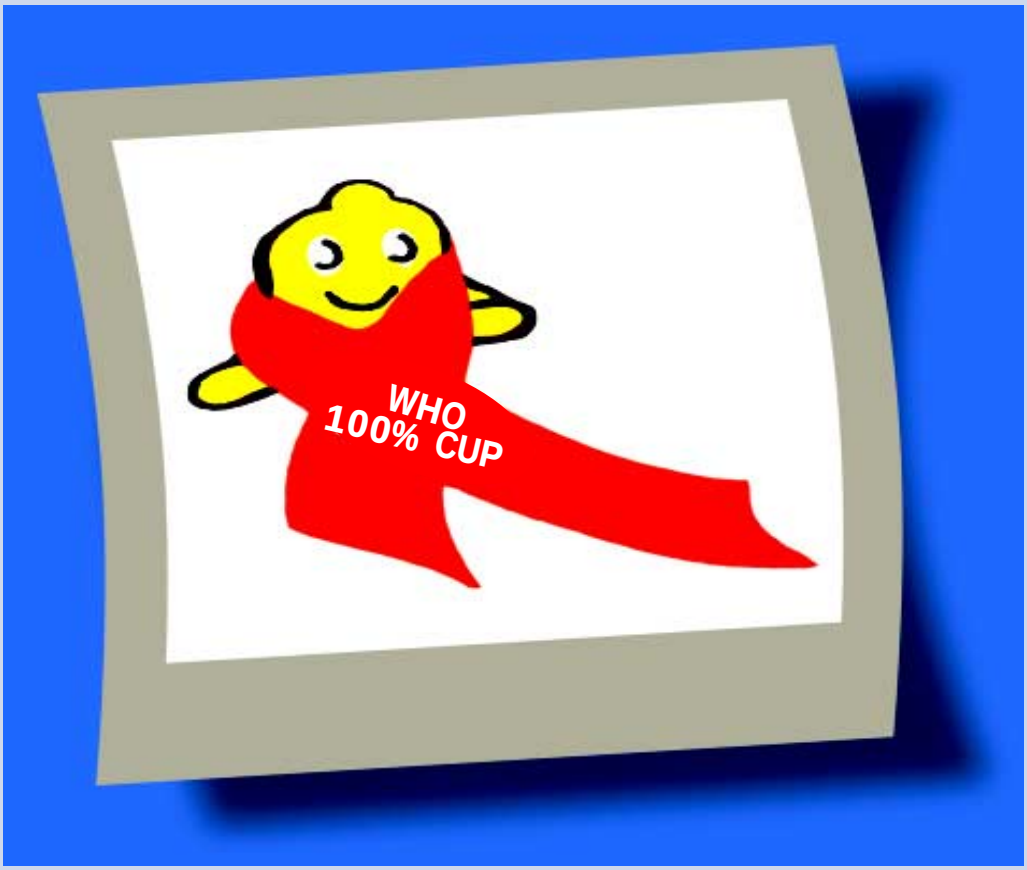
World Health Organization
Regional Office for the Western Pacific

MONITORING AND EVALUATION OF THE 100% CONDOM USE PROGRAMME IN ENTERTAINMENT ESTABLISHMENTS 2002



STI/HIV

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in Entertainment Establishments
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STI/HIV

MONITORING AND EVALUATION OF THE 100% CONDOM USE PROGRAMME IN ENTERTAINMENT ESTABLISHMENTS

CONTENTS

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ABBREVIATIONS AND ACRONYMS

100% CUP	100% condom use programme
AIDS	acquired immune deficiency syndrome
ELISA	enzyme-linked immunosorbent assay
FP	family planning
FPC	family planning commission
HIV	human immunodeficiency virus
LCR	ligase chain reaction
NGO	non governmental organization
OD	optical density
PCR	polymerase chain reaction
SMO	social marketing organization
STI	sexually transmitted infection

1 INTRODUCTION

A 100% condom use programme (100% CUP), targeting female sex workers in entertainment establishments, is important in prevention and control of STIs, including HIV. Monitoring and evaluation to measure the progress of the programme is one of its essential components, and requires appropriate indicators.

An indicator is a way in which to quantify or measure the magnitude of progress toward something one is trying to achieve in a programme, whether it is a process, an outcome or an impact. Indicators are just that - they simply give an indication of magnitude or direction of change over time. They cannot tell managers much about why the changes have or have not taken place.

While a single indicator cannot measure everything, knowing the magnitude and direction of change in achieving a programme objective is critical information for a manager. A good indicator for monitoring and evaluation needs to be:

GOOD INDICATOR:

A good indicator for monitoring and evaluation needs to be relevant to the programme, feasible to collect and analyse, easy to interpret and able to measure change over time.

- relevant to the programme;
- feasible to collect and analyse;
- easy to interpret; and
- able to measure change over time.

Identifying an indicator to be followed in a 100% CUP also demands attention to how that indicator will be defined, the source of the information needed for it, and the time-frame for its collection and analysis.

Table 1 is an overview of the essential indicators that should be used in monitoring and evaluating a 100% CUP. The chart also characterizes the indicator by type (process, outcome or impact), method of measurement, and frequency of measurement. It is strongly encouraged that the definitions presented here should be used to ensure standardization of information across countries and overtime. However, if there is a compelling reason to change any indicator - its definition or methodology, these changes should be fully described, so that the indicator can be measured in the same way in the future.

In addition to the essential indicators, countries could select some other indicators from a list of optional indicators (Table 2) or develop their own indicators for their 100% CUP in the light of their specific conditions and programme needs.

Table 1 - ***Overview of essential indicators for monitoring and evaluating a 100% CUP***

	INDICATOR	MEASUREMENT METHODS			DATA COLLECTION
		QI	RC	LS	FREQUENCY
Process indicators					
1	Number of condoms distributed to outlets		X		Annually
Outcome indicators					
2	Proportion of sex workers reporting condom use during last sex with client	X			Annually
Impact indicators					
3	Proportion of young female sex workers with HIV infection			X	Annually
4	Proportion of young female sex workers with chlamydial infection			X	Annually

QI: Questionnaire interview; **RC**: Records check; **LS**: Laboratory-based survey

Table 2 - ***Optional indicators for monitoring and evaluating a 100% CUP***

	INDICATOR
Process Indicator	
1	Proportion of 100% CUP districts with documentation
2	Proportion of districts holding regular advocacy meeting for 100% CUP
3	Proportion of monthly site visits by working groups to sex establishments
4	Number of condoms to sex workers through sex establishments
5	Proportion of sex entertainments with enough condoms in stock
6	Proportion of sex workers with correct perception of condom promotion
7	Proportion of sex workers who have been informed of 100% CUP by owners
8	Proportion of establishments with accessible promotion materials for 100% CUP
9	Proportion of sex workers attending monthly routine screening
10	Proportion of sex workers who were correctly treated for STI
Outcome Indicators	
11	Proportion of sex workers reporting consistent condom use at sex with client
12	Proportion of clients reporting condom use at last sex with female sex worker
13	Proportion of clients reporting consistent condom use at sex with sex workers
14	Proportion of sex workers whose clients refused condom use in the last sex
15	Proportion of sex workers who accept a sex relation without condom use
Impact Indicators	
16	Number of reported STIs among sex workers from establishments
17	Number of reported STIs among clients from establishments

2 PROPOSED INDICATORS: AN OVERVIEW

1. PROCESS INDICATOR

***Indicator 1*:**
Number of condoms distributed to outlets

Definition:
Absolute number of condoms distributed (free of charge or paid for) by public and commercial distributors to traditional and non-traditional outlets in the last 12 months.

2. OUTCOME INDICATOR

***Indicator 2*:**

Proportion of sex workers reporting condom use during most recent sex act with a client

Definition:

Number of sex workers from entertainment establishments using a condom with their last client

---

Total number of sex worker interviewed in entertainment establishments and who had sex with clients in the last 12 months

3. IMPACT INDICATORS

***Indicator 3*:**
Proportion of young female sex workers aged < 21 years with HIV infection

***Definition*:**
Number of young female sex workers (aged < 21 years) infected with HIV

Total number of young female sex workers (aged < 21 years) surveyed

Age could be defined according to the age structure of local female sex workers, but is usually not more than 25 years.

Indicator 4:
Proportion of young female sex workers aged < 21 years with laboratory-confirmed chlamydial infection

Definition:
Number of young female sex workers (aged < 21 years) infected with laboratory-confirmed chlamydial infection
---
Total number of young female sex workers (aged < 21 years) surveyed

Age could be defined according to the age structure of local female sex workers but is usually not more than 25 years.

Laboratory-confirmed chlamydial infection refers to the detection of chlamydial infection through PCR or LCR tests.

