

J. Panth

HIV SENTINEL SURVEILLANCE IN
SRI LANKA

1. REVIEW OF THE ACTUAL SITUATION

1. Epidemiology

Screening for HIV infection has started in Sri Lanka in 1986.

The first HIV infected person detected in Sri Lanka was a foreign tourist suffering from AIDS in September 1986. The first Sri Lankan to be detected with the infection was an adult man diagnosed with AIDS in April 1987.

The first HIV infected pregnant woman gave birth to a healthy baby in April 1990. The baby's Antibody level has since dropped to zero, while the mother has progressed to ARC.

Systematic screening for surveillance purposes among high risk behaviour groups was initiated in mid 1987.

As of June 1991, out of around 180,000 persons tested in Sri Lanka, a cumulative total of 37 HIV infections have been detected (i.e. 0.18 per thousand). Although absolute numbers are increasing no conclusion can be drawn as to the prevalence of HIV infection in the Sri Lankan population. Among the 37 HIV infected, 28 were nationals and 9 foreigners. They included 8 clinical AIDS cases.

All but one HIV infections were due to HIV 1. The only HIV 2 infection was in a seaman who acquired the infection in the East Coast of Africa.

Table 1 gives an overview of all persons tested in Sri Lanka from 1986 until April 1991, by category and by year.

2. HIV Sentinel Surveillance

A workshop on sentinel surveillance was held in June 1990 for 20 participants of 5 selected sentinel sites : Colombo, Galle, Ratnapura, Kandy, and Jaffna.

In July 1990, a first batch of 1,000 persons were tested for HIV in each of the selected sentinel sites. However, for reasons of political unrest, and logistics, the sentinel surveillance in Jaffna could not be carried out completely. It was reported though that among an unknown number of STD patients tested, one was found HIV seropositive.

TABLE 1

HIV TESTING IN SRI LANKA FROM 1986 UNTIL APRIL 1991

By Category tested and by year

Category	1986		1987		1988		1989		1990		1991 (upto Apr.) Cumulative totals			
	Tested	HIV(+)	Tested	HIV(+)	Tested	HIV(+)	Tested	HIV(+)	Tested	HIV(+)	Tested	HIV(+)	Tested	HIV(+)
Sero survey	1,151	0	3,773	0	5,662	0	839	0	814	1	283	0	12,522	1
Sentinel Surveillance									4,000	1			4,000	1
Blood donations			175	0	20,578	0	37,686	1	49,509	0	12,497	1	120,445	2
STD clinics - Male	128	0	232	0	881	0	381	0	518	0	147	0	2,287	0
STD clinics - Female	76	0	267	0	811	0	470	0	519	0	150	0	2,293	0
Screening for Visa	1,742	0	4,691	0	3,136	0	7,530	3	10,804	2	2,532	2	30,435	7
Seaman Screening			445	0	765	2	548	5	44	1			1,802	8
Clinical suspect AIDS	2	1	93	4	125	3	202	1	229	4	28	2	679	15
Ante-natal attendees					1,226	0							1,226	0
Haemophiliacs					33	0	37	0	18	0			88	0
Volunt. Anonymous tests									23	0	5	0	28	0
Partner notification							3	1	2	1	2	1	7	3
Others	23	0	85	0	1,326	0	165	0	342	0	116	0	2,057	0
Totals	3,122	1	9,761	4	34,543	5	47,861	11	66,822	10	15,760	6	177,869	37

72 - not done

93

94 ✓

95 - still pending

Table 2 summarizes the population groups and sample sizes tested in each sentinel site. Of the 4,683 persons tested, the Jaffna STD patient mentioned above was the only HIV seropositive. This first round provides valuable baseline data for further epidemiological follow up.

However, as can be seen in the table, sample sizes vary widely, and the methods used for testing are not always the same. Moreover, different sentinel populations were included in different sites.

3. Findings in the field

Three of the four sentinel sites have been visited : Galle, Ratnapura, and Colombo. Hereafter follows a summary of the findings done. They should be seen as the rationale behind the proposals made for some modifications in the original set up of the Sri Lankan sentinel surveillance system, and in particular as a justification for this protocol outline being used as a basic document in all sentinel sites.

