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ORIGINAL: ENGLISH

Guidelines for estimating the economic burden of diarrhoeal disease with focus on assessing the costs of rotavirus diarrhoea

Immunization, Vaccines and Biologicals

World Health Organization

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Abbreviations

CHOICE	CHOosing Interventions that are Cost Effective
CBD	complete blood count
CT scan	computed tomography (CAT scan)
DDC	diarrhoeal disease control
DOB	date of birth
FBC	full blood count
ID	identity
IV	intravenous
LOS	length of stay
OPD	outpatient department
ORS	oral rehydration solution
ORT	oral rehydration therapy
PPP	purchasing power parity
RMO	resident medical officer
WHO	World Health Organization

1. Introduction

1.1 Background

Diarrhoea is one of the most common childhood illnesses, in both developing and developed countries. While the disease is rarely a cause of death in developed countries, it is estimated that approximately 1.6 million children die each year from diarrhoea in the developing world *(1)*. The highest mortality rate occurs during the first year of life *(2)*. Since almost all diarrhoea can be treated with simple, prompt case management, including oral rehydration therapy, almost all deaths could be prevented if the world's poor had access to basic health services. The principal reason for death from diarrhoea is thus limited access to health care.

A standard definition of diarrhoea could be the passing of three or more liquid stools in a 24-hour period *(3)*. Diarrhoea is generally characterized as "acute watery", "persistent" or "dysentery". Acute watery diarrhoea has an abrupt beginning and lasts less than 14 days. Persistent diarrhoea lasts more than 14 days, which generally results in significant weight loss and nutritional problems. Dysentery is diarrhoea in which blood is obviously seen in the faeces.

An optimal strategy for the case management of diarrhoea in children includes correct fluid therapy, correct feeding therapy, appropriate use of antibiotics, no use of anti-diarrhoeals and effective education of the mother or caretaker. Oral rehydration therapy (ORT) is the management of diarrhoeal disease through the administration of plenty of fluids, in an effort to maintain or replenish proper levels of hydration in the body *(4)*.

The etiologic agents that cause diarrhoea consist of viral, bacterial and protozoan organisms. The viral agents include rotavirus, enteric adenoviruses, astroviruses and caliciviruses. The bacterial agents include the pathogenic and enterotoxigenic *Escherichia coli* strains, shigellae, salmonellae, *Vibrio cholerae* and *Campylobacter jejuni*. *Giardia lamblia* and cryptosporidium are the most common parasitic agents *(5)*. While improved sanitation and clean water have virtually eliminated the bacterial and parasitic agents in children in developed countries, the occurrence of viral agents remains comparable in developing and developed countries.

Rotavirus has consistently been reported to be the single most common cause of diarrhoea worldwide *(5)*. In both developed and developing countries virtually all children are infected with rotavirus during early childhood and rotavirus is the most common cause of diarrhoeal hospitalizations *(6)*. A recently licensed rotavirus vaccine is therefore expected to have an important role in reducing diarrhoeal incidence and mortality.

1.2 Objective of the guidelines

The objective of these guidelines is to present a method for determining the costs associated with diarrhoeal disease in children under five years of age. Methods for estimating the costs from the viewpoint of the health sector and for society as a whole are explained. Costs associated with diarrhoea include direct medical costs (medication, diagnostics, personnel and hospital bed-day costs) borne by providers, patients and caregivers, non-medical direct costs (e.g. travel costs) borne by patients/caregivers, and costs of time lost from productive work (indirect costs) borne by patients/caregivers and/or society. These guidelines provide recommendations on how to estimate all these types of costs.

An estimate of the overall economic burden of diarrhoeal disease can be used for three major purposes and types of analysis.

1) **Raising awareness:** By demonstrating the economic burden of the disease, politicians, community leaders and health administrators can become convinced of the problem and be encouraged to engage in prevention.

2) **Planning and budgeting:** An estimate of the resources used to treat diarrhoea can be used in an analysis of health sector expenditures and priorities.

3) **Cost-effectiveness analysis of interventions for the control of diarrhoea:** Direct and indirect costs of diarrhoeal disease could be avoided if effective interventions were introduced to prevent and/or reduce the severity of the disease. The cost estimate is thus an integral part of a cost-effectiveness analysis of potential interventions, such as:
   - rotavirus vaccination
   - cholera vaccination
   - measles vaccination
   - promotion of breastfeeding
   - improving water supply and sanitation
   - promoting personal and domestic hygiene
   - expanding coverage and/or access to ORT.

The guidelines are targeted at health economists, public health planners and epidemiologists. In particular, researchers involved in hospital or community-based surveillance of diarrhoeal disease could use the guidelines to add an economic burden component to their study.

1.3 Structure of the guidelines

The guidelines are divided into four parts. Section 2 describes how to plan the study and select the sample frame for data collection. Section 3 consists of five modules explaining how to collect data on resource utilization and unit cost. Section 4 provides suggestions on how to present and analyse the results; and explains how to estimate the national economic burden of diarrhoea and how to incorporate the data into a cost-effectiveness analysis of preventive interventions, in particular rotavirus vaccination.

2. Planning the study and selecting the sampling frame

2.1 Getting an overview of treatment patterns for diarrhoea

It is recommended to start the study with a relatively quick assessment of the health system to determine the types of facility that are important in the treatment of diarrhoea. For instance, if most patients are being treated in nongovernmental outpatient facilities, these types of facility should be included in the sample. Tables 1 and 2 can be used to assess where patients seek treatment for diarrhoea. While it will be difficult to develop an exact estimate of health services utilization according to type of provider, efforts should be made to record the most likely picture. It should moreover be assessed what proportion of diarrhoea cases are not taken to any health-care provider for treatment.

Data to complete the tables can be collected from a number of sources. Demographic and health surveys, which are undertaken periodically in a number of developing countries, normally include a section on the treatment of diarrhoea, where data is usually available on the percentage of cases taken to a health facility (*http://www.measuredhs.com/*). Data on the proportion of patients receiving hospital treatment compared to outpatient services can be difficult to estimate, as well as the public versus private facility choice. Likely sources for this information could be:

- health care utilization surveys;
- interviews with doctors, nurses and/or ministry of health officials; and
- published and unpublished studies from the country in question or comparable countries.

Table 1: Stratifying health service utilization of diarrhoea cases (percentage of cases seeking care at different levels)

Type of care	%
Treatment in hospital	
Formal outpatient care	
Traditional healers	
Pharmacy	
Other	
No access to treatment	

Note: Sum of percentages may exceed 100%, as patients may use more than one type of care.

Table 2: Stratifying formal health service utilization of diarrhoea cases (percentage of episodes at various levels of health care seen in different settings)

	Public	Private not-for-profit	Private for profit	Total
Hospital treatment				
Tertiary hospitals, inpatient department				100%
Secondary hospitals, inpatient department				100%
Outpatient care				
Tertiary hospitals, outpatient department				100%
Secondary hospitals, outpatient department				100%
Primary health-care providers				100%

2.2 Determining the sample of facilities for data collection

The decision on which facilities to include in the sample depends, first of all, on the objective of the analysis and the perspective to be taken. If the objective is to estimate the costs of diarrhoea treated in hospitals, only a representative selection of hospitals should be included in the sample. If the objective is to carry out a cost-effectiveness analysis of a preventive intervention from the point of view of the governmental health sector, only public health facilities should be included. If the study objective is a cost-effectiveness analysis from the societal viewpoint, a sample of all types of health facilities should be included in the analysis.

The number of each type of facility to include in the sample depends mainly on the desired precision of the analysis and on the resources available to undertake the study. Table 3 should be used to summarize the type and number of facilities included in the sample for data collection. Justification for the choice of types of facility as well the sample size should always be given.

The following factors can be considered when developing a representative sample.

- When variation in costs among types of facility is expected to be small, it may be appropriate to consider them together as one type of facility instead of sampling them separately.
- If it is known that limited variability in resource use and/or unit costs exists among facilities of a particular type, it is justified to include only one or two of these facilities in the sample.
- If a type of facility provides care to a small percentage of patients, extrapolation of data from other facility types may be appropriate.
- For a facility type(s) that is expected to account for a large portion of care/ costs, it is advised to choose a representative sample (i.e. from 3 to 5 facilities) based on size, location and other characteristics, at the investigator's discretion.

Table 3: The sample of facilities chosen for data collection

	Public not-for-profit	Private for profit	Private of facilities	Total no.
Hospital-based cases				
Tertiary hospitals, inpatient department				
Secondary hospitals, inpatient department				
Subtotal				
Outpatient care				
Tertiary hospitals, outpatient department				
Secondary hospitals, outpatient department				
Primary heath-care providers				
Subtotal				
TOTAL				

Note: Categories that are different from those shown here can be used for rows or columns.

