

GUIDELINES FOR HIV SURVEILLANCE AMONG TUBERCULOSIS PATIENTS



SECOND EDITION

2004





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LIST OF ABBREVIATIONS

AIDS	<i>Acquired Immune Deficiency Syndrome</i>
ART	<i>AntiRetroviral Therapy</i>
ELISA	<i>Enzyme-Linked Immunosorbent Assay</i>
HIV	<i>Human Immunodeficiency Virus</i>
IPT	<i>Isoniazid Preventive Therapy</i>
IUALTD	<i>International Union Against Tuberculosis and Lung Disease</i>
KNCV	<i>Royal Netherlands Tuberculosis Association</i>
NAP	<i>National AIDS Programme</i>
NTP	<i>National Tuberculosis Programme</i>
SGS	<i>Second Generation Surveillance</i>
TB	<i>Tuberculosis</i>
TB/HIV	<i>TB and HIV infection</i>
UAT	<i>Unlinked Anonymous Testing</i>
VCT	<i>Voluntary Counselling and Testing (for HIV)</i>
WHO	<i>World Health Organisation</i>

Executive summary

These guidelines are addressed to the managers of National TB Programmes (NTP) and National AIDS Programmes (NAP), those people responsible for HIV surveillance and public health decision makers at national and sub national level. This document is a part of the documents developed in the TB/HIV series produced by the Stop TB Department in the World Health Organisation and also is one of the "Second Generation Surveillance" (SGS) series.

The main objective of these guidelines is to provide a framework for the methods to be used for measuring HIV prevalence among tuberculosis patients and to encourage its implementation.

Surveillance of HIV among tuberculosis patients has become increasingly recognized as important, as the HIV epidemic continues to fuel the global tuberculosis epidemic. In many countries HIV prevalence in tuberculosis patients is a sensitive indicator for the spreading of HIV into the general population. Information on HIV levels in TB patients is essential to respond to the increasing commitment to provide comprehensive HIV/AIDS care and support, including ART, to HIV positive TB patients.

WHO previous guidance on the surveillance of HIV among tuberculosis patients, published in 1994, detailed one specific approach to determine HIV prevalence through cluster sampling and unlinked anonymous sero-prevalence surveys. The increasing availability of routine HIV testing and counselling as an entry point to HIV/AIDS care for TB patients has highlighted the need for updated and broader guidelines.

WHO's "3 by 5" initiative to reach 3 million HIV infected people with anti-retroviral therapy by the end of the year 2005 will further increase demand for ART delivery with surveillance system and adapted to the country situation. HIV testing is the entry point for ART delivery, and the applies equally to patient with TB. The presence of reliable HIV surveillance systems for TB patients and large scale access to HIV testing and counselling services is cornerstone for effective collaboration between.

This document outlines the three main strategies for surveillance of HIV among tuberculosis patients: data from the routine testing of tuberculosis patients for HIV; sentinel surveillance and special surveys.

Selecting the appropriate strategy for HIV surveillance among TB patients will depend on the existing surveillance system, the underlying HIV epidemic state in a country, the status of implementation of antiretroviral therapy as well as the overall tuberculosis situation. This document provides an overview of the principal issues that will need to be considered by countries in strengthening their existing surveillance systems or developing new systems, and increasing their utility.

At all levels of an HIV epidemic (low-level, concentrated, generalised), when routine HIV testing data are available, these should be used for surveillance purposes. This routine data can be calibrated by periodic (special) or sentinel surveys.

In countries where HIV prevalence among tuberculosis is unknown a sero-prevalence survey should be undertaken as part of the initial assessment of the situation.

WHO recommends the following HIV surveillance methods, which vary according to the level of the HIV epidemic:

1. All countries with a generalised HIV epidemic state (HIV prevalence consistently over 1% in pregnant women in urban areas) should aim to ensure that HIV counselling and testing are actively promoted and offered to all tuberculosis patients. Whenever possible this should be done in conjunction with the provision of ARVs. The data so obtained can form the basis of a reliable surveillance system where high coverage (>80%) of testing among tuberculosis patients is achieved. One of the best systems for capturing this information is through a computerised tuberculosis notification system, which also captures information on HIV status.

In addition we recommend periodic (special) surveys or sentinel surveys to calibrate results from routine testing.

2. In countries with a concentrated epidemic state (HIV prevalence consistently over 5% in at least one defined sub-population, e.g. intravenous drug users (IDUs); sex workers (SWs); and HIV prevalence is below 1% in pregnant women in urban areas.) Offering HIV counselling and testing to all TB patients should still form the basis for the surveillance.

If this system is not yet in place, then periodic (special) surveys or sentinel surveys are suitable alternatives.

3. In countries with a low level HIV epidemic state (HIV prevalence has not consistently exceeded 5% in any defined sub-population, e.g. IDUs; SWs), where HIV testing is not routinely offered to TB patients, periodic (special) surveys (at 2-3 yearly intervals) or sentinel surveys among tuberculosis patients should be conducted.

Sentinel serosurveillance for HIV in general, (which, depending on the level of the epidemic, uses data from serosurveillance among: pregnant women, the general population, or population groups with high risk behaviour) is useful for monitoring the trends in HIV prevalence and can identify, at an early stage, areas where routine HIV counselling and testing of individuals with tuberculosis should be undertaken.

Although HIV tests other than on serum or blood (principally gingival secretions) are available and being further developed (for example for sputum testing), we do not recommend their use in HIV surveillance among TB patients, unless these tests have been validated in the country, against gold standard sero-HIV tests, and found to be sufficiently reliable.

It is intended to pilot these guidelines in several sites around the world in 2004 which will permit the evaluation of their feasibility and will answer questions regarding sputum-based HIV testing under different conditions.

1. Introduction

1.1. Background

The human immunodeficiency virus (HIV) epidemic has increased the global tuberculosis burden and focused attention on the need to strengthen links between the tuberculosis and HIV/AIDS programmes, in order to tackle these public health emergencies more effectively. In response to this situation, the World Health Organisation (WHO) has developed an expanded strategy aimed at decreasing the burden of HIV-related tuberculosis through close collaboration between the tuberculosis and HIV/AIDS programmes.¹ This multi-faceted strategy comprises interventions targeted against tuberculosis, including intensified case finding and preventative treatment, as well as interventions against HIV, including counselling, provision of condoms and antiretroviral therapy (ART).

As the HIV/AIDS and tuberculosis epidemics have progressed, surveillance has become widely recognized as a critical activity in understanding the trends of the epidemics and in enabling sound strategies to be developed on how best to respond to them.⁶ Surveillance of HIV among tuberculosis patients has become increasingly recognized as important, as the HIV epidemic has continued to fuel the tuberculosis problem and as new solutions have emerged to tackle this developing situation.

The WHO produced guidance on surveillance of HIV among tuberculosis patients in 1994, detailing a specific approach of determining HIV prevalence rates among this population group.² These guidelines were produced by a group of experts from around the world based on experience from surveillance systems that had worked well in countries in sub-Saharan Africa. The guidelines outline the methodology behind undertaking an unlinked anonymous sero-prevalence survey of HIV infection among newly diagnosed adult patients with tuberculosis.

Some countries have undertaken surveys based on the 1994 guidelines. In these countries the guidance in this document has been generally reported to be useful. However, the methods outlined in the 1994 document detail one specific approach to surveillance and whilst surveys using this approach continue to have a specific role, many countries are now undertaking surveillance using alternative methods. In particular, HIV prevalence data on tuberculosis patients are increasingly available from health care delivery settings, where HIV testing is being routinely promoted and offered.

The changing epidemiological situation combined with the emergence of new knowledge, technologies, treatments and strategies for tackling the TB/HIV problem, highlight the need for updated and broader guidelines that reflect these changes.

1.2 Rationale for surveillance

Surveillance is a 'system for collecting information needed for advocating, designing, planning and evaluating public health action.'³ The overall objective for any communicable disease surveillance system is to collect, analyse and disseminate accurate epidemiological data.⁴ It should contribute to a better understanding of the magnitude of the problem and provide reliable, timely and cost-efficient information for action.