3.1 In total, 15 different sentinel populations have been used. They can be classified as follows :

	Number	Range of sample sizes
High risk	6	13 - 150
Medium risk	5	50 - 300
Low risk	4	100 - 200

The diversion of so many groups is a constraint on the already scarce manpower, and does not give additional benefit in terms of adequate information. Seven samples contain 50 or less individuals, and some are so small that they are inappropriate for epidemiological use.

3.2 There has been no geographical consistency in the use of survey methods :

- different methods have been used for the same sentinel population in different places ;
- only for 2 sentinel populations have the same methods been used consistently, and were relatively big samples drawn :

blood donors (total for the 4 sites is 700)
ANC attendees (total for the 4 sites is 676)

- the methods used are interpreted in different ways by those who had to implement the sentinel surveillance :

* Unlinked Anonymous Testing was used for pre-employment recruits and ANC attendees in Ratnapura. However, the names of the people tested appeared in the registry next to their test results.;

* Voluntary Screening was sometimes interpreted as persons volunteering for being tested after a presentation on AIDS had been made to a group, eg. Army personnel in Ratnapura, beach boys in Colombo.

3.3 Sampling methods varied widely from one sample to another (in the same of different sites) :

TABLE 2

HIV SENTINEL SURVEILLANCE IN SRI LANKA (FIRST ROUND: JULY 1990)
Sentinel Populations, sample sizes, and methods used for screening

Sentinel Population	COLOMBO		GALLE		KANDY		RATNAPURA		Totals
	Method used	Sample size	Method used	Sample size	Method used	Sample size	Method used	Sample size	
Prostitutes		100					V.C.T	24	124
STD clinic attenders		150	R.C.T.	100		100	V.C.T	50	400
Blood donors		200	Mand.	100		200	Mand.	200	700
ANC attenders		200	U.A.T.	200		100	U.A.T	176	676
Pre-employment recruits		200	U.A.T	100		100	U.A.T	167	567
Drug addicts		100	V.A.T	100		50			250
Prisoners		200	V.A.T	100		200	V.C.T	50	550
CTB drivers & conductors			V.A.T	100					100
Private labs		100				50	U.A.T	25	175
Medical wards						100	U.A.T	100	200
Chest Hospitals		100							100
Army personnel			V.A.T	100		100	V.C.T	200	400
Factory Workers			V.A.T	100					100
Hospitality girls							?	13	13
Totals		1350		1000		1000		1005	4355

Survey Techniques : V.C.T = Voluntary Confidential Testing
V.A.T = Voluntary Anonymous Testing
U.A.T = Unlinked Anonymous Testing
Mand. = Mandatory Testing
R.C.T = Routine Confidential Testing

- in some places, medical ward patients were selected on the basis of suspicion of AIDS, but no clear criteria other than "chronic illness" was given ;
- the sample of remand prisoners in Colombo was constituted by the officer in charge on the basis of likely high risk behaviour. The criteria was the age between 20 and 35 years, but some older individuals who claimed risky sexual behaviour were also included. In Galle, however, no such criteria had been used.

3.4 Some situations encountered pose serious ethical problems :

- the "unlinked anonymous screening", as it is used for the sample of pre-employment recruits in Ratnapura, is not at all unlinked : the name and file number is recorded together with the test result. Yet the HIV test has been done without the person's knowledge.
- the same method (no information nor consent, but still not unlinked) is used in other places, but here it is called "routine confidential", eg. STD patients in Galle, or pre-employment recruits in Colombo. Since no AIDS health education nor pre-test counselling was provided to these persons, it could be very prejudicious if they were to be informed afterwards that an HIV test was done and they had been found HIV seropositive.

3.5 Some of the samples would eventually suffer severe selection bias as compared to the sentinel population they are supposed to represent. Drug addicts, for example, were exclusively recruited from prisons.

3.6 The sentinel population called "Private labs" contains in fact exclusively STD patients, but those were selected on a quite uncertain basis, eg. in Ratnapura some of the sera for this sample were provided by a GP, while others were collected from MLTs who had used unknown criteria for inclusion in the sample.

3.7 In the absence of written instructions, methods were changed over time : in Ratnapura the MO decided to no longer include the medical wards patients among the sentinel populations, but rather a sample of dam site workers who had come to the area recently.

3.8 On many occasions, police has been cited as "helping to constitute the samples". It needs no argument that coercion could in the long run be extremely counter-productive.