2.3 Determining the sample of patients at each facility

For each facility, a sample of patients should be selected for collection of patient-specific health care utilization data and patient interviews. It is recommended that the sample size of patients is determined based on: the desired precision of the overall result (in general, the larger the sample size, the greater precision); the total number of patients receiving diarrhoea treatment at the facility; and the perceived variation in treatment costs among patients. The following two steps should be followed when determining the sample size.

1) From the medical records office of the facility, collect a list of the patients with discharge diagnosis of diarrhoea. This can be done using the ICD-10 codes for diarrhoeal diseases (A00-A09), or perusing through discharge logbooks if ICD coding of discharge diagnosis is not done in the facility. Count all diarrhoea patients under five years of age by month, for one full calendar year.

2) Use Table 4 to determine the appropriate sample size. The suggested sample sizes in the table have been calculated by a standard sample size formula for estimating a population mean *(7)*.[1] The coefficient of variation of treatment costs per patient is defined as the ratio of the standard deviation to the mean. Previous studies suggest a coefficient of variation of 0.5 for treatment cost data of diarrhoea *(8, 9)*. Hence, the 0.5 coefficient of variation column is highlighted in the table. Alternatively, the coefficient of variation can be calculated from conducting a pilot treatment cost study. The recommended level of precision is either 10% or 15%. For example, if the facility had 200 cases in the past year, and a 10% level of precision is chosen, the sample size would be 65 patients.

[1] Given the precision and coefficient of variation (CV), as well as the (1-á/2) th quantile from the normal distribution, $Z^{2}_{1-\alpha/2}$ (where (1-á) is the confidence level), the formula for the sample size is given by:

$$n = ceiling\left[\left(\frac{precision^2}{CV^2 \times Z^2_{1-\alpha/2}} + \frac{1}{N_0}\right)^{-1}\right]$$

Table 4: Determining the sample size of patients

Precision	**10%**					
Total number of cases in prior year	Coefficient of variation					
	0.25	0.5	0.75	1	1.5	2
100	20	49	69	80	90	94
200	22	65	104	132	163	177
500	23	81	151	218	317	378
1000	24	88	178	278	464	606
2000	24	92	196	323	604	869
Precision	**15%**					
Total number of cases in prior year	Coefficient of variation					
	0.25	0.5	0.75	1	1.5	2
100	10	30	49	64	80	88
200	11	36	65	93	132	155
500	11	40	81	128	218	289
1000	11	41	88	146	278	406
2000	11	42	92	158	323	510

Once the sample size has been determined, the sampling interval *(k)* can be calculated as the ratio of the expected number of cases (N_0) to the sample size (n).

$$k = \text{floor}(N_0/n)$$

For example, using a 10% precision and 0.75 coefficient of variation, if N_0=1000 then n=178 (see Table 4), and k=floor(1000/178)=floor(5.61)=5. So every fifth patient should be selected for the sample. If the ratio were rounded rather than taking the floor, the resulting sample size would be less than n, and it is better to slightly over-sample than to under-sample.

Systematic sampling should be used to identify patients. A random number should be selected between 1 and k to choose the starting patient in a given month. For each month of data collection from patient records, after the first patient is randomly selected, every subsequent k^{th} patient should be selected for inclusion. Children with other acute co-morbidities (e.g. pneumonia, measles) should be excluded from the analysis. In these cases, the next patient on the list should be selected as a replacement. Continuing the example above, a random number between 1 and 5 would be selected. If the random starting point was 4, then the patient records selected would be (from among diarrhoeal patients only), 4, 9, 14, 19, 19+5, ……

In order to avoid seasonal variation, data from medical records should be collected for a one-year period. A combination of retrospective and prospective data can be used at the investigator's discretion (e.g. 11 months of retrospective and 1 month of prospective, 6 months retrospective and 6 months prospective, etc.). In some settings, the hospital records may not have sufficient detail, requiring the use of prospective data collection.

For the collection of data on out-of-pocket expenses, a prospective approach must be used. Table 4 can be used for calculation of the sample size for the patient interviews as well. The importance of out-of-pocket expenses in terms of the overall fraction of the economic burden varies between settings. In places with a credible and accessible public health system, out-of-pocket expenses are likely to be less than in places with malfunctioning public health services *(10, 11)*. If out-of-pocket expenses are expected to amount to only a small proportion of total costs, a lower level of precision (15%) may be acceptable. The period of prospective data collection through patient interviews can range from 1 to 12 months (based on the overall strategy described above). An alternative approach to avoiding seasonal variation would be to carry out prospective data collection for selected months during the course of the year. Using this approach, data would be collected every 3 months during a 12 month period (e.g. January, April, July and October). Whatever the strategy, investigators must assess the extent to which the selected sampling strategy accounts for seasonal variability in costs.

If prospective patient interview data are collected for a shorter period of time than that covered by medical records, then the sampling interval for this component of data collection may need to be higher in order to reach the desired sample size in the shorter time period.

Care should be taken to ensure that both medical records and patient interview data are collected for the same subset of patients. This will allow investigators to explore relationships between the variables and calculate patient-specific total treatment costs. The *same* prospective patients should be followed for out-of-pocket as well as direct medical costs. If a 12-month prospective approach is used for both record reviews and patient interviews, then the samples may overlap completely.

3. Data collection

3.1 Module 1: Hospital resource utilization

Direct medical costs are defined as the costs of resources incurred for the treatment of a disease. Typically, these will include the cost of hospital stay/visit (including medical staff time), diagnostic tests and pharmaceuticals. In contrast, indirect costs of an illness are defined as the value of the time lost due to the illness episode. This module describes techniques that should be applied in order to identify and measure all patient-specific resources used in the treatment of diarrhoea in hospital inpatient settings. Hospital inpatients are considered patients who are admitted to a hospital for an overnight stay. Collection of resource-use data for outpatients (in hospitals, clinics or other settings) is discussed in Module 2; methods for attaching unit costs to these resources are discussed in Module 3. The estimation of indirect costs is described in Module 4.

When estimating resource use for hospitalizations of diarrhoea patients, the resources used during the whole illness episode should be included. That is, if the patient was referred from the outpatient clinic, this resource use should be included as well. Moreover, medications prescribed to the patient after discharge should be included.

Data collection

Data on hospital resource use should be collected from a sample of patients, as explained in Section 2.3. The sample of patients should be drawn from the population of children less than five years of age treated for diarrhoea at the selected facilities.

All patient records in the sample should be carefully reviewed with the objective of documenting the level of utilization of resources per patient. Table 5 provides an example of a standardized data collection form to extract the patient-specific resource utilization data for direct medical costs for inpatients. The following resource-use data should be recorded in Table 5.

- The length of stay in days at different levels of care (e.g. intensive care unit, paediatric unit and observation unit).
- The type, frequency, amount, duration and route of administration of oral rehydration solution (ORS), intravenous (IV) fluids and other medications (e.g. antibiotics, antidiarrhoeal and antipyretics). Data on discharge medications directly related to the diarrhoeal episode should also be recorded, as well as their frequency, amount, duration and route of administration.

- Laboratory tests and procedures performed by quantity and type. The most common laboratory tests performed for diarrhoea are blood tests, blood culture, urinalysis and stool tests.

Quality control

The validity of the data collected is dependent upon whether the patient records accurately record the resources consumed and that data abstraction is reliable. The following steps should be undertaken to try to validate these assumptions.

1) **Missing data.** A preliminary assessment of the completeness of patient records should be obtained by asking the physicians practicing in the facility about their opinion of the completeness of recording of resource use. Utilization rates of patients included in the sample can be shown to them for assessment. If patient records are judged to be incomplete, the missing information should be completed in conjunction with medical experts. These decisions should be documented and consistently applied to other cases of a similar nature. Missing values which have been imputed through expert opinion should be noted, and the proportion that they contribute to the total costs should also be computed and evaluated.

2) **Quality of data abstraction from the chart.** The data collectors to be hired should undergo training in data abstraction prior to the start of the study. In order to assess the quality of ongoing data abstraction, the project's principal investigator should review 5% of the patient records.

Data management and analysis

A patient-level database should be developed to record the quantities of each input used in the treatment of each patient. Each record in the database should include information on individual patients, including demographics, type of facility and duration of stay.

Data should also be captured on each diagnostic test and medication used. To do this, a comprehensive list of all types of tests and medications (by dose and route) should be developed, based on the information collected in the data abstraction forms. For each patient, the quantity of each item should be recorded in the database. A sample database table is shown in Table 6.

