

**INTRODUCING ZINC IN A DIARRHEAL
CONTROL PROGRAM:**

**A MANUAL FOR CONDUCTING
FORMATIVE RESEARCH**

*Dr. Mark Nichter¹, Dr. Cecilia S. Acuin²,
and Ms. Alberta Vargas²*

¹ University of Arizona, USA

² National Institutes of Health, University
of the Philippines, Manila

ACKNOWLEDGMENTS

This formative research manual summarizes a process for employing qualitative research when introducing a new drug (zinc) to communities in a clinical trial and evaluating its impact. The model was developed by Dr. Mark Nichter (University of Arizona), Dr. Cecilia S. Acuin (University of the Philippines), and Ms. Alberta Vargas (University of the Philippines) who led the qualitative component of the zinc trial in the Philippines. Inputs were also provided by Dr. Shally Awasthi (King George Medical University, Lucknow, India), Dr. Robert Black (Johns Hopkins University), and Dr. Olivier Fontaine (World Health Organization), the Principal Investigators of the project titled “Acceptability and Cost-effectiveness of Zinc Supplementation in Treatment of Acute Watery Diarrhea in Children” which is a collaborative undertaking of the INCLEN-Childnet, Johns Hopkins University and the World Health Organization.

The qualitative component of the Philippine trial was supported financially by the World Health Organization and the USAID through the INCLEN Philadelphia Office.



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Section 1. Introduction

1.1. Background

Several recent studies in developing countries have found that Zinc supplementation is efficacious in reducing the severity and duration of diarrheaⁱ resulting in lower rates of diarrhea-associated mortality.ⁱⁱ A study conducted in Bangladesh by the Centre for Health and Population Research (ICDDR,B) and the Johns Hopkins University (JHU) further documented that when zinc supplementation was given along with ORS there was a decrease in the irrational use of antimicrobials and antidiarrheals, and an increase in the use of ORS.ⁱⁱⁱ This makes use of zinc supplementation with ORS doubly attractive for the management of cases of acute watery diarrhea. While the results from the Bangladesh study are promising, research on local response to zinc provision needs to be replicated in other settings. The findings of the Bangladesh study may not be generalizable to locations where diarrhea control efforts have been less intensive. If such is the case, efforts will need to be taken to ensure that zinc is promoted and used appropriately.

There is clearly a need to assess local response to zinc in different social and cultural settings as a step toward developing global zinc supplementation policy. This demands both a study of how best to introduce and explain zinc use to local populations and an evaluation of the impact of such zinc supplementation on ORT when: a) zinc is introduced along with ORS in clinical settings and, b) zinc is introduced into community contexts by health care workers and/or through the private sector. Considerable time and effort have been invested in community based ORT related education over the past three decades. We need to make sure that efforts to introduce zinc enhance and do not undermine efforts to increase ORT use. This is of vital importance because ORT is essential to prevent diarrhea related death..

To test community response to zinc supplementation, messages need to be developed to promote the benefits of zinc in such a way that the health concerns of mothers are addressed. Toward this end, formative research is called for to develop messages that are culturally appropriate. Formative research is also needed to help design studies that evaluate changes in ORS and anti-diarrheal medicine use pre- and post-zinc introduction.

The Challenge

Moderately difficult:

To market zinc as a medicine for diarrhea that reduces severity and duration

- ◆ Need right name, right message, right packaging
- ◆ Decrease use of other medicines by offering zinc tablets for free

More difficult :

- ◆ Get mothers to keep giving zinc to children for 14 days after symptoms have disappeared
- ◆ Get mothers to give zinc without reducing ORS

Harder still:

- ◆ Get mothers to purchase zinc and use it appropriately and routinely for all types of diarrhea

This research is challenging for two reasons. First, zinc needs to be taken for approximately 14 days in order to have full therapeutic effect. This demands that messages be developed to both i) encourage mothers to give their children zinc when ill, and ii) to continue giving them zinc when symptoms abate for a full 14 day course of supplementation. Mothers adherence to zinc instructions must be measured at different points in time during the 14 days and reasons for stopping therapy carefully assessed at each stage. Second, it is necessary for evaluations of zinc adherence to take into account several different variables that may affect patterns of use. For example, local categories of illness associated with diarrhea need to be taken into account as the perceived need for treatment may differ by type of illness, however classified. Differences in ORS use by illness type have been documented in carefully designed studies in Bangladesh.^{iv} Other factors that will need to be considered are perceived severity of illness, accompanying symptoms (e.g. vomiting, nausea, blood in the stool, fever), age of the child, and season.

This guide

This guide to formative research on zinc administration during diarrhea was designed to assist a multicenter zinc study coordinated by The International Network of Clinical Epidemiology (INCLLEN) between 2002-2004^v, and jointly supported by INCLLEN, JHU, USAID and WHO. A zinc intervention and effectiveness trial was carried out in seven sites: (1) Lucknow, India; (2) Nagpur, India; (3) Manila, Philippines; (4) Pretoria, South Africa; (5) Cairo, Egypt; (6) Addis Ababa, Ethiopia; and (7) Fortaleza, Brazil. Prior to the intervention trial, formative research was to take place in each site to facilitate instrument construction, zinc message development in local languages, intervention monitoring, and evaluation. The guide was largely created in the field in the Philippines by a team of three social scientists having considerable research experience on diarrheal disease and pharmaceutical practice. Given the absence of well trained social scientists at most of the trial sites, the guide was developed for use by teams having little expertise in health social science. Researchers at each site were encouraged to review existing social science research on diarrhea and ORT in their locale, and when possible to enlist the assistance of local social scientists in the formative stage of their research.

Research teams at each site chose to conduct formative research on their own, and each team used the formative research guide in a slightly different manner. Presented here is a revised guide to formative research that has benefited from the experience gained in the above-mentioned study. Revisions of the guide were made following a data analysis meeting held in Lucknow, India in September 2004. At this time lessons learned during the project were discussed by representatives from the different field sites. Examples used in this iteration of the guide are drawn from several of the sites. A second part of the guide contains question that the social scientists developed in the field to assist in the monitoring and evaluation of the zinc intervention trial. These items capture important differences in zinc use by such factors as local classification of diarrhea and perceptions of illness severity, perceptions of zinc benefits and side effect (e.g. appetite), ways that mothers would describe zinc to friends, and how much they would be willing to pay for zinc as a routine treatment for diarrhea if the tablets were available. We hope this guide

will be useful for those planning zinc intervention trials as well as those planning on introducing zinc other supplements and/or medicines into clinic or community settings. Many of the research steps we outline would be applicable to other pilot interventions.

1.2. Phases or Stages of the Formative Research

This research draws upon the “Eight Stages of Formative Research” model developed for INCLEN by Nichter (1990)^{vi}. Data collected contributes to intervention design, message development, intervention implementation, monitoring, and evaluation (Figure 1.1) A baseline data gathering stage provides information upon which zinc messages are based, and is instrumental in the design of instruments measuring behavioral change associated with taking zinc. Practices such as ORS use, feeding (including breastfeeding), and use of medicine (including antibiotics) are documented at entry into the study and monitored in both intervention and control arms to determine how much the use (or not use) of zinc affects these behaviors. Initial stage one formative research determines what were the key behaviors that should be tracked and monitored from the phase of the research to the next.

A second phase of formative research, the message development and testing phase, uses baseline data to generate viable candidate messages related to the behaviors we would want to promote or change, i.e., adherence to zinc, continued use of ORS, non-use of antibiotics, among the population to which the intervention is targeted. This phase determines the mix of simple and effective messages and/or instructions that are most likely to motivate mothers to correctly give and administer the zinc tablet for 14 days. Weeded out are messages found confusing or controversial.

The monitoring and evaluation stages of formative research involve identifying lead mothers to adhere to or discontinue zinc therapy, identifying what did they like and/or did not like about the medicine, and whether they like it enough to recommend it to others and pay for it.

1.3. Methods for Formative Research

The general plan for conducting formative research presented in this guide and recommended for use in zinc implementation and effectiveness makes use of the following methods: literature review, in-depth interviews, focus group discussions (FGDs), behavioral trial, and observations of health care provider- mother interactions.

Of key importance to the any zinc effectiveness trial is the identification of suitable messages to accompany the distribution of zinc tablets. This message development stage of formative research generates viable candidate zinc messages tested in intervention. Data generated during the trial is useful for subsequent social marketing research that needs to be conducted before a zinc distribution program goes national. The objective of this formative research is to look at diarrhea management and zinc use from the

perspective of the mother. Zinc messages are designed to fit mother's ideas of what an acceptable and effective medicine is for diarrhea and illness convalescence.

Formative research is process-driven and iterative. Data collected at one point of time influence research conducted at a subsequent point of time as new research questions emerge. In this intervention, formative research was initiated before the trial and guided instrument development and evaluation. An exit interview conducted at the end of the trial contributed to the refinement and modification of zinc messages and protocol (Figure 1.2).

The formative research consists of eight main steps enumerated below:

- Step 1. Determine local terms, concepts and practices related to diarrhea and its management

Through literature review and key informant interviews you will know:

- ❑ the local terms for types of diarrhea, local ideas about causes of diarrhea, and common practices about treatment and feeding
- ❑ concerns mothers have when children experience diarrhea

Through a Cards Matching exercise, you will be able to:

- ❑ determine the different treatments and feeding practices commonly associated with the different kinds of diarrheas

- Step 2. Develop Key Messages

By using findings from Step 1, you will:

- ❑ know terms and concerns that are important to consider when developing messages
- ❑ be able to develop candidate messages for zinc
- ❑ eliminate potential messages that are likely to be confusing or conflict with mothers' perceptions and concerns

- Step 3. Test the Messages

Through a Message Testing exercise, you will be able to:

- ❑ test potential messages developed from Step 2
- ❑ identify final messages for the behavioral trial

- Step 4. Gather mothers' reactions towards the zinc tablet

- ❑ get the mothers' reaction towards the zinc pill and its administration
- ❑ determine issues and concerns of mothers that may be included in the Counseling Cards

- Step 5. Develop the Counseling Cards

In this step, you will:

- design and develop the Counseling Cards that will address the issues and concerns of mothers determined from the previous steps

- Step 6. Conduct the behavioral trial

By conducting the behavioral trial, you will:

- find out which among the messages identified in Step 3 has the best recall and understanding by mothers
- identify new message possibilities by listening to how mothers would describe zinc to friends after having the experience of using it

- Step 7. Process documentation and monitoring of intervention

Through conducting observations and exit interviews within the first month of the intervention, you will:

- determine how zinc messages are being delivered by health providers to target clients
- observe health provider-patient interaction, which may provide information that could explain mothers' other perceptions of zinc
- gather additional concerns from mothers that should be addressed in counseling cards

- Step 8. Final evaluation at end of intervention

Reviewing exit interviews following the behavioral trial :

- Determine whether any changes need to be made in the way the intervention is to be carried out, messages to be presented to mothers, any ways the intervention is going to be evaluated.

1.4. Timeframe for Formative Research Leading up to Intervention

The research can be completed within six weeks as suggested below:

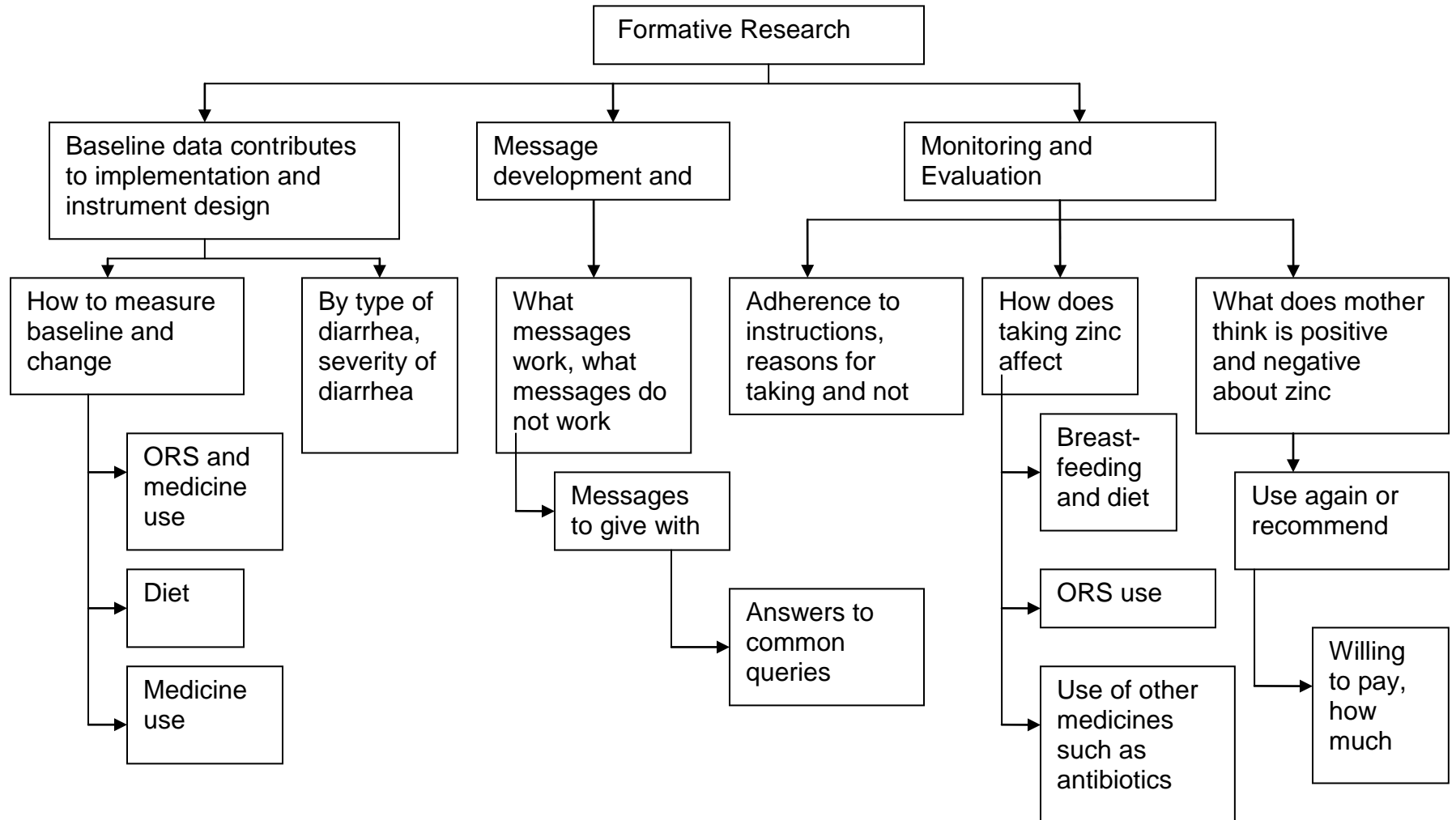
| Activity | Week | | | | | |
|---|------|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 |
| 1. Preparatory activities | | | | | | |
| 2. Review of literature, in-depth interviews, survey of pharmacies | | | | | | |
| 3. FGDs: card matching | | | | | | |
| 4. Development of messages | | | | | | |
| 5. FGDs to test messages, get reactions to zinc | | | | | | |
| 6. Design and pre-test label and logo | | | | | | |
| 7. Refine messages | | | | | | |
| 8. Develop counseling cards | | | | | | |
| 9. Prepare for behavioral trial: translate instruments, train/orient interviewers | | | | | | |
| 10. Conduct behavioral trial | | | | | | |
| 11. Analyze behavioral trial data | | | | | | |
| 12. Finalize messages | | | | | | |

1.5. Logistics

The following are the minimum requirements for conducting the research:

1. Personnel: at least two research interviewers
 - During the FGDs, one is tasked to document, the other to assist. The Project Team Leader should preferably facilitate.
 - During the behavioral trial, one interviewer should screen, recruit, gather baseline information, demonstrate preparation and administration of zinc, deliver messages, and conduct home follow-up interviews. The second interviewer should conduct the exit interview.
2. Venue
 - For the FGDs, an area accessible to mothers and free from distractions.
 - For the behavioral trial, a local primary health care facility from which to recruit mother and child pairs.
3. Supplies and materials
 - Visual aids are needed as described in the formative research steps.
 - Reproduction of behavioral trial instruments.
4. Budget for FGD refreshments (optional), interviewers' travel, incentives, etc.

