Guide to Measure the Prevalence of Active TB Disease Among Health Care Workers

Contents

Foreword

It's a well known fact that health care workers (HCWs) are at high risk of contracting tuberculosis (TB) in all settings in which they find themselves. However, it is both evident and unfortunate that there is very little done by health systems, health managers, administrators and HCWs themselves to reduce this risk.

In recent times reported outbreaks of TB among HCWs have raised concerns about the relevance of TB infection control (IC) interventions in health care settings and facilities. To this end there is no reason why the prevalence of TB among HCWs should not be monitored as part of TB IC interventions.

In light of this, I recommend this guide to fellow National Tuberculosis Program (NTP) managers as part of global efforts to preserve human resources in global TB control. This guide is the product of years of painstaking research, as well as debates and discussions about monitoring the prevalence of TB among HCWs. The burden of TB among HCWs reflects in a subtle way, the quality of the TB program in each country. It is therefore important that each NTP monitors the prevalence of TB among HCWs contributing to the global fight against TB.

This guide is directed at everyone who is responsible for HCWs at all levels and in all places, including NTP managers, National AIDS Control Program managers, those responsible for Infection Prevention and Control Programs, those responsible for Occupational Health and Safety, labor inspectors, epidemiologists, TB Focal Persons and frontline HCWs themselves. Measuring the TB prevalence among HCWs provides the necessary information to guide NTPs in the development of interventions to protect HCWs and helps to improve programming, enabling the tailoring of NTP interventions to ensure the adequate protection of all HCWs.

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Abbreviations

ACHE	American College of Healthcare Executives
APIC	Association of Practitioners in Infection Control
ATS	American Thoracic Society
BCG	Bacillus Calmette-Guérin
CHW	Community Health Worker
CXR	Chest x-ray
EPTB	Extra-pulmonary TB
EQA	External Quality Assurance
ERS	European Respiratory Society
HCW	Healthcare Worker
IADH	International Academy for Design and Health
IAS	International AIDS Society
ICN	International Council of Nurses
IDSA	Infectious Disease Society of America
IDU	Intravenous/Injection Drug Users
IGRA	Interferon-gamma release assay
IFIC	International Federation of Infection Control
IFRC	International Federation of Red Cross and Red Crescent Societies
IHF	International Hospital Federation
ILO	International Labour Organization
IPCAN	Infection Prevention and Control Africa Network
IPT	Isoniazid Preventive Therapy
JATA	Japan Anti-Tuberculosis Association
KSA	Knowledge, Skills and Attitudes
LTBI	Latent tuberculosis infection
MDR-TB	Multi-Drug Resistant TB
M&E	Monitoring and Evaluation
MGIT	Mycobacteria growth indicator tube
MoH	Ministry of Health
MSH	Management Sciences for Health
MSM	Men who have sex with men
MTB	Mycobacterium tuberculosis
NAAT	Nucleic acid amplification test
NACP	National AIDS Control Program
NTM	Nontuberculous mycobacteria
NTP	National TB Control Program
PEPFAR	Presidents Emergency Plan for AIDS Relief
PIH	Partners in Health
PPS	Probability proportional to size
PSU	Primary sampling units
RIF	Rifampicin
SAM	Service Availability Mapping
TB	Tuberculosis
TB-IC	Tuberculosis Infection Control
UNAIDS	United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
URC	University Research Council
WHO	World Health Organization
WMA	World Medical Association

Glossary

(Terms as used in this document)

Guideline(s)	A WHO guideline is any document, whatever its title, that contains WHO recommendations about health interventions, whether they be clinical, public health or policy interventions.
Healthcare	Services provided to individuals or communities by agents of the health services or professions to promote, maintain, monitor, or restore health. Healthcare is not limited to medical care, which implies therapeutic action by or under the supervision of a physician.
Healthcare facility	Any structure used to deliver healthcare (see definition of Healthcare above).
Healthcare worker (HCW)	All people engaged in actions whose primary intent is to enhance health. For the scope of this guide, only paid HCWs are taken into account and workers and cleaners working in a health facility should also be included.
High-burden Country	One of the 22 countries which together account for approximately 80% of all new TB cases arising each year. The WHO also identifies another 27 high MDR-TB burden countries that concentrate more than 85% of MDR-TB cases emerging globally.
Incidence	The number of new and recurrent cases of TB (all forms) occurring in a given year per 100,000 population. Incidence should ideally have person-time in the denominator. Recurrent cases are those successfully treated for TB in the past and who develop a new episode of TB as a result of true relapse or re-infection.
Indicator	A summary statistic that informs about the status or progress of a process.
Infection Control (IC)	A combination of measures aimed at minimizing the risk of TB transmission within populations.
Monitoring	The intermittent performance and analysis of routine measurements, aimed at detecting changes in the environment or health status of populations.
Multidrug-Resistant tuberculosis (MDR-TB)	Strains of Mycobacterium tuberculosis complex showing in-vitro resistance to at least isoniazid and rifampicin.
National TB Program (NTP)	The official authority responsible for control of TB in the country.
Notification rate	Number of all TB cases registered during a specified period (usually one year) and notified to the national health authorities per 100,000 population.

Notification rate of new smear positive TB cases	Number of previously untreated sputum smear positive TB patients registered during a specified period (usually one year) and notified to the national health authorities per 100,000 population.
Occupational disease	An illness associated with a particular occupation or industry.
Prevalence	Number of TB cases (all forms) per 100,000 population at a given point in time.
Risk groups	A group of individuals in the population with increased likelihood of infection with TB. A subset of this group may be at increased risk of drug-resistant TB strains, such as contacts of MDR-TB patients. This term is to be distinguished from other groups who are more likely to develop active TB or to suffer adverse outcomes of TB disease.
Screening	The presumptive identification of unrecognized disease or defect by the application of tests, examinations or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic.
Surveillance	Systematic ongoing collection, collation and analysis of data and the timely dissemination of information to those who need to know, so that action can be taken
Tuberculosis (TB)	Active disease attributable to Mycobacterium tuberculosis complex, typically affecting the lungs and airways in which case it is directly transmissible through droplet. For the scope of this document, this term does not include latent TB infection.
Xpert MTB/RIF	A test that employs automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance.

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Chapter 1:   Rationale, Indications and Scope

1.1 Rationale

It has been proven that in many settings the burden of tuberculosis (TB) is higher among healthcare workers (HCWs) than among the general population [Menzies 2007, Joshi 2006, Baussano 2011]. It is very important to prevent the transmission of TB in facilities, thereby preventing TB among HCWs. The burden of TB disease among HCWs should be monitored regularly, therefore a guide to monitor active TB disease incidence among HCWs through routine surveillance has been developed by the TB CARE consortium (http://tbcare.net) (Tool 1).

This alone may not be enough. Countries may want to measure additional estimates of TB burden among HCWs. These may include estimates of TB infection, disease and mortality. This guide focuses on TB disease (See paragraph 1.3 on Scope).

Routine surveillance of active TB disease among HCWs leads to an estimate of TB incidence. Routine surveillance could be supplemented by specific surveys of the prevalence of active TB among HCWs. This would be similar to routine TB notification which is supplemented by prevalence surveys [WHO 2011]. This guide describes why, when and how to do a prevalence survey of TB disease among HCWs by active case finding (Tool 2), and what the limitations of such prevalence surveys are. Table 1 outlines the differences between Tool 1 and Tool 2.

Table 1. Differences between Tool 1 and Tool 2

	Tool 1	Tool 2
Scope	Surveillance, M&E	Survey, research
Case finding	Passive and/or active	Active
Data collected by	NTP, Facilities, other Ministries (than Health)	Research team
How often	Regular, continuous	Once, or every 3-5 years; for research purposes
Outcome	Incidence of active TB	Prevalence of active TB, characteristics of undetected cases, risk or predictive factors of being prevalent TB cases
Variables to collect	Few	Many
Facilities to cover*	All	Sample
Selection of participants	All people in health care sector (see chapter 3)	Random selection of those

*It is also possible to only do surveillance in selected facilities such as (TB) hospitals, MDR wards and laboratories.

This guide focuses on TB disease rather than TB infection (see paragraph 1.3 scope). Many studies have been done on measuring the prevalence and incidence of latent TB infection (LTBI) among HCWs [Joshi, Baussano]. Several studies in middle (50-100/100,000) and high (> 100/100,000) incidence countries measured the incidence of TB disease among HCWs by retrospective cohorts [Joshi 2006, Baussano 2011], but only a few in prospective cohorts [Jiamrajarasangi Thailand 2005, Rao India 2004] and they used mainly passive case finding methods. Only three published studies reported measuring the effect of TB infection control (TB-IC) measures on TB burden among HCWs [Harries 2002, Yanai 2003, Roth 2005] and they found a decrease in LTBI but not in TB disease.

Although guidelines for population-based TB disease prevalence surveys exist (WHO Tuberculosis Prevalence Surveys: a handbook), these cannot readily be used for measuring the prevalence of TB disease among HCWs, specific adaptations are needed. This guide is intended to provide that guidance for the specific setting of HCWs. This guide should be used in combination with the WHO TB Prevalence Surveys: A Handbook [WHO 2011]. The concepts and methods described in the WHO handbook are not duplicated in this guide.

1.2 Indications

Data from prevalence surveys of TB among HCWs can lead to country- or health facility- specific policy evaluation, policy revision and action. A country may decide to do a prevalence survey on TB disease among HCWs in the following situations:

1. There is no information available on TB among HCWs and no routine surveillance in place, and it is not possible to implement a surveillance system in the short term. There is a need for a baseline survey for advocacy to start routine screening of TB among HCWs
2. Routine surveillance of active TB disease among HCWs is in place, but it is suspected that this system may not be functioning properly. Although HCWs may have better access to TB diagnosis and treatment than the general population, they are less likely to take part in routine TB screening systems because of stigma and more likely to seek care from providers who do not report to the NTP. Therefore NTPs may have incomplete data on TB among HCWs:

   a. A prevalence survey may highlight where cases have been missed by routine screening and/ or challenges HCWs face accessing health facilities or the under-utilization of health facilities by HCWs
   b. Since prevalence surveys often have add-on in-depth interviews, they may also identify issues surrounding stigma and its possible causes

   Such information can help to improve active case finding of TB among HCWs, lead to earlier case detection, improve HCW access to the appropriate facilities for diagnosis, treatment and support services, as well as combating stigma. The information can also be used to fine tune the recording and reporting of TB cases among HCWs and better surveillance of the cadre. Gaps in the system may be assessed in part, by a smaller study, e.g. by interviewing HCWs on whether or not they participate in HCWs screening and why, and whether they had TB in the past.
3. To identify areas within health facilities which pose more risk for nosocomial transmission to HCWs, for example emergency rooms, outpatient departments, HIV counseling rooms, TB culture laboratories, X-ray departments, etc. The information can be used to focus infection control (IC) efforts on these higher risk areas. It may also be possible that TB disease risk does not differ between departments; hence TB-IC should be scaled-up across the facility. It may help to improve workplace policies and practices on TB control, improve IC measures and minimize the risk of nosocomial TB transmission among HCW
4. When implementing TB-IC measures and wishing to evaluate their impact in a more scientific way, there may be a need for a baseline and repeat survey. The repeat survey should be at least 3-5 years after the implementation of TB-IC measures; in order for a possible effect on transmission also affecting disease (see Chapter 5). If two cross-sectional prevalence surveys are done some years apart and there is strong monitoring in between, this effectively becomes a cohort study which allows the incidence of new active TB since the baseline survey, to be measured [see Joshi R et al. ERJ 2011]
5. If a nationwide prevalence survey among the general population has been carried out, the prevalence of TB in HCWs can be compared to the prevalence in the general population.

When possible, surveys of TB among HCWs should be combined with those for another disease, such as HIV, Hepatitis B or non-communicable diseases. The prevalence of other diseases is usually higher, so for those diseases a lower sample size is needed. The relatively low prevalence of TB will determine the sample size. It is recommended in high HIV settings, to combine a prevalence survey for TB with a prevalence survey on HIV.

1.3 Scope

This guide is meant for both middle and high incidence countries (> 50/100,000), as the burden of TB among HCWs is usually too low to do a prevalence survey in low incidence countries. A very large sample size (> 100,000) would be needed for a precise estimate to be determined.