Table 5: Data abstraction form for patient records

1. Data collector's code ☐☐
2. Hospital name _____
3. Hospital study ID code ☐☐

Patient information

4. Patient study ID ☐☐☐
5. Patient ID No. from hospital record ☐☐☐☐☐☐☐☐☐☐
6. Date of admission ☐☐ ☐☐ ☐☐☐☐ (day month year) Date of discharge ☐☐ ☐☐ ☐☐☐☐ (day month year)
7. Age ☐☐ ☐☐ ☐☐☐☐ (day month year) ☐ Missing
8. Area patient is from: **urban / rural / unknown** (please circle one).
9. Height ☐☐☐.☐☐ cm Weight ☐☐.☐☐ Kg
10. Gender of patient:
    - ☐ Male
    - ☐ Female
    - ☐ Missing

Patient treatment /Diagnostic history

11. Number of days of illness before hospitalization ☐☐☐
12. Where did the patient receive care prior to arriving to this facility? (*Multiple responses allowed).*
    - ☐ Not applicable
    - ☐ Traditional healer
    - ☐ Herbalist
    - ☐ Over-the-counter drugs
    - ☐ Another facility similar to this
    - ☐ District hospital
    - ☐ Health centre
    - ☐ Others, specify _____

Table 5: Data abstraction form for patient records *(cont'd...)*

13. Outcome on discharge _____

- ☐ Alive, well
- ☐ Alive, partially recovered
- ☐ Died
- ☐ Alive, but outcome unknown/missing
- ☐ Referred
- ☐ Discharged against medical advice
- ☐ Absconded
- ☐ Missing/unknown

14. What is the admission diagnosis? _____

15. What is the final diagnosis? _____

16. How many co-morbidities did the patient have? ☐☐

17. Specify the co-morbidities _____

_____

_____

18. Length of stay by location (record length of stay in each type of room, including zeros).
If length of stay is 1–11 hours write ½ day. If 12–24 hours, write 1 day.

Type of room	Length of stay (days)
☐ *Outpatient clinic*	
☐ Paediatric ward	
☐ Intensive care unit or special care baby unit	
☐ Isolation unit	
☐ Emergency room	
☐ Other (specify) _____	
☐ Missing	

Table 5: Data abstraction form for patient records *(cont'd...)*

19. Were any of these other special services used? *(If "YES" but no quantity stated, write "missing" in last column.)*

Type		Unit of measure where applicable	Quantity
Ambulance services	Yes / No		
Special diet	Yes / No		
Specialist consultations	Yes / No		
Intravenous fluids	Yes / No		
Cardiopulmonary resuscitation	Yes / No		
Autopsy	Yes / No		
Other	Yes / No		

20. Which diagnostic tests were used? (*Tick the applicable tests)*

- ☐ **No diagnostic test**
- ☐ **Blood count. (***If "yes", which one(s)***)**
  - ☐ Full blood count/complete blood count _____
  - ☐ Hb/haemoglobin _____
  - ☐ Haematocrit/packed cell volume (HCT/PCV) _____
- ☐ **Blood culture**
- **HIV test**
  - ☐ ELISA _____
  - ☐ Rapid test _____
- ☐ **Other microbiology (***If "yes", which one(s)and how many***)**
  - ☐ Name(s) of sample _____
  - ☐ Gram stain/microscopy _____
  - ☐ Culture _____
  - ☐ Sensitivity _____
  - ☐ Antigen testing
- ☐ **Radiology (***If "yes", which one(s)***)**
  - ☐ Computed tomography (CT scan) _____
  - ☐ Ultrasound _____
  - ☐ Other X-ray _____
- ☐ **Blood chemistry (***If "yes", which one(s)***)**
  - ☐ Electrolytes _____
  - ☐ Glucose _____
- ☐ **Other (specify)** _____

Table 5: Data abstraction form for patient records *(cont'd...)*

21. Drugs taken (*include any drugs prescribed on discharge). Write "missing" for any data not there (e.g. if number of days administered is missing).*

Name of drug	Code	Route*	Dose units (e.g. µg/ml, ml, mg	Dose amount (e.g. 50, 100)	Frequency of administering (e.g. once/day, 3/ day)	No. of days administered during admission (e.g. 3 days)	No. of days administered after discharge (e.g. 3 days)

* 1 = intravenous; 2 = injection; 3 = oral; 4 = nasal/gastric tube; 5 = rectal; 6 = topical (ointments); 7 = drops for ear, nose, throat; 8 = inhalation

22. Please describe any unusual or complicated case that you come across.

Table 6: Summary of patient hospital utilization data

Name of hospital _____

Patient ID	Etiology or type [a]	No. of outpatient clinic consultations	Length of stay in days	Quantity of different medications used [b]			Quantity of different diagnostics used [c]		
				Med1	Med2	Med3	Diag1	Diag2	Diag3

[a] Cases can be classified according to etiology or severity; i.e. "mild" or "severe".

[b] Medication types (Med1, Med2, Med3) refer to the different medication, route and dose combinations found among patients (e.g. 1 litre IV fluids, 50 mg ciprofloxacin). The number of columns can be expanded to reflect the total number of different types of combination.

[c] Diagnostic test type (Diag1, Diag2, Diag3) refer to the different tests identified among the patient records. The number of columns can be expanded to reflect the total number of different types of combinations.

3.2 Module 2: Outpatient resource utilization

The aim of this module is to collect data on resource utilization for treating diarrhoea patients in outpatient facilities. The management of diarrhoea in outpatient services can be provided at a range of facilities, including hospitals where the service may occur in a dedicated rehydration room, general outpatient area or emergency room (ER). In addition, the provision of health care at primary heath-care facilities without beds is defined as outpatient care. In short, outpatient care refers to all care provided which does not require hospital admission. Below we outline two approaches for estimating resource utilization. Methods for attaching unit costs to these resources are discussed in Module 3 (Section 3.3).

Approach 1: Review of patient records

If comprehensive patient medical records are held in the outpatient department(s) and/or at health centres, these should be used to estimate resource use in an analogous fashion, as described in Module 1. Table 7 provides an example of the type of data extraction form that should be used in these instances; it mirrors the range of questions asked in Table 5, with the exception of those relating to the place and duration of admission. Table 8 should be used to summarize the outpatient utilization data collected. Table 8 can also be used to collect data prospectively on a sample of patients, as described in Section 2.3.

Most often the patient records at outpatient facilities are, however, incomplete, with the exception being specific diarrhoeal disease control (DDC) programmes, often operated in a rehydration room/ORT corner. Table 9 provides an example of the type of data that may be available from these records and suggests some ways in which records could be selected and extracted. If this approach is used, the sample of patients should be selected as described in Section 2.3.

Approach 2: Physician interviews

In many outpatient settings, the recording of information is frequently incomplete or indeed absent. Interviews with heath-care practitioners in order to ascertain routine treatment regimens are relatively efficient, as it is anticipated that much of the variation in the costs of outpatient management of diarrhoea is attributable more to differences in the physicians' preferred mode of management than to differences in patient characteristics. However, what physicians say they do is not necessarily what they practice, and this needs to be borne in mind when interpreting the results. Indeed, where records have been abstracted and interviews performed, comparisons can shed light on the divergence between the two. But it is important to stress that the aim of the interview is to get a detailed description of how physicians at health centres and outpatient departments of hospitals *usually* treat a patient with diarrhoea at *their* facility with the means at *their* disposal. Resources should, for example, not include advice to a patient to seek a specific type of diagnostic test and/or prescribe a drug which is unavailable in their own facility. Therefore, it is important to note among lower level facilities, whether, and if so to where, a patient would be referred.

Step 1: Identify the physician.

In health centres, this will usually involve interviewing the one individual who treats patients. However, in hospitals, there will be several physicians from which to choose. In these facilities, it is suggested that the interview should be administered to a minimum of three people from the following groups (where time and budget permit, the sample size should be increased, particularly in tertiary facilities where it is not unusual to have 20–30 physicians working in the OPD):

- resident medical officer (RMO)
- consultant paediatrics
- consultant general medicine
- senior medical officers.

Therefore, the first step involves identifying the range of health staff working at the facility in question – the RMO should be able to help with that, and also to select physicians to interview.

Step 2: Administer the questionnaire.

After the physician(s) has been identified and agreed to be interviewed (see sample letter in Table 10), the questionnaire (Table 11) should be administered by a research assistant. At health centres, where staff is likely to have some free time, the interviews should be conducted on a face-to-face basis. In contrast, outpatient departments attached to hospitals are likely to be extremely busy; in this case the questionnaire could be left behind and self-administered, although you should explain the purpose of the interview and the data required before leaving. You should return at a time convenient for the physician(s) to review their form(s) for completeness and to discuss any areas of confusion. In particular, use this occasion to collect data on the implications of age/weight on the dosage of a drug and to assess the validity of the answers, by checking that the diagnostics tests and/or drugs mentioned are available in the facility.

Step 3: Summarize the results.

The patient utilization data collected by the physician interviews should be organized in a summary table similar to Table 12.