Figure 1.1. Phases or Stages of the Formative Research



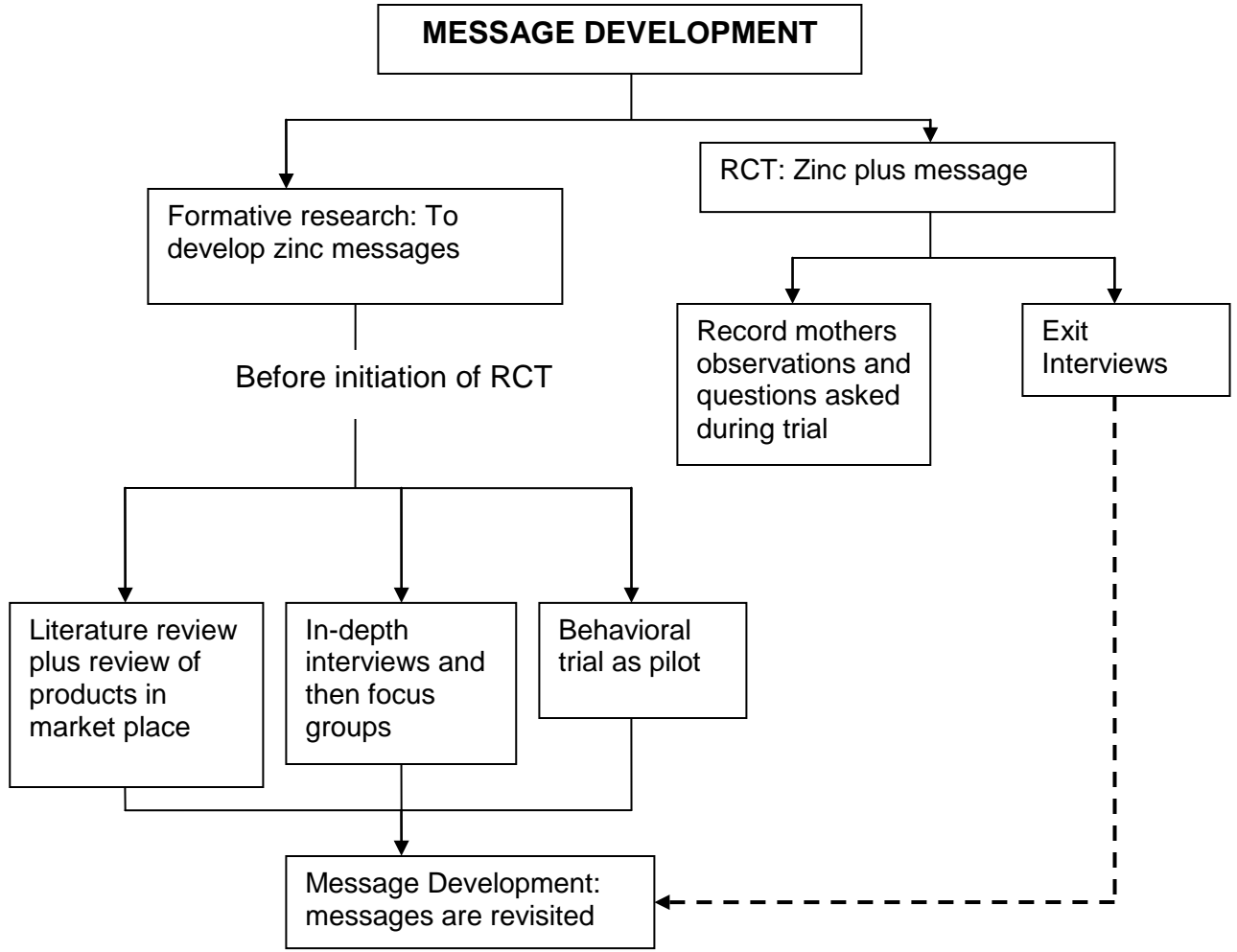


Figure 1.2. Formative Research: message development

SECTION 2.

How Are Mothers Thinking About and Responding to Childhood Diarrhea: Local Illness Terminology, Health Concerns, and Health Related Practices Matter

2.1. Objectives

After having completed the tasks listed in this section, you should have:

- made a list of the different kinds of diarrhea and terms for diarrhea in the local language or dialect that mothers use
- determined the treatments associated with the different kinds of diarrhea including medicines, herbals, and ORT
- gotten some idea of feeding practices during diarrhea, including the giving of breast-milk, other milk supplements, fluids, and solid foods
- learned of any other concepts or beliefs about diarrhea that could be important to adherence to zinc/ORS intake
- validated data provided from key informants and a reading of the local literature by a Card Matching interview exercise with groups of mothers

2.2. The Literature Review

After reading through this manual and getting a sense of the kinds of information needed for the formative research, it is best to start with what is already available. As an initial step, the team should collect all literature relevant to diarrhea-related perceptions and behavior. Mine these materials for data related to the main headings in the flowchart (i.e., illness classification, management of diarrhea, etc.). Some areas will have more data available, while others may need anthropological research to gather the required information. Make a note of how recent the available information is. Some of these data might need to be updated. Check also if the data from the literature applies to the locality where you are planning to have the intervention and the population living in this area. Remember that there may be important ethnic differences or language differences that could make the available data not applicable to your site. Where data is not available or up-to-date, conduct a focused ethnography (rapid appraisal), following the series of steps suggested in Section 2.4 of the manual. If possible, seek a trained health social scientist to assist you.

In many places where a diarrhea control program has been in place for some time, information about the following may have been collected at some point:

- 1) Ethnographic studies on diarrhea home management and community norms and practices related to diarrhea, specific to the population or area where you plan to promote zinc – how diarrhea is perceived as an illness, terms used, concepts related to severity, care seeking behavior, etc.

- 2) Extent of ORS and ORT use at home and in health facilities, as well as the distribution and supply channels within the health system and within the community for ORS packets (you might consider tapping these same channels for distributing your zinc)
- 3) Use of other medicines or treatments during a diarrhea episode – depending on the country, this may include anti-diarrheals, antimicrobials, antimalarials, and traditional medicines or treatments
- 4) Kinds of training health personnel (especially those who may be involved in promoting zinc, including village health workers) may have had on diarrhea management and communication and/or health education skills, as well as their literacy and competency levels
- 5) Information about zinc preparations that are already available in the market and how they are being promoted (As treatment? As tonics? As nutrient supplement? In milk formula? In multi-vitamin preparations? For adults? Or for children?) – this information will not come from diarrhea control program files, but more likely from the Food & Drug Administration or its counterpart in the country

If you have access to the internet, you may want to search the web. However, these kinds of information are not often published or posted on webpages so you may not find them. The best places to look for them are:

- 1) Diarrhea control program files
- 2) Studies done in schools of public health or medical anthropology or other health-related social science programs or medical schools
- 3) Research institutions, particularly those that do research on diarrheal diseases
- 4) Personal files of investigators or of people who may have been involved with the diarrhea control program at the time the studies were done

While the literature gives you a place to start, much of the available information may come from studies that have been done a long time ago. Unless the studies are fairly recent, it will be important to carry out the steps described in this manual to make sure of the relevance of your messages and other changes that may need to be put in place when introducing zinc supplementation to your diarrhea control program.

2.3. Why Is the Information Collected?

Local terms related to diarrhea and health concerns related to children's health need to be identified as a first stage in the process of developing culturally appropriate zinc messages. When developing zinc messages, care should be taken to note that zinc is (a) not a medicine that will immediately stop or cure diarrhea as this will foster unrealistic expectations, and (b) not a medicine to treat dehydration as this may interfere with ORS use. Zinc needs to be promoted as a **complement** to ORT and in such a way that mothers will still be motivated to administer it after the diarrhea has stopped. Researchers therefore seek to identify concerns a mother might have about a child's health following illness that

might lead her to continue giving zinc. This entails a consideration of local notions of vulnerability to illness and ways of preventing illness in the future.

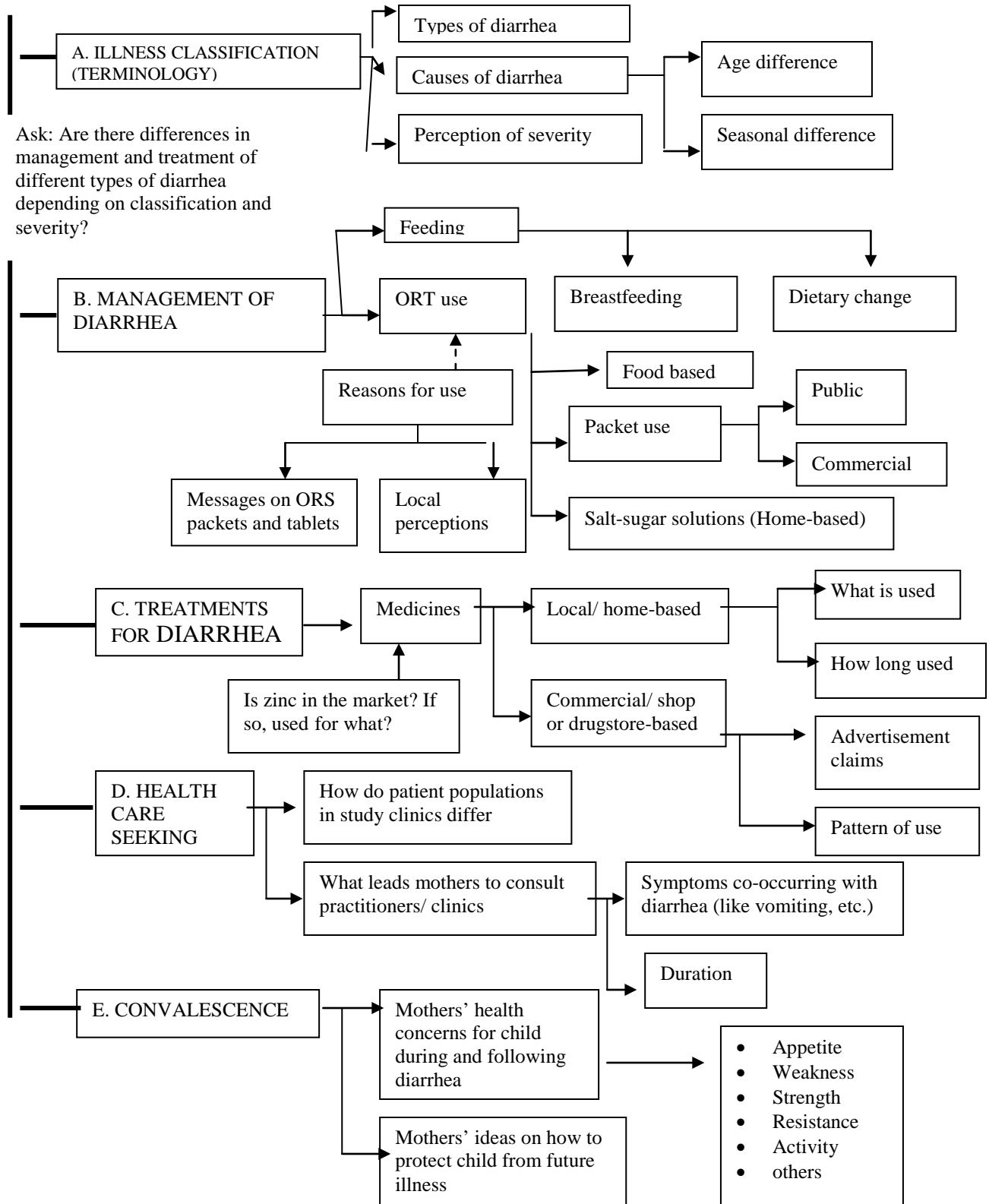
Beyond message development, formative research enables a grounded approach to health communication that anticipates the questions and doubts mothers are likely to have about zinc, ORT, and diarrhea related behavior (such as child feeding). Information can be placed on counseling cards following a question–answer format for use by health care providers (or persons who will counsel mothers about the use of zinc). Standardized responses to common questions related to diarrhea and its treatment are required during a zinc effectiveness trial. In general practice, having standardized answers to common questions raises the confidence of providers to communicate with mothers about health concerns. Standardized responses also minimize confusion from conflicting messages. Formative research is required not only to identify common questions, but also culturally appropriate responses that are scientifically valid.

The information gathered from this initial data gathering step of formative research also contributes to the development of tools to monitor and evaluate the impact of zinc supplementation on the population. It is important to monitor whether zinc is used more or less often for specific types of diarrhea (by cause, severity, age of child) identified in the community. It is important to know how mothers treat different types of diarrhea before zinc is introduced in order to assess the impact of zinc after it is administered. For instance, one would want to examine whether the use of home remedies, oral rehydration solutions, or commercial medications have changed in the case of “teething diarrhea” once the use of zinc has been introduced for all types of diarrhea.

It is also important to identify the popularity and use of diarrhea medicines and child health products (such as vitamins and tonics) that exist in the marketplace as they may influence the way zinc is perceived. All zinc products available in the marketplace should be identified. It will be necessary to investigate how these products are promoted and with what illnesses or health conditions people associate zinc.

Figure 2.1 illustrates the types of baseline information that might be useful to consider when designing a zinc intervention. This flowchart may be used as a guide or a checklist in determining the availability of resources in a particular locality.

FIGURE 2.1. FLOWCHART FOR THE COLLECTION OF BASELINE DATA



2.4. Conducting a Focused Ethnographic Study on Diarrhea

1. Conduct key informant interviews on mothers:
 - a) Select three to five mothers with children less than five years old; they may be selected from those consulting the health facility in the community. It would be better if these mothers have had recent experience taking care of their children during a diarrhea episode.
 - b) Ask these mothers questions to gather information that would contribute to most of the topics in the flowchart. See Table 2.1 for a list of possible questions you could ask the mothers.
 - c) Take note of keywords used for illness terms, causes and home, management practices.

2. Conduct in-depth interviews with key informants who could provide you with an idea of health practices prevalent in the community:
 - a) Identify persons in the village whom mothers commonly consult when their children are sick. They may include experienced mothers or grandmothers, herbalists, traditional birth attendants, or other respected members of the community.
 - b) Explore with them what they have observed are common patterns of health care seeking behavior for mothers of children with diarrhea. Consider this data in relation to answers you obtained from 1b above.
 - c) Take note of the health care practices. Are there any differences between home care practices and health care seeking practices (and advice) by type of diarrhea, perceived cause, or severity?

3. Make a survey of three to five pharmacies or stores selling drugs:
 - a) Conduct in-depth interviews with pharmacists and drug sellers. See Table 2.2 for a list of guide questions that you can use.
 - b) Ask the pharmacists and store owners for the names of medicines for diarrhea that are available in the market. Ask which are most popular and what medicines are purchased together – including commercial forms of ORS. Request to see how the medicines are labeled and packaged. Note how these are promoted. Examine key words and graphics used in the packaging.
 - c) Also ask about the different commercial ORSs available and what instructions they give for their use.
 - d) Create an inventory of the names of medicines and ORSs that you have gathered. Take note of these names.

4. Visit a few local health clinics or facilities that mothers in the study community commonly frequent. If conducting an effectiveness trial, it is best if all clinics to be included in the trial are visited.

- a) Conduct brief open-ended interviews with health providers and ask what kind of clients come to their facilities. You want to know whether most clients coming to the clinic tend to come early or late in an illness episode, and how likely they are to have engaged in self medication. Ask if clinic staff have a sense as to whether many mothers have seen other practitioners before coming to the facility.
 - b) In the case of an intervention trial it will be important to match client populations in intervention and control clinics. During evaluation of the zinc intervention, clinic-specific information may also prove insightful if clinic-specific differences are reported in adherence to zinc and use of ORS or antidiarrheal medications.
5. Conduct focus group discussions (FGDs) to further validate the information you have gathered so far about how diarrhea is classified, managed at home, treated with medicines and ORS, when health care outside the home is sought, and how mothers think about disease resistance and vulnerability.
- a) FGDs are usually:
 - i. Informal: participating mothers should feel at ease with each other
 - ii. conducive to interaction: mothers are usually seated in a circle
 - iii. guided: there should be an assigned person from the Project who will facilitate and lead the discussion
 - iv. focused: in addition to questions as discussion prompts, the use of props such as pictures, card prompts, and medicine labels are useful to keep the group on task
 - v. documented: in addition to the group facilitator, there should be an assigned person from the Project who will write down and record the important points shared and asked by the mothers.
 - b) You will need five or six mothers per FGD recruited from the clinic or the community. Each should have at least one child less than five years old to make the discussion more relevant.
 - c) During the FGD, we suggest introducing a card matching exercise as a relatively easy method for carrying out a focus group for those who do not have expertise in this research method. Prepare for the card matching exercise – see Section 2.5.
 - d) Conduct the exercise – see Section 2.6

Table 2.1. Guide questions for in-depth interviews with mothers

1. What are the types of diarrhea commonly seen in babies and children? What are they called?
2. Are different types more common in different seasons?
3. What are the causes of these diarrheas? What are the symptoms?
4. What are the treatments given for these kinds of diarrhea? (Include home treatments, herbal medicines, over-the-counter drugs, ORS, others.) What are the perceived roles of these treatments?
5. What are examples of medicines for diarrhea? Which ones are antibiotics? Are there medicines for different kinds of diarrhea or different severity of diarrhea? Do you still give ORS if these medicines are being given?
6. What do doctors usually give or prescribe for the different types of diarrhea?
7. Have you used ORT for diarrhea? Was this home-made or ORS bought commercially? If home-made, how was this prepared? How much is given to child who is ill?
8. What are the ORSs available commercially?
9. What does ORS do for children with diarrhea? (Determine mothers' concepts of dehydration and oral rehydration therapy.)
10. What foods are usually given to children during and after diarrhea? What are the perceived roles of these foods during diarrhea?
11. Are there certain foods usually withheld during diarrhea? Why?
12. Is breastfeeding continued during diarrhea? Why?
13. What liquids are usually given to babies and children during and after diarrhea? What are the perceived roles of these liquids?
14. Is liquid intake usually increased or decreased during diarrhea? Why?
15. Are there children who usually get diarrhea more frequently than others (recurrent)? What are the treatments?
16. Are there children who get sick with diarrhea longer than other children (prolonged or persistent)? What are the causes of such diarrheas? What are the treatments?

Table 2.2. Guide Questions for Drug Store Owners and Sellers

Ask:

- What are the usual terms clients use for diarrhea when they ask for medicine? What are the differences between these terms?
- What are the common medicines sold for diarrhea? How much do they sell for?
- How much medicine do mothers usually buy at a time?
- How often do mothers ask to buy ORS?
- What common combinations of medicines for diarrhea do mothers buy?
- Do mothers ask you questions about diarrhea in children? What kinds of questions do they ask?
- Are zinc tablets sold? If so what are they used for? What dose are they and for how long are they taken (collect a sample)?
- Are any products promoted as having zinc in them? What are these products? How are they promoted?

Examine

- How are the medicines for children advertised?
- How are these medicines packaged? What kinds of pictures or drawings, if any, are used? (Ask to see examples.) Is there different packaging for medicines for babies and for older children?
- What are the key words or phrases used in the labels?
- What are the usual messages written on packages of vitamins for children?

2.5. Prepare for the Cards Matching Exercise

At the minimum, you will need to make three sets of cards: one set for local diarrhea terms, one set for treatments, and one set for local feeding practices. The terms that you have gathered from your literature review and the ethnographic study done in Sections 2.2 and 2.4 should be included here. Health concerns that mothers have related to a child that

is ill could comprise another set of cards. Each card in a set should contain only one item. Table 2.3 shows possible items or terms that can be written on the cards.

| Table 2.3. Examples of possible items in different sets of cards | | | |
|--|---|---|---|
| <i>SET A</i> <i>Diarrhea terms</i> | <i>SET B</i> <i>Treatments</i> | <i>SET C</i> <i>Feeding practices</i> | <i>SET D</i> <i>Common medicines for diarrhea</i> |
| Terms associated with <ul style="list-style-type: none"> teething food and milk intake spoiled breastmilk blood in feces weather indigestion | cards for each <ul style="list-style-type: none"> herbals anti-diarrheals antibiotics* oral rehydration solutions teas * be careful to examine what antibiotic means locally | <ul style="list-style-type: none"> give more fluids give less fluids give more foods give less foods same amount of fluids breastfeed more often stop breastfeeding special foods advised (ask what) foods prohibited (ask what) | <ul style="list-style-type: none"> antibiotics (give examples of names) medicine for watery, bloody, etc. diarrhea medicine for dehydrating diarrhea medicine for mild diarrhea |

The cards may be prepared two ways: the first using text or words for literate communities and the second using graphics and drawings for illiterate communities.