Surveillance activities for HIV usually refer to the intentional collection of data, through surveys, for example. However, it is increasingly recognized that surveillance systems can also make use of data that result from other activities, where surveillance is a secondary objective. For example, HIV data from voluntary counselling and testing (VCT) services may in the future be used for surveillance purposes, although these data can be affected by biases. Data from blood bank may be useful, although here again biases may operate.

Surveillance systems for measuring HIV prevalence among tuberculosis patients have a variety of specific objectives, which are likely to vary between countries, according to the different needs and demands within these countries (Box 1).

Box 1: Objectives of surveillance of HIV prevalence among tuberculosis patients in different HIV prevalence settings⁶

All HIV prevalence settings

- To inform the targeting of resources and the planning of activities for people with HIV and tuberculosis and for monitoring the effectiveness of these activities
- To increase political, professional and civil society awareness of the situation
- To assess the need for collaboration between the HIV/AIDS and the tuberculosis programmes on formulation and implementation of a joint tuberculosis/HIV strategy
- To provide information on the epidemic of HIV/AIDS and its impact on tuberculosis patients
- To quantify the need for providing ART to TB patients

Low-level HIV epidemic state

- To alert tuberculosis and HIV/AIDS programmes to a potential HIV problem to enable appropriate changes to be made to programmes, which may include the institution of more systematic surveillance methods or the development of joint strategies

Concentrated or generalised HIV epidemic state

- To assess the impact of the HIV epidemic upon the tuberculosis situation

1.3 Challenges to surveillance

The main challenges to any type of surveillance may be categorised as ethical, organisational and/or financial.

¹Classified according to the WHO definitions (low level: HIV prevalence has not consistently exceeded 5% in any defined sub-population; concentrated: HIV prevalence consistently over 5% in at least one defined sub-population. HIV prevalence below 1% in pregnant women in urban areas; Generalised: HIV prevalence consistently over 1% in the pregnant women). Definitions outlined in World Health Organization /UNAIDS. *Guidelines for second generation HIV surveillance*. Geneva: World Health Organization and the Joint United Nations Programme on HIV/AIDS; 2000. WHO document WHO/CDS/CSR/EDC/2000.5 & UNAIDS/00.03E.

➤ **Ethical**

A major challenge to any HIV surveillance system is the ethical minefield around HIV testing. The ethical issues related to HIV testing have been widely debated in the published literature and are complex. The main ethical problem with regards to surveillance of HIV among tuberculosis patients is around the use of unlinked anonymous or ‘blinded’ methods, especially in the context of increased access to ART. Unlinked anonymous testing is where blood or other specimens are taken for other purposes and the left over part of the specimen is stripped of all identifying markers and tested for HIV infection without the consent of the individual concerned.⁵ Unlinked anonymous methods are used in surveys and sentinel methods to help control for the participation bias that may result when people refuse to have their blood tested.

Testing without informed consent, for the purpose of surveillance, has been generally considered ethical if it is not only anonymous but also unlinked, so that all identifiers are removed from specimens, making it impossible to link test results to the individual person. However, blinded HIV prevalence surveys have always provoked considerable controversy,⁶ particularly in economically developed nations including the US, United Kingdom and the Netherlands.

The high rates of HIV infection among tuberculosis patients in many countries and the increasing prospects for care of HIV infected individuals have led some to challenge the ethical validity of unlinked anonymous methods. A further problem concerning the use of these methods in tuberculosis patients relates to the collection of the sample. Usually unlinked anonymous methods in HIV surveillance rely on blood samples, collected for other purposes e.g. syphilis testing among pregnant women.³ A problem with blinded sero-prevalence surveys among tuberculosis patients is that blood is often not routinely collected and has to be specially collected for the purpose of the survey. This has led to debate over whether these methods should be undertaken in such settings,⁷ and has prompted a focus on the possibility of testing sputum samples in such circumstances.

UNAIDS and WHO have published new guidelines for HIV surveillance among pregnant women, which contains information concerning ethical issues around HIV surveillance.⁸ Despite the emphasis that “*UAT can lead to missed opportunities for referring patients /clients to available prevention services...*” this guidance is likely to recommend that unlinked anonymous surveillance strategy is still in fact ethical as long as certain provisos are adhered to the surveillance protocol. The main proviso relevant to tuberculosis patients is that in instances where blood is drawn *exclusively* for the purposes of unlinked anonymous surveillance, the fully informed consent of each individual subject should be obtained, even though the rate of refusals may compromise the initial rationale of such methods – the elimination of participation bias. A further proviso stipulates that every effort should be made to refer subjects included in unlinked anonymous sero-prevalence surveys to whatever local services may exist for voluntary counselling and testing for HIV infection.

However, individual countries should weigh up the advantages and disadvantages of using unlinked anonymous testing in the light of any local issues and the available ethical guidance from the WHO that is currently under revision.

➤ **Organisational and/or financial**

Current communicable diseases surveillance systems vary markedly between countries and systems which work well in some countries may fail to meet the needs and demands of other countries and vice versa. An understanding of the country's specific needs and demands is important and surveillance systems should be tailored accordingly.

There is often a general lack of understanding among senior health policy makers of the importance of surveillance as a planning and evaluation tool, which results in low priority given to surveillance activities and insufficient investment in the infrastructure necessary for an effective surveillance system. 3 A specific problem of surveillance systems for monitoring HIV prevalence among tuberculosis patients is that, as an area which bridges the HIV/AIDS and tuberculosis programmes, it may suffer from the problem of falling between these two programmes, with neither programme fully aware of its importance or willing to fund or accept responsibility for this surveillance.

A considerable challenge to the establishment and maintenance of communicable disease surveillance systems in many countries is the lack of skilled epidemiology personnel. Staff working in the field often have insufficient training and are often ill informed of the purpose of surveillance activities. Feedback to staff involved in surveillance activities is often inadequate which may lead to staff becoming demotivated and the system functioning poorly.

A problem with many of the current HIV surveillance systems among TB patients is that they reflect more the access of patients to health care services than the true occurrence of HIV within the overall tuberculosis population. The bias introduced through differential access and through patients' reluctance to be tested for HIV, may be a particular problem for surveillance systems that rely on data from HIV routinely testing services. Problems also often exist around collecting data from the private sector, with data from private services often omitted from surveillance systems leading to under-representation of all those who use these services.⁹

2. Methods for HIV surveillance among tuberculosis patients

2.1 An overview of different surveillance methods

This section describes the main methods that should be used in the surveillance of HIV among tuberculosis patients. Recommendations for the appropriate method mix for individual countries according to their HIV epidemic state are outlined in the second part of this chapter.

A summary of the three main surveillance methods for measuring the prevalence of HIV infection among tuberculosis patients is shown in Box 2.

Box 2: Different surveillance methods for measuring the prevalence of HIV infection among tuberculosis patients			
Surveillance method	Periodic (special) surveys	Sentinel methods	Data from routine care
Description	<p>Cross-sectional HIV sero-prevalence surveys among a sample of tuberculosis patients within a country. Surveys should include all newly registered tuberculosis cases, but countries may choose to focus on a sub-group of patients, such as adult cases with smear positive disease for ease.</p>	<p>Includes tuberculosis patients as a sentinel group as part of the general HIV sentinel surveillance system. A predetermined number of tuberculosis patients routinely tested at selected sentinel sites, and testing is performed in a regular and consistent way. As with surveys, all tuberculosis cases should be included, but countries may choose to focus on a sub-group of patients, such as adult cases with smear positive disease for ease.</p>	<p>Data collected from routine care of tuberculosis patients who are tested for HIV on voluntary and confidential basis. With increasing levels of HIV in the general population, countries should aim to test all tuberculosis patients for HIV. Countries with a generalised HIV epidemic state should aim to ensure that HIV testing is actively promoted and offered to all tuberculosis patients.</p>
Key objectives	<ul style="list-style-type: none"> • This method should be used where the prevalence is previously unknown. It aims to provide tuberculosis programmes with rough point prevalence estimates of the level of HIV infection among tuberculosis patients, as part of the initial assessment of the situation. • This information may alert tuberculosis programmes to a potential HIV problem to enable appropriate changes to be made to programmes, which may include the institution of more systematic surveillance methods. • This system may also be used in countries with established surveillance systems based on data from routine patient care, to corroborate prevalence estimates. 	<ul style="list-style-type: none"> • This surveillance method aims to provide more systematic information that is able to provide point HIV prevalence among TB patients estimates as well as be able to identify trends. • This information is of value in designing, implementing and monitoring public health programmes for the prevention and control of tuberculosis. • These regular prevalence estimates can also be used to identify, at an early stage, areas where HIV testing programmes directed to the individual should be developed. 	<ul style="list-style-type: none"> • The primary objective of this type of surveillance is the identification of individuals who are co-infected with HIV and tuberculosis to provide them with the medical and psychosocial support they need. • The secondary objective is to provide information that is of value in designing, implementing and monitoring public health programmes for the prevention and control of tuberculosis.