Table 7: Outpatient health care utilization form

1. Data collector's code ☐☐

2. Type of facility:

   ☐ Health clinic
   ☐ Doctor visit
   ☐ Emergency dept.
   ☐ Outpatient dept. (in hospital)
   ☐ ORT room
   ☐ Others, specify _____

3. Facility name _____

4. Facility study ID code ☐☐

Patient information

5. Patient study ID ☐☐☐

6. Patient ID No. from clinic record ☐☐☐☐☐☐☐☐☐

7. Date of visit

   ☐☐ ☐☐ ☐☐☐☐
   day month year

8. Age ☐☐ ☐☐ ☐☐☐☐ ☐ Missing
   day month year

9. Area patient is from: **urban / rural / unknown** (please circle one).

10. Height ☐☐☐.☐☐ cm Weight ☐☐.☐☐ Kg

11. Gender of patient:

    ☐ Male
    ☐ Female
    ☐ Missing

Table 7: Outpatient health care utilization form *(cont'd...)*

Patient treatment /Diagnostic history

12. Number of days of illness before visit ☐☐☐

13. Where did the patient receive care prior to arriving to this facility? (*Multiple responses allowed.)*

- ☐ Not applicable
- ☐ Traditional healer
- ☐ Herbalist
- ☐ Over-the-counter drugs
- ☐ Another facility similar to this
- ☐ District hospital
- ☐ Health centre
- ☐ Others, specify _____

14. Outcome on discharge _____

- ☐ Alive, well
- ☐ Alive, partially recovered
- ☐ Died
- ☐ Alive, but outcome unknown/missing
- ☐ Referred
- ☐ Missing/unknown

15. What is the admission diagnosis? _____

16. What is the final diagnosis? _____

17. How many co-morbidities did the patient have? ☐☐
(NB this includes any condition in addition to the primary diagnoses.)

18. Specify the co-morbidities _____

_____

_____

_____

_____

_____

Table 7: Outpatient health care utilization form *(cont'd...)*

19. Medication use: *Include any drugs prescribed on discharge. Write "missing" for any data not there (e.g. if number of days administered is missing).*

Name of drug	Code	Route*	Dose units (e.g. µg/ml, ml, mg	Dose amount (e.g. 50, 100)	Frequency of administering (e.g. once/day, 3/day)	No. of days administered (e.g. 3 days)

* 1 = intravenous; 2 = injection; 3 = oral; 4 = nasal/gastric tube; 5 = rectal; 6 = topical (ointments); 7 = drops for ear, nose, throat; 8 = inhalation

20. Were any of these diagnostic tests used? *(If "YES" but no quantity stated, write "missing" in last column.)*

Type	Circle the correct answer	Number of tests performed
Blood test	Yes / No	
Blood culture	Yes / No	
Urinalysis	Yes / No	
Stool	Yes / No	
Other (specify)	Yes / No	
	Yes / No	
	Yes / No	
	Yes / No	

Table 8: Summary of outpatient utilization data

Patient ID	Etiology or type [a]	Med1 [b]	Med2	Med3	Diag1 [c]	Diag2	Diag3

[a] Cases can be classified either according to etiology or severity; i.e. “mild” or “severe”.

[b] Medication types (Med1, Med2, Med3) refer to the different medication, route and dose combinations found among patients (e.g. 1 litre IV fluids, 50 mg ciprofloxacin). The number of columns can be expanded to reflect the total number of different types of combination.

[c] Diagnostic test type (Diag1, Diag2, Diag3) refers to the different tests identified.

Table 9: Rehydration room/ORT-corner patient record

Facility name _____

Facility ID code from study _____

Contact person in hospital _____

Data collector's name _____

Code for month in hospital (Jan = 01, Dec = 12)	Sex 1 = male 2 = female	Age (in months)	Assessment[a] 1 = no dehydration; 2 = some dehydration; 3 = severe dehydration	Quantity of ORS provided at ORT centre	Quantity of ORS provided for home

[a] Or use other classification in use, e.g. mild, moderate and severe etc.

Table 10: Example letter to physician for participation in study on direct medical costs of outpatient care of diarrhoeal disease

Date:

Dear Dr _____ ,

The [*enter name of institution coordinating the study*] is undertaking a study to determine the treatment costs of patients with diarrhoea. You have been treating patients with this illness recently. One of the components of the costs of treating these patients is the cost of outpatient care. Kindly answer the questions in the attached two-page questionnaire. If your records are complete, we would also like to be allowed to abstract the records of 10 patients with diarrhoea.

Thank you for your cooperation. A summary of the results will be sent to you once the study is completed.

Respectfully yours,

[*Name*]
Principal Investigator

Table 11: Physician interview form: outpatient health care utilization

1. Questionnaire ID | | | | |
2. Facility type _____
3. Facility name _____
4. Name of respondent _____
5. Name of data collector _____
6. Date of data collection: | | Date | | | Month | | | Year
7. What approximate proportion (as percentage) of diarrhoea patients you treat at your facility fall into the following categories:

   Diarrhoea with no dehydration _____

   Diarrhoea with some dehydration _____

   Diarrhoea with severe dehydration _____

First there are some questions about how you would **usually** care for a child under five years of age who presented with **diarrhoea** at **this** facility.

8. Would it be **usual** for you to perform diagnostic tests **at this facility** for patients presenting with diarrhoea with no/some or severe dehydration at this facility?

   YES / NO (*If "no", go to question 10*)

9. Which diagnostic tests would you **usually** perform at this facility for each type of diarrhoea? *(Please consider the three diarrhoeas in the table below and write the answer in the second column of the table.*)

10. How many of each of these tests would you **usually** do for each type of diarrhoea? *(Please consider the three diarrhoeas and write the answer in the third column of the table below.*)

Type of diarrhoea	State the *name* of the tests you would usually perform in this facility	State the *number* of tests you would usually perform in this facility
Diarrhoea with no dehydration		
Diarrhoea with some dehydration		
Diarrhoea with severe dehydration		

Table 11: Physician interview form: outpatient health care utilization *(cont'd...)*

11. At this facility, would it be **usual** for you to prescribe any drugs (including either ORS or IV fluid) for patients presenting with diarrhoea with no/some or severe dehydration?

YES / NO (*If "no", survey is completed*)

12. Please think about the types of drugs that you usually dispense from this facility (including ORS or IV fluid) for these three types of diarrhoea. When answering the question, please consider your usual stock of drugs and answer the questions in the table below. Only state multiple drugs if more than one would **usually** be dispensed **at the same time**.

	Which drug(s) would you usually dispense at this facility for this condition?	Which route?	Dose per kg (mg/ml)	How many times a day would you recommend it being taken?	How many days would you prescribe it for?	Who would pay for the prescribed drug?
Diarrhoea with no dehydration						
Diarrhoea with some dehydration						
Diarrhoea with severe dehydration						

Table 12: Summary of patient OPD utilization data based on physician interviews

Type of provider/state of dehydration [a]	Med1 [b]	Med2	Med3	Diag1 [c]	Diag2	Diag3
Tertiary OPD:						
No dehydration						
Some dehydration						
Severe dehydration						
Health centre:						
No dehydration						
Some dehydration						
Severe dehydration						

[a] Note: The classifications used as row headings should be those most commonly known, e.g. mild, moderate and severe.

[b] Medication types (Med1, Med2, Med3) refer to the different medication, route and dose combinations found among patients (e.g. 1 litre IV fluids, 50 mg ciprofloxacin). The number of columns can be expanded to reflect the total number of different types of combination.

[c] Diagnostic test type (Diag1, Diag2, Diag3) refers to the different tests identified. The number of columns can be expanded to reflect the total number of different types of combination.

3.3 Module 3: Unit cost estimates of hospital and outpatient resources

In the resource utilization modules, estimates were made of the quantities of medications, tests, hospital days and number of visits used in the treatment of a sample of children with diarrhoea. In this module, unit cost estimates are collected for each of these resources. Information on unit costs and quantities should then be combined to estimate the total cost of treatment of a diarrhoea case.

Economists define costs as the value of resources used to produce goods or services. However, the way these resources are measured can differ. Financial costs only include the actual expenditure on goods and services purchased. Economic costs also include the opportunity costs of resources. This could, for instance, be the value of donated medications or the value of volunteers' time. Whether to use financial or economic costs depends on the purpose of the analysis. If the aim is to prepare a budget for a facility, only the financial costs should be included. If, however, a cost-effectiveness analysis or a sustainability assessment of an intervention is required, the economic costs should be used.

Unit cost data can either be presented in local currency, US$ or "international dollars".[2] However, all unit cost estimates should be presented in the same currency. Similarly, an index year for the analysis should be selected and all costs used in the analysis should be for that index year. Methods for transferring costs from one year to another can be found in the *Health Policy Plan 2000 (12)* and *2002 (13)*.

Unit cost estimates must be collected for each of the following items:

- medications
- diagnostic tests
- a hospital bed-day
- an outpatient visit.