This guide focuses on TB disease rather than TB infection, because:
a. In most high incidence countries more than half the adults have been infected with Mycobacterium tuberculosis (MTB). Therefore the prevalence of infection among HCWs is unlikely to differ from that in the general population, although useful studies have been done among medical and nursing students
b. Surveys of infection have been done repeatedly, and therefore many example protocols are available [Baussano 2011, Joshi 2006]. Surveys of infection have also been done using IGRAs [Zwerling 2011]
c. The difficulty in measuring infection in High TB burden setting due to high BCG coverage, the influence of MOTT and the limited predictive values of new tests such as IGRA [Rangaka 2011].

In this guide, reference is repeatedly made to the methodology in the WHO TB Prevalence Surveys: A Handbook [WHO 2011]. The TB CARE framework on TB-IC already includes some examples of collecting data on TB among HCWs, but does not give enough detail for a full prevalence survey [TB CARE I 2011].

A large scale TB prevalence survey among HCWs has both the aspects of regular field settings and of research settings. Both are discussed in the WHO TB prevalence survey handbook and this guide. The combination of regular field settings and research has for example an influence on logistics, access to laboratory services and the follow up of detected (possible) TB suspects.

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Chapter 2: Objectives and Limitations

2.1 Objectives

The objectives of a prevalence survey among HCWs can be the following:

1. To estimate the prevalence of TB disease among HCWs: This may include the point prevalence (The proportion of HCWs which have TB disease on the day of the survey) and/or the lifetime prevalence (The proportion of HCWs which have ever had TB disease). The latter is easier to collect but will only give a proxy of the TB prevalence. Sub-objectives may be:
   a. To validate routine surveillance systems, and to understand the strengths and weaknesses in the system. Routine surveillance of TB among HCWs may underestimate actual disease rates and usually collects a limited number of variables. In a prevalence survey we can assess what proportion of cases have previously been notified by the routine system.
   b. To analyze the economic and psychological effects of TB among HCWs and the possible barriers to care for TB cases among HCWs. This is possible when adding to the prevalence survey interviews with HCWs diagnosed with TB. A prevalence survey may be used to gain a better understanding of why HCWs with TB are not being diagnosed and/or notified to NTPs. It may also assist in the design of strategies to achieve earlier and more complete detection of TB cases.
   c. To collect more information in order to adjust for confounding factors in estimating disease rates by risk factors (e.g. on exposure level, such as cadre and type of work, previous TB etc). For example, a survey can identify in which type of facilities or professions, cases among HCWs have been missed by the routine surveillance system. Repeat surveys (with an interval of three to five years) allow for the measurement of trends in the burden of TB among HCWs.
   d. In a country where HCW screening is not applied, and surveillance of the burden of TB among HCWs does not take place, a prevalence survey can be useful in advocating for the provision of better care for HCWs, and the start-up of a routine screening program. There may also be cheaper options for use in advocacy, such as using famous people who have or have had TB.

2. To assess the impact of TB-IC measures: A prevalence survey before and after the implementation of TB-IC measures gives complementary information to routine surveillance of TB in HCWs. Cross-sectional comparisons of routine surveillance of incidence of TB among HCWs (Tool 1), and a routine assessment of the implementation of TB-IC measures, can give an estimate of a possible association between TB incidence and TB-IC. These comparisons can be improved by using prevalence surveys, since more variables can be collected and data is more reliable. These variables may assist in assessing the plausibility that any measured impact on TB disease burden is due to TB-IC measures. Prevalence surveys can be used by the NTP and occupational health services to evaluate IC interventions and develop policies. When repeat surveys are done, with a question on whether the HCW was diagnosed with TB in between the surveys, the TB incidence can be estimated [Joshi 2011].

This guide focuses on baseline prevalence surveys (Objective 1); and gives some references for impact surveys (Objective 2), as for the latter a more extensive research protocol is needed.

2.2 Limitations of Prevalence Surveys Among HCWs

Prevalence surveys are part of research methodology. Research cannot replace routine surveillance of HCWs. Routine surveillance should be a first priority of countries considering assessing the burden of TB among HCWs.

Limitations can be split between those for incidental prevalence surveys (objective 1) and those of impact surveys (objective 2). For each limitation, possible solutions are given.

a.   Incidental Prevalence Surveys

1. Since routine surveillance estimates TB incidence, while a prevalence survey measures prevalence, the 2 estimates are not necessarily comparable. Prevalence is usually defined as incidence multiplied duration of disease. Since the duration of diagnosable disease (e.g. being sputum positive or culture positive) is highly variable, this calculation cannot easily be made [see footnote page 8 WHO TB prevalence surveys: a handbook]. Patterns of cases can be compared, such as the proportion of TB cases in different settings, e.g. in large hospitals versus smaller health care facilities and/or patterns in the differences between healthcare cadres.

2. Large sample sizes are needed for accurate estimates of prevalence, unless the sampling fraction is high or all the HCWs in a country are included, therefore such studies may only be possible in countries with high TB incidence. In smaller countries all HCWs may need to be included. Smaller sample sizes limit the possibility to adjust the prevalence for different settings and risk levels and confounders for these risk levels (such as age) at the same time. Sample sizes may be smaller when only asking about lifetime prevalence of TB disease rather than point prevalence; but limits the options of associating prevalence with current work locations. Further, it is possible to choose a limited geographical survey in selected high-risk facilities/areas; obviously this would not give a nationwide estimate, but only an estimate for the selected area/facilities.

3. When the intention is to compare the TB prevalence in the general population with that of HCWs, the following aspects should be taken into account:
(a) surveys among general population are rare (although some are currently being done)
(b) age range may differ
(c) methodology of case finding may differ
(d) exposure and risk factor profiles differ (for example a 'healthy worker effect' versus the higher exposure of HCWs to TB). Adjustments can be made in the calculations in order to compare the two.

4. Prevalence surveys may detect cases earlier due to active case finding. It is therefore likely that a small proportion of cases detected were not yet known to the health system. It is not known what proportion is acceptable, but a high proportion of previously undetected cases indicates gaps in the routine surveillance system. Since HCWs may have better access to TB diagnosis than the general population; it is likely that the proportion of undetected cases is lower than that in the general population. On the other hand, since HCWs may more often be diagnosed by the private sector and the private sector often under-notifies the NTP, HCWs with diagnosed TB may be notified less often than TB cases among the general population.

5. There are limited screening methods available for extra-pulmonary TB (EPTB), although a high proportion of TB cases may be extra-pulmonary TB, especially among HIV infected HCWs. Among EPTB, the most common presentations are TB lymphadenitis and pleuritis. With the current screening methods most cases detected will be pulmonary TB and these are usually the most infectious. When asking about lifetime prevalence, EPTB should be included. Creative methods should be developed to screen for EPTB.

b.   Impact Surveys

1. Measuring the impact of TB-IC measures on TB disease may take a long time as although TB-IC measures may affect the transmission of TB infection, the breakdown of infection to TB disease is dependent on many factors, but mainly the immune system of the person infected. Latent TB infection may exist for many years before the development of the disease. HCWs which develop TB may have been infected long before the IC measures were implemented. It is therefore recommended to have a 3-5 year gap between the first and second surveys. Measuring the impact on the annual risk of TB infection should be considered, but is beyond the scope of this guide.
2. Similarly, a reduction of TB prevalence among HCWs may not be caused by TB-IC measures in the facility. Inferences on causality are limited. DNA fingerprinting of MTB strains of both patients and HCWs may assist in proving causality, but it may be difficult to implement in settings with a high burden of patients. This depends on DNA fingerprint strain variability in the area. Strains common in hospitalized patients may also be common in the community.
3. For several reasons, prevalence surveys themselves have an impact on the occurrence of TB thereafter. Sample size calculations can be adapted in accommodate these factors.

   a. Cases which would normally be diagnosed later (as incident cases), are detected earlier due to the prevalence survey, so in the first 6-12 months after a survey the incidence may decrease.
   b. TB cases detected during a survey should be treated, and will therefore no longer be infectious. This leads to the prevention of further transmission and may reduce prevalence in a second survey, although most transmissions will be due to undiagnosed visiting patients rather than HCWs with TB.
   c. Possibly some people with chest x-ray (CXR) abnormalities such as fibrotic lesions but no active TB should be treated, depending on the policy of the country. This may lead to less TB cases in future surveys.
   d. Improved awareness may be the positive effect of a survey and this may increase passive case finding.

2.3 Prerequisites for a Successful Survey

The pre-requisites for a successful prevalence survey can be found in the WHO TB prevalence surveys: a handbook (chapter 1.4). It should be noted that experienced researchers should be involved in carrying out large scale surveys. Additionally, it is important to involve departments/ministries that deal with health care facilities and occupational health and also to involve HCW professional associations, such as nurses associations and specialist associations.

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Chapter 3:   Inclusion and Exclusion Criteria

3.1 Introduction and Definition of Health Care Workers

An important aspect of sample design for a TB prevalence survey among HCWs is the definition of the eligible population required for the purposes of the survey. In this chapter, essential factors for setting the survey inclusion and exclusion criteria at the level of geographical/administrative area, facility, and the individual are summarized and discussed. In order to reach the eligible number of individuals, a step-wise approach is often necessary.

The WHO defines health workers/healthcare workers as "*all people engaged in actions whose primary intent is to enhance health*" [WHO, 2006]. Countries may choose to use other definitions, such as 'anyone who is employed by the local Department of Health and working at the facility'. Besides regular HCWs, many countries also have community health workers (CHWs), sometimes unpaid and sometimes employed by NGOs. For the purpose of TB-IC, it is also proposed to include other personnel working in healthcare facilities that may get into contact with TB patients, or the infectious material of TB patients, such as cleaners, and drivers [joint WHO/ILO 2010]. It may be challenging to reach a consensus on their definition because CHWs are known by many different names in different countries and often include a variety of community health activities. The widely accepted definition of CHWs proposed by WHO is as follows: "*Community health workers should be members of the communities where they work, should be selected by the communities, should be answerable to the communities for their activities, should be supported by the health system but not necessarily a part of its organization, and have shorter training than professional workers.*"[WHO, 2007].

3.2 Sampling Frame

TB prevalence surveys among HCWs have two major objectives:
(i) to measure the prevalence of TB disease among HCWs
(ii) to measure the impact of IC activities.
For the second objective several sampling strategies may be possible, which are described further in Chapter 5. For the first objective, there are several options, given below.

3.2.1   Countrywide Representative Sample

When the aim is to have a countrywide representative sample, multi-stage clustered sampling design is recommended. First geographical or administrative areas are selected (sampled) as the primary sampling units (primary stage clusters). Within these areas, either all facilities can be included; or facilities can be sampled as secondary stage clusters. All HCWs in the selected facilities will be investigated to assess whether they are eligible for the survey or not. In the case where health facilities in the selected area only have small numbers of HCWs, geographical/ administrative areas will be defined as single stage clusters and all HCWs in the area will be invited to any facility and investigated to assess whether they are eligible for the survey or not.

3.2.2   High-Risk Areas

High-risk areas can be defined in different ways. These may be facilities with the most TB patients, the most TB suspects, or a high proportion of cases having MDR-TB. When the team wants to know the burden of TB among HCWs in specific high-risk facilities or areas, purposeful sampling is preferred. In such situations all facilities in high-risk areas should be selected, or all high-risk facilities in the country. Sampling may not be needed.

3.3 Inclusion and Exclusion Criteria

3.3.1   Eligible Areas and Facilities

Firstly, investigators need to define and confirm the geographical areas and type of facilities which will be targeted by the TB prevalence survey among HCWs. Areas or facilities where the implementation of the survey including IC measures is not feasible should be excluded from the sampling frame. These include geographical areas such as conflict zones or facilities where HCWs are not governed by the Ministry of Health (MoH) but by something different such as diplomatic or military body. Large facilities such as education/teaching hospitals under the Ministry of Education should however be included since their exclusion might limit the representativeness of the sampling frame and render the results of the survey biased. A detailed and well explained section of the survey protocol on the exclusion of geographical areas and facilities should exist, including a section about the potential biases introduced into the results due to these exclusions.

