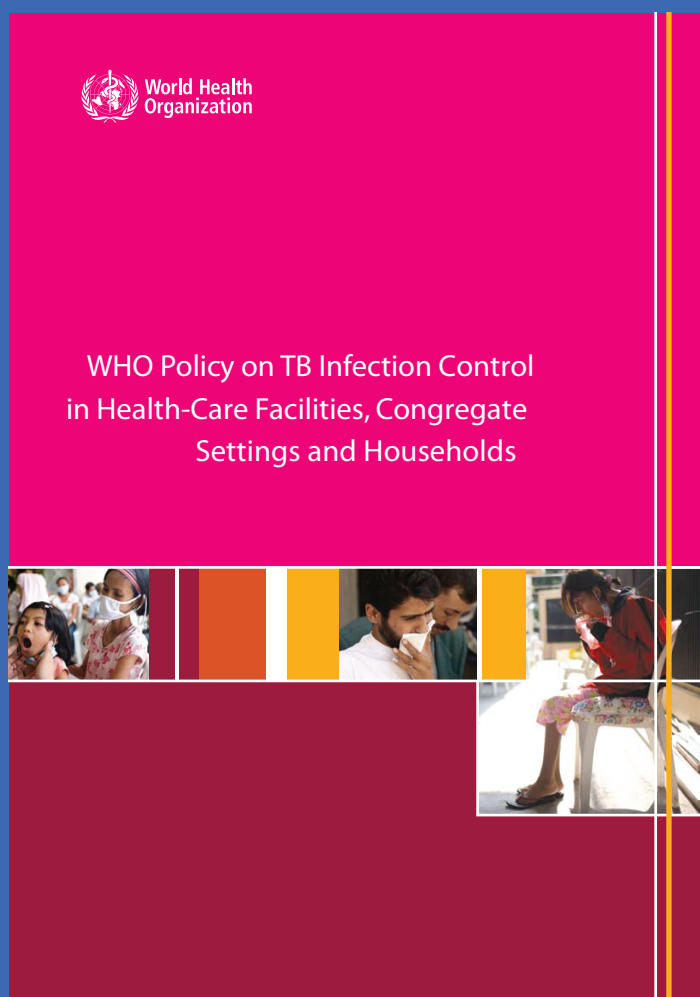
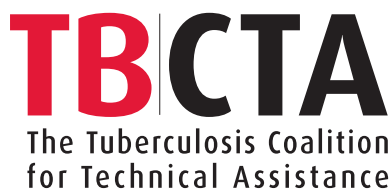


IMPLEMENTING the WHO Policy on TB Infection Control in Health-Care Facilities, Congregate Settings and Households

A framework to plan, implement and scale-up TB infection control activities at country, facility and community level



Developed by the Tuberculosis Coalition for Technical Assistance (TBCTA) under the auspices of the TB-Infection Control Sub-group of the Stop TB Partnership.



Disclaimer

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Preface

It is a great pleasure to present this *TB Infection Control Implementation Framework* which is compiled to complement the 2009 *WHO Policy on TB Infection Control in Health-Care Facilities¹, Congregate Settings and Households*. This framework has been developed so that National Tuberculosis Control Programs, partners and interested parties have access to key sources of guidance to promote awareness on infection prevention and control within their individual service.

Healthcare-associated infections can exact a heavy price, both in terms of human lives and also in resources. From the smallest facility to the most complex healthcare system, organization-appropriate infection control interventions have to be part of an organization's overall strategy and long-term planning. Infection prevention and control should be proactive and appropriate for the unique characteristics and challenges of that country, facility or community.

Successful infection prevention and control can be summarized as follows: Applying basic infection control strategies, quality management practices, and effective work practices which avoid transmission of infectious organisms. Organizations need to conduct periodic risk assessments, modify their interventions, plan and use a collaborative approach to prevent infections.

TB infection control should not be viewed as an isolated intervention, rather it is part of general infection prevention and control (IPC) and an important part of a TB prevention and treatment package, along with Isoniazid Preventive Therapy (IPT), Intensified TB Case Finding (ICF), TB treatment and access to early Anti Retroviral Therapy (ART).

This framework has been designed for resource limited countries and is a living document which will need to be updated at regular intervals to reflect changes in work practices, lessons learned and new evidence from operational research.

Working within the framework, healthcare workers, facility managers, policy makers and program managers will have an opportunity to exchange knowledge and experiences with infection prevention practitioners, engineers, and architects.

The framework provides practical examples, tools, fact sheets and case studies drawn from countries for easy adaptation and use. All examples are downloadable² and can be customized to meet your specific setting.

¹ <http://www.who.int/tb/publications/2009/en/index.html> (Document Number: WHO/HTM/TB/2009.419)

² <http://www.tbcta.org/Library>

How to use this Framework

This framework has been designed for those clinics, hospitals, congregate settings and households wishing to start TB-IC implementation efforts but lacking strategies on how to make IC part of their daily work process.

The framework walks you through the WHO policy, tells you what the policy states for each recommendation, what the objective should be, who should be involved, what should be implemented and the recommended actions, and then offers suggestions and examples which have worked for others. Those examples which require a little more time to review have been placed in the Annex at the back of the book and also offer great ideas designed to help you achieve your TB-IC goals.

Often, the best way to start is with one or two items, such as the daily monitoring of natural ventilation or the monitoring of how effective your early triage of coughers is, before going forward with more strategies to reduce risk. Give your staff time to fully understand and to build the task into their daily activities, so that the measures can be built upon a foundation of prior accomplishment.

The framework contains guidance documents on how to monitor your progress and what types of data can be collected to show the improvements in your Infection Control program and in the care of your patients.

Acknowledgements

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Abbreviations

ACH	Air Changes per Hour
ACSM	Advocacy, Communication, Social Mobilization
AFB	Acid Fast Bacilli
AIDS	Acquired Immune Deficiency Syndrome
APIC	Association for Professionals in Infection Control
ART	Anti Retroviral Therapy
BSC	Biological Safety Cabinet
CDC	Centers for Disease Control and Prevention
C/DST	Culture and Drug Sensitivity Testing
CPT	Cotrimoxazole Preventive Therapy
CS	Congregate Setting
CXR	Chest X-Ray
DOTS	Directly Observed Therapy Short Course
DR-TB	Drug Resistant Tuberculosis
GOPD	General OPD
HATIP	HIV/AIDS Treatment in Practice
HF	Healthcare Facility
HCW	Healthcare Worker
HEPA	High Efficiency Particulate Air
HIV	Human Immune-deficiency Virus
HR	Human Resource(s)
IC	Infection Control
IEC	Information, Education and Communication
IGRA	Interferon Gamma Release Assay
INH	Isoniazid
ILO	International Labour Organization
IPC	Infection Prevention and Control (General)
IPT	Isoniazid Preventive Therapy
LTBI	Latent Tuberculosis Infection
MDR-TB	Multi Drug Resistant Tuberculosis
MOH	Ministry of Health
MSF	Médecins Sans Frontières
Mtb	Mycobacterium tuberculosis
M&E	Monitoring and Evaluation
NACP	National AIDS Control Program
NISOH	National Institute for Occupational Safety and Health
NTP	National Tuberculosis Program
OHS	Occupational Health and Safety
OR	Operational Research
PLHIV	People Living With HIV
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure
TB	Tuberculosis
TBCTA	Tuberculosis Coalition For Technical Assistance
TB-IC	Tuberculosis Infection Control
TST	Tuberculin Skin Test
USAID	United States Agency for International Development
UVGI	Ultra Violet Germicidal Irradiation
VCT	Voluntary Counseling and Testing
WHO	World Health Organization
XDR-TB	Extensively Drug Resistant Tuberculosis

Part 1: Introduction

All healthcare facilities, both public and private, and all other settings where TB patients or persons suspected of having TB congregate, should implement TB Infection Control (TB-IC) measures. The measures selected will depend on the infection control (IC) risk assessment, which in turn is based upon the local epidemiological, climatic and socioeconomic conditions, as well as the burden of TB, HIV and drug-resistant TB.

The increasing importance of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB), as well as the impact of HIV infection, has led to a reappraisal of the importance of TB-IC in healthcare facilities, congregate settings and households. TB-IC is one of the WHO recommended 12 collaborative TB/HIV activities³. Interventions to reduce TB morbidity and mortality in people living with HIV, in addition to the provision of ART include ICF, IPT and IC for TB.

These interventions are also branded as the Three 'I's for HIV/TB. The presence of many HIV-infected and immune compromised patients in healthcare and congregate settings and the absence of, or non-adherence to, appropriate IC policy and practice, create a favorable environment for the transmission of TB among hospital patients, HCWs and the community. There is therefore an urgent need to refocus attention on TB-IC, particularly in high risk settings and to accelerate the scale-up of TB-IC activities.

The lack of IC technical expertise and the many competing demands for TB control make it important to describe IC implementation as a feasible and step wise process. The goal of this document is to break down the implementation of TB-IC policy by clarifying actionable steps and explaining the rationale behind them, enabling countries to fully integrate TB-IC.

Structure of the Framework

Part 2 - describes the managerial activities which are considered to be essential, for the smooth implementation of the TB-IC measures. Managerial activities are necessary at national, sub-national and facility levels.

Parts 3-7 - describe the trio of administrative, environmental and respiratory protection controls in healthcare facilities and outlines specific recommendations for TB-IC in congregate settings and households.

Behind each policy topic are tools/examples/templates which can be downloaded and altered to meet your specific setting.

Parts 8-10 - contain all the references, the glossary and the annexes (which provide additional tools and examples).

3 See 'Annex: Collaborative TB/HIV Activities' page 98 for more details

Target Audiences

The primary audience for this document includes those providing healthcare at decentralized levels (regions, provinces, districts, facilities and communities), managers of healthcare facilities and community-based health services, managers of other congregate settings, such as correctional facilities, homeless shelters, barracks, refugee camps and representatives from professional associations (nurses, physicians, laboratory technicians etc.).

This document can also be helpful for those responsible for implementing national health systems planning and specific disease control programs such as National Tuberculosis Program (NTP) managers, National AIDS Control Program (NACP) managers and those responsible for Occupational Health and Safety (OHS) and Infection Prevention and Control (IPC) Programs.

Other stakeholders include academic institutions which provide training for healthcare workers, allied healthcare professionals (industrial hygienists, laboratory technicians, environmental engineers and architects) and consultants providing technical assistance to countries.

Representatives from the civil society such as advocacy groups, community-based and faith-based organizations and those which are affected by TB and/or HIV disease may also find this document useful.

Specific key target audiences which should be involved in each policy recommendation will be further listed in each segment of the document.

Getting Started

Prior to actual implementation, a risk assessment should be performed in each healthcare facility, congregate setting or community based organization in order to determine the types of interventions which will help form the IC plan for the site.

Actual implementation takes its lead from the national policies and takes into consideration socioeconomic circumstances, availability of resources, climatic conditions, opportunities for linkage with other programs and the current structure of the healthcare system with regard to the different levels of management and service delivery. Ideally, a description of the policies and actions should be defined for each and every management and service delivery level, but sometimes these are absent or not well defined.

TB-IC includes a spectrum of activities, from the simpler education of HCWs and patients about cough etiquette, to the more time intensive and complex creation of standard operating procedures (SOPs) related to clinic operations to address TB-IC and the conduct of a comprehensive needs assessment on which to base a full fledged TB-IC plan. However, TB-IC activities can be scaled up, starting from the easier to implement activities, even as country programs are working on the more complex components. All activities, even the simpler ones if well planned, can contribute to reducing the risk of acquiring airborne TB. The programs are strongly encouraged to start implementing TB-IC, learn from that experience, and concurrently develop a more comprehensive TB-IC plan. The absence of a comprehensive plan which fully addresses all components, including the more complex activities, should not prevent a country or clinic from implementing at least some relevant TB-IC activities.

