



**USAID**  
FROM THE AMERICAN PEOPLE

# Country Assessment Tool for the Introduction of Zinc in the Clinical Management of Diarrhea

May 2006

This publication was produced for review by the United States Agency for International Development. It was prepared by Grace Adeya of RPM Plus, Phil Harvey of A2Z, Micheline Ntiru of Helen Keller International, and Eric Swedberg and Emmanuel Wansi of BASICS.

**Recommended Citation**

Grace Adeya, Phil Harvey, Micheline Ntiru, Eric Swedberg, and Emmanuel Wansi. 2006. *Country Assessment Tool for the Introduction of Zinc in the Clinical Management of Diarrhea*. Rational Pharmaceutical Management Plus (RPM Plus), A2Z Micronutrient and Child Blindness Project (A2Z), Helen Keller International, and Basic Support for Institutionalizing Child Survival (BASICS) for the United States Agency for International Development (USAID).

This report would not have been possible without the technical and editorial involvement of Jane Briggs of RPM Plus, and Diana Silimperi, Tom Schaetzel, Paul Crystal and Perri Sutton of BASICS.

Support for this publication was provided by USAID/Madagascar and the U.S. Agency for International Development/Bureau for Global Health/Office of Health, Infectious Diseases and Nutrition/Maternal and Child Health Unit.

# Country Assessment Tool for the Introduction of Zinc in the Clinical Management of Diarrhea

## I. Introduction

Since the release of the 2004 WHO and UNICEF revised recommendations for the management of diarrheal disease using the new ORS formulation and zinc therapy in addition to rehydration therapy, many countries are taking steps to incorporate these recommendations into their own strategies, policies and programs. These revisions provide an opportunity for countries to revitalize all of their diarrheal disease control activities. Country assessments engaging stakeholders in the decision-making process are an important first step toward incorporating the new recommendations. USAID has supported such country assessments in Tanzania and Madagascar, and the Madagascar assessment team was requested to document their process and develop a country assessment tool for use in future assessments. The country assessment tool will complement guidelines that WHO is developing for policymakers and program managers for introducing the new strategy for clinical management of diarrhea, and it includes checklists/topic guides for interviews, focus group discussions, and site visits at both national and peripheral levels.

The specific country context will influence the focus and the ability of an assessment team to translate the WHO/UNICEF recommendations into an agreed upon national implementation plan. For example, the assessment team will need to consider the overall environment for child health, and the level of MOH and donor support may vary considerably between countries due to competing priorities. These issues need to be considered when timing an assessment visit and during planning. Ideally an assessment should take place once advocacy for the introduction of the new guidelines has been completed: the primary focus of the assessment team should be to develop a country implementation plan rather than on building consensus for policy change.

## II. Assessment Steps

### **STEPS IN COUNTRY ASSESSMENT FOR THE INTRODUCTION OF ZINC IN THE CLINICAL MANAGEMENT OF DIARRHEA**

- 1. Assembly of a Task Force and Assessment Team**
- 2. Activity planning prior to the assessment**
- 3. Desk review of epidemiology and service statistics**
- 4. Checklist/topic guide development**
- 5. Data collection at the central level**
- 6. Data collection in peripheral sites**
- 7. Validation of field site findings**
- 8. Analysis of data**
- 9. Presentation of Assessment Team findings and development of a draft action plan**
- 10. Debriefing with donors and completion/dissemination of report**

The steps outlined below are suggested as a guideline for country assessment. They are presented sequentially but they may be conducted in parallel to ensure adequate preparation and efficient implementation. Each of these steps is described in detail below.

## **1. Creation of a Task Force and Assessment Team**

A Task Force should be created, led by the MOH, to lead the assessment process and subsequent introduction of the zinc intervention. Two categories of persons will need to participate: an “implementation” group comprising those who will facilitate or implement the intervention in country; and a “technical” group of experts (the assessment team) who will collect and process the data and facilitate discussions during the assessment.

The implementation group will include decision makers in the following program areas: CDD, IMCI, other child health programs, PHC, BCC, Pharmacy, Central Medical Stores, EPI, Nutrition, HMIS, MOH Partners in Child Health (UNICEF, WHO, USAID, etc.) and Medical and Nursing Training schools.

The mix of technical or clinical expertise to be covered in the assessment team should include: CDD, pharmaceutical management and logistics, case management for childhood illness, IEC/BCC, training and quality improvement/supervision, monitoring and evaluation, and experience/knowledge in applying the zinc intervention. If this expertise cannot be found locally, various external organizations or consultants can be of assistance.

Importantly, some individuals may participate in both the implementation and the assessment groups. The optimal size for the assessment group of experts will depend on a number of factors, since larger groups can cover more within a short time, but smaller groups will have more cohesion and reach consensus more easily. A team with three to four experts seems to be ideal. Regardless of the size of the team, strong leadership is important. Importantly, language barriers may pose a challenge when external experts are used, especially because this group will work closely with local partners in all sites visited.

## **2. Activity Planning Prior to the Assessment**

Activity planning includes scheduling a date for in-country activities, setting a timetable of activities and dividing responsibilities among team members.

The assessment team should select dates for the assessment to ensure that most decision makers will be available, no other major activities will compete for the participation of key players; and no major holidays occur during the assessment period.

The assessment team will need to first list all activities and develop a timeline for the completion of each. The list will include a description of the methods (determined by consensus) to be used

for conducting the desk review, finalizing data collection tools, collecting and analyzing data, drafting an action plan, and writing disseminating the assessment report. This planning should include clear delineation of responsibilities among team members, as well as lines, methods and frequency of communication for each member of the team (both in-country and external team members).

Team members and the MOH should begin communicating by e-mail and teleconference several weeks prior to the in-country visit to clarify expectations, share background information, and begin specific activity planning. A partner organization may want to provide communications support if the MOH has limited internet and/or telephone access facilities.

### **3. Desk Review of Epidemiology and Service Statistics**

The desk review must be completed prior to finalizing the data collection tool because information from the review is essential for constructing the tools and also because it is too difficult to complete when combined with other ongoing activities. Unless an MOH staff member can be assigned to the task, identification of a consultant or a partner organization with experience, time and communications resources to conduct the desk review is recommended. Many data sources (*e.g.*, DHS and the MICs) will be easily accessible, but in some countries a substantial amount of useful information is unpublished and found only within the ministry or among in-country implementing partners. Obviously, it is important to start the review early so enough time is available to complete it before data collection begins.

