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PROTOCOL FOR THE ASSESSMENT OF STI CASE MANAGEMENT THROUGH HEALTH FACILITY SURVEY

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1.

Introduction

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1. INTRODUCTION

Sexually transmitted infections (STIs) are a major public health problem in many countries. Since the presence of other STIs increases the likelihood of HIV transmission, the advent of AIDS has led to a new push to treat and prevent STIs. One of the cornerstones of STI control is adequate case management of patients with STIs. This includes diagnosis, treatment and individual health education and counseling on disease prevention and partner notification. Many programmes also focus on increasing the use of STI treatment facilities, especially among young people whose needs were largely neglected by existing services.

The package of STI care can include aetiologic or syndromic diagnosis. In high prevalence, low resource situations, STI programmes are focusing on syndromic management of STIs as the most practical approach, while in middle-income countries aetiologic diagnosis is also used. The shift to syndromic management has increased the potential coverage of care, since there is no need for laboratory equipment. Nevertheless, it has required a huge investment in training for nurses and other health care providers who were new to the approach and often to STI care in general.

In terms of monitoring and evaluation, there is a need to continue monitoring program efforts to treat STIs effectively and efficiently. The use of STI services as an entry point for prevention of further sexual risk behavior, as well as a point of access (through partner referral) to other people at high risk for HIV and STIs, should also be monitored.

There is more experience with M&E of STI programmes than with most other areas of HIV-related programming. In terms of the HIV epidemic, monitoring STIs is especially important at two levels: effective treatment of STIs is important because STIs significantly increase the chance of HIV transmission per act of unprotected sex between an infected and an uninfected partner. At an impact level, STIs can be used as a proxy measure for the impact of HIV prevention programmes because STIs are, like HIV, a marker of unprotected sex with a non-monogamous partner. Unlike HIV, however, bacterial STIs are curable, and therefore new cases are likely to reflect much more recent sexual activity than HIV, which can be a marker of risk behavior as long as a decade before. So HIV prevention programmes ought to have a visible impact on STIs before any significant changes in HIV prevalence can be seen.

Key questions

- Are STI services providing adequate care for men and women infected with STIs?
- Are drugs necessary for treatment available?
- Are STI services used effectively as an entry point for HIV prevention?

This protocol provides guidance on data collection methods to assess the pattern of health service utilization for STIs through health facility surveys. Such information is essential for planning the next steps in evaluating the quality of STI care in a more comprehensive way. Information from health facility assessments complements information collected to evaluate the total effort of an HIV/AIDS/STI programme (see Guide and other methods packages for information on other indicators and data collection strategies).

2. OBJECTIVES

The main objectives of the health facility survey are as follows:

- (a) To ascertain the appropriateness of case management provided to male and female health facility attendees reporting with an STI or symptoms of an STI;
- (b) To determine the proportion of health facility attendees reporting with complaints of STI who receive appropriate advice regarding condom use, partner notification and referral for voluntary HIV testing; and
- (c) To assess the adequacy of health facility infrastructure for case management of STIs.

The following sub-objectives can be distinguished:

- To list the sources of health care facilities where STI case management is provided;
- To help targeting of continuing in-service training in STI case management for providers;
- To assess areas of strength and weakness in availability of antibiotics and condoms, in systems for partner notification, in referral for voluntary HIV testing and in potential constraints to improvement in these areas; and
- To assess provider attitudes towards STI clients.

National programmes may have additional specific objectives.

3. **DEFINITIONS**

A health care provider (HCP) is defined as a person trained in allopathic methods. This definition includes nurses, doctors, pharmacists, and traditional healers who have received training in allopathic methods. Excluded are providers who are only qualified in non-allopathic medicine.

A health care facility (HCF) is defined as a setting where health care is provided by at least one person trained in allopathic methods.

Syndromic management is defined as the diagnosis and treatment of select symptomatic STIs based on the presence of specific symptoms which suggest an infection. The patient is questioned and physically examined, if the symptoms through their presentation suggest an infection, the patient is then treated for a spectrum of organisms that may be causing the symptoms from which they are suffering. Syndromic management is most commonly conducted for urethral discharge in men and genital ulcer disease in men and women. In addition, some programs have also included vaginal discharge in women. This approach removes the need for logistically difficult and sometimes expensive laboratory testing in many settings.

Aetiologic management is defined as the diagnosis and treatment of STIs based on laboratory tests to identify the specific organisms which are causing the symptoms from which a patient is suffering. The patient is then treated for the organism(s) identified.

4. DESCRIPTION OF INDICATORS

This protocol describes procedures for measuring three indicators to assess the quality of STI services.

Summary of indicators

STI Service Indicator 1: Appropriate diagnosis and treatment of STIs

STI Service Indicator 2: Advice to STI patients on prevention and referral to HIV testing services

STI Service Indicator 3: Drug supply at STI clinics

4.1 STI Service indicators 1 and 2

STI Service indicators 1 and 2 presented below are adapted from prevention indicators (PIs) 6 & 7, two of the core PIs developed by WHO's Global Programme on AIDS (GPA) in 1994 to assist national AIDS programmes (NAPs) in evaluating prevention efforts. These indicators measure the quality of case management provided to patients who present at HCFs with a possible STI. Both indicators should be assessed against the national guidelines for STI case management. Where national guidelines are not available, WHO guidelines on the syndromic management of STIs may be used to guide assessment of appropriate treatment.

This protocol presents a revised version of PI 6 & 7 that includes alternative data collection strategies. The PI 6 & 7 protocol called for the measurement of these indicators through provider interviews and observation of provider and client interaction. However, only the observed data are used in constructing the indicator. Providers are assessed on the following three items: history taking, examination and treatment of patients. A provider must score positively on all three items of client interaction for that client to enter the numerator of the indicator.

Subsequent field applications have also assessed STI case management through provider interviews alone, exit interviews with clients, and interactions with "mystery" clients — that is, trained assessors posing as clients (Saidel et.al., 1998). These alternative data collection strategies were used to respond to programmatic interests and/or difficulties in implementing the original protocol. This protocol presents the observation and provider interviews as the preferred methods of data collection, but also presents alternative data collection strategies.

In addition, this protocol has broadened the type of health care providers and health care facilities that can be assessed. An additional modification to PI 6 & 7 includes adopting the same denominator for both indicators.

Both STI Service Indicators 1 and 2 will be assessed on clients presenting at HCFs for the first time during a given episode of a possible STI, since the components of case management in the indicators would not necessarily apply to repeat consultations during a single episode.

STI Service Indicator 1: Appropriate diagnosis and treatment of STIs.

Number of individuals presenting with specific STIs or STI symptoms in health facilities who are assessed and treated in an appropriate way (according to national standards)

Number of individuals presenting with specific STIs or STI symptoms in health facilities

Definition

The percentage of patients with STIs or STI symptoms at selected HCFs who are appropriately diagnosed and treated according to national guidelines, among all STI patients seeking STI care.

What it measures

This indicator reflects the success of provider training in STI case management, combined with efforts to ensure adequate supplies of drugs and other necessary materials to facilities. It tracks changes in the provision of adequate care to patients seeking care for STIs. The quality of care provided is expressed in terms of the adequacy of the history taking, assessment and treatment of patients reporting to facilities with specific STIs.

The choice of STI service delivery points surveyed is important. Traditionally, this indicator has been constructed primarily for public sector STI clinics. This is largely because most of the early training in syndromic management was of public sector employees. However it is widely recognized that people with STIs often seek treatment in other sectors — either at private sector clinics, from pharmacies or from traditional healers. Some countries have begun to include these sectors in training programmes for syndromic management, and evaluations using this indicator have successfully been carried out in these sectors. Service delivery points surveyed should include representative service providers from any sector that has received training in syndromic management of STIs.

How to measure it

"Appropriate" diagnosis and treatment is assessed according to national guidelines governing STI services. In developing countries these will most commonly include protocols for the syndromic management of common local sexually transmitted pathogens, including treatment with drugs specified in national drug lists. In some countries, both syndromic and aetiological management is recognized as appropriate, according to the diagnostic capacity of the service provider. Where national guidelines are not available, WHO guidelines on the syndromic management of STIs may be used to guide assessment of appropriate treatment.

Measurement details are provided in section 5 below.

Strengths and limitations

This indicator, measured through observation, but including provider interviews in the process of data collection for validation purposes, has been widely used and proven to be feasible (Saidel et.al. 1998). There has been discussion of the extent to which the direct observation and provider interview methodologies bias data. It is thought that service providers perform better under observation than they normally would, or over-report "correct" diagnosis and treatment, diminishing the gap between knowledge and practice. In addition to proving to be feasible, the application of client exit interviews and mystery patient methodologies has demonstrated that the

biases are not as great as was assumed. The gap between knowledge and practice regarding treatment is often shaped by the fact that service providers are aware that STI fighting drugs are unavailable or unaffordable, and thus the appropriate protocol which call for their use is not followed. Because of this, it is recommended that this indicator be presented together with indicators of drug availability, such as that proposed in STI Service Indicator 3. When conducting exit interviews, it is worth examining the drugs that were actually prescribed, as the drugs obtained from the pharmacy may often be incorrect due to inadequate supplies or other reasons.