The MoH or Health Statistical Unit usually has a list of all health facilities divided by category, for example, tertiary, secondary and primary level hospitals, clinics or dispensaries, pharmacies, health centres, health posts, laboratories, etc. It may be convenient to use this list to categorize the facilities for the study. This categorization of facilities and professions might be used for stratification, for sampling efficiency (see sampling chapter 5) or for the evaluation of the level of TB exposure. It might happen that the reported number of HCWs and their type of professions in the targeted facilities are different from reality. In those cases, investigators need to start with confirming the number and type of health workers in each facility; for example by a HCW census in all facilities; or in a sample of the facilities.

All health facilities (including private for profit, private non-profit, government hospitals and health centers) which register, screen, diagnose or treat TB cases will constitute the sample frame for the prevalence survey. Special efforts may be needed to ensure the participation of the private sector.

3.3.2   Eligible Health Care Workers

All HCWs and workers who meet the facility and occupational categories of the study should be assessed to see if they are eligible for the study. Therefore, the first step is to set the inclusion and exclusion criteria at individual level, investigators need to define which professional categories should be included in or excluded from the survey. This depends on the survey objectives and the actual working situation of HCWs in each county. Professional categories can be used as they are used in official documentation, see Table 1 and 2. Some of these professions may need to be excluded since they are not represented in high TB risk settings. Some professional categories may need to be grouped together, if only a few workers in certain specialties are available. Therefore a reduced list may be used, and an example list of categorizations of HCWs is shown in Table 3. The investigators can modify this table depending on the type of HCWs in each country.

The country should also decide whether to include unpaid workers. In the surveillance guide to monitor TB incidence among HCWs (Tool 1), these have been excluded in order to have a clear denominator. Countries may decide to include them when a definition can be developed to systematically count them.

The following categories can be considered at risk of TB exposure: workers and trainees assigned to the sampled health facilities, and who by the nature of their occupations or roles within the health facility, are likely to come into contact with diagnosed and suspected TB patients visiting these facilities. This population consists of:

i. Health professionals (i.e. medical doctors, nursing and midwifery professionals, paramedical practitioners, laboratory staff, radiologists and other health professionals)
ii. Health associate professionals (i.e. medical and pharmaceutical technicians, nursing and midwifery associate professionals, and other health associate professionals such as medical records and health information technicians, community health workers, medical assistants, environmental and occupational health inspectors, and ambulance workers);
iii. Clerical support workers (including receptionists, inquiry clerks, office clerks, secretaries, and keyboard operators) who may come into contact or interact with the patient population on a regular basis;
iv. Personal care workers in health services (including healthcare assistants)
v. Helpers (including patient attendants, ward attendants, cleaners, drivers and guards).
vi. Medical and nursing trainees and students (e.g. residents, fellows and nursing degree students) have a high-risk of TB infection [Pai 2006; Christopher 2011].

If for resource or logistical reasons, a country wishes to study only "sentinel" groups, they may choose nurses and young medical/nursing students. These groups will give a good idea of the burden of TB among HCWs as a whole.

These categories are consistent with international classifications of occupations and would permit the cross-country comparison of prevalence rates by major occupational categories.

Eligibility will be determined based upon age, the length of employment as a HCW, the proportion of time spent working and number of places in which they work, as follows:

Inclusion Criteria
– Age: The age cut-off point depends at what age HCWs are recruited. Students should be included. In some countries this may be health workers who are 18 years or older. However, some countries may allow the recruiting of workers who are 15 years of age or higher.
– Length of employment as a HCW: All HCWs should be included, no matter what their length of employment, since HCWs may have been infected in previous jobs or during their training/traineeship. The length of employment in health sector may be recorded for later sub-analysis.
– Proportion of working time: Both part-time and full-time workers should be included as eligible HCWs. The length of the working time in each facility can be recorded, this can be used during data analysis to adjust for, and investigate the effect of working time. Both permanent and contractual staff should be included.

Exclusion Criteria
– Multiple working places: HCWs who have two or more workplaces should only be included in their main working place unless a study assesses a specific health facility situation including part-time workers. To identify main working places, the amount of time the individual spends at each facility should be assessed. Other working places and the amount of time spent there also need to be recorded in order to adjust and investigate the effect and bias of multiple working places at the time of analysis.

It should be noted that eligible HCWs who are either absent during the period (day, week or weeks) of survey operations or do not give their consent to participate, are not excluded from the eligible survey population, despite the fact no examination results are available for them. In order to investigate possible bias introduced in the result, all eligible individuals should be enumerated

and classified as i) survey participants, ii) absent, iii) did not consent to participation [WHO, 2011]. The reasons of absenteeism should be recorded as much as possible in order to guarantee quality of a survey. An attempt should be made to include those who are absent on another day. The investigators should try to obtain basic information from those excluded, i.e. age, sex, working cadre, etc. for comparison with the HCWs included in the study.

3.4 The Classification of HCWs

Table 2. Classification of HCWs in detailed categories

Classification of healthcare workers (Broad categories)	Sub classification
Physicians	Includes generalists and specialists
Nursing and midwifery personnel	Includes professional nurses, professional midwives, auxiliary nurses, auxiliary midwives, enrolled nurses, enrolled midwives and other personnel, such as dental nurses and primary care nurses. Traditional birth attendants are not counted here, but as community/traditional health workers.
Dentistry personnel	Includes dentists, dental assistants, dental technicians and related occupations.
Pharmaceutical personnel	Includes pharmacists, pharmaceutical assistants, pharmaceutical technicians and related occupations.
Laboratory health workers	Includes laboratory scientists, laboratory assistants, laboratory technicians, radiographers and related occupations.
Environment and public health workers	Includes environmental and public health officers, environmental and public health technicians, sanitarians, hygienists, district health officers, public health inspectors, food inspectors, malaria inspectors and related occupations.
Community and traditional health workers	Includes community health officers, community health-education workers, community health aides, family health workers, lady health visitors, health extension package workers, traditional and complementary medicine practitioners, community midwives, traditional birth attendants and related occupations.
Other health workers	Includes a large range of other cadres of health service providers such as medical assistants, dieticians and nutritionists, occupational therapists, operators of medical and dentistry equipment, optometrists and opticians, physiotherapists, podiatrists, personal care workers, psychologists, radiographers, respiratory therapists, speech pathologists, medical trainees and interns.

Health management and support workers	Includes other categories of health systems personnel, such as managers of health and personal-care services, health economists, health statisticians, health policy lawyers, medical records/health information technicians, ambulance drivers, building maintenance staff and other general management and support staff.
Trainees and students	Medical students, nursing students, students in paramedical programs (e.g. physiotherapy, radiology technician courses, etc)

Table 3. Classification of HCWs in detailed categories

Classification of HCWs (Detailed categories)	Sub Classification
Physicians	Includes generalists and specialists.
Nursing personnel	Includes professional nurses, auxiliary nurses, enrolled nurses and other personnel, such as dental nurses and primary care nurses. In some countries this also includes nurse-midwives.
Midwifery personnel	Includes professional midwives, auxiliary midwives and enrolled midwives. *(Note that for some countries, nurses with midwifery training are counted under nursing personnel.)*
Dentists	Includes dentists.
Pharmacists	Includes pharmacists.
Pharmaceutical technicians/assistants	Includes pharmaceutical assistants, pharmaceutical technicians and related occupations.
Laboratory scientists	Includes laboratory scientists.
Laboratory technicians/assistants	Includes laboratory assistants, laboratory technicians and related occupations.
Radiographers	Includes radiographers and related occupations.
Environmental and public health workers	Includes environmental and public health officers, environmental and public health technicians, sanitarians, hygienists, district health officers, public health inspectors, food inspectors, malaria inspectors and related occupations.
Community health workers	Includes community health officers, community health-education workers, community health aides, family health workers, health visitors, health extension package workers, community midwives and related occupations.
Traditional medicine practitioners	Includes traditional and complementary medicine practitioners and associates.
Traditional birth attendants	Includes traditional birth attendants.

Medical assistants	Includes medical assistants, clinical officers and related occupations.
Personal care workers	Includes institution-based personal care workers, home-based personal care workers, healthcare assistants and other categories of care attendants in health services.
Other health workers	Includes dieticians and nutritionists, occupational therapists, operators of medical and dentistry equipment, optometrists and opticians, physiotherapists, podiatrists, psychologists, respiratory therapists, speech pathologists, medical trainees and interns.
Health management and support workers	Includes other categories of health systems personnel, such as managers of health and personal-care services, health economists, health statisticians, health policy lawyers, medical records and health information technicians, ambulance drivers, building maintenance staff and other general management and support staff.
Trainees and students	Medical students, nursing students and students in paramedical programs (e.g. physiotherapy, radiology technician courses, etc)

Table 4. Example list of the classification of HCWs for a TB prevalence survey among HCWs [adapted from references: CDC, 2004; WHO, 2006; Galgalo T et al, 2008]

Broad Categories	Sub Categories
Physicians	Generalist
	Specialist
Nursing and Midwifery Personnel	Nurse
	Midwife
Pharmaceutical Personnel	Pharmacist
	Pharmaceutical technician/assistant
Laboratory Health Worker	Laboratory scientist/technician/assistant
	Radiographer and related worker
	Other laboratory health worker: Ultrasound, ECG etc.
Environment and Public Health Worker	
Community health worker	
Health Management and Support Worker	Administration staff
	Paper staff/Clerical: accountant, receptionist, secretary etc.
	Cleaner
	Driver
	Cook

Other Health Workers	Physiotherapist
	Occupational therapist
	Respiratory therapist
	Speech pathologist
	Psychologist
Others	

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Chapter 4: Proposed Case Definitions and Screening Strategies

4.1 Introduction

All TB prevalence surveys, regardless of the populations in which they are conducted, require tools for identifying TB cases and case definitions, as well as screening strategies to identify those most at risk of having TB disease. Here we summarize the tools, case definitions and screening strategies which are advised by the WHO TB prevalence surveys: a handbook. We present new data on screening strategies amongst populations with high HIV prevalence. We discuss the factors which need to be considered when developing strategies for conducting TB prevalence surveys amongst HCWs. The focus will be on pulmonary TB, since this leads to the most transmission, although some forms of EPTB may be identified.

4.2 Measurement and Case Definitions

In any TB prevalence survey, the tools which are used to determine whether an individual should be considered a TB case or not, are:
• Sputum smear microscopy for the demonstration of acid-fast bacilli
• Sputum culture for *MTB*
• Approved molecular technology for the demonstration nucleic acid specific to *MTB*
• Abnormal chest radiography
• Questionnaire pertaining to TB symptoms and signs, history of previous and current TB disease and treatment (includes self-reported TB), and other risk factors pertinent to the survey objectives.

Using these tools, 'Case definitions for TB prevalence surveys' are derived and 'types of TB cases' are assigned. These case definitions and types of TB cases are listed in Chapter 4, Box 4 of the WHO TB prevalence surveys: a handbook (WHO 2011). They may differ from the definitions used by the NTPs.

4.2.1 Case Definitions for TB Prevalence Surveys amongst the General Population, and amongst HCWs

The reasons for case definitions in TB prevalence surveys are as follows:
• To maintain a constant understanding of what constitutes a TB case, so that surveys amongst different population groups, or surveys separated by time can be compared. This allows observers to interpret trends in the epidemiology and burden of TB. Of course new tests can be added
• To understand the kinds of TB cases that are identified (the proportion that are smear-positive). This allows observers to infer the infectiousness of TB cases within the epidemic and the consequent risks of transmitting TB
• To understand the proportions of TB cases that are identified by the NTP. This allows observers to develop an understanding of the gaps in the TB control program which allow cases to go undetected.

4.2.2 Case Definitions for TB Prevalence Surveys and Case Definitions of the NTP

The NTP in each country uses similar tools to identify TB cases, but not similar screening strategies:

- The NTP usually relies on passive case finding – i.e. self-presentation of ill persons at health care facilities. They usually apply a combination of symptom screening, sputum testing and chest radiography depending on national algorithms, to diagnose TB and initiate TB treatment
- TB prevalence surveys use active case finding amongst populations that are expected to be generally well and apply a different combination of symptom screening, sputum testing and chest radiography
- TB prevalence surveys identify all cases of TB among HCWs, including those that are already diagnosed by the NTP and on treatment, and those not identified by the NTP who need to initiate treatment. This implies that HCWs already on treatment should undergo all the same diagnostics as other study participants
- Cases detected by the NTP are usually detected passively. Among all the suspects self reporting to a clinic, 5-15% usually have TB. In a prevalence survey this proportion is much lower, increasing the proportion of false positive laboratory results. Therefore cases detected in surveys need confirmation.