The desk review should cover routine diarrheal disease epidemiology, the organization and current performance of CDD programs or related CDD services, routine data collection, and reporting and data utilization for CDD services (including recommendations for improvement). The following is a sample of questions/topics to guide the desk review:

#### **A. Epidemiology**

- Trends of childhood diarrhea prevalence; and
- Trends of mortality due to childhood diarrhea

#### **B. Service Delivery**

What proportion of children with acute diarrhea were:

- taken to a health facility?
- taken to another care provider (specify)?
- treated with ORS?
- treated with homemade "sugar salt solution"?
- treated with antibiotics?
- treated with other remedies (specify)?

#### **C. What are factors that influence caregivers to treat a child with diarrhea at home and, secondly, to seek care outside of the home?**

#### **4. Checklist/Topic Guide Development**

These guides will include questions to inform the assessment of: (1) MOH policies and legal framework related to current and potential zinc product availability in country; (2) key diarrhea prevention and treatment issues and standard treatment guidelines; (3) pharmaceutical management (procurement, distribution, inventory management); (4) IEC/BCC approaches including mass communications, community mobilization/education and counseling; (5) human resources (pre- and in-service training, supervision and quality improvement); (6) health information systems and opportunities/needs for operations research; (7) the role of the private sector role (for-profit, subsidized social marketing, non-profit); and (7) financing and sustainability.

Draft checklists/topic guides for these topic areas have been developed for central and peripheral level interviews, focus group discussions, and observations. Because these questionnaires were first developed by topic area and then combined for each person/institution to be interviewed (*e.g.*, District Health Officers have in-depth interviews covering several topic areas), they are lengthy and should be reviewed and, if possible, reduced as appropriate in the country context.

Importantly, the attached guides are illustrative and must be adapted for the specific country context based on the desk review.

#### **5. Data Collection at the Central Level**

The sequence of activities in-country typically will include interviews with key informants and meetings with key stakeholders in the capital, and a meeting with the implementation group to identify the strengths, weaknesses and opportunities for the introduction of zinc treatment. These interviews and meetings are then followed by travel to peripheral regions for data collection. Additional interviews are held in the capital following peripheral data collection to discuss findings and to plan next steps, and the team can also collect additional information prompted by the field visits and/or catch up with key informants who may have been unavailable during the first round of interviews.

An exhaustive list of interviewees or groups to be interviewed at the central level is provided below. At the central level all assessment team members should meet with the key members of the MOH Division responsible for child health, and ensure other key stakeholders are engaged, *e.g.* professional organizations, the pharmaceutical industry and regulatory agencies. Visits should be made by the entire group to other key stakeholders including WHO, UNICEF and USAID. Following these initial visits the assessment team should divide into subgroups according to their areas of expertise, pairing external participants with nationals if external experts are participating. For example one subgroup may focus on logistics and pharmaceutical management, another on the BCC component and another on case management and information systems.

## **6. Data Collection in Peripheral Sites**

Criteria for the selection of regions and districts for field visits include diarrhea prevalence, potential as initial implementation sites, and logistics for the assessment team. Visits to both high and low performing facilities are useful since they provide complementary information. Special effort should be made to ensure that selection follows these criteria without external influence.

The number of regions/districts to be visited depends on the diversity of existing CDD activities and related factors that may need consideration for the revival of CDD interventions.

For peripheral field visits, the assessment team should include a central level representative from the MOH and be guided by local staff. At the peripheral level the team should have discussions with key stakeholders in the regions, districts, health centers, and communities. Wherever possible, visits should be made to regional and district pharmacies as well. At the community level, focus group discussions should be held with village health workers, community leaders, and caregivers. Translation will likely be required at the community level.

Whenever possible, debriefings need to be conducted with district and regional staff involved in CDD. This will lengthen the time spent in the field. Regional teams may need to plan for an introductory presentation on zinc to address interest about zinc and its benefits. The assessment team should include any presentations in the plan and prepare technical materials for distribution during visits.

Checklists/topic guides are presented below for each category of facility or actors. During the field visit, different team members may simultaneously administer questionnaires to different individuals. Most health facilities in rural areas are run by only one health worker who therefore has to answer most of the questions. In such cases, only one questionnaire is completed at a time making the second member of the team less productive. When this situation arises, team members should work separately: one can go into the community while the other is working at the health facility. This decision should be discussed with the appropriate district staff prior to the field visit so that districts and health centers can plan for sufficient staff to work with the assessment team.

## **7. Validation of Central and Field Site Findings**

The debriefing sessions in the districts/regions are the first step for validating the assessment findings. The second stage of validation occurs at the central level with a wider group of stakeholders, including MOH partners and other stakeholders. This stage covers major findings, especially points that could be contentious for the MOH. In some circumstances, the MOH may require prior notification of points for discussion at meetings, especially after data collection, as discussions may disclose problems uncovered in the field. This step does not require a written report.

## **8. Analysis of Data Collected**

During this step, the assessment team organizes their notes and begins to analyze and summarize their findings by assessment topic areas in preparation for presentations to the implementation team in the next step.

## **9. Presentation of Assessment Team Findings and Development of a Draft Action Plan**

For the introduction of zinc treatment for diarrhea to be successful, consensus will be necessary among all members of the Task Force. Additionally, representation from “the field” will be necessary to ensure that action plans are realistic.

The assessment team should first present their findings to the Task Force, with an outline of the main steps recommended to facilitate the introduction of zinc. Division of these steps topically (*e.g.*, pharmaceutical management, case management of diarrhea, advocacy, behavior change) may help facilitate discussion. After the presentation, the Task Force should divide into three smaller working groups, based on expertise, for discussion of the steps for each component (or a combination of related components). After discussion, the sub-groups can present their findings and make recommendations for solutions to identified problems in a plenary.

Immediately following presentations, and during the plenary session, a proposed work plan proposing a timeline and assigning responsibilities to appropriate persons/agencies will need to be developed. This sequence enables information generated by the various groups to be built into the plan. This work plan is then submitted to the child health committee or other appropriate official body.