	<ul style="list-style-type: none"> This system may also be used in resource limited countries with under-developed surveillance systems where HIV prevalence in the general population may be high but where the institution of more systematic methods of surveillance is not possible. 		
Advantages	<ul style="list-style-type: none"> Simple No need for major investment in infrastructure Established method With representative sampling, may provide reliable estimate of HIV among TB patients Can be helpful in indicating possible sources of bias in surveillance based on sentinel methods or data from routine care of patients 	<ul style="list-style-type: none"> Fairly simple and inexpensive method Good information on trends Focuses on easily accessible patients Often part of a well established HIV sentinel system 	<ul style="list-style-type: none"> The testing and reporting of HIV among tuberculosis patients is important in individual case management and provides the opportunity for co-infected patients to receive collaborative prevention and care programmes Public health advantages around the HIV prevention activities that can be associated with large scale HIV counselling and testing programmes System which has most benefit to patient Provides tangible evidence of the presence of the HIV epidemic and depending on the completeness of the reporting may provide a basis for estimating the burden of HIV related disease and the demand for health care If testing widely available and uptake is high, data may provide reliable HIV prevalence estimates among tuberculosis patients
Disadvantages	<ul style="list-style-type: none"> Provides poor information on trends if undertaken infrequently May be expensive and time consuming 	<ul style="list-style-type: none"> Representativeness of sentinel sites Lack of a consistent sampling frame may lead to biased estimates of 	<ul style="list-style-type: none"> Necessary infrastructure for the surveillance system may be complex and may be time consuming and

	<ul style="list-style-type: none"> • Problems with the inclusion of smear negative tuberculosis patients who may have complicated diagnostic pathways • Problems in obtaining sample for testing if specimen is not one that is routinely taken • Ethical issues over unlinked anonymous methods • Difficulty in keeping specimens unlinked and anonymous • Sample sizes may be too small for detailed analyses • Representativeness of sample often questionable, so may be open to selection bias • Has been found to provide inconsistent results in countries with poor testing procedures and inadequate quality control 	<p>trends</p> <ul style="list-style-type: none"> • Problems with the inclusion of smear negative tuberculosis patients who may have complicated diagnostic pathways • Ethical issues over unlinked anonymous methods • Difficulty in keeping specimens unlinked and anonymous • Problems over who has responsibility for the system • Has been found to provide inconsistent results in countries with poor testing procedures and inadequate quality control 	<p>expensive to maintain</p> <ul style="list-style-type: none"> • May provide biased estimate if HIV testing rate is low • Completeness often affected by the quality of the reporting itself, health seeking behaviour and the availability of testing. • May reflect more the access to health care services than the true occurrence of HIV within the tuberculosis population • Has been found to provide inconsistent results in countries with poor testing procedures and inadequate quality control
HIV prevalence level of country*	For countries of all HIV epidemic levels	"Low level, concentrated or generalised"	"Generalised or concentrated"

* Classified according to the WHO definitions (low level: HIV prevalence has not consistently exceeded 5% in any defined sub-population; concentrated: HIV prevalence consistently over 5% in at least one defined sub-population. HIV prevalence below 1% in pregnant women in urban areas; Generalised: HIV prevalence consistently over 1% in the pregnant women).

➤ **Periodic (special) surveys**

Periodic (special) sero-prevalence surveys have been the main surveillance method for measuring HIV prevalence among tuberculosis patients for many countries around the world.^{10 11 12 13 14 15 16} Well conducted, cross-sectional sero-prevalence surveys can provide tuberculosis programmes with sufficiently precise point prevalence estimates of the HIV prevalence among tuberculosis patients^{38 39}. Such surveys are useful in settings where the prevalence is previously unknown as part of the initial assessment of the situation. These surveys are also useful in resource poor countries with under-developed surveillance systems where HIV prevalence in the general population may be high but where the institution of more systematic methods of surveillance is not possible. Periodic (special) surveys can also be used to corroborate from other surveillance methods.

Prevalence surveys are a well-established surveillance method and can be undertaken relatively simply compared to other methods of surveillance. They obviate the need for any major investment in infrastructure that other surveillance methods may require. However, surveys can still be time consuming and expensive, and if they are not undertaken using appropriate methods, the results may be subject to bias. Where possible, countries should aim to undertake surveys using unlinked anonymous testing (UAT) and appropriate methods for sampling and calculation of sample size.

In countries where UAT can not be conducted without informed consent for diverse reasons, UAT should be performed with informed consent⁹.

Alternatively the survey could be conducted using Linked Anonymous Testing. In this case the blood specimen of the TB patient consents to having a HIV test and will be labelled with a code. Only the patient can get back the result presenting the specimen code².

Since, principally, the sample for this survey should be composed of the new diagnosed TB cases, the surveys taken over a short time periods of time, within 2 – 3 months to avoid the same individual being included in the study population more than once, provide a ‘point prevalence’ estimate. These surveys provide local programmes with a useful snapshot of the situation and may be undertaken as part of an initial assessment of the problem. In some situations it may take a longer time period to recruit large enough samples to give statistically meaningful results. In such circumstances, which are less than ideal, the estimate obtained is a ‘period prevalence’, measured over a stated time period.⁵

Ideally periodic (special) surveys should be repeated after a period of 2 to 3 years. There is little distinction between prevalence surveys, which use a consecutive sample of patients from specific health care settings and are undertaken in a regular and consistent way over time, and the methods of ‘sentinel surveillance’ outlined in the next section.

➤ **Sentinel surveillance**

Many countries undertake surveillance of HIV among tuberculosis patients using the sentinel surveillance methods outlined in the WHO guidance for HIV surveillance^{9 17} However, there are very few reports of the results from these methods in the published literature.¹⁸

The sentinel surveillance system was developed specifically to collect information on HIV prevalence, based on the measurement of HIV infection in pregnant women and other groups from whom blood is usually drawn for purposes other than HIV testing.⁹ The WHO guidance describes sentinel surveillance as the system by which ‘specific sites and population groups are selected; a predetermined number of persons are routinely tested, and testing is performed in a regular and consistent way’.^{9 17}

When conducted properly, sentinel surveillance should be fully integrated into the normal activities of health care facilities and should aim to not disrupt day-to-day activities at these sites.¹⁹ Indeed, the testing of tuberculosis patients for surveillance at “sentinel sites” should be undertaken as part of the routine work at these sites and similar procedures should be followed for each survey to ensure consistency.^{9 17} Like special surveillance, sentinel surveillance systems are based on unlinked anonymous methods, using blood specimens that have been collected for other purposes and stripped of all identifying markers.

Sentinel sites are generally selected “because they provide access to populations that are of particular interest” or because they are considered “representative of a larger population”.⁵ One of the problems with sentinel surveillance methods however, is determining how representative these sentinel sites are. In interpreting the results from sentinel methods, it is important to estimate firstly the extent to which the people tested are representative of the sentinel population from which they are drawn and secondly, the extent to which the sentinel population is representative of the general tuberculosis population.

If sentinel sites are not selected through probability-based sampling methods, the results can only be applied confidently to the selected populations and sites surveyed. However, when data from many different sentinel populations and sites are considered together they may provide a reasonable overview of the situation in a particular country.