As a consequence, different combinations of results arise amongst participants in TB prevalence surveys compared with persons presenting to the TB control program. For this reason, the case definitions for TB prevalence surveys, and the case definitions of the NTP may not be the same.

It is important when conducting a TB prevalence survey that case definitions are decided on at the onset of the study. This will ensure a standard approach in both case detection and management, and ensure consistency in reporting of results.

Box 1. Case Definitions
(from chapter 4 in the WHO TB prevalence surveys: a handbook [WHO 2011]).

Laboratory TB Case Definitions
- Culture-positive TB definite: At least one culture TB positive
- Smear-positive, culture-positive TB definite: culture TB positive AND at least one AFB-S Positive
- Smear -positive, NAATB-positive TB definite – optional: NAATB positive AND at least one AFB-S positive
- Smear-negative, NAATB-positive TB definite – optional: NAATB positive AND all specimens AFB-S negative

Survey TB Case Definitions
- Definite survey TB case (bacteriologically-confirmed survey TB case):
  - One CTB positive specimen AND at least one of the following conditions:
    - AFB-S positive (smear-positive, culture-positive TB definite case)
    - CTB-positive in another specimen
    - Chest X-ray abnormal finding in lung at central audited reading
    - Evidence from follow-up investigations if planned in the survey protocol
- AFB-S positive survey TB case (smear-positive TB case):
  - One AFB-S positive specimen AND at least one of the following conditions:
    - CTB-positive (definite survey TB case)
    - AFB-S positive in another specimen BUT not CTB positive AND no isolation of MOTT (probable TB case)
    - Chest X-ray abnormal finding in lung at central reading BUT not CTB (or NAATB) positive AND no isolation of MOTT (probable TB case)

4.3 The Place of Specific TB Screening and Diagnostic Tools in TB Prevalence Surveys Amongst the General Population and Specific Populations

The role and place of symptom screening, CXR, sputum smear microscopy, approved nucleic amplification technology and culture in TB prevalence survey are discussed in detail in the WHO TB prevalence surveys: a handbook (WHO 2011), and are summarized below in Table 5.

Table 5. The role of different diganostics in a TB prevalence survey, approximate sensitivity and specificity, and the effect on tool performance in high HIV and low TB prevalence settings.

	Usual role in TB prevalence survey	Approximate Sensitivity vs MGIT culture	Approximate Specificity vs MGIT culture	Effect on tool when population under surveillance has a:	
				High HIV prevalence	Low TB prevalence
Symptom screening (interview: any of current / 2-3 weeks cough, fever, night sweats or weight loss)	To identify persons for further TB investigations including smear/culture/NAAT	70%	50%	Symptoms become less useful in identifying persons for further investigation. The specificity of symptoms decreases	Symptoms have very high negative predictive value (99%)
Symptom screening (any of current /2-3 weeks cough, fever, night sweats or weight loss) AND CXR (any abnormality)*	To identify persons for further TB investigations including smear/culture/NAAT	90%	40%	In spite of symptom screening and CXR, some cases of TB will be missed when HIV prevalence is high	Negative predictive value of CXR for TB very high, leading to high sensitivity for Culture positive TB
Smear microscopy	To determine the infectiousness of cases, or to identify cases, or to identify persons for further investigation including culture/NAAT	50-70%	99%	Sensitivity decreases	Sensitivity increases

MGIT Culture	To confirm cases	Gold standard	Gold standard	When HIV prevalence is high, consideration could be given to culturing all survey participants	When TB prevalence is low, contaminated cultures, or cultures growing non-clinically significant NTMs become more common
Approved Nucleic amplification tests	Untried in TB prevalence surveys to date	85-95%	99%	Latest data suggests that sensitivity is unchanged or minimally reduced in high HIV prevalent contexts	

4.3.1   Extrapulmonary TB

Most prevalence surveys focus on pulmonary TB since that causes most transmission and is therefore most important from a public health perspective. In a prevalence survey among HCWs we may want to add screening for EPTB. For budget reasons, this may include symptom screening only or self-reported EPTB. The following symptoms should be considered: pleural effusion and lymph node enlargement. A biopsy with histology should only be considered in persons who are strongly suspected of having EPTB. A separate definition should be designed.

4.4 Screening Strategies for Conducting a TB Prevalence Survey Amongst HCWs

4.4.1   Introduction

To date, all the studies describing the rates of TB disease amongst HCWs which were reviewed, used retrospective case ascertainment to identify cases of TB [Joshi 2006; Baussano 2011]. Therefore, these studies used TB case definitions from their country NTP and relied on passive case finding and self-presentation (or self-report) of HCWs to care providers. These studies did not use standardized screening strategies in a population of HCWs to identify persons eligible for further TB investigations. To our knowledge, and at the time of writing, no prospective survey to determine the incidence of TB amongst HCWs using active case finding has been conducted. The probable reason is that at any given time, only a small percentage of HCWs in a hospital will have the signs and symptoms of TB, and only a small percentage of these will actually have TB disease. Therefore most surveys ask about a period in the past (e.g. lifetime prevalence).

4.4.2   Recommended Strategies

Three TB screening strategies for conducting population-based TB prevalence surveys are discussed in the TB prevalence survey guidelines and are summarized below in Table 6. Below the table we discuss a fourth strategy including the recently recommended GeneXpert MTB/Rif.

Table 6. Screening strategies recommended by the TB prevalence survey guidelines (adapted from Table 4.2 in the WHO Prevalence Survey Handbook)

Strategy	Description of Strategy	Identified Cases	Missed Cases	Comments
Recommended Strategy	Symptom screening + CXR; any abnormality requires smear and culture	Most S(+); most C(+)	S(+) sym (-), CXR (-); S(-) C(+) sym (-) CXR (-)	Most common screening
Alternative Strategy 1	Symptom screening + CXR + sputum smear; any abnormality requires culture	All S (+); most C (+)	S(+) sym (-), CXR (-); S(-) C(+) sym (-) CXR (-) S(-) C(+) sym (-) CXR (-)	Very intensive for the laboratory
Alternative Strategy 2	No screening; all participants undergo smear and culture (but symptoms, CXR advised for comparative purposes); challenging if not able to produce sputum	All S (+); all C(+)	None	Very intensive for the laboratory and very expensive
Alternative Strategy 3	No screening; all participants undergo GeneXpert MTB/Rif (but symptoms, smear, CXR advised for comparative purposes); challenging if not able to produce sputum	All S(+), most C(+)	GeneXpert MTB/Rif (-), culture + cases	Requires accessibility of Xpert MTB/Rif platform, very expensive

Using GeneXpert technology (Xpert MTB/Rif) for the diagnosis of TB has both excellent sensitivity and specificity when compared with MGIT culture, however the test performance is slightly lower amongst HIV+ persons [refs Boehme, Scott, Lawn]. In the light of the costs of 'Alternative Strategy 2' and the improved performance of Xpert MTB/Rif, a third alternative screening strategy could be to use Xpert MTB/Rif for everyone and reserve culture confirmation for those identified with rifampicin resistant disease. Applying this expensive test may not be possible in prevalence surveys with large sample sizes and using a test which combines TB diagnosis with drug resistance testing, leads to ethical discussions on guaranteeing treatment for cases identified as MDR-TB. These ethical concerns should be debated before the survey takes place.

All positive cultures should be confirmed with molecular testing to rule out non-tuberculous mycobacteria (NTM), especially if liquid culture is used.

4.4.3 Screening Strategies in Populations with High HIV Prevalence (> 5%)

HIV infection increases the risk of TB, alters the clinical presentation of TB and changes the performance of screening algorithms in co-infected persons. Most notably, amongst HIV infected populations, the prevalence of asymptomatic, culture positive TB with normal CXRs increases. Screening strategies need to accommodate these changes. If the HIV prevalence among HCWs is not known/not available, the HIV prevalence can be inferred from the HIV prevalence of the general population, as HCW populations reflect the HIV prevalence of their communities [O Shisana S Afr Med J 2004].

Although these studies are done in passive case finding settings as opposed to active case finding settings; we recommend that for HCWs working in settings with a high HIV prevalence (>5%), TB suspects should include HCWs with any duration of symptoms and not only those with symptoms > 2 weeks (as in populations with low HIV).[Getahun 2011, Kranzer 2010]

In such settings both the recommended strategy and 'Alternative Strategy 1' for TB prevalence surveys in the general population may underestimate the burden of TB disease. Alternative Strategies 2 and 3 are possible. A further argument is that a screening strategy for HCWs may be more intensive than in a nationwide prevalence survey since:
a. The incidence is probably higher
b. Undiagnosed TB among HCWs has a high-risk of transmission to patients with weak immune systems
c. HCWs need to care for other patients
d. HCWs have more access to health care and are nearer to a laboratory.

However sample size, as well as the cost and accessibility of laboratory diagnostic assays may need to be considered. In large scale surveys using 'Alternative strategies 2 and 3' may not be feasible as the number of samples to be tested is too high, which increases the proportion of false positive cultures. In any case, a follow-up mechanism is needed to confirm cases diagnosed by the laboratory. It should be noted that taking two specimens from a limited number of screened positive persons (15-25%) may detect more TB than one specimen from everybody.

4.4.4 Past TB

Surveys should always ask individual HCWs about past TB. This is not only to establish previous TB disease but also to identify cases diagnosed and treated outside their own facility. Some hospitals will have employee health clinics which keep records; reviewing these records will give an estimate of TB that has been diagnosed and treated in HCWs. HCWs should give permission to review their records; or a member of the staff clinic should only give aggregated information. Since those who have had TB before have a higher risk of developing it again, HCWs with a past history of TB should always be in the group which gives sputum samples for smear and/or culture.

4.5 HIV Testing

It is also recommended to offer HIV testing when screening for TB. Depending on the country situation it may be decided to offer HIV testing to all the HCWs in the prevalence survey, or only TB suspects. At the very least, all TB cases should be offered HIV testing. Surveillance of the prevalence of HIV among people with TB is one of the 12 essential activities included in the WHO policy on collaborative TB/HIV activities (see WHO TB prevalence surveys: a handbook chapter 11.2).

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Chapter 5:   Sampling Design and Methodology

This section describes the sampling design and sample size estimation methods that can be used in prevalence surveys of TB disease among HCWs by active case finding. The methodologies and approaches recommended in this guide are consistent with or similar to, the ones described in the WHO TB prevalence surveys: a handbook for the general population [WHO, 2011].

5.1 Baseline Prevalence Survey of TB among HCWs

5.1.1   Study Population

There are several populations considered in this study:
  i. The population of all health facilities; and
  ii. The population of HCWs within selected facilities or
  iii. The population of HCWs within selected geographical areas

5.1.2   Sample Size Determination

The following section provides an overview of the critical elements and steps required to determine an appropriate sample size for a cluster facility-based survey of TB prevalence among HCWs. For more detailed information please refer to Chapter 5 of WHO TB prevalence surveys: a handbook [WHO, 2011] and Chapter 4 of [Iarossi 2006].

Sample size criteria when sampling health facilities and HCWs may differ from those in household-based TB prevalence surveys of the general population in some important aspects:

1. HCWs often have a higher TB incidence than the general population, since they are more likely to interact or come into contact with TB patients. On the other hand, TB incidence among HCWs may be lower as they are often in a higher socio-economic stratum than the general population and have better access to care, but this difference will be small since HCWs also includes CHWs, cleaners, drivers, etc. Furthermore, HCWs and the general population may have a large difference in TB incidence, but smaller difference in TB prevalence, since HCWs have better access to care than the general population, therefore they may be diagnosed earlier and have a shorter period of infectiousness. For the purpose of sample size calculations we may assume a 50% higher baseline estimate of TB prevalence among HCWs than the general population, although this may differ between countries.
2. HCWs may have a lower non-participation rate than the general population, since they can easily be accessed, screened and examined during work hours. Some groups, e.g. doctors, may be less likely to participate.
3. Some smaller countries may not have many HCWs. Such countries can decide to include all HCWs in a survey rather than just a sample, or only include HCWs in high-risk areas or facilities.