4. Conclusion

- 4.1 The findings related provide broad evidence of a lack of consistency, both geographically and over time. This would preclude the possibility of establishing time trends as well as comparison of HIV seroprevalence rates among regions or provinces.
- 4.2 The generally small sample sizes do not yield epidemiological data accurate enough to detect even relatively big changes in HIV seroprevalence. Unexperienced interpretations could even give rise to very wrong conclusions. These small samples probably originate in the multiplicity of sentinel populations, together with limited resources in manpower and test kits.

4.3 Too little attention has been given to high risk behaviour groups to the benefit of several groups representing the general public, and significantly lower risk.

5. Recommendations

For the reasons listed above, it is recommended :

- to reduce the number of sentinel populations, in particular those at lower risk of HIV infection,
- to increase the size of the samples ;
- to impose strict respect of a study protocol to all implementors
- to use pooling of sera for testing.

The HIV Sentinel Surveillance Protocol Outline proposed hereafter is based on the above mentioned findings, conclusions and recommendations.

II. PROTOCOL OUTLINE

1. Objectives of the HIV Surveillance System

- 1.1 To provide estimates of the prevalence of HIV infection in selected population groups and geographical locations.
- 1.2 To monitor the trends of HIV infection in selected groups and places over time.
- 1.3 To consequently provide indications to better target preventive interventions against AIDS/HIV infection.

2. Selection of Surveillance System

Sentinel Surveillance is considered the optimal method for the assessment of seroprevalence in selected population groups and for the monitoring of its changes in time, with the use of limited means.

Participation bias (*) which could be important enough to invalidate the results of this epidemiological study, can be avoided by the use of unlinked anonymous testing. Indeed, by "un-linking" each collected blood sample from the identity of the person tested, the necessity of obtaining informed consent can be bypassed, and therefore the eventuality of withdrawal from the study avoided.

(*) Participation (or self-selection) bias refers to the impact of persons who are at risk or know they are infected being either more or less likely to be tested than persons who are otherwise similar but without recognized risk. Participation bias poses a methodological problem because of its quantitatively unpredictable impact of the data.

The logical draw back of this method is that no seropositive individual can be traced back for further investigation and/or counselling. Therefore, sufficient epidemiological data such as sex, age group, date and place of collection of the sample, need to be kept with the blood sample. In addition, voluntary confidential testing should be made available in appropriate places. On the other hand, sentinel surveillance is not meant to detect HIV infected persons for individual follow up, but to provide indications on priority areas for interventions targetted to particular population groups as a whole.

For the reasons mentioned above, sentinel surveillance using unlinked anonymous testing for HIV has been selected as the method of choice for epidemiological assessment in a way that is compatible with preventive activities such as health education and information, counselling, condom promotion, etc.

However, for ethical reasons, UAT is only possible if blood is already drawn for other purposes on which the person tested has agreed : blood should not be drawn for the exclusive purpose of UAT.

As a consequence, wherever prostitutes are to be included in the sentinel surveillance population groups, voluntary anonymous - or confidential - testing after informed consent is recommended. The proportion of refusals should then be monitored carefully, and mentioned with the study results so as to allow correct interpretation of the surveillance data.

In the case of voluntary testing, pre- and post- test counselling should be available at the sentinel site.

A periodicity of testing of 6 months is advisable for high risk behaviour groups. If sentinel populations at low risk of HIV infection, other than blood donors (such as ANC attendees), are to be included, a 1 year periodicity would be sufficient to detect changes in seroprevalence.

3. Sentinel Sites

In the 1st round of HIV sentinel surveillance carried out in July 1990, 4 sites had been included: Colombo, Galle, Kandy and Ratnapura. (Jaffna in the Northern Province had also been selected but could not participate in the study).

The following criteria were taken into account for the selection of the sites :

- 3.1 the area is known to have large population groups with high risk behaviour ;
- 3.2 the availability of well-motivated manpower ;
- 3.3 HIV screening was performed in at least 1 centre of the site during the last 2 years ;
- 3.4 there are facilities where a sufficient number of persons of selected population groups can be accessed easily by health workers;
- 3.5 from these persons, blood samples are routinely drawn for purposes other than HIV testing ;

3.6 in cases where conditions 3.4 and 3.5 are not feasible, voluntary anonymous or voluntary confidential testing was performed with preliminary informed consent, with health education provided before and continuously after the test. No case of refusal to participate after due information, has been recorded during this 1st round.