Example: Getting Started in Manafwa District

The following are examples of activities undertaken when Uganda had nothing more than draft TB-IC Guidelines.

Manafwa district, situated in Eastern Uganda, has a total population of 317,000 which are served by 165 HCWs working in 22 healthcare facilities. In 2008/9 the national TB and Leprosy Program registered 125 TB cases in the district. With support from the Union/TB CAP, the Manafwa district first developed an assessment tool and thereafter conducted a TB-IC needs assessment. The findings showed that unless something was done, most patients, attendants and staff were at high risk of being exposed to TB infection at the healthcare facilities:

Patients, including TB suspects, mingled freely in waiting areas, ventilation in consulting rooms and laboratories was poor, most of the staff were not aware of recommended TB-IC measures and TB suspects waited for long hours in queues with other patients.

Over one year, HCWs in 12 districts were trained in all aspects of TB-IC. Healthcare facilities put in place interventions such as triage, moving TB suspects to the front of the line, creating separate waiting areas, appointing one staff member to ensure that windows are opened at the start of each day's activities, assisting health centers to develop TB-IC plans, radio programs to enhance community awareness and the renovation of the health center laboratory in order to improve ventilation.

After one year, a review of TB-IC measures in place in 105 healthcare facilities in the 12 districts (including Manafwa) showed 70% had TB-IC plans; 95% had a TB-IC officer in place; 85% were separating coughers; 81% were conducting health education on cough etiquette and 90% were using the ICF tools for TB assessment of PLHIV in the facilities.

Table: WHO Policy Recommendations

Set of Activities for National and Sub-national TB Infection Control

Managerial Activities:

The national and sub-national managerial activities listed below provide the managerial framework for the implementation of TB-IC in healthcare facilities, congregate settings and households.

1. Identify and strengthen a coordinating body for TB-IC, and develop a comprehensive budgeted plan that includes human resource requirements for implementation of TB-IC at all levels.
2. Ensure that health facility design, construction, renovation and use are appropriate.
3. Conduct surveillance of TB disease among health workers and conduct assessment at all levels of the health system and in congregate settings.
4. Address TB-IC advocacy, communication and social mobilization (ACSM), including engagement of civil society.
5. Monitor and evaluate the set of TB-IC measures.
6. Enable and conduct operational research.

Set of Measures for Facility-level TB Infection Control

The measures listed below are specific to healthcare facilities. More details on congregate settings and households are given in Part 6 and 7, respectively.

Facility-level Measures

7. Implement the set of facility-level managerial activities:
 - a. Identify and strengthen local coordinating bodies for TB-IC and develop a facility plan (including human resources, policies and procedures to ensure the proper implementation of the controls listed below) for implementation.
 - b. Rethink the use of available spaces and consider renovation of existing facilities or construction of new ones to optimize implementation of controls.
 - c. Conduct on-site surveillance of TB disease among HCWs and assess the facility.
 - d. Address advocacy, communication and social mobilization (ACSM) for health workers, patients and visitors.
 - e. Monitor and evaluate the set of TB-IC measures.
 - f. Participate in research efforts.

Administrative Controls

8. Promptly identify people with TB symptoms (triage), separate infectious patients, control the spread of pathogens (cough etiquette and respiratory hygiene) and minimize time spent in healthcare facilities.
9. Provide a package of prevention and care interventions for staff, including HIV prevention, ART and IPT for HIV-positive staff.

The administrative controls include (in addition to the items listed above) reduction of diagnostic delays, use of rapid diagnostic tests, reduction of turnaround time for sputum testing and culture, and prompt initiation of treatment.

Environmental Controls

10. Use ventilation systems.
11. Use ultraviolet germicidal irradiation (UVGI) fixtures, at least when adequate ventilation cannot be achieved.

Personal Protective Equipment

12. Use particulate respirators.

Part 2 Managerial Activities



Part 2: Managerial Activities - Coordination and Organization

TOPIC: Identify and Strengthen a Coordinating Body for Infection Control

WHAT THE WHO POLICY STATES: Infection prevention and control practices cut across many institutions. The involvement of dedicated leaders in TB-IC, calls for a strong coordination effort in planning, implementing and evaluating control measures at all levels.

What is the objective:

To define the leaders who will oversee successful implementation of TB-IC activities.

Who should be involved:

All IPC, NTPs, NACPs, Police, Army, Correctional services, non-governmental and international collaborative partners and representatives of the society at large and patients in particular at national level and all departments and auxiliary units at facility level.

What should be implemented:

Establish a working group of interested key leaders from various institutions and assign responsibilities for the planning, implementation and evaluation of TB-IC within their jurisdiction. With good commitment, the establishment of coordinating bodies or teams is very feasible. Also include those (international experts) in TB-IC to provide assistance as required⁴.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and identify the persons responsible for those actions.

1. List existing coordinating bodies within the health service delivery system who are willing to take responsibility for TB-IC;
2. Establish a working group, committee, task force, team or focal person to oversee major activities regarding TB-IC;
3. Define the terms of reference (membership, responsibilities, tasks, meeting and reporting guidelines) of the selected group to incorporate TB-IC content;
4. Ensure adequate technical assistance to do the following:
 - Do a situational analysis/facility assessment on TB-IC.
 - Develop or review technical guidelines, standards & policies.
 - Draft a budgeted country or facility implementation plan.

4 <http://www.stoptb.org/countries/tbteam/>

Example: How Vietnam formally established a National TB-IC Team related to its MDR-TB program. Vietnam appointed a National Task Force with the following tasks and responsibilities (Courtesy of NTP Vietnam)

Ministry of Health Viet Nam Socialistic Republic

**National Hospital of
Tuberculosis and Respiratory
Diseases**

No: 298/QD-BVL&BPTU-DAPCL

Independence - Freedom - Happiness

Hanoi, August 12th , 2009

Decision

About establishment of the national TB infection control team

Director of the national hospital of tuberculosis and respiratory diseases

- Based on the Prime Minister Decree No 273/TTg dated June 24th, 1957 about the establishment of the National Institute of Tuberculosis;
- Based on the Ministry of Health's Decision No 1975/QD-BYT dated June 2nd, 2005 that defined the function, task of the National Hospital of Tuberculosis and Respiratory Diseases;
- Based on the Ministry of the Interior Degree No 10/2004/TT-BNV dated February 19th, 2004 about the guidance of some articles in the Government Decree No 116/2003/ND-CP dated October 10th, 2003 17/8/2007 about recruitment, utilization and management of the staff of state organizations.
- Based on the Minister of Health Decree No 4048/QD-BYT dated October 17th, 2008 about approval of the proposal for roles and responsibility in implementation, organization, staff of the National Hospital of Tuberculosis and Respiratory Diseases (NHTRD) according to the inter-Ministry of Health and Ministry of the Interior Degree No 02/2008/TTLT/BYT-BNV dated January 23rd, 2008;
- Based on the Ministry of Health Degree No 352/QD-BYT dated January 30th, 2008 about establishment management board of the TB disease control and prevention project under the targeted program of some social, danger diseases and HIV/AIDS control and prevention for the period of 2006-2010;

According to the proposal of the secretary of the TB disease control and prevention project,

Decides

Article 1: Establish the National TB infection control team

Article 2: Roles and responsibilities of the team:

- Develop comprehensive plan on TB infection control for the MDR-TB management centers
- Monitor and evaluate TB infection control activities in the MDR-TB management centers
- Develop training curriculums and plans, participate as a trainer in the training courses on TB infection control
- Develop the SOPs for use of IC equipments
- Develop a guideline on infection control maintenance
- Develop performance indicators for infection control and a monitoring system
- Implement TB IC plans in the MDR-TB management centers

Article 3: This decision takes validity since the date of issue

Article 4: Head of Personnel Department, secretary of the TB disease control and prevention project and persons named in article 1 have responsibility for implementing this decision.

Receiving places:

- As in article 4
- Keep in archives, Personnel Department

TB disease control and prevention project

Director

Ass. Prof. Dr. Dinh Ngoc Sy
(signed & stamped)

Example: How Zambia Assigned the Existing TB/HIV Coordinating Body (Courtesy of NTP and TB CAP, Zambia).

Although TB-IC is not explicitly noted in the 'Terms of Reference', it is one of the 12 collaborative activities given priority. Zambia assigned the TB/HIV committees to take active responsibility for the implementation of TB-IC. The responsibilities are described for the national, provincial, district, health facility and community levels. The national TB/HIV committee started by developing national TB-IC guidelines, immediately followed by a TB-IC training program.

Terms of reference of Zambian National TB/HIV coordinating body:

- To foster and coordinate the establishment of provincial, districts and community TB/HIV coordinating bodies.
- To develop national policy guidelines and monitoring tools for TB/HIV collaborative activities and periodically review and update the guidelines.
- To provide technical expertise in capacity building for the implementation of such guidelines at all levels of healthcare.
- To foster and coordinate the implementation of TB/HIV activities at various levels of healthcare.
- To monitor and evaluate the implementation of collaborative TB/HIV activities.
- To facilitate the development and dissemination of information on collaborative TB/HIV activities.
- To promote relevant TB/HIV operational research.
- To be proactive in identifying actual and potential sources of funding for the implementation of TB/HIV activities.
- To give feedback on reports from provincial TB/HIV coordinating bodies.

Example: How Cambodia formulated responsibilities for IC at facility level (Source: National Infection Control Policy MOH Cambodia)

The 2009 National Infection Control Policy of Cambodia includes TB and other airborne infections. The policy specifically addresses responsibilities for its implementation at all levels. Shown are the Terms of Reference for the health center level.

Terms of Reference of IC Team (ICT) at Health Centers:

1. Focal contact for IC in the health center
2. Ensure the appropriate implementation of IC guidelines
3. Work with local rapid response team to implement IC activities at the community level

In healthcare facilities there must be an ICT.

This team will follow guidance both from the provincial ICT and the Department of Hospital Services (DHS). The team is responsible for day-to-day running of IC activities.

The ICT must ensure that there is a comprehensive plan for IC in their healthcare facility.

The team should meet on a regular basis to discuss relevant issues and report to Operational District, Provincial Health Department, and DHS respectively.

The secretary of the ICT plays a role as an IC nurse and must spend dedicated time on IC activities in Health Centers.

Membership of the ICT at Health Centers

- Health Center Director, Chair
- IC Nurse, Secretary
- Program Managers, Member
- Representative(s) of Village Health Volunteers, Member(s)

Organization of TB-IC at Facility Level

As with all other functions of a healthcare facility, the ultimate responsibility for the prevention and control of infection rests with the administrator.

The administrator/head of hospital should:

- Establish an IC committee which will in turn appoint an IC team;
- Provide adequate resources for effective functioning of the infection control program.

Infection Control Committee

An IC committee provides a forum for multidisciplinary input, cooperation and information sharing. This committee should include wide representation from relevant departments: e.g. management, physicians, other HCWs, clinical microbiology, pharmacy, sterilizing service, maintenance, housekeeping and training services.

It should elect one member of the committee as the chairperson (who should have direct access to the head of the hospital administration) and appoint an infection control practitioner (HCW trained in the principles and practices of infection control, e.g. a physician, microbiologist or registered nurse) as secretary.

The IC committee should meet regularly (ideally monthly but not less than three times a year), develop its own infection control manual/s and monitor and evaluate the performance of the infection control program. The committee must have a reporting relationship directly to either the administration or the medical staff to promote program visibility and effectiveness.