## **10. Debriefing with donors and completion/dissemination of report**

Debriefing by the assessment team for donor agencies involved in the assessment is important for gaining their support and input on next steps. The report will need to be written and disseminated to guide the detailed planning necessary for implementation of the work plan. Initially, a draft report is useful based upon the desk review findings and draft action. The final report will include sections written by the sub-teams that focused on specific elements of the assessment. The report also may require translation for dissemination in-country. After the MOH has identified sources of funding for the introduction of zinc, further detailed planning will be required for each step of zinc introduction.

### III. Topic Guides

#### A. DATA COLLECTION AT THE CENTRAL LEVEL

##### 1. Pharmaceutical Management

###### Drug Regulatory Authority

###### **Regulation**

- What is the regulatory authority for essential drugs?
- What is the process for registering a drug?
- How long does it take on average? Can it be fast tracked?
- Should zinc be registered as a medicine or a food supplement? And why?
- What zinc formulations are currently available in the country? Are they registered by responsible authority?
- Is ORS registered? Is this the new or the old formulation?
- Is there any regulation to facilitate phasing out of old formulation of ORS?
- How is ORS scheduled? How would zinc be scheduled once introduced? What are the implications for who can prescribe or sell it?
- If a drug is pre-qualified and imported by UNICEF or other similar agency does it still need to be registered?

###### **Policies**

- Is there a government policy on good manufacturing practices (GMP)?

###### **Quality Assurance & Pharmacovigilance**

- What systems exist for quality assurance during drug registration and drug procurement?
- Is post marketing surveillance done on a regular basis? How and by whom?
- What systems exist for monitoring adverse drug reactions (ADRs)? Does it need to be adapted? How are results reported? To whom? Have reporting forms been developed?

###### **Human Resources (Specific to Pharmaceutical Management)**

- Who are the staff members? Is there need for consultants/external TA?
- Have human resource needs been identified?
- Are there provisions for training?

###### Directorate of Pharmacy

###### **Policies**

- Is there a policy for private sector distribution?
- Is there a policy for donation of medicines?
- What is the policy on cost recovery or subsidies on medicines in the public sector?
- Are medicines exempt from tax?

## **Quantification**

- Who does the quantification? The procuring agency? A division of the pharmacy board (Salama in Madagascar) or other division of the MoH? Is the quantification decentralized?
- How is quantification of ORS done for diarrhea treatment? By consumption or epidemiological data? Is the data accurate and reliable?
- How accurate are utilization records (patient utilization of facility by disease)?
- In the quantification, did they allow for buffer stocks, shelf life, lead time, current inventory levels, quantities on order etc.?
- Are there systems in place to monitor previous consumption of ORS at the central level?
- Is there a system for reporting drug/ORS consumption from the peripheral levels to the central level?
- Determine the current pipeline of old ORS at central level as well as regional and district stores and also at facility level.
- Has MOH quantification of ORS been harmonized with parallel procurement efforts of other agencies (UNICEF, World Bank, NGOs etc)?

## **Procurement**

- Is procurement centralized or decentralized (buying and paying of drugs)?
- Does all public procurement go through a central medical store (CMS)? What is the capacity of the CMS to manage the procurements?
- Is there an agency that procures essential medicines on behalf of the government? What government division supports or oversees this agency?
- Are there procedures for contracting out procurement to a third party agency e.g. UNICEF, WHO?
- Is there any parallel procurement (UNICEF, World Bank and NGOs)?
- What drugs are procured through UNICEF? ORS?
- Is there a major agency procuring drugs for the mission sector?
- Does the government provide direct financial support for CMS and is there anybody else providing support?
- What are the procurement procedures? How often is procurement done? What is the time taken to prepare the order?
- Is there a system for supplier prequalification and performance monitoring?
- Who are the major suppliers to the public and private sectors?
- What is the average procurement lead time by supplier for the public sector?
- What is the cost of procurement mechanism? If done by an agency are there associated fees? Differentiate between procurement and storage fees.
- What is the rate of import tax on medicines or on imported raw materials?

## **Finance and Resource Mobilization**

- Identify funding sources for zinc and ORS procurement? Are there any other potential sources of funding?
- What is the total current budget for ORS procurement (MOH and other funds)?
- What is the total current budget needed for scale up?
- Is payment for procured drugs decentralized?

- Is there a cost recovery scheme? Are there exemptions and how do these exemptions work?
- Are there price controls on medicines sold either in the public or private sector?

### **Introduction of New Stock of ORS**

- Is there a national plan for the introduction of the new ORS formulation?
- Determine pipelines at central and peripheral levels (both private and public) of old ORS formulation.
- Provision for adjusting future procurements.

### **Distribution**

- Is there a kit, push or pull system for essential drugs?
- Are there parallel distribution systems for distribution of certain drugs?
- How ORS and other IMCI treatment and prevention commodities are currently distributed?
- Are there regional and districts stores? What is their role?
- Do facilities have drugs delivered or do they have to go and fetch them?
- What is the average lead time between facilities ordering and receiving drugs?
- What is the periodicity frequency of orders/receiving?
- What is the current status of community-based treatment of diarrhea, ARI and malaria? Do CHWs provide drugs? If so which ones and how do they get them?
- Is there a system to monitor the efficiency of the distribution system?
- What are the indicators used to monitor or evaluate the distribution system? Are drugs, especially ORS generally available? What drugs are most often out of stock? At what levels?
- What systems exist for coordination between public and private sectors to improve distribution?

### **Inventory Management**

- What is the status of the inventory management system at central and peripheral levels? Are records computerized?
- Are physical inventories conducted? How frequently?
- Are stock cards used and up to date (accurate/correspond to physical stock?)
- What systems exist to remove expired stocks or drugs near to expiry?
- Are there Pharmaceutical Management Information Systems (PMIS) in place? What are they? What information is reported and to where? Is this integrated into the larger HMIS?

### **Storage**

- What security measures are in place to prevent theft?
- What is the storage capacity and condition?
- Are there guidelines for good storage practices (i.e. first-in/first-out)

## **Transport**

- How are drugs transported from the CMS to the peripheral stores? And then to the facilities?
- How long does it take to move drugs from the CMS to the district store?
- Is this public or contracted out? Are there procedures for contracting this out?
- What are the constraints to ensuring an efficient transportation system?