When using text or words:

- the terms should be written clearly and legibly on the cards;
- the letters should be large enough for the mothers to read in a small group setting;
- no other words or markings should be written on the cards.

Tables 2.4 through 2.6 show examples of some Hindi terms related to diarrhea, treatment and foods that maybe placed on the cards.

Table 2.4. Examples of Hindi terms related to diarrhea

| | |
|-------------------|---|
| <i>Peele dast</i> | <p><i>Dast</i> is the common term for diarrhea. The color or appearance of the stool is how the diarrhea is described and is usually related to its perceived cause.</p> <p><i>Peele dast</i> means yellow diarrhea and is due to exposure to hot weather.</p> <p><i>Hare dast</i> means green diarrhea and is due to cold weather or chill.</p> <p><i>Safed dast</i> means white diarrhea and is due to excessive milk intake.</p> <p><i>Beej jaise</i> means stool has seed-like appearance and the diarrhea is caused by worms in the child's stomach.</p> |
| <i>Hare dast</i> | |
| <i>Safed dast</i> | |
| <i>Beej jaise</i> | |

Table 2.5. Examples of Hindi terms related to diarrhea treatment

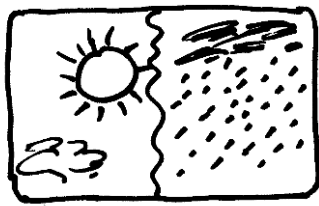
| | |
|--|------------|
| Ghuttis | Asafoetida |
| Electrol | |
| <p>These are common Indian treatments for diarrhea. Ghuttis and Asafoetida are traditional treatments while Electrol is a brand name of an oral rehydration salt solution.</p> | |

Table 2.6. Examples of Hindi terms related to foods given during diarrhea

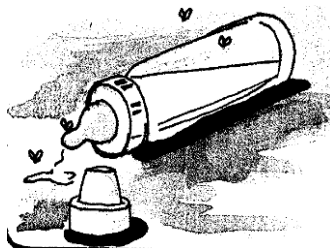
| | |
|---|-------------|
| Khichadi | Dal ka pani |
| <p>These are examples of Indian foods given during diarrhea. "Light" foods like <i>khichadi</i> (rice gruel) and <i>dal ka pani</i> (biscuits) are usually given. Other foods that are withheld may also be made into cards with the appropriate message.</p> | |

When using drawings for the cards, a little creativity is needed. Team effort may be required to come up with drawings that would be easy for mothers to grasp. The drawings need not be artistic but they should help mothers associate them with the terms you included in the exercise. Figures 2.2 through 2.4 show illustrations of such drawings.

Figure 2.2. Examples of drawings to convey diarrhea terms



This drawing shows the sun and rain and may be used to illustrate the kind of diarrhea caused by changes in weather. It would be helpful if you can supply the term for this kind of diarrhea or ask the mothers what they call it.



This drawing may be used to illustrate the kind of diarrhea caused by dirty milk.

Figure 2.3. Examples of drawings to convey diarrhea treatment

Some kinds of banana are perceived to be an anti-diarrheal food both in India and the Philippines.

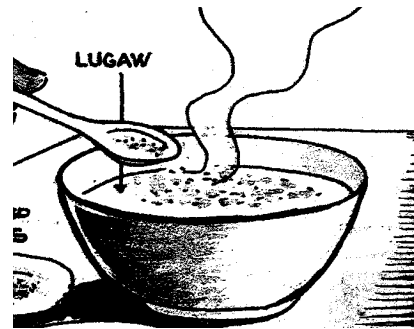


Actual pictures of ORT solutions or medicines may be used to illustrate different kinds of treatments.

Figure 2.4. Examples of drawings to illustrate feeding practices during diarrhea



“Continue breastfeeding during diarrhea.”



“Give rice gruel during diarrhea.”

2.6. Conducting the Cards Matching Exercise

2.6.1. Prepare the Cards Matching Kit, which will include the following:

- the cards that you have made in Section 2.4 (text or drawings) of diarrhea terms, treatment and feeding practices,
- extra blank cards and pens for additional terms,
- adhesive tape (optional) if cards need to be put up on a wall or a board.

2.6.2. Give appropriate introductions. Introduce the project team, which in this case includes the facilitator and the rapporteur, to the participating mothers. State your profession and what institution you are connected with. Read informed consent statement.

2.6.3. Give the mothers a chance to introduce themselves one by one. Let them tell you what area they come from, how many children they have, their reasons for consulting the clinic.

2.6.4. Explain the purposes of the meeting. Tell them that you want to learn from mothers like them the different kinds of diarrhea present in the community and the common treatments and feeding practices associated with them.

2.6.5. Proceed to the Cards Matching exercise. See Table 2.5 for the procedure of the exercise. Encourage the mothers to participate by directing questions toward each of them in turn.

When using cards with drawings, extra effort should be given to explain to mothers what the drawings mean. You also have to make sure that all the mothers participating in the meeting have the same understanding of the drawings. For example, the illustrations shown in Figures 2.2 through 2.4 may be described as follows:

Figure showing sun and rain (Figure 2.2) – example of a kind of diarrhea: “This drawing shows sun and rain. This indicates a change in weather. This drawing represents a kind of diarrhea seen in our community that is caused by changes in weather. Some mothers call this kind of diarrhea ‘_____’. Do you also call this kind of diarrhea this, or do you have another name for it?”

Figure showing a feeding bottle (Figure 2.2) – example of a kind of diarrhea: “This drawing shows a feeding bottle with milk in it. This can be a cause of diarrhea. This drawing refers to this kind of diarrhea. Do you have a name for this kind of diarrhea?”

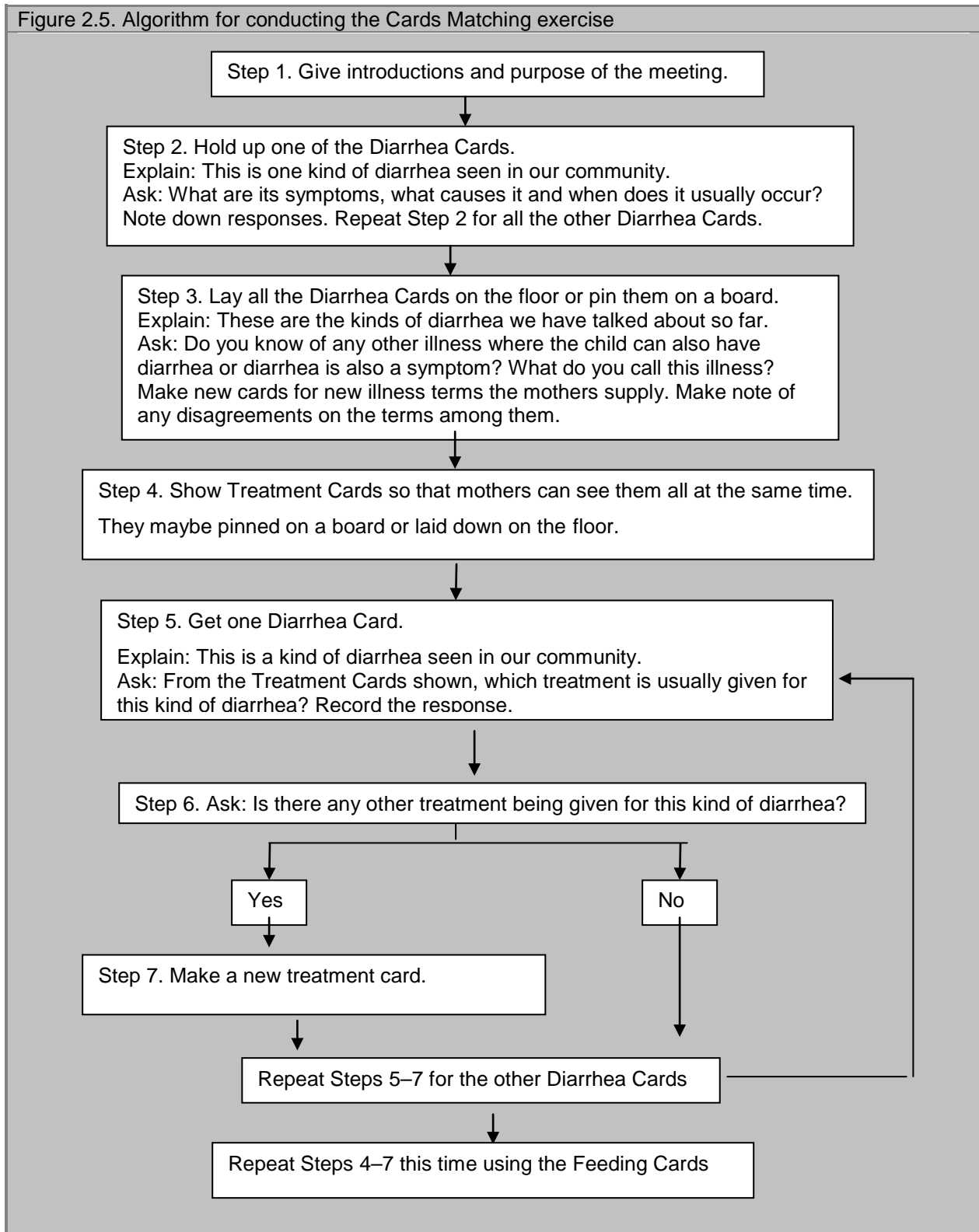
Figure showing an ORS packet (Figure 2.3) – example of treatment: “This is an illustration of Oral Rehydration Salt (or whatever it is locally called). It is one of the treatments given for diarrhea.”

Figure showing a breastfeeding mother (Figure 2.4) – example of a feeding practice during diarrhea: “This picture shows a mother breastfeeding her baby. This picture means that you should continue breastfeeding when the baby is sick with diarrhea.”

This manner of explanation may be repeatedly used for the other illustrations to make sure that the mothers have a uniform understanding of the drawings. If the mothers supply a new term for the drawing, take note of it. The group may in fact agree on a term to refer to a drawing. If this is the case, take note of it because the term may come in useful when you are constructing your key messages and developing your counseling cards.

2.6.5. Close the meeting by thanking the mothers for the time and information they shared with you. Ask if they in turn have any concerns or questions for you.

Figure 2.5. Algorithm for conducting the Cards Matching exercise



2.7. Analyzing Your Data

With the data that you have, you will have a clearer idea of the kinds of diarrhea in your site and how these are described by mothers. You now know what diarrheas are treated with medicines, given ORT, etc. You will also have an idea about the feeding practices of mothers when their children have diarrhea.

Other topics you might want to explore in the group include:

- What is ORS used for, what does it do (i.e., medicine for diarrhea, for dehydration)?
- What is the mother's concept of dehydration/rehydration?
- Is it acceptable to give medicines for diarrhea and ORT at the same time while a child is still sick? Or is one a substitute for the other?
- Are the practices related to giving medicines and ORT similar among breast-fed and non-breastfed children?
- Are there medicines given even after the child has recovered from diarrhea or any other illness?
- Do mothers change the way they give foods and fluids to children after they get well from diarrhea or any other illness?
- Do mothers have a concept of "contra-indication" where certain foods or another medicine should not be given to a child with diarrhea if he is already taking some medication?
- Do mothers have a concept of what is "prohibited" where certain medicines, fluids, or foods should not be given when a child has diarrhea?
- Are vitamins given to a child when they have diarrhea? Are they valued as a resource when a child is recovering from illness? Are there different types of vitamins good for children who have had diarrhea?
- Why do some children become sick more easily than others? Is there a local notion of resistance or vulnerability? How do mothers try to prevent illness in such children?
- Is there a local perception of strength associated with a child being protected from illness – what fosters strength in children?

You may need to conduct a few more Cards Matching exercises if you continue to generate new ideas – that is, if saturation in answers is not reached.

Section 3. Development of the Key Messages

3.1. Objective

By the end of this section, you should have:

- Developed the potential messages to explain to mothers the actions and effects of zinc for children with diarrhea.

3.2. The Need for Balanced Messages

The formative research recommended in this manual is a tool to identify potential candidate messages to use for the social marketing of zinc. However, this research is just the first stage of message development and the methods specified were not designed to identify the definitive set of messages to be used in the country. In focus groups, for instance, we not only want to learn what are the most common health concerns that should be considered for a few key messages, but more importantly, we want to eliminate candidate messages that mothers (the target audience) respond to negatively or have trouble understanding. We need to eliminate messages that even a minority of mothers might find confusing or problematic.

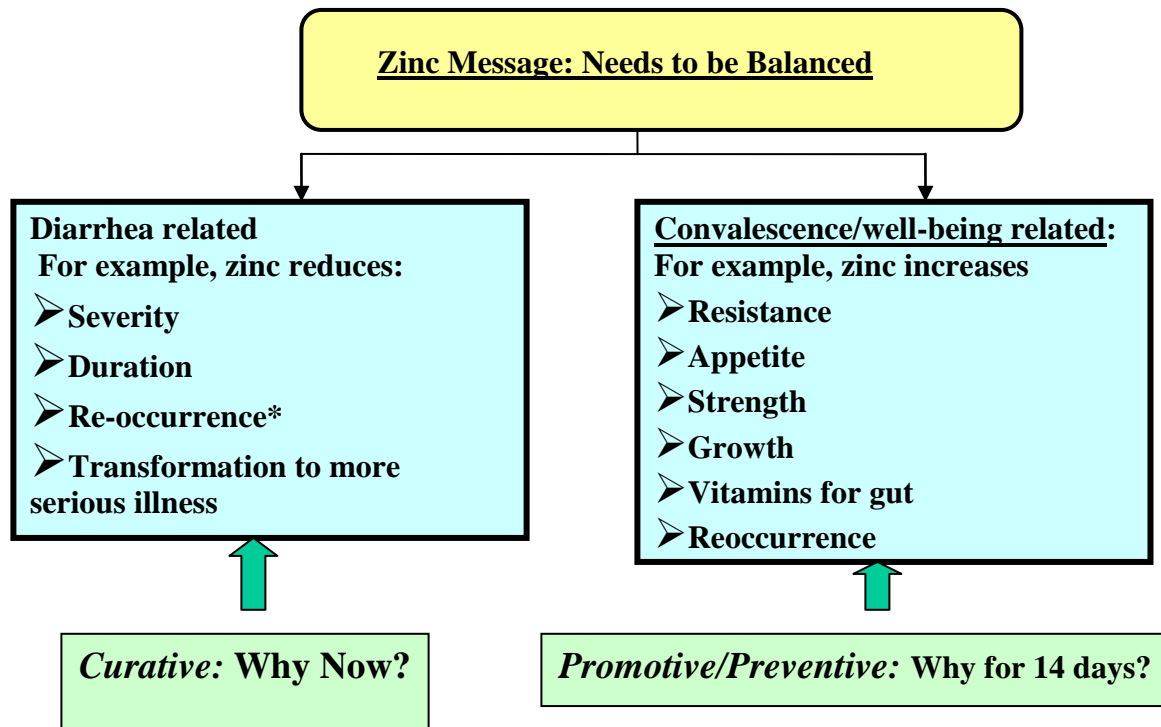
The messages need to be based on the scientific evidence, but phrased in a way that will enable mothers to give zinc appropriately to their children. Sufficient information supports zinc's therapeutic effects for acute watery diarrheas among young children. Its immediate effects include shorter duration of episodes and fewer loose stools. A complete 14-day zinc supplementation is needed for optimal recovery of the child's gastrointestinal tract, which in turn results in prevention of future episodes.

Our experience suggests that it is optimal if key zinc messages include curative as well as preventive health messages to ensure adherence. The real challenge in developing zinc messages is how to encourage mothers to continue using zinc after the diarrheal episode has abated and there are no longer symptoms. Local zinc messages should ideally be locally relevant and address both zinc's impact on diarrhea and the continued well-being of the child.

Figure 3.1 illustrates how these two concerns should be balanced. During the INCLEN intervention trial, each site came up with its own set of messages responsive to local health concerns. In some cases, only curative messages were included. While these messages proved popular, we would advise that future research try to come up with a better balance so that zinc is not just associated with acute diarrhea. Another concern that we have is that messages do not overstate the benefits of zinc. ORS research has taught us that when mothers had unrealistic expectations for ORS they tried the "medicine" and were disappointed that it did not immediately cure diarrhea. The demonstration effect of

zinc will take some time and involves harm reduction (prevention and health promotion) as well as diarrhea cure.

Figure 3.1. Curative and promotive messages for zinc



3.3. Reviewing Existing Messages in Advertisements

While keeping in mind the main actions of zinc you want to explore in your messages, take a look at current advertisements for children’s medicines:

- Look at the key words that are used.
In the Philippine trial, for instance, the words *resistensya* (resistance), *malusog* (healthy), *malakas* (strong), and *magana* (good appetite) were common words associated with a healthy child and frequently used in labels and advertisements for milk and vitamins. Different ways of using these key words were explored during the development of the messages.
- Take note of the ideas used to sell the product.
Again, the concept of resistance was taken into consideration for the Philippine formative research. It is a widely accepted notion and mothers understand well its meaning in the context of a child’s health.

- Keep in mind zinc’s actions since we do not want to have a message that would make mothers identify zinc with another product.

In developing the Philippine messages, for example, the team came up with the idea of zinc as a vitamin for the gut. Mothers know that diarrhea has something to do with a problem in the stomach and described diarrhea as a condition of weakness in the stomach. The idea of a vitamin providing over-all strength for the body was adopted, but a vitamin’s action in the case of zinc was specifically focused on the stomach to differentiate it from the accepted effect of vitamins, in general. Describing zinc as a vitamin for the gut also differentiated it from the action of an antidiarrheal drug since we do not want mothers to think that zinc is a cure for diarrhea.