INDICATOR 1

NUMBER OF CONDOMS DISTRIBUTED TO OUTLETS

1. INTRODUCTION

A 100% condom use programme (100% CUP) promotes condom use in commercial sex. Availability, accessibility and affordability of condoms are a pre-requisite for their extensive use. The 100% CUP encourages the distribution of condoms through as many channels as possible so that they are available in as many outlets as possible, particularly entertainment establishments.

2. OBJECTIVE

The primary objective of this indicator is to measure how many condoms were distributed to outlets in the previous 12 months and to monitor the trends.

If used for monitoring, condom data may have to be collected more regularly, such as at monthly, quarterly or half yearly intervals.

3. DEFINITION

The absolute number of condoms distributed (free of charge or paid for) by public and commercial distributors to traditional and non-traditional outlets in the last 12 months.

4. METHODOLOGY

4.1 Document review

Background documents on condom supply and distribution (both for family planning and STI/HIV/AIDS programmes) should be reviewed. Such documents include annual reports of the national STI/AIDS Programme, reports of family planning programmes, NGOs' reports, donors' reports, retail audits, project documents, monitoring and evaluation reports of condom use in the previous years, etc. This process will also help to identify key informants involved in condom activities.

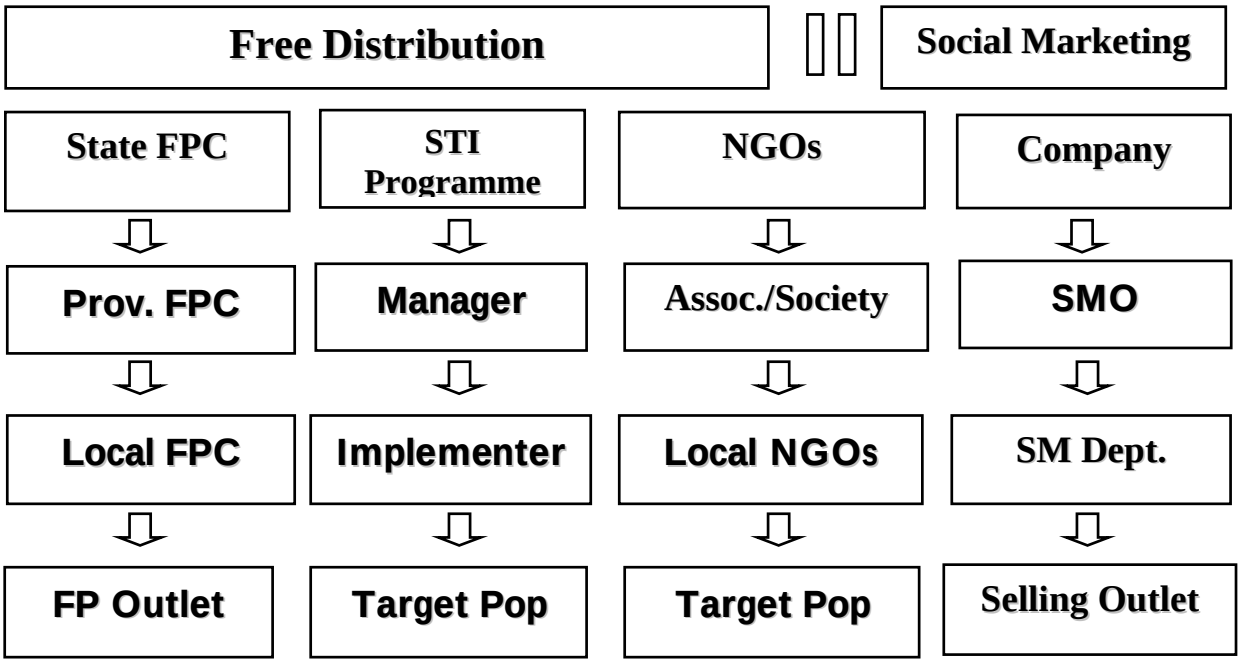
4.2 Identification of distributors

A thorough list of condom distributors will have to be compiled in collaboration with responsible persons for family planning programmes and STI/HIV/AIDS prevention and control programmes. Such a list of distributors might include:

- the national STI/HIV/AIDS programme;
- family planning associations/committees;
- government and NGO agencies involved in the purchase and distribution of condoms;
- social marketing groups;
- condom associations;
- condom storage facilities:
  - » national;
  - » regional;
  - » provincial;
  - » community;
- pharmaceutical and medical supply importers;
- donors;
- medical associations;
- condom manufacturers, etc.

Where condom promotion activities are mainly through social marketing, sales of condoms by social marketing agencies will provide an essential indication of condom distribution. Organizations responsible for the social marketing of condoms typically keep very good records of condoms distributed, down to the retail level.

IDENTIFICATION OF DISTRIBUTORS AND OUTLETS



4.3 Interview with key informants

A letter of introduction from the local authority should be prepared for the interviewers. This letter will describe the objectives of the interview and the use that will be made of the information collected. Through the interviews, information will be obtained to fill in the Condom Distribution Assessment Form (see Annex 1).

4.4 Collection of data

- Time period: the period should be the same for every agency.
- Brand of condom: name on the condom package. All brands available, including generic.
- Source: name of company/agency that provided the condoms.

  (For example, if Agency 1 supplied condoms to Agency 2 and the latter supplied them to Agency 3, then Agency 1 would be the source for Agency 2 and Agency 2 would be the source for Agency 3.)
- Type of target outlets: outlets receiving the condoms from the company/agency interviewed. A list of targets should be prepared.

  (Outlets could be: pharmacies, medical clinics, shops, bars, guesthouses, hotels, brothels, nightclubs, massage parlours, gasoline stations, etc.)
- Quantity: number of condoms distributed directly to the specified outlets.
  (not the number of boxes or cartons).

4.5 Management and analysis of data

The total number of condoms distributed on each Condom Distribution Assessment Form should be calculated by the interviewer and checked by the principal investigator. The completed forms for all distributors should be compiled on a Condom Distribution Summary Form (see Annex 2).

5. REPORTING OF RESULTS

A summary report should be prepared, providing analysis of data per area, outlet, distributor, and type/brand of condom. The analysis should provide elements to determine where the programme can be strengthened and should be sent to managers and relevant decision-makers.

6. TRAINING REQUIREMENTS

A one-day training session will be needed for the interviewers and those collecting data in order to standardize the procedures for recruitment, interview, data collection, etc.

7. RESOURCE REQUIREMENTS

7.1. Staff

A principal investigator familiar with condom issues and retail sales auditing should be selected. He/she should also have good coordination skills and be able to interpret data. The survey team should include a variety of skilled personnel, such as someone with good government and NGO contacts or a statistician experienced in data compilation, management and analysis.

7.2. Budget

The financial resources required will depend on the extent of the condom distribution structure in the programme areas. However, the budget will usually be small and will include allowances for:

- staff;
- training;
- transportation;
- supplies for data collection;
- data management and analysis costs; and
- miscellaneous expenditure.

8. LOGISTICAL SUPPORT

Interviews should be conducted on the site of the agencies. Transportation to the agencies and supplies (10-15% more than required) for the interviews should be prepared in advance. Appointments should be made prior to interviews to ensure that key informants and/or relevant officers are available for one to two hours to cooperate with the data collection.

9. TIME FRAME

A time-frame for a two-month study period is outlined in Annex 3.

Annex 1

Indicator 1
CONDOM DISTRIBUTION ASSESSMENT FORM

A. Background information

1. Date (Day/Month/Year): _____/_____/_____

   Name of interviewer: _____

2. Name of distributor: _____

3. Person interviewed:

   Name: _____

   Title: _____

4. 12-month period from (Month/Year)

   _____/_____ to _____/_____

B. Status of annual condom distribution

Brand and Type (e.g.)	Price	Area of distribution	Outlets	Source			Total Quantity (Pieces)
				Public	Private	Others	
POWER	0.2 cts	Northern Region	Pharmacies	10 000	20 000	30 000	60 000
		Southern Region	Bars Hotels				
LOVE	0.4 cts		Hotels				
			Bars				
Generic			Health Centers				
Total	**----**		**----**				**XXXXX**

Annex 2

Indicator 1
CONDOM DISTRIBUTION SUMMARY FORM

A. 12-month period from (Month/Year) _____/_____ to _____ /_____

B. Summary of annual condom distribution

Name of distributor	Quantity (Pieces)
A. Public	
A1 -	
A2 -	
Sub Total	
B. Private	
B1 -	
B2 -	
B3 -	
Sub Total	
C. Others	
C1 -	
C2 -	
C3 -	
Sub Total	
Total (A+B+C)	**XXXXXXX**

Annex 3

Indicator 1
EXAMPLE OF TIME-FRAME FOR CONDOM DISTRIBUTION ASSESSMENT SURVEY

Activities	Month 1				Month 2			
	W1	W2	W3	W4	W5	W6	W7	W8
Protocol development	X							
Training		X	X					
Document review			X	X				
Identification of distributors				X				
Interview of key informants				X	X	X		
Data compilation							X	
Data analysis							X	
Reporting								X

INDICATOR 2

PROPORTION OF SEX WORKERS REPORTING CONDOM USE DURING MOST RECENT SEX ACT WITH A CLIENT

1. INTRODUCTION

Two indicators, consistent use of condoms in high-risk sexual relationships and condom use during last high-risk sexual intercourse, have often been used in behavioural surveillance. Although the 100% CUP aims to increase the use of condoms in all high-risk sexual intercourse, the indicator "condom use during the most recent sex act" has been selected as the most appropriate measurement of level of condom use among female sex workers. Asking about condom use during the most recent sexual act minimizes recall bias and gives a good cross-sectional picture of condom use.