## **Monitoring and Evaluation**

- Do they have a PMIS?
- Do they use the system as part of decision making?
- Is there a need to adapt existing systems?

## **Rational Drug Use**

- Is there any study/assessment that has documented the use of antibiotics, ORS, antidiarrheals in management of diarrhea in children? In the public as well as private sector.
- Is there a need to investigate current antibiotic use and prescribing practices for diarrhea treatment before zinc supplements become available in order to monitor/evaluate the impact of zinc on irrational antibiotic use?
- Would there be a need for TA?

## **Human Resources (Specific to Pharmaceutical Management?)**

- Who are the staff members and what are their roles? Is there need for external TA?
- Have human resource needs been identified?
- Are there provisions for training?

## **Procurement Unit or Central Medical Stores**

### **Quantification**

- Who does the quantification? The procuring agency? A division of the pharmacy board or other division of the MoH? Is the quantification decentralized?
- How is quantification of ORS done for diarrhea treatment? By consumption or epidemiological data? Is the data accurate and reliable?
- How accurate are utilization records (patient utilization of facility by disease)?
- In the quantification, did they allow for buffer stocks, shelf life, lead time, current inventory levels, quantities on order etc.?
- Are there systems in place to monitor previous consumption of ORS at the central level?
- Is there a system for reporting drug/ORS consumption from the peripheral levels to the central level?
- Determine the current pipeline of old ORS at central level as well as regional and district stores and also at facility level.
- Has MOH quantification of ORS been harmonized with parallel procurement efforts of other agencies (UNICEF, World Bank, NGOs etc)?

## **Procurement**

- Is procurement centralized or decentralized (buying and paying of drugs)?
- Does all public procurement go through CMS? What is the capacity of the CMS to manage the procurements?
- Is there an agency that procures essential medicines on behalf of the government? What government division supports or oversees this agency?
- Are there procedures for contracting out procurement to a third party agency e.g. UNICEF, WHO?
- Is there any parallel procurement (UNICEF, World Bank and NGOs)?
- What drugs are procured through UNICEF? ORS?
- Is there a major agency procuring drugs for the mission sector?
- Does the government provide direct financial support for CMS and is there anybody else providing support?
- What are the procurement procedures? How often is procurement done? What is the time taken to prepare the order?
- Is there a system for supplier prequalification and performance monitoring?
- Who are the major suppliers to the public and private sectors?
- What is the average procurement lead time by supplier for the public sector?
- What is the cost of procurement mechanism? If done by an agency are there associated fees? Differentiate between procurement and storage fees.
- What is the rate of import tax on medicines or on imported raw materials?

## **Finance and Resource Mobilization**

- Identify funding sources for zinc and ORS procurement. Are there any other potential sources of funding?
- What is the total current budget for ORS procurement (MOH and other funds)?
- What is the total budget necessary for scale up?
- Is payment for procured drugs decentralized?
- Is there a cost recovery scheme? Are there exemptions and if so, how do these exemptions work?
- Are there price controls on medicines sold either in the public or private sector?

## **Introduction of New Stock of ORS**

- Is there a national plan for the introduction of the new ORS formulation?
- Determine pipelines at central and peripheral levels (both private and public) of old ORS formulation.
- Provision for adjusting future procurements.

## **Distribution**

- Is there a kit, push or pull system for essential drugs?
- Are there parallel distribution systems for certain drugs?
- How are ORS and other IMCI treatment and prevention commodities currently distributed?
- Are there regional and districts stores? What is their role?
- Do facilities have drugs delivered or do they have to go and fetch them?
- What is the average lead time between facilities ordering and receiving drugs?

- What is the periodicity frequency of orders/receiving?
- Do CHWs provide drugs? If so, what is their source?
- Is there a system to monitor the efficiency of distribution systems?
- What are the indicators used to monitor or evaluate the distribution system? Are drugs, especially ORS generally available? What drugs are most often out of stock? At what levels?
- What systems exist for coordination between public and private sectors to improve distribution?

### **Inventory Management**

- What is the status of the inventory management system at central and peripheral levels? Are records computerized?
- Are physical inventories conducted? How frequently?
- Are stock cards used and up to date (accurate/correspond to physical stock)?
- What systems exist to remove expired stock or drugs near to expiry?
- Are there Pharmaceutical Management Information Systems (PMIS) in place? What are they? What information is reported to where? Is this integrated into the larger HMIS?

### **Storage**

- What security measures are in place to prevent theft?
- What is the storage capacity and condition?
- Are there guidelines for good storage practices (i.e. first-in/first-out)?

### **Transport**

- How are drugs transported from the CMS to the peripheral stores? And then to the facilities?
- How long does it take to move drugs from the CMS to the district store?
- Is this public or contracted out? Are there procedures for contracting this out?
- What are the constraints to ensuring an efficient transportation system?

### **Drug Wholesalers**

- From where do wholesalers import (countries and suppliers)?
- To where do they supply?
- Do they transport their products to facilities, do they contract out the transportation, or do the clients come to collect their orders? Is there a system in place to collaborate with the public sector to support the distribution of supplies?
- Do they sell/distribute generic drugs or only branded drugs?
- Do they import any raw materials? Or just finished products?

### **Private Sector Distribution**

- Is ORS available and distributed in the private sector? By what type of outlets?
- Has there been a discussion on zinc distribution in the private sector? What is the current and future role of the private sector in zinc and ORS provision?
- What is the current status of community-based treatment of diarrhea but also ARI and malaria?

- Have there been any discussions on innovative strategies/partnerships with the private sector to improve access?
- What are the brands and formulations available of ORS and zinc supplements? Determine the amount of available zinc in each of the brands.

### **MoH Coordination Unit for Private Sector and Professional Associations**

- What zinc formulations are currently available in the country?
- Are they registered?
- Is ORS registered? Is this the new or the old formulation?
- What schedule is ORS? What schedule would zinc be once introduced? What are the implications for who can prescribe or sell it?

### **Private Sector Distribution**

- Is ORS available and distributed in the private sector? By what type of outlets?
- Has there been a discussion on zinc distribution in the private sector? What is the current and future role of the private sector in zinc and ORS provision?
- What is the current status of community-based treatment of diarrhea but also ARI and malaria?
- Have there been any discussions on innovative strategies/partnerships with the private sector to improve access?
- What are the brands and formulations available of ORS and zinc supplements? Determine the amount of available zinc in each of the brands.