As with all composite indicators, improvements in some areas may mask deterioration in others. If service in one area is poor, the facility will score poorly on the indicator, even if service provision in other areas has progressed significantly. Programme managers need scores reported separately by area of knowledge and performance in order to identify areas of weakness and to improve training programmes.

STI Service Indicator 2: Advice to STI patients on prevention and referral to voluntary HIV testing services

Number of individuals seeking STI care in health facilities that have received appropriate advice on condom use, partner notification, and who are referred for HIV testing

Number of individuals presenting with specific STIs or STI symptoms at health facilities

Definition

Percent of patients with STIs or STI symptoms who are given advice on condom use, partner notification and who are referred for HIV testing, among all STI patients seeking STI care.

What it measures

STI services seek not just to treat STIs but also to prevent their recurrence by promoting condom use and by encouraging the treatment of partners to avoid reinfection. In addition, STI care is increasingly seen as an entry point for referral for voluntary counseling and testing (VCT) for HIV. This indicator measures the extent to which these aspects of STI service provisions are functioning.

How to measure it

P I7 only includes the first two elements of this indicator: advice on condom use and partner notification (a health care provider has to score positively on both condom advice and partner notification advice for the client to enter the numerator for this indicator). STI Service Indicator 2 includes an additional element, referral for VCT for HIV. A health care provider must score positively on all three items (condom advice, partner notification and referral for VCT for HIV) for the client to enter the numerator for this indicator. However, if it is not a national policy to refer STI patients for VCT of HIV or if VCT services are unavailable and not actively promoted by national AIDS/STI programmes, this item should be excluded from this indicator. For this reason and others described below, it is important that the different components of this indicator be reported separately.

This protocol describes how to measure the three elements of STI Service Indicator 2 through direct observation of interaction between care providers and clients or through one of several alternative methods. Further details on measuring this indicator are provided in section 5.

Strengths and limitations

If a client is at an STI clinic, previous efforts to promote safe behavior have failed them. This indicator is not intended for assessing impact of prevention initiatives — it merely assesses the extent to which service providers are complying with standards. As mentioned previously, there is debate on the extent to which direct observation may introduce bias, as it is thought that service providers perform better under observation. It has also been suggested that exit interviews with clients may be more cost-effective than direct observation; although this may lead client misreport of the actual content of the counseling. Further research is needed to determine the reliability of exit interviews in collecting data for this indicator.

Condom promotion, advice on partner referral and referral for VCT for HIV are quite distinct activities. The value of an aggregate indicator in this field is therefore somewhat limited, at least to programme staff. In addition, referral to HIV testing services will depend upon the local availability of these services. Further, the addition of this component will disrupt trends over time in those countries where WHO/GPA Prevention Indicator 7 has been calculated in the past. For these reasons, care must be taken to ensure than the three separate elements of this indicator are reported separately.

4.2 STI Service Indicator 3: Drug supply at STI clinics

Number of individuals served by HCFs that provide STI services that have a current supply of essential STI drugs and that have reported no stock-outs lasting longer than one week in the preceding 12 months

Number of individuals presenting with specific STIs or STI symptoms at HCFs

Definition

Percentage of clients served by STI HCFs that have a current supply of essential STI drugs and report no stock-outs lasting longer than one week in the preceding 12 months, among all STI patients seeking STI care.

What it measures

Correct history taking, diagnosis and prescription are all important, but if drugs are not available these will not translate into cases cured and will therefore have no positive impact on reducing the likelihood of HIV infection. National AIDS programmes engaged in improving STI services have invested resources into improving drug distribution services and ensuring adequate supply of the essential drugs used for STI syndromic management. This indicator is intended to measure the impact of these efforts and ensuring that service providers are consistently supplied with essential STI drugs.

How to measure it

Countries promoting syndromic management of STIs should have protocols for prescribing drugs for a particular syndrome. These drugs should also be part of the nation's essential drug list. Drugs necessary to treat each of the important syndromes should be included in the stock-check for this indicator. This is accomplished by taking a random sample of STI-providing HCFs to

stock-check their supplies of designated drugs. In addition, clinic management is questioned about stock-outs in the last 12 months, and clinic stock records are reviewed for that period. The number of clients seen by the HCF (client volume) is also recorded. The sampling frame for the selection of sites may include private clinics, hospitals, non-government run services, as well as public facilities. Because a stock-out at a smaller clinic will likely have a less dramatic impact on STIs compared to the same event at a larger clinic, HCFs are weighted by their client volume. Further details on measurement of this indicator are provided in section 5.

Strengths and limitations

While this indicator provides an accurate measure of a consistent supply of drugs to STI service facilities, it is often the case that clients may be buying their prescriptions for STIs at other sources, such as a pharmacy or local market. Indeed, in countries where the control of drug supplies is lax, a stock-out in a public clinic may simply mean that the supply of drugs has been diverted to another nearby outlet. While this may affect the cost of the drug to the client (and therefore accessibility), it may not necessarily affect the physical availability of the drug.

Again, the selection of STI facilities may have a major influence on this indicator. The facility survey should attempt to include a mix of all major provider categories in both the public and the private sectors.

5. DESIGN AND METHODS

This protocol outlines the procedures for carrying out a descriptive survey of a sample of HCFs providing care to people presenting with a STI or symptoms of STIs. Several different data collection strategies can be applied in the sample of HCFs to measure STI Service Indicators 1-3, including observation, provider interviews, patient exit interviews, mystery patient and register reviews. While all these methods have their advantages and disadvantages (see section 5.3), observation of interaction between care providers and clients, together with provider interviews, is generally considered the preferred method because it assesses actual case management of STI patients.

Section 5.1 will present the sampling strategy for selecting HCFs (that is applicable to all the data collection strategies presented in this protocol) and the procedures for carrying out the observation and provider interviews. Adaptations for collecting data using the alternative data collection strategies are presented in section 5.3. Below is a summary of the different methods that will be presented in this protocol.

Summary of data collection strategies

Preferred method

• Observation of interaction of care providers and clients, and provider interviews

Alternative methods

- Provider interviews alone
- Patient Exit interviews
- Mystery Patient (simulation) studies
- Register reviews/patient encounter forms/supervisory visits

Data collection will involve:

- (a) An enumeration of HCFs in the selected areas to obtain a list of all those providing STI care;
- (b) a detailed observation of the interaction/practice of HCPs with their clients in selected HCFs to measure STI Service Indicators 1 and 2 (or one of the alternative data collection strategies);
- (c) an interview with HCPs (or one of the alternative data collection strategies) to measure STI Service Indicators 1 and 2; and
- (d) inventory of drugs available in selected HCFs to measure STI Service Indicator 3.

Note: Steps (a) and (d) are common to all data collection strategies.

This design enables one to obtain both an overview of STI health facilities and an evaluation of individual case management. The interview with HCPs also allows for identification of problems in training, organization and supply. Where observation or interviews with HCPs are not possible or where additional information is desired, the alternative data collection strategies can be used.

5.1 Sampling for HCFs, Observation, and Provider Interviews

The sampling design for measuring the three facility-based STI Service Indicators involves the following stages:

- (a) An enumeration of HCFs in the selected geographical areas to obtain a list of all possible facilities providing STI services (this includes different types of facilities);
- (b) a systematic or random selection of HCFs providing STI care (this can be stratified by type if necessary);
- (c) a systematic selection of patients at each HCF for STI care; and
- (d) a census (or sample if there are many) of all HCPs providing STI care at each HCF.

5.1.1 Sample size requirements

Determining sample size is a complex subject for any survey. For a facility survey there is added complexity because the survey has three target populations: facilities, staff and clients. Each of these requires its own sample, and thus its own sample size considerations. The complexity of determining a sample size is often due to the elusive issue of required level of precision. Survey budget and resource constraints, plus the likelihood of having to produce reliable estimates for domains also compound this issue.

The unit of analysis for the three STI service indicators is the clients. This presents some sampling challenges, since information on client volume is needed to determine the client sample size, which is not likely to be available from the sampling frame until after the interview with the facility sample has been conducted. **Therefore, information about client volume must be collected in the facility sample interview (Form 1).** This information will then be used by the sampler and survey team to decide on the size of the client sample and the best method for selecting the sample and conducting the interviews. Client volume information that should be entered on the facility survey-listing sheet includes average

number of STI clients per week¹. The days of the week that the facility is open for patients and its hours of operation should also be collected in the facility interview.

The sample size per facility should be in the range of 3-6 clients, on average. Selecting fewer than 3 clients per facility would not be cost effective, given the consequences of having to travel to each sample facility for only 1 or 2 client interviews. In contrast, more than 6 clients would likely pose a budget problem in the other direction, that is, the overall sample size for clients could easily exceed the budget, especially when the facility sample itself is large.

With a client sample in the range of 3-6 clients per facility, the reliability of the client estimates would be expected to be somewhat better than facility estimates, even though the design effect for the client sample may be higher than the facility sample. The larger sample would more than compensate, however, for the increased design effect. For example, with an expected sample size of 4 clients per facility, the sample size for the client sample would be, obviously, 4 times the facility sample size.