2. OBJECTIVE

To assess the magnitude of non-protected sex among female sex workers working at entertainment establishments and to monitor the outcome of the 100% CUP on condom usage.

3. DEFINITION

Numerator: number of sex workers interviewed in entertainment establishments who had penetrative (penile/vagina, penile/oral and penile/anal) sex with clients in the last 12 months and report using a condom with their last client.

Denominator: total number of sex workers interviewed in entertainment establishments who had penetrative sex with clients in the last 12 months.

4. METHODOLOGY

4.1. Sampling approaches

The sampling frame should be carefully designed to give a representative sample and be replicable over time.

4.1.1. Sample size

The sample size requirement to allow measurement of changes on this indicator is based on five parameters:

- the initial level of the indicator;
- the magnitude of change expected to be detected;
- how sure you want to be that this magnitude has not occurred by chance (i.e. 1-a, the level of significance - traditionally, this level is set at 95%);
- how sure you want to be to observe this magnitude if it did occur ([1-b = the power of study] - to ensure sufficient power, a minimum study power value of 0.8 should be used);
- the expected proportion of entertainment workers who will be eligible for the survey.

Previous survey or anecdotal information might be consulted to estimate the initial level of this indicator and the proportion of eligible entertainment workers. If resources permit, a small pilot survey might be conducted to better estimate the sample size.

Annex 1 provides the sample sizes required to measure an absolute change of 10%, 15% and 20% between P1 (smaller proportion) and P2 (larger proportion) using (1-a) = 0.95 and selected (1-b) values (0.80, 0.90 and 0.95).

> *Example: Suppose you want to detect an increase of 15% from the initial level of 40% in the proportion of sex workers working in entertainment establishments who had penetrative sex in the last 12 months and used a condom with a client during their most recent sex. Furthermore, you want your results to be significant at the 95% level (default value) and your study power to be 90% (b = 0.1). Set P1 = 40%, P2 = 40%+15% = 55%, and (1-b) = 0.90. Annex I indicates a sample size for each survey round of n = 376.*

4.1.2. Number of establishments

Once the sample size is calculated, the number of establishments and the average number of sex workers in each establishment should be determined for the two-stage sampling scheme. To calculate the number of sex establishments needed, an average number of sex workers per establishment should be estimated.

Example: If the final sample size is 376 and the average number of sex workers per establishment is 15, a total of 26 establishments are needed. Because there is not likely to be homogeneity in terms of population characteristics among female sex workers between different types of establishments, a relatively larger number of establishments are required to provide good coverage, let's say 30.

A minimum of 20 establishments is always recommended.

4.1.3. Number of sex workers in each establishment

The number of sex workers to be sampled in each establishment is calculated by dividing the final sample size by the number of establishments to be selected.

Example above: The final sample size is 376. If the number of establishments to be selected is 30, the number of sex workers to be surveyed in each establishment will be 13 = 376/30.

It is recommended that a maximum of 20-25 study subjects should be selected per establishment. As the number increases in each establishment, the reliability of the survey results will decrease. A larger sample size is fine if there's a wide coverage of establishments.

4.1.4. Sampling frame

A two-stage sampling scheme is used in this survey. Entertainment establishments are selected with equal probability at the first stage of sample selection. A fixed number of sex workers are selected, by simple random or systematic sampling methods, from each establishment at the second stage.

First stage - selection of a systematic-random sample of establishments:

1. List all the establishments, preferably ordered by type (such as brothel, massage parlour, karaoke lounge, etc).
2. Decide the number of establishments to be selected (see 4.1.3).
3. Calculate the sampling interval (SI) by dividing the total number of establishments (M) by the number of establishments to be selected (a); SI = M/a.

   Example: The number of establishments in the surveyed area is 122, and the number of establishments to be selected is 30; SI = 122/30 = 4.
4. Select a random number (RS) between 1 and SI, say RS = 2. The establishment with the number corresponding to this number will be the first establishment to be selected.
5. Subsequent establishments are chosen by adding the SI to the RS number identified in step (4), i.e. RS+SI, RS+2SI, RS+3SI, etc. When the decimal part of the sample selection number is <0.5, the lower numbered establishment is chosen, and when the decimal part is >0.5, the higher numbered establishment is chosen.
6. This procedure is followed until the list has been exhausted.

The Establishment Selection Form (Annex 2) can be used in the field to assist with the selection of establishments with the equal probability sampling method.

Second stage - selection of a systematic-random sample of sex workers

Once the first stage of sampling (selection of establishments) has been completed, a defined number of sex workers should be chosen in each selected establishment from a list of sex workers. Simple random or systematic sampling should be used. It should be noted that it is never advisable to interview volunteers to minimize selection bias. For each selected sex worker who refuses to be interviewed, another sex worker should be selected randomly.

4.2. Collection of data

A letter of introduction or relevant document from the local authority should be prepared for the interviewers. This letter should be shown to establishment owners to explain the purposes of the survey and the use of data collected. Ideally, the collection of behavioural data should be integrated into national or regional second-generation STI/HIV surveillance.

The data are collected through in-depth interviews with establishment-based sex workers. Interviews should, whenever possible, be administered by a trained female. Sex workers, who have had penetrative sex with clients in the last month, should be asked if they used a condom during last sex.

Data to be collected for this indicator are:

- Interview result (completed, sex worker not available, refused, etc.);
- Site of survey (name of establishment);
- Study number;
- Date of birth or age;
- Sex in the last month;
- Condom use at last sex with a client;
- Date of interview.

4.3. Questionnaire and study forms

A questionnaire is proposed in Annex 3. After completion of the survey in an establishment, a summary form - the Establishment Information Sheet, in Annex 4, should be filled in. This questionnaire may be a part of the behavioural surveillance survey (BSS) questionnaire in the national or regional second-generation STI/HIV surveillance.

4.4. Management and analysis of data

A template for data entry and management could be developed using computer software, such as EpiInfo 5.0. To minimize data entry errors, the template should be designed to restrict the range of values that can be entered and should require entries for all data fields. The statistics clerk should compile the completed questionnaires, and the data should be entered for analysis. Double entry should be performed for at least 20% of the data to assess the extent of data entry error. If this is found to be more than 10%, then data entry procedures will need to be reviewed and the accuracy of data already entered checked.

The denominator of the indicator will be the total number of sex workers who had penetrative sex with at least one client in the month previous to the interview and agreed to participate in the survey. The numerator will be the total number of those who report condom use during their most recent penetrative sexual intercourse. The proportion of sex workers reporting condom use during their last penetrative sex can be calculated with 95% confidence intervals, and the chi-squared tests for trend and odds ratios with 95% confidence intervals could be done to assess the trends of this indicator over time. In addition, the association of this indicator with other variables (e.g. age) can also be analysed using advanced statistical analyses.

5. REPORTING OF RESULTS

A report providing and analysing the results should be prepared. The report will be one of the elements needed to evaluate the outcomes of the 100% CUP. This report should be sent to the managers and other relevant decision-makers.

6. TRAINING REQUIREMENTS

The principal investigator should identify the training needed to conduct the survey. Usually, a one- to two-day training session will be needed for all interviewers to standardize the recruitment criteria, interviewing procedures and data-recording methods, and for role-play practice.

7. RESOURCE REQUIREMENTS

7.1. Staff

The gender and professional qualifications required for interviewers at the study sites should be in accordance with local cultural and social customs. In addition to the interviewers, at least one supervisor and a logistics clerk are needed in each study team. A statistics clerk should be employed for data preparation, management and analysis.

7.2. Budget items

The main items to consider for the budget are allowances for:

- staff;
- training;
- transportation;
- supplies for data collection;
- data management and analysis; and
- miscellaneous expenditure.

