Introducing Zinc in a Diarrhoeal Disease Control Programme

Guide to conducting formative research

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Foreword

This guide shows how to conduct formative research in the context of introducing zinc in a diarrhoeal disease control programme. It was originally designed to assist a multicentre zinc study coordinated by the International Clinical Epidemiology Network (INCLEN) between 2002 and 2004. The study was jointly supported by INCLEN, the Johns Hopkins Bloomberg School of Public Health (JHU), the United States Agency for International Development (USAID) and the World Health Organization (WHO). This zinc intervention and effectiveness trial was carried out in five countries and six sites: Fortaleza, Brazil; Cairo, Egypt; Addis Ababa, Ethiopia; Lucknow and Nagpur, India; and Manila, Philippines. Prior to the intervention trial, formative research took place in each site to facilitate the construction of the research instrument, develop messages in the local languages, and assist in the monitoring and evaluation of the intervention.

The research methods on which the present guide is based were largely developed during fieldwork in the Philippines by the three authors, social scientists with considerable research experience in diarrhoeal disease and pharmaceutical practice. The guide is designed for use by teams with little expertise in social science.

Researchers at each site were encouraged to review existing social science research on diarrhoea and oral rehydration therapy in their area, and where possible to enlist the assistance of local social scientists in the formative stage of their research. In the event, the research teams at each of the sites chose to conduct formative research on their own, and each team used the formative research guide in a slightly different manner.

Lessons learned during the project were discussed by representatives from the different field sites. Revisions to the guide were made following a data analysis meeting held in Lucknow, India, in September 2004. The revised version of the guide presented here reflects the experience gained, and examples are drawn from several of the sites.

The guide also contains questions 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 diarrhoea and perceptions of illness severity, perceptions of zinc benefits and side-effects (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 diarrhoea if the tablets were available.

We hope that this guide will be useful for those planning zinc intervention trials, as well as for those planning on introducing zinc or other supplements or medicines, in clinical or community settings. Many of the research steps we outline would be applicable to other pilot interventions.

Introduction

1.1 Background

The use of zinc in the management of childhood diarrhoea is recommended by WHO/UNICEF (1) because zinc has been found to reduce the duration and severity of diarrhoea and prevent subsequent episodes (2-16). A randomized effectiveness trial (17) was conducted in outpatient health facilities at six sites in five countries: Fortaleza (Brazil), Addis Adaba (Ethiopia), Cairo (Egypt), Lucknow and Nagpur (India), and Manila (Philippines). The trial, involving 2002 children aged 2 to 59 months, concluded that zinc was acceptable and feasible to implement in developing country settings, that it did not interfere with the use of Oral Rehydration Salts solution (ORS), and that it was associated with a reduction in the use of antimicrobials and antidiarrhoeals (18,19). This makes use of zinc treatment with ORS doubly attractive for the management of cases of acute watery diarrhoea. The authors of the study recommended that formative research be conducted prior to the introduction of zinc in different cultural settings to ensure culturally appropriate promotion of zinc together with ORS in the treatment of childhood diarrhoea.

There is clearly a need to assess local response to zinc in different social and cultural settings as a step towards developing a global policy on zinc treatment (20). Such an assessment demands both a study of how best to introduce and explain zinc use to local populations, and an evaluation of the impact of zinc treatment on Oral Rehydration Therapy (ORT) when: (a) zinc is introduced

Box 1.1 Challenges to marketing zinc as a medicine that reduces severity and duration of diarrhoea

Moderately difficult:

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

More difficult:

- Convince mothers to keep giving zinc to children for 10 to 14 days after symptoms have disappeared
- Convince mothers to give zinc while still giving ORS

Harder still:

 Convince mothers to purchase zinc and use it appropriately and routinely for all types of diarrhoea along with ORS in clinical settings; (b) zinc is introduced in community contexts by health-care providers or through the private sector. Considerable time, effort and resources have been invested in community-based education on ORT over the past three decades. We need to make sure that efforts to introduce zinc enhance and do not undermine efforts to increase the use of ORS. This is of vital importance because ORS is essential to prevent diarrhoea-related deaths.

To test the community response to zinc treatment, messages need to be developed to promote the benefits of zinc in such a way that the health concerns of mothers are addressed. That presupposes formative research to develop messages that are culturally appropriate. Formative research is also needed to help assess possible changes in the use of ORS and other medicines, such as antidiarrhoeals and antibiotics, prior to and after zinc introduction. Such changes, particularly any reduction in the use of ORS, will need to be addressed through appropriate interventions after the formative research.

This research is challenging for two reasons (see Box 1.1). First, zinc needs to be taken for approximately 10 to 14 days in order to have full therapeutic effect. This demands that messages be developed to: (a) encourage mothers to give their children zinc when ill; (b) continue giving the children zinc after diarrhoea has stopped, for a full course of 10 to 14 days. The adherence of mothers to zinc instructions must be measured at different times during the 10 to 14 days and reasons for stopping therapy carefully assessed at each stage. Second, it is necessary for evaluations of zinc adherence to take account of different variables that may affect patterns of use. For example, local categories of illness associated with diarrhoea need to be considered, as the perceived need for treatment may differ by type of illness, however classified. Differences in the use of ORS by illness type have been documented in carefully designed studies in Bangladesh (21,22). 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.

1.2 Phases of the formative research

The formative research draws on the Eight stages of formative research model developed for the International Clinical Epidemiology Network (INCLEN) by M. Nichter in 1990 (see Box 1.2). The data collected contribute to the design of the intervention, the development of the messages, and the implementation, monitoring and evaluation of the intervention (see Figure 1.1).

Box 1.2 Eight steps of formative research

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

Through literature review and key informant interviews you will know:

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

Through a card-matching exercise, you will be able to:

determine the different treatments and feeding practices commonly associated with the different kinds of diarrhoea.

Step 2. Develop key messages. By using the findings from step 1, you will:

- know the 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 candidate messages developed in step 2;
- identify final messages for the behavioural trial.

Step 4. Gather mothers' reactions to the zinc tablet. Through focus group discussions, you will:

- get mothers' reactions towards the zinc tablet and its administration;
- determine issues and concerns of mothers that may be included in the draft counselling cards.

Step 5. Develop the counselling cards. In this step, you will:

 design and develop the counselling cards that will address the issues and concerns of mothers, as determined from the previous steps.

Step 6. Conduct the behavioural trial. By conducting the behavioural trial, you will:

- find out which among the candidate 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.

Box 1.2 Eight steps of formative research (continued)

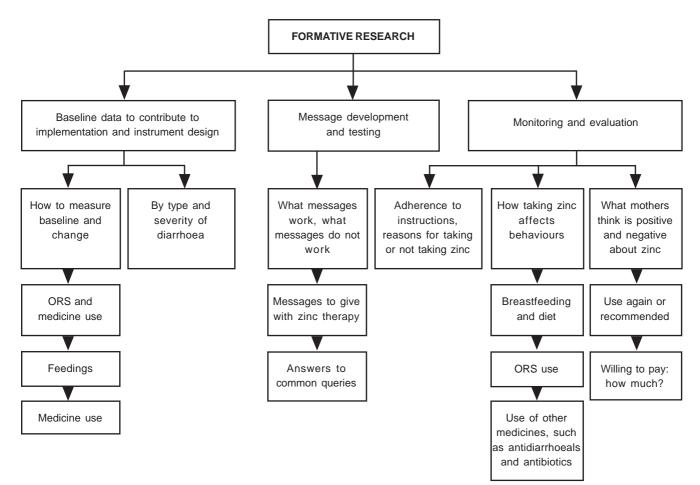
Step 7. Document the research process and monitor the intervention. Through conducting observations and exit interviews within the first month of the intervention, you will:

- determine how zinc messages are being delivered by health-care providers to target clients;
- observe interactions between health-care providers and patients, which may provide information that could explain mothers' other perceptions of zinc;
- gather additional concerns from mothers that should be addressed in revised counselling cards.

Step 8. Carry out a final evaluation at end of intervention. By reviewing the exit interviews following the behavioural trial, you will:

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

Figure 1.1 Phases in the formative research



In the first phase (step 1), a baseline data-gathering exercise provides information on which zinc messages are based. It also provides information essential for the design of instruments to measure the behavioural changes associated with taking zinc. Practices such as the use of ORS, feeding (including breastfeeding), and the use of medicines (including antidiarrhoeals and antibiotics) are documented to determine how much the use (or non-use) of zinc may affect these behaviours. This initial phase of the formative research determines the key behaviours that should be tracked and monitored from this phase of the research to the next.

A second phase of formative research (steps 2 to 6) uses the baseline data to generate viable candidate messages related to the behaviours we wish to promote or change (i.e. adherence to zinc, continued use of ORS, non-use of antidiarrhoeals and antibiotics) among the target population. This phase determines the mix of simple and effective messages or instructions that are most likely to motivate mothers to correctly administer the zinc tablets for 10 to 14 days. Messages found to be confusing or controversial are excluded.

The third phase of formative research is about monitoring and evaluation (steps 7 to 8). It involves finding out:(a) which factors influenced mothers to adhere to or discontinue zinc therapy; (b) what the mothers liked or did not like about zinc; and (c) whether the mothers liked the zinc treatment enough to recommend it to others and pay for it.

1.3 Methods for formative research

This guide covers the following methods for formative research: literature review; in-depth interviews; focus group discussions; behavioural trials; and observation of interactions between health-care providers and mothers.

A key component of this formative research is the identification and development of suitable messages to accompany the distribution of zinc tablets. These messages can be tested during implementation or intervention. The data generated during the trial are useful for subsequent social marketing research, which needs to be conducted before a zinc distribution programme can be expanded to national level. The objective of this formative research is to look at diarrhoea management and zinc use from the perspective of the mother. Zinc messages should be designed to fit a mother's idea of an acceptable and effective treatment for diarrhoea, and for care during convalescence after the illness.

Formative research is process-driven and iterative. Data collected from earlier phases influence research conducted at a subsequent phase as new research questions emerge. Formative research may be initiated before an intervention trial and its results can be used to guide the development and evaluation of research instruments. An exit interview (conducted at the end of the trial) can contribute to the refinement and modification of zinc messages (Figure 1.2).

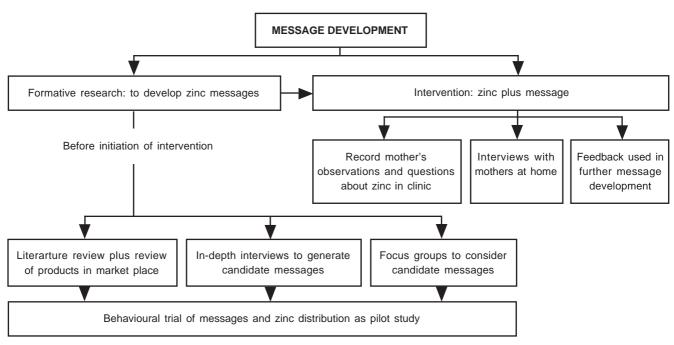


Figure 1.2 Formative research: message development

The research can be completed within six weeks, as outlined in the timeframe in Table 1.1.