5.1.2 Determining the sample

The initial obstacle is usually the lack of information about the number of HCFs providing STI care and their client volumes. The first stage of the survey is the selection of geographical areas. The following steps are suggested for the selection of geographical areas, HCFs, HCPs, and clients.

5.1.2.1 Geographical areas

The geographical areas to be covered by the survey should be selected by the NAP. Areas to be covered will depend on program focus, population size, feasibility, and the geographical (and perhaps geopolitical) nature of the country. For example, in a small country the survey may cover all eligible facilities (see inclusion criteria below). However, in a large country the survey may be limited to a few provinces.

The NAP may decide to evaluate STI case management in the capital city alone; in all regional towns with populations above a designated size; or in a randomly selected sample of towns from a list of all those with a designated population. This will depend on national objectives and on resources.

5.1.2.2 Enumeration of health care facilities (Form 1)

The three STI Service Indicators will be measured on the basis of the scores obtained during *observations* in HCFs—clients are therefore the unit of analysis. Eligible HCFs can be public, private and non-governmental, but must include at least one registered allopathic health care worker who has seen at least five patients presenting with genital symptoms of STI in the week prior to the enumeration.

The first stage of the survey is to compile a list of all HCFs in the chosen geographical area. This should be done through interviews with key local informants (medical officers, administrators, health specialists etc.), using additional sources of information to identify private clinics/doctors where necessary (information from practitioners in public facilities, telephone directories, advertisements etc.).

Once the list of HCFs is compiled, trained interviewers should contact each facility by visit or telephone to establish whether or not they meet the inclusion criteria (the HCF has at least one HCP who has seen at least five STI patients in the previous week to being contacted). This should be done using Form 1

¹ The averages may be expressed, depending upon the information available at the facility, as daily, weekly, monthly or annual.

(appended), which should include the number of patients seen for STIs in the previous week, the number of practitioners who see STI patients and whether there are any specific days when STI patients are seen.

At this point HCPs should be asked whether they are willing to participate in the survey through later observation and interview. Where possible an appointment for the observation and interview should also be made at this time. This process should be facilitated by a formal letter of introduction from the Ministry of Health and an identity card.

When the enumeration has been completed, a total sampling frame of eligible HCFs will exist, including numbers of HCPs and an estimated patient volume for each site. The facility and client sample sizes will be determined once this information is obtained. Box 1 provides a detailed example of this procedure.

5.1.2.3 Observations of HCP-patient contacts (Form 2)

For each sample facility, a client sample is selected by having the interview team visit the facility for one full day and conduct an interview with an average of 4 clients that show up for consultation on that day. If there are no STI clients in a given day, the observer should record this fact at the end of the day and the observation ceased.

A list should be compiled by the interview team of all clients that come to the HCF on the day of the interview. A systematically selected sample of clients from this list should then be taken. For each selected client, client-staff observation data should be collected. Table 1 presents sampling intervals by average daily client volume.

Daily client volumes are shown in Table 1 as whole numbers. If the recorded volume for a given facility is fractional, it should be rounded to the nearest whole number. The volume ranges in the left-hand column will yield an average sample of four clients when the corresponding sampling interval in the right-hand column is used. When the recorded volume is 5 or less, all clients are to be interviewed, irrespective of the number that happen to show on the day the interviewing is scheduled.

In selecting the sample, the interviewing team must begin with a random start (randomly selected between 1 and the recommended sampling interval in the left-hand column of Table 1). The sampling interval is then added to the random start until an average of four client spots are established. Each corresponding client that comes in will then be selected, starting with the one that corresponds to the randomly selected start.

Example: Suppose the facility has average daily client volume of 16; Table 1 shows the sampling interval to be 4. A random number (to serve as the random start) between 1 and 4 must be selected; suppose it is 2. Then the second client who comes in for consultation that day will be sampled and subject to interview and client-staff observation. Every fourth client thereafter will also be sampled and interviewed.

Table 1: Sampling intervals for selecting average of 4 clients

Average daily client volume	Sampling interval
5 or less	1 (take all)
6-9	2
10-13	3
14-18	4
19-21	5
22-26	6
27-29	7
30-34	8
35-37	9
38-42	10

It is very important to keep track, accurately, of the number of clients that come in, so that the sampling interval is applied correctly. Therefore, a listing sheet of clients must be used for the sampling operation. The listing sheet can be very simple in form, containing only the names of the clients in the order in which they appear at the facility. The sample would then be selected from this list as it is compiled. The random start and sample selection numbers should also be entered on the blank listing sheet prior to the visit by the interviewing team to the facility, because the sampling interval will be known in advance.

Example: In the preceding example, the random start would be 2 and the sample selection numbers would be 2, 6, 10, 14. These numbers would be indicated on the blank listing sheet and the particular clients that fall into the sample would correspond to those whose names are listed on those lines. To avoid selection bias, the sample selection numbers should be extended beyond the expected 4 sample cases, since the exact number of clients that will show up on a given day will vary. In our example, therefore, the selection numbers might be extended to 18, 22, 26, 30, etc.

Note, the sample must include every kth client on the listing sheet (where k is the sampling interval), no matter how many the list contains, even when the sample results in many more than the expected 4 cases. This is done to avoid only selecting those clients that show up early, which may result in selection bias.

The steps for the client sample may be summarized as follows:

- (1) For each sampled facility, select a random day of the week to conduct the client interviews.
- (2) Look up the average daily volume of clients in the study universe.

- (3) Visit the facility for one full day of client interviewing.
- (4) Select clients who show up at the facility on that day, in accordance with Table 1.

Box 1 provides a detailed example of this procedure.

Box 1: Detailed example of sampling methodology

- Step 1: Enumeration of HCFs in selected region- After selecting the region that the HCF survey will cover, a sampling frame consisting of all eligible HCFs needs to be established. This list of eligible facilities (at least one HCP who has seen at least five STI patients in the previous week to being contacted) will be established through contact with key informants from the NAP, MOH and/or others. Ideally, a list will already exist of all eligible HCFs in the region. For this example, lets say we include 1,000 eligible HCFs in our sampling frame, which we will denote with N (N = 1,000). We would then have an enumerated list of HCFs from 1 to 1,000.
- Step 2: Sample size calculations- The sample size requirements will be calculated based on the following criteria: desired level of precision (d); an estimate of the population proportion (p) of the variable in question (0.5 should be used when an estimate is unavailable); and the acceptable level of committing a Type I error (is typically set at .05). When attempting to measure the difference between two indicators, as would be the case when measuring changes at two points in time, the probability of committing a Type II error must also be considered (). For this example, lets say n has been calculated to be 400 clients. Since we are to take an average of 4 clients per HCF, 100 HCFs would need to be sampled and visited in order to get 400 clients.
- Step 3: Simple random or systematical sampling of HCFs- After the facilities have been enumerated, simple random sampling (SRS) or systematic random sampling (SYS) can be used to select the HCFs. Remember that in our example we need to select 100 HCF to get our n of 400 clients. SRS would then require simply using a random number table (or generator) to get 100 random numbers between 1 and the total number of HCFs listed on our sampling frame (1,000). The HCFs corresponding to our 100 random numbers would then be selected. For SYS, we would first need to calculate a sampling interval (SI) by dividing N (1,000) by the number of HCFs needed (100). The resulting SI would thus be 1,000/100 = 10. We would then need to select a random start between 1 and our SI, which is 10 (a random numbers table or generator can be used for this purpose). Lets say we select 7. We would then take the 7th HCF on our sampling frame and every 10^{th} HCF thereafter until we obtain 100 HCFs (i.e. we would take the 7^{th} HCF, 17^{th} , 27^{th} , 37^{th}997th, which will yield 100 HCFs).
- Step 4: Getting the average client volume for each selected HCF- The average client volume for each HCF will need to be obtained. Ideally, a call or visit can be made to each HCF and the client volume obtained from records. If only weakly or monthly client volume records exist, they will need to be converted to daily average volumes. Where no records exist of client volumes, a field staff will be required to visit the HCF and observe the number of clients seeking STI services in a day. The average daily client for each clinic is then recorded onto the sampling frame next to the corresponding HCF.
- Step 5: Visiting selected HCFs and obtaining a sample of 4 STI clients each- Each of the HCF selected in step 3 will require a visit to observe/interview 4 STI-clients (this will result in an n of 400). Prior to arrival at HCF: The field staff will use Table 1 to get the appropriate SI, which will yield a sample of 4. From the sampling frame, the average daily client volume will be obtained. Table 1 will then be used to identify the appropriate SI that corresponds to this volume (ranges of client intervals are given in the right hand column). SYS will then be used to select the 4 clients from the expected client volume in exactly the same way SYS is explained in step 3. At the HCF: Suppose the HCF has an average daily client volume of 16; Table 1 shows the sampling interval to be 4. A random number (to serve as the random start) between 1 and 4 must be selected; suppose it is 2. Then the second client who comes in for consultation that day will be sampled and subject to interview and client-staff observation. Every fourth client thereafter will also be sampled and interviewed. A simple list can established that dictates which clients in order of arrival will be selected. In our example, about 20 spaces would be put on a piece of paper with the 2nd, 6th, 10th and 14th spots marked. As clients come in, their names are written down in order of arrival; the clients that fall on the selected spots would then be interviewed/observed. Note that to avoid selection bias, the sample selection numbers should be extended beyond the expected 4 sample cases, since the exact number of clients that will show up on a given day will vary.