### **Local Pharmaceutical Manufacturers**

#### **Local Production Capacity**

- What local manufacturers exist and what do they manufacture?
- Do they comply with GMP?
- Is there a local production capacity for both zinc syrup and tablets? If none exists; is it feasible to establish the local production (capital, technical, viable market)?
- Is there private sector interest to produce and supply ORS and zinc? (For this a rough quantification may be required, e.g. based on ORS supply and for each 2 sachets of ORS count 10 tabs of zinc, although this is inaccurate and depends on the current supply and demand for ORS)
- What incentives (disincentives) are there for local production?
- Is there a policy/plan for local production (public and private)?
- What type of TA is needed for local production?

### **UNICEF**

- Does UNICEF procure ORS for the MoH?
- If so is it the new formulation?
- Is ORS registered in the country?
- If UNICEF imports and procures the drugs, do the drugs still have to be registered?
- Does UNICEF have the capacity to handle procurement of zinc?

## **Procurement Division of Faith Based Organizations**

### **Procurement**

- Is there a major agency procuring drugs for the mission sector?
- Does the government provide direct financial support for CMS and is there anybody else providing support?
- What are the procurement procedures? How often is procurement done? What is the time taken to prepare the order?
- Is there a system for supplier prequalification and performance monitoring?
- Who are the major suppliers?
- What is the average procurement lead time by supplier for the public sector?

### **Distribution**

- How are ORS and other IMCI treatment and prevention commodities currently distributed?
- Do facilities have drugs delivered or do they have to go fetch them?
- What is the average lead time between facilities ordering and receiving drugs?
- What is the periodicity frequency of orders/receiving?
- Is there a system to monitor the efficiency of the distribution system?
- What are the indicators used to monitor or evaluate the distribution system? Are drugs, especially ORS generally available? What drugs are most often out of stock? At what levels?
- What systems exist for coordination between public and private sectors to improve distribution?

### **Inventory Management**

- What is the status of the inventory management system at central and peripheral levels? Are records computerized?
- Are physical inventories conducted? How frequently?
- Are stock cards used and up to date (accurate/correspond to physical stock)?
- What systems exist to remove expired stock or drugs near to expiry?
- Are there Pharmaceutical Management Information Systems (PMIS) in place? What are they? What information is reported to where? Is this integrated into the larger HMIS?

### **Storage**

- What security measures are in place to prevent theft?
- What is the storage capacity and condition?
- Are there guidelines for good storage practices (i.e. first-in/first-out)?

### **Transport**

- How are drugs transported to the facilities?
- How long does it take?
- Is this public/contracted out or are there procedures for contracting this out?
- What are the constraints to ensuring an efficient transportation system?

## **2. Information, Education and Communication**

### **Ministry of Health IMCI Department and/or CDD Program**

#### **IMCI and C-IMCI Training**

- What training exists for the treatment of diarrhea?
- Who is trained and by who?
- What types of training exist to educate the population about the treatment of diarrhea?

#### **IMCI Guidelines**

- Who was responsible for preparing IMCI guidelines?
- Who would be responsible for modifying these guidelines to include the zinc component?
- What are the types of media used to educate the community on the treatment of diarrhea?
- Is there a department for communication responsible for all communication materials?

### **Pharmacists and their Sales Assistants in the Capital City**

- What types of communication do they receive when a new product is introduced on the market?
- Observe meetings between pharmacists and their clients.
- Observe whether there are communication materials in pharmacies, stores or depots where pharmacists work.

### **NGO Active in Child Survival**

- Who is responsible for the nutrition/child survival trainings for this NGO?
- What types of child health campaigns have you implemented?
- Where they successful? How could they be improved?
- Review communication materials and note your impression of the quality and of the specific messages used.
- What are their messages specific to the treatment of diarrhea?
- Do you think materials for diarrheal treatment are adequate? How could they be improved?
- Which type of media is most appropriate for health/nutrition campaigns at the community level?
- What kind of materials do you use to educate individuals at the community level on diarrheal treatment? What kinds of materials do you think are the most appropriate for this level?
- What are the opportunities for BCC activities relating to diarrheal treatment?
- What are challenges for BCC activities relating to diarrheal treatment?
- What are the threats for BCC activities relating to diarrheal treatment?

### **3. Diarrhea Prevention and Treatment**

#### **Ministry of Health IMCI Department and/or CDD Program**

- To what extent have the standard WHO IMCI guidelines been modified in the country? The team will like to review the complete IMCI package of guidelines, training materials, associated communication materials.
- What pre-service IMCI training curriculums exist for medical and paramedical cadres?
- What is the current IMCI in-service training curriculum?
- Has there been a recent review of the national IMCI program? If so, what were the main findings and recommendations?
- Is there a program for diarrheal disease control that is separate from IMCI?
- Which organizations in the country are involved in promoting the use of IMCI guidelines?
- What proportion of health workers have been trained in IMCI procedures? Does this proportion vary across different regions of the country?
- What proportion of sick children who are brought to health facilities are treated according to IMCI guidelines? Is this proportion increasing, decreasing, or steady?
- What is the standard treatment given to children brought to health facilities with acute diarrhea? How about children with chronic diarrhea?
- Is the standard practice to use packets of ORS or to teach care givers how to make home made "sugar salt solution"?
- Are there plans to modify other components of the IMCI protocol e.g. malaria treatment?
- On the very practical side of things, in what electronic format are the current guidelines? Who will be responsible for modifying these guidelines? Is TA needed? Who will pay for the reproduction?
- How experiences/lessons from previous introductions of new health technologies are relevant to the introduction of zinc, e.g. ACT for malaria, GAVI?

#### **Human Resources and Finance**

- What plans are there for refresher training of health workers (facility and community) that will be an opportunity to introduce zinc treatment.
- How much do different types of diarrhea treatment currently cost (include both consultation fees and drug costs)?
  - acute diarrhea at home
  - acute diarrhea in community
  - acute diarrhea in facility
  - severe diarrhea in facility
  - diarrhea with blood in stools in facility
- How much will it cost to add zinc tablets?
- What options are there for financing the addition of zinc?