Activity			Wee	k		
	1	2	3	4	5	6
Complete preparatory activities						
Review literature, carry out in-depth interviews, survey pharmacies						
Hold focus group discussions: card matching						
Develop messages						
Hold focus group discussions to test messages, get reactions to zinc						
Design and pre-test label and logo						
Refine messages						
Develop counseling cards						
Prepare for behavioural trial: translate instruments, train or orient interviewers						
Conduct behavioural trial						
Analyse behavioural trial data						
Finalize messages						

Table 1.1 Timeframe	for formative	research le	eading up	to the	intervention
	for formative	10000010111	out any up		

1.4 Logistics

The following are the basic requirements for conducting the research.

Personnel

The project team needs a leader and at least two research interviewers. During the focus group discussions, one interviewer should act as the rapporteur and document the points raised, the other should assist. Ideally, the project team leader should facilitate the discussion. During the behavioural trial, one interviewer should screen, recruit, gather baseline information, demonstrate the preparation and administration of zinc, deliver messages and conduct home follow-up interviews. The other interviewer should conduct the exit interviews.

Venue

For the focus group discussions, there needs to be an area that is accessible to mothers and free from distractions. For the behavioural trial, mother and child pairs will need to be recruited. Therefore, the team leader will need to find a local primary health-care facility where children with diarrhoea are brought for care, from which the mother and child pairs can be recruited.

Supplies and materials

Visual aids are needed as described in the formative research steps. Behavioural trial instruments (i.e. cards) will need to be reproduced.

Budget

The costs of interviewers' travel will need to be covered. Although no incentives will be offered for participation in the focus groups, it may be appropriate to pay participants for their time and travel. It may also be appropriate to pay for refreshments to offer during the focus group discussions.

2

How mothers think about and respond to childhood diarrhoea: local illness terminology, health concerns, and related health practices

2.1 Objectives

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

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

2.2 The literature review

After reading through this guide and having listed all the 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 diarrhoea-related perceptions and behaviour (see Box 2.1).

Examine these materials for data related to the main headings in the flowchart in Figure 2.1 (i.e. illness classification, management of diarrhoea, etc.). There will be adequate data available in some areas, whereas in other areas you may need to carry out a focused ethnographic survey 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 whether the data from the literature apply to the locality where you are planning to implement the intervention, as well as to the population living in that area. Remember that there may be important ethnic differences or language differences that could make the available data inapplicable to your site. Where data are not available or are not up to date, conduct a focused ethnography survey (rapid appraisal), following the series of steps suggested in section 2.4 of this guide. If possible, seek a trained health social scientist to assist you.

Where a diarrhoeal disease control programme has been in place for some time, information about the following may well have been collected at some point:

- ethnographic studies on diarrhoea home management, and community norms and practices related to diarrhoea, specific to the population or area where you plan to promote zinc; how diarrhoea is perceived as an illness, terms used, and concepts related to such aspects as severity and care-seeking behaviour;
- extent of the use of ORS and ORT 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 using these same channels for distributing your zinc);
- use of other medicines or treatments during a diarrhoea episode, depending on the country, these may include antidiarrhoeals, antimicrobials, antimalarials, and traditional medicines or treatments;
- kinds of training that health personnel (especially those who may be involved in promoting zinc, including village health workers) may have had on diarrhoea management and communication or health education skills, as well as their literacy and competency levels;
- information about zinc preparations that are already available on the market and how they are being promoted (As treatment? As tonics? As nutrient supplement? In milk formula? In multivitamin preparations? For adults? For children?) – this information will not come from

Box 2.1 Questions to ask in order to gather baseline data

- What are the local names for types of diarrhoea?
- What are the local perceptions of causality, seasonality, and relative severity of diarrhoea?
- Is diarrhoea associated with developmental milestones?
- Does a local conception of dehydration exist?
- Is ORS commonly used? If so, for what types of diarrhoea?
- What forms of ORS are used, in what quantity and for how long?
- Is ORS seen as a treatment for dehydration or a medicine to stop diarrhoea?
- How are different types of diarrhoea managed by diet, local medicine, and medicines purchased from shops?
- What are the most common medicines purchased for diarrhoea and how much is taken?
- How are "weakness", "strength" and "appetite" described in the local language?

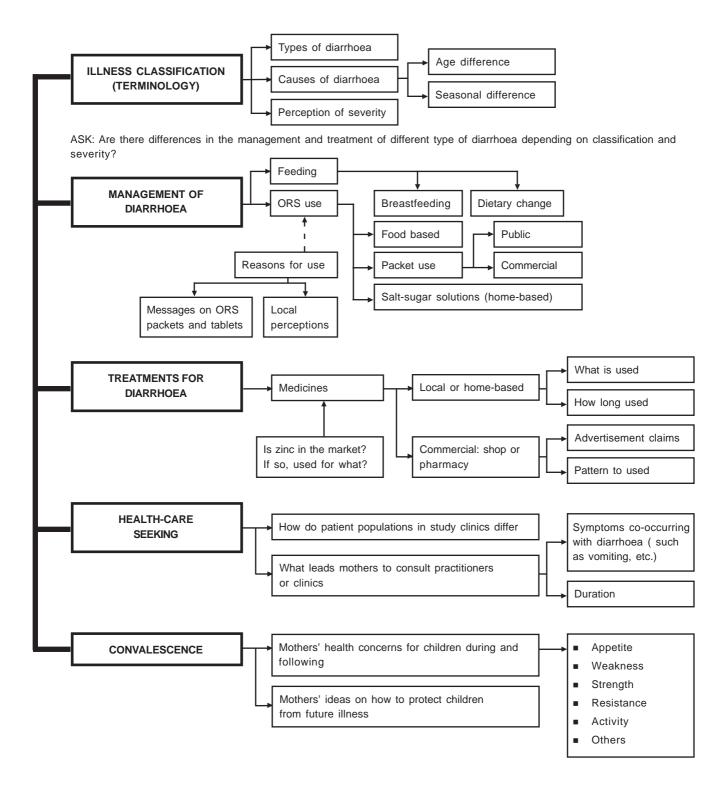
diarrhoeal disease control programme files, but more likely from the food and drug administration or its counterpart in the country.

If you have access to the Internet, you may want to search the web sites of bilateral agencies, nongovernmental organizations, UNICEF, WHO, DHS, etc. However, these kinds of data are not often published or posted on web pages, so you may not find them. The best places to look are:

- diarrhoeal disease control programme files;
- studies done in schools of public health or medical anthropology or other health-related social science programmes or medical schools;
- research institutions, particularly those that do research on diarrhoeal diseases;
- personal files of investigators or of people who may have been involved with the diarrhoeal disease control programme at the time the studies were done.

Although the literature gives you a place to start, much of the available information may come from studies that were done a long time ago. Unless the studies are recent, it is important to carry out the steps described in this guide to make sure that your messages are relevant. Other changes may also need to be made when introducing zinc treatment in your diarrhoeal disease control programme.





2.3 Baseline information

Local terms related to diarrhoea and 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 make it clear that zinc is: (a) not a medicine that will immediately stop or cure diarrhoea (such messages would foster unrealistic expectations); (b) not a medicine to treat dehydration (such a message might interfere with the use of ORS). Zinc needs to be promoted as a *complement* to ORS, and in such a way that mothers will still be motivated to administer zinc after the diarrhoea has stopped. Researchers should therefore seek to identify the concerns a mother might have about her child's health following illness that might lead her to continue giving zinc. This idea entails considering the local notions of vulnerability to illness, convalescence and ways of preventing illness in the future.

Beyond the development of messages, formative research enables a grounded approach to health communication that anticipates the questions and doubts mothers are likely to have about zinc, ORS and diarrhoea-related behaviour (such as child feeding). Information can be placed on counselling cards, in a question and answer format, for use by health-care providers (or people who will counsel mothers about the use of zinc). Standardized responses to common questions related to diarrhoea and its treatment, and in this case regarding the use of zinc, raise 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 obtained from this initial data-gathering step of formative research also contributes to the development of tools to monitor and evaluate the impact of zinc treatment on the population. Zinc use may differ by perceived types of diarrhoea (by cause, severity, age of child) identified in the community. Before zinc is introduced, it is important to know how mothers treat different types of diarrhoea, in order to assess the impact of administering zinc. For instance, in the case of "teething diarrhoea", we would want to examine whether the use of home remedies, ORS or commercial medication changes when zinc is introduced.

It is also important to identify the popularity and use of diarrhoea 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.

2.4 Conducting a focused ethnographic study on diarrhoea

The sequence of steps to take in conducting a focused ethnographic study on diarrhoea is as follows.

Conduct interviews with mothers.

Select three to five mothers with children less than five years old; the mothers may be selected from those consulting the health facility in the community. It would be better if these mothers have had recent experience of taking care of their children during a diarrhoea episode.

- Ask these mothers questions to gather information about most of the topics in the flowchart in Figure 2.1. See Box 2.2 for a list of possible questions you could ask the mothers.
- Take note of terms used for illness, causes of illness, and home management practices.

Box 2.2 Questions to ask in interviews with mothers

- What are the types of diarrhoea commonly occurring in babies and children? What are they called?
- Are different types more common in different seasons?
- What are the causes of these different types of diarrhoea? What are the signs and symptoms of each type?
- What are the treatments given for these types of diarrhoea? (Include home treatments, herbal medicines, over-the-counter drugs, ORS and any other treatments.) What are the perceived roles of these treatments?
- What are examples of medicines for diarrhoea? Which ones are antibiotics? Are there medicines for different kinds of diarrhoea or different severity of diarrhoea? Do you still give ORS if these medicines are being given? What utensils are usually used to administer these medicines and ORS ?
- Where are children with diarrhoea usually brought for care? What do healers or doctors usually give or prescribe for the different types of diarrhoea?
- Have you used ORS for diarrhoea? Was the ORS bought commercially? Have you used home-made solution? If you have used home-made solution, how was it prepared? How much ORS is given to child who is ill?
- What types of ORS are available commercially?
- What does ORS do for children with diarrhoea? (Determine mothers' concepts of dehydration and oral rehydration.)
- What foods are usually given to children during and after diarrhoea? What are the perceived roles of these foods during diarrhoea?
- Are there certain foods usually withheld during diarrhoea? Why?
- Is breastfeeding continued during diarrhoea? Why?
- What liquids are usually given to babies and children during and after diarrhoea? What are the perceived roles of these liquids?
- Is liquid intake usually increased or decreased during diarrhoea? Why?
- Are there children who usually get diarrhoea more frequently (recurrent diarrhoea) than others? What are the treatments?
- Are there children who get sick with diarrhoea longer (prolonged or persistent diarrhoea) than other children? What are the causes of such diarrhoea? What are the treatments?

Conduct in-depth interviews with key informants who could provide you with an idea of health practices prevalent in the community.