5.1.2.4 Health care providers (Form 3)

5.2 Detailed method of data collection

5.2.1 Enumeration of health care facilities (Form 1)

See section 5.1.2.2

5.2.2 Observation of the practice of health care providers (Form 2)

5.2.2.1 Organization of the fieldwork

Fieldworkers who are recruited must have training at least in nursing and preferably in medicine (doctors or clinical medical students). Their medical background will facilitate the assessment of the quality of the HCP-patient interaction. If possible, there should be both male and female fieldworkers.

In each site a local coordinator will allocate one fieldworker to each HCP for one day. If an HCP sees mainly female patients, a female fieldworker should be allocated.

The fieldworkers will observe the HCP and complete the observation form (Form 2) for each HCP-patient contact. Observation should last for one day, regardless of the number of contacts observed. Form 2 should be completed for all patients seeking STI care.

Although limited, some information about the patient such as sex, age, marital status, presences of a STI symptom, and/or other relevant risk factors are to be recorded on Form 2. This information will assist in assessing the appropriateness of the components of STI Service Indicators 1 and 2. For example, it is important to record on the form if the patient is a prostitute, a man reporting casual anonymous sex, a child, or if there is any other factor that may influence case management or advice given.

The objective of the observation is to determine the quality of care received by the client by observing whether the HCP is following an agreed set of procedures in relation to STI case management. The standards against which the HCP will be tested are shown below and relate to history taking, examination, diagnosis, and treatment and prevention advice.

5.2.2.2 Standards for STI Service Indicator 1

In order for STI Service Indicator 1 to be marked positive, the HCP must meet the standards in history taking, examination, diagnosis and treatment.

(a) History

The patient must be asked about all of the following:

- Symptoms
- Onset/duration of symptoms
- Recent sexual contacts

(b) Examinations

Male patients should:

- Be undress so that the genitals are fully exposed

- Be examined for urethral discharge
- Be examined for genital lesions after retracting foreskin

Female patients should:

- Be asked to undress so that the genitals are fully exposed
- Be asked to lie down
- Have the labia separated and inspected

All patients should also be examined for inguinal lymphadenopathy. If sterile specula, lighting and gloves are available, women should have a speculum and bimanual pelvic examination. (These do not contribute to STI Service Indicator 1.)

(c) Diagnosis and treatment

The treatment should be in line with the guidelines established by the national AIDS/STI programme. A provisional list of treatments has been drawn up (Appendix 1) which should be modified to suit local conditions through discussions with experts. It is essential that these guidelines are specified at the outset of the study and that all observations and interviews are judged against the same criteria.

The guidelines should indicate whether a treatment is considered acceptable for a particular diagnosis. Treatments will be categorized as acceptable (according to recommended national and/or WHO guidelines) or not acceptable.

The appropriateness of the treatment clearly depends on the type of diagnosis. Where the diagnosis is aetiological [i.e. based on gram stain showing gram-negative intracellular diplococci (GNID)]—treatment for the correct corresponding agent is appropriate. Where such facilities do not exist (either on-site or through a near-by laboratory), or the HCP does not wait for the result before prescribing treatment, the syndromic approach to treatment should be followed. This will require the observer to record clearly what information was available to the HCP prior to making the diagnosis. The appropriateness of the treatment prescribed will depend on this information. The recommended guideline would be:

- For urethral discharge (UD) in men: Gonorrheal and chlamydial infections are the commonest causes of UD. According to the WHO Technical Report Series, No. 810 entitled *Management of Patients with Sexually Transmitted Diseases, concurrent* regimens for *both* gonorrhea and chlamydeous should be given (patterns of resistance of gonococci isolates in the region should be considered).
- <u>For genital ulcer disease (GUD) in men and in women:</u> Syphilis and chancroid are the most important/common and treatable causes of GUD. *Concurrent* regimens for *both* agents should be given following indications in Technical Report Series, No. 810.

STI Service Indicator 1 - A positive score requires that the HCP is satisfactory in history (a), examination (b) and treatment (c).

5.2.2.3 Standards for STI Service Indicator 2

For STI Service Indicator 2 to be marked positive, the HCP must do all of the following: promote condoms for the prevention of STI and HIV infection (this requires that the HCP discuss this with the patient); advise patients to refer sex partners for treatment or be given drugs for their partner(s); and advise patients on where to get HIV test and counseling.

The information required for the calculation of STI Service Indicator 2 will be obtained through observation of the following:

- i) Was advice on condom use provided during the encounter?
- ii) Was the patient encouraged to notify and refer his/her sexual partner(s)?
- iii) Was information on where to get an HIV test provided during the encounter?

All three of these elements must be scored positive for STI Service Indicator 2 to be positive. The only exception would be if there were clear reasons why, for example, it would be inappropriate to trace sex partners for notification, or if HIV testing were not available anywhere. Such reasons should be revealed by Q3 (i.e. code 2 = not married) and Q4 (i.e. contact with sex worker, child abuse, etc.).

STI Service Indicator 2 - A positive score requires that during the encounter with a patient the HCP does all of the following: (i) provides advice on condom use; (ii) effectively promotes partner notification; and (iii) provides information on where to get an HIV test.

5.2.3 Interviews with health care providers (Form 3)

Interviews with the HCPs will usually follow the observation sessions and use Form 3. The interviews will explore what diagnosis and treatment routines the HCP has for the three relevant syndromes (GUD in men, GUD in women and urethral discharge in men). Obviously, such information cannot replace the observation but it will provide insight into the consistency between observed and reported behavior. The results of these interviews will not contribute directly to the calculation of STI Service Indicators 1 or 2. They will, however, provide additional information about the knowledge of HCPs and the constraints that they identify in relation to case management and advice on prevention.

5.2.4 Individual log sheets (Form 4)

Form 4 is completed by the observer or interviewer as a log sheet to keep a record of all health care providers met, whether or not they have been successfully interviewed or observed.

5.2.5 Drug supply checklist (Form 5)

The observer or interviewer completes this checklist in order to assess the adequacy of the drug supply. The objective of the checklist is to determine whether the essential drugs needed to treat STIs are available at each HCF. The standards against which the HCF will be tested are shown below and relate to availability of essential drugs on the day of data collection and stock-outs in the preceding 12 months.

5.2.5.1 Standards for STI Service Indicator 3

For STI Service Indicator 3 to be marked positive, the HCF must have a current supply of STI drugs on the day the field staff visiting the clinic, and report no stock outs in the preceding 12 months. The first

element of this indicator assesses whether the necessary drugs are available to clients served by the health facility on the day of the research team visit. The second element of the indicator assesses whether drugs have been available to clients over the preceding 12 months. The drugs that will be assessed in this indicator will be those on the countries' essential drug list for STIs. Drugs necessary to treat each of the important syndromes should be included in the stock-check for this indicator.

The following information, obtained from observation and interviews, will be used to calculate STI Service Indicator 3 (only if *both* of these items are confirmed can STI Service Indicator 3 be positive):

- i) Are essential drugs for treating STIs available on the day of data collection?
- ii) Has there been no stock-out in any of the essential drugs for treating STIs in the preceding 12 months?

.STI Service Indicator 3 - A positive score requires that (a) on the day when clients are observed/interviewed there is a current supply of essential STI drugs and (b) the HCF reports no stock outs in the preceding 12 months

5.3 Alternative Data Collection Strategies to the Observation Approach

The measurement of PI 6 & 7 as described in the WHO/GPA protocol relies upon direct observation of the provider/client interaction along with interviews with the providers. With this approach, trained personnel observe how well the provider follows established guidelines on history taking, physical examination, diagnosis and choice of treatment. Many countries have attempted this methodology, but some found that it was not feasible and required significant adaptations for their local context, particularly in resource poor settings [1].

There are several limitations to the observation approach including: extensive financial and staff resource requirements, which may not be available in some settings; obtaining the cooperation of health authorities can pose a barrier; and bias can be introduced if providers behave differently while under observation (it is generally thought they perform better under observation).

Numerous countries that used PI 6 and PI 7 chose to adopt alternative evaluation methods that differed significantly from WHO/GPA protocol. These included patient exit interviews; mystery patient studies; register reviews; and patient encounter forms with supervisory visits. The following table presents the advantages and disadvantages of each approach.