➤ **Data from routine patient care**

In some countries, particularly those where HIV prevalence in the general population is high, HIV testing of tuberculosis patients for diagnostic purposes is becoming more routine. As treatment and care options for HIV infection increase, diagnostic testing of tuberculosis patients for HIV in an “opt out” fashion (i.e. routinely testing TB patients for HIV unless they decline to be tested) will be increasingly performed in such settings.

Data from the routine care of tuberculosis patients form the basis of information for surveillance in several countries. Although systems in most countries for recording this information are still crude, progress towards more systematic approaches of data collection lessens need for data from specific surveys or sentinel methods. In the Côte d’Ivoire for example, the National Tuberculosis Program (NTP) has developed and implemented a free, voluntary and confidential HIV counselling and testing programme for all newly diagnosed tuberculosis patients, which provides ongoing sero-surveillance data.²⁰ Uptake of testing is good, with 92% of those counselled consenting to testing, and whilst coverage of

the entire country is incomplete, “valuable epidemiological inferences” have been drawn from the data.

In a few countries, data on HIV status are collected on the tuberculosis register or on the tuberculosis notification form. In the United States for example, where electronic individual tuberculosis cases reporting has existed since 1993, the tuberculosis case report has been expanded to collect additional information on tuberculosis risk factors, including HIV status.²¹

Such problems have led the United States and other countries, such as the UK, which have sophisticated, computerised communicable disease surveillance systems, to resort to cross-matching of their tuberculosis and HIV/AIDS surveillance systems in order to obtain reliable information on the numbers of co-infected cases.^{21 22 23} Cross matching, which is undertaken using a combination of identifiers, such as date of birth and sex, aims to enhance the completeness of the two systems ‘leading to a more valid appraisal of the overlap of the two interrelated epidemics’.²² Although problems in terms of differences in the definition of an active tuberculosis case have been noted, these differences are not considered to substantially detract from a good match. Although some efforts to cross-match between systems have been conducted manually, due to the relatively small databases involved, in most circumstances electronic matching is used for logistic reasons using carefully selected parameters to ensure a sound match.

Data from routine patient care may be collected through a variety of different methods. The main features of these different methods and their strengths and weaknesses are outlined in Annex III. In general, the methods used to capture data from routine care will largely depend upon the existing tuberculosis and HIV/AIDS programmes in a country, as well as the available resources for surveillance activities. However, data from routine patient care should be based on the routine reporting of all individuals with tuberculosis who test positive for HIV antibodies for any reason and should include individuals tested for HIV for diagnostic reasons as well as clients of VCT services. One of the best systems for capturing this information is through a computerised tuberculosis notification system, which also captures information on HIV status. The capture of data through other methods, such as the use of VCT registers may provide extremely biased estimates of the prevalence of HIV among tuberculosis patients.

➤ **Special studies**

Data gathered from special studies can provide useful information to supplement general surveillance data from other sources. Such studies are usually focused on subgroups of the population, which limits their generalisability. An example of such a study is a pathology study undertaken in Zambia, which focused on children who had died from acute respiratory infections.²⁴ Post-mortem investigations of these children looked for the presence of HIV and tuberculosis infections, among others. Many similar studies have been undertaken in other African countries including the Côte d’Ivoire.²⁵

A few studies have been designed to study the relationship between HIV infection and the outcomes of tuberculosis treatment, such as the occurrence of drug resistance.^{10 26 27} Some of these studies have used cohort survey methods.

2.2 Surveillance methods in different HIV prevalence settings

The framework suggested in Boxes 1,2 and Figure 1 is intended to be flexible in relation to identifying the system that may be suitable for a particular country. Countries should be encouraged towards developing systems which best fit the needs and demands of their country and which build upon any strengths within their HIV/AIDS and tuberculosis programmes and their communicable disease surveillance systems. However, as detailed in the framework, the methods used to provide estimates of the number of people with tuberculosis who are co-infected with HIV should vary according to the underlying **HIV epidemic state**, as well as the type and quality of existing surveillance systems.

Figure 1: Flow table for selection of surveillance method:

CRITERIA	RECOMMENDED HIV SURVEILLANCE METHODS
I. Generalised level of the HIV epidemic state (HIV prevalence over 1% in pregnant women in urban areas).	Data from routine HIV testing of tuberculosis patients. And Periodic (special) or sentinel surveys to calibrate the data from routine HIV testing or in the administrative areas where HIV level unknown (routine data not yet available).
II. Concentrated epidemic of the HIV epidemic state (HIV prevalence consistently over 5% in at least one defined sub-population for e.g. IDUs, SWs. HIV prevalence below 1% in pregnant women in urban areas)	Data from routine HIV testing of TB patients Or Periodic (special) or sentinel surveys to calibrate the data from routine HIV testing or in the administrative areas where HIV level unknown (routine data not yet available).
III. Low level of the HIV epidemic state (HIV prevalence has not consistently exceeded 5% in any defined population for e.g. IDUs, SWs)	Periodic (special) or sentinel surveys

i. Surveillance in countries with a generalised HIV epidemic state

All countries with a generalised HIV epidemic state should aim to ensure that HIV testing is actively promoted and offered to all tuberculosis patients. The data available from these initiatives can form the basis of a reliable surveillance system where high coverage (>80%) of testing among tuberculosis patients is achieved.

The strength of data from such systems depends on the methods used to capture the data as well as the uptake of testing among tuberculosis patients. If the uptake is poor and data from this system are considered incomplete or unrepresentative, countries may wish to corroborate this data with surveillance information collected through the periodic (special) surveys (on a 2 – 3 yearly basis) or sentinel surveys undertaken, if possible.

In resource limited countries, where the HIV and tuberculosis burden in the general population may be high but where the institution of more systematic methods of surveillance is not possible, tailored periodic (special) or sentinel surveys should be undertaken. The results of these surveys, providing the estimates of HIV prevalence among TB patients should encourage the routine offer of the HIV counselling and testing for all TB patients.

In such settings, small special surveys of new adult tuberculosis cases should be undertaken using convenience methods of sampling (see section 3.4). In these settings, surveys may chose to focus on smear positive pulmonary cases for ease.

ii Surveillance in countries with a concentrated HIV epidemic state

In countries with a concentrated HIV epidemic state, HIV testing on and counselling to all TB patients should form the basis for the surveillance. If this is not yet in place, then periodic (special) surveys or sentinel surveys are suitable alternatives.

Sentinel surveillance methods are particularly useful for monitoring the trends in countries, which is important if the underlying HIV epidemic state is rapidly evolving. In such situations, sentinel methods can identify, at an early stage, areas where HIV testing and tuberculosis screening programmes directed towards the individual should be developed.

iii Surveillance in countries with a low level HIV epidemic state

Both periodic (special) and sentinel surveys can be used in countries with a low level state.

Special surveys have a specific role in all countries where the prevalence of HIV among tuberculosis patients has not been previously estimated. Surveys based around the methodology outlined in the 1994 WHO guidance, using representative sampling methods and appropriate sample sizes, can provide accurate estimates of the burden of HIV upon the tuberculosis situation and are an essential part of the initial assessment of the situation. This information may alert tuberculosis programmes of a potential HIV problem to enable appropriate changes to be made to programmes, which may include the institution of a more systematic surveillance system. Periodic (special) surveys should be repeated at 2-3 year intervals.

iv Additional surveillance methods

In addition to these systems, additional methods may also be considered useful in obtaining information on HIV prevalence among tuberculosis patients. Firstly, many studies are undertaken using tuberculosis patients for research and planning purposes, in which blood is often drawn. These studies provide an opportunity for the samples to be also used for unlinked anonymous HIV testing.⁵ Ideally the results from such testing should be correlated where possible with existing sentinel sites or prevalence survey sites so that the data sets can be compared. Secondly, in countries with well-established vital registration systems, death certificates may provide further information about deaths in patients who are co-infected, which can be used to supplement data gathered from other surveillance methods. Finally, some countries may also consider corroborating data obtained through standard methods with data collected from reviews of hospital data, lists of persons receiving medications and laboratories.³

3. Methodological issues

3.1 Indicators to be used for surveillance and information needed for the indicators.

The point or period prevalence of HIV infection among tuberculosis patients (the case definition, Box 3) is the main indicator to be measured by the surveillance methods described.