Identify people in the village whom mothers commonly consult when their children are sick. Such people may include experienced mothers or grandmothers, herbalists, traditional birth attendants, or other respected members of the community.

- Explore with them what common patterns of behaviour they have observed when mothers of children with diarrhoea seek health care. Consider this information in relation to answers you obtained from the interviews with mothers.
- Take note of the health-care practices, including home care, care-seeking and health-care advice. Do these practices differ by type of diarrhoea, perceived cause or severity?

Conduct in-depth interviews with pharmacists and drug sellers.

Make a survey of three to five pharmacies or stores selling drugs (see Box 2.3 for a list of questions that you could ask).

- Ask the pharmacists and store owners for the names of medicines for diarrhoea that are available in the market. Ask which are most popular and what medicines are purchased together, including commercial forms of ORS. Ask to see how the medicines are labelled and packaged. Note how they are promoted. Examine the keywords and graphics used in the packaging.
- Also ask about the different commercial ORS available and the instructions that are given for their use.
- Create an inventory of the names of medicines and ORS that you have gathered.

Box 2.3 Questions to ask in interviews with sellers of pharmaceuticals

- What are the usual terms that clients use for diarrhoea when they ask for medicine? What are the differences among these terms?
- What are the common medicines sold for diarrhoea? 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 diarrhoea do mothers buy?
- Do mothers ask you questions about diarrhoea in children? What kinds of questions do they ask?
- Are zinc preparations sold? If so, what are they used for? What dose are they and for how long are they taken? What is their cost? How popular are they? (If possible, collect a sample for analysis by a laboratory.)
- Are any products promoted as having zinc in them? What are these products? How are they promoted?(If a camera is available, ask for permission to take pictures of the products and the way they are displayed.)
- 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 keywords or phrases used on the labels?
- What are the usual messages written on packages of vitamins for children?

Visit a few local health clinics or facilities that mothers in the study community commonly frequent.

If you are conducting an effectiveness trial, it is best to visit all the clinics to be included in the trial.

- Conduct brief open-ended interviews with health-care providers and ask what kinds of clients come to their facilities. You want to know whether clients tend to come early or late to the clinic during an episode of illness, and how likely they are to have engaged in self-medication. Ask clinic staff if they have a sense as to whether many mothers have seen other practitioners before coming to the clinic.
- In the case of an intervention trial it will be important to match client populations in the intervention and control clinics. During the evaluation of the zinc intervention, clinic-specific information might give an insight into any clinic-specific differences reported in adherence to zinc and use of ORS or antidiarrhoeal medications.

Conduct focus group discussions with mothers.

You need to conduct focus group discussions with mothers to further validate the information you have gathered so far about how diarrhoea 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.

- Focus group discussions 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 (preferably the project team leader) who will facilitate and lead the discussion;
 - iv. focused in addition to using questions to prompt discussion, 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.
- You will need five or six mothers per focus group discussion, recruited from the clinic or the community. To make the discussion more relevant, each mother should have at least one child less than five years old.
- For those who do not have expertise in this research method, we suggest introducing a cardmatching exercise as a relatively easy way of stimulating discussions during the focus group. To prepare for the card-matching exercise, see section 2.5.
- For guidance in conducting the card-matching exercise, see section 2.6.

2.5 Preparing for the card-matching exercise

As a minimum, for the card-matching exercise, you will need to make three sets of cards: one set reflecting local diarrhoea terms; one set covering treatments; and one set showing 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 who is ill could comprise another set of cards. Each card in a set should contain only one item. Table 2.1 shows possible items or terms that can be written on the cards.

Cards may be prepared in two ways, to suit the needs of the community. For literate communities, cards may be prepared using words or text. For illiterate communities, cards should be prepared using graphics and drawings.

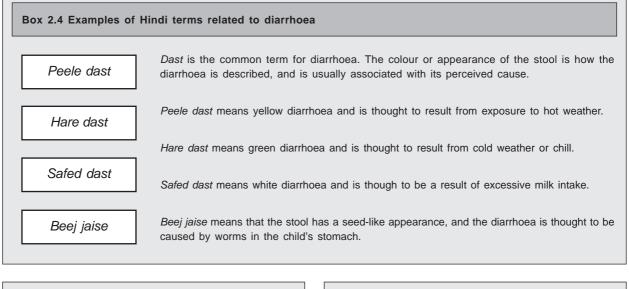
When using words or text:

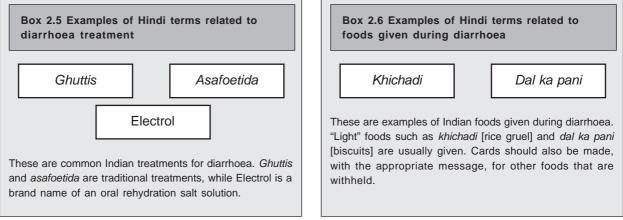
- the terms should be written clearly and legibly on the cards;
- the letters should be large enough for the mothers to read in a small-group setting;
- no other words or markings should be written on the cards.

Boxes 2.4 to 2.6 show examples of some Hindi terms related to diarrhoea, treatments for diarrhoea, and foods given during diarrhoea. These words may be placed on cards to be shown to mothers in a Hindi-speaking community.

Set of cards on terms associated with diarrhoea	Set of cards on treatments	Set of cards on feeding practices	Set of cards on common medicines for diarrhoea
 teething food and milk intake spoiled breast milk blood in faeces weather indigestion 	 herbal remedies antidiarrhoeals antibiotics ORS home-recommended fluids teas (Make a separate card for each treatment with a different herbal remedy, each antidiarrhoeal treatment, each antibiotic treatment. Examine carefully what "antibiotic" means locally.) 	 give more fluids give less fluids give more foods give less foods give same amount of fluids breastfeed more often stop breastfeeding give special foods (Ask which foods are advised.) do not give certain foods (Ask which foods are prohibited.) 	 antidiarrhoeals (Give examples of names.) antibiotics (Give examples of names.) medicine for watery diarrhoea, bloody diarrhoea etc. medicine for dehydrating diarrhoea medicine for mild diarrhoea

Table 2.1 Examples of items to include in different sets of cards





Try to be creative in making drawings for the cards. Team efforts may be required to make drawings that are easy for mothers to grasp. The drawings need not be artistic, but mothers should associate them with the terms included in the card-matching exercise. Figures 2.2 to 2.4 illustrations such drawings.

2.6 Conducting the card-matching exercise

You will need to take the following steps to conduct the card-matching exercise.

Prepare the card-matching kit, which will include the following:

- the cards that you have made, as explained in section 2.4, with text or drawings reflecting terms for diarrhoea, treatments 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.

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 institutional affiliation. Read the informed consent statement. If mothers speak a different language, a translator may be needed. The translator needs to understand the objective of the activity so that he or she can relay the appropriate meaning.

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

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

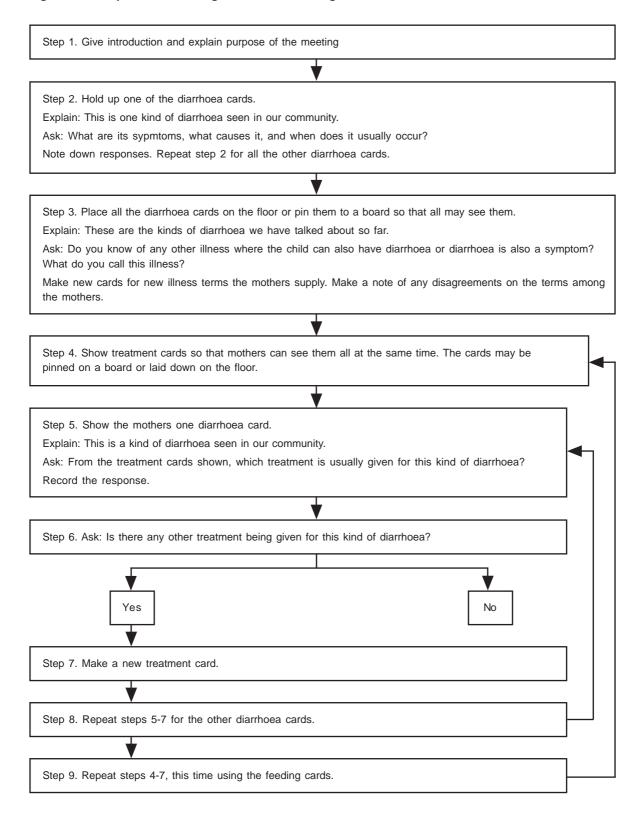
Proceed to the card-matching exercise. See Figure 2.2 for the procedure of the exercise. Encourage the mothers to participate by directing questions towards each of them in turn.

When using cards with drawings, you should make an extra effort to explain to the 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 to 2.4. may be described as follows.

Figure showing sun and rain (Figure 2.3) – example of a kind of diarrhoea: "This drawing shows sun and rain. This indicates a change in weather. This drawing represents a kind of diarrhoea seen in our community that is caused by changes in weather. Some mothers call this kind of diarrhoea '_____'. Do you also use this term for this kind of diarrhoea, or do you have another name for it?"

Figure showing a feeding bottle (Figure 2.3) – example of a kind of diarrhoea: "This drawing shows a feeding bottle with milk in it. Dirty milk can be a cause of diarrhoea. This drawing refers to this kind of diarrhoea. Do you have a name for this kind of diarrhoea?"

Figure 2.2 Steps in conducting the card-matching exercise



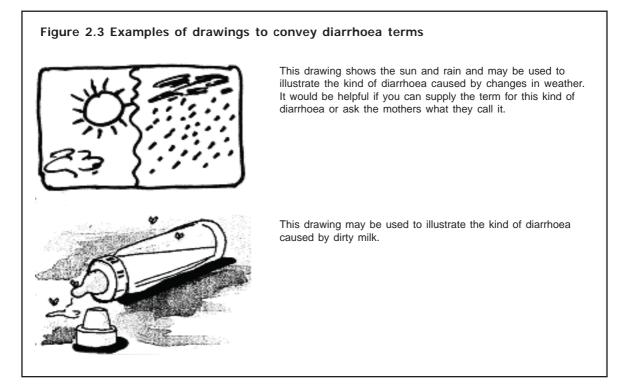


Figure showing an ORS packet (Figure 2.4) – example of treatment: "This is an illustration of a packet of oral rehydration salts (or whatever ORS are called locally). ORS are one of the treatments given for diarrhoea."