5.1.3   High Risk Sampling or Representative Sampling?

Countries may choose between three options:

1. Include all HCWs in the country.
2. Do purposeful sampling of only geographic areas, facilities or HCWs which are thought to be at high risk, e.g. TB hospitals. This will not give a representative estimate for all HCWs in the country, but may assist in answering other objectives of a prevalence survey, such as size

of the risk of TB in those high risk areas/facilities, the proportion of cases missed by a routine surveillance system and reasons for under-notification.

3. Sampling to get a representative sample of the HCWs population in the country. For this objective, a cluster survey is recommended, which is described in the paragraphs below.

5.1.4 Steps in Determining a Sample Size for a Representative Cluster Survey of TB Prevalence Among HCWs

For a representative countrywide TB prevalence survey, the cluster sampling design is recommended as the most appropriate sampling design in most situations. See Chapter 5 of the WHO TB prevalence surveys: a handbook [WHO, 2011].

In order to calculate the minimum sample size for a baseline prevalence survey of TB among HCWs using a cluster sample survey design, the formula as presented in the handbook can be used. The formula uses the required relative precision and the prior guess of true TB prevalence. We need to have information or reasonable guesses on the following key elements:

i.   A prior "guess" of the true population prevalence of pulmonary TB disease among HCWs (expressed as a proportion of the number of survey confirmed TB cases among HCWs per 100,000 HCWs in a given country). If not available, the notified incidence in the general population may be used as an estimate. For surveys that only intend to estimate the lifetime prevalence and not point prevalence at time of the survey, sample sizes will be considerable lower, since lifetime prevalence is estimated to be larger.

ii. The relative precision of the estimate of TB prevalence is the width of the confidence interval for the true TB prevalence, and is expressed as a proportion or percentage of the true population prevalence.

iii. A prior "guess" about the size of the 'design effect', which is essentially the multiple by which the sample size needs to be increased because of the cluster design of the TB prevalence survey, to account for the difference in sample size that would have been required if simple random sampling of the population had been used.

iv. The calculated sample size needs to be adjusted to compensate for non-participation in the survey. For TB prevalence surveys among HCWs, between 85% and 90% of the eligible population should be expected to participate.

v.   The number of clusters (geographical areas) is determined by the total sample size divided by the chosen cluster size. It is recommended that the number of clusters to be sampled be at least 50, in order to ensure adequate representative coverage of the eligible HCW population and obtain reliable estimates of between-cluster variation in the true TB prevalence [WHO, 2011]. In small countries this could be 50 groups of facilities rather than 50 geographical areas. A typical cluster size is 400-1000 HCWs. For a HCW survey other types of sampling may be used, with varying cluster sizes.

5.1.5 Sampling Methodology

In smaller countries all HCWs can be included in a survey. The sampling methodology recommended for TB prevalence surveys of HCWs in larger countries is a multi-stage clustered sampling design. In such a design, information on TB disease and other relevant indicators is collected from representative samples of HCWs within representative clusters (or samples of health facilities).

The selection of HCWs should be done through a multi-stage Probability Proportional to Size (PPS) method. We will describe a three-stage PPS sampling method to illustrate the steps that could be used in a multi-stage PPS method.

–   The first stage is the random selection of primary sampling units (PSUs) from a list of the

administrative units of health facilities, such as districts or sub-districts. These PSUs should be selected using PPS, the size is determined by the number of health facilities in each district. The survey team will need to review available national and regional lists of health facilities at national, regional and local levels in order to determine the number of health facilities in each district.

– The second stage would be to select using PPS, a sample of health facilities within each selected district. This second stage would require updating existing listings or creating a new, more accurate and complete listing of health facilities in the selected districts and then identifying and mapping all the facilities which register, screen or treat TB patients. It will be necessary to have an estimate of the number of HCWs per facility. Facilities can be stratified by size, e.g. big, medium and small, then they can be sampled within these strata.

– The third and final stage of sampling would be to select all HCWs in each selected health facility, as needed to meet the required sample size.

5.1.6 Stratification, Oversampling and Sampling Weights

The health facilities may be stratified into different mutually exclusive sub-groups (e.g. whether they are public or private) from which samples are then drawn. This can be done to improve the statistical power and the precision of estimates for a given sample or to ensure that each group is adequately represented [Wassenich and Munoz, 2007].

If a survey seeks to assess whether TB prevalence differs between different groups of HCWs, the sampling strategy may need to be adjusted to address this objective by oversampling those groups which are not adequately represented in the study population. For example, we may suspect that the TB prevalence is lower in private for profit healthcare facilities than in the public healthcare facilities. Private facilities tend to have a smaller than average number of HCWs, therefore it may be necessary to oversample this group in order to have an adequate number of observations to perform the required statistical analyses. This would be done by first stratifying the sample of health facilities by type (private versus public), and then assigning a higher number of health facilities to the private stratum than it would have received under a PPS sampling method. When stratification or oversampling is used, sample weights should be used to account for the higher than expected probabilities of selecting oversampled groups to ensure that the statistics obtained correspond to the overall study population. For further guidance on implementing multi-stage sampling procedures see references [Grosh and Munoz 1996, Iarossi 2006, Wassenich and Munoz 2007, Levy and Lemeshow 2008, and WHO 2011].

5.2 Impact Survey

The design of repeat surveys of TB prevalence is discussed in Chapter 9 of the WHO TB prevalence surveys: a handbook [WHO, 2011]. Repeat surveys among the general population will NOT contain the same participants as the first survey. For HCWs a repeat survey may be done in the same group, since the number of HCWs in a country may be too small to do repeat surveys with different HCWs. When planning a survey or surveys to assess the impact of TB-IC measures, it is advised to involve experienced researchers in impact designs. Some guidelines are given below.

It should be noted that impact surveys usually take place in the same facilities among the same HCWs - and therefore can be used to actually compute TB incidence. As discussed in chapter 2, the first survey may affect the second survey in several ways. Therefore it is recommended to have several years between the measurement of TB prevalence among HCWs before and after interventions. Impact will be measured as a reduction in TB prevalence and/or incidence among HCWs. The impact will depend a lot on whether TB-IC includes isoniazid preventive therapy (IPT) for HCWs.

5.2.1   Sample Size Consideration for an Impact Survey

It is beyond the scope of this guide to discuss the sample size of impact surveys in detail. It is recommended to involve a statistician and two points should be considered:

1. When measuring the impact of implemented TB-IC measures, it should be noted that not all TB among HCWs is due to transmission in the facility. HCWs can also be infected in the community. Therefore TB-IC measures in the facility can only reduce TB prevalence to a limited extent. It may be assumed that half the infections are due to occupational transmission and half due to community transmission, since TB among HCWs is often twice that in the general population [Menzies 2007, Joshi 2006, Baussano 2011] therefore the introduction of TB-IC measures could reduce occupational transmission by half. Thus, a reduction in TB prevalence of 25% over several years would be a reasonable expected outcome between two rounds of surveys.

2. When conducting a TB prevalence survey among HCWs to examine the effect of TB-IC measures across several outcomes (e.g. prevalence of TB disease, screening participation rate and the proportion of cases notified), the minimum sample size required for each outcome (as each outcome may require a different sample size) and the largest sample size derived from the various calculations should be used, resources permitting. However, if the available budget is too small, the survey team needs to reduce the scope of the impact survey [Wassenich and Munoz, 2007].

5.2.2   Use of the Stepped Wedge Design and Difference–in-Differences Method to assess impact

In some countries, it may be possible to show a decline in TB prevalence among HCWs after the implementation of TB-IC measures. In parallel with a decline in case notifications, this is a strong argument in favor of TB-IC, although there may be other reasons for the reduction, besides TB-IC measures.

When the intention is to build evidence for a causal relationship between TB-IC measures and the prevalence of TB among HCWs, facilities with TB-IC measures need to be compared to those without TB-IC measures. Like most other public health measures, the introduction of TB-IC measures cannot be withheld from facilities in a case control design (in which half the facilities would not get TB-IC measures), for ethical reasons. For such research where program assignment is not based on explicit criteria, a stepped wedge design (also called phased introduction or implementation design), permits sequential roll-out of the intervention (introduction of TB-IC measures) to various units and study sites over different time periods. This design will allow comparisons between health facilities, and controlling for confounding, selection bias and underlying time trends [Brown and Lilford, 2006, Squire 2011]. The order in which the selected zones receive the intervention is determined at random. A stepped wedge design can go hand-in-hand with a planned phased country-wide introduction of TB-IC measures. Health facilities can serve as their own control; also the total pre- and post-intervention period of all health facilities together will be compared [TBCTA, 2011; pages 48-50].

The phased implementation approach provides an opportunity to compare the changes in TB prevalence among HCWs over time, between a group of health facilities which have introduced TB-IC measures (the treatment group) and a group of health facilities which is yet to implement TB-IC measures (the comparison group). This can be done by using the Difference-in-Differences (DD) method in [Gertler et al, 2011 Table 5.1].

Table 7. Difference-in-Differences Method

	After	Before	Difference
Treatment group (TB-IC measures in place)	B	A	B - A
Comparison (no TB-IC measures)	D	C	D - C
Difference	B - D	A - C	DD = (B –A) – (D – C)

Source: [Gertler 2011]. DD = (B –A) – (D – C) represents the impact estimate.

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Chapter 6:   Data Collection and Analysis

This chapter describes the main methods of data collection and discusses strategies for identifying potential sources of data. For general guidelines see Chapter 15 (Documents and data management) of the WHO TB prevalence surveys: a handbook. Some aspects that may differ for HCW surveys are described here.

6.1 Preparation for Data Collection

The following preparations may differ between a HCW survey and a community survey.

- **Asking permissions from health facilities:**
  In order for a survey among HCWs to succeed, it is necessary to obtain buy-in from the relevant stakeholders, such as the MoH (both the departments of TB control and the department of occupational health), the Ministry of Labor, medical specialty organizations, such as doctors associations and nurses associations, district/provincial authorities and facility heads. They may assist in advocacy for survey participation and/or advise you on how to convince HCWs to participate. Convincing private health facilities may be a challenge.

  Assess how much time is needed to persuade to HCWs to participate in the survey, in large hospitals you may need to do several advocacy sessions.

  Discuss the following with facility management:
  – What is the best time and location for screening tests. HCWs will usually be surveyed during working hours, in contrast with community surveys which are often outside working hours
  – How to communicate results about HCWs diagnosed with TB by the survey - at home, in facility, verbally, in writing or both
  – What type of feedback they want at what stage
  – What information can be collected about HCWs not willing to participate? Only facility name, or also occupation/department? How can we ensure proper care even for those who refuse to participate?

- **Identifying and mapping the sample of health facilities to be surveyed:** Before beginning the survey, each field supervisor should identify and map the selected facilities in his/her assigned area so as to be able to determine where and how to deploy field teams to these facilities for data collection.
- **Pilot-testing, revising and finalizing the survey procedures and data collection instruments:** A limited number of HCWs (20-30) representing different occupational groups and levels of the health system (primary, secondary and tertiary health facilities), and sectors (private and public facilities) should be invited to answer the questionnaires as part of the pilot-test.
- **Specifically for impact surveys:** The research team should review all the different indicators which were part of the results chain (beginning with the impact indicators and moving back to the intermediate outcomes, measures of the delivery of TB-IC interventions, and explanatory and control variables) and select a smaller set of indicators to measure for the cross-sectional prevalence survey or impact evaluation.

6.2 Data Collection Methods and Procedures

6.2.1   Timing of data collection

For a baseline TB survey, data on relevant indicators needs to be collected before the TB-IC measures have been implemented. When assessing the effects of the TB-IC measures, data will need to be collected at at least two points in time (before and after the implementation of TB-IC measures). Depending upon the type of outcome measured, it would be useful to collect outcome data at least 3-5 years after the introduction of TB-IC interventions, when the benefits are expected to be measurable.

6.2.2   Data Collection Procedures and Tools

Chapter 6 and Annex 1 of the WHO TB prevalence surveys: a handbook [WHO 2011] describe and provide samples of the types of tools (questionnaires and other forms) which have been used in various adaptations in previous TB prevalence surveys of the general population. These tools include the enumeration or census form, the screening questionnaire, the questionnaire for participants eligible for sputum examination, the risk factor questionnaire, and the follow-up questionnaire. All these questionnaires and other forms collect individual-level information and can be easily adapted for use among HCWs, and pilot-tested for ease of understanding and administration, as well as the cultural appropriateness in the specific country context.