It has the following tasks and responsibilities:

- Oversee the implementation of the infection control program;
- Review and approve a yearly program of activities for surveillance and prevention;
- Review epidemiological surveillance data and identify areas for intervention;
- Develop hospital policies for the prevention and control of infection;
- Assess and promote improved practice at all levels of the health facility;
- Ensure appropriate staff training in IC and safety management;
- Ensure provision of safety materials such as personal protective equipment;
- Organize the training of HCWs.

Infection Control Team/Focal Person

The IC team is responsible for the day-to-day activities of the infection control program. Health care establishments must have access to specialists in infection control, epidemiology, and infectious disease, including physicians and infection control practitioners.

In some countries, these professionals are specialized teams working for a hospital or a group of healthcare establishments; they may be administratively part of another unit (e.g. a microbiology laboratory, medical or nursing administration, public health services). The optimal structure will vary with the type, needs and resources. The reporting structure must, however, ensure the IC team has the appropriate authority to manage an effective infection control program. In large facilities, this will usually mean a direct reporting relationship with senior administration.

The IC team or individual/focal person is responsible for the day-to-day functions of infection control, as well as preparing the yearly work plan for review by the IC committee and administration.

The infection control team should:

- Consist of at least an infection control practitioner who should be trained for the purpose;
- Carry out the surveillance program;
- Develop, disseminate and supervise infection control policies;
- Monitor and manage critical incidents;
- Coordinate and conduct training activities.

Part 2: Managerial Activities - National Policies, Standards, Technical Guidelines and Procedures

TOPIC: Adopt Policies, Standards and Technical Guidelines

WHAT THE WHO POLICY STATES: The 2009 WHO policy provides guidance for national authorities on how to develop their own policy and technical guidelines according to the local situation in their country. Countries are encouraged to create a national policy, standards and technical guidelines supported by sound, evidence-based practices.

What is the objective:

To provide national guidance to managers/providers at all levels of the healthcare system and other relevant sectors, regarding what needs to be achieved to reduce the transmission of TB.

Who should be involved:

Department of Planning and Policy Development, NTP, Department of Clinical Services, Human Resources Department, Department of Infrastructure, Department of Prisons, Provincial, Regional and District Health Offices, Environmental Engineers or Hygienists, Facility Management, Regulatory bodies and civil society activists and non-governmental organizations that are based in communities with high rates of TB.

What should be implemented:

National policies, standards and guidelines should be adhered to and reflected in work practice.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and other relevant sectors, and identify the persons responsible for those actions.

1. Gather and review any existing relevant/related national policies, guidelines, manuals and procedures; taking into consideration the new WHO policy on TB-IC. Request the assistance of international TB-IC experts if needed;
2. Where possible, incorporate TB-IC into existing IPC policies or use TB-IC as a starting point for developing IPC plans;
3. Amend the general IPC policy periodically to incorporate newer evidence-based practices in the control of TB and other airborne diseases;
4. Amend any separate related policies and regulations, for example the Occupational Health and Safety policy, HIV and AIDS Workplace policy, or Infrastructure policy to reflect advances in the science of TB-IC;
5. Ensure that training and other capacity building programs reflect the recommendations in the national policies and guidelines and result in change in behavior;
6. Disseminate updated policies, guidelines and manuals to all affected ministries, departments of public health, schools of medicine and nursing, and hospitals;
7. Provide a timeline for adoption, then monitor and evaluate the incorporation of and compliance with the policies. Report back to the MOH for further action if needed.

Example: Table of Contents of the National Guideline for the Prevention of the Transmission of Tuberculosis, Ethiopia

The Federal Ministry of Health (FMOH) had Global Fund support for the development of MDR-TB guidelines. The FMOH and its collaborative partners in TB Control realized the importance of the transmission of drug-resistant TB and engaged international experts to conduct a situational analysis of TB-IC practice in the healthcare facilities. Based on the situational analysis report the FMOH decided to also formulate national TB-IC Guidelines⁵ for ALL healthcare facilities. Ethiopia was one of the first countries to develop TB-IC technical guidelines which are in line with the WHO Policy. Below is the 'table of contents' from the document showing how the guidelines are structured. (Courtesy of NTP, FMOH, Ethiopia and TB CAP, Ethiopia).

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- LIST OF BOXES
- LIST OF FIGURES
- ABBREVIATIONS
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- GLOSSARY

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- 3.3 Environmental controls
 - 3.3.1 Intervention 9: Natural ventilation
 - 3.3.2 Intervention 10: Mechanical ventilation
 - 3.3.3 Intervention 11: Upper room or shielded ultraviolet irradiation
- 3.4 Personal protective interventions
 - 3.4.1 Intervention 12: Use of respirators
- 3.5 Consideration for special areas

- 3.5.1 TB Hospitals and MDR-TB Treatment Facilities
- 3.5.2 Waiting Areas
- 3.5.3 Radiology
- 3.5.4 Sputum induction and cough-inducing procedures
- 3.5.5 Surgical and Autopsy suite
- 3.5.6 Intensive care areas
- 3.5.7 Immune suppression and TB

- 4.1 TB infection control interventions
- 4.2 TB Infection Control Plan
 - 4.2.1 Lifecycle of infection control plans
 - 4.2.2 Training of Staff

5. REDUCING TRANSMISSION OF TB IN HOUSEHOLDS

6. TB INFECTION CONTROL FOR CONGREGATE SETTINGS

- 6.1 Managerial activities in congregate settings
- 6.2 Administrative controls in congregate settings
- 6.3 Environmental controls in congregate settings
- 6.4 Personal protective interventions in congregate settings

7. LABORATORY SAFETY

- 7.1 AFB Smear preparation
- 7.2 Preparation of liquid suspensions of M. Tuberculosis
- 7.3 Ventilated Cabinets
 - 7.3.1 Laboratory Fume Hoods
 - 7.3.2 Biological Safety Cabinets (BSCs)
- 7.4 Respiratory protection in the laboratory
- 7.5 Document laboratory accidents and investigate accordingly
- 7.6 Disinfection, sterilization and disposal of contaminated materials

ANNEX 1 SUMMARY OF ADMINISTRATIVE CONTROL MEASURES

ANNEX 2. SAMPLE OF INFECTION CONTROL PLAN

ANNEX 3. AN EXAMPLE OF MONITORING TOOLS

ANNEX 4. TB INFECTION CONTROL ASSESSMENT TOOLS

ANNEX 5. PROTOCOL FOR RISK ASSESSMENT

ANNEX 6. PATIENT MANAGEMENT

ANNEX 7. AIR CHANGES IN A ROOM

REFERENCES

5 http://www.tbcta.org/Uploaded_files/Zelf/MinistryofHealthEthiopia1280040820.pdf

Guidelines For Developing, Reviewing and Revising Policies and Procedures

[LOGO OF THE FACILITY OR THE NATIONAL SEAL]	YOUR HEALTH FACILITY [ADDRESS, ETC.]
Policy Title:	
Department(s):	Code #:
Original Date:	Page 1 of
Date Approved/Revised:	Approved By:
Document Filename:	Title:

I. POLICY: Policy statement

II. APPLICABILITY: Which staff is responsible for following policy?

III. DEFINITIONS: Define any terms used in policy if applicable.

IV. PROCEDURE: How the policy will be implemented and monitored.

V. REFERENCES: If applicable, indicate specific regulations or references, such as your national policy, provincial or district policies, WHO guidelines, etc.

VI. RESPONSIBILITY: Who is responsible for reviewing this policy?

VII. DATE OF NEXT REVIEW: Every year? Every two years? Policies are living documents that need periodic updating to reflect new science, lab tests, and optimal practices. This policy will be reviewed and updated as needed to reflect changes in national and international policies and scientific breakthroughs.

Policy Statements	Keep their descriptions brief, containing only what must be done or the desired outcome.
Procedure Statements	Describe the “how to do it” of a given task or procedure.
Audience	The employees, staff or community volunteers within your facility identified by their department or position.
Focus	Limit the document to only what is needed for the task and how you want the task to be completed.
Current Practices	When creating new policies for your site review all current research and literature including national standards and practice guidelines. Be sure to include them in your reference section as this is the foundation of your policy and practice.
Format	Keep the format simple and easy to read. Describe the process step by step, noting who is to do the task and if others are required to be involved. Write only one action step per line. Cross reference related policies within the document whenever possible.
Definitions	Define complex medical terms or abbreviations. Be specific and descriptive in your writing and use phrases that command the attention of the reader. For example, “Suspected TB patients must use tissues to cover their cough” and not say “Suspected TB patient should use tissues to cover their cough”.
Reality Check	Have other healthcare colleagues read the policy. Is it clear to them? If not, revise it for clarity.
References	When reviewing and revising a policy you must again consider all of the current literature, research and changes in practice which have occurred, including changes in national statutes, ethical standards and the professional scopes of practice. Be sure to update the policy’s reference section if new information has been added. Since policies are considered “living documents” they must be kept current to reflect the best standards of care for our patients.

Part 2: Managerial Activities - Facility Assessments

TOPIC: Conduct assessments at all levels of the health system and in congregate settings*

WHAT THE WHO POLICY STATES: The national coordinating body is responsible for ensuring the assessments of healthcare facilities in the country, to determine the risk for TB transmission and to monitor the status of implementation of control measures. This is particularly important due to the increased risk of TB exposure of HIV positive patients who may also be at the facility.

What is the objective:

To ensure that periodic facility assessments are undertaken at each facility, particularly prioritizing large hospitals, MDR-TB facilities and facilities which care for HIV patients, and that TB-IC problems and infrastructure issues are addressed and promptly remedied.

Who should be involved:

Department of Planning and Policy Development, NTP, Department of Infrastructure, Department of Clinical Services, Provincial, Regional and District Health Offices, Directors of Environmental Hygiene and Quality Control, Facility Management, Other Ministries and Non-governmental Organizations responsible for congregate settings.

What should be implemented:

Promote a system for conducting TB-IC facility assessments at regular intervals and develop a monitoring tool that ensures that TB-IC problems have been corrected, in order to maintain a safer environment in which staff members can work and patients can receive care.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and other relevant sectors and identify the persons responsible for those actions.

1. Allocate a budget provision for facility assessments in the TB-IC country or facility implementation plan;
2. Consider engaging (international) technical assistance (Ventilation engineers, Infection Control Practitioners or Environmental Hygienists) to conduct the initial facility assessments which will provide a base of information;
3. Ensure that a pool of national, regional and local assessors are trained and competent to conduct facility assessments;
4. Modify the standardized TB-IC facility assessment tool as needed to meet the needs of the facility;
5. Reassess a large number of facilities every year, to see if TB-IC standards are being applied in each site and where staff retraining and environmental/ building safety assistance is needed.
6. Incorporate TB-IC specific standards and indicators in an existing quality of care assessment tool or into the routine TB supervisory checklist;
7. Analyze findings and report all recommendations for improvement to the facility administration for action. Follow-up to ensure that changes have been made and adopted before the next planned site assessment.