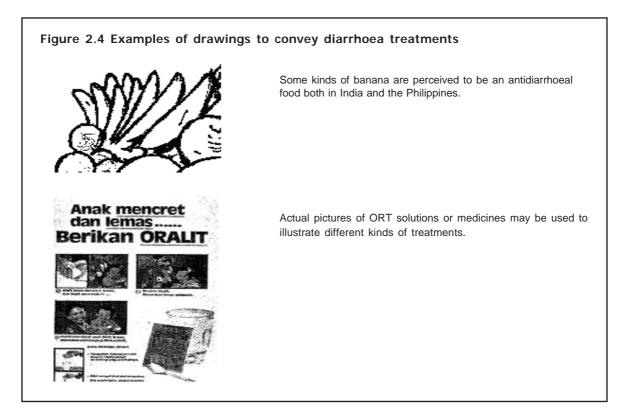
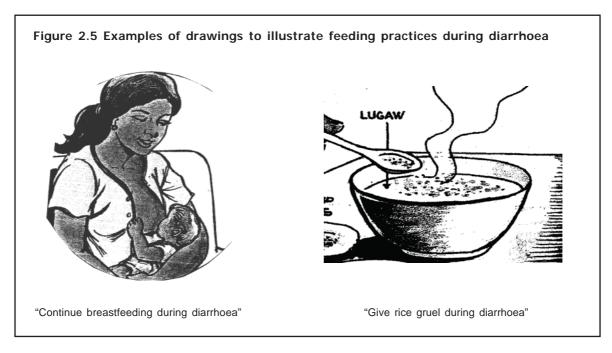


Figure showing a breastfeeding mother (Figure 2.5) – example of a feeding practice during diarrhoea: "This picture shows a mother breastfeeding her baby. This picture means that you should continue breastfeeding when the baby is sick with diarrhoea."



You should use this manner of explaining the pictures for all the illustrations to make sure that the mothers have a uniform understanding of the drawings. If the mothers supply a new term for a 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 the term because it may be useful when you are constructing your key messages and developing your counselling cards.

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.

2.7 Analysing your data

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

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

- What is ORS used for, what does it do (is it seen as medicine for diarrhoea or for dehydration)?
- What is the mothers' concept of dehydration and rehydration?
- Is it acceptable to give medicines for diarrhoea and ORS 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 ORS similar among breastfed and nonbreastfed children?
- Are there medicines given even after the child has recovered from diarrhoea or any other illness?
- Do mothers change the way they give foods and fluids to children after they get well from diarrhoea or any other illness?
- Do mothers have a concept of "contraindication", where certain foods or another medicine should not be given to a child with diarrhoea if he or she is already taking some medication?

- Do mothers have a concept of certain things being "prohibited"? That is, do mothers think that certain medicines, fluids or foods should not be given while a child has diarrhoea?
- Are vitamins given to a child who has diarrhoea? Are they valued as a resource when a child is recovering from illness? Are there different types of vitamins that are good for children who have had diarrhoea?
- 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 that strength in children?

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

3

Development of candidate messages

3.1 Objective

By the end of this section, you should have:

 developed the candidate messages to explain to mothers the actions and effects of zinc for children with diarrhoea.

3.2 The need for balanced messages

The formative research recommended in this guide is a tool to identify potential candidate messages to use in the social marketing of zinc. But this research is just the first stage in developing the messages. The methods described in the previous sections of the guide are 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 about the most common health concerns as a focus for a few key messages, but perhaps, more importantly, we want to identify issues and information that mothers (the target audience) respond to negatively or have trouble understanding. In the candidate messages, we want to avoid the issues that even a minority of mothers might find confusing or problematic.

The messages need to be based on the scientific evidence, and phrased in a way that will encourage mothers to give zinc appropriately to their children. There is sufficient evidence to conclude that zinc has a therapeutic effect on acute watery diarrhoea among young children (see Box 3.1).

Our experience suggests that zinc messages are more likely to result in adherence if they include curative as well as preventive health messages. One important challenge in developing zinc

Box 3.1 Therapeutic effects of zinc in treating acute watery diarrhoea

Zinc administration at the time of diarrhoea leads to:

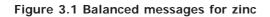
- shorter duration of the episode
- fewer loose stools.

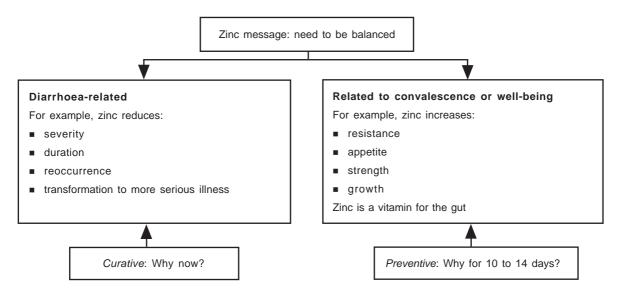
A complete course of 10 to 14 days of zinc treatment results in prevention of diarrhoea episodes in the following 2 to 3 months.

messages is how to encourage mothers to continue using zinc after the diarrhoeal episode has stopped and there are no longer any symptoms. Local zinc messages should address both zinc's impact on diarrhoea 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. Although 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 diarrhoea. Another concern that we have is that messages should not overstate the benefits of zinc. Research on ORS has taught us that when mothers had unrealistic expectations for ORS, they tried the "medicine" and were disappointed that it did not immediately cure diarrhoea. In developing messages, you should bear in mind that it will take some time to demonstrate the effect of zinc, and that the benefits of zinc therapy involve harm reduction (prevention and health

promotion) as well as the cure of diarrhoea. We are also concerned that zinc might be perceived as a substitute for ORS, and consequently reduce the use of ORS.





3.3 Reviewing existing messages in medicine advertisements

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

• Look at the keywords that are used.

In the Philippines trial, for instance, the words *resistensya* [resistance], *malusog* [healthy], *malakas* [strong] and *magana* [good appetite] were commonly associated with a healthy child, and frequently used in labels and advertisements for milk and vitamins. Different ways of using these keywords 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 in the formative research in the Philippines. Resistance is a widely accepted notion, and mothers well understand its meaning in the context of a child's health.

• Keep in mind zinc's action. Avoid choosing a message that would make mothers identify zinc with another product (see Box 3.2).

Box 3.2 Example of the successful development of zinc messages in the Philippines

Because vitamins are very popular and clearly identified with a protective effect, the team in the Philippines came up with the idea of promoting zinc as a "vitamin for the gut". Of course, zinc is a mineral in the scientific sense, not a vitamin. Mothers in the Philippines, however, tend to group these micronutrients together, and to use the term "vitamins" for them.

Mothers know that diarrhoea has something to do with a problem in the stomach. They described diarrhoea as a condition of weakness in the stomach. The team took the idea of a vitamin providing overall strength for the body, but its action in the case of zinc was specifically focused on the stomach. This approach sought to differentiate the action of zinc from the accepted effect of vitamins in general. Describing zinc as a vitamin for the gut also differentiated the effect of zinc from the action of an antidiarrhoeal drug. This is important because we do not want mothers to think that zinc is a cure for diarrhoea.

3.4 Adapting and translating the messages

Adapt and translate the messages for local use. Remember the following points.

- In translating the messages, consider the terms, associations, relationships and concepts gathered in section 2.
- It is possible that a single message may be translated more than one way, or that in translation it may become more than one sentence.
- As far as possible, keep the translations simple. Each message should contain only one or two ideas. To illustrate that approach, Table 3.1 shows the five potential messages developed in the Philippines. The first two messages address the disease, while the remaining three messages address concerns about the child's well-being. The first column of Table 3.1 explains why the team came up with these messages and shows that the mothers' concepts of illness and health played an important role in the development of the messages.
- Learn from advertisements for popular medicines. Examine the messages used for such products. What concerns have been addressed to give the advertisements commercial appeal?
- All the messages that are pilot-tested should also be back-translated to ensure that the translation is correct and that mothers understand the message as intended

Note that if there are many illiterate mothers in the community, you will need to adapt the procedure described above. When describing the items (concepts, resources, messages, etc.) on the cards, use images that are easily recognizable to mothers as prompts or memory aids.

Basis for the message	Message	Message translated into Tagalog
Mothers are very concerned about the child's diarrhoea 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 diarrhoea from becoming serious.	Gamot para hindi lumala ang pagtatae ng bata.
Mothers understand and fear the conditions (such as dehydration, loss of weight and appetite) brought on by diarrhoea, and the thought that a drug could prevent them has some appeal.	Drug to prevent the child from getting sick again with diarrhoea.	Gamot para maiwasan ang muling pagtatae ng bata.
Questions about appetite and feeding are among the most common among those that mothers ask during consultations for diarrhoea. The message's appeal is based on the mothers' knowledge that appetite decreases during illness. The message makes it clear that this drug is for children who are in the acute or convalescent phases of diarrhoea, so that even if the diarrhoea has become better, mothers understand that the medicine still needs to be given.	Drug that increases the appetite of a child with diarrhoea or just recovering from diarrhoea.	Gamot na pampagana pag nagtatae o gumagaling sa pagtatae ang bata.
The key word of this message is <i>resistensya</i> [resistance], which is thought important in the Philippine culture. Among mothers, one indicator of a child's health is that he or she 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 become seriously ill as a result of common diseases.	Drug that strengthens the resistance of a child with diarrhoea.	Gamot pampatibay ng resistensya ng batang nagtatae.
Vitamins are known to mothers and are popular in the Philippines. A local study indicated that mothers do not distinguish between vitamins and minerals. The idea of a "vitamin for the gut" was based on a message found locally effective for a TB drug (vitamins for the lungs). This message could also explain why zinc needs to be taken for 14 days, the time needed for the gastrointestinal mucosa to be replaced.	A vitamin for the gut of a child with diarrhoea.	Bitamina para sa tiyan ng batang nagtatae.

Table 3.1 Potential messages developed for use in the Philippines

4

Testing the messages

4.1 Objectives

By the end of this section, you should have:

- tested the messages with two or three groups of mothers with children 1–59 months of age;
- identified the final messages for the behavioural trial.

4.2 The message testing exercise

The message-testing exercise involves the following steps.

Make the message cards. These are cards (about 8 cm by 11 cm) on which the messages are written. The messages are translated, as explained in section 3.4. Make sure that:

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

Prepare the message testing setting. The message testing will be done with small groups, similar to those involved in the card-matching exercise (section 2.5). You may need to conduct the test with two or three such groups in order to see whether popular messages can be identified, and to screen out confusing messages and messages that raise doubts from mothers.

Follow the procedure for testing potential zinc messages. A step-by-step procedure for testing the messages is described below. Figure 4.1 provides a summary of the procedures.

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

"We would like to inform you that there is a new treatment for diarrhoea 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 treatment 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 treatment."

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 treatment."

Ask the following six questions:

- Is this message easy to understand?
- What is it trying to say?

- Does the message clearly explain the treatment it accompanies?
- Do you know of any other treatment that has the same effect?
- Would you doubt the message if it said a treatment could do such a thing?
- Is there anything that might concern you about such a treatment?

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 a table or on the ground 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, which 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 of much interest to you?

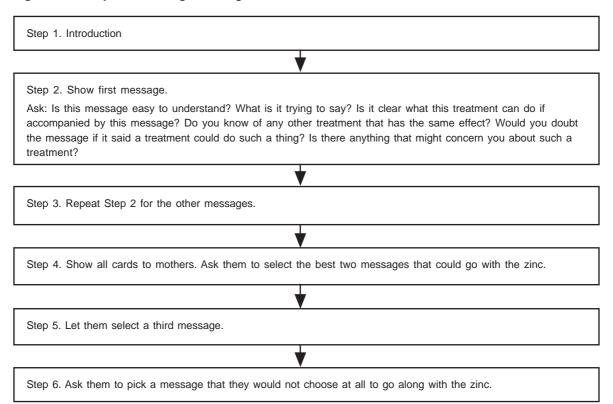
Write down the choice of each of the mothers.