3.4. Adapting and Translating the Messages

Adapt and translate the messages to local use. Remember:

- In translating, consider the terminologies, associations, relationships, and concepts gathered in Section 2.
- It is possible that a single message may be translated more than one way or in translation become more than one sentence.
- As much as possible, keep the translations simple and containing only one or two ideas at a time. To illustrate, Table 3.1 shows the five potential messages developed from the Philippines. Messages 1 and 2 address the disease while messages 3 through 5 address concerns about the child’s well-being. Explanations are also given for why the team came up with these messages, including the mothers’ concepts of illness and health, which played a role in their development.
- Learn from popular medicine advertisements. Examine messages used for these products. What concerns have been addressed that have “commercial appeal”?

Note: If your population has many non-literate mothers you will need to adapt the procedure described above. Use images easily recognizable to mothers as prompts/memory aids when describing items (concepts, resources, messages, etc.) contained on cards.

Table 3.1. Potential messages from the Philippines

| Adapted/Translated Message | Translated message (Tagalog) | Basis for adapting the message |
|---|---|--|
| Drug to prevent the diarrhea from becoming serious | <i>Gamot para hindi lumala ang pagtatae ng bata.</i> | Mothers are very concerned about the diarrhea becoming prolonged, worsening, or changing to a more serious form. Care-seeking patterns show that mothers may go to another health practitioner if the child does not improve after the first consultation. |
| Drug to prevent the child from getting sick again with diarrhea. | <i>Gamot para maiwasan ang muling pagtatae ng bata.</i> | Mothers understand and fear the conditions (such as dehydration, loss of weight and appetite) brought on by diarrhea and the thought that a drug could prevent it presents some appeal. |
| Drug that increases the appetite of a child with diarrhea or just recovering from diarrhea. | <i>Gamot na pampagana pag nagtatae o gumagaling sa pagtatae ang bata.</i> | Questions about appetite and feeding are among the most common that mothers ask during consultation for diarrhea. The message's appeal was based on the mothers' knowledge that appetite decreases during illness. The phrase " <i>pag nagtatae o gumagaling sa pagtatae</i> " further qualifies that this drug is for children who are in the acute or convalescent phases of diarrhea, so that even if the diarrhea has become better, mothers understand that the medicine still needs to be given. |
| Drug that strengthens the resistance of a child with diarrhea. | <i>Gamot pampatibay ng resistensya ng batang nagtatae.</i> | The key word of this message is <i>resistensya</i> , which is a big thing in the Philippine culture. Among mothers, one indicator of child's health is that he is not sickly and is "resistant." This word implies a range of ideas including strength, absence of illness, ability to fight off infections (resistant to infections), and being well enough not to be taken seriously ill by common diseases. |
| A vitamin for the gut of a child with diarrhea. | <i>Bitamina para sa tiyan ng batang nagtatae.</i> | Vitamins are known to mothers and are popular in the Philippines. A local study indicated that vitamins and minerals are not distinguished from each other. The idea of "vitamin for the gut" was based on a message found locally effective for a TB drug (vitamins for the lungs). This message can also explain why zinc needs to be taken for 14 days, which is actually the time needed for the gastrointestinal mucosa to be replaced. |

Section 4. Testing the Messages

4.1. Objectives

By the end of this section, you should have:

- Identified the potential messages to introduce zinc
- Tested the messages with two or three groups of mothers with children 2–59 months of age
- Identified final messages for the behavioral trial.

4.2. The Message Testing Exercise

4.2.1. The message cards

Make the message cards. These are cards, about 8”x11”, on which the messages translated from Section 3.3 are written. Make sure that:

- only one message is written on each card
- the cards are sturdy enough for easy handling
- the letters are large enough for mothers to read in a small group setting.

4.2.2. The Message Testing setting

The description of the small group meetings for Message Testing follows that of the Cards Matching exercise (Section 2.5). You may need to conduct at least two or three such meetings in order to see if popular messages can be identified and to screen out confusing messages and messages mothers have a doubt about.

4.2.3. The Message Testing procedure

Test potential zinc messages. Described below is the step-by-step procedure for message testing. The summary of procedures is in Figure 4.1.

Step 1. Introduce the project team. Let the mothers introduce themselves. Explain to them the purpose of the meeting. The following explanation is suggested:

“We would like to inform you that there is a new medicine for diarrhea that will soon be introduced at clinics and be available in the market. But before it is introduced, messages must be developed to accompany the medicine to explain its effects and actions to mothers. We would therefore like to ask for your opinion regarding some potential messages to be introduced with this new medicine.”

Step 2. Show the first message card to the mothers and tell them, “This is one of the messages that can explain the action of this medicine.”

Ask the following 6 questions:

- Is this message easy to understand?
- What is it trying to say?
- Is it clear what this drug can do if accompanied by this message?
- Do you know of any other medicine that has the same effect?
- Would you have a doubt if told a medicine could do such a thing?
- Is there anything that might concern you about such a medicine?

Write down the mothers’ reactions.

Step 3. Repeat Step 2 for the other potential messages. Always write down the reactions of the mothers.

Step 4. After you have gone through all the messages, tape the cards up on a board or lay them on the floor so that the mothers can see them all at the same time. Ask:

- If you could choose two messages that you think should go with this medicine, what would they be?

Write down the choices of each of the mothers.

Step 5. After the mothers have chosen their two messages, ask:

- If you could select a third message that could go with the first two you have chosen, which one would it be?

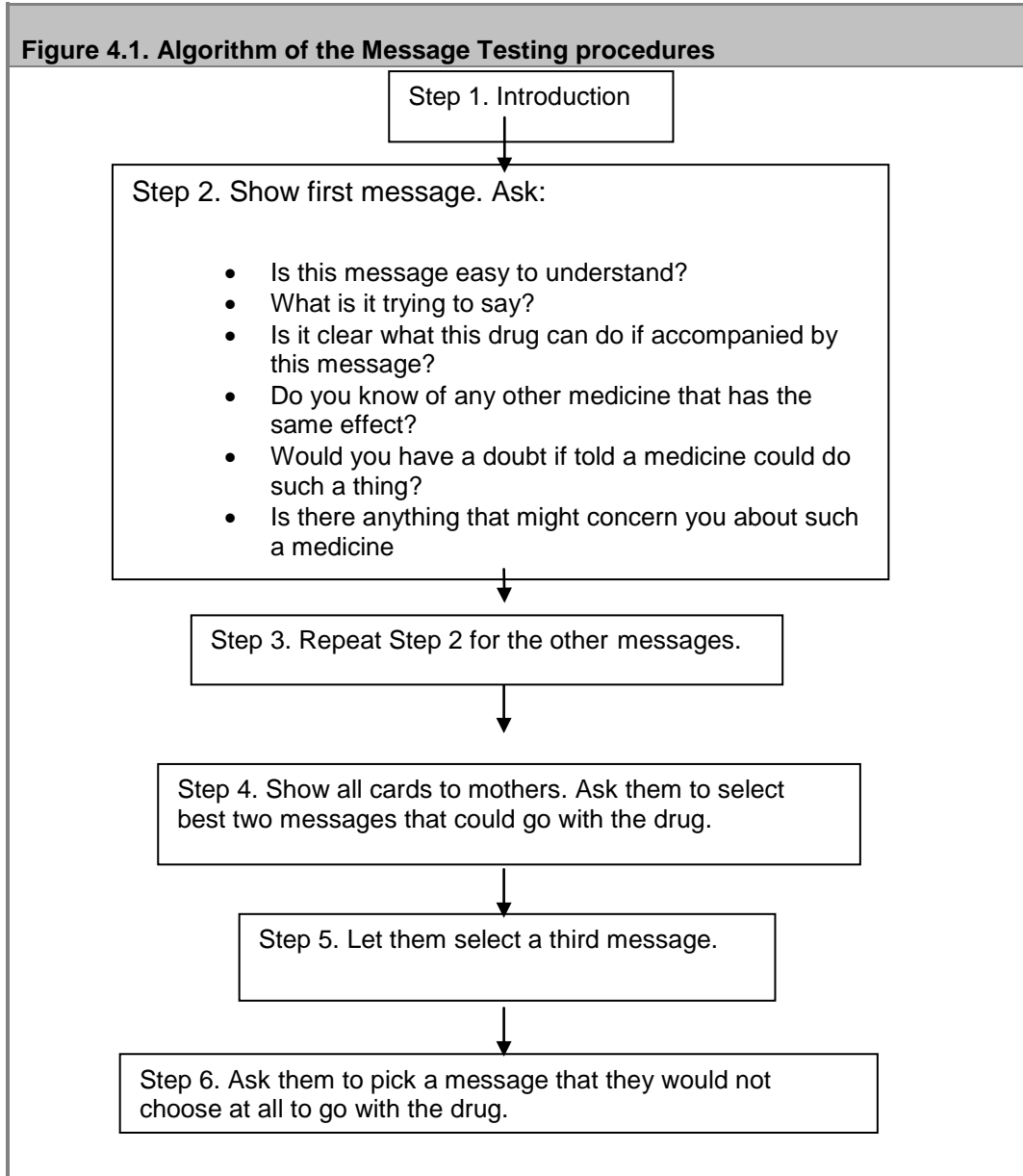
Write down the choice of each of the mothers.

Step 6. The last question for the message cards is:

- If there is one message here that you would not choose at all, which one would it be?
- Why – is it hard to understand? Do you disagree with what it has to say? Is this not something that interests you that much?

Write down the choice of each of the mothers.

Figure 4.1. Algorithm of the Message Testing procedures



4.3. Analyzing the Results of the Message Testing

Analyze the results of the small group meetings.

- Additional messages (and rewording of messages) may be added to the deck of message cards if new messages come up during any of the small group meetings.
- Test the refined messages in succeeding meetings.
- Make a matrix to show how frequently each of the messages were chosen by the mothers; distinguish the top two choices, the third choice, and all messages that would not be chosen at all. (See Table 4.1 for illustration.)

- Make a list and discuss all messages that mothers found confusing or had a doubt about. These are the messages most important to identify even if only a small number of mothers were confused by them. If these messages were found to be popular by many other mothers, consider if there is a way of clarifying the message to reduce doubt or concern. Test reframed messages.
- Take note of issues and concerns frequently raised by the mothers when discussing the cards. Consider these concerns when you develop your counseling cards.

| Table 4.1. Results of Message Testing, Philippines | | | | | | | | | | | | | | | |
|--|------------------|----|----|----|----|------------------|----|----|----|----|------------------|----|----|----|----|
| Message | Group Meeting #1 | | | | | Group Meeting #2 | | | | | Group Meeting #3 | | | | |
| | M1 | M2 | M3 | M4 | M5 | M1 | M2 | M3 | M4 | M5 | M1 | M2 | M3 | M4 | M5 |
| #1. Increases appetite | ✓ | ✓ | | | ✓ | | ✓ | | | ◆ | | | ✓ | | |
| #2. Prevents diarrhea from getting worse | ◆ | ✓ | ◆ | ◆ | ◆ | ◆ | x | ◆ | ◆ | x | | | ✓ | | |
| #3. Increases the resistance of a child with diarrhea | ✓ | | ✓ | ✓ | ✓ | ✓ | ◆ | ✓ | ✓ | ✓ | | ✓ | ✓ | 0 | 0 |
| #4. Vitamins for the gut of a child with diarrhea | x | x | X | ✓ | x | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | | |
| #5. Prevents child from getting sick again of diarrhea | | ◆ | ✓ | | | ✓ | | | | | ✓ | ◆ | ◆ | | |
| | | 0 | 0 | | 0 | | | x | | 0 | | 0 | 0 | | |

- ✓ - First two messages chosen
- ◆ - third message chosen
- x - message was not chosen at all
- 0 - messages for which a mother raised a concern

4.4. Deciding on the Messages to Use in the Intervention

Decide on the final messages. From the matrix, identify the most liked messages. Also identify messages where doubt or concern was raised by more than one mother. Messages chosen for the behavioral trial should both be popular and not be seen as confusing by even a minority of mothers.

As an illustration, Table 4.1 shows that most mothers in the Philippine Message Testing exercise chose a message of *resistensya* as a first choice coupled with the message of *bitamina*. While *bitamina* was eliminated by the first group of mothers, it was chosen as a potential message in the other two groups. In the first group, one of the mothers made the comment that her doctor had asked her to stop all vitamins while her child had diarrhea. Most of the mothers apparently concurred with this and so chose to eliminate this message. However, the researchers reframed the message so that zinc would be promoted as a special “vitamin for the gut” by doctors useful for diarrhea and valuable to continue taking when symptoms were no longer present to promote resistance to future disease. This reframed message was tested in subsequent groups, where mothers were accepting of the message.

A third message might be the message on appetite (*pampangana*) or on the prevention of diarrhea worsening (*para hindi lumala*). The former message may be more acceptable because the latter came only as a third choice and was eliminated by a number of mothers in the second group.

In deciding what messages to consider for inclusion in the trial, remember that you are not simply looking for the most popular messages among a non-random sample of mothers attending a small number of focus groups. You are trying to weed out confusing messages. This requires paying as much attention to what messages mothers do not like and why as what mothers do like and why. A message that is misleading to even 20% of the community may undermine the zinc program. As an illustration, from Table 4.1, the fifth message (prevents getting sick again) was found to raise issues for a number of mothers. They thought that if the child is no longer sick, it might be hard to make him take the zinc. Some mothers also thought that diarrhea could not really be prevented and small children normally go through such episodes of “normal” diarrhea. One example given was diarrhea due to teething which was perceived as something a baby usually goes through as part of growing up. The message on resistance, while seen as a highly potential message, also received some concerns from a number of mothers. They thought that a medicine with such actions similar to vitamins and fruits might be expensive and not very affordable.

Table 4.2 summarizes the messages chosen by five of the sites participating in the zinc trial. The table shows that mothers’ preferences differ from one setting to the next depending on local health concerns and differences in popular health culture.

Table 4.2. Messages generated, tested and used in five zinc trial sites

| | Philippines | Lucknow | Nagpur | Brazil | Egypt |
|---|--|---|--|--|---|
| Curative message used in the trial | | Cure this episode of diarrhea and prevents future episodes | If given with ORS, prevents diarrhea from getting worse | A treatment for diarrhea | Decreases duration of episode Decreases the number of loose stools Prevents diarrhea from getting worse |
| Well-being message used in the trial | Increases appetite Increases resistance Vitamins for the gut | | Increases appetite Replenishes zinc, which is essential for growth | Increases appetite Increases resistance Vitamins for the gut | Increases appetite |
| Messages generated & tested, but not chosen | Prevents diarrhea from getting worse Prevents child from getting sick again with diarrhea | Ensures that child is fully recovered from this episode of diarrhea | Helps cure diarrhea fast Prevents diarrhea induced weight-loss and weakness Increases resistance of child and prevents diarrhea from recurring | | Prevents future diarrhea Increases resistance Vitamins for the gut |

When introducing zinc messages, the research team should also consider how ORT and oral rehydration solutions are perceived by the mothers in the community. In the Philippines, for instance, ORT is well understood and mothers are aware of the dangers of dehydration and how oral rehydration therapy works to address it. It was, therefore, found unnecessary during formative research that distinct messages for use of oral rehydration solutions should be developed and delivered together with the zinc messages. On the other hand, in Nagpur, India, rehydration is not well understood and, while mothers are aware of the ORS available through the public health system, they are not satisfied with its effect on the child's diarrhea. The team therefore thought that a zinc message that had a distinct ORS message should be tested in the site.

Section 5.

Mothers' Reactions to the Zinc Tablet

5.1. Objectives

By the end of this section, you should have:

- gathered concerns about the giving of medicines
- obtained mothers' initial reactions toward the zinc tablet

5.2. FGDs to Introduce the Tablet to Mothers and Get Their Reactions

5.2.1. Prepare the materials

- a blister pack of zinc to show to mothers as a sample (use the formulation that will eventually be used by the program)
- a cup of clean water and a teaspoon for demonstration

5.2.2. Organize an FGD session. Refer to section 2.5 on how FGDs are organized and conducted. Give appropriate introductions when you start the session. Introduce the project team, which in this case includes the facilitator and the documentor, to the participating mothers. State your profession and what institution you are connected with.

5.2.3. Give the mothers a chance to introduce themselves one by one. Let them tell you what area they come from, how many children they have, and their reasons for consulting the clinic.

5.2.4. Introduce the zinc pill

Follow the steps described below in carrying out this FGD:

Step 1. Show the blister pack of the zinc tablets to the mothers. The following explanation is suggested:

“Here is the medicine that we have been talking of. It has no name yet. The reason we are showing this to you is to ask for your help on how to explain it to other mothers like you. This way, it will be easier to introduce it to all mothers.”

Step 2. Show the mothers a sample of the tablet. Write down any reaction.

Step 3. Get the mothers' opinions regarding the following concerns:

- Size of the tablet (same whole tablet for infants and toddlers)
- Preparation (no infant drops or syrup preparation; needs to be dissolved in water)
- Daily dosage (should be given once a day)
- Duration of medication (should be given for 14 days)
- Packaging and labeling of medicines
- Taste of medicine

Step 4. Demonstrate to the mothers how the zinc tablet dissolves in water. Get a spoonful of water. Drop the tablet into it. Let the mothers observe how easily the tablet dissolves in a teaspoonful of water. Get their reactions.

Step 5. Let the mothers taste the solution. Get their reactions.

5.3. Analyzing the Information Gathered

When analyzing your data for this part of the study, remember the concerns mentioned earlier, such as:

Pill size. During the trial, one tablet size for both infants and young children was used. The team should determine whether mothers would halve the tablet for infants upon seeing that same tablet size will also be given to older children and toddlers. In Brazil, the size of the tablet was a concern, even when it was demonstrated to be easily dissolved in water (see Table 5.1). Halving the tablet (and giving two equal but smaller doses) may therefore be an acceptable way of addressing this concern. However, note that in Egypt, mothers had the opposite reaction, preferring to give only a single daily dose. You will have to find out how mothers in your area will react.