WHO Facility Assessment Checklist

Part 2

Name of the Health Facility:			
Address:			
Telephone Number:			
Name of Responsible Person for Infection Control in this Facility:			
Services provided in this facility * Please tick with ✓	<input type="checkbox"/> Integrated TB-HIV Services	<input type="checkbox"/> TB Services	
	<input type="checkbox"/> VCT/ART Services	<input type="checkbox"/> GOPD	
	<input type="checkbox"/> In-patient Services		

TB Infection Control measures implemented in this health facility:

Managerial	Yes	No	Issues to be Assessed and Guide for Comments
1. Is there an IC team or responsible person in place?			<ul style="list-style-type: none"> At which level? Composition of the team? Comments:
2. Is there a Facility IC plan in place?			<ul style="list-style-type: none"> Provide copy of the plan, policies, and standard procedures and / or describe. Is the plan part of the facility plan? Is the plan properly budgeted? Is budget available for TB-IC? Does IC plan include staff training on IC? How many staff members have been trained in IC last year? Is there continuous professional education in IC? Is there coordination between TB and HIV departments? ART, VCT, CPT, IPT available? How are planned IC activities monitored and evaluated? Comments:
3. Has an IC assessment been done?			<ul style="list-style-type: none"> When was the last IC check or facility IC risk assessment done? Is there a plan (renovation and/or re-location) to optimize implementation of IC controls at the facility? Have any improvements been completed within the last year? Comments:

4. Is "on-site" surveillance on TB disease among staff being conducted (including monitoring and evaluation of IC)			<p>"on-site" surveillance systematically / regularly performed?</p> <p>Who is responsible for IC surveillance?</p> <p>How is it performed?</p> <p>How many staff developed TB disease?</p> <p>Are data / reports available?</p> <p>Give examples of indicators?</p> <p>Comments:</p>
5. Is health education on IC ensured for HCWs, patients, and visitors?			<ul style="list-style-type: none"> • How is it performed? • Any evidence of activity? • Are materials available for IEC • Provide examples of materials. <p>Comments:</p>
6. Does the facility participate in operational research (OR)?			<ul style="list-style-type: none"> • Are there any OR activities on IC? • How is it organized? <p>Comments:</p>

Administrative			Issues to be Assessed
<p>7. Which of the following recommended controls are practiced?</p> <ul style="list-style-type: none"> • Triage; • Separation; • Cough etiquette; • Expedient service delivery (prompt services for "coughers"). 			<ul style="list-style-type: none"> • Is there systematic screening of all patients for cough? • Are patients with cough separated early from other patients? • Are suspected or diagnosed TB patients separated from suspected or diagnosed HIV patients. • Is there a system established to prioritize smear positive cases such as creating an "express lane" to minimize the stay of these patients. • Is the flow of TB suspects / patients in the facility a risk for transmission? • Is there IEC regarding cough etiquette on site? How is it conducted? • What is the average waiting/turn-around time for lab investigations? • Are masks, tissues provided for coughing patients? <p>Comments:</p>

8. Package of prevention for HCWs, including HIV prevention, ART and IPT for HIV-positive staff			<ul style="list-style-type: none"> Periodic and or symptomatic TB screening of staff? If periodic, how often? HIV testing offered to staff? If necessary, where is (preventive) treatment offered? Can HIV positive staff opt out from work in a high risk area? <p>Comments:</p>
---	--	--	--

Environmental	Yes	No	Issue to be assessed:
1. Natural and/or mechanical ventilation in place, especially in waiting areas, examination room, sputum collection room and patient wards			<ul style="list-style-type: none"> What ventilation is in place? Provide sketch of windows, doors, fans and cross ventilation with measurements State of moving parts of windows? Check air flow (with smoke, vaneometer) Calculate ACH Maintenance of fans? Log complete? What is the average waiting time? <p>Comments:</p>
2. Outdoor waiting areas or open space			<ul style="list-style-type: none"> Are outdoor waiting areas large enough to seat patients without crowding. Use low walls that facilitate movement of fresh air. The roof of the structure should have sufficient overhang to protect occupants from sun and rain. <p>Comments:</p>
3. UVGI			<ul style="list-style-type: none"> Sketch if available. Functioning? Check with UVC meter Last maintenance check? Log complete? When were the lamps last replaced? <p>Comments:</p>

Personal Protection	Yes	No	Issue to be assessed:
1. Respirators available for staff			<ul style="list-style-type: none"> Which respirator model/type is used? In which departments? <p>Comments:</p>
2. Fit testing and/or fit check for respirators			<ul style="list-style-type: none"> How is it organized? Frequency of fit test <p>Comments:</p>

Specific activities of the assessment:

1. Make a flowchart of the patient flow through the facility.
2. Visit the OPD and TB wards and calculate the ACH at various sites.
3. Sketch of the facility: Include main room, anteroom, hallway, UV lights, other controls, windows, doors, etc.

Summary of the Assessment Visit:

Strengths	Weaknesses
-	-
-	-
-	-
-	-
Problems Identified	
-	
-	
-	
-	

Prioritization Table for IC Assessment:

	Priority High/Medium/ Low	Description	How to implement? Who is responsible?	When?	Estimate Budget	Comment
Managerial Activities						
1						
2						
3						
Administrative Control						
1						
2						
3						
Environmental Control						
1						
2						
3						
Personal Protective Equipment						
1						
2						
3						
4						
Date of Assessment:						
Date of Next Assessment:						

See 'Annex: ICAP TB Infection Control Practices: Facility Assessment' page 99 for more details.

Part 2: Managerial Activities - TB-IC Country and Facility Action Plans

TOPIC: Conduct Comprehensive Planning and Budgeting

WHAT THE WHO POLICY STATES: A country should have a comprehensive budgeted TB-specific infection control plan, which could be the model for action at provincial, regional and district levels. The planned activities in the country action plan should be based on the situational analysis e.g. TB prevalence, HIV prevalence, multi-drug resistant TB prevalence, health policies, and infection control assessments of facilities where TB patients are known to gather.

Every facility should also have an integrated budgeted IC plan and a focal person or team responsible for the implementation. The facility IC plan describes the high risk areas for TB transmission, provides information and targets on reducing TB and HIV rates among HCWs and patients. If the site has a laboratory, it should have its own biosafety plan and procedures.

What is the objective:

To plan and budget all major activities, which are essential for implementation of TB-IC at all levels.

Who should be involved:

Department of Planning and Policy Development, NTP, Departments of Infrastructure, Department of Clinical Services, Human Resources, Quality Improvement and the Department of Prisons, Provincial, Regional and District Health Offices, Facility Management and Non-Governmental Organizations which have oversight of, or work in facilities, congregate settings or community centers with high rates of TB/HIV.

What should be implemented:

Set priorities for implementation, reporting and accountability tasks for those persons responsible for performance indicators/ targets, time lines, budget and funds. All funding gaps should be reported to the local and national audiences noted above.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and other relevant sectors and identify the persons responsible for those actions;

1. Assign a coordinating body to develop and cost the country or facility action plan;
2. Identify funding sources (core budget, program budget, gaps) to the plan;
3. Merge planned activities in 'Over-arching' Strategic Plans;
4. Copy and send the country action plan to provincial, regional and district health offices, other Ministries and collaborative partners responsible for high risk congregate settings;
5. Include TB-IC in the annual Guidelines for provincial, regional and district health planning, including determined budgets for integration in their annual plans;
6. Review provincial, regional and districts health plans and visit some of their sites to see if TB-IC activities are being done;
7. Report back periodically to the Ministry, Provincial, Regional or District health offices and other interested departments on the findings, suggestions for improvement and the timeline for improvements to be completed.

Example: Draft Country Action Plan, Indonesia, which has been integrated in the National TB Strategic Plan. Shown are the major strategies and activities. (Courtesy of NTP Indonesia and TB CAP partners).

The plan also includes (not shown) responsible actors, performance indicators and targets, estimated budget, funding sources and gaps, time lines and the means of verification for each activity.

Overall responsible department:

National Tuberculosis Control Program

Implementing responsible partners:

YanMed Specialized Care

YanMed Puskesmas

Ministry of Public Security and Human Rights

Private sector

Objective⁷:

Contribute to health systems strengthening and management of TB control.

Strategies & Major Activities:

A. Strengthen coordination and build organizational capacity.

A.1 Establish national coordination team comprising of relevant stakeholders and link up with provincial DOTS teams at provincial level.

A.2 Conduct TB-IC in-service training and mainstream TB-IC in pre-service training curricula.

B. Regulate and facilitate uniform TB-IC implementation through service-specific guidelines, standards, policies and procedures.

B.1 Disseminate hospital guidelines and develop/disseminate guidelines for laboratories, health centers and prisons.

B.2 Develop and enforce building design standards for hospitals (accreditation standards), laboratories, health centers and prisons, taking into account the variety of activities that will be performed, the number of people entering and leaving daily and how to take advantage of the climatic environment.

B.3 Develop and disseminate IEC messages and materials for patients and HCWs.

B.4 Develop model TB-IC policies and procedures.

B.5 Determine procurement specifications for TB-IC equipment.

C. Monitor and evaluate TB-IC implementation including the impact of training, surveillance and reassessments.

C.1 Conduct surveillance of TB disease among HCWs.

C.2 Define a set of national core indicators to measure implementation progress and impact.

C.3 Assemble and train national and provincial assessment teams.

⁷ The focus of a country action plan is on managerial functions and procurement of adequate TB-IC equipment and supplies, whilst facilities focus on control measures (work practices) and procurement.

Example: Creating A Facility Infection Control Plan

It is important to take into consideration personal perceptions, motivations and people's beliefs which can derail the best intentions of an Infection Control Plan. The type of clinical focus (TB, HIV general services, etc) the number of beds, the number of employees, location, disease prevalence in the community, volume of patients and the risks of exposure to employees and patients should all be evaluated prior to the creation of the action plan. A key part of the strategy is engaging administrators, managers and other healthcare professionals and workers to visibly support the adoption of the plan and to diplomatically address and resolve issues with employees, patients and families through education. Written IC policies often relate to patient care activities, employee health or those practices related to prevention of illness. For instance, there might be general policies which affect all workers regardless of duty or status, or one might write specific policies for a particular unit or area. Either way the policies need to be supported by science and reflect the needs of the facility. Lastly, any policies should be consistently implemented if they are to benefit both patients and staff members whilst achieving the desired outcomes.

The facility plan will include, but not be limited to, the following areas:

- I. Identification / description of prioritized risks and risk areas related to infection control.
- II. Risk and Area-specific infection control recommendations and strategies to minimize, reduce or eliminate the identified prioritized risks.
- III. Assessment of TB disease among HCWs.
- IV. Assessment of TB and HIV prevalence in the patient population.
- V. Assessment of HCW training needs.
- VI. Training staff on TB, TB control and the TB infection control plan.
- VII. Educating staff periodically on signs and symptoms of TB disease, specific risks for TB for HIV-infected persons, and need for diagnostic investigation for those with signs or symptoms of TB.
- VIII. Assessment of patients to identify persons with symptoms of TB disease or who report being under investigation or treatment for TB disease.
- IX. Providing face masks or tissues to persons with symptoms of TB disease ("TB suspects") or who report being under investigation or treatment for TB disease ("TB suspects or cases"), and providing waste containers for disposal of tissues and masks.
- X. Patient flow and placing TB suspects and patients with TB in a separate waiting area or ensuring that they receive services faster.
- XI. Carry out laboratory investigation where facilities exist or immediately refer TB suspects to TB diagnostic services.
- XII. Ensuring that patients with TB are adhering to treatment.
- XIII. Using and maintaining environmental and respiratory control measures such as ensuring adequate ventilation and respirators, if applicable.
- XIV. Time-line and budget (e.g. material and personnel costs).
- XV. Monitoring the implementation of the plan.

Part 2: Managerial Activities – Human Resource Development

TOPIC: Develop Human Resources and Build Capacity

WHAT THE WHO POLICY STATES: Training on TB-IC work practices should be incorporated into the existing pre-service and in-service training programs. HCWs at all levels and all facilities should receive training and be engaged in improving safety for their patients and themselves.

What is the objective:

To build the capacity of HCWs to know when and how to protect themselves against health hazards at their place of work. Given that HCWs are the first line of defence in protecting themselves and others, adequate and appropriate capacity building and behavior change are crucial to the success of any TB-IC intervention.

Who should be involved:

All HCWs, trainers-of-trainers, managers and program coordinators, medical schools and nursing schools, credential bodies, professional bodies and associations.

What should be implemented:

Review the national HRD plan and incorporate TB-IC into the training curriculums of medical/nursing schools and related in-service training programs. Ministries of Education and Provincial, Regional and District health departments should be involved in the plans.