For the near future, it is recommended that sentinel surveillance continue in the same 4 sentinel sites. The Northern and North-Eastern Provinces should be included as soon as logistically possible, because of their proximity to Madras with higher HIV seroprevalence and also because a significant number of injecting drug users (IDUs) have been reported.

4. Sentinel populations

The following population groups will be considered for inclusion in the sentinel surveillance system ;

- high risk : female prostitutes
STD patients
- medium risk : TB patients
- low risk : blood donors
antenatal clinic attendees

Whether they will be included and in which sentinel site will depend on their availability in sufficient numbers, and their accessibility without coercion.

TABLE 3 : PROPOSED SET UP FOR THE NEXT ROUNDS OF SENTINEL SURVEILLANCE

	COLOMBO		GALLE		RATNAPURA		KANDY	
	Method	Sample Size	Method	Sample Size	Method	Sample Size	Method	Sample Size
♀ Prostitutes	VC	250 400	VC	100 200	VC	100 200	VC	100 200
STD Patients	UA	200 400	UA	100 200	UA	100 200	UA	100 200
TB Patients +	UA	200	UA	200	UA	200	UA	200
Blood Donors	Mand.	600	Mand.	600	Mand.	600	Mand.	600
ANC Attenders	UA	600	-	-	-	-	-	-
TOTAL		2200		1200		1200		1200

Abbreviations : VC - Voluntary Confidential
UA - Unlinked Anonymous
Mand. - Mandatory

TB pts
+
pts = LRTI infec

5. Periodicity

In view of their quite high variability, the high and medium risk groups would be tested every 6 months.

Because changes in HIV seroprevalence are much slower among low risk behaviour groups and because lower seroprevalence rates require larger samples to yield the same accuracy, it is advisable that ANC attendees be included only once a year.

Blood donors however, for reasons of convenience, (blood tested for HIV mandatorily, and no additional cost for epidemiological testing) and although they represent the general public, at low risk would be included bi-annually.

As soon as Jaffna becomes operational as a sentinel site, IDUs should be included among the high risk behaviour groups.

6. Sampling methods

The sample should be constituted by consecutive enrolment of eligible individuals, from the onset of the collection period until the pre-determined sample size has been reached, or until the limit date for sample collection.

6.1 To the extent possible, samples of 600 blood donors will be collected in each sentinel site as part of the sentinel surveillance system. No additional testing needs to be carried out: 600 consecutive HIV test results will be recorded from the blood bank, from the onset of the sentinel surveillance period.

6.2 Female prostitutes will be invited to participate in the study after specific AIDS health education and pre-test counselling has been provided. It is essential for the Programme that their collaboration be obtained through education and eventual incentives, eg. condom distribution, rather than through coercion. It is recommended that arrangements be made in advance with the brothel keeper or madam, well before the beginning of the screening period.

Since blood will be drawn specifically for the purpose of HIV testing, the screening method can only be voluntary, either anonymous or confidential. In that case, the drop-out rate, because of refusal to participate, will be mentioned in the surveillance report. Information from samples with a drop-out rate higher than 10% may be subjected to participation bias and should therefore be interpreted with precaution.

The sample size for Colombo will be 400, while everything should be done to reach samples of 200 in Galle, Ratnapura and Kandy. Strict respect of confidentiality is of the highest importance in this group.

6.3 The methods for collection samples of STD patients, TB patients and ANC attendees are similar, since these groups will be included on the basis of unlinked anonymous screening. From the starting date, part of the serum that has been collected for other purposes from eligible persons will be separated, stripped of any identifying markers, and tested for HIV, until the requested sample sizes are reached.

Tentative sample sizes and screening methods for the respective sentinel population groups and sentinel sites, are given in Table 2, below :

7. Operational Procedures

As a general rule drawing of blood and actual testing of the blood sample should be kept separated as much as possible, and performed by different persons, in order to protect anonymity.

For the group of female prostitutes the usual procedures of confidential blood testing will be applied. Participation should be totally voluntary, but much effort should be made to keep refusal to participate at a minimum possible. Incentives in the form of free condoms could be envisaged. In other countries, testing for other STD and eventual free treatment has been offered as an incentive.