## **4. Health Information System**

### **Health Information System Focal Point at the Ministry of Health**

- How are data collection and transmission organized within the MOH
- Which data are available on the control of diarrhea diseases? (Cases seen, treatment, stock of ORS)
- Do the forms contain the IMCI classification?
- How are data processed? What is the frequency
- What uses are made of data? Any retro information? If yes, what is the frequency?
- Any examples of data utilization for action? Any example for diarrhea diseases?
- Is it possible to modify data collection forms to add a new compound? If yes, what is the process?
- Are there any data generated at community level? If yes, are there any community based data integrated into the district and national data? If yes which data?
- What are the challenges to managing data at central and peripheral levels?

## **B. DATA COLLECTION AT THE REGIONAL AND DISTRICT LEVELS**

### **1. Pharmaceutical Management**

#### **Regional District Stores**

##### **Quantification**

- Who does the quantification?
- How is quantification of ORS done for diarrhea treatment? Using consumption data or epidemiological data? Are the data precise and reliable?
- Is the health system utilization data by patient and by disease reliable?
- Determine whether quantification includes buffer stocks, the expiry dates of the products, the procurement lead time, the levels of remaining stocks, and quantities on order.
- Is there a system for reporting information on the consumption of drugs (including ORS) from the peripheral levels to the central level?
- What is the existing quantity of old formulation ORS stock?

##### **Distribution**

- Are there parallel systems of distribution for certain drugs?
- How are ORS, drugs and other commodities for prevention currently distributed?
- Are the drugs delivered to the structures or do the staff of the structures have to come themselves to collect them?
- How long on average is the time between ordering and receiving drugs?
- What is the frequency of orders?
- Who currently treats diarrhea and malaria at the community level?
- Do ASCs (community health agents) provide drugs? If so, which drugs and how do they obtain them?
- Is there a mechanism to monitor the system of distribution? If so what indicators are used?
- Are the drugs, particularly the ORS, generally available? Which drugs are most frequently out of stock? At which levels are these stock-outs recorded?

##### **Inventory Control**

- What is the status of inventory management? Is there a computerized system?
- Are physical inventories of stock carried out? If so, at what frequency?
- Are there stock cards and are they updated and accurate (does the stock balance recorded correspond to the remaining stock)?
- Is stock rotated according to first expiry first out (FEFO)? Is there a mechanism to dispose of expired stock or to move drugs that have a short shelf life?
- Is there a Pharmaceutical Management Information System (PMIS)? What information is reported and to where? Is this information integrated into the larger SIGS?

### **Storage**

- What security measures are in place to avoid theft?
- What is the storage capacity and condition?
- Are there guidelines for good storage practices?

### **Transport**

- How are drugs transported from the central medical stores to the peripheral stores?
- Is the transport of drugs managed by a public body or contracted out to a private transporter?
- How long does it take to transport drugs from the CMS to the district store?
- What are the obstacles to an effective drug transport system?

## **2. Information, Education and Communication**

### **Regional and District MOH and Other Local Partners**

- Are there health education sessions in health facilities? How much time is spent? How many people participate? What are the principal materials, messages, and monitoring methods used?
- Is mass media used (radio, television)? How often? What are the principal messages and monitoring methods used?
- Are visits made to households? How much time is spent? What are the principal messages and monitoring methods used?
- What are the principal messages and materials used for interpersonal consultations?
- What are the primary difficulties in the control and treatment of diarrhea?
- What is the perception of the population on the best treatment for diarrhea?

### **District Based NGO Active in Child Survival**

- Who is responsible for the nutrition/child survival trainings for this NGO?
- What types of child health campaigns have you implemented?
- Where they successful? How could they be improved?
- Review communication materials and note your impression of the quality and of the specific messages used.
- What are their messages specific to the treatment of diarrhea?
- Do you think materials for diarrheal treatment are adequate? How could they be improved?
- Which type of media is most appropriate for health/nutrition campaigns at the community level?
- What kind of materials do you use to educate individuals at the community level on diarrheal treatment? What kinds of materials do you think are the most appropriate for this level?
- What are the opportunities for BCC activities relating to diarrheal treatment?
- What are challenges for BCC activities relating to diarrheal treatment?
- What are the threats for BCC activities relating to diarrheal treatment?

### **3. Diarrhea Prevention and Treatment**

#### **Regional and District MOH and Other Local Partners**

- Approximately how many U5 children are treated per month? What is the U5 mortality due to diarrheal disease?
- What is the availability of ORS in health centers, the private sector (pharmacies, private clinics, kiosks, etc) and elsewhere in the communities? How often do ORS stock-outs occur? What are the reasons for the stock-outs?
- What is the standard treatment given to the children who are brought to the health center with acute diarrhea? And for children with chronic diarrhea?
- What is the management of children with serious cases of dehydration at the health centre?
- Which oral rehydration therapy methods are used (ORS sachets, homemade sugar and salt solution, others)?
- What is the availability and use of chlorine for disinfection of water?
- What is the frequency of use of ORS per month during the last year?
- What is the cost of ORS and consultations?
- What is the functionality of the ORT corner in the health center?

#### **Human Resources and Financial Access**

- What proportion of medical personnel have been trained in IMCI protocols?
- Is there follow-up to IMCI training? If so, how often?
- What are you doing or what have you done to improve the quality of the services provided? (quality improvement initiatives)
- Is it difficult for parents to pay for ORS? What is done when parents are unable to purchase ORS at the health facility?
- What is the local population's capacity to pay for ORS?
- Compare the prices of ORS between the public sector and private sector.
- Is there a systematic review of services or is supervision focused on certain areas?
- If there is a supervision guide, how is the case management of diarrhea included?

#### **Private Pharmacists and Sales Assistants**

- What types of communication do they receive when a new product is introduced on the market?
- What is the standard treatment given to the children who are brought to the pharmacies with acute diarrhea? And for children with chronic diarrhea?
- Do pharmacists and sales assistants look for any special signs in children presenting with diarrhea
- Observe interactions between pharmacists and their clients especially involving children
- Observe whether there are communication materials in pharmacies, stores or depots where pharmacists work.