Recommended Actions:

Adopt appropriate actions different levels of the healthcare system and other relevant sectors and identify the persons responsible for those actions:

1. Complete a training needs assessment and determine the relevant groups and numbers of personnel;
2. As necessary modify job descriptions to incorporate responsibilities for TB-IC;
3. Determine the groups and numbers of staff to be trained annually on TB-IC. Consider adding TB-IC training to all newly hired staff at all levels;
4. Define professional standards, performance criteria and evidences of compliance of HCWs at key positions in implementing TB-IC;
5. Develop an integrated training plan, a performance-based TB-IC curriculum, trainers' and participants' manual, and training materials; Modify existing pre- and in-service training curricula, refresher courses, continuous medical education programs and training materials to include TB-IC;
6. Determine the resources and funding needed to support a national training and supervision plan;
7. Conduct parallel cascade training courses or incorporate TB-IC into current training efforts in TB, HIV, IC and/or OHS programs;
8. Document the names of trainees and the dates that training was received in both training registers/log books and the worker's personnel files. Maintain these numbers for reporting to MOH and other reporting bodies;
9. Monitor, assess and document changes in work practices after training and intervention. Report all improvements and non-compliance issues to the appropriate managers or ministries for retraining or further action.

Tool: The 10-Step Process for Developing Training Courses⁸

The process of developing performance-based training includes the following 10 steps. The first four steps constitute the task analysis which is necessary to design and develop both relevant and useful training materials. Steps 5–10 constitute the design and development process.

1. Define the target population for training (trainers, implementors, engineers, managers)
2. List the tasks to be performed by the target population on the job.
3. List the skills and knowledge needed to do the tasks.
4. Select the skills and knowledge to be taught. (These make up the “training objectives”)
5. Organize the selected skills and knowledge into suitable teaching units (Modules) and develop the training design (including brief outlines of module content and planned training methods).
6. Draft expanded outlines of modules, including instructional objectives, main body of text and the descriptions of training methods, examples and exercises.
7. Experts provide realistic examples and information for use in exercises.
8. Draft the complete modules, facilitator guidelines and course director guidelines.
9. Field-test the training materials*.
10. Revise and finalize training materials based on the field test.

* The Generic Training Modules can be downloaded here:

http://www.tbcta.org/Uploaded_files/Zelf/TBInfectionControlTraining1280047532.zip

Example: A country’s development and implementation of a TB-IC training cascade (Submitted by Zambia to the Union Conference 2010⁹)

Background

The introduction of TB-IC in Zambia has provided an opportunity to address the country’s efforts to combat TB infection. This example describes the process and challenges, associated with the rollout of TB-IC in Zambia.

Methods

In 2007, Zambia developed a national TB-IC strategy¹⁰ which included training key staff in facility risk assessment and the implementation of infection control measures.

Results

77 doctors, nurses, clinical officers, environmental and laboratory specialists and building professionals from all nine provinces were trained in the national TB-IC guidelines. Including the building professionals and environmental specialists ensured appropriate renovations in TB clinics and laboratories. The facility risk assessments visits found the need for administrative and environment control measures including patient triage and cough etiquette in all out-patient units including ART clinics. Maximum utilization of natural and mechanical ventilation in medical wards and laboratories was also assessed. Two of the three hospitals evaluated for possible programmatic management of MDR-TB were recommended as favorable sites.

Conclusion

Zambia can use the momentum of the national TB-IC scale up strategy to facilitate implementation of measures countrywide. Reducing risk of TB transmission in HIV care and treatment sites remains a challenge that will require implementation of strategies in collaboration with key partners. The existing efforts in general infection prevention and control committees at all levels of healthcare provide an entry point to emphasize implementation of TB-IC, including TB screening of HCW’s.

⁸ According to the need assessment and training plan, develop TB-IC courses and integrated training and refresher courses.

⁹ Authors: S. Kaminsa Kabanje , L. Zulu , C.M. Mukwangole, N. Mwananyambe , N. Kapata, C. Kaayunga, M. Maboshe , J. Nikisi , N. Kancheya , C. Thompson, M. Meis, Y.D. Mukadi.

¹⁰ See also ‘Annex: Strategic HRD for TB Infection Control’ Page 117 for more details

Tool: Assessment Tool to Evaluate and Document Changes in Work Practice
(V. Lipke, CDC, Modified from The Joint Commission on Hospital Accreditation)

This is an example of an assessment tool to evaluate and document changes in behavior or work practice following training and capacity building.

Assess if the following changes in work practice occurred after training	Yes (tick)	No (tick)
Develops an IC facility plan based on the population served, the organization goals, services provided and community disease burden.		
Evaluates periodically the effectiveness of the facility plan and modifies as needed. Measures compliance to regulations and standards.		
Develops and reviews infection control policies and procedures to be current with evidence-based methods and approaches.		
Serves as Infection Control Liaison for health facility, medical staff, community and local Health Department.		
Identifies opportunities for improvement based on observation, process indicators, outcome measures and other findings.		
Prepares, presents and coordinates educational workshops, lectures, discussions or instruction on a variety of infections control topics, and assists in the infection control orientation for new HCWs.		
Instructs patients/families in methods to prevent infection and illness.		
Recommends policies and procedures to screen HCWs annually for healthcare acquired illnesses.		
Supports evidence based Infection Control best practices and customizes the methods to the clinical situation.		
Uses data to support cost effectiveness of Infection Control methods and approaches to prevent infection.		

Part 2: Managerial Activities - Building Design, Construction, Renovation and Use

Part 2

TOPIC: Ensure that Building Design, Construction, Renovation and Use are Appropriate

WHAT THE WHO POLICY STATES: Building designs for hospitals, clinics and any other facility where TB patients are housed should incorporate features which reduce TB transmission. The location of a facility, climatic conditions, prevailing wind, space, national construction standards, actual and foreseen population volume and the types of services provided, patient flow and specimen movement, number of staff, furniture arrangements, capital investment budget and contracting regulations, all may need to be considered prior to any renovation or new construction.

What is the objective:

To ensure that building design, construction, renovations are appropriate for the buildings intended use and ease of operation and maximize the impact of available resources and advocate for increase in resources as needed.

Who should be involved:

Funding partners, Ministry of Works, Planning department of Ministry of Health, Infrastructure departments of other Ministries and Non-Governmental Organizations responsible for congregate settings, Infrastructure and Maintenance departments at sub-national and facility levels, architects, ventilation experts, hospital engineers, environmental engineers and facility managers.

What should be implemented:

Develop standards for airborne precautions specific for healthcare facilities which will be incorporated into the design of any construction or renovation project to the site. Require that engineers, architects, etc. share their plans for implementing TB-IC and risk reduction measures prior to the start of construction and renovation.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and other relevant sectors and identify the persons responsible for those actions.

1. Define and prioritize high-risk facilities and areas for greatest risk of airborne transmission;
2. Specify national building standards and examples for those identified high-risk facilities and areas;
3. Assemble a multidisciplinary team including an infection control point person, an architect and ventilation engineer before the design phase of every construction / renovation project;
4. Evaluate the use and utilisation of a facility and designated high risk spaces for example: MDR-TB clinics and wards, TB/HIV clinics, isolation rooms, waiting areas, interior corridors, sputum collection areas, laboratories and consultation rooms for maximum ventilation;
5. Periodically inspect the construction/renovation site. Question all deviations from the original plan and make notations for the provincial or district health department follow-up;
6. Garner high-level political commitment i.e. ministerial or cabinet, given the capital investment involved in construction and renovation.

Example: Design Standards for Adequate Ventilation of Spaces (Standard Operating Procedures for Reducing the Risk of Spreading M. Tuberculosis Health Care Facilities in Afghanistan and Building TB Facilities; Recommended Minimum Requirements, MSF)

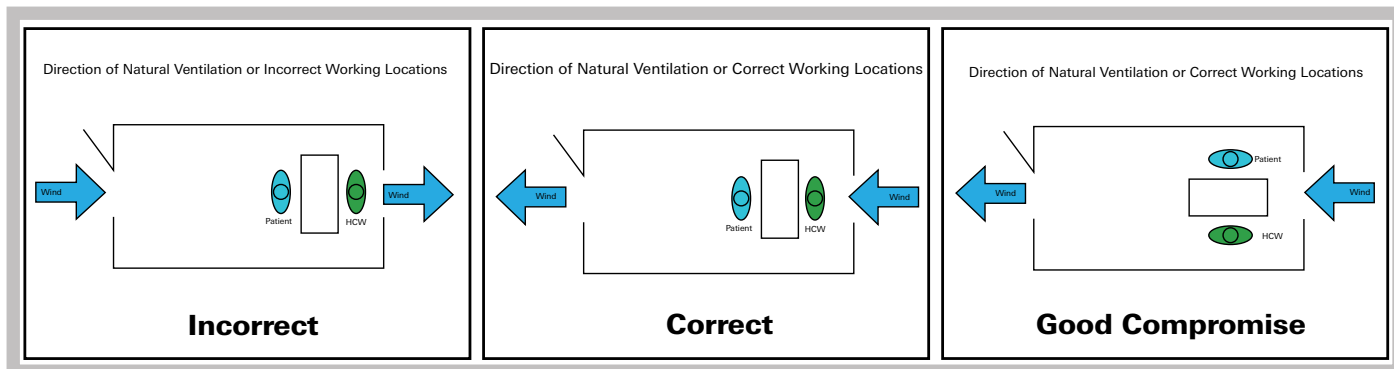
Create a ventilation rate of a minimum of 12 Air changes per Hour in TB/MDR-TB wards, waiting areas and all other areas with high risk.

- Place new building or select existing building for converting into TB ward/clinic in windy areas, such as mountains and coastal areas. Natural ventilation will improve infection control at minimum cost compared to mechanical ventilation.
- Position new buildings or select existing buildings for converting into TB ward/clinic separate from other buildings or urban settings, keeping in mind the need for access to care.
- If possible, construct buildings at least 4m apart to allow for adequate ventilation.
- Design buildings/spaces with openings in opposing walls transverse to the prevailing wind direction; place new buildings or select existing building for converting into TB ward/clinic on site where there is a good cross breeze.
- Separate staff areas from patient areas with additional doors in the halls as needed and reallocate the different sections within the building.
- Create anterooms before entering high risk areas, i.e. isolation wards, laboratories, sputum collection points indoor, between staff and patients areas.
- Create multiple separate waiting areas for different patients; big waiting areas can be sub divided for the separation of different groups of patients.
- Construct open-air sheltered or half-open spaces – with a roof to protect patients from sun and rain – to function as waiting areas, sputum production & collection points and day-time recreational areas.
- If possible, allocate 8-10m² of space for each smear positive patient bed. Create separate night accommodation for guardians.
- Construct rooms with high ceilings (2.5m minimum). Spaces with upper room UVGI require high ceilings.
- Design sloping ceilings/roofs with open gaps at the highest points that allow for the “stack” effect and will create a natural airflow as hot air rises.
- Using wind driven turbines on roofs is another way of increasing the ventilation.
- Openings at the end of passage ways allow for a constant draft of fresh air through often crowded passages.
- Consider large functional windows and grills/ventilation openings in and above entrance doors to create cross ventilation even if doors are closed.
- Additional high level windows, airbricks or vents just under the ceiling can improve ventilation during the night without the effect of a cold breeze directly over the patients.
- For natural ventilation a window with different opening parts is recommended above the window with one opening part. More openings allows for the regulation of the air flow.
- Construct showers and toilets which are well ventilated, especially as they are confined spaces used by many patients. In warm climates, the use of walls with holes will allow ventilation and privacy, a row of these in the wall at face level is recommended. Windows should be as large as possible. Opaque glass in louvers/shutters is another suggestion for the windows.
- Position furniture and seating within patient areas so as to allow for free airflow over desks and tables without affecting other patients and HCWs.
- The above recommendations are more compelling for MDR-TB management centers.