8. LOGISTICAL SUPPORT

The interview should be conducted in the entertainment establishments, with interviewers travelling between the institutions and establishments on a daily basis. Arrangements will need to be made to coordinate the necessary transportation. The timing of the survey will need to be appropriate for a 20-30 minute interview with each sex worker. Interview forms (10%-15% extra) should be prepared in advance.

9. TIME FRAME

A time frame for a two-month study period is proposed in Annex 5.

Annex 1

Indicator 2
SAMPLE SIZE REQUIREMENTS FOR (1-A) OF 0.95 AND SELECTED COMBINATIONS OF P1, P2 AND (1-B)*

Absolute charge	10 %				15 %				20%			
P_1	P_2	1 - β =			P_2	1 - β =			P_2	1 - β =		
		0.80	0.90	0.95		0.80	0.90	0.95		0.80	0.90	0.95
90	**100**	114	159	200	**--**	--	--	--	**--**	--	--	--
85	**95**	218	305	384	**100**	73	102	128	**--**	--	--	--
80	**90**	310	433	547	**95**	117	163	205	**100**	53	73	92
75	**85**	390	545	687	**90**	155	216	272	**95**	76	105	133
70	**80**	457	639	806	**85**	188	262	330	**90**	96	133	168
65	**75**	512	716	904	**80**	215	300	378	**85**	113	157	198
60	**70**	555	776	980	**75**	237	330	417	**80**	127	176	222
55	**65**	586	819	1034	**70**	253	353	446	**75**	137	191	241
50	**60**	604	844	1066	**65**	264	368	465	**70**	145	202	254
45	**55**	611	853	1077	**60**	270	376	474	**65**	150	208	262
40	**50**	604	844	1066	**55**	270	376	474	**60**	151	210	265
35	**45**	586	819	1034	**50**	264	368	465	**55**	150	208	262
30	**40**	555	776	980	**45**	253	353	446	**50**	145	202	254
25	**35**	512	716	904	**40**	237	330	417	**45**	137	191	241
20	**30**	457	639	806	**35**	215	300	378	**40**	127	176	222
15	**25**	390	545	687	**30**	188	262	330	**35**	113	157	198
10	**20**	310	433	547	**25**	155	216	272	**30**	96	133	168
5	**15**	218	305	384	**20**	117	163	205	**25**	76	105	133

*Note: Sample sizes assume a design effect of 2.

Annex 2

Indicator 2
ESTABLISHMENT SELECTION FORM

Province:		**City:**	

Establishment number	**Establishment selected**	
		Total cumulative no. of establishments (M): _____ Planned no. of sampled establishments (a): _____ Sampling interval (SI = M/a): _____ Random number (between 1 and SI): _____

Annex 3

Indicator 2
STUDY FORM FOR BEHAVIOURAL SURVEY

01 STUDY NUMBER: |___|___| |___|___|___|

02 CITY: _____

03 DISTRICT: _____

04 ESTABLISHMENT: _____ (provide locally appropriate categories)

Introduction: "My name is… I'm working for… We're interviewing some people in this establishment to better understand people's health. Have you been interviewed in another establishment for this study? IF THE SEX WORKER HAS BEEN INTERVIEWED BEFORE DURING THIS SURVEY ROUND, DO NOT INTERVIEW THIS PERSON AGAIN. Tell them you cannot interview them a second time, thank them, and end the interview. If they have not been interviewed before, continue.

Confidentiality and consent: "I'm going to ask you some very personal questions that some people find difficult to answer. Your answers are completely confidential. Your name will not be written on this form, and will never be used in connection with any of the information you tell me. You do not have to answer any questions that you do not want to answer, and you may end this interview at any time you want to. We would greatly appreciate your help in responding to this survey. The survey will take only a few minutes to ask the questions. Would you be willing to participate?"

_____

(Signature of interviewer certifying that informed consent has been given verbally by respondent)

Interviewer

	Visit 1	Visit 2	Visit 3
Date			
Interviewer			
Result			

Result codes: Completed 1; Respondent not available 2; Refused 3; Partially completed 4; Other 5.

05 INTERVIEWER: _____

06 DATE OF INTERVIEW: __\ ____ \ _____

07 SUPERVISOR: _____

BEHAVIOURAL SURVEY FOR FEMALE SEX WORKERS

1. BACKGROUND CHARACTERISTICS

No.	Questions	Coding categories
Q1	In what month and year were you born?	MONTH [__|__] DON'T KNOW MONTH 88 NO RESPONSE 99 YEAR [__|__] DON'T KNOW YEAR 88 NO RESPONSE 99
Q2	How old were you at your last birthday? (Compare/reconcile Q1 & 2 if needed)	AGE IN COMPLETED YEARS [__|__] DON'T KNOW 88 NO RESPONSE 99 ESTIMATE BEST ANSWER

2. CONDOM USE WITH A CLIENT

No.	Questions	Coding categories	
Q3	Have you had penetrative sex with any client in the last 12 months?	YES NO DON'T KNOW NO RESPONSE	1 2 8 9
Q4	The last time you had penetrative sex with a client, did you and your client use a condom?	YES NO DON'T KNOW NO RESPONSE	1 2 8 9
Q5	Why didn't you use a condom the last time you had penetrative sex with a client?	CONDOM NOT AVAILABLE IT IS A REGULAR CLIENT CLIENT PAYING MORE I WAS DRUNK / DRUGGED I WAS THREATENED CLIENT WITH GOOD APPEARANCE NO LUBRICANT AVAILABLE DON'T KNOW NO RESPONSE	1 2 3 4 5 6 7 8 9

Annex 4

Indicator 2
ESTABLISHMENT INFORMATION SHEET

Province:		**City:**	

Name of the establishment: _____

Geographical location: _____

Name of owner: _____ Contact :_____

Type of establishment (circle):

1. Bar
2. Beer company
3. Brothel
4. Massage parlour
5. Karaoke lounge
6. Nightclub
7. Discotheque
8. Snooker hall
9. Other (specify): _____

Date and time establishment was visited (D/M/Y, Time): _____

	Items	Number
1	Actual number of sex workers in the establishment on the day of the survey:	
2	Number of sex workers approached for interview[1]:	
3	Number of sex workers who refused to be interviewed after being approached[2]:	
4	Number of duplicates among sex workers approached for interview[3]:	
5	Number of sex workers who completed an interview[4]:	

1. *Sex workers approached for interview refers to those who were randomly selected at the establishment.*
2. *Sex workers who refused to be interviewed refers to those who were invited to participate in the survey but declined to be interviewed.*
3. *Duplicates refers to those who had already been interviewed as part of the survey at another site.*
4. *Sex workers who completed an interview refers to those who where invited to be interviewed and for whom a questionnaire was completed.*

Annex 5

Indicator 2
EXAMPLE OF TIME-FRAME FOR CONDOM USE BEHAVIOURAL SURVEY

Activities	Month 1				Month 2			
	W 1	W 2	W 3	W 4	W 5	W 6	W 7	W 8
Identification of principal investigator	X							
Key informant interview	X							
Numeration of establishments		X						
Sampling of establishments		X						
Coordination meeting			X					
Training			X					
Interviews			X	X	X			
Data entry				X	X	X		
Data analysis						X	X	
Reporting								X

INDICATOR 3

PROPORTION OF YOUNG FEMALE SEX WORKERS WITH HIV INFECTION

1. INTRODUCTION

The 100% condom use programme (100% CUP) promotes condom use in high-risk sexual relations. If effectively implemented, the programme is expected to have a significant impact in reducing HIV transmission.

Trends in HIV infections have been selected to monitor and evaluate the impact of the 100% CUP because reducing the incidence of sexual HIV transmission is the ultimate goal of the programme.

2. OBJECTIVES

The objective of this indicator is to monitor the prevalence of HIV infection among sex workers working in entertainment establishments and to monitor and evaluate the impact of the 100% CUP on HIV transmission. It is expected that this indicator will be a good proxy of HIV incidence in the population of sex workers, since only the younger ones (e.g. < 21 years of age) will be retained. Age could be adjusted locally, depending on the feasibility of finding enough young sex workers.

3. DEFINITION

Numerator: Number of young female sex workers (aged < 21 years) with laboratory-confirmed HIV infection.

Denominator: Total number of young female sex workers (aged < 21 years) surveyed.

4. METHODOLOGY

4.1. Sampling approaches

Sampling strategies should be systematic to be replicable over time.

4.1.1. Sample size

The sample size requirement to allow measurement of changes on this indicator is based on five parameters:

- the initial level of the indicator;
- the magnitude of change expected to be detected;
- how sure you want to be that this magnitude has not occurred by chance (i.e. 1-a, the level of significance - traditionally, this level is set at 95%.);
- how sure you want to be to observe this magnitude if it did occur (1-b), the power of study - to ensure sufficient power, a minimum value of study power of 0.8 should be used); and
- the expected proportion of young entertainment workers who will be eligible for the survey.