## **4. Health Information System**

### **District Level Health Information System Focal Point**

- Are data collection forms completed and received from everyone who is expected to submit?
- Discuss data analysis methods and use. (computerized, manual tally)
- Discuss utilization of data based on real examples? Any for diarrhea?
- Discuss challenges related to data collection and analysis with a focus on diarrhea diseases
- Review data displayed (tables, charts). Are diarrhea data among those monitored? If yes, what specifically is monitored (total number? dehydration?)
- What is the frequency and content of feedback?
- Is any data from community level included in statistics at the intermediate and district levels?
- Is it possible to collect and include data on zinc treatment and stock?

## **C. DATA COLLECTION AT THE HEALTH CENTER LEVEL**

### **1. Pharmaceutical Management**

#### **Health Center Pharmacist**

##### **Quantification**

- Who does the quantification?
- How is quantification of ORS done for diarrhea treatment? Using consumption data or epidemiological data? Are the data precise and reliable?
- Is the health system utilization data by patient and by disease reliable?
- Determine whether quantification includes buffer stocks, the expiry dates of the products, the procurement lead time, the levels of remaining stocks, and quantities on order.
- Is there a system for reporting information on the consumption of drugs (including ORS) from the peripheral levels to the central level?
- What is the existing quantity of old formulation ORS stock?

##### **Distribution**

- How are ORS, drugs and other commodities for prevention currently distributed?
- Are the drugs delivered to the facilities or do the facility staff have to collect them?
- How long on average is the time between ordering and receiving drugs?
- What is the frequency of the orders?
- Who currently treats diarrhea and malaria at the community level?
- Do ASCs (community health agents) provide drugs? If so, which drugs and how do they obtain them?
- Is there a mechanism to monitor the distribution system? If so what indicators are used?
- Are drugs, particularly the ORS, generally available? Which drugs are most frequently out of stock? At which levels are these stock-outs recorded?

##### **Inventory Control**

- What is the status of inventory management? Is there a computerized system?
- Are physical inventories of stock carried out? If so, at what frequency?
- Are there stock cards and are they updated and accurate (does the stock balance recorded correspond to the remaining stock)?
- Is stock rotated according to first expiry first out (FEFO)? Is there a mechanism to dispose of expired stock or to move drugs that have a short shelf life?
- Is there a Pharmaceutical Management Information System (PMIS)? What information is reported and to where? Is this information integrated into the larger SIGS?

##### **Storage**

- What security measures are in place to avoid theft?
- What is the storage capacity and condition?
- Are there guidelines for good storage practices?

## **Transport**

- How are drugs transported from the peripheral stores to facilities?
- How long does it take to transport drugs from the district store to facilities?
- What are the obstacles to an effective drug transport system?

## **Private Drug Wholesalers or Retailers**

- Where do you get your stock (country and suppliers)?
- Is there collaboration with the public sector to facilitate the distribution of products?
- Are the drugs distributed generic or brand name drugs?

## **Community Agents**

- Where do obtain your drug stock?
- How do you track your drug stock?
- Note the costs of each type of drug.

## **2. Information, Education and Communication**

### **Facility Health Workers**

- Review all available IEC materials related to nutrition, IMCI, and child survival.
- Does the health worker have enough materials/tools/job aids to help with their work?
  - If not, which materials does the health worker wish to have?
- Observe a counseling session for the treatment of diarrhea and/or any other topic related to the nutrition/health of children. What communication materials are used during the session? What tools for training (job aids) are relevant?
- Have you received information on campaign X? Mention a health campaign which is in progress or recent campaign by PSI or another social-marketing organization/Ministry of Health event.
- When was your last nutrition/child survival training?
- Summarize your activities related to IMCI? Have you received training in IMCI? When? Do you have materials/guides/algorithms which contain information on IMCI? (Review the materials available)
- How would you advise a mother who has a child with diarrhea?
- Do mothers follow your advice on the treatment for diarrhea? If so, how? If not, why?
- What diarrheal treatment practices are common in your community?
- Do mothers use ORS for diarrhea treatment? If not, why?
- Have you heard about zinc in the treatment of diarrhea? If yes, what do you know about zinc?
- How are you informed of current events in your community?
- Apart from the CSB from where do you receive information on health?

## **Pharmacy Agent**

- What types of communication do you receive when a new product is introduced in the market?
- Is this communication adequate? How can it be improved?
- What types of communication would you like to receive when a new product is introduced?
- Which drugs are purchased for the treatment of diarrhea? What information do you give to people when they buy this drug for the treatment of diarrhea?
- Do people ask for additional information when they buy drugs? Give examples.
- Who are your primary customers, men or women?
- Which drugs do you sell the most?
- Do you know what ORS is? Do you sell ORS? What is your selling price for ORS? In your view, is this price affordable for your customers?
- Do you know anything about zinc? What is zinc?
- Observe a meeting between the pharmacy vendor and the customers.
- Are there communication materials in pharmacies/stores/depots? What types of materials?

## **3. Diarrhea Prevention and Treatment**

### **Facility Health Workers**

- Approximately how many U5 children are treated per month? What is the U5 mortality due to diarrheal disease?
- How do health personnel manage diarrhea cases? When do you refer cases to the next level of care?
- Find at least 5 to 10 cases with the diarrhea to evaluate case management practices: fluids at home, use of ORS, antibiotics, other antidiarrhetics, injections, intravenous solutions, or other therapies.
- What is the availability of ORS in the health centers. See the monthly reports and pharmacy records (stock cards). Note stock-outs and the reasons for these stock-outs.
- What is the availability and use of chlorine for disinfection of water.
- What is the cost of ORS and a consultation? What proportion of families cannot pay?
- Are there mechanisms to address the needs of those who cannot pay?
- What is the functionality of the ORT corner in the health center?
- Are there health education sessions? How much time is spent? How many people participate? What are the principal materials, messages, and monitoring methods used?
- Is mass media used (radio, television)? How much time is spent? What are the principal messages and monitoring methods used?
- Are visits made to households? How much time is spent? What are the principal messages and monitoring methods used?
- What are the principal messages and materials used for interpersonal consultations?
- What is the perception of the population on the best treatment for diarrhea?
- What are the primary difficulties in the prevention and the treatment of diarrhea?

- What are your suggestions?
- What new approaches to the treatment of diarrhea are you aware of?