While medications and diagnostic tests are patient-specific resource utilization items, the unit cost of a hospital day and an outpatient visit do not vary to a great extent from patient to patient within a given facility. Resource items included in the cost of a hospital day and an outpatient visit include the value of the staff, building, equipment, electricity, laundry, food, etc. In reality the amount of time the staff spend on patients can vary considerably, but it is difficult and time consuming to allocate staff costs on a patient-specific basis, as this would involve physically observing how much time staff spend on different patients through time-and-motion studies. Hence, we include this cost item in the hospital day and outpatient visit costs.

[2] An international dollar has the same purchasing power as the US dollar has in the United States. Costs in local currency units are converted to international dollars using purchasing power parity (PPP) exchange rates. A PPP exchange rate is the number of units of a country's currency required to buy the same amounts of goods and services in the domestic market as US dollars would buy in the United States. An international dollar is, therefore, a hypothetical currency that is used as a means of translating and comparing costs from one country to another using a common reference point, the US dollar. The PPP exchange rates can be found on the WHO CHOICE web page (*http://www.who.int/whosis/cea/prices/*). To convert local currency units to international dollars, divide the local currency unit by the PPP exchange rate. To convert international dollars to local currency units, multiply the international dollar figure by the PPP exchange rate.

Different approaches can be used to estimate unit costs based on the data available, required level of precision, and the resources available to do the study. These different levels of data collection intensity are most marked for costs per hospital day and outpatient visit.

3.3.1 Drugs and medical supplies

In the hospital and outpatient resource utilization modules, a list of medications used was developed. This list should include different doses and routes. For each item on the list a unit cost should be identified.

The unit cost worksheet for medications and diagnostic tests (Table 13) should be used to develop and organize the unit cost estimates. All items used in the treatment of diarrhoea (inpatient and outpatient) should be included in the second column.

Alternative sources of unit cost estimates for medication and medical supplies are likely to be available, including those listed below.

1) **National price lists.** Many countries maintain price lists for medications used by public hospitals and clinics. Since these prices are based on volume government purchases, the prices may approximate to the actual economic costs. If these prices are subsidized by the government, they may not be an appropriate source of information. Price lists should be available from hospital or clinic administrators.

2) **Purchase price.** If standardized national prices are not available, actual purchase prices may be used. For each item, purchase prices should be determined for the sample of facilities used. Prices should include any discounts and delivery/ shipping charges. Most often, purchase prices can be found in the accounts department of the ministry of health, the hospital or the Central Pharmacy Board.

3) **In the absence of a national price list** or reliable data on purchase prices, standardized international price lists may be used. These lists include many common medications and reflect economic costs. Information is available from the Management Sciences for Health (MSH) International Drug Price Indicator Guide (*http://erc.msh.org*).

3.3.2 Diagnostic tests

In the hospital and outpatient resource utilization modules a list of diagnostic tests was generated. This list should include the different tests used in both settings. For each item on the list a unit cost must be identified. The unit cost worksheet for medications and diagnostic tests (Table 13) can be used to develop and organize the unit cost estimates.

Alternative sources of unit cost estimates are described below.

1) **National price lists.** In some countries, national price lists are available for common diagnostic or laboratory tests. In comparison to charges at private laboratories, the prices may approximate the actual economic costs. If these prices are subsidized by the government, they may not be an appropriate source of information. Price lists should be available from hospital or clinic administrators or national laboratories. This source is likely to be most useful if laboratory procedures are routinely done outside of the hospital or clinic in a separate laboratory.

2) **Prices charged by private laboratories.** If standardized national prices are not available, the prices charged by private laboratories for the tests may be used as a substitute. For each item, private laboratory prices should be determined from a sample of laboratories. Private laboratory prices are likely to be an overestimate of the true economic cost of the procedures. As a result, they are most appropriate when national price lists are not available or to complement standardized international cost estimates, as described below.

3) **Full costing study of laboratory services.** This is a resource-intensive approach, which involves assessment of all resources used to perform the laboratory tests and the unit costs of all resources. Items such as the laboratory kit, staff time and transport of samples should be included. Guidelines on how to do this can be found in the *Training manual for programme managers (14).*

3.3.3 Costs per hospital bed-day, excluding drugs, medical supplies and diagnostic tests

The purpose of this section is to describe alternative approaches for estimating the unit cost of a hospital bed-day. In these guidelines, we define hospital costs per bed-day as the cost per patient day of hospital personnel, the building, equipment, maintenance, administration, laundry, food, cleaning, etc. Cost per bed-day does not include the patient-specific costs of diagnostic tests, medications and medical supplies.

Three different approaches can be used for estimating the costs per hospital bed-day. These methods differ in their intensity (financial and time resources required to carry them out) as well as the accuracy of the estimates they produce. The method used in a particular study should be selected based on the purpose and scope of the study and the needs of decision-makers. The alternative methods described below are presented in order of increasing intensity.

1) **Standardized WHO-CHOICE estimates.** As a part of its WHO-CHOICE project, WHO has developed estimates of the unit costs of a hospital bed-day in different settings *(15)*. Data from hospital cost studies in 49 countries have been used in a regression model to predict the cost per bed-day in countries for which these data are not yet available. In the regression model, country estimates are a function of gross domestic product, ownership (public/private), level of the facility (primary, secondary and tertiary), the level of capacity utilization and whether or not capital and food costs are included. The estimates are given in international dollars, which can be converted to local currency (see footnote 2). Estimates are available for the 14 WHO epidemiological subregions based on an occupancy rate of 80% (*http://www.who.int/whosis/cea/prices/*).

2) **Existing estimates of hospital per bed-day cost.** In some countries estimates of the cost per hospital bed-day may be available for some facilities. These estimates may be from administrative sources or previous costing studies. In order to be used for the cost per bed-day estimates in this study, the costs should include all relevant cost components (facilities, equipment, maintenance, administration, personnel, etc.). Care should, however, be taken in making sure that the sample is representative and that adjustment for inflation has been made if the cost data were collected in years earlier than the one chosen for the study *(12, 13)*.

3) **Full costing study.** This final approach is the most detailed and resource intensive. The approach uses detailed cost and health care utilization data from the hospital. The costs of all activities of the hospital are estimated separately and all cost items are divided into capital and recurrent costs. The costs of outpatient and inpatient services are estimated separately to ensure that the costs per bed-day and per visit can be generated. This detailed approach should only be used if very precise estimates are needed and if it is considered worth the additional efforts and resources to produce the estimates. A detailed description of the method can be found in three publications *(16–18)*.

3.3.4 Outpatient visit costs

The purpose of this section is to describe alternative approaches for estimating the cost of outpatient visits. Separate estimates should be developed for each type of facility considered in the analysis (consultation visit, hospital outpatient department, health posts, emergency rooms, etc.). Separate estimates may be developed for facilities in different parts of the country (for example urban and rural).

As in the case of hospital costs, several approaches can be used for estimating the costs of each type of visit. These methods differ in their intensity (financial and time resources required to carry them out) as well as the accuracy of the estimates they produce. The method used in a particular study should be selected based on the purpose of the study and the needs of decision-makers. The alternative methods described below are presented in order of increasing intensity.

1) **Standardized WHO-CHOICE estimates.** As a part of its WHO-CHOICE project WHO has developed estimates of the economic cost of outpatient visits in different settings. Regional and country estimates have been developed using empirical data from a sample of countries of varying economic income levels. In the regression model, regional and country estimates are a function of gross domestic product, type of facility, and the level of capacity utilization. The estimates are given in international dollars, which can be converted to local currency. Estimates are available for each region based on mortality strata, health service utilization rate and facility type (*http://www.who.int/whosis/cea/prices/*).

2) **Existing estimates of cost per outpatient visit.** For some countries and facilities, estimates of outpatient visit cost may be available. These estimates may be from administrative sources or previous costing activities. In order to be used for the outpatient-visit cost estimates in this study, the costs should include all relevant cost components (building, maintenance, personnel, etc.).

3) **Full costing activity for estimating outpatient visits.** This final approach is the most detailed and resource intensive. The approach uses detailed cost and health-care utilization data from the heath-care facility. The costs of all activities of the outpatient facility are estimated separately and all cost items are divided into capital and recurrent costs. This detailed approach should only be used if very precise estimates are needed and if it is considered worth the additional efforts and resources to produce the estimates. A detailed description of the method can be found in the *Training manual for programme managers (14)*.

Table 13: Unit cost worksheet for medication and diagnostic tests

Item number	Item name	Unit of measure	Unit cost	Source

Table 14: Hospital cost worksheet

Patient ID	Length of stay In days	Cost per bed-day	Total bed-day	Medication				Total medication cost	Diagnostics				Total diagnostic cost	Costs of outpatient consultations	Total costs
				qMed1	pMed1	qMed2	pMed2		qDiag1	pDiag1	qDiag2	pDiag2			

Step-by-step guide to complete the table:
1. Enter length of stay and cost per bed-day.
2. Total bed-day cost = length of stay x cost per bed-day.
3. Enter number of units for each item (qMed, qDiag).
4. Enter prices of each item (pMed, pDiag).
5. Total medication cost = pMed1 x qMed1 + pMed2 x qMed2.
6. Total diagnostic cost = pDiag1 x qDiag1 + pDiag2 x qDiag2.
7. Total hospitalization cost = total bed-day cost + total medication cost + total diagnostic cost + cost of outpatient consultations.

