therapy.

Successful health promotion programs are able to take into account local knowledge, beliefs and practices related to the disease being addressed. This has been demonstrated in both ORT[9,10,11]and other micronutrient supplementation promotions. For example, iodized salt was promoted in

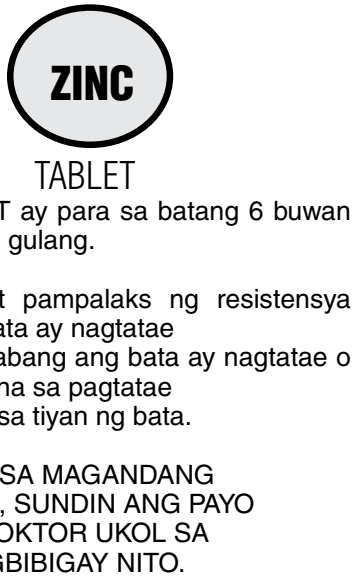


Figure 2. Label tested during the behavioral trial[k]

Pakistan as a way of enhancing the child's ability to gain education since education was a highly esteemed cultural value.[12] In cultures where women restrict eating during pregnancies to avoid bearing big babies and difficult deliveries[13,14,15], iron supplements did not state or imply that it could give them "bigger babies." In Burma, iron tablets were promoted to "help new blood regeneration" and "give strength to the blood," the perceived actions of locally accepted herbs and medicines for pregnant women.[12] In the same manner, the zinc messages adapted for the Philippine trial were based on existing concepts of health and common practices on feeding and diarrhea: *resistensya*, weakness of the digestive system during diarrhea, and popularity and belief on the efficacy of vitamins in strengthening the body.

The techniques employed in this formative research are similar to those used in social marketing, and are here used as part of developing the communications component of an RCT. The FGDs, the use of visual cards, and the message preference exercise were used creatively and logically to arrive at the particular messages that would have the most appeal to the target mothers and address their concerns regarding child care during diarrhea. The message preference procedure, which is a ranking process, helped eliminate the messages that least satisfied the mothers' expectations of zinc.

Product presentation, including packaging and labeling, is an important component of social marketing research. For micronutrient products, as in other drugs and medicines, attractive packaging can help promote acceptance and consumption.[11] While the zinc tablets for this trial already come in a blister pack that are regarded in itself as attractive because of their high status and longer shelf life,[11] the formative research nonetheless conducted FGDs and testing to choose a logo to accompany the zinc messages. Instructions on the label were in Filipino, the preferred language by the mothers. Whereas the use of pictures with minimum words was effective and recommended for developing countries,[11] the formative research found that a name and a logo were sufficient in this setting for identifying the zinc tablets.

Similar to pilot testing in intervention programs and to "trials of improved practices" or TIPs, as household trials are now called in social marketing parlance,[15] the behavioral trial tested the acceptance and comprehensibility of the chosen messages among target mothers when delivered in a clinical setting and followed up with actual household visits. The behavioral trial was necessary to detect any problem, concern, or resistance the mothers may have to the zinc therapy before the actual trial. This would enable the team to refine the messages or modify procedures.

The issues surrounding the introduction of a new drug like zinc were addressed by the formative research. These include the long duration of zinc therapy relative to the diarrhea episode, the size and nature of tablets being given to infants and toddlers, the giving of zinc together with other medicines and/or vitamins, and possible contraindications to certain foods and fluids, were discussed with mothers and standardized responses that are both scientifically and culturally acceptable were incorporated in counseling card messages. Conducting a behavioral trial was found to be an efficient way not only to test these responses but also to generate other concerns that were not expected during the early phases such as the cost and availability of zinc tablets and administering the treatment to older children and adults. While compliance did not appear to be a problem among the small number of clients in the behavioral trial, there were a few concerns like giving zinc to a well child and dissolving the tablet in other kinds of fluids such as juice. The development of the counseling cards also made sure that the health providers could give correct and consistent responses to mothers' concerns.

Zinc was perceived by the mothers in the behavior trial as a medicine to stop the diarrhea or make its symptoms disappear faster. There should be some effort during the clinical trial to downplay this effect and more emphasis given to the role of zinc on improvement of appetite and full recovery through "increased resistance." It should be noted, though, that increased appetite, together with increased activity, became apparent to most mothers only on the second follow-up period (Days 13 to 15). This perhaps confirms the need to complete the zinc therapy in order for its results to be perceptible.

While the main objective of the formative research was how to present the benefits of zinc to mothers by identifying the effective messages, the behavioral trial also served as an opportunity to 1) detect operational problems that could be encountered in the RCT itself and 2) to field test the trial's data collection instruments. By conducting the behavioral

[k] Zinc Tablet is for children aged 2 months to 5 years old. It is a medicine that: strengthens the resistance of a child with diarrhea; increases the appetite of a child with diarrhea or getting well of diarrhea; a vitamin for the gut of the child. For best results, follow the doctor's advice on giving this medicine.

trial, possible measures were proposed to correct or minimize any problem met while carrying out the procedures and at the same time determine the understandability of and convenience in administering the instruments. The trial run also led to the development of other useful management forms that would facilitate and streamline the procedures of data collection and follow-up.

Finally, from the point of view of health program managers, this study demonstrates the necessity of conducting formative research in local settings to help design an intervention. When cultural beliefs and health practices play a role in the acceptance or resistance to a new behavior being introduced, site-specific baseline information needs to be incorporated in the content and strategies of communication activities. This formative research could be useful for other social marketing activities, in general, and future zinc effectiveness efforts, in particular. The procedures and methods applied could serve as a template for other formative researches.

Conclusions

In conclusion, this formative research was able to: 1) develop and pre-test a set of procedures for a formative research which enabled the formulation of relevant and acceptable messages for zinc; and 2) contribute to the conduct of the randomized clinical trial on zinc adherence by:

- Coming up with locally adapted messages that are scientifically sound and have "marketable appeal";
- Designing an acceptable and understandable packet label;
- Standardizing the responses to concerns regarding zinc raised by mothers as the basis for messages on counseling cards;
- Field testing the data collection procedures and instruments; and
- Determining operational issues that could minimize the problems in carrying out the clinical trial.

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