Example: Importance of sitting arrangement in naturally ventilated consultation room

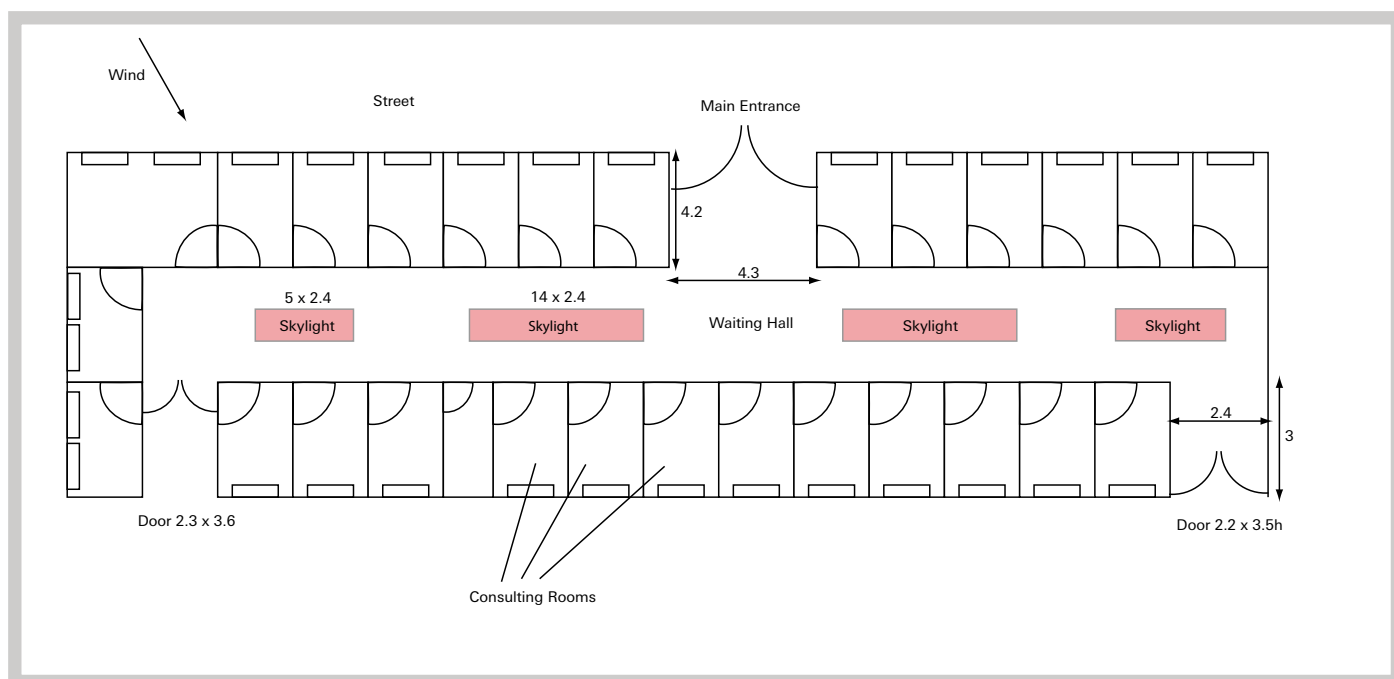
Knowing how to position yourself in a room can reduce the risk of acquiring TB. Make sure that everyone knows how to reduce their risk.

Part 2



Example: General Medical Out-patients Department Waiting Room (Courtesy of R. Escombe)

Just by something as simple as allowing air to escape through skylights, increased airflow and reduced the risk of transmitting TB to other patients and staff.



Internal photos of the waiting room with skylights:

Intervention: the sealed glass roof was raised on 1m stilts to create 4 skylights.

Mean ACH windows and doors open: 5.5

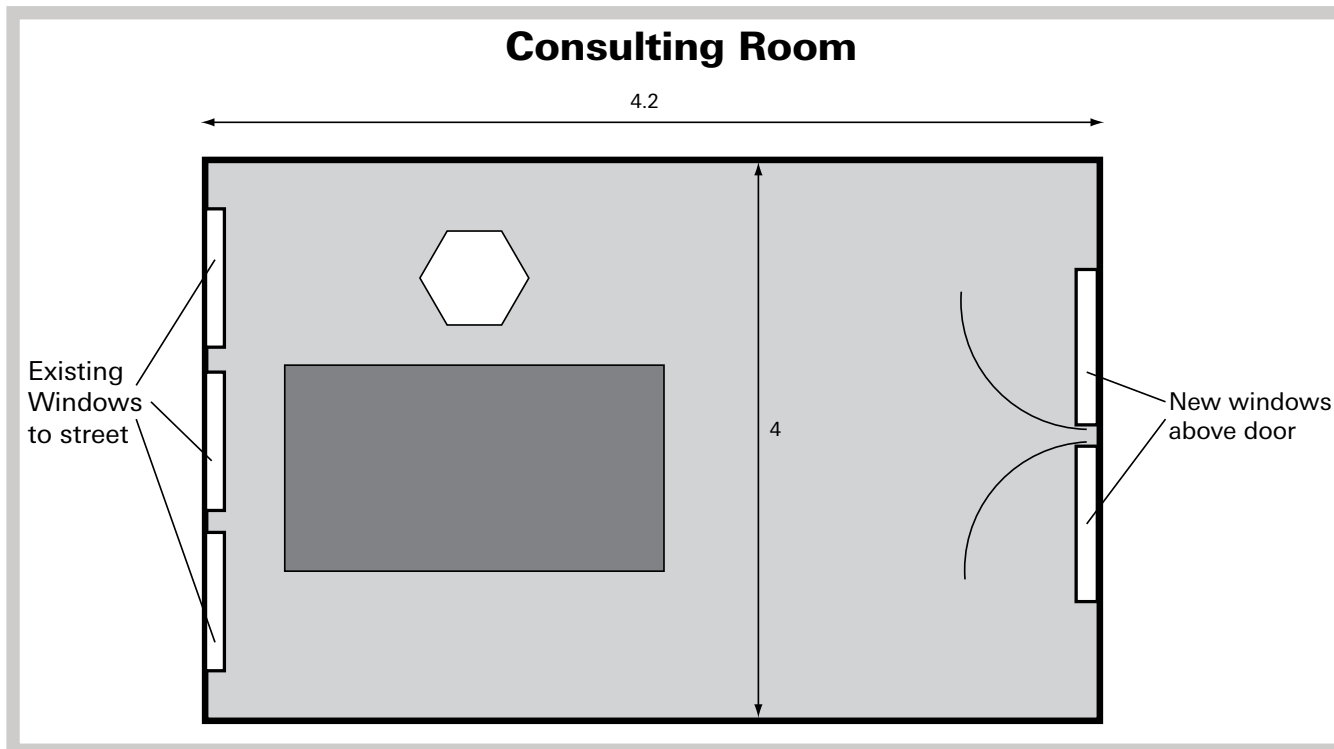
Mean ACH windows and doors and skylights open: 15

n=4 tracer gas experiments

By raising the glass sky light by 1m, it changed the amount of air exchanges per hour from 5.5 to 15. This significantly reduced the risk of TB transmission in the crowded waiting area.

Example: Medical Out-patients Consulting Room (adjacent to waiting room) (Courtesy of R. Escombe)

Part 2



Intervention:

Repair the windows above the door to allow cross ventilation.

Mean ACH:

Windows to street open (door closed, windows above door closed) 3.6.

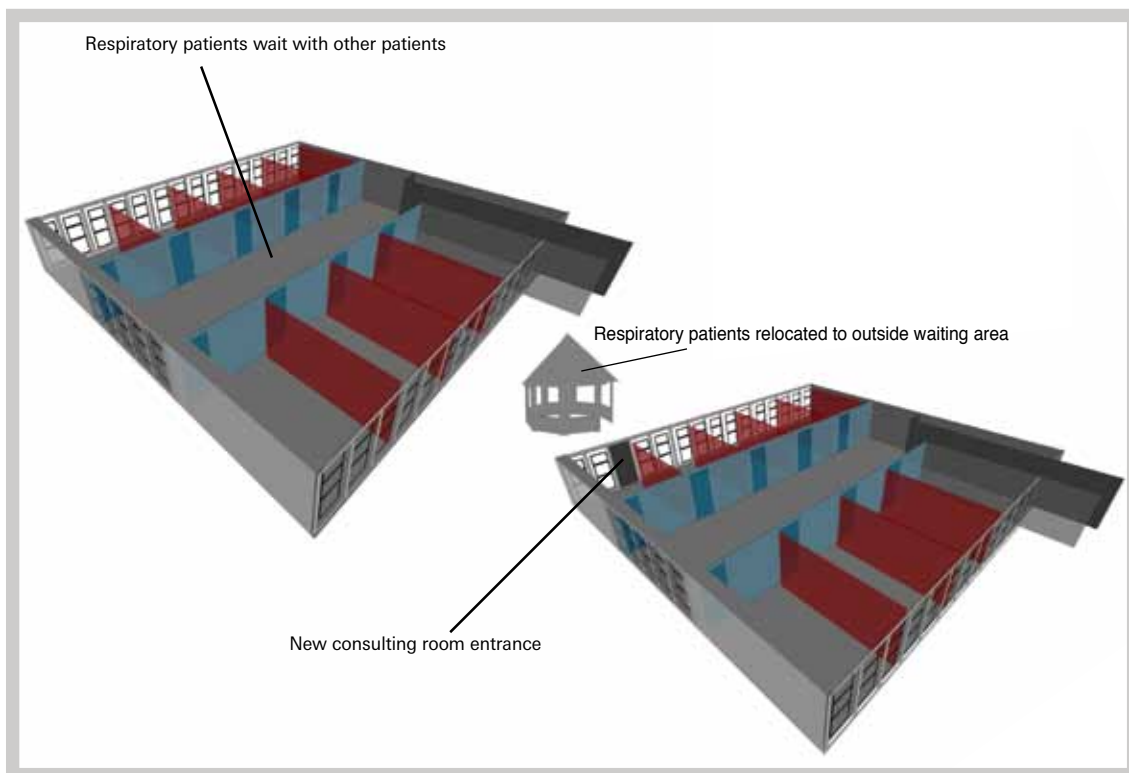
Mean ACH:

Windows to street open, windows above door open (door closed) 17.

In this example the windows in the room were not enough to adequately ventilate the room at only 3.6 ACH, but by adding windows above the doorway and keeping them open, the air exchanges increased to 17 per hour.

Example: Respiratory Out-Patients Waiting Room (Courtesy of S Gazzard)

Outside waiting areas remove patients from waiting rooms with poor ventilation, whilst providing a safe protected area with a higher rate of fresh air movement.



Part 2: Managerial Activities - Surveillance of TB Disease Among Staff

TOPIC: Conduct Surveillance of TB Disease among Staff

WHAT THE WHO POLICY STATES: Surveillance of TB disease among staff, and assessment of the burden of TB, MDR/XDR-TB and HIV in different settings and geographical areas will provide national data that is essential for gauging the effectiveness of TB-IC measures. Results from surveillance will also provide a basis for setting targets and prioritizing more intense action.

What is the objective:

To protect all staff from TB infection and disease⁷.

Who should be involved:

Human Resource Department, NTP, Occupational healthcare workers, HCWs, managers, supervisors and staff.

What should be implemented:

Develop a confidential data collection system for TB disease among staff and a means to share the aggregate data with the workers.