Note: Columns should be added for additional medication and diagnostic tests (quantities and prices).

Table 15: Outpatient visit cost worksheet

Patient ID	Overhead cost	Medication						Total medication cost	Diagnostics						Total diagnostic cost	Total outpatient cost
		qMed1	pMed1	qMed2	pMed2	qMed3	pMed3		qDiag1	pDiag1	qDiag2	pDiag2	qDiag3	pDiag3		

Step-by-step guide to complete the table:

1. Enter number units for each item (qMed, qDiag).
2. Enter prices of each item (pMed, pDiag).
3. Total medication cost = pMed1 x qMed1 + pMed2 x qMed2 + pMed3 x qMed3.
4. Total diagnostic cost = pDiag1 x qDiag1 + pDiag2 x qDiag2 + pDiag3 x qDiag3.
5. Total outpatient cost = visit cost + total medication cost + total diagnostic cost.

Note: Columns can be added for additional medication and diagnostic tests (quantities and prices).

3.4 Module 4: Out-of-pocket and indirect costs

The preceding modules have explained how to analyse the cost to the health-care system of treating diarrhoea. However, the resources spent by caregivers during treatment can also be substantial. Therefore, to obtain a complete picture, one should determine the magnitude of out-of-pocket expenses as well as the time lost from productive activities while caring for a sick child.

"Out-of-pocket" expenditures are defined as direct medical costs paid for by patients and/or caregivers and non-medical costs, such as transportation to and from heath-care facilities and household costs to accommodate the needs of the patient.

Indirect costs are defined as the value of the time lost by patients and caregivers from other productive activities during the illness episode. These are often also referred to as productivity losses related to illness or death. In these guidelines, estimation of indirect costs will be limited to productivity losses borne by caregivers of children during the acute episode of diarrhoea.

Out-of-pocket costs

Out-of-pocket costs should be ascertained through the administration of a questionnaire to caregivers. An example questionnaire is included in Table 16. The questionnaire includes questions about the out-of-pocket costs incurred through ambulatory and emergency room visits prior to consultation or hospitalization, daily expenditures for those caregivers whose child has been hospitalized, transportation costs and expenditures for follow-up consultation fees. For those caregivers who state that they did not pay for transport to the facility, although they travelled other than by foot, an estimate of the distance travelled and local estimates of per kilometre fuel costs should be used to impute a cost of transport. It should be remembered to multiply the estimate of cost by two to reflect a round-trip cost of transport.

Household out-of-pocket medical costs associated with inpatient and outpatient visits reflect the portion of the direct medical costs borne by households. When estimating total treatment costs, caution should be taken not to include these costs in the direct medical costs calculated in earlier chapters, as this will result in double-counting. When estimating treatment costs it should thus always be specified who bears the costs.

Productivity losses

In order to measure the days of time spent to care for a sick child, the questionnaire in Table 16 includes the amount of time spent away from productive activities (changes in cash or non-cash production). An estimate of the hours/days required to care for a sick child should be estimated. However, the valuation of this time is not straightforward. First, the economic impact of lost time will differ according to the age and the occupation of the individual; and secondly, the societal welfare loss of this time is difficult to quantify especially in a situation with unemployment. It may well be the case that other workers can fill in for the caregiver and moreover, the carers can catch up the lost time at work at a later stage and the welfare loss is therefore very small, if any. One of the questions in Table 16 is concerned with the estimated value of lost income due to the illness. However, when analysing the answers

to this question, it should be borne in mind that people may be inclined to give an upwards-biased figure to this question. There are two methods available to the researchers to value the time and impute indirect costs.

- Use the stated values of lost income.
- Apply the local minimum wage to individuals for the amount of time from productive activities they state they lost.

However, since both of these methods are problematic, it is recommended to present the overall results with and without inclusion of the productivity loss. A more detailed discussion about the problems of valuing productivity gains or losses can be found in Chapter 3 of the *WHO guide to cost-effectiveness analysis (19)*.

Those seeking to explain the variation of costs using variables beyond those already included in the questionnaire (e.g. type of facility, age, gender, etc.), may wish to include a variable(s) which reveals the socioeconomic status of the child/caregiver, among others.

The results of the interviews can be summarized as illustrated in Table 17.

Table 16: Caregiver and out-of-pocket costs questionnaire

Facility information

1. Facility name: _____

2. Type of facility:

   ☐ National hospital
   ☐ Provincial hospital
   ☐ District hospital
   ☐ Mission hospital

3. Facility study ID code: ☐☐

Patient information:

4. Patient study ID _____

5. Patient ID from patient records: _____

   Gender

   ☐ Male
   ☐ Female

6. Date of birth: ☐☐ ☐☐ ☐☐☐☐

   age in days / mths / years if date of birth not available

   day month year

7. Informed consent date: ☐☐ ☐☐ ☐☐☐☐

   day month year

Caregiver information:

8. Relationship to the patient:

   ☐ Mother
   ☐ Father
   ☐ Sister
   ☐ Brother
   ☐ Grandmother
   ☐ Grandfather
   ☐ Other relative
   ☐ Friend
   ☐ Other (specify) _____

Table 16: Caregiver and out-of-pocket costs questionnaire *(cont'd...)*

Travel information

9. How long did it take to get here from your home (including the journey time and any waiting for transport)?

   Minutes ☐☐

   Hours ☐☐

   ☐ Unknown

10. What kind of transportation did you use to bring your child to this hospital or clinic?

    In case of multiple means of transportation during this trip, please tick only the transportation that was used for the longest distance.

    ☐ Car
    ☐ Bus / train
    ☐ Bicycle
    ☐ Motorbike
    ☐ Taxi
    ☐ By foot
    ☐ Boat
    ☐ Ambulance
    ☐ Other, specify: _____

11. If you paid for transportation to bring the child to the hospital or clinic, how much did you pay?

    _____ *(put **0** if no payment was made)*

12. How many trips did you or other household members make to visit your child?

    (Total numbers of round trips)
    *(put **0** if no visit was made)* ☐☐

    *Examples: 3 relatives' visit one time [**n = 3 trips**]*
    *One relative visits three times [**n = 3 trips**]*

Table 16: Caregiver and out-of-pocket costs questionnaire *(cont'd...)*

13. What kind of transportation did ***you*** use to come to this hospital or clinic to visit your child? *(It concerns the last used transportation that has been used to visit your child.)*

- ☐ Car
- ☐ Bus / train
- ☐ Bicycle
- ☐ Motorbike
- ☐ Taxi
- ☐ By foot
- ☐ Boat
- ☐ Other, specify _____

14. If you paid for transportation, how much did ***you*** pay to visit this heath-care facility? *(Round trip, one person)*

_____ *(Put **0** if no payment was made and 999 if don't know)*

If you used different means of transportation, please choose the one you used most often.

15. Treatment costs

Before visiting this facility, did you seek help from any of the following? How much did it cost you for drugs, tests, consultation and other financial costs? (***Caregiver to list all the facilities visited, then ask the costs of each item for each place visited, one at a time.)***

Expenditure/ Facility	Private hospital	Private clinic	Public clinic	Pharmacy	Traditional healer	Friend	Shop	Other
Drug								
Diagnostic tests								
Consultation								
Other financial costs								
Total cost								

Table 16: Caregiver and out-of-pocket costs questionnaire *(cont'd...)*

16. How much did the household actually pay for: drugs, tests, consultation and other fees for this visit or hospitalization? How much were you required to pay?

Item	Drug	Tests	Consultation fee	Other fees	Total
Cost *(Put 0 if no payment and 999 if don't know)*					
How much were you required to pay?					