4.3 Analysing the results of the message testing

Analyse the results of the small group meetings. If new messages came up during any of the small group meetings with mothers, you may decide to add messages to the sets of cards. Depending on the comments made by the mothers, you may also decide to reword some of the messages. Then you will need to do the following.

- Test the refined messages in succeeding meetings.
- Make a matrix to show how frequently the different messages were chosen by the mothers. Distinguish the top two choices, the third choice, and the messages that would not be chosen at all (see Table 4.1 for an illustration of the use of a matrix).
- Discuss all the messages that mothers found confusing or had a doubt about. You will need to draw up a list of these messages as a basis for the discussion. It is most important to identify these messages, even if only a small number of mothers were confused by them. If these messages were popular with many of the other mothers, consider whether there is a way of clarifying the message to reduce the doubts or concerns expressed. Test the revised messages.
- Take note of the issues and concerns frequently raised by the mothers when discussing the cards. Consider these concerns when you develop your counselling cards.

Figure 4.1 Steps in message-testing exercise



4.4 Deciding on the messages to use in the intervention

Now you need to decide on the final messages for use in the intervention. From the matrix, identify the most liked messages. Also identify the messages where a doubt or concern was raised by more than one mother. Messages chosen for the behavioural trial should be popular and not be seen as confusing, even by a minority of mothers.

As an illustration, Table 4.1 shows that most mothers in the Philippine message-testing exercise chose a message concerning resistance (*resistensya*) as a first choice coupled with the message mentioning vitamins (*bitamina*). Although the *bitamina* message 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 diarrhoea. 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 by doctors as a special "vitamin for the gut", useful for diarrhoea 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 (*pampagana*) or the message on preventing the diarrhoea worsening (*para hindi lumala*). The message on appetite may be the more acceptable of the two as it was among the first two choices for some mothers, while the message on preventing diarrhoea worsening was selected only as a third choice and was eliminated by a number of mothers in the second group meeting.

In deciding which 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

Message	First group meeting			Second group meeting			Third group meeting								
	M1	M2	M3	M4	M5	M1	M2	MЗ	M4	M5	M1	M2	M3	M4	M5
Increases appetite	~	√			~		√						√		
									х	•					
Prevents diarrhoea from getting worse	•	√	•	•	•	•			•						
			•	·	•		Х	·	•	Х			Х		
						0									
Increases the resistance of a child with diarrhoea	~		\checkmark	\checkmark	\checkmark	~	•	\checkmark	\checkmark	\checkmark		\checkmark	\checkmark		
							•							0	0
Vitamins for the gut of a				\checkmark			\checkmark	~	~	~	~	\checkmark			
child with diarrhoea	х	Х	Х		Х										
Prevents child from			✓			~					~				
getting sick again with diarrhoea		•						X				•	•		
		0	0		0			Х		0		0	0		

Table 4.1 Results of message testing, Philippines

M - mother

🗸 – first two messages chosen

♦ – third message chosen

X – message not chosen at all

O - messages for which a mother raised a concern

as much attention to what messages mothers do not like, and why, as to what mothers do like, and why. A message that is misleading to even 20% of the community may undermine the zinc programme. As an illustration, in Table 4.1, the fifth message (prevents child from getting sick again) was found to raise issues for a number of mothers. They thought that if a child is no longer sick, it might be hard to make him or her take the zinc. Some mothers also thought that diarrhoea could not really be prevented, and that small children normally go through episodes of "normal" diarrhoea. One example given was diarrhoea resulting from teething. This was perceived as something a baby usually goes through as part of growing up. The message on resistance, although seen as having a high potential for promoting the zinc intervention, also raised some concerns from a number of mothers. They thought that a medicine with effects similar to the effects of vitamins and fruits might be expensive and unaffordable.

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

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

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

When introducing zinc messages, the research team should also consider how ORS solutions are perceived by the mothers in the community. In the Philippines, for instance, ORS 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 in the Philippines to develop distinct messages for the use of ORS solutions to be delivered with the zinc messages. In contrast, in Nagpur, India, rehydration is not well understood. Although mothers are aware of the ORS available through the public health system, they are not satisfied with its effect on the child's diarrhoea. The team therefore thought that a zinc message that had a distinct ORS message should be tested at the site.

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 to the zinc tablet.

5.2 Focus group discussions to introduce the tablet to mothers and get their reactions

The following steps explain how to hold focus group discussions to introduce the zinc tablet to mothers and get their reactions.

Prepare the materials. You will need:

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

Organize a focus group discussion session. Refer to section 2.4 to see how focus group discussions 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 rapporteur, to the participating mothers. State your profession and institutional affiliation. If mothers speak a different language, a translator may be needed. The translator needs to understand the objective of the activity so that he or she can relay the appropriate meaning.

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.

Introduce the zinc tablet. Then follow the steps described below to carry out this focus group discussion.

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

"Here is the treatment that we have been talking about. 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 (the 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 labelling 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 Analysing the information gathered

When analysing your data for this part of the study, remember the concerns mentioned earlier.

Tablet size - During the trial, one tablet size was used for both infants and young children. The team should determine whether mothers would halve the tablet for infants upon seeing that the same size tablet 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. Note that in Egypt, however, 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 tablet in liquid for infants, in terms of the extra preparation time needed. Would they prefer syrup (as mothers in Brazil preferred) or infant drops (as Filipino mothers did) over tablets? Is it their practice to dissolve medicines that are provided in tablet form? If so, do they usually use water or another liquid (breast milk, juice, tea, etc.)?

Dosage - Do mothers think the dosage (one tablet per day) is too much for babies? Do they have a 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 tablet and give it to the child over the course of the day? Try to find out what kind of decision-making processes mothers go through 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? Do they stop once the signs or symptoms of illness disappear? Do they keep leftover medicines for future use? What are their experiences regarding antibiotics and vitamins?

Packaging and labelling - What are the mothers' impressions relating to the packaging of medicines? 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 labelling and packaging are needed for zinc, the team must conduct additional focus group discussions 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 have demonstrated it to them.

Table 5.1 summarizes some highlights of the research findings from a number of the zinc trial sites.

Table 5.1 R	eactions to	the zinc	tablet in	different	trial sites
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	Concerns raised by mothers with regard to the zinc tablet
Philippines	 Syrup might be a better preparation for infants. If the tablet is dissolved, could it be administered through a dropper? Medicines are usually given after meals when the stomach is full. Drugs for diarrhoea may not have pictures on their labels. A period of 10 to 14 days for zinc therapy is acceptable; it is similar to that for antibiotics, which are given for a number of days.
Brazil	 A period of 10 to 14 days may be too long. The tablet seems large for a young child, even when it is dissolved. Liquid medicines more acceptable.
South Africa	 Is it possible to administer whole tablet? If mothers feel that it is too much, the dose could be divided into two, or the dose for the day halved. Dissolving the tablet makes giving it to children of all ages easy.
Lucknow, India	 Mothers need repeated instructions on dissolving the tablet. What time of the day should the medicine be given? Is a 24-hour interval needed in between administration of tablets?
Egypt	 Mothers prefer giving the medicine in one daily dose, rather than giving it in divided doses. Mothers are uncomfortable with giving unlabelled medicine.

Designing the zinc label and logo

6.1 Objectives

Based on the findings of previous focus group discussions (section 5) and concerns about mothers being easily able to identify zinc tablets, a research team might need to come up with a culturally appropriate name and logo for zinc for use in an intervention or trial. By the end of this section, you will be able to determine:

- whether the target population needs a distinct label and name for the zinc tablets;
- if a distinct label and name are needed, how to go about designing and choosing the label and name to use.

6.2 Designing and testing candidate labels and logos

The following steps will guide you through designing and testing candidate labels and logos.

First analyse the information gathered from the focus group discussions.

- Do mothers need to see a label on the medicine?
- Does the package have to have a picture? What kind?
- What should be written on the label? Test mothers' reactions to several candidate names for zinc.
- Do mothers expect written instructions to come with the medicine? You might need to design a card insert or put the instructions on the label.

For some questions to ask mothers about the zinc tablets and their packaging, see Box 6.1.

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 trial



Box 6.1 Questions to ask mothers relating to the zinc tablets and their packaging

- One zinc tablet may be used for children of all ages. Are you concerned about giving the same tablet (dose of medicine) to children of different ages? Would you be less concerned if this medicine came in different sizes and packaging for very young and for older children?
- The zinc tablet may be dissolved in water, breast milk or juice to be given to young children. Do you see dissolving a tablet in water as less effective than giving a child liquid medicine? Does dissolving a tablet concern you? Do you dissolve other tablets to give to young children?
- A child should be given the medicine once a day. Do you have any questions or concerns about giving medicine just once? Do you have questions about dosage related to how severe a child's diarrhea is or if the child vomits?
- A child should take this medicine every day for 10 or 14 days. Do you have any concerns about giving a child this medicine for such a long time if a child no longer has diarrhea?
- What is the name of this medication? What would you call it when explaining it to a friend who had never heard about it? What do you think about the name of the medication on the tablet? What do you think about the name of the medication on the package (show informant)? What does the name suggest?
- What do you think about the packaging of the medication?
- If there is an image on the package, what does it suggest?
- Would you prefer the pills in a blister pack to being handed to you as loose pills? If so why?
- Taste the medication. What do you think of the taste? Is the taste of any concern to you?

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

Conduct two or three focus group discussions where the labels are shown to mothers. Focus group discussions should be organized as described in section 2.4. For the Philippines trial, two focus group discussions were conducted to test the logos: one among the midwives in a local health centre; and one among mothers consulting the centre. The tablet can be introduced this way:

"We are now coming up with a treatment that can be given to children with diarrhoea. This treatment can (*repeat the zinc messages that were identified in section 4*). The treatment does not have a name yet and we are right now getting ideas from mothers like you on how best to name and package this treatment."

Show the mothers the candidate labels you have printed. Get their reactions and let them choose which among the candidate labels best fits with the treatment.

6.3 Analysing the results of the focus group discussions

Analyse the results of the focus group discussions qualitatively. In the Philippines, for instance, the two groups of participants preferred the third logo because of its simplicity. The respondents also liked the round shape of the symbol, which was easily identified with a tablet. The middle logo, patterned after the "Superman" symbol, was described as conveying "super effects" or actions that might be "over" (or too much) for a child's needs and a mother's expectations. The participants in the focus group discussions also said that it was not offensive to use the local word for diarrhoea (*pagtatae*) on the label. The final label decided upon in the trial is shown in Figure 6.2.

Figure 6.2 Final label chosen in the Philippines behavioural trial



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

- increases the resistance of a child with diarrhoea
- increases the appetite of a child with diarrhoea
- act as a vitamin 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 unlabelled medicine. Figure 6.3 shows the logo and label developed by the Egyptian team for the zinc trial in Egypt.