DATA COLLECTION APPROACH	ADVANTAGES OVER OBSERVATION	DISADVANTAGES OVER OBERVATION
Provider interview alone	- Less expensive	- Provides information on provider knowledge rather than provider behavior
Client Exit Interviews	 More acceptable to program Less time consuming Less expensive Easier to implement Identifies what patients learned, rather than what the provider said 	 Patients not knowledgeable about medical examinations Patients not able to identify all procedures performed Cannot identify STI cases that the provider failed to diagnose Clients reluctant to say negative things about the provider (courtesy bias).
Mystery Patient (Simulation) Studies	- Removes observation bias (evaluators to observe the provider under real conditions) - Practical for pharmacy where observation is difficult	 Simulated patients do not have the clinical signs Ethical problems As expensive as observation
Register review/ Patient Encounter Forms and Supervisory Visit (only appropriate for resource poor countries)	- Simple - Less expensive	- Depends on adequate recording of information - Recall bias

References

- [1] Saidel et al. 1998. Indicators and the measurement of STI case management in developing countries. *AIDS*, Vol 12 (suppl 2).
- [2] Family Health International. 1997. Evaluation of STI Case Management Using Exit Interviews: A Pilot Study in Brazil. Arlington, VA.

5.3.1 Detailed methods of data collection for alternative data collection strategies

The data collection methods for the alternative data collection strategies are largely the same as for the preferred method (observation together with provider interview). The enumeration and sampling procedures for the HCF level is identical for all of the data collection strategies presented in this protocol. The following presents the data collection procedures for the providers and clients.

5.3.1.1 Provider interview alone (Form 3)

Some researchers in the field have argued for the need to have provider-based measures as an alternative to client-based measures of the quality of STI case management. However, making the provider the unit

of analysis will require an altogether new indicator, rather than an adjustment of how the existing indicator is measured. The provider, rather than the client, becomes the denominator, and this requires a different sampling strategy. Measurement of both client and provider based indicators could nevertheless occur simultaneously in a facility, although this may be too complicated and it may be preferable to adopt one of the two strategies.

The argument for provider-based measures are that they would link better to the provider interviews, and provide more useful guidance for improving the training of providers and for national programs more generally. In this case, one would conduct only one observation per provider. While this strategy would eliminate the design effect, there are often not enough providers. In addition, there is the drawback of only observing one type of syndrome per provider (be it GUD, UT or in some cases VD).

If the provider interview is conducted alone, then it is necessary to select a census or sample of providers to interview from each HCF, depending on how many providers work in the HCF.

5.3.1.2 Client Exit Interviews (Form 6)

If client exit interviews are conducted, the sampling and data collection procedures are the same as those for selecting clients for observation as presented in section 5.1.2.4.

5.3.1.3 Mystery Patient (Simulation) Studies

The mystery patient (simulation) methodology does not require any sampling of clients since the mystery patient poses as a client. However, it may be necessary to select providers (census or sample depending on number) in order to assess the quality of services from each provider.

The mystery patient methodology has been most commonly used in pharmacy settings where it can be difficult to observe a client-provider interaction. Therefore, this method may only be applied in a sub-set of facilities or in a study that is specifically assessing the quality of STI services in pharmacies.

5.3.1.4 Register review, Patient Encounter Forms and Supervisory Visit

The register review, patient encounter forms and supervisory visit methodology is based on clients, but rather than directly observing clients, information on the quality of STI services will be based on written records (either HCF records or supervisor records). The sample of client records to review is done systematically (just as the sampling of clients for observation is done in section 5.1.2.4). Therefore, every k^{th} record is reviewed depending on the client volume and the corresponding sampling interval.

As clinic records are often incomplete, this approach is only appropriate in resource-constrained settings, where it is not possible to interview or observe clients and/or providers.

6. COORDINATION AND TRAINING

A national principal investigator will take responsibility for the survey. The principal investigator should be a doctor experienced in STI work and control programmes and should be free to concentrate on the work for six weeks. If the survey is to be done in different regions/towns, medically qualified local coordinators should also be appointed.

One or two interviewers who have been given a half-day-training in the use of the enumeration form by the national principal investigator should do the first enumeration of HCFs. They should then carry out the enumeration in the two weeks prior to the recruitment of fieldworkers for the main part of the survey. If several regions of a country are selected to participate in the survey, central-level training of regional

coordinators will be organized. These regional principal investigators will be responsible for regional (or district) training.

The medically trained interviewers will be trained for their survey work at a one-week workshop run by the national principal investigator. Two days of training and role-play with the observation and interview schedules will be followed by three days of observation and interview under close supervision.

The first days of fieldwork will be very closely supervised and the coordinator will go over each questionnaire with the fieldworkers until they have completed five of each satisfactorily. Close supervision will continue throughout the fieldwork period. The coordinator will check each questionnaire as well as the coding of the diagnosis and treatment sections of the observation. This will preferably be done at the central office on a daily basis after the sessions.

7. DATA MANAGEMENT AND ANALYSIS

Supervisory visits by the principal investigator, and daily scrutiny of the completed observation forms by the supervisor and the principal investigator will ensure consistency in recording and will minimize inter-observer variations during the data collection phase. At these supervisory sessions, decisions will be made about the influence of patient characteristics on the scoring of STI Service Indicators 1 and 2. Coding of all forms should also be carried out at these sessions.

The calculation of STI Service Indicators 1 and 2 can be derived directly from the forms and should be done in each region by hand. Forms should then be sent to the national principal investigator for entry onto a computer database for a more sophisticated analysis. Data will be entered and checked using the EPI-INFO programme. Since the sample of HCP-patient contacts is selected in more than one stage, and may also be stratified, appropriate variance formulae should be used in the calculation of confidence intervals on the estimates of STI Service Indicators 1 and 2, and on their change over repeated surveys. The analysis should be overseen by the principal investigator together with a statistician assigned to the project.

8. TIME FRAME FOR THE HEALTH FACILITY SURVEY

The following chart notes the time frame for completion of each activity.

9. STAFF REQUIREMENTS AND TRAINING

The following staff are required for the survey:

- **Principal investigator** (1). The principal investigator should be recruited from the Ministry of Health, preferably from the national AIDS/STI programme or the epidemiology unit. He or she will be responsible for the whole data collection exercise as well as conducting the key informant interviews to identify HCFs.

TIME FRAME FOR THE HEALTH FACILITY SURVEY

Activity		Month 1			Month 2			Month 3				
Week:	1	2	3	4	5	6	7	8	9	10	11	12
Identification of coordinators	х											
Briefing of coordinators		X										
Key informant interviews			X									
Enumeration of HCPs (+ training of enumerators)				Х	х							
Sampling of health facilities					X							
Training of coordinators						X						
Training of fieldworkers							x					
Observations and interviews							x	x	X			
Data entry								x	X	x		
Analysis										X	X	
Reporting												X

- Fieldworkers or observers (10). Ten nurses/medical assistants or medical doctors, preferably over 30 years old, will be recruited for the health facility enumeration, the observation of HCP-patient encounters and the HCP interviews. These persons will receive training in the following areas: interpersonal and observational skills; interviewing, recording observations on a standard recording sheet; and assessing the quality of case management provided by the HCP. The duration of training will be four days.
- **Statistical clerk** (1). A clerk will be employed to transfer data from the observation recording sheets to summary sheets and to prepare these data for analysis.
- **Drivers.** Depending on the geographical setting it may be necessary to provide transport and drivers for the fieldworkers.
- Data analyst.

10. BUDGET ITEMS

The total cost of the collection of information to measure the three STI Service Indicators will depend on the area and population covered by the study and the sample size. The following presents an illustrative listing of items needed for a health facility survey (with a sample size of approximately 60 facilities):

I. Allowances

- 1 Office editor
- 1 Survey director
- 1 Survey assistant director
- 1 Secretary
- 1 Clerk
- 1 Data analyst
- 2 Drivers
- 2 Keyboard operators for data entry
- 3 Supervisors
- 10 Medical assistants for observations

II. Training

(15 x 4 days)

III. Transportation

- 2 vehicles for survey
- 1 vehicle for coordination
- Fuel
- Repair and maintenance

IV. Supplies

- Ouestionnaires
- File folders
- Other documents

V. Miscellaneous

- Insurance
- Contingencies
- Report writing
- Photocopying
- Workshop (30 persons)

11. REPORTING

STI indicators 1 and 2 measure the extent to which case management of STI patients can be considered adequate in a given setting. An aggregate score for each indicator can be calculated to provide a national figure for the adequacy of STI case management, which will allow for assessing trends over time.

It is important that the data be presented in a desegregated format to identify areas of weakness and constraints that should be addressed to render the programme more effective and assist national programme managers in developing and/or adapting their national STI programmes.