17. Are you losing some income for being here today?

- ☐ Yes
- ☐ No

If you weren't here today, what would you be doing? (*Multiple responses allowed.)*

- ☐ Nothing
- ☐ Housework
- ☐ Looking after my children
- ☐ Working (specify)
- ☐ Other (specify)
- ☐ Don't know

18. How much income have you or other family members lost as a result of taking care of your child instead of working? *(Put **0** if nothing and 999 if don't know.)*

_____

Table 16: Caregiver and out-of-pocket costs questionnaire *(cont'd...)*

Financing of the costs of treatment and transport

19. Has the illness affected the family financially? ☐ Yes ☐ No

20. Where did the money come from to pay for these expenses? *(Multiple responses allowed.)*

- ☐ Cutting down on other expenses
- ☐ Using savings
- ☐ Borrowing
- ☐ Selling assets
- ☐ Asking for donations from friends and relatives
- ☐ Others, specify _____

21. What is the total number of people in your household?

_____	Adults	_____	Children
_____	18–28 yrs	_____	0–5 yrs
_____	29–38 yrs	_____	6–10 yrs
_____	39–48 yrs	_____	11–17 yrs
_____	49+ yrs		

22. What are the total expenses of the household where the child lives?

Item/ Amount	Per day	Per week	Per month
Food			
Education			
Rent			
Household items			
Medical/Health			
Total			

This form was completed by: _____

Date ☐☐ ☐☐ ☐☐☐☐ (day month year)

Date of admission ☐☐ ☐☐ ☐☐☐☐ (day month year)

Date of discharge / referral ☐☐ ☐☐ ☐☐☐☐ (day month year)

Table 17: Summary of out-of-pocket and indirect costs

Patient ID	Type of care	Length of stay (where applicable)	Patient age	Transport cost (1)	Drugs cost	Diagnostic test cost	User fees	Total medical cost	Time loss (mins) (2)	Indirect cost (3)	Total cost (= 1+2+3)

Note: Additional variables can be added on type of facility and patient characteristics that can explain any variances.

3.5 Module 5: Costs of treatment in the informal sector

Numerous studies on health seeking behaviour for childhood illnesses have illustrated that self-treatment or parent treatment as well consultations with pharmacists, village doctors and traditional healers are extremely common *(20–23)*. In some settings, informal health care is the first choice of treatment *(21, 23)*. Hence, in some settings, exclusion of the costs of informal health care for the treatment of diarrhoea will underestimate the total costs of the disease. This is, however, only if a societal perspective is taken. Studies of the economic burden of diarrhoea from the public health-care system perspective would not include the costs of informal health-care.

The purpose of this module is to describe methods for estimating the direct and indirect costs of diarrhoeal events that do not result in formal outpatient visits or hospitalization.

The primary source of data on these diarrhoeal events is community-based household surveys. The sample population should be caregivers of children (under five years of age) who have recently experienced a diarrhoeal event.

Surveys should include information on:

- type of care sought (where, from whom);
- transportation costs;
- payment for medications, tests (if any), and consultations;
- time lost from paid work/lost income.

Several approaches are available for obtaining this information through existing secondary data and new data collection. The approach selected in each setting will depend on the availability of secondary data and resources for primary data collection.

Existing national household surveys

In many countries, household health and living standard surveys are conducted periodically. Examples of these surveys include living standard measurement surveys (designed by the World Bank) and national health surveys. Although these surveys differ slightly between countries, they generally include sections on patterns of treatment for childhood diarrhoea and the costs associated with it. Demographic and health surveys include some information on patterns of treatment of childhood diarrhoea (including the informal sector), but do not include information on costs associated with care.

In most cases, data from these surveys are available to public health investigators in each country. Specific procedures for data analysis will depend on the exact design of the survey. However, the following general analyses should be considered:

- Patterns of treatment for childhood diarrhoea. Identify a subsample of children who have recently (typically two weeks or one month) had a diarrhoeal event (as reported by the parent). Within this population calculate the portion of children who received care from different formal and informal providers, and the portion for which no care was sought.

- For each treatment pattern group of concern (e.g. pharmacists, healers, family members, etc.) estimate the mean reported expense for medication, consultations and other expenditures (e.g. transportation). Mean time lost from paid work can also be calculated if such information is included in the survey.
- For those cases not seeking care at formal medical facilities, estimate the portion that used oral rehydration therapy. This information can be used to estimate a portion of the out-of-pocket expense.

Community surveys

The second approach to estimating the costs of treatment in the informal sector involves primary data collection. In some settings there may be an opportunity to directly collect data on the patterns and costs of childhood diarrhoea treatment in a community setting. This may be appropriate in settings where a community health utilization survey will be carried out.

Survey data should be collected from a sample of caregivers of children under five years of age. Surveys should collect information on whether the child has recently had a diarrhoeal illness and, if so, the type of care that was sought. The following general analyses should be considered.

- Patterns of treatment for childhood diarrhoea. Identify the subsample of children who have recently (typically two weeks or one month) had a diarrhoeal event (as reported by the parent). Within this population, calculate the portion of children who received care from different formal and informal providers, and the portion for which no care was sought.
- For each treatment pattern group of concern (e.g. pharmacists, healers, family members, etc.) estimate the mean reported expense for medication, consultations, and other expenditures (transportation).

Wherever possible, data collection should be combined with existing data collection efforts. Table 18 provides a sample survey that could be used as a stand-alone survey or as an add-on to an existing survey.

Table 18: Household and indirect costs questionnaire

Patient ID: _____ Gender: ☐ Male ☐ Female

Date of birth: ☐☐ ☐☐ ☐☐☐☐ (day month year) Informed consent date: ☐☐ ☐☐ ☐☐☐☐ (day month year)

Caregiver information

1. Relationship to the child:

☐ Mother ☐ Grandfather
☐ Father ☐ Other relative
☐ Sister ☐ Friend
☐ Brother ☐ Other (specify)
☐ Grandmother _____

2. Number of children < 5 years ☐☐

3. In the past 2 weeks have any of them had diarrhoea?

☐ Yes ☐ No *(if "no", the survey finishes here.)*

Consider the last episode of diarrhoea for one of your children.

Treatment costs

4. Did you seek assistance from any of the following? (***Note***: "other" excludes clinics etc.)

☐ Pharmacy
☐ Traditional healer/herbalist
☐ Friend or relative
☐ Other, please specify: _____

5. If so, approximately how much did it cost you in total (for transport, fees and medication)? (***Note***: excludes clinics etc.) ☐☐☐☐☐☐ *(express in national currency) (put **0** if no payment was made)*

6. Did you seek assistance from any of the following?

☐ Hospital
☐ Private clinic
☐ Public clinic

Table 18: Household and indirect costs questionnaire *(cont'd...)*

7. If so, how much did the household pay in total (for transport, fees and medication)? ☐☐☐☐☐☐
   (express in national currency)
   *(put **0** if no payment was made)*

8. How many hours have you or other family members lost from paid work as a result of taking care of your child? ☐☐☐☐
   (*express in hours*)
   (*put **0** if no time was lost*)

9. Has the illness affected the family financially?
   ☐ No
   ☐ Yes

10. Where did the money come from to pay for these expenses? *(Check all that apply.)*
    - ☐ Cutting down on other expenses
    - ☐ Using savings
    - ☐ Borrowing
    - ☐ Selling assets
    - ☐ Asking for donations from friends and relatives
    - ☐ Others, specify

11. What is the total number of people in your household?

    _____ Adults _____ Children

12. What is the total for household expenses (in national currency) of the household where the child lives? *(If two or more household members have income, please add up.)*

    ☐☐☐☐☐ per:
    - ☐ Day
    - ☐ Week
    - ☐ Month
    - ☐ Year

This form was completed by: _____

Date ☐☐ ☐☐ ☐☐☐☐
day month year

4. Analysis and presentation of results

In this section suggestions are given with regard to how the cost data can be analysed and presented. The patient-specific cost data should be used for calculation of an arithmetic mean and standard deviation. The data should moreover be extrapolated so that an estimate of the national economic burden of diarrhoeal disease can be made.

4.1 Patient-specific costs

The patient-specific resource-use data collected in Module 3 and 5 should be coupled with the unit cost estimates to generate a patient-specific cost estimate. For each facility, the sample of patient-specific cost estimates should be used to generate an average cost per patient treated for diarrhoea.

Patient-specific cost data can be described as being stochastic data, as resource use varies from patient to patient. This contrasts to deterministic cost data, where resource use is the same for all patients. Standard statistical analysis can be used to describe stochastic patient level data and explore any differences in costs between two or more defined groups of patients (for example by etiology, gender, age, etc.). However, statistical analysis of cost data can present several challenges. The distribution of costs is typically right-skewed, with very few patients incurring large costs; and cost distributions also tend to exhibit large variability. Information on the variability or range of costs is important to enable the reader to judge to what extent the average cost data presented is typical for the patients studied. For those interested in detailed statistical analyses of cost data, see Briggs & Gray *(24)*.

A simple analysis of the patient-specific cost data includes presentation of the mean[3] and standard deviation[4] of the following indicators:

1) costs per inpatient stay for diarrhoea treatment from the viewpoint of the heath-care provider;
2) costs per outpatient visit for diarrhoea treatment from the viewpoint of the heath-care provider;
3) costs per visit to an informal heath-care provider for diarrhoea treatment;
4) out-of-pocket costs per inpatient and outpatient episode;
5) total treatment cost per patient, with and without indirect costs.

[3] The arithmetic mean should be calculated using the formula, $\bar{x} = \sum x_i / n$ where x_i are the observations, i=1…n.

[4] The standard deviation should be calculated using the formula $sd = \sqrt{\sum (x_i - \bar{x})^2 / (n-1)}$.

When presenting the mean cost estimates, it is recommended to break them up into the most important resource items. An example of how this can be done is illustrated in Table 19.