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



Development of the counselling cards

7.1 Objectives

By the end of this section, you should have:

- developed acceptable responses to common questions that doctors anticipate mothers may ask them related to zinc administration and its possible side-effects;
- identified questions that some mothers are likely to have about zinc by reviewing the formative research notes gathered in sections 1 to 5;
- designed a set of question and answer counselling cards for anticipated questions;
- pre-tested these cards.

7.2 Purposes of the counselling cards

The counselling cards:

- are designed and developed for use by the health-care 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 lists some of the issues and concerns identified during formative research in India and the Philippines that were addressed by counselling cards. These issues and concerns are generic, in that might need to be addressed at other sites as well. Other issues and concerns related to concepts of illness, beliefs and practices, that are important locally, will also need to be addressed. It is likely that these specifically local matters will emerge during your card-matching and message-testing exercises.

7.4 Deciding on the contents of the counselling 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 pre-tested. The following aspects need to be considered when developing and designing responses to questions that mothers are likely to have about zinc:

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

Issue	Possible questions and concerns of mothers
Vomiting	Should I stop giving the medicine when my child starts to vomit?If my child vomits after I gave the medicine, should I give another dose?
Fever	- What will I do if my child's fever continues?
Feeding	 Can I give my child (certain foods)? Should I increase or decrease my child's intake of (certain foods)?
Milk feeding	Should I stop or continue giving my child milk?Should I increase or decrease my child's intake of milk?
Breastfeeding	Should I stop or continue breastfeeding?What should I do if my breast milk is bad and is the cause of my child's diarrhoea?
Co-morbidity	- My child has a fever and you prescribed a medicine for fever. Does this medicine (zinc) counteract the fever medicine?
Other medicines	- My child has a cough and fever, and is already taking two medicines. Can I give my child this third medicine (zinc)?
Vitamins and minerals during diarrhoea	 My child's stomach is not okay. Why should I still give my child this medicine (zinc)? I heard a doctor say that vitamins and minerals should not be given during diarrhoea. Is this true? My child is already taking a multivitamin. Should I still give the zinc?
Bloody diarrhoea	- What will I do if I see blood in my child's stool?
Prolonged or increased diarrhoea	 My child's diarrhoea continued for more than 3 (or 4 or 5) days. Could this be the effect of this medicine (zinc)?
Overdose from zinc	This tablet seems to be too large for my baby. Will my baby be overdosed by it?If my child takes several tablets a day, will my child get overdosed?
Zinc with oral rehydration therapy	Does the zinc counteract the ORS?Should I give more or less ORS if I am already giving zinc?
Zinc for 14 days	Why is the zinc given for 10 to 14 days?If this is a medicine for diarrhoea, why should it be given if the diarrhoea is already cured?

Table 7.1 Issues and concerns that should be included in the counselling cards

In order to develop responses to anticipated questions, researchers need to engage in "conceptual translation". Conceptual translation involves generating potential responses to common questions, and then investigating how these potential responses are understood. For example, one of the generic issues identified was giving vitamins and minerals during diarrhoea. In the Philippines, there is a common belief among mothers that children who are sick with diarrhoea should not be given vitamins or minerals. One of the preferred messages among the study sites overall – that zinc is a vitamin for the gut – would probably then give a contradictory message to mothers in the Philippines. 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 the mothers believe in.

The Philippines team listed three possible questions relating to vitamins and minerals. These questions were presented to a clinician (in this case, a paediatric gastroenterologist) to provide

clinical responses that should imply some scientific basis. Next, these responses were integrated with known local beliefs, which had been gathered from the earlier literature review, the in-depth interviews and the focus group discussions. The resulting responses were then translated into the local language. This translation served as the health-care provider's script when answering queries from mothers and caregivers. If possible, the script should likewise be pre-tested for comprehension in the setting of a focus group discussion.

Table 7.2 illustrates the way information is progressively gathered and used in order to develop the scripts.

Торіс	Topic Vitamins and minerals during diarrhoea			
Question	My child's stomach is not okay. Why should I still give my child this medicine (zinc)?	I heard a doctor say that vitamins and minerals should not be given during diarrhoea. Is this true?	My child is already taking a multivitamin. 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 diarrhoea.	Yes. Iron should not be given during diarrhoea as this might cause irritation of the stomach. Other vitamins and minerals may be given.	Yes. Most multivitamin 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 from the diarrhoea.	
Step 2: integrate clinical response with local concepts and beliefs	During diarrhoea, a child's stomach is weak. Zinc is a vitamin specially formulated for the child's stomach to help it recover faster from the diarrhoea.	During diarrhoea, a child's stomach is weak. There is only one kind of mineral that cannot be given to the child, and that is iron. Other vitamins and minerals can still be given to the child. Zinc is a vitamin specially formulated for the child's stomach to help it recover faster from the diarrhoea.	Yes, zinc should still be given to the child. Most multivitamin preparations available in the market do not contain zinc. 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 the diarrhoea.	
Step 3: translate the answer into the local language (to create the health- care provider's script)	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.	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. Maaaring mas maging grabe ang kondisyon ng kanyang tiyan kung siya ay bibigyan ng 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	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.	

Table 7.2 Steps undertaken	to develop scripts for t	the counselling cards, Philippines

Step 4: pre-test the scripts among health-care providers in the setting of a focus group discussion, and also among mothers to check for comprehension.

dati nitong kondisyon.

Step 5: modify the scripts as necessary, and eliminate any that may be confusing either for health-care providers or mothers.

7.5 Constructing the counselling cards

A suggested format for constructing counselling cards is shown in Figure 7.1.

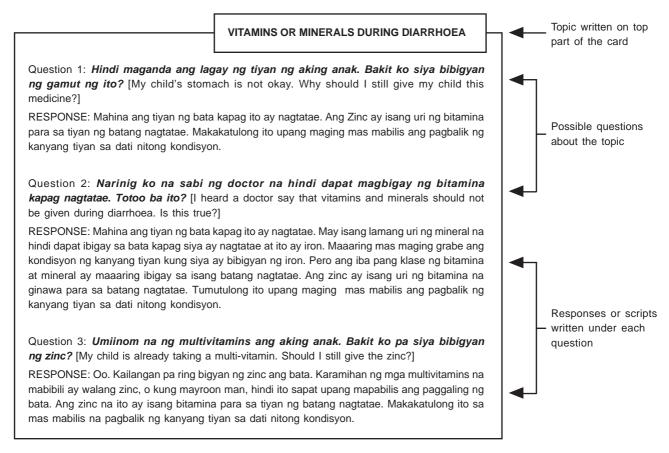
re 7.1. Suggested format of the counselling cards	ISSUE OR TOPIC
Concern 1	
Response:	
Concern 2	
Response:	
Concern 3	
Response:	

The following are some pointers for designing the cards.

- The material for the card should be sturdy enough for easy handling.
- The issue or topic name should be written on the top portion of the card, 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 should be listed on the card, together with the standard responses.

The counselling scripts illustrated in Table 7.2 can then be transferred or written on the cards. The completed cards will then look as shown in Figure 7.2.

Figure 7.2 Example of how a counselling card can be filled in



The behavioural trial

8.1 Objectives

The behavioural trial is conducted to:

- determine how well the mothers adhere to the zinc regimen and what factors, if any, negatively
 affect adherence;
- identify which of the zinc messages mothers best recall and agree with after using zinc for 10 to 14 days;
- determine whether the zinc messages, labelling or tablet packaging need to be modified to make zinc therapy more acceptable and better recognized;
- gather additional issues and concerns that need to be covered by the counselling cards.

8.2 The behavioural trial at a glance

During the behavioural trial, the team will carry out following activities :

- screen and recruit about ten mothers with children 2–59 months old who are consulting a health-care facility for diarrhoea;
- provide the mothers with zinc tablets for 10 to14 days, and give them instructions on preparing and administering the zinc;
- follow up with mothers on day 3;
- follow up with mothers on day 10 or 14;

The instruments suggested for the behavioural trial should be translated into the local language.

8.3 Preparing for the behavioural trial

The team should adequately prepare the personnel, materials, site and other logistics for the behavioural trial.

- Personnel: 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 the zinc tablet and what to observe, delivering the instructions and messages that go with the zinc, etc.
- Materials: supplies are needed for the reproduction of interview schedules, etc. Make sure that you have translated the instruments for local use.
- Site: make sure that you have informed the necessary people that you are conducting research in the community. The health facility where you are recruiting the mothers should likewise be informed and requisite permission obtained. Select a facility that 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 labelled, based on the consumer preferences identified in section 6.

8.4 Day 1 of the trial

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

- screening and recruitment: use Form 1 (Appendix A);
- secure informed consent from the mother: refer to Box 8.1 for guidance in producing an informed consent form, and to the informed consent template (Appendix B) which should be adapted to local conditions;
- gather baseline information: refer to Box 8.2 for guidance on what questions to ask to mothers;
- demonstrate the preparation of the zinc tablet, give the first dose, and the zinc messages;
- give the zinc tablets and the instructions;
- make an appointment for follow-up (on day 3); get a map or sketch of the mother's residence;
- before the mother leaves, administer the exit interview form: use Form 3 (Appendix C).

8.5 Follow-up and monitoring

Follow-up visits are done on day 3 and day 10 or 14 of the trial through home visits. It is therefore important to obtain the mother's correct address in order to minimize loss to follow-up. You will need to do following:

- Use Form 4 (Appendix D) for follow-up on zinc adherence, the mother's reactions towards the zinc, and her perceptions of the child's status. Ask the questions in column A on day 3. Ask the questions in column B on day 10 or 14.
- Check the child for dehydration; if necessary, rehydrate or refer the child to a health facility (if visited at home).
- Ask the mother whether she has any concerns or problems with zinc.

Box 8.1 Guidance for producing an informed consent form

The informed consent form should cover:

- the purpose of the study;
- the methods that will be applied;
- what being a participant in the study entails;
- the advantages of being a participant;
- the disadvantages and possible complications of receiving zinc;
- incentives;
- confidentiality.

The form should also provide a space where the mother can sign to give her consent.

Box 8.2 Guidance on questions to ask to mothers

- 1. How long has the child's diarrhoea lasted now?
- 2. Does the child experience vomiting?
- 3. What is the child's level of dehydration upon consultation?
- 4. Did you give the child ORS before coming to this facility?
 - What kind of ORS did you use?
 - Why did you give this kind of ORS?
- 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 the child's problem was? (Record the answer verbatim.)
 - (If diarrhoea-related:) What kind of diarrhoea is this? What is its cause? Is there a local term for this kind of diarrhoea?
- 7. How severe is the child's diarrhoea?
- 8. Are you breastfeeding your child?
 - If so, are you continuing breastfeeding now?
 - Is breastfeeding increased, reduced, or just the same?
- What is your perception of the child's appetite? Please give a score from 1 to 10, with 1 lowest and 10 the best appetite the child ever had:
 - pre-episode
 - current.
- 10.What is your perception of the child's activity? Please give a score from 1 to 10, with 1 the least active and 10 the most active the child has ever been:
 - pre-episode
 - current.