What should be measured: The proportion of registered tuberculosis patients who are HIV positive. The people responsible for the surveillance system at country level should define the numerator and denominator as well as the surveillance time scale according to the method used (Box 2).

The proportion of tuberculosis diagnosed among HIV positive people should be measured in countries where the surveillance system is based on the capture of data obtained from routine HIV/AIDS care (Annex III). However, the technical and managerial difficulties limit the use of to this system to industrial countries.

Before a surveillance protocol is formulated an elaborate situational analysis should be conducted. This may include:

- Analysis of current System for HIV and TB surveillance (is there a system for monitoring the prevalence of HIV infection among TB patients and/or TB among HIV positive people; if so, what is the system(s)?)
- Are Systems for linkage between HIV and TB reporting databases possible or available?
- What is the HIV infection prevalence in the general population and/or at risk population groups (IDUs, SWs, MSM, prisoners)?
- TB prevalence in the general population and/or at risk population groups (e.g. IDUs, prisoners) and is it reliable?
- What laboratory capacity is currently available for diagnosing the TB and HIV infections?
- To what extent are services available to those seeking HIV testing and counselling?
- To what extent are services available for TB patients seeking HIV testing and counselling?
- To what extent is there appropriately trained staff to conduct the surveillance?

3.2 Case definitions

The case definition for tuberculosis patients who are co-infected with HIV should integrate the two current standard reporting criteria for tuberculosis and HIV infections. The standard case definition for HIV infection has been outlined in the WHO Recommended Surveillance Standards.²⁸ The international case definitions for tuberculosis have been highlighted in the WHO Treatment of tuberculosis guidelines for National programmes, 2003.²⁹

Box 3: WHO recommended case definitions for tuberculosis and HIV infection.

HIV infection

- **Clinical description:** There is no clinical description; the diagnosis is based on laboratory criteria
- **Confirmed case:** A laboratory confirmed case
Laboratory criteria: 1) for surveillance purposes - HIV positive serology (Enzyme-Linked Immunosorbent Assay {ELISA}); confirmation by a second serological test (ELISA or simple /rapid assay based on a different antigen preparation and/or a different test principle) is necessary only in settings where estimated HIV prevalence is known to be < 10%. **2) for diagnostic purposes** – in low level countries (HIV prevalence has not consistently exceeded 5% in any defined population) a third test or confirmatory test (WB) may be necessary if the second ELISA is indeterminate.

Tuberculosis

- **A case of tuberculosis:** a patient in whom tuberculosis has been bacteriologically confirmed, or has been diagnosed by a clinician.
 Note: Any person given treatment for tuberculosis should be recorded.
- **A definite tuberculosis case:** a patient with culture positive for the *Mycobacterium tuberculosis* complex (in countries where culture is not

3.3 Population under surveillance

3.3.1 Eligibility criteria

Ideally all newly registered patients with tuberculosis, in accordance with the standard international case definition (see above), should be considered for surveillance. However, if periodic (special) surveys or sentinel methods are used and resources are limited, countries may choose to focus only on adult smear-positive pulmonary patients, as diagnosis in this group of patients is generally easier and quicker to confirm and the patient pathway likely to be less complex. Indeed, for these reasons most of the published surveys have included only smear positive cases and there is limited information on HIV infection rates among children with tuberculosis in the published literature.²⁹ Countries with scarce resources where the HIV epidemic state is either low or concentrated may also choose to only include patients between the ages of 15 and 59 years.

3.3.2 Exclusion criteria

Where possible relapse cases should be excluded from surveillance systems, because of the risk of surveying the same patient twice, unless they are identified as such and the results are analysed separately.² Should be reference 3 However, relapse cases may be included and need not be identified as such, if surveillance is based on survey methods and these surveys are undertaken over a short period of time, ideally less than 2 -3 months.

3.4 Sampling

Sampling as a statistical method to form a group of patients to be tested should be used only for periodic (special) or sentinel surveys. When HIV counselling and testing are routinely offered to all TB patients the sampling method is not necessary. In this case the size of the simple would be exhaustive.

3.4.1 Sample size

The sample size necessary to provide a reasonably accurate estimate of the prevalence should be calculated prior to undertaking any survey. This calculation should use standard techniques, based on the anticipated prevalence and using appropriate levels of precision. Annex V outlines the main steps that should be taken in calculating a sample size for surveys. The STATCALC feature in the Epi-Info software also provides a user-friendly sample size calculator for calculating setting specific sample sizes, which some may find easier to apply.

The minimum sample size for any survey should exceed 150 patients. However, surveys that are undertaken in resource-poor settings, with a high tuberculosis incidence, may use a sample size of 150 adult patients (expected prevalence of between 10 – 20% with a 5% error margin). In such circumstances, new tuberculosis cases should be selected on a consecutive basis, from one key institution involved in the treatment of tuberculosis patients, for the period of time necessary to reach the sample size.

3.4.2 Sampling procedure

Ideally representative sampling methods should be used wherever a sample of the population is used to estimate the prevalence in the wider population. The three main sampling methods used for selecting individuals for inclusion in the sample are described below:¹⁹

- **Simple random sampling:** Using this method, each tuberculosis patient in the population being sampled has an equal probability of selection in the sample. This method requires the use of random number tables or some other method to generate random numbers to identify the patients for inclusion in the sample.
- **Systematic sampling:** This consists of randomly selecting the initial patient who meets the eligibility criteria and then selecting every “nth” (e.g.5th) eligible patient thereafter until the predetermined sample size is reached.
- **Consecutive sampling:** This consists of sampling every patient that meets the eligibility criteria at a particular site until the required sample size is reached or until the survey period is over.

In practice, random or systematic sampling methods can be logistically complex and expensive, and most surveys use consecutive sampling methods at a few selected sites. Where random selection procedures are not feasible, and convenience based methods of sampling are used, patients should be tested under standardised conditions and if only a limited number of diagnostic centres are used, care should be taken in extrapolating the results to the wider population.

More reliable prevalence estimates for a population may be obtained if “cluster” sampling methods are used, whereby “clusters” of patients from different diagnostic centres in the country are randomly selected, using the “clusters” as

sampling units rather than single persons.² This methodology, which is described in the 1994 guidance, is simpler than using random selection methods for individual patients and consists of testing all eligible patients on a consecutive basis in each of the randomly selected clusters until the required cluster size is reached.

If sentinel surveillance methods are used, once the sample size has been calculated, sentinel sites should be selected. These sites should be chosen taking into consideration the geographical coverage of the site, the type of population (urban and rural) and the number of tuberculosis patients seen at the specific site. Other criteria that should be taken into consideration include the willingness of the staff at the site to participate and cooperate in surveillance and the access to a reliable laboratory that is able to perform HIV tests.

Experience from the field has indicated that where sentinel surveillance or surveys are carried out it is often advantageous to concentrate resources on a few selected sites where the required minimum of managerial and technical capacity exists to produce reliable data.³ The eventual goal should be to extend the number of sites to a broad distribution of geographical areas, depending upon the availability of staff and financial and logistical resources.

In surveys and sentinel surveillance, experience has also shown that it is more practical if staff are given instructions to begin and end surveillance activities on certain dates using fixed dates.¹⁹ The duration of the sampling will vary according to the clinic volume and the number of patients seen in the clinic who meet the eligibility criteria. Ideally the sampling duration should be about 8 weeks, and ideally should not exceed 12 weeks. Surveys should not be repeated more than once every year to allow sufficient time for data collation, analysis, interpretation and report writing and dissemination.¹⁹

3.5 Specimen selection

3.5.1 Advantages and disadvantages of different specimens

There are many different types of specimen that can be used in HIV biological surveillance: whole blood, plasma, serum, oral fluids, sputum and urine.^{Error!}
 Bookmark not defined. With the emergence of new HIV testing technologies, there have been a number of prevalence surveys undertaken in countries around the world using new technologies such as the Oraquick testing kit, which provides on the spot testing for blood, sputum and saliva. The choice of specimen for HIV testing depends on several factors, including the overall validity of the tests for each specimen, available resources and the logistics for undertaking surveillance activities within the country. The choice will also depend on the underlying contextual factors such as the country policy as well as the underlying HIV epidemic state.^{19 40}

The advantages and disadvantages of using the different types of specimen are clearly outlined in the guidelines on HIV testing technologies produced by the WHO and the Joint United Nations Programme on HIV/AIDS in 2001.^{Error!}
 Bookmark not defined. In addition to the disadvantages and advantages described in this guidance, there are two further issues that are particularly relevant to the issue of HIV testing for surveillance among tuberculosis patients.