Preparation. Investigate how willing mothers are to dissolve the pill in liquids for infants in terms of extra preparation time needed. Would they prefer syrup (as mothers in Brazil preferred) or infant drops (like Filipino mothers did) over tablets? Is it their practice to dissolve medicines in tablet forms? If so, do they usually use just water or any other liquid (breastmilk, juice, teas, etc.)?

Dosage. Do mothers think the dosage (one tablet per day) is too much for babies? Do they have the tendency to reduce the amount of the prescribed dose if they feel it is too much for the child? Are they likely to divide the pill and give it to the child over the course of the day? Try to find out what kind of decision-making processes mothers make with regard to giving medicines.

Medicines given over a number of days. Determine how much experience mothers have in giving medicines over a period of time. Do they usually comply, or do they have problems with completing the medication? What are their experiences regarding antibiotics and vitamins?

Packaging and labeling. What are the mothers' impressions of medicine packaging? Do mothers think that medicines that come in blister packs are higher in quality or higher in status, making them more acceptable? Do mothers have more confidence in medicines that come in boxes or blister packs with pictures? How do they feel about the names for zinc that have been considered for use? These are some of the things that the team needs to consider. If the mothers feel that specific labeling and packaging are needed for zinc, the team must conduct additional focus groups to come up with candidate labels and logos.

Instructions on preparation. Find out if the instructions on zinc preparation are easily understood by the mothers. Ask them to demonstrate to you how the tablet is dissolved after you demonstrate it to them.

Table 5.1 summarizes some highlights of research found in a number of zinc trial sites.

Table 5.1. Reactions to the zinc tablet in different trial sites

| SITE | CONCERNS WITH REGARD TO TABLET |
|----------------|--|
| Philippines | <ul style="list-style-type: none"> • Syrup might be a better preparation for infants • If tablet is dissolved, can it be administered through dropper • Medicines usually given after meals when the stomach is full • Drugs for diarrhea may not have pictures on their labels • 14-day therapy for zinc is acceptable; similar to antibiotics that are given for a number of days |
| Brazil | <ul style="list-style-type: none"> • 14 days may be too long • Tablet seemed large for a young child even when dissolved • Liquid medicines more acceptable |
| South Africa | <ul style="list-style-type: none"> • Possible to administer whole tablet; if mothers felt it was too much, dose could be divided into two, or dose for the day halved • Dissolving tablet makes giving easy to children of all ages |
| Lucknow, India | <ul style="list-style-type: none"> • Mothers needed repeat instructions on dissolving the tablet • Mothers asked what time of the day medicine should be given; is a 24-hour interval needed in between tablets |
| Egypt | <ul style="list-style-type: none"> • Mothers preferred giving medicine in one daily dose, rather than giving it in divided doses • Mothers uncomfortable with giving unlabelled medicine |

Section 6. Designing the Zinc Label and Logo

6.1. Objectives

Based on the findings of previous FGDs (section 5) and concerns about mothers being able to identify zinc tablets as unique, a research team might need to come up with a culturally appropriate name and logo for zinc for use in an intervention or trial. At the end of this section, the team will determine whether, first, the targeted population needs a distinct label name for the tablet, and second, if so needed, how to go about designing and choosing what to use.

6.2. Designing and Testing Candidate Logos and Labels

Step 1. First analyze the information gathered from the FGDs:

- Do mothers need to see a label on the medicine?
- Does it have to have a picture? What kind?
- What should be written on the label? Test several candidate names of zinc to be presented to mothers.
- Do mothers expect written instructions to come with the medicines? You might need to design a card insert or accommodate the instructions on the label.

Step 2. Design two or three candidate labels and names. Figure 6.1 illustrates the candidate labels used in the Philippines.



Figure 6.1. Candidate labels and logos from the Philippines

The first label used an “arrow up” symbol to denote an “increased resistance.” The second symbol was taken from the Superman logo and was accompanied by the name “Super Zinc,” while the third logo was a circular symbol that could be associated with the shape of the pill. For the labels, both English and Tagalog (the local dialect) were used. The candidate labels were then printed.

Step 3. Conduct two or three FGDs wherein the labels are shown to mothers. FGDs should be organized similar to section 2.5. For the Philippine trial, two FGDs were conducted to test the logos:

one among the midwives in a local health center and one among mothers consulting the center. The tablet can be introduced this way:

“We are now coming up with a medicine that can be given to children with diarrhea. This medicine can (enumerate the zinc messages that were identified in Section 4). The medicine doesn’t have a name yet and we are right now getting ideas from mothers like you on how best to call and package this medicine.”

Step 4. Show the mothers the candidate labels you have printed. Get their reactions and let them choose which among the candidates fits with the medicine.

6.3. Analyzing the FGD results

Analyze the results of the FGDs qualitatively. In the Philippines, for instance, the two groups of participants preferred the third logo due to its simplicity. The respondents also liked the round shape of the symbol, which was easily identified with a pill. The middle logo, patterned after the “Superman” symbol, was described to convey “super effects” or actions that might be “over” (or too much) for a child’s needs and a mother’s expectations. The FGD participants also said that it was not offensive to use the local word for diarrhea (*pagtatae*) on the label. The final label decided upon in the trial is shown in Figure 6.2.

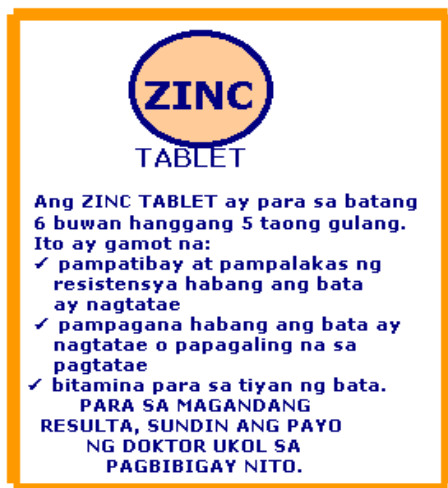


Figure 6.2. Final label used in Philippine behavioral trial

LABEL TRANSLATION:

ZINC Tablet is for children 6 months to 5 years old. It is a medicine that:

- *Increases the resistance of a child with diarrhea*
- *Increases the appetite of a child with diarrhea*
- *Vitamins for the gut of the child*

FOR BEST RESULTS, FOLLOW THE DOCTOR'S ADVICE REGARDING ITS USE.

One other site that deemed that a label was necessary was Egypt, where the team found that mothers were uncomfortable giving unlabeled medicine. Shown in Figure 6.3 is the logo and label developed by the team for its zinc trial.

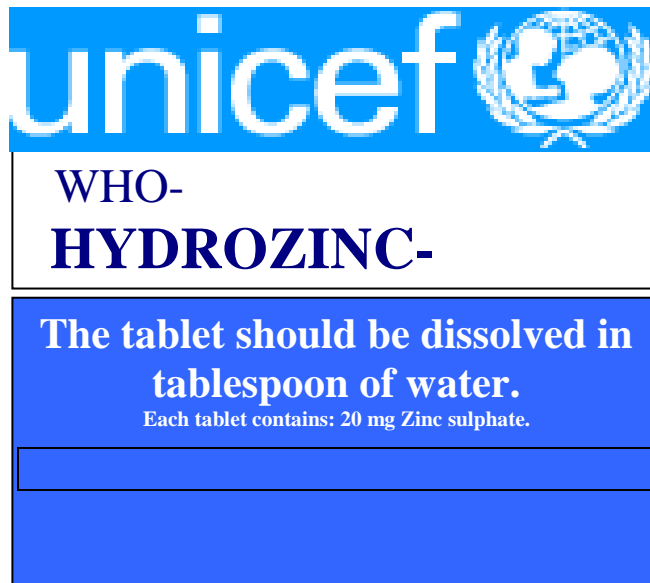


Figure 6.3. Logo and label developed by the Egyptian team for the zinc trial

Section 7. Development of the Counseling Cards

7.1. Objectives

By the end of this section, you should have:

- Crafted acceptable responses to common questions doctors anticipate mothers may ask them related to zinc administration and possible side effects
- Identified questions that some mothers are likely to have about zinc by reviewing formative research notes gather in Sections 1 through 5
- Designed a set of question–answer counseling cards for anticipated questions
- Pre-tested these cards.

7.2. Purposes of the Counseling Cards

The Counseling Cards:

- Are designed and developed for use by the health providers seeing mothers at the clinic
- Will be referred to only when mothers raise particular issues or concerns
- Are needed so that there is consistency of responses to common questions across sites and across health providers.

7.3. General Issues and Concerns

Table 7.1 illustrates some of the issues and concerns identified during formative research in India and the Philippines that were addressed by counseling cards. The issues enumerated in the table are “generic issues” that might need to be addressed in other sites as well. Other issues related to local illness concepts, beliefs and practices will also need to be addressed. It is likely that these issues will emerge during your Cards Matching and Message Testing exercises.

7.4. Deciding on the Contents of the Counseling Cards

Concerns mothers are likely to have about zinc should be turned into a series of questions. Culturally appropriate responses to these questions then need to be developed and pretested. The following issues need to be considered when developing and designing responses to questions mothers are likely to have about zinc:

- scientific basis of responses
- local concepts and beliefs
- local language/dialect
- ease of use by the health provider

Table 7.1. Issues and concerns that should be included in the Counseling Cards

| Issue | Possible questions and concerns of mothers |
|-------------------------------------|---|
| Vomiting | <ul style="list-style-type: none">• Should I stop giving the medicine when my child starts to vomit?• If he vomits after I gave him the medicine, should I give another dose? |
| Fever | <ul style="list-style-type: none">• What will I do if his or her fever continues? |
| Feeding | <ul style="list-style-type: none">• Can I give the child (certain foods)?• Should I increase/decrease his/her intake of (certain foods)? |
| Milk feeding | <ul style="list-style-type: none">• Should I stop/continue giving him milk?• Should I increase/decrease his intake of milk? |
| Breastfeeding | <ul style="list-style-type: none">• Should I stop/continue breastfeeding?• What should I do if my breastmilk is bad and is the cause of my child's diarrhea? |
| Co-morbidity | <ul style="list-style-type: none">• My child has a fever and you prescribed a medicine for fever. Doesn't this one (zinc) counter-act with the fever medicine? |
| Other medicines | <ul style="list-style-type: none">• My child has a cough and fever and is already taking two medicines. Can I give him this third one (referring to zinc)? |
| Vitamins/minerals during diarrhea | <ul style="list-style-type: none">• My child's stomach is not okay. Why should I still give him this medicine?• I heard a doctor say that vitamins and minerals should not be given during diarrhea. Is this true?• My child is already taking a multi-vitamin. Should I still give the zinc? |
| Bloody diarrhea | <ul style="list-style-type: none">• What will I do if I see blood in my child's stool? |
| Prolonged and/or increased diarrhea | <ul style="list-style-type: none">• My child's diarrhea continued for more than 3 (or 4 or 5) days. Could this be the effect of this medicine (zinc)? |
| Overdose from zinc | <ul style="list-style-type: none">• This tablet seems to be too large for my baby. Won't he get overdosed by it?• If my child took more than several tablets a day, won't he get overdosed by it? |
| Zinc with ORT | <ul style="list-style-type: none">• Doesn't the zinc counter-act with ORT?• Should I give more/less ORT if I'm already giving zinc? |
| Zinc for 14 days | <ul style="list-style-type: none">• Why is the zinc given for 14 days?• If this is a medicine for diarrhea, why should it be given if the diarrhea is already cured? |

Developing responses to anticipated questions requires that researchers engage in conceptual translation, wherein they generate potential responses to common questions and then investigate how these potential responses are understood. For example, one of the generic issues identified was giving of vitamins and minerals during diarrhea. In the Philippines, there is a common belief among mothers that children sick with diarrhea should not be given vitamins or minerals. One of the site's preferred messages – that zinc is a vitamins for the gut – would probably then give a contradictory message to mothers. Responses to questions related to vitamins and minerals should therefore not only address the real concern of mothers but also highlight the zinc actions being promoted without being inconsistent with what they believe in.

The Philippine team listed three possible questions relating to vitamins/minerals. These questions were presented to a clinician (in this case, a pediatric gastroenterologist) to provide clinical responses that should imply some scientific basis. Next, these responses were integrated with local beliefs that were already known and gathered from previous literature review, in-depth interviews, and FGDs. The resulting responses were then translated into the local language. This translation served as the health provider's script when answering queries from mothers and caretakers. If possible, the script should likewise be pre-tested for comprehension in an FGD setting.

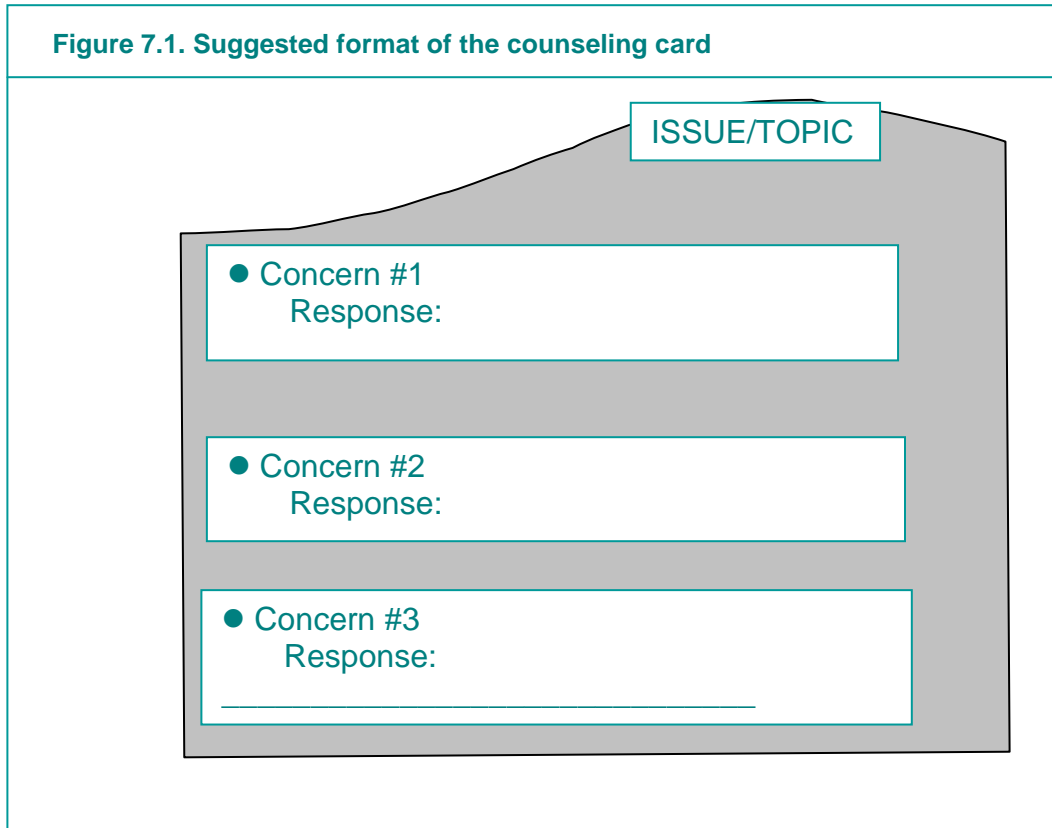
Table 7.2 illustrates the progression and utilization of information in order to come up with the scripts.

Table 7.2. Steps undertaken to come up with scripts for the counseling cards, Philippines

| TOPIC: VITAMINS/MINERALS DURING DIARRHEA | | | |
|--|--|--|--|
| | Question 1: My child's stomach is not okay. Why should I still give him this medicine? | Question 2: I heard a doctor say that vitamins and minerals should not be given during diarrhea. Is this true? | Question 3: My child is already taking a multi-vitamin. Should I still give the zinc? |
| Step 1. Obtain clinical response | Studies have shown that zinc helps the lining of the stomach to recover faster after the diarrhea. | Yes. Iron should not be given during diarrhea as this might cause irritation of the stomach. Other vitamins and minerals may be given. | Yes. Most multi-vitamin preparations do not contain zinc. If they do, they contain a very small amount of zinc, not the amount that should be given to help the stomach recover faster. |
| Step 2. Integrate with local concepts and beliefs. | During diarrhea, a child's stomach is weak. Zinc is a vitamin specially formulated for the child's stomach to help it recover faster from the diarrhea. | During diarrhea, a child's stomach is weak. There is only one kind of mineral that cannot be given to him and it is iron. Other vitamins and minerals can still be given to him. Zinc is a vitamin specially formulated for the child's stomach to help it recover faster from the diarrhea. | Yes, zinc should still be given to the child. Most multivitamin preparations available in the market do not contain zinc, or if they do, the amount is not enough to help the child's stomach recover faster. The zinc that will be given to you is a vitamin specially formulated for the child's stomach to help it recover faster from diarrhea. |
| Step 3. Translate to local language (health provider's script). | <i>Mahina ang tiyan ng bata kapag ito ay nagtatae. Ang Zinc ay isang uri ng bitamina para sa tiyan ng batang nagtatae. Makakatulong ito upang maging mas mabilis ang pagbalik ng kanyang tiyan sa dati nitong kondisyon.</i> | <i>Mahina ang tiyan ng bata kapag ito ay nagtatae. May isang lamang uri ng mineral na hindi dapat ibigay sa bata kapag siya ay nagtatae at ito ay iron. Pero ang iba pang klase ng bitamina at mineral ay maaaring ibigay sa isang batang nagtatae. Ang zinc ay isang uri ng bitamina na ginawa para sa batang nagtatae. Tumutulong ito upang maging mas mabilis ang pagbalik ng kanyang tiyan sa dati nitong kondisyon.</i> | <i>Oo. Kailangan pa ring bigyan ng zinc ang bata. Karamihan ng mga multivitamins na mabibili ay walang zinc, o kung mayroon man, hindi ito sapat upang mapabilis ang paggaling ng bata. Ang zinc na ito ay isang bitamina para sa tiyan ng batang nagtatae. Makakatulong ito sa mas mabilis na pagbalik ng kanyang tiyan sa dati nitong kondisyon.</i> |
| Step 4. Pretest the scripts among health providers in an FGD setting and also among mothers for comprehension. | | | |
| Step 5. Modify scripts as needed or eliminate those that may be confusing for both health providers and mothers. | | | |

7.5. Constructing the Counseling Cards

A suggested format for constructing counseling cards is shown in Figure 7.1



Some pointers for designing the cards:

- the material for the card should be sturdy and handy enough for easy handling;
- the Issue or Topic Name is written on the top portion, preferably on a label or a projecting part of the card for easy retrieval;
- the possible concerns that the mothers may raise regarding the issue or topic are enumerated on the card together with the standard responses.