HEALTH FACILITY SURVEY ENUMERATION OF HEALTH CARE FACILITY (HCF)

HEALTH FACILITY SURVEY ENUMERATION OF HEALTH CARE FACILITY (HCF)

				Questionnaire number
				Date: _
Inter Regi	viewer Code on	 		nd Address of HCF
Heal Priva NGC Othe	th Center th Station ate Clinic O Clinic		Phone N Person I (name an	nterviewed nd position)
1.	How many STI patients health care facility last v			
2.	How many health care p During any one day (i.e. How many of th How many of th	HCPs that prescrib ese are doctors?		
3.	Are there any specific da care providers see STI p - If yes, which	atients		Y N
4.	•	1?		Y N
5.	Would you agree to obse carried out in this health - Observation - Interviews	care facility?	iews being	Y N Y N
If ap	propriate: Appointment for observa Appointment for intervie]	Date:

Summary of enumeration				
Region				
Type of facility				
Eligible	Yes / No			
Number of HCP to be observed				
Maximum number of HCP-patient observations to be observed *				
Selected	Yes / No			

^{*} average daily STI patients per HCP (i.e. Total number of STI patients per HCP in last week divided by 5)

HEALTH FACILITY SURVEY OBSERVATION

HEALTH FACILITY SURVEY OBSERVATION

		Questionnaire number _
		Date:
Obser Facilit Health	PLETE THIS SECTION BEFORE OBSERVATION: ver's code by number in care provider (HCP) code vation number	_ _
	sion of HCP (nurse = 1; doctor = 2) FHCP (male = 1; female = 2)	
	Patient characteristics:	
1. 2.	Sex (male = 1; female = 2) Age (less than 30 years = 1; 30 or over = 3)	
3.	Marital status (married = 1; other = 2)	
4.	Other relevant circumstances relating to last sexual contacts (e.g. prostitute, truck driver, victim of assault)	
5.	Remarks Presenting STI complaint*	
*Refe	r to code portion of this section Observation	
6		
6.	 Are the following issues addressed: Nature of present symptoms? Onset or duration of symptoms? History of recent sexual contacts? 	Y N Y N Y N
7.	Are patient's genitals fully exposed, with female patient lying down	? Y N
8.	Are examination gloves used?	Y N
9.	Are the external genitalia thoroughly examined for discharge and lesions?	

		OR UNCIRCUMCISED MEN, is the foreskin retror OR WOMEN, are labia separated and inspected?	racted? Y N Y N
FOR W	VOMEN	ONLY:	
10.	Is a sp	eculum examination performed?	Y N NA
	If YES	, is an adequate light source used?	Y N NA
11.	Is a bin	manual examination performed?	Y N
12. Is a	a Gram	stain obtained?	Y N NA
		s, is the result of the Gram stain available on the deconsultation?	lay Y N
13. Is I	Darkfiel	d microscopy obtained?	Y N NA
		s, is the result of Darkfield microscopy available day of the consultation?	Y N
14. Is a	an RPR/	VDRL obtained?	Y N
		s, is the result of the RPR/VDRL available on the consultation	day Y N
15. Do	Investi	ICP obtain/request laboratory gations OTHER than those in ons 12-14?	Y N
	If YES	, which tests?	
	•••••		Refer to code portion of this section
16. AS	K the H	ICP what his/her diagnosis is and write down:	
			Refer to code portion of this section
	16a.	Were the results of any laboratory tests available to the HCP before this diagnosis?	e Y N

17. ASK the HCP what therapy he or she is prescribing/providing to the patient, at this consultation

	DRUG 1 name	*
	 Quantity 	
	 Dosage: daily bid tid qid other 	
	■ Route: im oral topical	
	■ Duration of treatment (days):	
	DRUG 2 name	*
	 Quantity 	The state of the s
	• Dosage: daily bid tid qid other	
	• Route: im oral topical	
	■ Duration of treatment (days):	
* effe	ective syndromic treatment = 1; effective aetiologic treatment = 2;	
18.	Will the final treatment depend on the results of laboratory test	ts? Y N
19.	Where does the patient obtain the prescribed drugs?	
	1. At this clinic same day (free)	
	2. At this clinic same day (paid)	
	3. At the pharmacy/chemist shop	
	4. At this clinic and at the pharmacy	
	5. Other, SPECIFY:	
20.	Is there any delay (more than four hours) between	
	the initial consultation and the provision of treatment?	Y N
	If yes, how long? More than 4 h	nours but same day
	if yes, now long:	Next day
		Longer
		Longer
21.	Does the HCP instruct the patient on the importance of	
	completing the full course of treatment?	Y N
	compround the run course of troubles.	2
22.	Is the risk of AIDS/HIV mentioned?	Y N
		1
23.	Are condoms promoted for STI/HIV prevention?	Y N
	•	
24.	Are condom(s) provided/sold to the patient?	Y N
	•	
	If YES, how many condoms are provided?	Number
25.	Are instructions on condom use offered?	Y N
26.	Is patient urged to refer partner(s) for treatment or is	
	patient given drugs for partner?	Y N
27.	Is patient given information on where to go for HIV testing?	Y N
• •		
28.	Was privacy maintained during the consultation?	Y N

FINAL RESULTS

- History (Q6) - Examination (Q9) - Treatment (Q17) Final Score - Advice on condom (Q23)	
STI 2 Advice on condom (O23)	
STI 2 - Advice on condom (Q23) - Advice on partner notification (Q26) - Information on HIV testing (Q27)	
Final score	

Remarks/observations:					

CODING OF OBSERVATIONS

Q. 15 First 3 tests only

- 1. GC culture
- 2. HIV test
- 3. TPHA
- 4. FTA (ABS)
- 5. Giemsa or Leishman's stain
- 6. TV culture
- 7. Urine C & S
- 8. Other (e.g. blood count)

Q. 16

3.

Aetiologic Syndromic 1. Gonorrhea 10. Urethritis 2. NGU/NSU 11. GUD

99.

No Answer

4. Chancroid

Syphilis

5. HSV

Donavonosis

6. Wart

Q.17 THERAPY SECTION

In the absence of laboratory information to guide treatment and with no laboratory results pending, treatment should be based on a syndromic diagnosis. Since data on the relative frequencies of the different etiologies of urethral discharge and GUD and of mixed infections are not available, it will be difficult to judge what an "appropriate" treatment consists of. National guidelines may be based only on an aetiologic diagnosis and will not usually recommend co-treatment when etiology is uncertain.

The following are WHO's recommendations:

- Urethral discharges should be treated as both GC AND CTD
- GUD should be treated as both syphilis AND chancroid
- Genital herpes should be kept dry and clean
- Genital warts should be treated according to guidelines

The following section describes the various treatment scenarios according to availability of laboratory tests and/or laboratory results.

URETHRAL DISCHARGE

Scenario A: Gram stain not performed or results not available

- 1. Effective against GC AND CT
- 2. Effective against GC only or effective against CT only
- 3. Not effective against either/not recommended/not appropriate

Scenario B: Gram stain positive for ICGC

- 1. Effective against GC AND CT
- 2. Effective against GC only
- 3. Effective against CT only or not effective against either/not recommended

Scenario C: Gram stain negative for GC

- 1. Effective against GC AND CT or effective against CT only
- 2. Effective against GC only or not effective against either/not recommended

GUD

Scenario A: Presence of vesicular lesions

1. Lesions kept clean and dry (not necessary to treat with acyclovir)

Scenario B: VDRL not performed

- 1. Effective against syphilis AND chancroid
- 2. Effective against syphilis only or effective against chancroid only
- 3. Not effective against either/not recommended

Scenario C: VDRL negative

- 1. Effective against syphilis AND chancroid or effective against chancroid only
- 2. Effective against syphilis only or not effective against either/not recommended

Scenario D: VDRL positive

- 1. Effective against syphilis ANDF chancroid or effective against syphilis only
- 2. Effective against chancroid only or not effective/not recommended

Scenario E: VDRL pending

- 1. Effective against syphilis AND chancroid or effective against chancroid only
- 2. Effective against syphilis only
- 3. Not effective against either

HEALTH FACILITY SURVEY INTERVIEW

HEALTH FACILITY SURVEY INTERVIEW

Questionnaire number |__|__|

		Date: _ _
COM	IPLETE THIS SECTION BEFORE INTERVIEW	
Inter	viewer's code:	
Name	e of health care facility:	
Facil	ity number	
Healt	th care provider (HCP) code	
Profe	ession of HCP (nurse = 1; doctor = 2)	
Sex o	of HCP (male = 1; female = 2)	
Was	this HCP observed managing an STI patient?	Y N
1.	How many cases of STI did you see at this clinic last week ?	M F
2.	How many cases of STI do you see at this clinic during an average month ?	M F
3.	When patients report with a complaint of STI, do you routinely ask them questions?	Y N
4.	IF YES, do you ask about:	
	• Present symptoms?	Y PROBED Y N
	• Onset/duration of symptoms?	Y PROBED Y N
	• Recent sexual contact?	Y PROBED Y N
5.	Do you routinely perform a physical examination on your male STI patients? (*HCP does not see male STI patients)	Y N NA*

II	F YES, please describe each step of how you would examin	ne a <i>male</i> STI patient:
	A Patient asked to undress so that genitals are fully exposed	Y PROBED Y N
	B Patient examined for a urethral/penile discharge	Y PROBED Y N
(C Genitals examined for lesions after retracting the foreskin	Y PROBED Y N
O	o you routinely perform a physical examination nyour female STI patients? HCP does not see female STI patients)	Y N NA*
If	YES, please describe each step of how you would examin	e a female STI patient:
	A Patient asked to undress so that genitals are fully exposed	Y PROBED Y N
]	B Patient asked to lie down	Y PROBED Y N
(C Patient examined for lesions on vulva and labia	Y PROBED Y N
]	D Patient examined for vaginal discharge	Y PROBED Y N
]	E Speculum examination performed	Y PROBED Y N
]	F Bimanual examination performed	Y PROBED Y N
D	o you have:	
•	an examination table?	Y N
•	bivalve vaginal specula? an examination light?	Y N Y N
•	examination gloves?	Y N
W	That type of diagnosis do you base your treatment on:	Y
•	An aetiologic diagnosis such as gonorrhea or syphilis? A syndromic diagnosis such as urethral discharge	Y N Y N
	or genital ulcer disease?	
•	Both	Y N
D	o you have a microscope in this clinic?	Y N
II	YES, in this clinic, do you perform:	
•	Wet-mount microscopy to diagnose STIs?	Y N
•	Gram stains to diagnose STIs? VDRL tests?	Y N Y N
•	Darkfield microscopy?	Y N