Firstly, an advantage of using sputum specimens is that in most countries sputum is routinely collected as part of the preliminary diagnostic investigations for all tuberculosis patients. This may favour in some settings the testing of sputum specimens over blood samples, particularly if unlinked anonymous methods are followed.

However, a second issue is that where HIV testing is undertaken for diagnostic reasons (i.e. HIV test is linked to the patient), the current sensitivity and specificity of HIV tests favours the use of blood testing over sputum testing.³⁰ Even when unlinked methods are used, the current sensitivity and specificity of sputum testing methods (93,5%-97,1% sensitivity and 99,7%-100% specificity, respectively)³¹ are still not sufficiently high to avoid having a low positive predictive value (71,9%) in countries where the HIV prevalence levels are low (5%).

Given the Sensitivity and Specificity of testing sputa for HIV it is only worth doing if the prevalence in TB patients is 10% and above. On the other hand, testing blood samples has much better Sensitivity and Specificity. If this can be done it would always be worth doing.

Based on the current evidence - until the technology surrounding sputum testing for HIV improves, HIV surveillance methods should use serological tests for determining HIV status.

3.5.2 HIV testing approaches

A detailed overview of HIV testing technologies and strategies has been recently outlined in guidance produced by the WHO and the Joint United Nations Programme on HIV/AIDS.^{Error! Bookmark not defined.} Countries undertaking HIV surveillance of tuberculosis patients, irrespective of which surveillance methods are used, should ensure that this guidance is strictly adhered to.

3.5.3 Laboratory issues

Quality control measures for laboratories are a key consideration in relation to HIV testing and should be clearly defined prior to the start of any surveillance activity. A system of internal and external quality control of laboratory procedures should be established in advance of any surveillance activity and should be based around the latest WHO guidelines for HIV testing.^{Error! Bookmark not defined.}

Information on the collection of sputum samples from tuberculosis patients and the transport of these samples has been clearly summarised by the WHO in the guidelines for the surveillance of drug resistance in tuberculosis.³¹

3.6 Data management

3.6.1 General

It is important that staff involved in the management of data are fully instructed and motivated in the task of data collection, collation and analysis, and that they are provided with the necessary facilities and materials to enable them to undertake these activities.³¹ Experience has revealed that the quality of information obtained from surveillance systems is dependent on health workers' understanding of the purpose and procedures of data collection and on the provision of regular feedback.³

Ideally training workshops for staff should be conducted prior to the initiation of any surveillance activities. This training should always include a clear description of the rationale for the surveillance. Follow-up visits to each location involved in surveillance activities should be conducted to monitor progress and ensure that the appropriate procedures are being followed and that the data obtained are accurate.¹⁰

The general principles for data management and analysis outlined in the 1994 guidelines are still valid for surveillance systems based on periodic surveys and sentinel methods.²

3.6.2 Data elements

Data quality rather than quantity should be the main consideration when designing a prevalence study. Data management, which in many countries relies on a few individuals, should focus on the use of simple report forms that do not require multiple data transfers to reduce the likelihood of errors and incomplete reporting.³

Countries collecting HIV data from routine care of tuberculosis patients should aim to develop standardised reporting forms for the entry of data into the national surveillance system (see Annex I). Sentinel methods and periodic surveys should also aim to collect a similar degree of basic information. An example of a data collection form, which may be used for both these systems, is given in Annex II.

3.6.3 Confidentiality

A confidential system for the transfer of information is essential. The security and confidentiality policies and procedures in countries should be consistent with recognised standards for the security of HIV/AIDS surveillance data.³² In general the standards concerning the use of HIV/AIDS data are more stringent than those for tuberculosis data. These confidentiality guidelines emphasise the importance of minimising storage and retention of unnecessary or redundant paper or electronic reports. Names should also be removed from surveillance records when they no longer serve the public health purpose for which they were collected. Records should be located in a secured area and electronic data should be protected by coded passwords and computer encryption, especially during data transfer.

3.6.4 Quality

Lessons learnt from surveillance have shown that the basic capacity to undertake surveillance can be strengthened and sustained through systematic quality control of data collection procedures and laboratory testing.³ This may be in part achieved through strengthening the capacity of central managers and reference laboratories to perform regular supervision, quality control and feedback.

The importance of reliable and reproducible HIV testing over time is widely recognised an important component of any HIV surveillance activity.^{Error! Bookmark not defined.} The ongoing process of monitoring the laboratory system through internal and external quality assurance is essential. There are clear guidelines for the quality assurance of HIV testing which should be adhered to, irrespective of which surveillance methods are used.

Surveillance systems should also establish clear standards for the quality of data. Ideally, data quality should be improved through the use of computerised systems. Such systems may use built-in error checks and may be able to generate reports to highlight missing data.³³ However, in the absence of computerised systems, data quality can be addressed through periodic examination of each of the steps in the data collection, collation and analysis process.

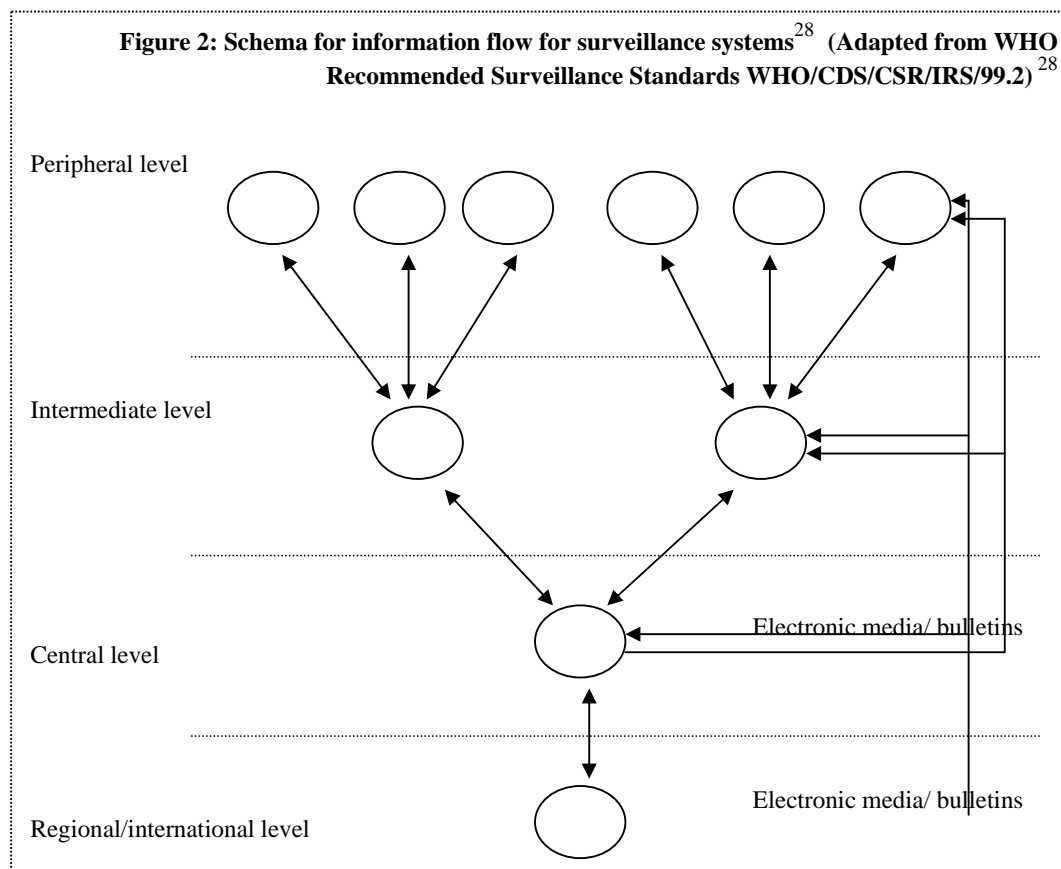
3.6.5 Analysis and dissemination

Whatever surveillance system is in operation, it is important that countries develop a plan for data analysis, with the frequency of data analysis and methods for the dissemination of the information established. This should promote regularity and consistency.⁴ The frequency of data analysis will depend on the type of surveillance activity undertaken. In the case of periodic surveys and sentinel surveillance methods, data should be analysed after completion of the survey period under the supervision of the survey coordinator. In the case of surveillance systems based on data from routine care, data analysis should be undertaken at least on a yearly basis and depending on resources countries may wish to undertake analysis on a more frequent basis e.g. quarterly.