The counseling scripts that were illustrated in Table 7.2 can then be transferred or written on the cards. The cards may be constructed as shown in Figure 7.2.

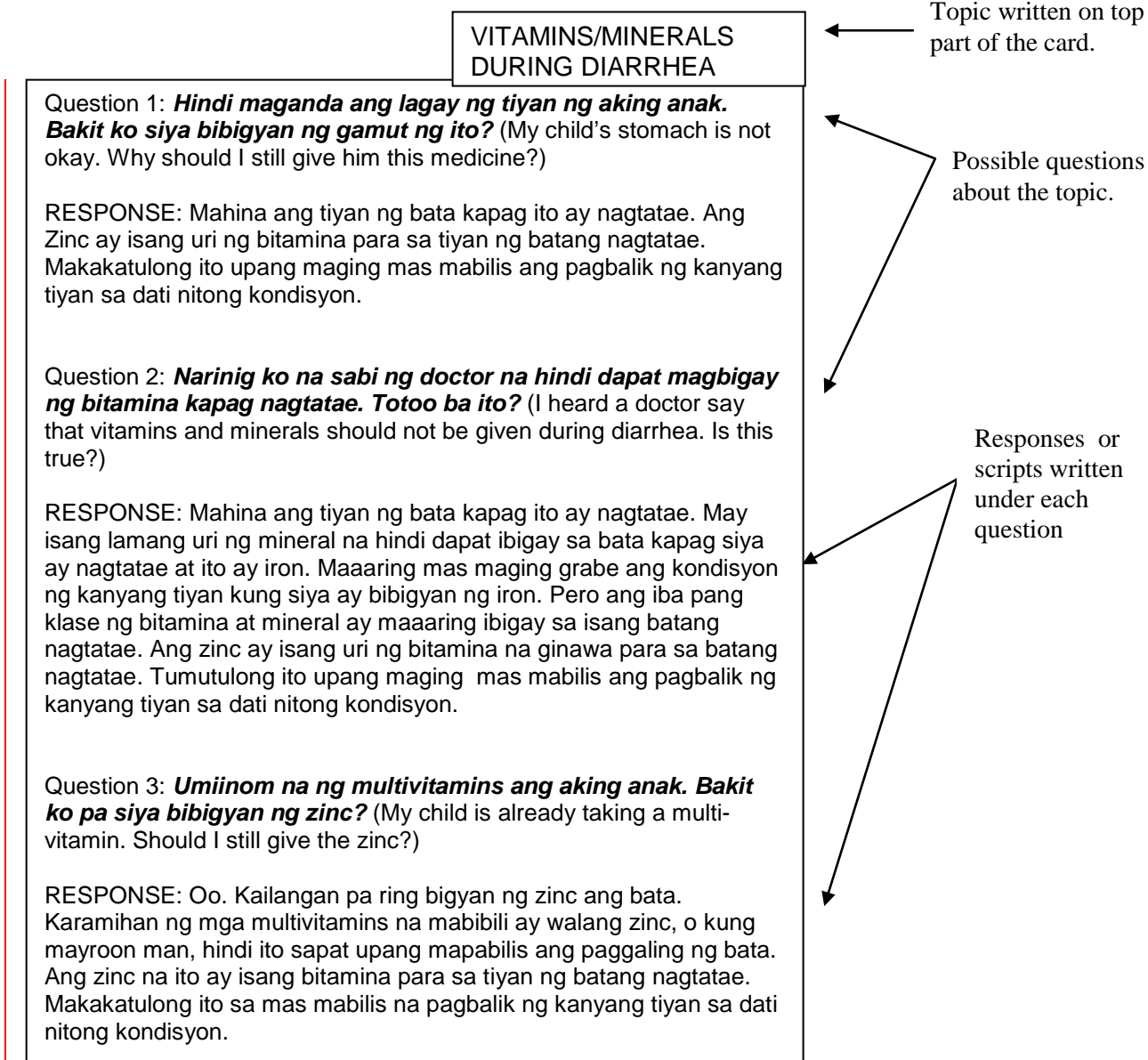


Figure 7.2. Example of how a counseling card can be constructed

Section 8. The Behavioral Trial

8.1. Objectives

The behavioral trial is conducted to:

- Determine how well the mothers adhere to the zinc regimen and what factors, if any, negatively effect adherence
- Identify which of the zinc messages mothers best recall and agree with after using zinc for 14 days
- Determine if modifications to the zinc messages labeling or tablet packaging are necessary for better acceptance and recognizability
- Gather additional issues and concerns that need to be covered by the counseling cards

8.2. Behavioral trial at a glance

The following describes the activities that will be carried out during the trial

- Screen and recruit about ten mothers with children 2–59 months old who are consulting a health care facility for diarrhea
- Provide mothers with zinc tablets for 14 days; give instructions on preparation and administration
- Follow-up with mothers on day 3
- Follow-up with mothers on day 14
- The instruments suggested for the behavioral trial should be translated into the local language

8.3. Preparing for the behavioral trial

The team should adequately prepare the manpower, materials, site and other logistics for the behavioral trial

- **Manpower:** as mentioned previously, at least two research interviewers are needed. Research interviewers need to be properly oriented on the objectives of the trial and trained on the different methods including: administration of the instruments, preparing the zinc tablet, giving of zinc tablet and what to observe, delivering the instructions and messages that go with the zinc, etc.
- **Materials:** supplies for reproductions of interview schedules, etc. Make sure you have translated the instruments for local use
- **Site:** make sure you have informed the necessary people that you are conducting a research in the community; the health facility where you are recruiting the mothers should likewise be informed and requisite permission obtained. Select a facility which sees enough cases and where mothers are likely to come from a reasonable distance for ease of follow-up.

- Prepare the zinc tablets for the trial. If found necessary, the tablets should be repackaged and labeled based on consumer preferences identified in Section 6.

8.4. Day 1 of the trial

Day 1 of the behavioral trial is the day of recruitment at the clinic. The following activities should be accomplished:

- Screening and recruitment: use Form 1 (see Appendices)
- Secure informed consent from mother: refer to Form 2 (see Appendices) to adapt the informed consent form locally. Sample Informed Consent forms from actual research conducted elsewhere are also given in the Appendices
- Gather baseline information: use Form 3 (see Appendices)
- Demonstrate preparation of zinc tablet, give first dose, and zinc messages
- Give zinc tablets and instructions
- Make appointment for follow-up (Day 3); get map or sketch of the mother's residence
- Before mother leaves, administer Exit Interview Form (see Appendices)

8.5. Follow-up and monitoring

Follow up visits are done on day 3 and day 14 of the trial through home visits. It is therefore important to obtain the mother's correct address to minimize loss to follow-up. The following activities should be done:

- Use Form 5A on day 3 and Form 5B on day 14 (see Appendices) to obtain zinc adherence, mother's reactions toward the zinc, and her perceptions of the child's status
- Check child for dehydration; rehydrate or refer to health facility (if visited at home) if necessary
- Ask for any concerns or problems with zinc

8.6. Analyzing the results of the behavioral trial

In analyzing the results of the behavioral trial, remember the two main questions we need to answer: (1) did the mothers adhere to zinc's 14-day therapy, and (2) did the mothers understand the zinc messages. From the answers to these two questions, we can explore more the data gathered from the trial and find out what factors affected the mothers' adherence or non-adherence to zinc; the effect of zinc on breastfeeding and intake of ORS, food, milk, and other liquids, and medicines like antibiotics and antidiarrheals; mothers' perception on the effect of zinc throughout the duration of therapy; and the effect of the messages received on how they perceived zinc. This section will guide the researcher on how the information gathered from the behavioral trial can be processed and analyzed to get the answers needed.

8.6.1. The basic tables

The first table that should be prepared must reflect the baseline characteristics of the children recruited into the behavioral trial as illustrated in Table 8.1. Information for this table can be obtained from the Screening Form (Form 1 in Appendices) and Baseline Information Form (Form 3 in Appendices).

Table 8.1. Baseline characteristics of the recruited children

| Characteristic | Number (n =) |
|--|------------------|
| Age in months 2–5 6–11 12–59 Range Mean | |
| Sex: Male/Female | |
| Birth order: First-born Second-born ...etc... | |
| Clinical status at time of consultation: | |
| Duration of diarrhea: 1 day 2 days ...etc.. Range Mean | |
| With vomiting | |
| Degree of dehydration None Some Severe | |
| Number who gave ORT before consult Kind of ORT: Home-based Commercial Others | |
| Number who gave medicine before consult Kind of medicine: Anti-diarrheal Anti-pyretic Vitamins/minerals Others | |
| Number of children being breastfed Number who continued bf | |
| Average Appetite score: Pre-episode Current | |
| Average Activity score: Pre-episode Current | |

The research team may also need to make a table summarizing the results of the exit interview (Exit Interview Form in Appendices) conducted at the time of recruitment, which was done after the mother was given the zinc tablets, instructions, and messages. Remember that the exit interview should be administered just before the mother leaves the health facility during the initial consult. Use Table 8.2 as template for this table. This information will provide data on how mothers interpreted the messages and how they perceived the action of zinc at the time of message delivery.

Table 8.2. Results of the exit interview

| | Mother 1 | Mother 2... | Mother 10 |
|---|----------|-------------|-----------|
| 1. Kind of medicine given (enter verbatim reply) | | | |
| 2. What was the medicine for? | | | |
| 3. Was the medicine an antibiotic? | | | |
| 4. Has mother heard of this medicine before? | | | |
| 5. How should medicine be given? | | | |
| 6. Does mother have questions about the medicine and its actions? | | | |
| 7. Does mother have any concerns or doubts about the medicine? | | | |

Basic tables showing the findings from the follow-up interviews may also be prepared by using Table 8.3 as a guide. The information from this table is descriptive and will provide overall and general characteristics of the participants in the trial.

Table 8.3 Results of the follow-up interviews

| | DAY 3 (n =) | DAY 14 (n =) |
|--|-----------------|------------------|
| Child's status now: Better Worse Same | | |
| Number with vomiting in past 24 hours | | |
| Number given ORS in past 24 hours | | |
| Number given medicine since clinic check up If yes: what kind of medicine | | |
| If status better, reason Better appetite Diarrhea stopped Etc. | | |
| If status worse, reason Diarrhea worse Etc. | | |
| Number being breastfed Number who stopped breastfeeding during diarrhea Reason for stopping breastfeeding | | |
| Number who gave zinc since clinic checkup/ since last visit For those who gave zinc: How many days zinc was given Number who experienced vomiting after intake Number who gave less than daily dose Perceived effect of zinc <ul style="list-style-type: none"> • increase appetite • stopped diarrhea • etc Number who would recommend zinc to others How zinc would be explained to others <ul style="list-style-type: none"> • can cure diarrhea • can increase appetite • can make child more active • etc | | |

8.6.2. Zinc adherence and factors affecting it

To prepare for this analysis, the team should first set definitions for the zinc adherent participants. In the zinc trial, this was defined as intake of the tablet for 80% of the time. For the day 3 follow-up, this would come out to about intake of zinc on two out of the three days of observation. Classify the participants according to this definition and tally the data using Table 8.4

Table 8.4. Factors affecting zinc adherence on day 3

| | Adherent (n=) | Non-adherent (n=) |
|--|----------------|--------------------|
| Child' status on day 3: Better Worse Same | | |
| No. with vomiting in the past 24 hours | | |
| No. given ORS in the past 24 hours | | |
| No. given other medicines Type of medicine given: antibiotic Antidiarrheal Others | | |
| Perceived effect of zinc: <ul style="list-style-type: none"> • increase appetite • stopped diarrhea • etc. | | |

A table similar to Table 8.4 should also be done for the day 14 follow-up. Likewise, 80% compliance to zinc therapy may be used to define the adherent population.

Mothers may think that zinc should be given for different kinds of diarrhea depending on how they interpreted the zinc messages and the instructions that they received. Table 8.5 is another way in which data can be presented to illustrate this. This table shows actual data obtained from the Philippine behavioral trial. The table shows whether zinc adherence differed among those who used different illness terms to describe the diarrhea.

A similar table may also be prepared for the day 14 follow-up. For non-adherent mothers, consider whether their perception of the action of the tablet on day 3 differed from that of day 14.

Table 8.5. Zinc intake according to illness terms used, Philippines

| | ILLNESS TERM | |
|---|---|---|
| | Diarrhea (n=3) | Diarrhea + vomiting (n=3) |
| Condition on day 3: Better Same | 3 0 | 2 1 |
| Reasons for better condition | better appetite and more active (2 responses) ♦ diarrhea cured | diarrhea cured; no more fever and vomiting; better appetite; more active ♦ better appetite and more active |
| With ORS intake in past 24 hrs | 2 | 1 |
| Effect of ORS | ♦ diarrhea stopped (2 responses) | ♦ not effective; still with some dehydration |
| With zinc intake since day 0 | 3 | 3 |
| Perceived effect of zinc | ♦ more active, better appetite (2 responses) ♦ became stronger and more active | ♦ diarrhea and vomiting stopped ♦ more active and better appetite ♦ better appetite |
| Gave less than the daily recommended dose | 0 | 0 |
| Would recommend zinc to others | 3 | 3 |
| Shared tablets with others | 0 | 0 |
| Told anyone about zinc | 1 [relative] | 2 [neighbors] |
| How would describe zinc to others | ♦ makes child gets better ♦ effective ♦ increases appetite | ♦ helps a child with diarrhea ♦ reduces weakness ♦ effective when child is getting well from diarrhea |

8.6.3. Message recall

It is important to compare the zinc messages delivered by the health care provider and on the medicine labeling to attributes of zinc that mothers report when asked during the exit interview at initial consultation and the two follow-up interviews. A table similar to Table 8.6 may be created.

Table 8.6. Zinc messages delivered and zinc actions reported by mothers

| Messages delivered | Exit interview: response to "What was the medicine for?" | Day 3: Perceived effect of zinc | Day 14: Perceived effect of zinc |
|--|---|--|---|
| <ul style="list-style-type: none"> Zinc increases appetite of a child with diarrhea Vitamins for the gut Zinc can increase the child's resistance | <p>For diarrhea – 2 responses</p> <p>Vitamins for the stomach – 4 responses</p> <p>To make child strong – 1 response</p> <p>For resistance of the stomach – 3 responses</p> <p>Increases appetite – 1 responses</p> | <p>For diarrhea – 7 responses</p> <p>To make child strong – 1 response</p> <p>Increases appetite – 3 responses</p> | <p>For diarrhea – 7 responses</p> <p>Increases appetite – 6 responses</p> |

Table 8.6 shows actual data obtained in the Philippines. Vitamins and resistance messages appeared to have strong recall during exit. On days 13 and 14, the perception that zinc can cure diarrhea received strong recall. The appetite message, which did not figure very prominently upon exit, became more perceptible on day 3 and more so on day 14.

This information showed that health care providers may not be emphasizing strongly enough the main actions of zinc that should to be delivered across to mothers. They were therefore advised to play down the action of zinc on the illness (curative effect) and emphasize more the zinc messages that should be delivered, especially the resistance and vitamins messages.

Data collected from days 3 and 14 interviews should be reviewed to answer the following questions:

- Which of the zinc messages tested seem to have the best recall among the mothers
- Did mothers understand the messages they received? Do you think some of the messages need refinement?
- Did the mothers tell anyone else about the medicine? What did they say?
- Did they see zinc as having attributes other than those contained in the messages? What were these attributes?
- Did the mothers understand the instructions regarding zinc administration? Did they correctly prepare and administer zinc? Did they change the instructions? What changes did they make?
- What concerns about zinc arose during the trial?

- What are the factors that appear to have affected adherence to zinc (use of ORS, vomiting, better or worse status, kind of diarrhea, breastfeeding, use of other medicines, perceived effects of zinc, etc.)?

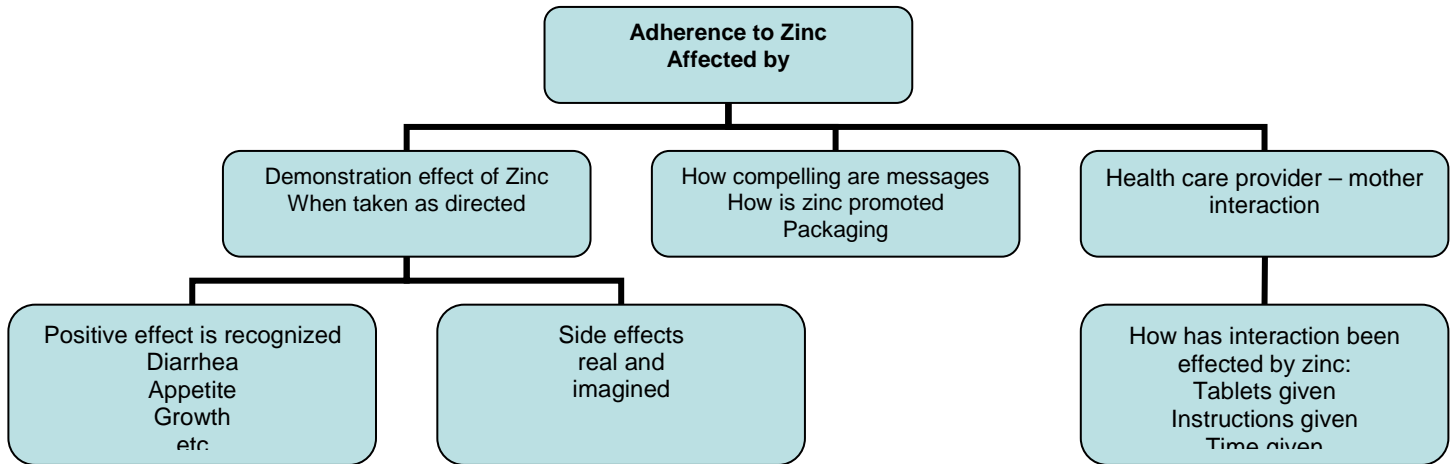


Figure 8.1. Factors affecting zinc adherence

Figure 8.1 shows other factors that can affect zinc adherence. Side effects, whether real or imagined, are important concerns and should be addressed. The exit interview should be the appropriate tool to pick up whatever concerns the mothers have, but negative experiences are likewise obtained during the monitoring visits.