4.1.2. Number of establishments

Annex 1 provides the sample size required to measure a proportional decline compared with baseline prevalence (%) with a 95% level of significance and a study power of 80%.

Once the sample size is calculated, the number of establishments and the average number of young sex workers in each establishment should be determined for the two-stage sampling scheme. To calculate the number of sex establishments needed, an average number of young female sex workers (<21) per establishment should be estimated.

> *Example: The final sample size is 150 and the average number of young female sex workers per establishment is 10, so a total of 15 establishments are needed. Because there is not likely to be homogeneity in terms of population characteristics among female sex workers or between different type of establishments, a relatively larger number of establishments is required to provide a good average, let's say 20.*

(A minimum of 20 establishments is always recommended).

4.1.3. Number of young female sex workers in each establishment

The number of young female sex workers to be sampled in each establishment is calculated by dividing the final sample size by the number of establishments to be selected.

Example above: the final sample size is 150. If the number of establishments to be selected is 20, the number of sex workers to be surveyed in each establishment will be 150/20 = 8.

It is recommended that a maximum of 20-25 study subjects should be selected per establishment. As the number increases in each establishment, the reliability of the survey results will decrease. A larger sample size is fine if there is a wide coverage of establishments.

4.1.4. Sampling frame

A two-stage sampling scheme is used in this survey. Entertainment establishments are selected with equal probability at the first stage of sample selection. A fixed number of sex workers are selected by simple random or systematic sampling methods from each establishment at the second stage.

First stage - selection of a systematic-random sample of establishments:

1. List all the establishments, preferably ordered by type of establishment (such *as* brothel, massage parlour, karaoke lounge, etc.).
2. Decide the number of establishments to be selected (see 4.1.3).
3. Calculate the sampling interval (SI) by dividing the total number of establishments (M) by the number of establishments to be selected (a); SI = M/a.

   Example: the number of establishments in the surveyed area is122, and the number of establishments to be selected is 20, then SI = 122/ 20 = 6.
4. Select a random number (RS) between 1 and SI, say RS = 2. The establishment with the number corresponding to this number will be the first establishment to be selected.
5. Subsequent establishments are chosen by adding the SI to the RS number identified in step (4), i.e. RS+SI, RS+2SI, RS+3SI, etc. When the decimal part of the sample selection number is < 0.5, the lower num bered establishment is chosen, and when the decimal part is >0.5, the higher numbered establishment is chosen.
6. This procedure is followed until the list has been exhausted.

The Establishment Selection Form (Annex 2) can be used in the field to assist with the selection of establishments with the equal probability sampling method.

EXAMPLE OF SELECTION OF A SYSTEMATIC-RANDOM SAMPLE OF ESTABLISHMENTS

Establishment number	Establishment selected	
001		Total no. of establishments (M) = 122 Planned no. of establishments (a) = 20 Sampling interval (M/a) = 122/20 = 6 Random start between 1 and 6 = 2 Establishments selected = 002, 008, 014, …
002	X	
003		
004		
005		
006		
007		
008	X	
009		
010		
011		
--		
--		
122 (Last)		

Second stage - selection of a systematic-random sample of young female sex workers

Once the first-stage of sampling (selection of establishments) has been completed, a defined number of young female sex workers should be chosen in each selected establishment from a list of sex workers aged below 21. Simple random or systematic sampling should be used. It should be noted that it is never advisable to interview volunteers to minimize selection bias. For each selected sex worker who refuses to be interviewed, another sex worker should be selected randomly.

4.2. Labels

In this unlinked HIV prevalence survey, the study number, rather than the sex worker's identification number, is used. The first sex worker to be recruited in establishment 1 will be numbered 01 001. Because unlinked anonymous HIV testing is being used, the number should not be written on the blood tube, which will be tested for HIV. However, age and date of specimen collection should appear on the tube.

4.3. Collection of data and specimens

A letter of introduction or relevant document from the local authority should be prepared for each study team who will conduct the study at the site. The investigator can show this letter or relevant document to the establishment owner to explain the purposes of the survey and how the information will be used.

4.3.1. Collection of data

Minimum elements of information for the indicator of HIV infection include:

- study result (completed, sex worker not available, refused and so on);
- study number;
- age (should be below 21);
- date of specimen collection.

All this information should be collected by a nurse using the Study Form for HIV Prevalence Survey in Annex 3. Ideally, the collection of the information should be integrated into the national or regional STI/HIV surveillance programme.

4.3.2. Collection of specimen

A 5ml sample of venous blood, for detection of HIV, should be obtained from each sex worker. Procedures for specimen collection are outlined in Annex 4. The specimen should be transported to the local laboratory on a daily basis for storage in a refrigerator while awaiting further transportation to a referral laboratory. After the survey in an establishment has been completed, a summary of the establishment information should be filled in on the Establishment Information Form in Annex 5. The specimen collection could become a part of STI/HIV prevalence surveys in the national or regional STI/HIV surveillance programme.

4.4 Laboratory tests

Two enzyme-linked immunosorbent assays (ELISAs), with different principals, should be used for detection of HIV infection in each sex worker. If both ELISAs show positive results in a sample, this sample can be reported as positive for HIV. If both of them are negative in a sample, this sample will be reported as HIV-negative. For the evaluation or surveillance purpose, if only one of the two ELISAs shows a positive result in a sample, this sample will be reported as HIV-negative too. Necessary internal and external quality control systems are needed for laboratory tests. Sample aliquots should be preserved to allow for later testing for other pathogens if required.

The results of tests should be entered as shown in Annex 6. One copy of the results should be kept on file at the laboratory and one copy should be sent to the principal investigator for preparation of an evaluation report. This is an unlinked anonymous testing for evaluation purpose among female sex workers at establishments, and no results are provided to the participants.

4.5 Management and analysis of data

A template for data entry and management could be developed using computer software, such as EpiInfo 5.0. To minimize data entry errors, the template should be designed to restrict the range of values that can be entered and should require entries for all data fields. The completed questionnaires should be compiled by the statistics clerk, and the data should be entered for analysis. Double entry should be performed for at least 20% of the data to assess the extent of data entry error. If this is found to be more than 10%, then data entry procedures will need to be reviewed and the accuracy of data already entered checked.

The proportion of sex workers with HIV infection should be calculated, with the total number of sex workers with final positive results and positive confirmatory results of HIV testing as the numerator, and all sex workers whose specimens are available for testing as the denominator. These proportions can be calculated with 95% confidence intervals, and the chi-squared tests for trend and odds ratios with 95% confidence intervals could be used to assess the trends of these indicators over time. In addition, the association between these indicators and other variables, such as age, can also be analysed using more advanced statistical analyses, with the assistance of a statistician.

5. REPORTING OF RESULTS

Once the data analysis has been completed, the results should be used to prepare a report to evaluate the impact of 100% CUP on HIV infection and to determine where the programme needs strengthening. This report should be sent to the managers and other relevant decision-makers.

6. TRAINING REQUIREMENTS

The principal investigator should identify the training needed to conduct the survey. Usually, a two-day training session for interviewers, nurses and technicians will be needed to standardize the procedures for recruitment, interviewing, labelling and specimen collection, etc. The technicians doing laboratory tests should be trained separately in the laboratory protocol, including preparation of the specimens, performance of the tests, filling out of the results etc.

7. RESOURCE REQUIREMENTS

7.1. Staff

The gender and professional qualifications required for staff at the study sites should be in accordance with local cultural and social customs. At least one interviewer, one nurse and one technician will be needed to perform filing work and collect data and specimens. In addition, an experienced senior laboratory officer and a logistics clerk are needed in each study team to provide technical and logistical support. A statistics clerk should be employed for data preparation, management and analysis.

7.2. Budget items

The main items to consider are allowances for:

- staff;
- training;
- transportation;
- supplies for data and specimen collection;
- laboratory tests;
- data management and analysis; and
- miscellaneous expenditure.

7.3 Equipment

A Microwell plate reader and a Microwell plater washer are needed in addition to the necessary equipment for an ordinary laboratory.

8. LOGISTICAL SUPPORT

Interviews and specimen collection can be conducted in the clinics by inviting the eligible sex workers to attend. However, it is preferable for this survey to be carried out on site. During the period of site study, investigators should travel between the institutions and establishments and the specimens should be transported to the local laboratory on a daily basis. Arrangements will need to be made to coordinate their transportation. The timing of the investigation will need to be worked out according to whether the sex workers are more likely to be at the sites or to come to the clinics and also to allow them to be available for one hour or more if they come to the clinics. Also, the timing of delivery of specimens needs to fit in with the working hours of the laboratory. Based on the sample size of the survey, enough supplies (10%-15% more than required) for interviews and specimen collection should be prepared in advance.