14.	Do you send your STI patients (or specimens) to anot facility for laboratory investigations?	her Y N
	IF YES, what tests have you requested most often in the past month ? MAXIMUM OF THREE TESTS	*Refer to code portion of this section
		2
15	In your experience, what is the first choice of treatme usually prescribe for a patient with:	nt that you
A	Gonorrhea? *Refer to code po	rtion of this section
•	DRUG name	
В	Non-gonococcal urethritis? *Refer to code por	tion of this section
•	DRUG name	
C	Primary syphilis? *Refer to code po	rtion of this section
•	DRUG name	

D	Chancroid?	*Refer to code portion of this section
•	Quantity:	qid other
16.	In the absence of a definitive diag prescribe for:	nosis, what is the first choice of treatment that you usually
•	-	rge? *Refer to code portion of this section
•	quantity: dosage: daily bid tid route: im oral topical	qid other
•	A male patient with a genital ulcer?	*Refer to code portion of this section
•	quantity: dosage: daily bid tid route: im oral topical	qid other
•	A female patient with a genital ulcer:	*Refer to code portion of this section
•	quantity: dosage: daily bid tid route: im oral topical _	qid other
17.	 At this clinic same day (free) At this clinic same day (paid) At the pharmacy/chemist shop At this clinic and at the pharma 	otain the drugs you prescribe for them? acy

18.	Do you have any problem with drug supply?	Y N
	IF YES, what problem(s)?	
19.	Are there any particular drugs which you feel are essential for the treatment of STIs but to which you have no access?	
	IF YES, which?	
20.	What type of syringes and needles do you usually use?	Disposable Reusable Both
21.	Do you give any special education/advice to your STI patie	ents?
	a) Do you tell your patients to take all the medications you have prescribed?	Y PROBED Y N
	b) Do you advise your patients to use condoms?	Y PROBED Y N
	c) Do you tell your patients to tell their sexual partner(s) to have treatment?	Y PROBED Y N
	IF YES, do you use contact cards or referral slips? (IF YES, ASK TO HAVE ONE)	Y N
22.	Do you keep a supply of condoms in this clinic?	Y ASK TO HAVE ONE N SKIP TO Q27
IF THE	E ANSWER TO QUESTION 22 IS YES:	
23.	How many condoms are in stock at this clinic today?	
	Did you verify this number?	Y N
24.	Was this clinic ever out of stock of condoms in the last 12 months?	Y N
25.	Do you provide condoms to your STI patients?	Always Sometimes Never
26.	IF ALWAYS OR SOMETIMES: How many condoms each time?	Number

	Are the condoms free?	Y N
27.	Do you provide instructions to your patients on how to use condoms?	Always Sometimes Never
28.	Do you follow any specific treatment guidelines in your management of STI patients?	Y N
	IF YES, which? *Refer to c	code portion of this section
29.	Have you received a copy of the STI treatment schedules recommended by the National STI Control Programme?	Y N NA
30.	Do you provide drugs to PREVENT your clients from contracting STIs (do you provide STI prophylaxis)?	Y N
31.	What is your main qualification	Qualified nurse Medical practitioner Other
32.	If medical practitioner, what is your specialty? SELECT ONLY ONE	
	1. Venereologist 5. Urologist 2. Dermato-venereologist 6. General Practitioner 3. Dermatologist 7. GP/Venereologist 4. OBGYN	
	Other, SPECIFY:	
33.	Do you work in both public and private clinics?	Y N
34.	What are the main constraints on your work with STI?	

CODING INTERVIEWS

Q.14

- 1. VDRL/FTA(ABS)
- 2. GC culture (swab or urine)
- 3. HIV test
- 4. Darkfield
- 5. Gram stain (urethral or ulcer)
- 6. Other

Q.15 In your experience, what is the first choice of treatment for a patient with:

A. Gonorrhea?

- 1. Fits national recommendations
- 2. Fits WHO recommendations
- 3. Fits both
- 4. Other effective treatment
- 5. Inadequate dosage
- 6. Ineffective treatment
- 7. Uncertain efficacy

B. Non-gonococcal urethritis?

- 1. Fits national recommendations
- 2. Fits WHO recommendations
- 3. Fits both
- 4. Other effective treatment
- 5. Inadequate dosage
- 6. Ineffective treatment
- 7. Uncertain efficacy

C. Primary syphilis?

- 1. Fits national recommendations
- 2. Fits WHO recommendations
- 3. Fits both
- 4. Other effective treatment
- 5. Inadequate dosage
- 6. Ineffective treatment
- 7. Efficacy unknown

D. Chancroid?

- 1. Fits national recommendations
- 2. Fits WHO recommendations
- 3. Fits both
- 4. Other effective treatment
- 5. Inadequate dosage
- 6. Ineffective treatment
- 7. Efficacy unknown

- **Q.16** In the absence of a definitive diagnosis, what, in your experience, is the first choice of treatment for:
- A male patient with a urethral discharge?
 - 1. Effective against NG
 - 2. Effective against CT
 - 3. Effective against both NG and CT
 - 4. Not effective/uncertain efficacy against either
- A male patient with a genital ulcer?
 - 1. Effective against syphilis only
 - 2. Effective against chancroid only
 - 3. Effective against both
 - 4. Not effective/uncertain efficacy against either
- A female patient with genital ulcer?
 - 1. Effective against syphilis only
 - 2. Effective against chancroid only
 - 3. Effective against both
 - 4. Not effective/uncertain efficacy against either

Q.28

- 1. National guidelines
- 2. WHO guidelines
- 3. CDC guidelines
- 4. Other

STI HEALTH FACILITY SURVEY: INDIVIDUAL FIELDWORKER REPORT FORM

STI HEALTH FACILITY SURVEY: INDIVIDUAL FIELDWORKER REPORT FORM

Name of field worker

Serial number of fieldworker

R	Region						
Pl	ease fill in one of these b	ooxes for e	each health	care facility	(HCF) you	visit:	
	HCF name: HCF number						
	Date of visit(s):						
	Names of all eligible health care providers ¹	N/Dr ²	HCP serial number ³	Observed (tick if yes) ⁴	Number of STI pts last week	Number of observations	Interview (tick if yes)

¹ All health care providers who see STI patients should be listed here, not only those to be observed.

² Record whether the HCP is a doctor (Dr) or nurse (N).

³If the HCP is to be observed, allocate a serial number, starting with 1 for each facility.

⁴ If a HCP is not observed or interviewed, please record why: not selected (other HCP observed/interviewed), refused, not convenient etc. This is important to calculate a response rate.

HCF name:			HCF number			
Date of visit(s):						
Names of all eligible health care providers	N/Dr	HCP serial number	Observed (tick if yes)	Number of STI pts last week	Number of observations	Interview (tick if yes)

HCF name:			HCF number			
Date of visit(s):						
Names of all eligible health care providers	N/Dr	HCP serial number	Observed (tick if yes)	Number of STI pts last week	Number of observations	Interview (tick if yes)

Form 5 Drug Supply Checklist

Form 5

Drug Supply Checklist

			Quest	ionnaire numb	oer _
			Date	:: day mon	_ th year
CC	MPLETE THIS SECTION BEFOR	E COMPLETING C	HECKLIST:		
Ob	server/interviewer code				_
Na	me of health care facility				•
Fac	cility number				_
01 03 05	sition of person interviewed: = Hospital Administrative Officer; 0 = Clinical Officer; 04 = KRN/M, KF = EM, EN or ECN; 06 = Midwife; = Other		N;	<u></u>	_[
1.	When was the last inventory of drug equipment or supplies? (MONTH A		MONTH YEAR	_	_ _ _
2.	Who holds requisitions for drugs, e	quipment and suppli	es? FACILITY IN CIDISTRICT REGION OTHER	HARGE	
3.	What is done with all supplies that	have expired dates?			
		RETURNED TO S THROWN IN GA			
4.	Is there a stock record for STI drug	s?		Y	N
5.	Are STI drugs stored by expiration	date		Y	N
6.	Are STI drugs stored such that they from rain, sun, adverse temperature			Y	N

STI DRUGS AVAILABLE IN THE FACILITY:
Now I would like to ask you about the medications available to treat STIs in this facility. When we are finished, I will need to see your stock of some of the medications that we discuss. ASK NO. 1107 FOR EACH MEDICATION AND IF IT IS NOT AVAILABLE, SKIP TO THE NEXT MEDICATION. VIEW THOSE MEDICINES NOT SHADED IN 1109.