Specific items that should be adapted for HCWs are as follows (see example in Annex page 49):

1. To the screening questionnaire (p266 of the WHO TB prevalence surveys: a handbook):
- *Reasons for Non-Response:* It is important to document the reasons for non-response or for the refusals to participate. While the loss of sample will not impact the data, it could potentially bias the results if the HCW refusing, differs from the responding HCW. HCWs are allowed to refuse to answer this question.

- *Demographic Information:* Age and sex are usually asked. For HCWs we can add: Occupation, the total duration in service as a health worker/in a health facility, the type of facility where the main part of their work is carried out, whether they are working in more than one facility (give type 1 and type 2), the number of years of service at the facility being surveyed; service/department of affiliation at the time of the survey (e.g. radiology, internal medicine, maternity/obstetrics and gynaecology, pharmacy, laboratory, general TB ward and MDR-TB ward).

- *Clinical Variables:* previous history of TB (yes, no, don't know, refused to answer; if yes, in what year was the latest episode, what was the site of the TB and whether they took 6 months of active TB treatment or not); is the HCW currently on TB treatment? One can choose to ask questions on HIV status of all participants, or only to those eligible for sputum examination.

- *Screening information:* Has the HCW even been screened for TB as part of a facility screening program or job entry screening?
    - If so, at this or another facility?
    - How often?
    - When was the last screening?
    - Which diagnostics methods were used?
    - What was the result?
- *Insurance:* Whether the HCW has medical insurance (and if so, whether it covers medical care at their own facility).

- *TB Contacts:* The question on contacts with TB should be clearly split in those in the private situation (within household or family) and those which are work related.

2. **To the questionnaire for participants eligible for sputum examination (p267 of the WHO TB prevalence surveys: a handbook):**
   In high HIV prevalence settings, HCWs may also be asked about their HIV status (positive, negative, don't know or refused to answer), and whether they are currently taking ART or IPT.
3. **To the Risk-factor questionnaire (p286 of the WHO TB prevalence surveys: a handbook):**
   The WHO handbook considers this questionnaire as optional for nationwide community prevalence surveys. For surveys among HCWs, several risk factors may be chosen, but at least the questions on occupation (as mentioned under screening questionnaire) should be added.

6.2.3   Characteristics of the Health Facility

Data obtained from health facility assessments and audits of service quality conducted prior to the TB prevalence survey can provide valuable information about facilities. For example, many countries have conducted Service Availability Mapping (SAM) exercises. SAM results and databases are country owned, and can be accessed free of charge through either a data use agreement with each country's MoH, or through the WHO's Global Atlas (http://www.who.int/globalatlas) [MEASURE Evaluation, 2008].

Depending on how current the health facility data is, the facility-level information (particularly the information on HCWs and services at the facility) may need to be checked and updated at the level of each facility during the survey. For example, in many countries, many clinics with a limited number of beds are listed as "hospitals", and there are also many instances where physicians working in government health facilities are also working in private-for-profit facilities which they either own, or whether they are engaged in a part-time basis or only on call for emergencies [Dutta et al, 2009].

The types of information that might be of interest to the prevalence survey include, but are not limited to:
i.   The type of facility (government-public; government - but not public (e.g. military, police hospitals); private (for-profit); private (non-profit)
ii. The number of health workers employed at the facility at the time of the survey (by occupation and function)
iii. The types of services provided at the facility (Yes/No; TB, HIV/AIDS, Malaria, Maternal health, child health, family planning, laboratory etc.)
iv. Total number of patients seen at the facility in the year prior to the survey
v.   Number of incoming and outgoing staff during the previous two years
vi. Digital maps of each facility.

6.3 TB-IC Facility Assessment Questionnaire

A structured facility assessment questionnaire with scoring sheets should be used to collect complementary facility-based data (through interviews with managers of the selected health facilities and the review of health facility records) about the implementation of TB-IC measures. Examples of these TB-IC facility assessment instruments can be found in the publication titled 'Implementing the WHO Policy on TB Infection Control' [TB CAP 2010].
Besides indicators that can easily be observed, one can consider collecting more complicated data that can indicate the effectiveness of TB-IC interventions, such as the (reduction in) diagnostic delay time achieved by the full or partial implementation of TB-IC measures.

6.4 Follow-up of Survey Participants

Any survey participant found to have symptoms or signs of TB must be referred for further examination according to national TB policy. For all TB patients HIV testing with pre- and post-test counseling should be offered by the HCW's own facility (or a collaborating laboratory facility, depending on local policies). Those found to be HIV-infected will be referred to ART clinics and managed accordingly. All patients diagnosed with TB, HIV or both, will be linked to the public health care system for appropriate management.

All TB cases among HCWs should also be notified in the regular TB notification system. If stigma is an issue, notification may be done in another facility, and by ID number rather than by name.

6.5 Data Analysis

Data analysis of prevalence surveys is discussed extensively in part IV of the WHO TB prevalence surveys: a handbook. Some aspects may differ in prevalence surveys among HCWs and these need to be developed in consultation with a statistician:

1. Weighting could be more complicated since HCWs can be divided into many different sub-groups related to the type of facility, exposure and job categories.
2. In population surveys, the sample in the survey is usually a small fraction of the population. In HCW surveys, the fraction of the HCWs in the country which are included in the survey may be large. We need to do finite population corrections in order to compute the variance of estimators which may reduce the sample size.
3. Missing data may be of a different nature, since certain job categories e.g. medical doctors or private facilities may be less likely to participate. This requires proper adjustments.
4. Sampling may not be optimal in the case of countries with limited documentation on existing facilities. This may need to be adjusted for, e.g. by post-stratification.
5. When comparing prevalence between 2 surveys, the changes in between surveys need to be taken into account. Trends in prevalence can be compared to trends in case notification.

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Chapter 7: Quality Assurance

Most guidance on quality assurance can be found in the WHO TB prevalence surveys: a handbook chapters 3.3 (standard operating procedures), 6.6 (questionnaires), 7.9 (Chest X Rays), 8.12 (laboratory procedures) and also in chapters 14 (field operations) and 15 (documents and data management). This chapter describes where quality assurance measures for HCW surveys differ from those in community surveys.

7.1 Quality Assurance in Diagnostic Procedures

Chest X-Ray

CXRs are discussed in detail in chapter 7 of the WHO handbook on TB prevalence surveys. They should be read using a standardized system, e.g. the Chest X-Ray Recording and Reporting System den Boon 2005]. In community surveys CXRs are usually read by a limited number of reviewers, in order to make sure that they are all read in the same way. In a prevalence survey among HCWs with a limited budget, it is possible that CXRs are read by the facilities where the HCWs work or the nearest district hospital. In such cases it is important to have centralized training on the reading of CXRs as well as continuous monitoring. A sample of CXRs can be cross read by a central facility. A mobile CXR unit should be considered.

CXRs for a prevalence survey should be read in a different way from CXRs for clinical purposes. For a prevalence survey, CXRs with any abnormalities should be referred for sputum collection, and not only those with TB related abnormalities, since the latter may be missed.

Furthermore, it should be ensured that HCWs who read CXRs are also surveyed, and that they do not read their own CXR. This should preferably be done in a different facility, so transport should be arranged.

Laboratory Diagnostics

In community surveys, laboratory procedures are usually done by a limited number of laboratories, in order to make sure they are all processed in the same way. In a prevalence survey among HCWs with a limited budget, it is possible that samples are processed by the facilities where the HCWs work, or nearby district hospitals. In such cases it is important to have centralized training on the harmonization of laboratory procedures and thorough external quality assurance (EQA) procedures before and during the survey.

Furthermore, it should be ensured that all laboratory staff are also surveyed, and that they do not process their own samples. This should preferably be done in a different facility, so transport should be arranged.

7.2 Translation

Translation has limited coverage in the WHO TTB prevalence surveys: a handbook, therefore some additional information is provided here. When translation of the survey/forms/questionnaires is required, guidelines on how the translation should be conducted should be provided. The WHS Translation Guidelines are available on the WHS web site at (http://www.who.int/healthinfo/survey/en/).

A summary list of points to be considered when reviewing of translation procedures includes:

- The languages spoken in the country; the coverage of major language groups
- Who was involved in the translation process?
- Were all the required materials translated?
  - Questionnaires
  - Appendices
  - Guide to administration (only when the interviewers do not understand English)
  - Survey manual (only when the interviewers do not understand English)
  - Result codes
- What issues came up in the translation?
- What protocol was undertaken (e.g. the full translation was sent to the WHO or just a list of the key items)?
- Were linguistic evaluation forms completed?

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Chapter 8:   Data Dissemination and Utilization

8.1 Use results for M&E, policy and action

The data from prevalence surveys of TB among HCWs can lead to country/health facility- specific policy evaluation, policy revision and action, as described under indications for a survey.

8.2 Data Dissemination levels

The dissemination of data at the right level and to the right target audience is the key to its utilization. Data on the prevalence of TB among HCWs can be disseminated at various levels; the individual level, the facility level, the country level (national level) and the global level.

8.2.1   Data Dissemination at the Individual Level

The provision of data or results of TB testing to an individual HCW must be carried out in a confidential manner. This can be done both verbally and in a written form. It should be noted that both the HCWs with (suspected) TB and those without (suspected) TB, should get their results in the same way, to ensure anonymity. Additionally, the HCWs with TB should be encouraged to share this information with the relevant people in order to get support and follow-up services. See also WHO TB prevalence surveys: a handbook Chapter 11 [WHO 2011].

8.2.2   Data Dissemination at the Facility Level

At the facility level, data can be disseminated in the form of a report to the facility administrator. Data should always be anonymous, unless individual HCWs have given permission to share their data. At the district level, anonymous details of TB cases among HCWs should be made available to clinicians to make them aware of their local resistance profiles and to enable them to make better empirical treatment choices [MoH Ghana, April 2009, p110]. If anonymous, data can also be shared at staff meetings and conferences. The prevalence of TB among health staff at a facility can also prompt an evaluation of current TB-IC measures and encourage adjustments for better IC and prevention.

It should be noted that data at facility level should not contain identifying information, for example name, sex, age or job title. It may be possible to aggregate such details at the national level, but at the facility level the number of cases will be too small to ensure anonymity. Data can be shared across facilities in the form of a regional or annual facility meeting.

8.2.3   Data Dissemination at National Level

When considering the dissemination of data, the following target audiences need to be considered; the MoH (departments that deal with TB, HIV/AIDS and those that deal with health facilities/hospitals and occupational health), the Ministry of Finance, Labor Unions, HCW representatives, NGOs delivering health services, prison health services, professional associations such as medical and nursing schools, hospital/health facility directors, laboratory directors, community health care providers, researchers, health insurance entities, occupational health entities and the local offices of funding agencies such as the Global Fund.

8.2.4   Data Dissemination at the Global Level

Dissemination of the prevalence of TB among HCWs at the global level could take the form of an annual report, such as the WHO Global Tuberculosis Control annual report, which has an indicator on TB among HCWs. A report could also be sent to other global bodies such as the International Labour Organization (ILO), International Council of Nurses (ICN), International Federation of Red Cross and Red Crescent Societies (IFRC), and the International Federation of Infection Control (IFIC) in order to magnify dissemination and advocacy.

Data can also be summarized and disseminated through documents developed by allied international organizations such as the ILO which translates relevant health information and disseminates it to the health sector workforce. Data can also be shared at annual congresses, e.g. the International Hospital Federation (IHF) which represents hospitals and health facilities worldwide.

8.3 Target audience

When a specific target audience has been identified for the data dissemination, it is important to keep several issues in mind:
- The objectives for the sharing of data
- The key messages to be delivered
- The specific actions requested of the target audience
- Opportunities and entry points for using the data.

Each of the objectives mentioned in chapter 2 will have a result, and each of those results can be used for advocacy on different levels.

Example Boxes 1 & 2 illustrate how messages can be targeted at the national level and used for advocacy purposes, and are adapted from the "Advocacy Strategy for Adoption and Dissemination of the WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households" [WHO 2010].