9. TIME-FRAME

A time-frame for a six-month study period is outlined in Annex 7.

Annex 1

Indicator 3

SAMPLE SIZE REQUIREMENTS FOR (1-A) OF 0.95, (1-B) OF 0.80 AND SELECTED COMBINATIONS OF BASELINE PREVALENCE, PROPORTIONAL DECLINE

Baseline prevalence (%)	Sample size requirement by proportional decline (%) compared with baseline prevalence								
	10	20	30	40	50	60	70	80	90
90	237	72	35	21	13	9	6	4	2
85	334	94	45	26	17	11	7	5	3
80	444	120	56	32	20	13	9	6	4
75	568	150	68	38	24	16	11	7	5
70	710	183	82	46	28	19	13	9	6
65	874	222	99	54	34	22	15	10	7
60	1065	267	118	64	40	26	18	12	8
55	1291	321	140	76	47	31	21	14	10
50	1562	385	167	91	55	36	25	17	12
45	1894	463	200	108	66	43	29	20	14
40	2308	562	241	130	79	51	35	24	17
35	2841	688	294	158	96	62	42	30	21
30	3551	856	365	195	118	77	52	37	26
25	4545	1091	463	248	150	97	66	47	33
20	6036	1445	612	326	197	128	87	61	44
15	8522	2033	859	457	275	179	122	86	62
10	13493	3211	1353	719	432	280	191	135	97
5	28406	6743	2836	1503	903	586	399	282	204
1	147710	34999	14696	7783	4671	3027	2065	1459	1057

Annex 2

Indicator 3
ESTABLISHMENT SELECTION FORM

Province:		**City:**	

Establishment number	**Establishment selected**	
		Total cumulative no. of establishments (M): _____ Planned no. of sampled establishments (a): _____ Sampling interval (SI = M/a): _____ Random number (between 1 and SI): _____

Conducted by: _____

Checked by supervisor: _____

Annex 3

Indicator 3
STUDY FORM FOR HIV PREVALENCE SURVEY

01 STUDY NUMBER: |___|___| |___|___|___|

02 CITY: _____ (provide locally appropriate categories)

03 DISTRICT: _____ (provide locally appropriate categories)

04 ESTABLISHMENT: _____ (provide locally appropriate categories)

Introduction: "My name is… I'm working for… We're conducting a survey to find out how many people have HIV infection. The HIV test will not be linked to your name or ID number.

What is you age? IF THE SEX WORKER IS 21 YEARS OLD OR ABOVE, DO NOT RETAIN HER FOR THE STUDY.

Have you been investigated in another establishment for this study? IF THE SEX WORKER HAS BEEN INVESTIGATED BEFORE DURING THIS SURVEY ROUND, DO NOT INTERVIEW THIS PERSON AGAIN. Tell them you cannot interview them a second time, thank them, and end the interview. If they have not been interviewed before, continue.

Confidentiality and consent: "The nurse will take a blood sample. The specimen will be sent to a laboratory for testing. We would greatly appreciate your cooperation in responding to this survey. The survey will take only a few minutes. Would you be willing to participate?"

_____
(Signature of investigator certifying that informed consent has been given verbally by respondent)

05 STUDY RESULT: |___| 1. Completed; 2. Sex worker not available; 3. Refused; 4. Other

06 AGE: |___|___| Years (should be below 21)

07 INTERVIEWER: _____

08 SPECIMEN COLLECTOR: _____(Blood)

09 DATE SPECIMEN COLLECTED (D/M/Y): _____/_____/_____

10 SUPERVISOR: _____

Annex 4

Indicator 3
COLLECTION OF SPECIMEN - BLOOD

1. Explain the reason for collecting the blood specimen.
2. Put on the gloves; gloves must be worn for collecting any biological specimen.
3. Write age of the sex worker and the date specimen taken on the blood collection tube.
4. Examine both of the patient's arms and choose the one most suitable for blood collection.
5. Apply the tourniquet to upper arm, which should be tight enough to reduce the flow of venous blood without without stopping arterial circulation.
6. Use an alcohol swab or alcohol-soaked cotton ball to disinfect the area from which the blood will be drawn; wait until dry.
7. Uncap the needle.
8. Pierce the vein with the needle, bevel side up, and advance the needle. For veins which are protruding, the skin and the vein can both be pierced with one motion. Since such veins are often hard to find, first pierce the skin adjacent to the vein, then pierce the vein.
9. Lightly pull the syringe shaft to draw the blood into the syringe. Draw at least 5 ml of blood.
10. If blood is flowing smoothly into the syringe, you can remove the tourniquet to ease any discomfort of the patient. The tourniquet must not be tied for more than two minutes. If the tourniquet is tied too tightly, it will cause the blood to condense, leading to inaccurate laboratory results.
11. After finishing drawing the blood, or if blood cannot be drawn, loosen the tourniquet, pull out the needle, and use the cotton pad to apply pressure to the puncture site to stop any bleeding. Have the patient straighten their arm. Always loosen the tourniquet before taking out the needle.
12. Place all used needles and needle holders into a biohazard safety pouch. Do not attempt to disassemble the equipment to recap the needle.
13. Apply a prepared label to the blood sample tube. In order to avoid haemolysis, do not vigorously shake or mix.
14. Wrap the blood sample tube in bubblewrap and then place in the cooler.

If you come into contact with the participant's blood or other fluid, carry out emergency prevention procedures.

Annex 5

Indicator 3
FORM FOR INFORMATION ON ENTERTAINMENT ESTABLISHMENT

Province:		**City:**	

Name of the establishment: _____

Geographic location: _____

Name of owner: _____ Contact: _____

Type of establishment (circle):

1. Bar
2. Beer company
3. Brothel
4. Massage parlour
5. Karaoke lounge
6. Nightclub
7. Discotheque
8. Snooker hall
9. Other (specified): _____

Date and time when establishment was visited (D/M/Y, Time):_____

	Items	**Number**
1	Actual number of sex workers <21 years old on the day of the survey:	
2	Number of sex workers approached for investigation[1]:	
3	Number of sex workers who refused to be investigated after being approached[2]:	
4	Number of duplicates among sex workers approached for investigation[3]:	
5	Number of sex workers who have completed an investigation[4]:	

1. *Sex workers approached for investigation refers to those who were randomly selected at the establishment.*
2. *Sex workers who refused to be investigated refers to those who were invited to participate in the survey, but who declined to be investigated, including interviewed and/or specimen-collected.*
3. *Duplicates refers to those who had already been investigated as part of this survey at another site.*
4. *Sex workers who have completed an investigation refers to those who were invited to be investigated and for whom data and specimen collection was completed.*

Annex 6

Indicator 3
FORM FOR LABORATORY TEST RESULTS - HIV

Laboratory name: _____

Technician: _____ Supervisor: _____

Name of kit: _____ Manufacturer: _____

Batch number: _____ Validity until: _____/_____/_____ (Day/Month/Year)

Age	ELISA 1			ELISA 2			Final result [1]
	OD value	Cut-off value	Result	OD value	Cut-off value	Result	

1 Final result: 0: Negative; 1: Positive.

Annex 7

Indicator 3
EXAMPLE OF TIME-FRAME FOR HIV SURVEY

Activities	Month					
	1	2	3	4	5	6
Protocol development	X					
Identification of principal investigator	X					
Key informant interview	X					
Numeration of establishments		X				
Sampling of establishments		X				
Coordination meeting		X				
Training		X				
Interviews and specimen collection			X	X		
Laboratory tests				X	X	
Data entry					X	
Data analysis					X	X
Reporting						X

INDICATOR 4

PROPORTION OF YOUNG FEMALE SEX WORKERS AGED <21 YEARS WITH LABORATORY-CONFIRMED CHLAMYDIAL INFECTION

1. INTRODUCTION

The 100% condom use programme (100% CUP) promotes condom use in high-risk sexual relations. If effectively implemented, the programme is expected to have a significant impact in reducing STI (including HIV) transmission.

Trends in chlamydial infections have been selected to monitor and evaluate the impact of the 100% CUP because chlamydial infection is the most highly prevalent STI among female sex workers in Asia. Gonococcal or syphilis infections have not been retained as the most appropriate infections to monitor because of the increasing self-treatment (sometimes treatment is even used as a preventive measure) of these infections and their high sensitivity to low doses of common antibiotics available over the counter all around Asia.

2. OBJECTIVE

The objective of this indicator is to monitor the prevalence of chlamydial infection among sex workers working in entertainment establishments and to monitor and evaluate the impact of the 100% CUP on STI transmission.