When assessing both mothers' adherence to zinc and what they see as zinc's attributes, consider differences in answers in relation to kind of diarrhea, age of child, use of ORS, use of medicines, and perception of child's condition (see Figure 8.2). Dummy tables are provided in the Appendices section to guide the team in analyzing relationships between the variables obtained from the behavioral trial. If attributes that mothers mention during exit interviews do not match messages used in promoting zinc, these promotional messages should be revisited.

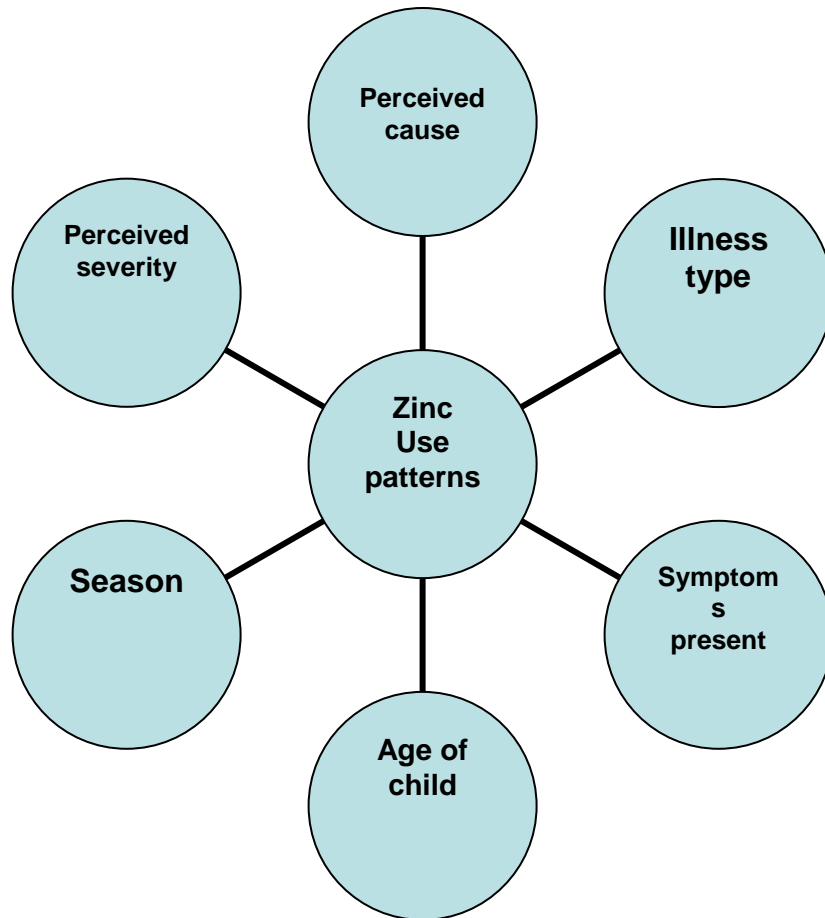


Figure 8.2. Variables that may affect use of zinc

8.6.4. Inputs to the counseling cards

The counseling cards were intended to improve practitioner–patient interactions. The interaction between health providers and patients affects mothers’ health care seeking and medicine adherence behavior. Aside from providing a standardized response to mothers’ questions, the counseling cards have been introduced to enhance zinc-related communication. Researchers should attempt to assess whether mothers feel practitioners are responsive to their concerns and whether practitioners (and those following up with patients during a trial) feel more confident about addressing these concerns as a result of having these cards on hand.

Exit and follow-up interviews were found helpful in generating more concerns that mothers have regarding the medicine. The Philippine trial was able to gather queries from respondents that were not anticipated at the start and were not included in the generic issues and concerns prepared before the start of the behavioral trial, which are enumerated in Table 7.1. Examples of concerns that came up during the behavioral trial are shown in Table 8.7.

Table 8.7. Concerns raised during the conduct of behavioral trial (obtained from exit interviews and follow-up interviews)

| CONCERN | POSSIBLE QUESTION FROM THE MOTHER/CARETAKER | STANDARD RESPONSE |
|--|--|---|
| SHARING OF ZINC TABLETS | <ul style="list-style-type: none"> Can I give this tablet to my other child who also gets sick with diarrhea? | No. This pack of 14 tablets is for this child only. He has to complete 14 days of zinc for its action to take effect. If another child of yours get sick of diarrhea, bring him to the hospital too for appropriate action. |
| CONTINUED ZINC THERAPY | <ul style="list-style-type: none"> What will happen after all the tablets have been consumed? What if my child seems suited to this medicine? | This zinc tablet is especially formulated to make your child's gut recover faster from diarrhea. After 14 days, your child can get zinc from his regular food, if you give him/her balanced meals. |
| ZINC AND ORT | <ul style="list-style-type: none"> If ORS has been stopped already, should zinc still be continued? | Yes. ORS is to correct and prevent dehydration, while zinc acts on the child's stomach for full recovery. |
| ZINC FOR ADULTS | <ul style="list-style-type: none"> Can zinc be taken by adults? | Yes, there are also zinc preparations for adults, but these tablets we give you are especially formulated for children 2–59 months old. |
| ALLERGY TO ZINC | <ul style="list-style-type: none"> Can the child develop allergy towards the zinc tablet? | No. Your child will not develop allergy towards zinc. |
| ZINC FOR OLDER CHILDREN | <ul style="list-style-type: none"> Can zinc be given to older children? | Yes, it can even be taken by adults, but these particular tablets are for this child with diarrhea. |
| TENDENCY TO SAVE TABLETS FOR FUTURE EPISODES | <ul style="list-style-type: none"> Can I save some of these tablets in case my child gets sick with diarrhea again in the future? | Your child should complete 14 days of zinc therapy for optimum effect. If your child gets sick again in the future, please bring him again to this facility for appropriate action. |
| ZINC AND A WELL CHILD | <ul style="list-style-type: none"> If this acts just like a vitamin/mineral, why is it not given to a well child? | This zinc tablet is not given to a well child because this is especially formulated for a child with diarrhea to replace zinc lost during the episode and to help his gut recover from the illness. |

Concerns about compliance and the duration of therapy were addressed by the main messages and reinforced by the supporting messages that became the basis of the counseling cards. For instance, promoting zinc as a vitamin took care of the duration issue and why it still has to be given even after the child is well. On the other hand, the justification why it is being given for just 14 days unlike other vitamins was explained by saying the child's gut takes only this long to recover from diarrhea.

Supporting advice was also prepared to answer questions regarding preparations. While there wasn't any problem with dosage, mothers asked whether the tablet could be dissolved in orange juice, chocolate drinks, and other liquids. Recognizing the reduced bioavailability of zinc with rice-based foods and fluids and those with high sugar content, the instructions were simplified to include dissolving zinc only in water, ORS, or breastmilk and giving it in between meals.

Lessons learned from the behavioral trial will be useful when finalizing the message, procedures, and instruments used in a larger intervention trial. Data collected during both formative research and intervention trials will prove valuable to those who ultimately conduct larger scale social marketing research.

Section 9. The Future for Zinc

In this guide we have focused our attention on how to introduce and measure the effectiveness of zinc in a diarrhea control program. Ongoing research suggests that zinc may be useful in the management and prevention of other health problems such as pneumonia and possibly TB.^{vii} We must bear future uses of zinc in mind when introducing zinc to the community in diarrhea disease programs if we want to minimize confusion in the future. This is another reason why zinc might better be introduced as having both a disease control and a health enhancement dimension that is relevant across health problems. We would encourage researchers to explore cultural concepts related to disease resistance (strength, protection, etc.) that have broad health relevance when developing zinc messages. “Resistance” to illness was looked into in some but not all project sites. The ideas of resistance and vitamins to increase resistance were found to be effective messages in the Philippines and Brazil, but not among poor mothers in Egypt.

As noted in this guide, one of the main challenges in introducing zinc in a diarrhea disease program is the need to make it clear to mothers that zinc should not be substituted for ORS, and that zinc is a complement for ORS therapy. The same challenge faces those wishing to introduce zinc as part of pneumonia therapy as mothers will have to be convinced that they should not substitute zinc for antibiotics. In both cases, it is important that zinc is explained and promoted as a complement and not a substitute for other therapy.

In the Philippines, the idea of promoting zinc as a “vitamin for the gut” was experimented with precisely for this reason. The case is instructive. Previous research had indicated that vitamins are popular and are seen by people as a supplement associated with both disease prevention and health promotion. Further, the population already maintains the idea that vitamins need to be taken for some time to have an effect, and not just for a few days. Moreover, a concept of “vitamins for the lungs” already exists. The local population understands the use of INH in TB control, especially for children, as “vitamins for the lungs” useful in the treatment of “weak lungs.”^{viii} During focus groups we found that describing zinc as a “vitamin for the gut” made sense to the local population. The only negative aspect of using this term to describe zinc was that some doctors discouraged mothers from giving children with diarrhea vitamins until their symptoms abated. Zinc would have to be marketed as being a special vitamin for the gut useful in cases in diarrhea, and doctors would have to be educated to distinguish between multivitamins and zinc. This seemed viable. Another reason marketing zinc as “vitamins” was appealing was that we reasoned that it was possible that misuse of INH as a “vitamin for the lung” in non-TB cases (for other types of chronic cough) might be addressed in the future if zinc could be marketed as a vitamin for the lungs as well as the gut. INH might then be reframed as a medicine specifically for TB and TB-related primary complex.

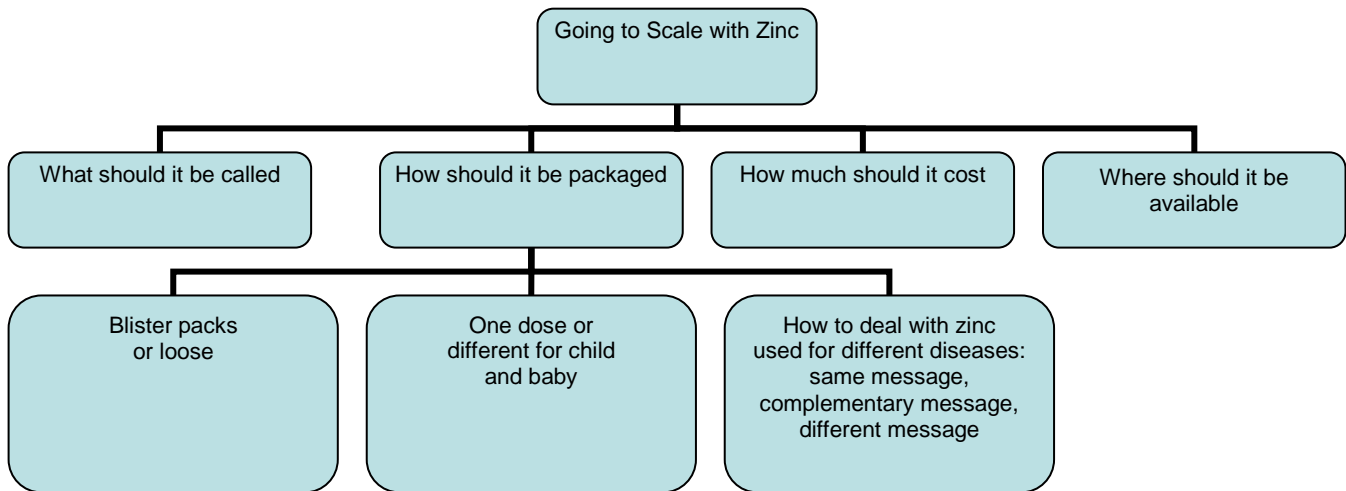


Figure 9.1. Going to scale with zinc

Looking into the future, those involved in zinc program planning and implementation will also need to look into the following factors, presented in Figure 9.1, when designing strategies for a wider zinc distribution.

Choosing the right packaging and appropriate messages will certainly require social marketing research attentive to market segmentation and target groups. Willingness-to-pay studies need to be conducted to determine zinc’s marketability both in the public health sector and the commercial and private routes. In Bangladesh, it was demonstrated that mothers will use zinc and ORT if these are given free. Antibiotics would also be used less. But what if these are sold? Would mothers still use them? Or will mothers use just one of them? How much should the price be for zinc if it is to be sold as a generic product? And would mothers who purchased zinc in 14-day blister packs be as likely to finish a course of zinc or keep some part of the dose in reserve the way they often do with other medications?

Another set of issues that needs to be thought of is how to best train those people who will be responsible for delivering zinc and zinc messages. As noted in this guide sufficient attention needs to be directed to identifying clients and anticipating questions. Developing (and growing) a question–answer guide and standardized counseling cards is advantageous so that a common core of ideas about zinc be rooted in the community, thus lessening possible confusion.

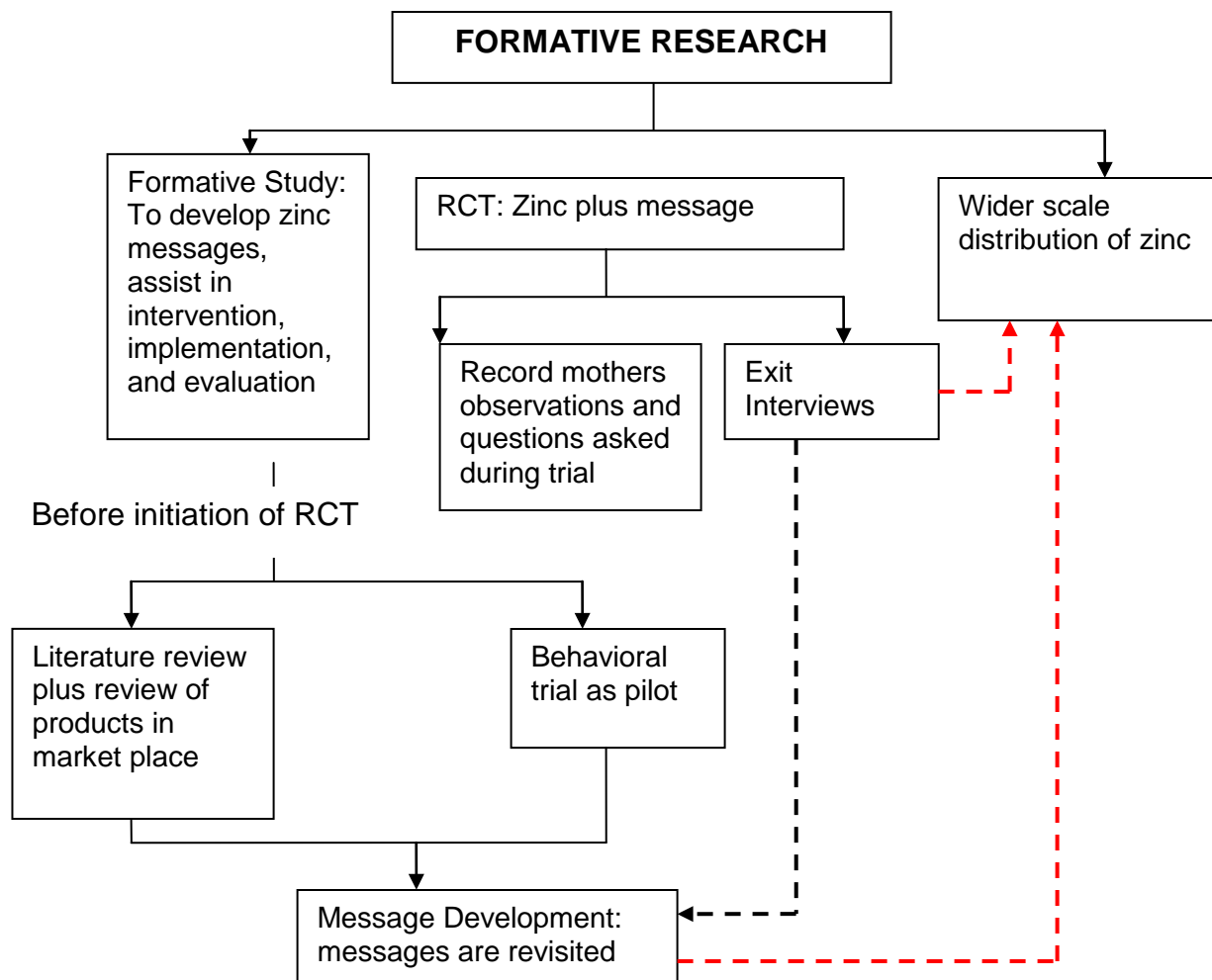


Figure 9.2. Formative Research provides feedback to intervention

Formative research doesn't end in message development and implementation, though. Findings from the research can also provide feedback to enhance the distribution of zinc when the program is already being implemented beyond the pilot stage. Exit interviews done during the first one to two months of actual program implementation can reveal how accurately the zinc messages is being delivered and how consistently the instructions are being given to clients (Figure 9.2). During the exit interviews, more concerns and doubts regarding the medicine can be generated that could expand the issues included in the counseling cards.

The steps carried out in this formative research are useful in designing larger studies for zinc supplementation. This formative research is an excellent exercise in preparing the teams for larger preparatory work for future zinc interventions.