8.6 Analysing the results of the behavioural trial

In analysing the results of the behavioural trial, remember the two main questions we need to answer: (a) Did the mothers adhere to the zinc therapy for 10 to 14 days? (b) Did the mothers recall and understand the zinc messages?

From the answers to these two questions, we can further explore the data gathered from the trial and find out what factors affected the mothers' adherence or non-adherence to zinc. We can assess the effect of zinc on breastfeeding and intake of ORS, food, milk and other liquids, and medicines such as antibiotics and antidiarrhoeals. We can also examine mothers' perceptions of the effect of zinc throughout the duration of therapy; and the effect of the messages received on how the mothers perceived zinc.

The following sections provide guidance on how the information gathered from the behavioural trial can be processed and analysed to get the answers needed.

The basic tables

The first table that should be prepared must reflect the baseline characteristics of the children recruited into the behavioural trial, as illustrated in Table 8.1(see page 43). Information for this table can be obtained from the screening Form (Form 1 in Appendices) and from the responses to the questions to mothers to gather baseline information (see Box 8.2).

The research team may also need to make a table summarizing the results of the exit interview conducted in the recruitment phase, 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 after the initial consultation. Use Table 8.2 as a template for this table, which will provide information on how mothers interpreted the messages and how they perceived the action of zinc at the time of message delivery.

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

Table 8.2 Template for presenting the results of the exit interviews

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

Characteristic	Number (n=)
Age in months: 1–5 6–11 12–59 range mean	
Sex: male/female	
Birth order: first-born second-born etc.	
Clinical status at time of consultation:	
Duration of diarrhoea: 2 days etc. range mean	
With vomiting	
Degree of dehydration: none some severe	
Number who were given oral rehydration therapy before the consultation: Type of oral rehydration therapy: home-based commercial other	
Number who were given medicine before the consultation: Type of medicine: antidiarrhoeal antipyretic vitamins or minerals others	
Number of children being breastfed: Number of children who continued breastfeeding:	
Average appetite score: pre-episode current	
Average activity score: pre-episode current	

Table 8.1 Template for presenting the baseline characteristics of the recruited children

Characteristic	Day 3 (n=)	Day 10 or 14 (n=)
Child's status now: better worse same		
Number with vomiting in past 24 hours		
Number given ORS in the past 24 hours or given recommended home fluids (specify what fluid was given)		
Number given medicine since clinic check-up If given medicine, what kind		
If status better, reason: better appetite diarrhoea stopped etc.		
If status worse, reason: diarrhoea worse etc.		
Number being breastfed Number who stopped breastfeeding during diarrhoea Reason for stopping breastfeeding		
Number who were given zinc since clinic check-up or since last visit		
For those who were given zinc: number of days zinc was given number of children who experienced vomiting after intake number of mothers who gave less than the daily dose effect of zinc as perceived by the mother: Increased appetite stopped diarrhoea etc. number of mothers who would recommend zinc to others how mothers would explain zinc to others:		
now mothers would explain zinc to others: can cure diarrhoea can increase appetite can make child more active etc.		

Table 8.3 Template for presenting the results of the follow-up interviews

Zinc adherence and factors affecting it

The next task is to analyse zinc adherence and the factors affecting it. To prepare for this analysis, the team should first decide how a zinc-adherent participant should be defined. In the zinc trial, we defined this as an intake of the tablet for 80% of the time. For the day 3 follow-up, this corresponded approximately to an intake of zinc on two out of the three days of observation. You will need to classify the participants according to the definition set, and tally the data using the format of Table 8.4.

		Adherent (n=)	Non-adherent (n=)
Child' status on day 3:	better worse same		
Number with vomiting in the past 24 hours			
Number given ORS in the past 24 hours or given recommended home fluids (specify what fluid was given)			
Number given other medicines			
Type of medicine given: antibiotic antidiarrhoeal other			
Effect of zinc as perceived by the mother	increased appetite stopped diarrhoea etc.		

Table 8.4 Template for presenting the factors affecting zinc adherence on day 3

A table similar to Table 8.4 should also be completed for the day 10 or 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 diarrhoea, 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 Philippines behavioural trial. The table shows whether zinc adherence differed between mothers who used different terms to describe their child's illness.

A similar table may also be prepared for the day 10 or 14 follow-up. For non-adherent mothers, consider whether their perception of the action of the tablet on day 3 differed from that on day 10 or 14.

Message recall

It is important to compare the zinc messages delivered by the health-care provider and through the labelling on the medicine to the attributes of zinc that the mothers report when asked during the exit interview after initial consultation and during the two follow-up interviews. You can put this information in a table similar to Table 8.6, which shows actual data obtained in the Philippines.

During the exit interviews in the Philippines, the mothers seemed to strongly recall the vitamins and resistance messages. On days 3 and 10 or 14, the perception that zinc can cure diarrhoea was strongly recalled. The appetite message, which did not figure very prominently during the exit interview, became more perceptible on day 3 and even more so on day 10 or 14.

This information showed that the health-care providers might not have been emphasizing strongly enough to mothers the main actions of zinc. The health-care providers were therefore advised to play down the action of zinc on the illness (curative effect), and rather to emphasize the specific messages that should be delivered about zinc, especially the resistance and vitamins messages.

	Terms used to describe the illness		
	Diarrhoea (n=)	Diarrhoea+vomiting (n=)	
Condition on day 3: better same	3 0	2 1	
Reasons for better condition	 Better appetite and more active (2 responses) Diarrhoea cured 	 Diarrhoea cured; no more fever and vomiting; better appetite; more active Better appetite and more active 	
With ORS intake in the past 24 hours	2	1	
Effect of ORS	 Diarrhoea 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 	 Diarrhoea 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 (neighbours)	
How would describe zinc to others	 Makes child get better Effective Increases appetite 	 Helps a child with diarrhoea Reduces weakness Effective when child is getting well from diarrhoea 	

Table 8.5 Zinc intake according to illness terms used, Philippines

Table 8.6 Zinc messages delivered and zinc actions reported by mothers, Philippines

Messages	Exit interview: response to	Day 3: perceived effect	Day 10 or 14: perceived
delivered	"What was the medicine for?"	of zinc	effect of zinc
 Zinc increases the appetite of a child with diarrhoea Vitamins for the gut Zinc can increase the child's resistance 	For diarrhoea - 2 responses Vitamins for the stomach - 4 responses To make the child strong - 1 response For resistance of the stomach - 3 responses Increases appetite - 1 response	For diarrhoea - 7 responses To make the child strong - 1 response Increases appetite - 3 responses	For diarrhoea - 7 responses Increases appetite - 6 responses

Data collected from the follow-up interviews on days 3 and 10 or 14 should be reviewed to answer the following questions:

- Which of the zinc messages tested seem to have been best recalled by the mothers?
- Did the mothers understand the messages they received? Do you think that some of the messages need refinement?
- Did the mothers tell anyone else about the medicine? What did they say?
- Did the mothers see zinc as having attributes other than those contained in the messages? What were those attributes?
- Did the mothers understand the instructions regarding zinc administration? Did they correctly prepare and administer zinc? Did they change the method described in 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 diarrhoea, breastfeeding, use of other medicines, perceived effects of zinc, etc.)?

Figure 8.1 Factors affecting zinc adherence

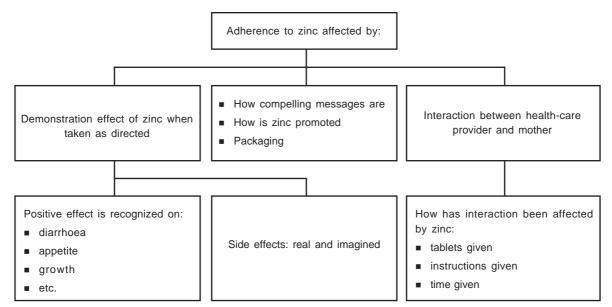
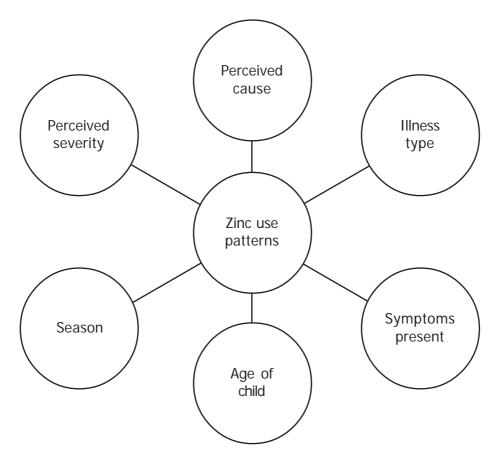


Figure 8.1 shows other factors that can affect zinc adherence. Side-effects, whether real or imagined, are important concerns and should be addressed. The exit interview is an appropriate tool for picking up any concerns the mothers might have at the outset, but comments on negative experiences will also be obtained during the monitoring visits.

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

Figure 8.2 Variables that may affect zinc use



Inputs to the counselling cards

The counselling cards are intended to improve interactions between practitioners and patients. The way health-care providers interact with patients affects mothers' behaviour in regard to seeking health care and adhering to therapy regimes. Aside from providing a standardized response to mothers' questions, the counselling cards aim to enhance communication about zinc. Researchers should attempt to assess whether mothers feel that practitioners are responsive to their concerns, and whether practitioners (and those following up with patients during a trial) feel more confident about addressing mothers' concerns as a result of having these cards on hand.

In the trials, the exit and follow-up interviews were found to be helpful in eliciting more of the concerns that mothers had regarding the medicine. In the Philippines trial, researchers were able to gather queries from respondents that were not anticipated at the beginning of the study, and were not included in the generic issues and concerns prepared before the start of the behavioural trial. These additional concerns elicited during the exit interviews are listed in Table 7.1. Examples of concerns that came up during the behavioural trial are shown in Table 8.7.

In the trials, 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 counselling cards. For instance, promoting zinc as a vitamin took care of questions about the duration of therapy and why zinc still has to be given even after the child is well. Questions about why zinc was being given for just 10 or 14 days, unlike other vitamins, were answered by explaining that the child's gut takes only this long to recover from diarrhoea.