### **Human Resources and Financial Access**

- When and what was the most recent training provided covering IMCI or other topics related to childhood illness?
- What was the most useful aspect of this training?
- Were you able to apply what you learned in this training with your work?
- Was there follow-up to this training? When and how much time was spent?
- How is the quality of your work measured?
- What are you doing or what have you done to improve the quality of the services provided? (quality improvement initiatives)
- Is it difficult for parents to pay for ORS? What is done when parents are unable to purchase ORS at the health facility?
- How are payment exemptions applied?
- How are drug and service prices determined?

## **4. Health Information System**

- Have any staff within the facility been trained in IMCI or CDD?
- Check the monthly reports for quality.
- Review patients' data in forms and registers for completeness. Are diarrhea cases registered based on IMCI classification for staff trained in IMCI or CDD? Is there space provided for that on the form?
- Review any data display (Tables, graphs); how old the display
- Any Data analysis and utilization at that level? Get real examples and probe any on diarrhea diseases
- Does the center get any feedback from the higher level??
  - If yes, which, what is the frequency and content of feedback
- Are there any data collected at community level?
- What are the challenges related to collecting, analyzing, using and transmitting data on DD?

## **D. DATA COLLECTION AT THE COMMUNITY LEVEL**

### **1. Pharmaceutical Management**

#### **Community Health Agents Who Treat Diarrhea**

- Where do they get to their stock of drugs and/or ORS?
- What quantities do they give?
- How do they keep track of their stock?
- Note the costs of each type of drug.

#### **Depots and Retailers**

- Where do they get their stock? Country and supplier name.
- Do they distribute generic drugs or drugs from major pharmaceuticals?
- What do you give for diarrhea?
- Note the cost of each type of ORS, antibiotic and antidiarrheal (minimum, maximum, and the most sold).

### **2. Information, Education and Communication**

#### **Community Health Agents Who Treat Diarrhea**

- Observe a counseling session for the treatment of diarrhea and/or any other topic related to the nutrition/health of children. What communication materials are used during the session? What tools for training (job aids) are relevant?
- Is mass media used (radio, television)? How often? What are the principal messages?
- How often do you make house visits? What are your primary activities?
- What are the primary difficulties in the prevention and the treatment of diarrhea?
- What are your suggestions?
- What new approaches to the treatment of diarrhea are you aware of?
- Observe a counseling session for the treatment of diarrhea and/or any other topic related to the nutrition/health of children. What communication materials are used during the session? What tools for training (job aids) are relevant?
- Review all available IEC materials related to nutrition, IMCI, and child survival.
- Does the health worker have enough materials/tools/job aids to help with their work?
- If not, which materials do you (the health worker) wish to have?
- Have you received information on campaign X? Mention a health campaign which is in progress or recent campaign by PSI or another social-marketing organization/Ministry of Health event.
- When was your last nutrition/child survival training?
- Summarize your activities related to IMCI? Have you received training in IMCI? When? Do you have materials/guides/algorithms which contain information on IMCI? (Review the materials available)

- How would you advise a mother who has a child with diarrhea?
- Do mothers follow your advice on the treatment for diarrhea? If so, how? If not, why?
- What diarrheal treatment practices are common in your community?
- Do mothers use ORS for diarrhea treatment? If not, why?
- Have you heard about zinc in the treatment of diarrhea? If yes, what do you know about zinc?
- How are you informed of current events in your community?
- Apart from the CSB from where do you receive information on health?

### **Focus Group with 7-10 Mothers**

- From where do you receive information on health, nutrition and care of children in your community?
- Which are the diseases that affect the children in this community the most?
- Who buys medicines in this family? From where?
- Have you had information on campaign X? Mention a health campaign which is in progress or recent campaign by the MOH or other NGOs in the community.
- Do you have children? Of what age?
- During the past year, how many times has your child of X age had diarrhea? Pick a mother with a young child.
- In your opinion how do children get diarrhea?
  - Probe – Through food? Hygiene? Others? How? Why?
- When a child suffers from diarrhea, what do you give him or her to eat? What food? In what quantity? Frequency? Duration?
- Apart from food, what else do you give children with diarrhea? Home prepared solutions? How are they prepared? Do you give ORS? How do you prepare it? For each food/liquid mentioned – why do you give this food/liquid? Do you give medicines? Herbal teas? Others? What? Why?
- Is there anything that is forbidden for a child with diarrhea to eat/drink? What? Why?
- If a mother gives ORS, ask, “from where do you receive ORS?”
- If a mother does not give ORS, ask, “have you heard about ORS? From where? Why do you not use it?”
- From where do mothers receive information on the treatment of diarrheal diseases?

### **Focus Group with 7-10 Fathers**

- Do you have children? Of what age?
- From where do you receive information on social events in your community?
- From where do you receive information on health/nutrition/care of children in your community?
- What is the disease that affects children in this community the most?
- Who buys medicines for the family? From where are these medicines bought?
- Have you received information on campaign X? Mention a health campaign which is in progress or recent campaign by the MOH or other NGOs in the community.
- In your opinion, how should diarrhea be treated?
- If you need advice on child health and nutrition, who do you ask?

### **Focus Group with 3-7 Community Leaders**

- What is your role in this community?
- Do you have children? Of what age?
- How do you disseminate information on the social events in your community?
- Do you help with health activities? Which ones?
- Do you have any materials concerning health? Which ones? Ask to see them.
- What are the diseases that affect children in this community the most?
- Have you had information on campaign X? Mention a health campaign which is in progress or recent campaign by the MOH or other NGOs in the community.
- In your opinion, how should diarrhea be treated? Who taught you how to treat diarrhea?

## **3. Diarrhea Prevention and Treatment**

### **Community Health Agents Who Treat Diarrhea**

- How do community agents manage diarrhea cases? When and how do they refer serious cases to health facilities?
- What is their technique for teaching mothers how to make “the sugar salt solution” at home?
- What is the availability of ORS?
- What is the availability and use of chlorine for disinfection of drinking water?

## **4. Health Information System**

### **Community Health Agents Who Treat Diarrhea**

- Which data are collected on DD? Are there records of ORS or any product used for diarrhea diseases?
- Which tools are used for data collection? (forms, registers)
- Check the way data is entered and used (are graphs and other methods of analysis used?).
- Does anybody provide support to collect, understand and use the data?
- What is the purpose of the data and is it utilized at the community level?
- Is there any feedback from the health center, district or regional level? What is the frequency and content of feedback?