Example Box 1: National Level Target Audience Example

NTPs often have little or no control over a number of the concrete actions that must be taken to improve TB-IC, so outreach to and advocacy by other ministries and other programs within the MOH may be essential to the success of TB-IC efforts. Specific mapping of key players at the national level will be needed to develop country-specific advocacy plans. These include:
- MoHs and their constituent National AIDS Control Programs (NACP), hospital services, and programs responsible for general IC
- Ministries of Infrastructure that are often responsible for the design, construction and renovation of public health facilities
- Ministries of Finance that are responsible for establishing budget priorities
- Ministries of Justice in order to promote TB-IC standards and implementation in prisons
- National HCW organizations and occupational health
- National hospital administrations

Advocacy Objectives:
- Countries adopt and implement national IC policies with a strong TB-IC component that is guided by the WHO's new TB-IC policy, and pandemic preparedness plans include measures that cover TB-IC as well

- Country health budgets include IC as an integral part of the health budget for training, procurement and infrastructure development
- MoHs mandate coordination between appropriate agencies, including NTPs and National AIDS Control Programs, in implementing TB-IC interventions and quantifying staff needs for the implementation of TB-IC
- High-burden countries submit an increased number of TB and HIV/AIDS applications to the Global Fund that request funding for implementation of IC measures consistent with WHO TB-IC policy
- Organizations responsible for the occupational health of HCWs value the impact of TB-IC measures in preventing TB among its workforce.

Key Messages:
- TB and M/XDR-TB transmission is occurring in health facilities, laboratories, prisons and other congregate settings, as well as in the community, with sometimes devastating impacts. Infection prevention and control is a cost-effective method of reducing TB transmission
- Implementing effective TB infection prevention and control can be accomplished in manageable steps and will contribute to the overall protection of the health workforce, the community and vulnerable populations, from airborne disease transmission. Such efforts will not only protect against TB transmission, but also avian influenza, SARS and other respiratory diseases. (This message should be tailored to country-specific conditions to include the greatest leverage points)
- The international community has mobilized resources, including funding, tools and technical support, to assist countries in adapting the WHO IC policy to their specific conditions and in achieving their IC implementation goals.

Advocacy Approaches:
- Use high level meetings to issue a call for action, sharing data about TB among HCWs
- Work with UNAIDS, the HIV Department, and PEPFAR programming to ensure uptake of the 3 I's strategy (intensified case finding, infection control and IPT), in MoHs and NACPs
- Use regional meetings, such as the African Union Health Ministers Meeting and East, Central and Southern African Health Community meetings to present the results of the prevalence survey directly to Health Ministers and other senior health officials
- Ask UNODC to take the lead in advocating to Ministries of Justice on issues of TB-IC in prison setting and care of prison staff
- Request that regional economic organizations and regional health organizations place TB-IC on the agendas of their Ministers of Health meetings and offer expert speakers.

Advocacy Opportunities and Entry Points:
- World Health Assembly
- WHO Regional meetings of the NTPs and NACPs
- Country level annual meetings

Example Box 2: An Example of Groups to Target Representing Professional Associations and Unions

Professional Associations and Unions

Professional associations representing HCWs are a critical target audience in the execution of a global strategy for measuring TB among HCWs, and many of them are already engaged in TB-IC activities. The broader IC community includes a number of organizations with well-developed communications systems that can greatly increase the reach of TB-IC messages. Organizations representing doctors, nurses, hospital administrators, IC practitioners, architects, engineers and others, are well-networked at the international, national, and local levels and are excellent conduits for the dissemination of advocacy messages on the value of prevalence surveys among HCWs through publications and professional meetings as well as IC policies and protocols through training programs. With their vested interest in broad HCW safety issues, their support can help bridge between TB-IC and broader IC messages.

Priority Target Groups:
The Academy of Architecture for Health
American Thoracic Society (ATS)
Association of Practitioners in Infection Control (APIC)
European Respiratory Society (ERS)
Infectious Disease Society of America (IDSA)
International AIDS Society (IAS)
International Council of Nurses (ICN)
International Federation of Infection Control (IFIC)
International Federation of the Red Cross (IFRC)
International Hospital Federation (IHF)
Infection Control Africa Network (ICAN)
International Academy for Design and Health (IADH)
World Medical Association (WMA)

8.4 Effective Data Dissemination

In addition to targeting the appropriate audience, it is also recommended that effective information dissemination must also consider the role of opinion leaders and the willingness of the information recipients to accept new knowledge [Duggan 2004]. Two further elements to address in the dissemination of data are:

1. The barriers to effective information dissemination created by information providers' assumptions about their audience
2. The need for communication to be to persons who share the same values, ideas, beliefs etc. as the person with whom they are interacting.

Table 8. Examples of effective data dissemination applicable to HCWs

Provider (TB-IC focal point)		Recipient (HCW in a MDR ward)	
Internal factors	External factors	External factors	Internal factors
Change in behavior, attitude	Cultural constraints	Perceived relevance of the information	Information seeking style
Knowledge of TB-IC effectiveness and measures	Socio-economic factors	Participation in the TB-IC action plan	Fear of stigma attached to TB
Readiness to effect change for the facility or organization	Research-based data	Awareness of the benefits (decrease TB among HCWs)	Willingness to accept new ideas and change behavior
Concern for HCWs' occupational health and welfare	Mandate or regulation to protect HCWs against exposure to TB	Opportunity for continuing education and data dissemination	Knowledge of the benefits for individual health and well being

8.5 Use of Data

8.5.1   Use of Data at the Facility Level

At the facility level, the prevalence of TB among HCWs can be utilized to validate the effectiveness of IC measures such as managerial activities, administrative and environmental controls, the use of personal protective equipment and to make adjustments based on the results. The results of data at the facility level, when combined with knowledge, attitude and practice studies, can also be utilized to analyze the economic and psychological effects and possible barriers to the accessing of care of suspected and confirmed TB cases among HCWs. When the survey includes measurement of knowledge, skills and attitudes (KSAs); the effects of in-service education and/or continuing education on TB-IC can be assessed. The latter can also be done with a sample size smaller than that needed for a TB prevalence survey.

8.5.2   Use of Data at the Global level

At the global level, the data on TB prevalence can be used to describe the burden of disease among HCWs at a point in time, or identify trends in the burden of disease. The data can also be used to advocate for human and financial resources, policy decisions, changes in work practice or occupational health regulations as well as adjustments and/or revisions to TB-IC policies and guidelines.

At the global level relevant partners and stakeholders should be informed, such as TB CARE I and TB CARE II partners (ATS, FHI 360, JATA, JHPIEGO, KNCV Tuberculosis Foundation, MSH, PIH, Project Hope, UNION, URC, WHO) PEPFAR and the Global Fund. Other possible channels of dissemination to be considered include; country-specific presentations, presentations in regional and international meetings and publications in peer-reviewed journals.

8.6 Presentation of Results

For the presentation of results we refer to paragraph 16.4 of the WHO TB prevalence surveys: a handbook [WHO 2011]. For HCWs, results can be summarized by the type of facility, the type of profession, exposure to TB patients and age. Essential indicators are given in 2 reviews [Joshi 2006, Baussano 2011].

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Chapter 9: Ethics & Strategies to Increase Participation Rate and Avoid Stigma

9.1 Introduction

This section describes the ethical considerations surrounding the conducting of TB prevalence surveys among HCWs. The main ethical issues and strategies to increase participation rate and avoid stigma can be read in chapter 10 the WHO TB prevalence surveys: a handbook [WHO, 2011]. Chapter 6 and Section 3 of Appendix 3, deal with informed consent process. We highlight some issues that are specific for HCWs or which have not been mentioned in the handbook.

9.2 Curricula on Ethics

Although ethical principles are universal, there are few tools available to help researchers learn about the development and philosophy of ethics or find out how ethical principals can be applied in a practical way.

Two examples are given here:
1. NIH. See http://www.nihtraining.com/gcp.html
2. FHI 360 has developed two curricula to help fill this need. Research Ethics Training Curriculum, Second Edition [http://www.fhi360.org/training/en/RETC2/index.html]

This edition updates the curriculum on fundamental ethical considerations in the design and implementation of research involving human participants. It complies with the training requirements of major funders and national and international research organizations. The curriculum can be used either as an interactive self-study program or for participatory group training.

9.3 Ethical Issues in HCW Prevalence Surveys

Some specific ethical issues in carrying out TB surveys are discussed in the WHO TB prevalence surveys: a handbook, chapter 10.4 [WHO 2011]. When embarking on surveys of TB among HCWs, the following additional issues should be taken into account:

1. In nationwide prevalence surveys screening usually takes place in the community, while surveys among HCWs may happen in their own facilities. Therefore extra attention should be paid to anonymity
2. HCWs have the responsibility to protect others against TB (not transmitting TB to others), but at the same time the results of the survey should be confidential. Therefore, HCWs diagnosed with TB should be encouraged to inform their facility heads, and at the same time facility heads should only get anonymous reports. (In community surveys, the local health authority is informed of the results)
3. HCWs may be more troubled by the stigma of TB because of work complications i.e. they may not be able to work and they may be avoided by colleagues.
4. Facility management may be reluctant to address TB among HCWs since HCWs can ask for financial compensation. It is rarely possible to prove that a HCW caught TB because of the work situation. However the compensation rules of the country and the facilities should be studied and discussed in advance
5. In some settings persons with CXR abnormalities need to be treated, even when their culture is negative

6. If a TB prevalence survey is combined with a survey on HIV, there are additional issues:
   a. If HCWs are HIV-infected, they may be advised not to work in TB and/or MDR-TB wards. Job relocation due to the increased risk of getting TB if infected (e.g. if HIV-infected) may be problematic due to stigmatization issues
   b. ART use and IPT use should be considered according to national policy.

9.4 Stigma Related to HIV/AIDS

HIV/AIDS has been a highly stigmatized illness because of its associations with sexual behavior, drug use and the fact that in many places it disproportionately affects those considered outside the so-called 'mainstream of society' - including men who have sex with men (MSM), sex workers, injection drug users (IDU) and migrant populations. Stigma can cause people to perceive individuals with or at risk of HIV as outsiders, reinforcing the feeling that HIV infection "couldn't happen to me." Stigma can manifest itself in a variety of ways, from ignoring the needs of a person or group, to inflicting psychological or physical harm.

A failure to deal with the issue of stigma may deter individuals from seeking voluntary counseling and testing or proper medical care. An emphasis on reducing stigma, particularly as it relates to women, is critical to eliminating discriminatory practices and laws, and to improving the quality of life for people living with or affected by HIV and AIDS.

A failure to address the issues surrounding stigma may hinder any prevalence survey of TB among HCWs, in that they will not come forward to be screened, and if screened they may fear the untoward consequences given the outcome of the screening.

For HIV testing see section 11.2 of the WHO TB prevalence surveys: a handbook.

Chapter 10: Budget Issues

Regarding budget development, guidelines can be found in the WHO TB prevalence surveys: a handbook, Chapter 12 and an example in the handbook annex 4.

For HCWs budgeting may differ in the following components:
1. The sample size will be smaller.
2. Diagnostic tools (CXR machines, field labs) will not be moved from community to community (unless there is a mobile CXR unit available) but diagnostic tests may be done in one central facility in a district or other geographical area and HCWs in surrounding smaller facilities may be asked to travel to the central facility.
3. Diagnostic tests may be funded by the facilities as a duty of care to their staff.

Some opportunities to save on budget are:
– Countries that have already completed or will complete nationwide surveys or that already have (or procured) equipment for active case detection in high-risk populations such as prisoners and refugees, since they may use the same equipment and staff.
– Utilization of routine health screening for HCWs, when this is already regulated.
  Some countries already screen HCWs annually or every two years. It would take some standardization efforts to adapt those routine events to a survey.
– Make the survey the start of routine HCW screening that should be funded by the facilities. Although data collection may be less standardized when compared to a separate research project, this method may be more sustainable.

Funding opportunities for prevalence surveys among HCWs may be found in several categories:
1. Research funding
2. Organizations with a mission to protect HCWs, e.g. the International Labour Organization (ILO), Eli Lilly Partnership, the American College of Healthcare Executives, (ACHE), the International Hospital Federation (IHF) and local unions
3. Funding for TB and HIV control, e.g. the Bill and Melinda Gates Foundation and the Global Fund.

Annexes: Example Registers and Forms

The example needs to be adapted to the country situation and survey situation, with regard to the screening algorithm, the diagnostic tools available and the terminology of cadres. This example assumes that only HCWs with symptoms will be investigated with sputum smear, culture and CXR. This will give an underestimate of actual TB point prevalence. In the example TB screening will be combined with HIV screening.