Recommended Actions:

Adopt appropriate actions to collect data on active TB disease (or latent TB Infection) among staff throughout the healthcare system and other relevant sectors and identify persons responsible for those actions:

1. Utilize the global indicator for surveillance of TB disease among staff;
2. Develop a case notification & data collection system and tools i.e. TB registry, staff risk assessment forms, analysis reports;
3. Identify persons responsible for confidential recording, collecting and reporting;
4. Explain to staff the importance of prompt disease notification, stigma reduction and support for their ill colleague(s);
5. Recognize the difficulty of conducting surveillance and at the same time the importance of doing so;
6. Identify role-models to give talks to others;
7. Evaluate the impact of control measures and if needed re-adjust interventions.

11 A package of prevention, care and treatment is further discussed in Part 3 'Healthcare Facilities' of the document see page 51

Tool: Ratio of TB Notification Rate (all forms) in Health Care Staff (all staff) over the TB notification rate in general population, adjusted by age and sex (WHO)

Ratio of TB Notification Rate (all forms) in Health Care Staff (all staff) over the TB notification rate in general population, adjusted by age and sex.	
Rationale	The Risk Ratio of developing an active TB among HCWs compared to the general population have been shown to range from 1.9 to 5.7, depending on income country setting and on the existence of IC measures in healthcare facilities. Environmental measures as well as the use of personal protective equipment by HCW (as recommended in IC policy guidelines) should progressively decrease the occurrence of TB infection and the development of active TB among HCW. When greater than one, the ratio of TB notification rates in HCW to the TB notification rate in the general population reflects the excess risk of TB in HCW due to exposure in healthcare settings. Effective IC measures can bring the notification rate ratio below 1.
Definition of the Indicator	
Numerator	Number of TB patients (all form) among HCWs (all types) during the assessment year divided by the total number of HCWs at the end of the year.
Denominator	Number of TB patients (all form) among general population during the assessment year divided by the population size at the end of the year.
Measurement	This indicator is expressed as a unit less number and reported annually. Data for the numerator of this indicator should be obtained from yearly survey or routine reporting. Data for the denominator are reported routinely by all countries. An adjustment for differences in age and sex and sex distributions between HCWs and the general population should be done.
Platform	Annual Report
Frequency	Annually
Resource	Stop TB Planning Tools for Global Fund Round 10 TB proposal preparation. http://www.who.int/tb/dots/planningframeworks/en/

IMPLEMENTING the WHO Policy on TB Infection Control

This tool can be used by a supervisor for the surveillance of TB among staff.

[illegible]

Part 2: Managerial Activities - ACSM

TOPIC: TB Infection Control Advocacy, Communication and Social Mobilization (ACSM) including Engagement of the Civil Society

WHAT THE WHO POLICY STATES: Involvement of stakeholders beyond the health sector is increasingly recognized as an essential component of modern public health programs. Involvement of affected communities is particularly important for measures such as TB-IC, which can occasionally produce conflicts between societal needs and the rights of individual patients. Control measures may include receiving healthcare in a community setting to avoid unnecessary admissions to hospitals. Creating demand for TB-IC is likely to expedite implementation of all country-level activities and help to maintain standards at the facility level.

What is the objective:

To mobilize a wide range of stakeholders to ensure that TB-IC policy and guidelines are adopted and implemented at national and local levels to reduce TB transmission. Patients should know their right to rapid TB diagnosis, prevention and treatment. Safety without stigma should be the goal—a request to wear a mask or provide a sputum specimen outside, or in a well ventilated room should not be stigmatizing but is part of a safer clinic for everyone.

Who should be involved:

Key target audiences include international and country-level organizations representing the TB and HIV community, managers of TB and HIV/AIDS programs, other Ministries responsible for congregate settings, donors, OHS, patient safety advocates, prisoners and prisoner rights organizations, and managers of other settings such as homeless shelters, refugee and displaced person camps, nursing homes and worker dormitories.

What should be implemented:

Motivate national governments and Ministries to make TB-IC part of their priority activities for disease control. Create an advocacy framework which influences decision-makers from the top down and the bottom up for adequate financial support. Promote, motivate and support individuals and organizations within key stakeholder groups to become TB-IC champions, in order to ensure broad support for IC as an integral part of comprehensive TB and HIV disease control.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and other relevant sectors, and utilize the existing communication channels for information and advocacy.

1. Present solid evidence to decision-makers and broader non-technical audiences to convince them that TB-IC is critical amongst their many competing priorities to ensure that healthcare facilities and congregate settings do not become a source of life threatening infections;
2. Mobilize large constituencies which have connections to national (e.g. professional associations of doctors or nurses) for widespread dissemination of IC advocacy messages;
3. Devise different sets of messages for different target audiences in part to minimize the stigma in HCWs, PLHIV and TB patients;
4. Add TB-IC to meeting agendas to bring TB-IC to the attention of others in the community;
5. Include TB and airborne IC in the formulation of policies, work plans and expert consultations, particularly those addressing pandemic preparedness and seasonal respiratory diseases.

Example: Messages for Healthcare Workers

Part 2

- Know your facility IC plan.
- Monitor IC practices.
- Screen patients to identify persons with a cough that lasted two weeks or more. The unsuspected, undiagnosed coughing patient in general outpatient and inpatient departments is the main concern.
- Provide prompt TB diagnosis and treatment.
- Educate people about cough etiquette when coughing.
- Separate persons suspected of having pulmonary TB and diagnosed TB patients, in particular sputum smear positive patients, from other patients, in particular, HIV positive patients and children.
- Encourage your patients to know their HIV status.
- Know your HIV status.
- Know the signs and symptoms of TB.
- Make sure that some windows remain open at all times.
- Wear a respirator when attending to MDR/XDR-TB patients, especially in enclosed spaces.
- Include congregate settings and local communities in advocacy campaigns.
- Evaluate close contacts, in particular household members, if they have TB signs and symptoms and educate them on IC practices.

Example: Poster Stating TB-IC is Practised in the Healthcare Facility (Source: RHRU, HIV Management Cluster, South Africa)

TB Infection Control is practised in this Health Care Facility



**If you are coughing,
tell us:**

- You may be seen faster!
- Ask for tissues or a mask!
- Cough into tissues, mask or your elbow to prevent spread of germs!



Citation from HIV & AIDS Treatment in Practice (HATIP) Publication

Part 2

Turning Panic Into Activism

Not every program will appoint and train an infection control officer, and as a number of people have pointed out, the responsibility is usually given to someone without much power to change things where they work.

TB-IC has to be made personal for both the healthcare community and patients, and in particular the HIV community, because they are the ones most at risk.

People should know that there are some pretty basic things which programs can implement and that healthcare workers can do to help protect themselves and their patients in the wards and waiting rooms, and that community members can do to make places where people with HIV gather safer (including demanding safety from their own health clinic). Just like treatment literacy efforts were used to help people understand some of the science around HIV, it can be used to help people protect themselves from TB.

Groups like the Treatment Action Campaign and the Treatment Action Group are beginning to mobilize around this issue and teach people the basics. But TB-IC needs to be rolled out into community-based organizations as well. Incorporating good TB-IC in their own community meeting points may further reduce TB transmission, and like the activists in Indonesia, also increase awareness of what to expect in their healthcare facilities.

"We need a bit of the same outrage that was associated with lack of ART in the developing world, a clarion call that says we have to roll-out ART responsibly - that means we can't get people sick by visiting the clinics," Dr. Rene Ridzon of 'The Gates Foundation' said at the 'Three Is' meeting in Geneva.

In Cape Town, Dr. Ken Castro of the CDC reminded the audience about what triggered the response to the MDR-TB outbreak in the early 1990s: "Healthcare worker unions who demanded to be protected, and the AIDS Coalition to Unleash Power, (ACT UP), doing protests and demonstrating in front of the Health Department. We need to also bring out that sense of outrage in the community that's most affected."

Part 2: Managerial Activities - M&E

TOPIC: Monitor and Evaluate the set of TB-IC Measures

WHAT THE WHO POLICY STATES: Countries should agree on a set of simple indicators and data collection tools. They should also decide on responsibilities for data collection and monitoring and for the evaluation of the different elements of TB-IC. Monitoring annual TB cases among staff should provide useful information on transmission of TB in facilities. Additional indicators to monitor the implementation of TB-IC are optional depending on the perceived local priorities. As a minimum, the Global Report indicators should be reflected in the national TB M&E framework.

What is the objective:

To provide policy makers with the information required for the purposes of policy changes, advocacy and program design to achieve the best results for patients and staff members by documenting the impact of TB-IC in reducing TB transmission.

Who should be involved:

A wide scope that may include the Department of Research, Monitoring and Evaluation, Planning and Program Development, NTP, Technical Working Group for Monitoring and Evaluation, WHO STOP TB Department, District Health Management teams, Facility management teams, facility leaders, data clerks, civil society activists and organizations which work/are based in communities with high burden of TB.

What should be implemented:

Identify sources and methods of TB-IC data collection. There should be a M&E system to this effect.

Recommended Actions:

Adopt appropriate actions for different levels of the healthcare system and other relevant sectors and identify the persons responsible for those actions.

1. Adopt a set of indicators for TB-IC, which include the international global report indicators and TB-IC related TB/HIV indicators;
2. Revise the current monitoring system and forms to include data collection for TB-IC;
3. Collect the global TB-IC indicators (do not adapt these) for global comparison of data and trends at regular intervals;
4. Determine how the data once collected will be compiled, reported and analyzed at national, sub-national and local levels;
5. Compare data to prior data sets for improvement and compliance. Work with local and district/provincial health departments if additional actions are warranted.
6. Compare TB case rates to those of the surrounding community. This may help to determine if there is transmission in the facility.

Example: TB Global Report Indicators

3.41 Number of staff diagnosed with TB in year... (Regardless of job position)?

3.42 Number of staff working in the country in the public and private sector in year...?

3.43 Have staff been trained in TB-IC in year..? Y / N

3.44 Number of tertiary (referral) hospitals with the following?

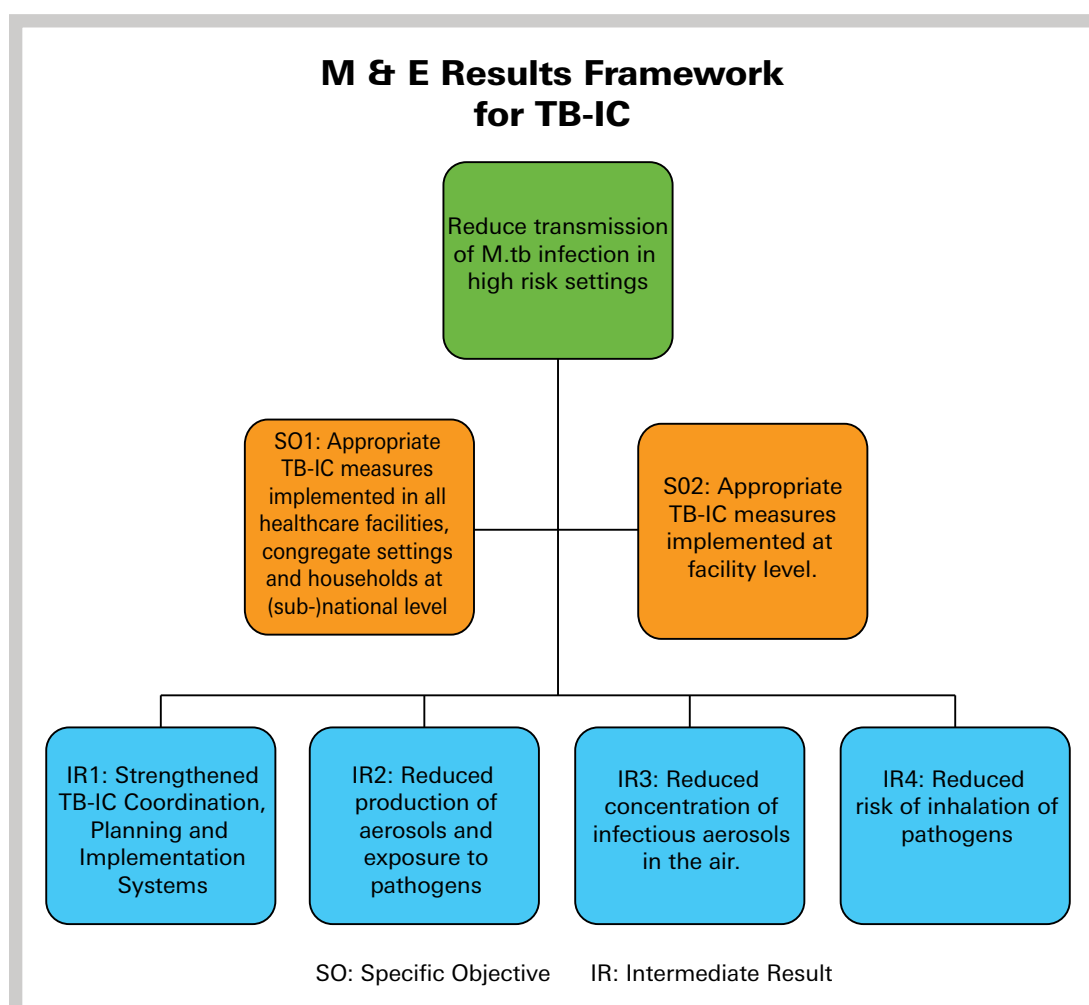
Person in charge of TB-IC

TB-IC assessment done in year....