The development of skills in data management and of simple packages for statistics and data presentation should be supported. Surveillance data should ideally be entered into a computer programme, such as Epi-Info, which is able to undertake basic data analysis. Simple methods of data analysis should be undertaken to determine the distribution and associations between the key variables.⁴ Data collected using sentinel surveillance methods should be analysed separately for each sentinel site.

Dissemination of surveillance data to the health centres, clinicians and laboratories who have reported the data can help to increase timely, valid and complete reporting.³³ It is increasingly recognized that feedback loops should be built into surveillance system.²⁸ This feedback may be through a variety of different media and in general when communicating surveillance data, the following types of reports should be considered:^{28;37}

- Annual reports
- Fact sheets
- Epi maps
- News letters
- Regular epidemiological bulletins with tables and graphs showing trends and progress towards targets
- Press releases



Efforts should be made to ensure that the data generated are utilised at all levels.¹⁹ At a national level, tuberculosis and HIV/AIDS programme managers should use the surveillance data to guide, target, evaluate and demonstrate the need for programmes of TB/HIV care and prevention.

3.7 Programme responsibility

The NTP in each country should take responsibility for ensuring that surveillance of HIV among tuberculosis patients is undertaken. However, the programme responsible for actually carrying out the surveillance activity may vary between countries and in some circumstances the NAP and NTP decide to take joint responsibility for conducting surveillance activities. However, whichever programme carries out the surveillance activities, the interaction between programmes, with respect to flow of information, should be clarified at a national level.

3.8 Resource considerations

The budget for surveillance will vary by country and is largely dependent upon how the surveillance activities fit into the existing infrastructure of the tuberculosis and HIV/AIDS programmes. It is important that the resource implications of proposed system are fully identified. Some of the likely direct and indirect costs are outlined in Box 4.

Box 4: Direct and indirect costs of surveillance

Direct

- Specimen collection equipment
- Transport of specimens
- Specimen testing kits
- Laboratory staff time
- Travel costs of staff
- Costs of data entry and analysis
- Dissemination of information (printing of reports, postage, presentations etc.)

Indirect

- Investment of staff time at all levels in activities ranging from specimen collection to the overall co-ordination of surveillance activities

3.9 Evaluation

Surveillance systems based on routine patient care should be evaluated on a regular basis within the framework of the WHO “Protocol for the Evaluation of Epidemiological Surveillance Systems”. (Box 5)³⁴

Following the evaluation, a plan should be developed for strengthening surveillance, which identifies priorities for action within the context of the national tuberculosis and HIV/AIDS programmes.

Box 5: Key points for evaluating surveillance systems^{33 34}

- The evaluation should begin with clarification of the overall aims and objectives of the surveillance system.
- All surveillance activities should be identified and categorised in terms of the system’s structure, process and outcome.
- The strengths and weaknesses of each component of the system should be assessed.
- Recommendations should be formulated for improvement of the performance of the system, identifying components that need to be strengthened, gaps, areas of duplication and activities that can be dropped.

4. Implementation

A first step in ensuring successful implementation of surveillance activities and in improving these activities is to gain advocacy for political support and funding at a national level. Effective surveillance is only possible if there is investment in the supporting infrastructure, in terms of manpower, laboratory support and logistics.³⁵ As a second step, it is important that a multi-disciplinary surveillance team is established, to agree on the objectives of the system and to clarify the roles and responsibilities of each of the team members.

Prior to setting up a surveillance system for monitoring HIV prevalence among tuberculosis patients, or expanding an existing one, a number of issues should be addressed in a strategic plan of action and developed into a protocol.¹⁹ This plan should be developed and agreed by all members of the surveillance team and should also include a budget for the proposed activities. This budget should cover all personnel and equipment requirements.

One of the main issues that should be considered by this team at an early stage is a review of the need for surveillance. An assessment of existing surveillance activities should also be undertaken and the current epidemiological situation with respect to HIV and tuberculosis should be reviewed. This background preparation is essential and should aid teams in identifying which surveillance systems are appropriate to their needs and which methods should be used. Whichever type of surveillance system is selected there should be adequate attention paid to training and supervision in all areas and to quality assurance procedures for specimen processing and data collection and analysis.

A detailed step-by-step guide to setting up an HIV sentinel surveillance system has been developed by the World Health Organization Regional Office for Africa in collaboration with the University of California and the United States Center for Disease Control and Prevention.¹⁹ This guide may be easily adapted for countries undertaking periodic (special) HIV surveys among tuberculosis patients and some of the general issues identified in this guide are relevant to any HIV surveillance system.

ANNEX I: Minimum data requirements from tuberculosis clinic settings where patients are routinely tested for HIV[†]

Minimum data required for annual reporting from tuberculosis clinic settings to national level are:

Clinic setting:.....

District/region in which clinic based:

Patient loads:

- Total number of tuberculosis patients per year.....
- Total number of tuberculosis patients tested for HIV per year.....

Age: Number of tuberculosis cases in the following age groups:

[0 – 4] [5 - 14] [15 - 24] [25 - 34] [35 - 44] [45+]

Sex: Number of females: Number of males:

Clinical

Presentation: Number of pulmonary cases:

Number of extra-pulmonary cases:

HIV test result:

Adult male (≥15)			Adult female (≥15)			Child (0-14) male			Child (0-14) female		
n	N	%	n	N	%	n	N	%	n	N	%

Adapted from *Third generation HIV/AIDS surveillance guidelines*. WHO Caribbean, 2002.

ANNEX II: Sample data collection form for use in HIV prevalence surveys or sentinel surveillance among tuberculosis patients

<u>Demographic data form*</u>	
Study site:
Date of patient visit:	___ / ___ / ____ (dd/mm/yyyy)
Patient ID number:
Age:	_____ (years)
Sex:	Male: <input type="checkbox"/> Female: <input type="checkbox"/>
Clinical Presentation:	
	Pulmonary: <input type="checkbox"/> Extra-pulmonary: <input type="checkbox"/>
If pulmonary:	Sputum smear positive: <input type="checkbox"/> Sputum smear negative: <input type="checkbox"/>
(If relapse cases are included)	
	New: <input type="checkbox"/> Relapse: <input type="checkbox"/>
.....	
<u>Laboratory form*</u>	
Patient ID number:
Results test 1:	Positive: <input type="checkbox"/> Negative: <input type="checkbox"/> Doubtful: <input type="checkbox"/> Not done: <input type="checkbox"/>
Results test 2: (if undertaken)	Positive: <input type="checkbox"/> Negative: <input type="checkbox"/> Doubtful: <input type="checkbox"/> Not done: <input type="checkbox"/>

Adapted from World Health Organization. *Guidelines for HIV surveillance among tuberculosis patients*. World Health Organization; 1994. WHO document WHO/TB/94.180.