Supporting advice was also prepared to answer questions regarding preparations. Although there was not 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-

Concern	Possible question from the mother	Standard response
Sharing of zinc tablets	Can I give this tablet to my other child who also gets sick with diarrhoea?	No. This pack of 14 tablets is for this child only. This child has to complete 14 days of zinc for its action to take effect. If another child of yours gets sick with diarrhoea, bring that child to the hospital also for appropriate action.
Continued zinc therapy	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 diarrhoea. After 14 days, your child can get zinc from regular food if you give him or her balanced meals.
Zinc and ORS	If ORS has been stopped already, should zinc still be continued?	Yes. ORS is to correct and prevent dehydration, whereas zinc acts on the child's stomach for full recovery.
Zinc for adults	Can zinc be taken by adults?	Yes, there are also zinc preparations for adults, but these tablets that we are giving you are especially formulated for children 2-59 months old.
Allergy to zinc	Can the child develop an allergy to the zinc tablet?	No. Your child will not develop an allergy to zinc.
Zinc for older children	Can zinc be given to older children?	Yes, it can even be taken by adults, but these particular tablets are for this child with diarrhoea.
Tendency to save tablets for future episodes	 Can I save some of these tablets in case my child gets sick with diarrhoea 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 or her to this facility again for appropriate action.
Zinc and a well child	If this zinc acts just like a vitamin or mineral, why is it not given to a well child?	This zinc tablet is not given to a well child because it is especially formulated for a child with diarrhoea to replace the zinc lost during the episode of diarrhoea and to help the child's gut recover from the illness.

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

based foods and fluids, and those with a high sugar content, the instructions were clarified to advise mothers to dissolve the zinc tablet only in water, ORS solution or breast milk, and to give it to the child between meals.

Lessons learned from the behavioural trials will be useful when finalizing the message, procedures and instruments to be 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.

9

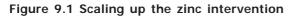
The future for zinc

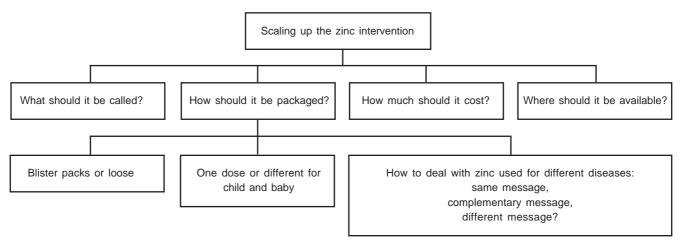
In this guide, we have focused on how to introduce and measure the effectiveness of zinc in a diarrhoeal disease control programme. Ongoing research suggests that zinc may also be useful in the prevention and management of other health problems, such as pneumonia and possibly TB (24–30). If we want to avoid confusion in the future, we should bear possible uses of zinc in mind when introducing zinc to a community as part of a diarrhoeal disease control programme. This is another reason for choosing messages that present zinc as having both a disease control and a health enhancement dimension that is relevant across health problems. We would encourage researchers, when developing zinc messages, to explore cultural concepts related to disease resistance (strength, protection, etc.) that have broad health relevance. Resistance to illness was looked into in some but not all of the 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 low-income mothers in Egypt.

As emphasized in this guide, one of the main challenges in introducing zinc in a diarrhoeal disease control programme is the need to make it clear to mothers that zinc is a complement to ORS and should not be substituted for oral rehydration therapy. The same challenge will face 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 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 has 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 isoniazid (INH) in TB control, especially for children, as "vitamins for the lungs" useful in the treatment of "weak lungs" (*31*). During focus group discussions for the zinc trial, 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 the risk of confusion with multivitamins. It was generally known that some doctors discouraged mothers from giving vitamins to children with diarrhoea until the diarrhoea had stopped. We recognized that zinc would have to be marketed as being a special "vitamin" for the gut, useful in cases of diarrhoea. Also, doctors would have to be educated in how to explain to mothers the difference between multivitamins and zinc. This approach seemed to be feasible.

Another appealing reason for marketing zinc as a "vitamin" is to establish a correct pattern of use. We are aware of the potential misuse of isoniazid as a "vitamin for the lung", in non-TB cases, for example for other types of chronic cough. This problem might be addressed in the future if zinc could be marketed as a vitamin for the lungs as well as the gut. Isoniazid might then be reframed as a medicine specifically for TB and TB-related illness.





Looking to the future, those involved in planning and implementing zinc programmes will also need to consider the factors presented in Figure 9.1, and discussed below, when designing strategies for the wider distribution of zinc.

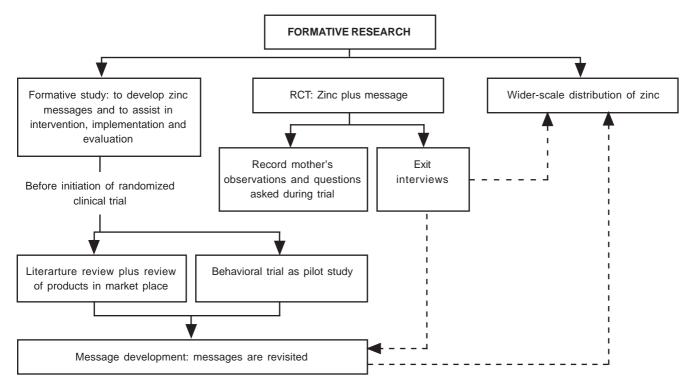
Choosing the right packaging and appropriate messages will require social marketing research that is attentive to market segmentation and target groups. Studies on willingness to pay will need to be conducted to determine zinc's marketability, both in the public health sector and through commercial or private routes. The five-country study and the study conducted in Bangladesh demonstrated that mothers will use zinc and ORS if these are given free of charge. The use of zinc and ORS would also decrease the use of antibiotics. But what if zinc and ORS are sold? Would mothers still use them? Or would mothers use just one of them? How much should zinc cost if it is to be sold as a generic product? And would mothers who purchased zinc in 10-day or 14-day blister packs finish the complete course, or would they keep some tablets in reserve, as they commonly do with other medications (20,31)?

Another question that needs to be considered is how best to train the people who will be responsible for delivering zinc and the zinc messages. As explained in this guide, attention needs to be directed to identifying clients and anticipating questions. Developing and expanding a set of questions and answers, along with standardized counselling cards, will help to root a common core of ideas about zinc in the community. This will lessen the possibility of confusion, and increase the effectiveness of diarrhoeal disease control programmes.

Formative research does not end with the development and implementation of a message. Findings from the research can provide feedback to enhance the distribution of zinc when the programme is already being implemented beyond the pilot stage. Exit interviews done during the first one to two months of actual programme implementation can reveal how accurately the zinc messages are 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 gathered. These additional issues can then be included in the counselling cards.

The steps carried out as part of formative research will be useful in designing larger studies on zinc treatment. The formative research described in this guide is an excellent exercise to prepare teams for larger-scale preparatory work for future zinc interventions.





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Zinc behavioural trial form 1: Screening and recruitment

Study centre:	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 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 diarrhoea > 7 days?	Yes	No
5	Is the child currently receiving zinc ?	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 diarrhoea 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: [][] . []		
12	Consult weight-for-height z-score chartsIs weight or height <-3 SD?	Yes	No

IF YES TO ANY ONE OF THE ABOVE, EXCLUDE

Zinc behavioural trial form 2: Informed consent template for focus group discussions

(The language used in the information sheet that accompanies the consent form should be such that it can be understood by a sixth to eighth year student in the locality of the study area.)

INSTITUTIONAL LETTER HEAD

Information sheet for the group of individuals participating in the research

Introduce yourself and what you are doing.

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

Purpose of the research

Explain in lay person's terms why the research is being done and what is expected from the results.

We would therefore like to find out what you know about, 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......, 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 people who have had similar experiences. This discussion will be moderated by (give name here).

Explain why a particular person is being selected to take part in the focus group discussion, for example as a social-worker, or as a person who has recently experienced the disease, or has a child who had the disease.

The expected duration of the discussion is about an hour.

Risks and discomforts

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

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 treat diarrhoea in this area.

Incentives

You will not be provided with any incentive to take part in the research. You will, however, be reimbursed for your time and travel expenses to a maximum amount of \$

Confidentiality

How will the confidentiality of the data be maintained? This will be difficult, 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 example: The information that we collect from this research project will be kept confidential. Information about you that will be collected during the study will be stored in a file that will not have your name on it. The file will be identified only by a number assigned to it. The list of 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, Data Safety Monitoring Board, your clinician.*).

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. The treatment of your child at this centre 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 Ethical Review Board*), which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about the Ethical Review Board, contact(*name, address, telephone number*).

If you have any questions, you may ask them 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, who 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 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
Moderator's name	Signature of moderator
Date	Place
Witness (name)	Signature
Date	Place

Zinc behavioural trial form 3: Exit interview

Identification

Questions to ask the mother

- 1. What did the doctor or nurse tell you about your child's condition?
- 2. What did the doctor or nurse do to assess your child's condition? What kind of actions or examinations did the doctor or nurse do?
- 3. What were the questions the doctor or nurse 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:) Should the tablets be given as long as the diarrhoea lasts or longer?
- 11. Do you have any question about this new medicine, regarding 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 that your child was chosen to participate in this study? Why?

Zinc behavioural trial form 4: Follow-up

Questions to ask the mother:	A Day 3 follow-up	B Day 10 or 14 follow-up
1. How is your child doing now? Better Worse Same		
2. Did your child experience vomiting during the past 24 hours?		
 3. Did you give your child ORS or home-made solution during the past 24 hours? What kind? What do you think it is for? 		
 4. Did you give your child 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, same] now. If better, what made you think so? no more diarrhoea or diarrhoea better no more vomiting no more fever better appetite more active other If the diarrhoea is better, in what way is the diarrhoea better now? (Verbatim) If you said your child is worse, in what way is the child worse now? more loose stools still with vomiting no appetite still with fever other 		
 6. Before the child got sick, were you breastfeeding? If so, are you still breastfeeding your child now? If yes, is breastfeeding increased, decreased or just the same? 		

Questions to ask the mother:	A Day 3 follow-up	B Day 10 or 14 follow-up
7. How would you rate your child's appetite on a scale of 1(lowest) to 10 (highest)?		
8. How would you rate your child's activity on a scale of 1(lowest) to 10 (highest)?		
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 the zinc?		
11. If yes, for how many days did you give zinc since your consultation at clinic or since the last follow-up?		
12. Did your child experience vomiting after taking zinc?		
 13. On 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?		
18. How much are you willing to pay for enough zinc tablets to last for a 14-day period?		

Dummy tables

Site: _

Major lessons and findings

Baseline = message given to 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 findings (examples)

Type of diarrhoea	Intervention group (percentage using ORS)	Control group (percentage using ORS)
Local name or type		

E

Type of diarrhoea	Child aged 12 months or more (percentage of mothers complaining about zinc)	Baby aged less than 12 months (percentage of mothers complaining about zinc)
Local name or type		

Severity of diarrhoea as classified by mother	Day 3 (percentage of mothers complaining about zinc)	Day 10 or 14 (percentage of mothers complaining about zinc)
Very severe		
Moderately severe		
Mildly severe		

Perceived change in diarrhoea as reported by mother	Day 3 (percentage of mothers complaining about zinc)	Day 10 or 14 (percentage of mothers complaining about zinc)
Much improved		
Moderately improved		
Little improved		
Same		

Severity of diarrhoea as classified by mother	Breastfeeding mother giving child zinc	Breastfeeding mother not giving child zinc
Very severe		
Moderately severe		
Mildly severe		

Type of diarrhoea	Breastfeeding mother giving child zinc	Breastfeeding mother not giving child zinc
Local name or type		