The utmost important point, however, is that prostitutes should be convinced that confidentiality will be respected. Experience in other AIDS programmes has shown that friendly relationships based on confidence and trust are the basis of successful collaboration.

HIV test results of blood donors will be taken from the blood bank registry files in a consistent way : from the starting date of the Sentinel Surveillance period up to reaching the requested sample size.

The operational procedures for the 3 groups on which AIDS will be done (STD and TB patients, and ANC attendees) are as follows :

At the site of the blood collection, the sera obtained after venipuncture and serum separation will be divided into 2 specimen tubes. The tube for HIV screening must contain a minimum of 0.5ml of serum. The label on the specimen for HIV testing is to be marked on the top line with the month and year, in the middle with a numeric code identifying the sentinel site, and on the bottom line of the label the age in years and sex of the patient. The specimen for ESS or syphilis screening is to be handled and labelled in the usual way. Specimens for HIV testing are placed in a special box to be provided by the SACP, and stored in the freezer compartment of the clinic refrigerator for collection and delivery to the HIV testing laboratory.

Month/year
SS code
Age/sex
lab code

The HIV testing laboratory, on receiving the samples, assigns an individual identifying code to each specimen, and enters the month and year of sample collection, the sentinel site code, and the age and sex against the corresponding laboratory code number for each specimen for HIV testing. This is to be the first occasion when each specimen for HIV testing receives an individual identifier. In this way, the possibility of tracing the source of any one HIV test result is made virtually impossible. All sera collected at any one sentinel site in any one sampling period are to be tested in the same laboratory, at the same time.

The method of pooling of 5 sera will be used for testing, according to the instructions that will be given by the expert visiting the country for this particular purpose in August. Guidelines on testing of individual samples once a pool is found HIV seropositive, as well as on confirmatory testing - if any is needed - will also be provided at the same time.

Confirmatory testing is needed whenever the person tested is to be informed of his/her HIV status, and counselling provided.

8. Data processing and Analysis

All data will be centralized in the STD/AIDS Control Programme Office, Colombo, where data analysis will be performed by using the computer and Epi-Info (version 5) software.

The 6-monthly - or eventually yearly - data will be tabulated on a master table to yield the following information for each sentinel site :

- number tested, number and % HIV seropositives as well as the 90% confidence interval* for each sentinel population as a whole;
- numbers tested, number and % HIV seropositive by age group within the various sentinel populations.

* The formula for the calculation of the confidence interval is as follows :

$$C.I = p \pm z \sqrt{\frac{p \times (1 - p)}{N}}$$

where P = the HIV prevalence estimate
N = the sample size used
Z = a constance depending on the desired confidence interval : Z = 1.65 for a 90% C.I
Z = 1.96 for a 95% C.I

9. Feed-back Information

The information gathered will be used for the objectives stated above, i.e. assessing the baseline situation and monitoring the trends of the HIV infection; and provide indications for better targeting preventive activities. It is therefore essential that regular and up-to-date information be given to the agencies where the data will be utilized for the prevention and control of AIDS.

The results generated by the sentinel surveillance will also be disseminated quickly and regularly to those who were designated in advance in the sentinel HIV surveillance protocol as having a legitimate need to have the information. The decision as to who should have surveillance information will be made in consultation with the National AIDS Committee and also with higher authorities. To maintain confidentiality, and to account for local sensitivities, the NACP may decide that the surveillance results should not be published by individual sentinel sites, regions, or cities. Instead a range of values by type of sentinel site might be presented regionally and nationally.

Regular epidemiological information will also be provided to all the provinces of the country, and will be reported to GPA/WHO.

10. Budget

Since the total number of individuals to be included in the sentinel surveillance is hardly higher than for the first round (5,800 per round against 4,683 for the 1st round), and since the number of test kits will be reduced very substantially (less than 50%) by using pools of sera, the overall budget requirements for the new version of the Sentinel Surveillance will be significantly lower than the one foreseen.

For example, it was foreseen that 10,000 tests would be needed per year while the reviewed system will need less than 3,000 (Quality Assurance 10% included), even if the overall HIV seroprevalence rate becomes as high as 4%.

Excess funds may be re-programmed, or used for the purchase of incentives such as condoms.

Prostitution	P
STD	S
TB	T
Chast wife ²	C
Bld Bank	B
Amc	A

2
3.4
29 | 100.0
87

13.0