**There are two main options for collating the demographic and laboratory data. One option is that the demographic details and laboratory details are recorded on separate forms and data from these forms are entered onto a computer and then matched centrally using the unique identifying number and merged into a single record. The other option is that the data are recorded on the same form. This method is not ideal if unlinked anonymous methods are used, as an individual's identify and the associated test results can be more easily disclosed.*

ANNEX III: Options for the capture of data obtained from routine care on HIV prevalence among tuberculosis patients			
Option	Description	Advantages	Disadvantages
1. Tuberculosis register	The tuberculosis register is a well-established system that works well in most countries as an integral part of DOTS. The register could be altered to incorporate extra fields recording whether or not an HIV test had been done, and the results of any test undertaken.	<ul style="list-style-type: none"> • Well established system that works well in most countries. • Simple system. 	<ul style="list-style-type: none"> • Confidentiality issues if HIV status entered into a register that includes the patient's name. • May be hard to change an already established system. • Replacement of registers could prove costly and may take time.
2. Tuberculosis notification form	System similar to the register where detailed information on each patient is collected and collated on a national level through a formal, mandatory notification system. Notification form could be adjusted to include information on HIV status. System computerised where possible to enable cross matching of data and revision of information. Computerisation may take place at level of data input or nationally at level of data collation and analysis.	<ul style="list-style-type: none"> • Detailed information collected which could be used for variety purposes. • Data could be corroborated with HIV surveillance systems through cross matching key variables. 	<ul style="list-style-type: none"> • Confidentiality issues if HIV status entered into a system which includes the patients name • If the notification is based on a paper system, the validity of the system depends on a patient having the test result at the time of the notification. • Development of a computerised system, which would enable data to be linked, requires considerable investment.
3. Specific register for tuberculosis patients diagnosed with HIV	New register set up in the tuberculosis clinic setting for all patients diagnosed with HIV.	<ul style="list-style-type: none"> • May provide reliable prevalence estimates if most patients with tuberculosis tested for HIV. • Easily identifiable cohort of patients who can be easily identified for ARVs and treatments against opportunistic infections. 	<ul style="list-style-type: none"> • Identifying the denominator may be difficult as patients with tuberculosis who are not tested for HIV for whatever reason not included on system. • Duplication of registers, which may result in it not being properly filled in by hard-pressed staff.

4. Cotrimoxazole register	Paper based cotrimoxazole register set up alongside tuberculosis register in tuberculosis clinic setting for all tuberculosis diagnosed with HIV. Primary purpose of register is to keep record of tuberculosis patients who are eligible for cotrimoxazole.	<ul style="list-style-type: none"> • If most tuberculosis patients are referred for testing the system may provide reliable estimates of HIV prevalence in these patients. • Simple system that requires minimal infrastructure. 	<ul style="list-style-type: none"> • Tuberculosis patients who are not tested will not be captured by system. • Problem of register ‘fatigue’ and increased workload. • Requires close collaboration between VCT staff and tuberculosis clinic staff.
5. IPT register	IPT register set up alongside VCT register for the main purpose of identifying patients who screen negative for tuberculosis and who are eligible for IPT. Register may contain details of all those who are screened for tuberculosis.	<ul style="list-style-type: none"> • System may work well if most patients who attend for VCT are screened for tuberculosis. • Simple system. • Low costs. 	<ul style="list-style-type: none"> • Will not capture data on tuberculosis patients who do not attend for VCT. • Requires close collaboration between VCT and tuberculosis clinic staff. • Problems of obtaining unbiased sample if not all patients who test positive for HIV accept offer of screening. • Tuberculosis status may be determined some time after the patient is tested for HIV, which may prove difficult in capturing data. • Problems of register ‘fatigue’ and increased workload.
6. VCT register	VCT register for everyone who turns up for HIV testing through VCT settings. Information on tuberculosis status routinely collected.	<ul style="list-style-type: none"> • In most countries this is an emerging system which offers the opportunity of developing a system as it is being set up to capture this data from the start. • Simple system. • Low costs. 	<ul style="list-style-type: none"> • Tuberculosis status may be determined some time after the patient is tested for HIV, which may prove difficult in capturing data. • Fails to capture patients who are tested for HIV outside the VCT system. • Problem of obtaining data from private VCT centres. • Relies on the commitment of a system that is primarily set up for benefit of HIV/AIDS programme. • Requires close collaboration between VCT and tuberculosis clinic staff.

7. Separate VCT register for patients with tuberculosis	Separate register set up alongside standard VCT register for known tuberculosis patients.	<ul style="list-style-type: none"> • System may work well when all tuberculosis patients are referred for VCT. • Simple system. • Low costs. 	<ul style="list-style-type: none"> • Problems of register ‘fatigue’ and increased workload. • Problem of capturing data on people are initially tuberculosis free when they test positive for HIV through VCT but who subsequently develop tuberculosis. • Fails to capture patients who are tested for HIV outside the VCT system. • Requires close collaboration between VCT staff and tuberculosis clinic staff.
8. HIV/AIDS case notification form	Notification form where detailed information on each patient is collected and collated on a national level through a formal and mandatory system of notification. Notification form could be adjusted to include information on whether a patient has tuberculosis. If system is computerised this would enable cross matching of data and revision of information.	<ul style="list-style-type: none"> • Captures all HIV positive individuals, including those outside the VCT system. 	<ul style="list-style-type: none"> • Tuberculosis status may be determined some time after the patient is tested for HIV, which may prove difficult to capture. • Additional workload for those maintaining register who may fail to see benefit of capturing the data. • Relies on the commitment of a system that is primarily set up for benefit of HIV/AIDS programme.
9. Cross-matching of HIV and tuberculosis notification systems	Where computerised surveillance systems for HIV and tuberculosis patients exists, linkage of data through key variables can identify numbers of patients who are co-infected.	<ul style="list-style-type: none"> • Avoids need of setting up new system. • Can be done relatively quickly and simply if appropriate resources available. 	<ul style="list-style-type: none"> • Complex. • Requires sophisticated computer database packages. • Data analysts may have to be trained. • Data from two systems may require considerable ‘cleaning’ prior to the matching process. • Unreliable data in two systems may result in problems when matching.

ANNEX IV: 1994 WHO Guidelines for HIV surveillance among tuberculosis patients

Corporate authors: WHO Tuberculosis Programme.
International Union against Tuberculosis and Lung Disease

Publication info: Geneva: World Health Organization, 1994.

Electronic access: http://whqlibdoc.who.int/hq/1994/WHO_TB_94.180.pdf

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ANNEX V: Sample size determination

The following table may be used as a quick guide to estimate the minimal sample size required for sero-prevalence surveys according to the expected sero-prevalence and the margin of sampling error tolerated. The margin of sampling error represents the absolute precision, for example, if the true prevalence was 20% and we took a sample size of 246, we could be 95% certain that the prevalence rate in the sample would be between 15% and 25% ($20 \pm 5\%$).

Minimum sample size for a prevalence survey according to the expected prevalence rate								
Margin of sampling error tolerated	Maximum expected prevalence rate (%)							
	1%	2.5%	5%	10%	20%	40%	40%	50%
0.5%	1522	3746	7300	13830	-	-	-	-
1%	381	937	1825	3458	6147	8068	9220	9604
2%	-	235	457	865	1537	2017	2305	2401
5%	-	-	73*	139*	246	323	369	385

* Ideally the minimum sample size for any survey should always exceed 150 patients.

Adapted from: Caribbean Epidemiology Centre (CAREC) Pan American Health Organization (PAHO)/ World Health Organization. Guidelines for the Upgrading of HIV/AIDS/STI Surveillance in the Caribbean: The Third Generation Surveillance of HIV/AIDS/STI; Linking HIV, AIDS and STI Case-Reporting; Behavioural and Care Surveillance. Caribbean Epidemiology Centre, 2002.

To calculate sample size for values not shown in the table, the following formula can be used:

$$N = PQ/(E/ Z^*)^2$$

N = the minimum sample size required

P = the maximum expected prevalence rate or anticipated population proportion

Q = 100 - P

E = the margin of sampling error tolerated (n.b. in general a sampling error of greater than 5% is not acceptable)

Z = the centile of the standard normal distribution

For example: If a country is undertaking an HIV prevalence survey among TB patients where the anticipated HIV prevalence rate among these patients (P) is 20%, Q will be 100 – 20 = 80; and if the margin of error chosen is 5; then the minimum sample size is = $80 \times 20 / (5 / 1.96)^2 = 246$.

If at the end of this survey, an HIV prevalence rate of 18.5% is observed, the real prevalence among the TB patients is between 14% (18.5% - 5%) and 24 (18.5% + 5%) within a 95% confidence interval.

* If the level of confidence chosen is 95%, $Z=1,96$, if another level of confidence, e.g. 99%, $Z=2,58$.

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