Here one example screening register with summary and two forms are presented. Only the register has names and that form will not be collected by project staff. Other forms use identification numbers. It is assumed that screening and suspect forms do not need names for proper patient care, since the screening person will also use their regular clinical forms for clinical care. The individual screening forms will not be entered in a database.

1. Register for screening of health facility staff:
   This register is a list of all staff which should be provided by head of facility and then be kept by the screening person. It contains names as the screening person should be able to identify who has not yet shown up and encourage them to come. It also registers the reasons for refusal, but this will not be collected by project staff. On this form, names can be linked to personal identification (PID) numbers. The PID numbers can be assigned consecutively by the facilities. The project will use a combination of the facility code and PID number.
2. Summary of the above register:
   Since the screening register contains names it cannot be shared with researchers. However, in order to assess bias in non-response and the reasons for non-response, this should be aggregated anonymously. In the example it was chosen to aggregate by cadre. It may also be possible to aggregate by other variables, although not too many at the same time, as this would require a full database which is not possible for people who decline.
3. Screening form of HCWs and treatment supporters for TB:
   This form should be filled in for every HCW that shows up for screening; it is needed to assess the risk of TB. It uses the personal ID number from the screening register.
4. HCW TB Suspect Form:
   This form is applicable to HCWs who are TB suspects; in order to make sure all results are collected and if TB treatment is started and completed. It uses the personal ID number from screening register.

Annex 1 - Register of TB Screening of Health Facility Staff
List all staff; to assess whether screening procedures completed. Start assigning ID number from number 1.

Facility name: _____   Name person screening: _____

Name	Sex	Dept.	Cadre*	Given ID nr	Date of assessment dd/mm/yyyy	Informed consent Y/N	If refused, reason?	If left facility tick here

DK = don't know. [Department is asked to make sure right person; not relevant smaller facilities].
Cadre: MO = Medical Officer, CO = Clinical officer, N = Nurse, A = administration/clerical officer, CDE=classified daily employee (driver, cleaner, kitchen, laundry, housekeeper, cleaner, guard), L = lab staff, EO = environmental officer, ML = Medical Licensees, TS = TB treatment supporter, P = pharmacy staff, O = other

Annex 2 - TB screening among HCWs: Summary Participant Register

Facility: _____Name of person(s) doing screening: _____

Reporting period (dates): __/__/20__ till __/__/20__

HCW screened by cadre. To be abstracted from screening register.

Cadre	Number working in facility	Number who reported for screening	Number who signed informed consent	Number of refusals
MO = Medical Officer				
CO = clinical officer				
N = nurse/midwife				
A = administration/clerk				
CDE=classified daily employee *				
L = lab staff				
EO = environmental officer				
ML = Medical Licensees				
P = pharmacy				
O = other				
TS = TB treatment supporter				
TOTAL				

*driver, cleaner, kitchen, laundry, housekeeper, cleaner, guard

Reasons for refusals and how often they occurred:

	Number
Already screened elsewhere	
Already on treatment	
Not willing to be screened in this facility	
Confidentiality	
Stigma	
Other:	

Annex 3 - Screening Form: Screening of HCWs for TB
(Adapted from TB CARE TB-IC Implementation Framework)

Identification

1. Health Facility: _____ 2. Date: __/__ /20__

2. Screener initials: _____

3. Personal unique number:_____ (copy from register)

4. Written informed consent: ☐ Yes   ☐ No   if no then stop!

5. Date of birth: __/__ /_____

6. Gender: ☐ Male   ☐ Female

Exposure History in Jobs

7. Job title/type of employment:

☐ Medical Officer ☐ Medical Licensee   ☐ Nurse/clinical Officer ☐ Environmental Health Technologist

☐ Pharmacy Staff ☐ Clinical Officer   ☐ Clerical Officer/ Administrative Staff   ☐ Classified Daily Employees/Driver/ Security Guard

☐ Laboratory Staff ☐ Treatment Supporter ☐ Other, specify:_____

8. Current work location(s) (more than 1 answer possible):

☐ Administrative areas with no patient contact (e.g. separate building from the one with patients)

☐ Administrative areas with limited patient contact

☐ Maternity wards   ☐ Pediatric Wards

☐ General outpatients Department   ☐ Emergency Departments/Rooms
(Waiting room and/or consultation room and/or most areas of health centres)

☐ TB Outpatient (DOT) Clinics   ☐ Dental/ENT

☐ Intensive Care   ☐ Radiology

☐ Inpatient medicine wards   ☐ Surgical wards

☐ MDR-TB Wards   ☐ ARV Clinic

☐ Laboratory   ☐ Pharmacy/dispensary

TB Contact

9. Did you have direct contact with TB patients in the last year?
(More than 1 answer possible)

☐ Yes, in own household   ☐ Yes, outside household

☐ Yes, in healthcare facility   ☐ No   ☐ Do not know

TB History

10.   Did you ever use medication to prevent you from developing TB, such as Isoniazid preventive therapy:

☐ Yes   ☐ No   ☐ Unknown

If yes
a.   in which year did you take IPT? _____
b.   duration of treatment: _____ weeks/months

11.   Are you currently on TB treatment

☐ Yes   ☐ No

12.   Did you ever have TB disease (if current fill yes):

☐ Yes   ☐ No   ☐ Unknown

If no, skip to next section on HIV
If yes can you tell about latest or current episode:
a.   Date of diagnosis: __/__/____ (if unknown tick here: ☐)
b.   Where was your TB diagnosed?
☐ Government facility   ☐ NGO facility   ☐ private facility   ☐ elsewhere, specify: _____
c.   How was the TB confirmed?
d.   Smear   ☐ yes ☐ no ☐ unknown
e.   Culture   ☐ yes ☐ no ☐ unknown
f.   Chest x-ray   ☐ yes ☐ no ☐ unknown
g.   Other   ☐ yes ☐ no ☐ unknown specify: _____
h.   Where did you receive treatment for your TB?
☐ Government facility   ☐ NGO facility   ☐ private facility   ☐ elsewhere, specify: _____
i.   Where was the TB notified?   ☐ own workplace   ☐ elsewhere   ☐ unknown
j.   Was your TB cured?   ☐ yes   ☐ no   ☐ unknown
k.   Have you had TB more than once? ☐ yes   ☐ no   ☐ unknown

13.   Have you ever been screened for TB as part of a facility screening program or job entry screening?   ☐ Yes ☐ No

a.   If so, where?   ☐ This Facility   ☐ Other Facility   ☐ Don't know
b.   How often?   ☐ Only job entry ☐ Every ___ months   ☐ Don't know
c.   When was the last screening? __/20__ (month/year)
d.   Which diagnostics methods were used? _____

14.   Are you part of a medical insurance scheme?   ☐ Yes   ☐ No
If yes, does it cover TB screening?

HIV Test and ARV Use

15.   Have you ever been tested for HIV?   ☐ Yes ☐ No
16.   Date of latest HIV test:__/__/20__ Is this less than 1 year ago? ☐ Yes   ☐ No
17.   Latest HIV test result: ☐ Positive ☐ Negative ☐ Unknown ☐ not willing to disclose
a.   If negative, never tested or unwilling to disclose: refer for voluntary counseling and testing
b.   If HIV positive: are you currently using ART? ☐ Yes ☐ No ☐ not willing to disclose

Other Risk Factors

18. Smoking history

a. Current smoker: ☐ Yes ☐ Yes

b. If no, past smoker: ☐ Yes ☐ No

19.　History of diabetes:
☐ Yes ☐ No ☐ Don't Know

TB Symptoms

20.　Do you currently have any of the following symptoms?

a. Cough ☐ Yes ☐ No if yes: duration _____days

b. Cough with blood ☐ Yes ☐ No if yes: duration _____days

c. Weight loss ☐ Yes ☐ No if yes: duration _____days

d. Night sweats ☐ Yes ☐ No if yes: duration _____days

e. Fever ☐ Yes ☐ No if yes: duration _____days

f. Chest pain ☐ Yes ☐ No if yes: duration _____days

g. Shortness of breath ☐ Yes ☐ No if yes: duration _____days

h. Other: _____ duration _____days

If the HCW has a cough for 2 weeks or more, or another combination of TB symptoms, consider TB suspect. For HCW known or suspected to be HIV infected, duration of symptoms is irrelevant.

21.　Is this HCW a TB suspect: ☐ Yes ☐ No ☐ unknown **If yes, fill suspect form.**

ACTIONS (tick box if done):

If TB suspect referred for sputum smears, culture and CXR evaluation to rule out TB ☐

For TB suspects who are HIV negative or unknown: arranged HIV counseling and testing. ☐

HIV test result date: __/__/__ ☐ positive ☐ negative ☐ unknown

Annex 4 - Example TB Suspect Form

1.   Health Facility: _____ Date: __/__ /20__
2.   Personal unique number:_____ (copy from register)
3.   Where was the staff referred for testing?

a.   Sputum smears ☐ own facility   ☐ elsewhere; where? _____
b.   Sputum culture ☐ own facility   ☐ elsewhere; where? _____
c.   CXR   ☐ own facility   ☐ elsewhere; where? _____
(this question is needed to collect outstanding results)

4.   Test results

	Date sputum collected	Date of result	Result
Smear 1			☐ Positive ☐ Negative ☐ Unknown ☐ ND
Smear 2			☐ Positive ☐ Negative ☐ Unknown ☐ ND
Culture 1			☐ Positive ☐ Negative ☐ Contaminated ☐ Unknown ☐ ND
Culture 2			☐ Positive ☐ Negative ☐ Contaminated ☐ Unknown ☐ ND
Chest X-ray			☐ Normal ☐ Cavitary ☐ Infiltrate ☐ Miliary ☐ Pleural Effusion ☐ Other, specify: _____ ☐ ND

Indicate ND if not done

5.   Does the employee have active TB disease: ☐ Yes ☐ No   If yes continue. If no STOP.

Encourage HCWs to disclose positive results to department in charge or facility in charge; but stress that project will not do this.

6.   Site of active TB disease:
☐ PULMONARY only ☐ Extra-pulmonary only ☐ Both pulmonary and extra-pulmonary

7.   Does the staff have bacteriologically confirmed MDR-TB? ☐ Yes ☐ No ☐ Unknown

8.   When did TB treatment start? __/__/_____

9.   Where is the HCW obtaining TB treatment: ☐ Own Facility ☐ Elsewhere: _____ ☐ DK

10. Was the HCW hospitalized? ☐ Yes ☐ No ☐ DK If yes, how long? _____days ☐ DK

11. Where was the case notified? ☐ Own Facility ☐ Elsewhere: _____ ☐ DK

12. How many days was the HCW on sick leave? _____ days ☐ DK

13. Treatment outcome: assessed date: __/__/__
a.   ☐ Cure   ☐ Treatment Completed
b.   ☐ Default ☐ Death   ☐ Failure   ☐ Transfer   ☐ Other

14. Any remarks?_____

Annex 5 - Example Summary Results

	Indicator name	Numerator	No	Denominator	No	%
1	HCW who had documented TB screening	Number of HCW who were screened		Number of HCW working in facility		
2	HCW with any past TB disease (lifetime prevalence)	HCW with past TB disease		HCW who were screened		
3	HCW with TB disease in last 5 years	HCW with TB in last 5 years		HCW who were screened		
4	Proportion TB suspects	HCW who were TB suspects during screening		HCW who were screened		
5	Proportion complete smears	HCW with suspected TB who had documented smear examination		HCW who had documented TB symptoms(=HCW with suspected TB)		
6	Proportion complete CXRs	HCW with suspected TB who had documented CXR		HCW who had documented TB symptoms (=HCW with suspected TB)		
7	Proportion complete culture	HCW with suspected TB who had documented culture		HCW who had documented TB symptoms (=HCW with suspected TB)		
8	Prevalence of total TB among HCW	Number of HCW with any type of TB Total		Number of HCW screened Total		
9	Prevalence of bacteriologically confirmed TB	Number of HCW with smear or culture positive TB		Number of HCW screened		
10	Cases of multidrug-resistant TB among HCW	HCW with drug resistant TB		Number of HCW with active TB		
11	HCW with active TB disease placed on TB treatment	Number of HCW placed on TB treatment		Number of HCW with active TB		