WEDICATION. VIEW THOSE WE	DICINES NOT STIADED I	11 1103.	I
MEDICATION	1107. Do you have this MEDICATION now?	1108. At any time in the last 12 months did this facility run out of MEDICATION?	1109. REGISTER IF AT LEAST TWO UNEXPIRED MEDICINES OBSERVED
1)	_	YES	
2)		YES	
3)		YES	
4)	_	YES	
5)		YES	
6)		YES	OBSERVED1 NOT OBSERVED2
7)	_	YES	
8)		YES	
9)		YES	
10)		YES	
11)		YES	OBSERVED
12)		YES	
13)		YES1 NO2	
14)		YES1 NO2	
15)		YES1 NO2	

FORM 6 CONSULTATION EXIT INTERVIEW

CONSULTATION EXIT INTERVIEW

Questionnai	ire No.
Date:	_ month year
<u> </u>	
M _	_ F
M	_ F
	_ years
 Single Married Divorced Widow 	
 None Elementary High school College Other 	
 Vaginal discharge Lower abdomen pain Genital ulcer Urethral discharge Other 	
	Date:

6.	How	did you feel during the conversation with the doctor?	
		Upset At ease Indiffer Don't K	·——·
7.	How	did you find the doctor's behavior toward you?	
		Kind Rude Indiffer Don't K	
8.	Wha	st did the doctor tell you about the causes of your illness? Sexually transm Infection (with resexual transmiss Did not say anyto Other (specify)	no mention of ssion) thing
9.	Wha	at did the doctor advise?	
	a)	To follow complete treatment	Y N
	b)	To return to clinic if not cured	Y N
	c)	To abstain from intercourse until completely cured	Y N
	d)	To use a condom as long as disease lasts	Y N
	e)	To always use a condom for protection in potentially unsafe sexual contacts	Y N
	f)	To be monogamous	Y N
	g)	To inform your partner about the disease	Y N
	h)	To advise your partner to seek treatment	Y N
	i)	Prescribed prophylactic medicines for potentially unsafe sexual contacts	Y N
	k)	Other (specify)	Y N
	j)	Nothing	
10.	How		Good Average Poor Don't know

11.	In the course of the visit, do you think your privacy has been	_	spected	
12.	Did the doctor request laboratory tests?		Y	N
	If YES, are you going to have these tests done?		Y	N
	If NOT, Why?			
13.	Did the doctor prescribe a medicine for your disease? If NOT, Why?		Y	N
	If YES, did he give you the whole quantity prescribed at the	•		
	If NOT, Why?			
	Do you intend to buy the rest of the medicine (or all)?		Y	N
	If NOT, Why?			
14.	Did you receive any means of prevention?		Y	N
	* *	ic medicine		 _
15.	Did you receive any documentation on STI?		Y	N
16.	If you contract STI again in the future, and you need to cons Health Care Facility, would you choose this same facility?	Y	N	
	Why?			

THANK YOU!

FORM 7 STI SIMULATION IN THE PHARMACY

STI SIMULATION IN THE PHARMACY

		Questionnaire No.			
		Date: _ day mon	_ th year		
Province Code					
Pharmacy Code			_		
Simulator Code _					
Simulator Sex					
Pharmacist/Shopkeeper Sex					
Did the shopkeeper (or pharmacist) question you about:					
Men		Women			
• Duration of symptoms	<u> </u>	• Duration of symptoms			
 Consistency of discharge 	<u> </u>	 Consistency of discharge 			
 Color of discharge 		 Color of discharge 			
• Pain associated w/discharge		 Odor of discharge 			
 Ulcerations 		 Heaviness of discharge 			
• Itching		• Pain associated w/discharge			
 Recent sexual contact 		 Ulcerations 			
• Sexual contact w/prostitute		• Itching			
		• Recent sexual contact			
		• Sexual contact w/new partner			

2.	Did th	Did the shopkeeper (or pharmacist) advise you to consult a doctor?						
			A	After a few question After giving treatments		treatment	 	
	2.1	2.1 What medicines did he/she recommend? How did he/she recommend them? (If the shopkeeper, or pharmacist, has written something down, please attach)						
	NAME	OF DRUG	DOSAGE	TIMES/DAY	No. of DAYS	If bought, PRICE		
		2.2 Did you buy everything that the pharmacist recommended? Y N If NOT, what did the shopkeeper (or pharmacist) answer, when you asked to buy only part of the medication?						
	What cure y		er (or pharmacist)	answer, when you	asked whethe	er this medicatio	n would	
3.	Did the shopkeeper (or pharmacist) advise you to use condoms during the disease? Y N							
	3.1	If YES, how m	nuch does one cond	om cost?				
	3.2	Did he explain	how to use condor	ns?		Y _	_ N	
	3.3	What brand of	condoms did he re		tegories are	country specific		
4.	Did t	the shopkeeper, or	r pharmacist mentic	·	J		_ N	
	4.1		recommend an HI			Y	N	

5.	What was the shopkeeper's, or pharmacist's, reaction when you told him about your disease?	Respect
	about your disease:	Indifference
	Nega	tive judgement
6.	Did the shopkeeper, or pharmacist recommend a treatment for your partner?	Y N
7.	Other comments:	

THANK YOU!

Box 1: Detailed example of sampling

- Step 1: Enumeration of HCFs in selected region- After selecting the region that the HCF survey will cover, a sampling frame consisting of all eligible HCFs needs to be established. This list of eligible facilities will be established through contact with key informants from the NAP, MOH and/or others. Ideally, a list will already exist of all eligible HCFs in the region. For this example, lets say we include 1,000 eligible HCFs in our sampling frame, which we will denote with N (N = 1,000). We would then have an enumerated list of HCFs from 1 to 1,000.
- Step 2: Sample size calculations- The sample size requirements will be calculated based on the following criteria: desired level of precision (d); an estimate of the population proportion (p) of the variable in question (0.5 should be used when an estimate is unavailable); and the acceptable level of committing a type I error (is typically set at .05). When attempting to measure the difference between two indicators, as would be the case when measuring changes at two points in time, the probability of committing a type II error must also be considered (). For this example, lets say n has been calculated to be 400 clients. Since we are to take an average of 4 clients per HCF, 100 HCFs would need to be sampled and visited in order to get 400 clients.
- Step 3: Simple random or systematical sampling of HCFs- After the facilities have been enumerated, simple random sampling (SRS) or systematic random sampling (SYS) can be used to select the HCFs. Remember that in our example we need to select 100 HCF to get our n of 400 clients. SRS would then require simply using a random number table (or generator) to get 100 random numbers between 1 and the total number of HCFs listed on our sampling frame (1,000). The HCFs corresponding to our 100 random numbers would then be selected. For SYS, we would first need to calculate a sampling interval (SI) by dividing N (1,000) by the number of HCFs needed (100). The resulting SI would thus be 1000/100 = 10. We would then need to select a random start between 1 and our SI, which is 10 (a random numbers table or generator can be used for this purpose). Lets say we select 7. We would then take the 7^{th} HCF on our sampling frame and every 10^{th} HCF thereafter until we obtain 100 HCFs to take part in the survey (i.e. we would take the 7^{th} HCF, 17^{th} , 27^{th} , 37^{th}997th).
- Step 4: Getting the average client volume for each selected HCF- The average client volume for each HCF will need to be obtained. Ideally, a call or visit can be made to each HCF and the client volume obtained from records. If only weakly or monthly client volume calculations exist, they will need to be converted to daily average volumes. Where no records exist of client volumes, a field staff will be required to visit the HCF and observe the number of clients seeking STI services. The average daily client for each clinic is then recorded onto the sampling frame next to the corresponding HCF.
- Step 5: Visiting selected HCFs and obtaining a sample of 4 STI clients each- Each of the HCF selected in step 3 will require a visit to observe/interview 4 STI-clients (this will result in an n of 400). Prior to arrival at HCF: The field staff will use Table 1 to get the appropriate sampling interval, which will yield a sample of 4. From the sampling frame, the average daily client volume will be obtained. Table 1 will then be used to identify the appropriate SI that corresponds to this volume (ranges of client intervals are given in the right hand column). SYS will be used to select the 4 clients from the expected client volume in exactly the same way SYS is explained in step 3. At the clinic: Suppose the HCF has an average daily client volume of 16; Table 1 shows the sampling interval to be 4. A random number (to serve as the random start) between 1 and 4 must be selected; suppose it is 2. Then the second client who comes in for consultation that day will be sampled and subject to interview and client-staff observation. Every fourth client thereafter will also be sampled and interviewed. A simple list can then established that dictates which clients in order of arrival will be selected. In our example, about 20 spaces would be put on a piece of paper with the 2nd, 6th, 10th and 14th spots marked. As clients come in, their names are written down in order of arrival, the clients that fall on the selected spots would then be interviewed. Note that to avoid

selection bias, the sample selection numbers should be extended beyond the expected 4 sample cases, since the exact number of clients that will show up on a given day will vary.

z Example:

Example: In the preceding example, the random start would be 2 and the sample selection numbers would be 2, 6, 10, 14. These numbers would be indicated on the blank listing sheet and the particular clients that fall into the sample would correspond to those whose names are listed on those lines. In our example, therefore, the selection numbers might be extended to 18, 22, 26, 30, etc.