Table 19: Mean direct medical costs per episode (standard deviations)

	Diagnostics	Medication	Costs per bed-day/visit	Total direct medical costs
Tertiary hospital				
Secondary hospital				
Outpatient visit				
Informal care				

4.2 The national economic burden of diarrhoea

Previous sections of this protocol have described how to estimate different types of costs (medical, non-medical, direct, indirect and total costs) associated with diarrhoea episodes of different levels of severity. In order to provide more complete information to decision-makers, this information should be combined with epidemiological burden data to estimate the national economic burden of diarrhoea.

The economic burden of diarrhoea in a country is estimated by combining the frequency of each type of event with information on the mean costs associated with each event. Estimates are typically calculated as the total costs for a given annual birth cohort, but they can also be expressed as an annual cost for all children less than five years of age. Costs can be expressed by type (direct medical, indirect or total), by the type of event (hospitalization, outpatient or total), or age.

The national epidemiological burden of rotavirus diarrhoea should be estimated for a cohort up to the age of five years. The key outcome measures are cases and deaths. Methods for estimating the burden of diarrhoea can be found in various publications *(3, 25, 26)*. When the number of cases and deaths have been estimated, the approximate proportion of cases receiving hospital and outpatient treatment should be determined. The cumulative incidence of hospitalization and outpatient visits should be estimated based on national surveillance studies, administrative data or other appropriate sources. By combining the total number of hospitalizations and outpatient visits with the mean costs and standard deviation of treatment at the different types of facility, a total economic burden estimate around a standard deviation can be generated.

According to the type of data collected, the total economic burden cost estimate can be presented according to the following perspectives.

1) **Public health sector perspective.** This includes total, annual treatment costs incurred at government health facilities. Costs recovered from patients (out-of-pocket costs) should be subtracted from the total treatment costs.
2) **Household perspective.** This includes out-of-pocket costs to government health facilities and formal and informal private health facilities, as well as the costs of transport to any type of facility.
3) **Societal perspective.** The sum of the government and household perspectives.

Due to the measurement problems with productivity losses these should always be reported separately.

Table 20 provides an example of how the data can be presented according to perspective.

Table 20: Total costs of diarrhoea according to perspective

Item	Government or health care system	Households				Total (societal perspective)
		Direct medical costs	Direct non-medical costs	Indirect costs	Total costs	
Hospitalized episodes:						
Tertiary						
Secondary						
Outpatient:						
Type 1						
Type 2						
Informal care						

4.3 Cost-effectiveness analysis of interventions to prevent diarrhoea

To maximize the usefulness of the treatment cost data collected, it is recommended to incorporate the data into a cost-effectiveness analysis of one or more interventions that can prevent diarrhoea in children. In this section, it is explained how to undertake a cost-effectiveness analysis of a rotavirus vaccine. However, most of these methods can also be used for evaluation of other types of interventions.

4.3.1 Estimating the cost effectiveness of a rotavirus vaccine

Improvements in hygiene, sanitation and access to clean water do not greatly affect the incidence of rotavirus diarrhoea, and vaccination is therefore considered as the only effective prevention measure *(27)*. A rotavirus vaccine has recently been licensed and more are expected to be available for use in infants in the near future. However, the vaccine is likely to be costly and it is therefore crucial to assess the cost effectiveness of vaccine delivery before deciding whether to introduce it into routine immunization services.

The following data should be collected for a cost-effectiveness analysis of a rotavirus vaccine:

1) epidemiological rotavirus diarrhoea data
2) health care utilization data according to different types of providers
3) treatment cost data
4) costs of vaccine delivery.

All these data, except the costs of vaccine delivery, have been explained in the previous sections. However, when looking at rotavirus vaccine, the proportion of total diarrhoea caused by rotavirus should be estimated. This can be based either on published global or country-specific references *(15)*. Moreover, it is also necessary to estimate the cases and deaths due to rotavirus diarrhoea according to age in months. This is due to the fact that the vaccine might be administered later than when some of the cases occur and it will therefore not prevent these.

4.3.2 Costs of vaccine delivery

The rotavirus vaccine is an oral vaccine and vaccine delivery is therefore relatively simple compared to vaccines delivered by injection. Children should receive three doses of rotavirus vaccine normally delivered at the same time as diphtheria–tetanus–pertussis (DTP) vaccine. Hence, no additional visits to health services are needed. The most important incremental cost item is therefore likely to be the vaccine. Annual costs of the vaccine are estimated from the vaccine price per dose multiplied by the annual number of doses, including wastage and reserve stock. In addition, it should be assessed whether any investment in the cold chain is needed to accommodate the new vaccine. This can be done by using the WHO vaccine volume calculator, which is a tool used for estimating the percentage increase in storage space needed with introduction of a new vaccine. The calculator is available from: *http://www.who.int/vaccines-documents/DoxGen/H3DoxList.htm*. Activities such as training and disease surveillance should also be included. Guidelines for estimating the incremental costs of introducing a new vaccine into the national immunization system have been developed by WHO *(28)*. In these guidelines, it is explained how to predict the quantities of all resources needed for the vaccine introduction along with their respective unit costs.

4.3.3 Estimating the incremental cost-effectiveness ratio

The incremental cost-effectiveness ratio of a rotavirus vaccine is estimated by combining the disease burden and cost data into a single ratio. The lower the value of the incremental cost-effectiveness ratio, the more favourable the intervention is. For vaccines, cost-effectiveness estimates are normally generated on a cohort basis. The costs of vaccinating a cohort of children with rotavirus vaccine should thus be estimated as well as the predicted rotavirus cases and deaths of a cohort, with and without vaccination.

The standard way of presenting the cost-effectiveness ratio is outlined in Table 21. According to conventional guidelines for economic evaluation, the results should be presented both with and without the discounting of future health effects *(29, 30)*. Future costs should always be discounted. Most guidelines recommend an annual discount rate of 3% for costs and effects *(30)*. For rotavirus diarrhoea, there will,

however, not be a big difference between the discounted and undiscounted results, as most cases and deaths occur early in a child's life. Hence, the effects will be seen relatively soon after vaccinations have been delivered. At the most, effects should be discounted 3–4 years into the future.

The net costs are defined as the difference between treatment costs saved and vaccine delivery. The costs can be presented according to various perspectives, as explained in Section 4.2. If the net costs of rotavirus vaccination are negative, the intervention is said to "dominate" the other alternative (no rotavirus vaccination) and the cost-effectiveness ratio cannot be calculated *(29)*. In this case, vaccine introduction is cost saving and should therefore be clearly recommended.

Table 21: Presentation of the incremental cost-effectiveness of a rotavirus vaccine

Intervention	Treatment costs	Vaccine delivery costs	Net costs	Total cases	Total deaths	Incr. costs (M)	Incr. cases (N)	Incr. deaths (O)	Incr. C/E (cases)	Incr. cost (deaths)
Undiscounted results										
No rotavirus vaccination	A	–	A	E	I	–	–	–	–	–
Rotavirus vaccination	B	D	D – B	F	J	(D – B) – A	E – F	I – J	M/N	M/O
Discounted results (3%)										
No rotavirus vaccination	A	–	A	G	K	–	–	–	–	–
Rotavirus vaccination	B	D	D – B	H	L	(D – B) – A	H – G	L – K	M/N	M/O

Key: Incr. = incremental
C/E = cost-effectiveness

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The World Health Organization has managed cooperation with its Member States and provided technical support in the field of vaccine-preventable diseases since 1975. In 2003, the office carrying out this function was renamed the WHO Department of Immunization, Vaccines and Biologicals.

The Department's goal is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. Work towards this goal can be visualized as occurring along a continuum. The range of activities spans from research, development and evaluation of vaccines to implementation and evaluation of immunization programmes in countries.

WHO facilitates and coordinates research and development on new vaccines and immunization-related technologies for viral, bacterial and parasitic diseases. Existing life-saving vaccines are further improved and new vaccines targeted at public health crises, such as HIV/AIDS and SARS, are discovered and tested (Initiative for Vaccine Research).

The quality and safety of vaccines and other biological medicines is ensured through the development and establishment of global norms and standards (Quality Assurance and Safety of Biologicals).

The evaluation of the impact of vaccine-preventable diseases informs decisions to introduce new vaccines. Optimal strategies and activities for reducing morbidity and mortality through the use of vaccines are implemented (Vaccine Assessment and Monitoring).

Efforts are directed towards reducing financial and technical barriers to the introduction of new and established vaccines and immunization-related technologies (Access to Technologies).

Under the guidance of its Member States, WHO, in conjunction with outside world experts, develops and promotes policies and strategies to maximize the use and delivery of vaccines of public health importance. Countries are supported so that they acquire the technical and managerial skills, competence and infrastructure needed to achieve disease control and/or elimination and eradication objectives (Expanded Programme on Immunization).

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