APPENDICES

APPENDIX A

ZINC BEHAVIORAL TRIAL FORM 1 Screening and Recruitment Form

Study center: _____ Date of screening (mm/dd/yyyy) _____
 First Name of Child: _____ Child's birthday (mm/dd/yyyy) _____
 Child's birth order: _____
 Child's age in months: _____
 Sex (1= Female; 2= Male): _____

Exclusion Criteria

| | | | |
|----|---|-----|----|
| 1 | Does the child live outside the catchment's area? | Yes | No |
| 2 | Has the child been previously recruited in the study? | Yes | No |
| 3 | Is age <2 months or >59 months? | Yes | No |
| 4 | Is the duration of Diarrhea > 7 days? | Yes | No |
| 5 | Is the child currently receiving zinc supplementation? | Yes | No |
| 6 | Is the child on ORS plan B or C? | Yes | No |
| 7 | Does the child have dysentery? | Yes | No |
| 8 | Has the child been hospitalized for diarrhea for >12 hours in this site hospital? | Yes | No |
| 9 | Does the child have a condition that requires antibiotics? | Yes | No |
| 10 | Does the child's mother report a positive HIV status? | Yes | No |
| 11 | Weight in KG: [][] . [] Length in CM: [][][] . [] Consult weight for height z-score charts | | |
| 12 | Is weight or height <-3 SD? | Yes | No |

IF YES TO ANY ONE OF THE ABOVE, EXCLUDE

APPENDIX B

ZINC BEHAVIORAL TRIAL FORM 2 Informed Consent Form

Guidelines:

The informed consent should include

- The purpose of the study
- The methods that will be applied; what entails being a participant in the study
- The advantages of being a participant
- The disadvantages and possible complications of receiving zinc
- Incentive
- Confidentiality
- Provide a space where parent/guardian would sign her consent

APPENDIX C

Informed Consent Template for Focus Group Discussions

(the language should be such that it is understood by a student of class 6th/8th of the local area)

| |
|---------------------------|
| INSTITUTIONAL LETTER HEAD |
|---------------------------|

Name of Principle Investigator:

Name of Organization:

Name of Sponsor:

**Information Sheet for the group of individuals participating in the research "*Community Response to Malaria*"
(Version.....)**

Introduce yourself and what you are doing

(I am XYZ, and I work at theorganization in Timbuktu. I am doing some research on the disease malaria, which as you know is very common in this country and more so in this region.)

Purpose of the research: Give in lay persons terms why the research is being done and what is expected from the results

(For example: Malaria is an important cause of illness in Timbuktu. Current methods to prevent malaria are dependent on knowing how widespread is the problem of malaria in this region. It is also dependent on understanding how people within communities react when they have some illness and more specifically how they react when they have malaria. Therefore, in order to find out the ways to reduce malaria in Timbuktu, we need to have a better understanding of the perceptions of the people within your community and what according to them are the social, economic, cultural and behavioral factors that affect the spread of the disease.

We would therefore like to find out what you know about malaria, how it is caused, how it spreads, how it can be prevented, and how it can be detected. We would also like to understand how the people of this community respond when they are ill, especially when they have malaria etc.)

Procedures

To find answers to some of these questions, we **invite** you to take part in this research project. If you accept, you will be required to take part in a discussion with 7-8 other persons with similar experiences. This discussion will be moderated by (give name here) or which I will moderate.

Give the reasons here, why a particular person is being selected to take part in the FGD, e.g. as a social-worker, or as a person who has recently experienced malaria, or a child has had malaria etc. *(For example, You are being invited to take part in this discussion, because we feel that your experience as a social-worker can contribute much to this discussion).* During this discussion, however, we do not wish you to tell us your personal experiences, but give us your opinion on the questions that we will pose to the group, based on your personal experiences, and your experience within your community. If you do not wish to answer any of the questions or take part in any part of the discussion, you may say so, and keep quiet. The discussion will take part in **(here give the place**

where the FGD will happen) and no-one else but the people who take part in the discussion and myself will be present during this discussion. The entire discussion will be tape-recorded but **no-one will be identified by name on the tape**. Additionally the tape will be kept (**here explain how the tape will be stored**). The information recorded is considered confidential, and no one else exceptwill have access to the tapes.

The expected duration of the discussion is about(e.g.40 to 75 minutes).

Risks and Discomforts:

There is a slight risk that you may share some personal or confidential information with the other participants by chance. Or that you may feel uncomfortable about talking about some of the topics. However, we do not wish this to happen, and you may refuse to answer any question or not take part in part of the discussion, if you feel they are personal or if talking about them makes you uncomfortable.

Benefits: There will be no direct benefit to you. But your participation is likely to help us find out more about why it is difficult to control and prevent malaria in these districts.

Incentives:

You will not be provided any incentive to take part in the research. However you will be reimbursed with \$.....(give amount) for your time, and travel expense.

Confidentiality: (How will the confidentiality of the data be maintained, especially with respect to the information about the participant, which otherwise would be known only to the physician, and now is available to the entire research team. Because something out of the routine is being done through research, any individual taking part in the research is likely to be more easily identified by the community members and therefore likely to be stigmatized)

(For e.g. The information that we collect from this research project will be kept confidential. Information about you that will be collected from the study will be stored in a file which will not have your name on it, but a number assigned to it. Which number belongs to which name will be kept under lock and key, and will not be divulged to anyone except (mention who will have access to the information - research sponsors, DSMB board, your clinician etc).

Right to refuse or withdraw:

You do not have to take part in this research if you do not wish to do so, and this will not affect your future treatment at the health facility here in any way. You will still have all the benefits that you would otherwise have.

You may stop participating in the discussion at any time that you wish to, without losing any of your rights as a patient here. Your treatment at this center will not be affected in any way, even if you decide to stop participating in the discussion.

Who to contact:

This proposal has been reviewed and approved by the(name of the local IRB) which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact(Name, address, tel. number)

If you have any questions you may ask those now or later. If you wish to ask questions later, you may contact any of the following: (provide name, address/telephone number/ e-mail address of the contact person)

(The person who is the contact person should be a 'local' person, who can actually be contacted)

Consent for Focus Group Discussion

“I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have been asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this study and understand that I have the right to withdraw from the discussion at any time without in any way affecting my further medical care.”

Participant's Name

Signature

1. _____

Moderator's name

Signature of Moderator

Date

Place

Witness (Name)

Signature

Date

Place

APPENDIX D

Informed Consent Form Template for clinical trials

(the language should be such that it is understood by a student of class 6th/8th of the local area)

| |
|---------------------------|
| INSTITUTIONAL LETTER HEAD |
|---------------------------|

Name of Principle Investigator

Name of Organization

Name of Sponsor

Information Sheet for the group of individuals (e.g. men and women attending the kidney clinic) participating in the research "Name of proposal" (Version.....)

Describe yourself and what you do

(e.g. I am XYZ, working for the -----Research Institute. We are trying to study the -----disease, which is very common in this country)

Purpose:

Explain the problem in lay terms

(Use local and simpler words for a disease e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors" etc.)

The reason for doing this research is to find out

(Give the research question in lay terms. Avoid use of terms like pathogenesis, indicators, determinants, equitable etc.)

Procedures

To find answers to some of these questions, we invite you (instead of 'request you' or 'ask you') to take part in this research project.

For answering that question without a bias, the scientific method is to divide all volunteers into two (or three or four) groups in such a way that each person has an equal chance of being in any of the group (as in drawing lots, for example). One half of the group will get the medicine that we are studying (or the test medicine), and the second half will get the medicine whose effect is already known (or an inactive substance, which the scientists call placebo) (or the control medicine). To help us know the true effect of the medicine, neither the doctors and the scientists working on this research project, nor the nurses will know who is in which group, till the end of the research. This does not mean that the persons looking after you in the clinic/hospital will not know the condition of your disease during this period, indeed, they will keep a very close watch on you. When necessitated by your condition or your response to the treatment being studied, we can break this code and find out which medicines you have been getting (if necessary may enumerate the conditions under which the code will be broken).

You will be required to

(Describe or explain the exact procedures that will be followed, the tests that will be done, and the medicines that will be given. For example, in the first visit, a small amount of blood, equal to about a teaspoonful will be taken from a vein in your hand. This will be tested for the presence of substances (instead of antibodies) that help your body to fight infections. You will then be given the test medicine -though as explained earlier, neither you nor us will know whether you have received the test or the control medicine etc.)

(Describe very clearly which procedure is routine and which is experimental or research)

The expected duration of the study isdays, and you will be required to come to the clinic/hospital/health facility ondays, each time forhours.

(Explain the number of visits that the participant will have to make, and how long will each visit last)

On each occasion the following procedure will be done

(Explain exactly what will be required each time)

If blood samples are needed, explain how many times, and how much in language that the person understands *(e.g. not 5 ml of blood but blood equal to about one tea-spoonful)*

If a biopsy needs to be taken, then whether it will be under local anesthesia, under sedation or under general anesthesia - and what sort of symptoms and side effects to expect under each category.

If any other procedure needs to be carried out, then what to expect.

If the tissues/blood samples or any other human biological material is to be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then information about this to be provided, and consent taken for this specifically.

Risks and Discomforts:

By participating in this research you are likely to have some discomfort *(mention discomfort e.g. the discomfort of repeated blood pressure readings or venipuncture)*

By participating in this research you are likely to have some increased risk *(mention the type of anticipated risk)*. We will try and decrease the chances of those risks happening, but if an untoward event happens, we will provide you the *(Mention what level of care will be available, and who will provide it and who will pay for it) .*

Benefits: *(Benefits may be divided into benefits to the individual, benefits to the community in which he is residing, and benefits to society as a whole)*

If you participate in this research in the research, you are likely to have the following benefits: any interim illnesses will be taken care of at no charge to you. If your child falls sick during this period he/she will be treated free of charge etc. *(mention only those activities that will be actual benefits and not those which they are anyway entitled to)*

There may not be any benefit for you but your participation is likely to help us find the answer to the research question *(mention what sort of answers you are looking for)*. *There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.*

Incentives:

You will not be provided any incentive to take part in the research. However you will be reimbursed (*give a figure, if money is involved*) for your lost time and your travel expense.

Or

As an appreciation of your time and inputs into the research, you will receive(*mention exactly what will be provided*)

Confidentiality: (*How will the confidentiality of the data be maintained, especially with respect to the information about the participant, which otherwise would be known only to the physician, and now is available to the entire research team. Because something out of the routine is being done through research, any individual taking part in the research is likely to be more easily identified by the community members and therefore likely to be stigmatized*)

The information that we collect from this research project will be kept confidential. Information about you that will be collected from the study will be stored in a file which will not have your name on it, but a number assigned to it. Which number belongs to which name will be kept under lock and key, and will not be divulged to anyone except (mention who will have access to the information - research sponsors, DSMB board, your clinician etc).

Right to refuse or withdraw:

You do not have to take part in this research if you do not wish to do so, and this will not affect your treatment at this center in any way.). You will still have all the benefits that you would have, if you were taking treatment at this center.

You may stop participating in the research at any time that you wish to, without losing any of your rights as a patient here. Your treatment at this center will not be affected in any way, even if you decide to stop participating in the research.

Alternatives to participating

When the study involves the administration of experimental drugs or use of new therapeutic procedures, the consent form should include a separate paragraph stating that the subject has been given the option of choosing the **established** standard treatment.

Who to contact:

This proposal has been reviewed and approved by the(name of the IRB) which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact(Name, address, tel. number)

If you have any questions you may ask those now or later. If you wish to ask questions later, you may contact any of the following: (provide name, address/telephone number/ e-mail address of the contact person)

(*The person who is the contact person should be a 'local' person*)

Consent form:

The **certificate of consent** should begin with a brief summary of the main items from the above statement. (*It should be written in the first person i.e. I have been invited to take part in the research..... I have been told the purpose of this research study is to..... etc*)

Each item should be stated in a separate paragraph, in the following order:

Purpose of the research.

Procedures that will be followed, including the total time involved for the subject.

Risks and discomforts, including psychological and social risks, if any.

Benefits of the research, separated into "benefits to you" (the subject) and "benefits to others".

Compensation, if any, provided to research subjects.

Alternatives to participation.

Contact information.

The certificate of consent should end with a paragraph such as the following:

'I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without in any way affecting my further medical care.'

Signed by:

Date.....

Place

If illiterate

Signed by the researcher.....

In the presence of an independent literate witness

(where possible, this person should be selected by the participant)

Date.....

Place

APPENDIX E

ZINC BEHAVIORAL TRIAL

Form 3

Baseline Information

1. How long has the child's diarrhea lasted now?
2. Does he experience vomiting?
3. What is the child's level of dehydration upon consultation?
4. Did you give the child oral rehydration therapy before coming to this facility?
 - What kind of ORT did you use?
 - Why did you give this kind of ORT?
5. Did you give the child other medicine before coming to this facility?
 - What kind (specify the name)?
 - What was it for?
6. Please tell me what was the child's problem? (Record answer verbatim.)
 - (If diarrhea-related): what kind of diarrhea is this? What is its cause? Is there a local term for this kind of diarrhea?
7. How severe is the child's diarrhea?
8. Are you breastfeeding your child?
 - If so, are you continuing it now?
 - Is breastfeeding increased, reduced, or just the same?
9. Mother's perception of child's appetite (Score from 1–10 with 1 lowest and 10 the best appetite the child ever had)
 - Pre-episode
 - Current
10. Mother's perception of child's activity (Score from 1–10 with 1 least active and 10 the most active the child ever had been)
 - Pre-episode
 - Current

APPENDIX F

ZINC BEHAVIORAL TRIAL Form 4 Exit Interview Form

| |
|---|
| Identification <ol style="list-style-type: none">1. Study Site: _____2. ID Code of respondent: _____3. First Name of child: _____4. Date of recruitment: _____5. Date of exit interview: _____ |
| 1. What did the doctor/nurse tell you about your child's condition? |
| 2. What did the doctor/nurse do to assess your child's condition? What kind of actions/examinations did he do? |
| 3. What were the questions they asked about your child? |
| 4. What did they tell you to do? |
| 5. What kind of medicine did they give you? What is it for? |
| 6. Is this medicine an antibiotic? |
| 7. Have you heard about this medicine before or is it a new medicine? |
| 8. How many tablets were you given? |
| 9. Were you told how the tablets should be given to your child? |
| 10. For how long should the tablets be given? PROBE IF SHOULD BE GIVEN AS LONG AS DIARRHEA LASTS OR LONGER. |
| 11. Do you have any question about this new medicine, like its action and how it should be given to the child? |
| 12. Do you have any doubts or concerns about this medicine? |
| 13. Were you told that you are participating in a research study or trial? |
| 14. Have you ever participated in a research study before? |
| 15. Are you happy your child was chosen to participate in this study? Why? |

APPENDIX G

ZINC BEHAVIORAL TRIAL Forms 5A & 5B: Follow-up Forms

| QUESTION | Ask question during | |
|--|----------------------------|-----------------------------|
| | FORM 5A Day 3 follow-up | FORM 5B Day 14 follow-up |
| 1. How is your child doing now? – Better – Worse – Same | ✓ | ✓ |
| 2. Did he experience vomiting during the past 24 hours? | ✓ | ✓ |
| 3. Did you give him oral rehydration therapy during the past 24 hours? – What kind? – What do you think is it for? | | |
| 4. Did you give him medicine, including vitamins, since your last consultation at the clinic? – What kind (specify brand name)? – What do you think it is for | ✓ | ✓ |
| 5. You said your child is [better, worse] now. – If better, what made you think so: – no more diarrhea/diarrhea better – no more vomiting – no more fever – better appetite – more active – other | ✓ | ✓ |
| – If diarrhea better, in what way is his diarrhea better now? Verbatim | ✓ | ✓ |
| – If worse, in what way the child is worse now: – more loose stools – still with vomiting – no appetite – still with fever – others | ✓ | ✓ |
| 6. Before the child got sick, were you breastfeeding him? – If so, are you still breastfeeding him now? – If yes, is breastfeeding increased, decreased or just the same? | ✓ | ✓ |
| 7. Rate the child's appetite (1–10) | ✓ | ✓ |
| 8. Rate the child's activity (1–10) | ✓ | ✓ |

Follow-up Form – continued

| | FORM 5A | FORM 5B |
|---|-----------------|------------------|
| ZINC ADHERENCE QUESTIONS: | Day 3 follow-up | Day 14 follow-up |
| 9. Since your consultation at the clinic, have you been giving zinc to your child? | ✓ | ✓ |
| 10. If no, what was the reason for not giving? | ✓ | ✓ |
| 11. If Yes, how many days did you give zinc since your consultation at clinic/since last follow-up? | ✓ | ✓ |
| 12. Did the child experience vomiting after taking zinc? | ✓ | ✓ |
| 13. At any day when you gave zinc, did you give less than the recommended daily dose? – If yes, in what way was it less than the recommended dose? – Why did you give less than the daily recommended dose? | ✓ | ✓ |
| 14. What do you think are the effects of zinc on your child? Verbatim | ✓ | ✓ |
| 15. Have you told anyone about zinc? | | ✓ |
| 16. Would you recommend zinc to others? | | ✓ |
| 17. What would you say to explain the action of zinc to others? | | ✓ |
| 8. How much are you willing to pay for enough zinc tablets to last for a 14 day period? | | ✓ |

APPENDIX H

DUMMY TABLES

Site: _____ major lessons / findings

| Baseline = message given mothers by providers | Exit interview: what mothers said were the virtues of zinc they would tell others | Comment on how similar or different from message originally given |
|--|--|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

Other dummy tables

| Type of Diarrhea | % using ORS Intervention group | % using ORS Control group |
|--------------------|-----------------------------------|------------------------------|
| Local name or type | | |
| | | |
| | | |
| | | |

| Type of Diarrhea | % complaint with zinc You might separate this by age of child >12 mos | % complaint with zinc Baby <12 mos |
|--------------------|---|--|
| Local name or type | | |
| | | |
| | | |
| | | |

| Severity of Diarrhea as classified by mother | % complaint with zinc One point in time | Second point in time |
|---|--|-----------------------------|
| Very severe | | |
| Moderately severe | | |
| Mildly severe | | |
| | | |

| Perceived change in diarrhea: as reported by mother | % complaint with zinc One point in time | Second point in time |
|--|--|-----------------------------|
| Much improved | | |
| Moderately improved | | |
| Little improved | | |
| Same | | |

| Diarrhea (Might be looked at by severity or type of diarrhea) | Breast feeding Those using zinc | Breast feeding Those not using zinc |
|---|--|--|
| Very severe | | |
| Moderately severe | | |
| Mildly severe | | |
| | | |

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^v For a brief description of the study and major results see Zinc supplementation for children with acute diarrhea is highly acceptable, generally does not affect oral rehydration therapy and is associated with less use of other medications: A randomized trial in five countries (IC-ZED Group, forthcoming)

^{vi} See Nichter, M. (1990) The Eight Stages of Formative Research:
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