It is expected that this indicator will be a good proxy of chlamydial incidence in the population of female sex workers since only the younger ones (< 21 years of age) will be retained.

3. DEFINITION

Numerator: Number of sex workers (e.g. < 21years old) with laboratory-confirmed chlamydial infection.

Denominator: Total number of sex workers (e.g. < 21years old) surveyed.

Age could be adjusted locally, depending on the feasibility of finding enough young sex workers as planned. Laboratory-confirmed chlamydial infection refers to the detection of chlamydial infection through polymerase chain reaction (PCR) or ligase chain reaction (LCR) laboratory tests.

4. METHODOLOGY

4.1. Sampling approaches

Sampling strategies should be systematic to be replicable over time.

4.1.1. Sample size

The sample size requirement to allow measurement of changes on this indicator is based on five parameters:

1. the initial level of the indicator;
2. the magnitude of change expected to be detected;
3. how sure you want to be that the change of magnitude has occurred by chance (i.e. 1-a, the level of significance - traditionally, this level is set at 95%);
4. how sure you want to be to observe a change of that magnitude if it did occur (1-b, the power of study - to ensure sufficient power, a mini mum value of study power of 0.8 should be used); and
5. the expected proportion of entertainment workers who will be eligible for the survey.

Previous survey or anecdotal information might be consulted to estimate the initial level of this indicator and the proportion of eligible entertainment workers. If resources permit, a small pilot survey might be conducted to better estimate the sample size.

Annex 1 provides the sample sizes required to measure a proportional decline compared with baseline prevalence (%) with a 95% level of significance and a study power of 80%.

> *Example: Suppose you have a baseline prevalence of 45% and want to detect a proportional decline of 30% (i.e. from baseline prevalence of 45% to 31.5% after intervention). Furthermore, you want your results to be significant at the 95% level (default value) and your study power to be 80% (i.e. b = 0.20). Set P1 = 45%,, proportion decline = 30% and (1-b) = 0.80. From the table in Annex 1, it could be found that the sample size for each survey round would be n = 200.*

4.1.2. Number of establishments

Once the sample size has been calculated, the number of establishments and the average number of sex workers in each establishment should be determined for the two-stage sampling scheme. To calculate the number of sex establishments needed, an average number of young sex workers (< 21years old) per establishment should be estimated.

> *Example: The final sample size is 200 and the average number of young sex workers per establishment is 10, so a total of 20 establishments are needed. Because there is not likely to be homogeneity in terms of population characteristics among female sex workers, or between different type of establishment, a relatively larger number of establishments is required to provide a good average, let's say 20.*

A minimum of 20 establishments is always recommended.

4.1.3. Number of sex workers in each establishment

The number of young female sex workers to be sampled in each establishment is calculated by dividing the final sample size by the number of establishments to be selected.

> *Example above: The final sample size is 200. If the number of establishments to be selected is 20, the number of young sex workers to be surveyed in each establishment will be 10 = 200/20.*

It is recommended that a maximum of 20-25 study subjects should be selected per establishment. As the number increases in each establishment, the reliability of the survey results will decrease. A larger sample size is fine, if there is a wide coverage of establishments.

4.1.4. Sampling frame

A two-stage sampling scheme is used in this survey. Entertainment establishments are selected with equal probability at the first stage of sample selection. A fixed number of sex workers are selected by a simple random or systematic sampling method from each establishment at the second stage.

First stage - selection of a systematic-random sample of establishments:

1. List all the establishments, preferably ordered by type (such as brothel, massage parlour, karaoke lounge, etc).
2. Decide the number of establishments to be selected (see 4.1.3).
3. Calculate the sampling interval (SI) by dividing the total number of establishments (M) by the number of establishments to be selected (a); SI = M/a.

   Example: The number of establishments in the surveyed area is 122, and the number of establishments to be selected is 20, then SI = 122/20 = 6.
4. Select a random number (RS) between 1 and SI, say RS = 2. The establishment with the number corresponding to this number will be the first establishment to be selected.
5. Subsequent establishments are chosen by adding the SI to the RS number identified in step (4), i.e. RS+SI, RS+2SI, RS+3SI, etc. When the decimal part of the sample selection number is <0.5, the lower numbered establishment is chosen, and when the decimal part is <0.5, the higher numbered establishment is chosen.
6. This procedure is followed until the list has been exhausted.

The Establishment Selection Form (Annex 2) can be used in the field to assist with the selection of establishments with the equal probability sampling method.

Example of selection of a systematic-random sample of establishments

Establishment number	Establishment selected	
001		
002	X	
003		Total no. of establishments (M) = 122
004		Planned no. of establishments (a) = 20
005		Sampling interval (M/a) = 122/20 = 6
006		Random start between 1 and 4 = 2
007		Establishments selected = 002, 008, 0014 …
008	X	
009		
010		
011		
--		
--		
122 (Last)		

Second stage - selection of a systematic-random sample of sex workers

Once the first stage of sampling (selection of establishments) has been completed, a defined number of sex workers should be chosen in each selected establishment from a list of young sex workers (<21), using simple random or systematic sampling. It should be noted that it is never advisable to interview volunteers to minimize selection bias. For each selected sex worker who refuses to be interviewed, another sex worker should be selected randomly.

4.2. Labels

In this prevalence survey, the study number, rather than the sex worker's identification number, is used. The first sex worker to be recruited in establishment 1 will be numbered 01 001. This number should be written on the study form and on the chlamydia medium tubes and other relevant testing tubes.

4.3. Collection of data and specimens

A letter of introduction or relevant document from the local authority should be prepared for each study team who will conduct the study on the site. The investigator can show this letter or relevant document to the establishment owner to explain the purposes of the survey and how the information will be used.

4.3.1. Collection of data

Minimum elements of information for the indicator of chlamydial infection include:

- √ study result (completed, sex worker not available, refused, etc.);
- √ site of survey (name of establishment);
- √ study number;
- √ age; and
- √ date of specimen collection.

All this information should be collected by a nurse using the Study Form for STI Prevalence Survey in Annex 3. Ideally, the collection of the information could be integrated into the national or regional STI/HIV surveillance programme.

4.3.2. Collection of specimens

A vaginal swab should be collected for detection of C. trachomatis from each sex worker. The procedures for specimen collection are outlined in Annex 4. These specimens should be transported to the local laboratory on a daily basis for storage in a refrigerator while awaiting further transportation to a referral laboratory. However, the specimens should be better kept in cool places or coolers particularly in hot climates. After the survey in an establishment has been completed, a summary of the establishment information should be filled in on the Establishment Information Form in Annex 5. Specimen collections could become a part of STI/HIV prevalence surveys in the national or regional surveys in the national or regional STI/HIV surveillance programme. Urine specimen can also be collected for PCR testing although testing with such specimen is not as sensitive as that with vaginal swab.

4.4 Laboratory tests

Polymerase chain reaction (PCR) or ligase chain reaction (LCR) amplification is recommended to detect C. trachomatis infection. This assay is highly sensitive. Unless specimens are carefully collected in the field, appropriately transported and handled carefully in the laboratory, they are susceptible to contamination and may give false-positive results. The kits of this assay are commercially available in many countries. However, it is advised that such tests should preferably be conducted by the reference laboratory at national level or sent out of the country for testing to ensure quality. Laboratory tests should be carried out according to the manufacturer's instructions.

The results of tests should be entered as shown in Annex 6. One copy of the results should be kept on file at the laboratory and one copy should be sent to the principal investigator for preparation of an evaluation report.

4.5 Management and analysis of data

A template for data entry and management could be developed with the assistance of computer software, such as EpiInfo 5.0. To minimize data entry errors, the template should be designed to restrict the range of values that can be entered and should require entries for all data fields. The statistics clerk should compile the completed questionnaires, and the data should be entered for analysis. Double entry should be performed for at least 20% of the data to assess the extent of data entry error. If it is found to be more than 10%, then data entry procedures will need to be reviewed and the accuracy of data already entered checked.

The proportion of sex workers with chlamydial infection should be calculated, with the total number of sex workers with positive results of C. trachomatis testing as the numerator and the total number of sex workers whose specimens are available for testing as the denominator. These proportions can be calculated with 95% confidence intervals, and the chi-squared tests for trend and odds ratios with 95% confidence intervals could be used to assess the trends of these indicators over time. In addition, the association between these indicators and other variables, such as age, can also be analysed using more advanced statistical analyses, with the assistance of a statistician.

5. REPORTING RESULTS

Once the data analysis has been completed, the results should be used to prepare a report to evaluate the impact of 100% CUP on STI infections and to determine where the programme can strengthen its activities. This report should be sent to the managers and other relevant decision-makers.

6. TRAINING REQUIREMENTS

The principal investigator should identify the training necessary to conduct the survey. Usually, a two-day training session for interviewers, nurses and technicians will be needed to standardize the procedures for recruitment, interviewing, labelling and specimen collection, etc. The technicians doing laboratory tests should be trained separately in the laboratory protocol, including preparation of the specimens, performance of the tests, filling out of the results, etc.

7. RESOURCE REQUIREMENTS

7.1. Staff

The gender and professional qualifications required for staff at the study sites should be in accordance with local cultural and social customs. At least one interviewer, one nurse and one technician will be needed to perform filing work and collect data and specimens. In addition, an experienced senior laboratory officer and a logistics clerk will be needed in each study team to provide technical and logistical support. A statistics clerk should be employed for data preparation, management and analysis.

7.2. Budget Items

The main items to consider are allowances for:

- √ staff;
- √ training;
- √ transportation;
- √ supplies for data and specimen collection;
- √ laboratory tests;
- √ data management and analysis; and
- √ miscellaneous expenditure.

7.3. Equipment

Thermal cycle equipment and an incubator are needed for detection of C. trachomatis by PCR in addition to the necessary equipment for an ordinary laboratory.

8. LOGISTICAL SUPPORT

Interviews and specimen collection can be conducted in the clinics by inviting the eligible sex workers to attend. However, it is preferable for this survey to be carried out on site. In this case, self-collected vaginal introitus swabs or tampons could be used for specimen collection. During the period of site study, investigators should travel between the institutions and establishments and the specimens should be transported to the local laboratory on a daily basis. Arrangements will need to be made to coordinate their transportation. The timing of the investigation will need to be worked out according to whether the sex workers are more likely to be at the sites or to come to the clinics, and also to allow them to be available for one hour or more if they come to the clinics. Also, the timing of delivery of specimens needs to fit in with the working hours of the laboratory. Based on the sample size of the survey, enough supplies (10%-15% more than required) for interviews and specimen collection should be prepared in advance.

9. TIME-FRAME

A time-frame for a six-month study period is outlined in Annex 7.

Annex 1

Indicator 4

SAMPLE SIZE REQUIREMENTS FOR (1-A) OF 0.95, (1-B) OF 0.80 AND SELECTED COMBINATIONS OF BASELINE PREVALENCE, PROPORTIONAL DECLINE

Baseline prevalence (%)	Sample size requirement by proportional decline (%) compared with baseline prevalence								
	10	20	30	40	50	60	70	80	90
90	237	72	35	21	13	9	6	4	2
85	334	94	45	26	17	11	7	5	3
80	444	120	56	32	20	13	9	6	4
75	568	150	68	38	24	16	11	7	5
70	710	183	82	46	28	19	13	9	6
65	874	222	99	54	34	22	15	10	7
60	1065	267	118	64	40	26	18	12	8
55	1291	321	140	76	47	31	21	14	10
50	1562	385	167	91	55	36	25	17	12
45	1894	463	200	108	66	43	29	20	14
40	2308	562	241	130	79	51	35	24	17
35	2841	688	294	158	96	62	42	30	21
30	3551	856	365	195	118	77	52	37	26
25	4545	1091	463	248	150	97	66	47	33
20	6036	1445	612	326	197	128	87	61	44
15	8522	2033	859	457	275	179	122	86	62
10	13493	3211	1353	719	432	280	191	135	97
5	28406	6743	2836	1503	903	586	399	282	204
1	147710	34999	14696	7783	4671	3027	2065	1459	1057

Annex 2

Indicator 4
FORM FOR INFORMATION ON ENTERTAINMENT ESTABLISHMENTS

Province:		**City:**	

Establishment number	**Establishment selected**	
		Total cumulative no. of establishments (M): _____ Planned no. of sampled establishments (a): _____ Sampling interval (SI = M/a): _____ Random number (between 1 and SI): _____

Conducted by: _____

Checked by supervisor: _____

Annex 3

Indicator 4
STUDY FORM FOR STI PREVALENCE SURVEY

01 STUDY NUMBER: |___|___| |___|___|___|

02 CITY: _____ (provide locally appropriate categories)

03 DISTRICT: _____ (provide locally appropriate categories)

04 ESTABLISHMENT: _____ (provide locally appropriate categories)

Introduction: "My name is… I'm working for… We're conducting a survey to find out how many people have a chlamydial infection. This infection can be treated and complications prevented by early treatment.

What is you age? IF THE SEX WORKER IS 21 OR ABOVE, DO NOT RETAIN HER FOR THE STUDY.

Have you been investigated in another establishment for this study? IF THE SEX WORKER HAS BEEN INVESTIGATED BEFORE DURING THIS SURVEY ROUND, DO NOT INTERVIEW THIS PERSON AGAIN. Tell them you cannot interview them a second time, thank them, and end the interview. If they have not been interviewed before, continue.

Confidentiality and consent: "You will be asked to insert a vaginal swab into your vagina and wipe it around the wall in the lower part of the vagina and then withdraw it. The nurse will explain how to do it. This specimen will be sent to a laboratory for testing. If it is positive for chlamydial infection, you will receive treatment. We would greatly appreciate your cooperation in responding to this survey. The survey will take about 30 minutes. Would you be willing to participate?"

_____

(Signature of investigator certifying that informed consent has been given verbally by respondent)

05 STUDY RESULT: |___| 1. Completed; 2. Sex worker not available; 3. Refused; 4. Other

06 AGE: |___|___| Years (Should be <21)

07 INTERVIEWER: _____

08 SPECIMEN COLLECTOR: _____(Swab)

09 DATE SPECIMEN COLLECTED (D/M/Y): _____/_____/_____

10 SUPERVISOR: _____

Annex 4

Indicator 4
COLLECTION OF SPECIMEN - VAGINAL SWAB

1. Explain to the participant the reason for the vaginal swab collection.
2. Write a number corresponding to the number on the study form on the PCR transport medium tube.
3. Use the specimen collection kits provided by the manufacturer to collect a vaginal sample.
4. Collect material from the vault of the vagina behind the cervix, using a high vaginal swab.
5. Roll the swab against the vaginal wall 2 to 3 times, ensuring that the entire circumference of the swab has touched the vaginal wall.
6. Open the PCR transport collection tube.
7. Place the swab into the transport tube. Break off the long end of swab, by snapping the stick against the side of the tube.
8. Place the cap on the transport tube and close tightly. Place the tube into a sealable bag.
9. After carrying the tube back to the laboratory, immediately store it in a refrigerator while waitng for further transportation to a referral laboratory.

Careful collection and transfer of specimens are critically important to avoid contamination.

Annex 5

Indicator 4
FORM FOR INFORMATION ON ENTERTAINMENT ESTABLISHMENT

Province:_____ City: _____

Name of the establishment: _____

Geographic location: _____

Name of owner: _____ Contact: _____

Type of establishment (circle):

1. Bar
2. Beer company
3. Brothel
4. Massage parlour
5. Karaoke lounge
6. Nightclub
7. Discotheque
8. Snooker hall
9. Other (specified): _____

Date and time when establishment is visited (D/M/Y, Time):_____

	Items	Number
1	Actual number of sex workers on the day of the survey:	
2	Number of sex workers approached for investigation[1]:	
3	Number of sex workers who refused to be investigated after being approached[2]:	
4	Number of duplicates among sex workers approached for investigation[3]:	
5	Number of sex workers who have completed an investigation[4]:	

1. Sex workers approached for investigation refers to those who were randomly selected at the establishment.
2. Sex workers who refused to be investigated refers to those who were invited to participate in the survey, but who decline to be investigated, including being interviewed and/or having a specimen-collected.
3. Duplicates refers to those who had already been investigated as part of this survey at another site.
4. Sex workers who have completed an investigation refers to those who were invited to be investigated and for whom data and specimen collection was completed.

Annex 6

Indicator 4
FORM FOR LABORATORY TEST RESULTS - CHLAMYDIA TRACHOMATIS

Laboratory name: _____

Technician: _____ Supervisor: _____

Name of kit: _____ Manufacturer: _____

Batch number: _____ Validity until: _____/_____/_____ (Day/Month/Year)

Study number	Test date (D/M/Y)	Internal reference OD value	OD value	Final result*

* Final result: 0: Negative; 1: Positive.

Annex 7

Indicator 4
EXAMPLE OF TIME-FRAME FOR CHLAMYDIA SURVEY

Activities	Month					
	1	2	3	4	5	6
Protocol development	X					
Identification of principal investigator	X					
Key informant interview	X					
Numeration of establishments		X				
Sampling of establishments		X				
Coordination meeting		X				
Training		X				
Interviews and specimen collection			X	X		
Laboratory tests				X	X	
Data entry					X	
Data analysis					X	X
Reporting						X