Training on TB -IC conducted in year...

Total number of tertiary (referral) hospitals?

Example: M&E Results Framework for TB-IC (Courtesy of S. Mullen, MEASURE)



See more: 'Annex Menu of TB-IC indicators' Page 123

Tool: Focussed Monitoring Tool for Clinical Sites (Courtesy of CDC)

Name of Infection Control Officer:		Pt.Pop:HIV TB MCH Peds	Date:
Site:		General OPD	Auditor:
Type of Site:	Inpatient	Outpatient	
TB Infection Control M&E Tool for Clinical Sites			
Please fill out and save to realign clinic specific SOPs.			
	Managerial		Scoring
1	An Infection Control Committee or Person is designated in this site.		Y or N
2	A written Infection Control (IC) plan or check list is available for this site.		Y or N
3	TB-IC training for all staff has been done.		Y or N
4	Facility design and patient flow have been assessed (best use of space & ventilation).		Y or N
5	Monitoring and evaluation of TB-IC data forms are routinely reviewed.		Y or N
6	A tracking system for all TB suspects, referrals and their sputum smear results is in place.		Y or N
7	A register is kept of all TB patients reported to the National TB Program.		Y or N
8	All patients with TB disease are managed on DOT as per the national guidelines.		Y or N
9	Patient and visitor information on TB-IC is available for all and offered by the staff.		Y or N
10	Operational research to improve TB-IC measures is conducted at this site.		Y or N
	Administrative		
11	Patients are routinely asked about cough upon entering facility.		Y or N
12	Patients which are coughing are separated from others and "fast tracked" to caregivers.		Y or N
13	A "Cough Monitor" gives cough etiquette guidance and assists with triage.		Y or N
14	Signage for cough etiquette is present in the clinic.		Y or N
15	Sputum samples are collected in a designated area and away from others.		Y or N
16	Health care workers that assist during sputum collection take precautions.		Y or N
17	Processing of sputum samples is expedited to lab. There is a tracking mechanism to monitor turn-around time of lab results.		Y or N
18	There is a tracking mechanism to monitor turn-around time of patient within the healthcare facility.		Y or N
19	A log is kept of all staff who are diagnosed with TB disease.		Y or N
20	Staff receive an evaluation for TB at least annually.		Y or N
21	Staff are offered an HIV test annually and offered ART if positive as per the national guidelines.		Y or N
22	HIV-infected staff are reassigned if requested.		Y or N
23	INH preventive treatment is offered to HIV-infected staff.		Y or N
	Environmental Controls		Y or N
24	Natural and/or mechanical airflow is monitored daily by staff (especially in waiting rooms, sputum collection room if available, and at least one exam room).		Y or N
25	Regular maintenance for directional and extractor fans is conducted.		Y or N
26	Signage is in place to keep doors and windows open when feasible.		Y or N
27	If UV lighting is used, routine maintenance is scheduled.		Y or N or NA
28	Patients are not crowded in hallways or waiting areas.		Y or N
	Personal Protective Equipment		Y or N
29	N95 or FFP2 respirators are readily available for staff.		Y or N
30	Staff have been trained on proper fit of respirators.		Y or N
31	Supplies are available to coughing patients (tissues, cloths, masks, trash bins, etc).		Y or N
32	Staff are provided continuing education opportunities and annual exams on TB-IC.		Y or N
Use the back side of form for additional comments, room design, patient flow, etc.			
You may also use the back to identify the facility's Strengths/Weaknesses and your solutions or recommendations for improvement.			

Part 2: Managerial Activities - Operational Research

TOPIC: Enable and Conduct Operational Research.

WHAT THE WHO POLICY STATES: Operational research is essential to adapt general recommendations to the needs of individual countries, to evaluate the effectiveness of interventions and to develop evidence-based policies to improve TB-IC. A comprehensive research agenda on TB-IC should be developed. Budgeting to fill the research gaps is essential, and advocating for additional resources to conduct more research aimed at improving TB-IC is needed.

What is the objective:

To provide a body of evidence for effective TB-IC interventions, particularly for recommended interventions where there is little pertinent data.

Who should be involved:

Ministry of Health monitoring and evaluation and research unit(s), Academic institutions (national and international), Infection control practitioners, National TB program management, National medical ethic committees/boards, Healthcare facilities, especially those with high TB burden, Epidemiologists, public health specialists, civil society activists and non-governmental organizations based in communities at high risk for TB.

What should be implemented:

Establish a research committee (if one does not exist). Promote the importance of medical ethics when considering protocols to accept and allocate sufficient funding for the research. Write a policy to this effect.

Recommended Actions:

Adopt appropriate actions for different levels of service of the healthcare system and other relevant sectors and identify persons responsible for those actions:

1. Identify strategic technical partnerships to support the development of a research committee and those that can mentor others on the committee;
2. Enhance research capacity through training and technical assistance;
3. Identify priority research problems and possible solutions;
4. Write operational research protocols;
5. Obtain ethical clearance and approval;
6. Conduct operational research and document all data;
7. Disseminate results of research to key stakeholders and write up results;
8. Report and, if applicable, publish internationally in peer-reviewed journals;
9. Utilize operational research results to guide policy development and alter direction of patient or HCW care. Make sure that HCWs, TB patients and communities are the beneficiaries of the results of operational research, leading to policies which minimize their risk of TB.

Example: Impact of implementation of TB-IC on TB among HCWs in Ethiopia: A Research Proposal

Background

Ethiopia has the 7th highest TB incidence in the world. In Ethiopia, so far, TB IC was introduced in 120 healthcare facilities (HFs) and the aim is to expand to 500 in 2011. We wish to evaluate the (cost) effectiveness, acceptability and sustainability of implementation of a package of measures containing the following measures: assignment of focal person; triage; cough hygiene; reduction of diagnostic delay; collection of sputum outdoors; adequate ventilation in areas with TB suspects; separation of TB patients in wards; and regular TB and HIV screening of HCW. Implementation starts with a 3-day training. After the training, trainees will be given 3 weeks to design their facility plan. Then, mentors will help in implementing these plans during a 2-months period.

Evaluation question(s)

1. What is the impact of this package in HFs in terms of reduction in the incidence of TB infections (TST conversions) among HCWs?
2. What is the impact of this package in HFs in terms of reduction in the incidence of active TB disease among HCWs?
3. How successful (in terms of feasibility, acceptability and sustainability) is implementation of the package and what are critical factors determining its success?
4. Which parts of the package are most successfully implemented and what are critical factors determining successful implementation?
5. What models for HCW screening are best accepted by HCW (compliance with screening)?
6. What is the reduction in diagnostic delay time that can be achieved by full or partial implementation of measures?
7. What is the cost-effectiveness of measures (of the total package and of different parts)?

Study population

This project will include different types of “populations” at two different levels: that of HFs and that of individuals (HCW and TB patients in the selected HFs).

Data collection

From the HF's registers, we will collect data about the number of HCW treated for TB and on diagnostic delay. Moreover, we will collect data on the costs of implementation of measures, and we will conduct HF assessments using internationally adopted assessment sheets including direct observation. We will also measure the time lag between the first visit of TB patients to the HF and start of TB treatment (called diagnostic delay). All consenting HCW will be tested by TST and HIV testing will be offered. Interviews will be conducted to collect data on demographic and job characteristics, TB history, exposure to TB outside the HF, and recent occurrence of signs and symptoms of TB. For each HF, from a random sample of HCW, we will collect data on knowledge, attitude and practice. From patients being put on treatment during the last 2 months, we will collect data on knowledge, attitude and practice concerning TB-IC and diagnostic delay (to crosscheck data from registers) by means of interviews.

Study design

All HFes in 12 different randomly selected zones will be included in the study; each month, one zone will start with introduction of TB-IC during a 3-month period until all have started, and evaluation will continue 1.5 year after the last has started by using a stepped wedge design (see figure below).

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																								
Zone 1	preparatory phase (including pilot)		FOTS		ICT	M	M	FOC	TS						TS						FOTS						TS																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																																	

Figure. Detailed time plan of study preparations and data collection.

Abbreviations used: F: facility assessment and collection of diagnostic delay data based on registers; Q: questionnaires for random sample of HCW and consenting patients being put on TB treatment during the past 2 months ; T: TST; S: interview of all consenting HCW on signs and symptoms of TB and recent TB exposure; ICT: 3-day training followed by 3-week period in which trainees are expected to make a facility plan; M: mentored implementation of facility plan, including review of plan and guidance and monitoring of the implementation; C: collection of cost data of intervention.

Sample design and size and power calculations

We calculated expected sample sizes both powering on incidence of active TB disease and on incidence of LTBI as measured by TST conversion using the approach for cluster randomized trials. For both TB burden endpoints, we calculated the sample size at a power of 80%, using a one sided alpha, assuming a coefficient of variation of 0.25, a mean HF size of 82 HCW, a participation rate among HCW of 75%, a 10% annual staff turnover rate, random allocation of the intervention, and that the intervention will reduce the incidence of TB and LTBI by 50%.

We assumed the incidence of active TB disease among HCW to be 2/100 persons per year in absence of the intervention. We assume 60% of HCW to have a positive TST at baseline. Assuming TST conversion rate to be 10% per year in absence of the intervention, the total study population to include is 12,650 HCW.

Part 3 Healthcare Facilities

Administrative Controls



Part 3: Healthcare Facilities – Administrative Controls - Triage

TOPIC: Promptly Identify People with TB Symptoms

WHAT THE WHO POLICY STATES: All patients should be screened routinely upon arrival for coughs lasting longer than two weeks, fever, weight loss and night sweats. HCWs should explain to patients that safety for all people is the goal and that the screening is part of quality care. Persons suspected of having pulmonary TB should be "fast-tracked" for rapid diagnosis and expedited services. If possible, direct them to a separate (outside) waiting area. Sputum collection should be done away from other people, preferably outside or if necessary, in specially designed rooms with adequate ventilation. Turn-around time for sputum AFB (acid-fast bacillus) smear results should be no more than 24 hours.

What is the objective:

To separate and fast-track (or prioritize) people with TB symptoms who have come into a healthcare facility.

Who should be involved:

All patients and HCWs.

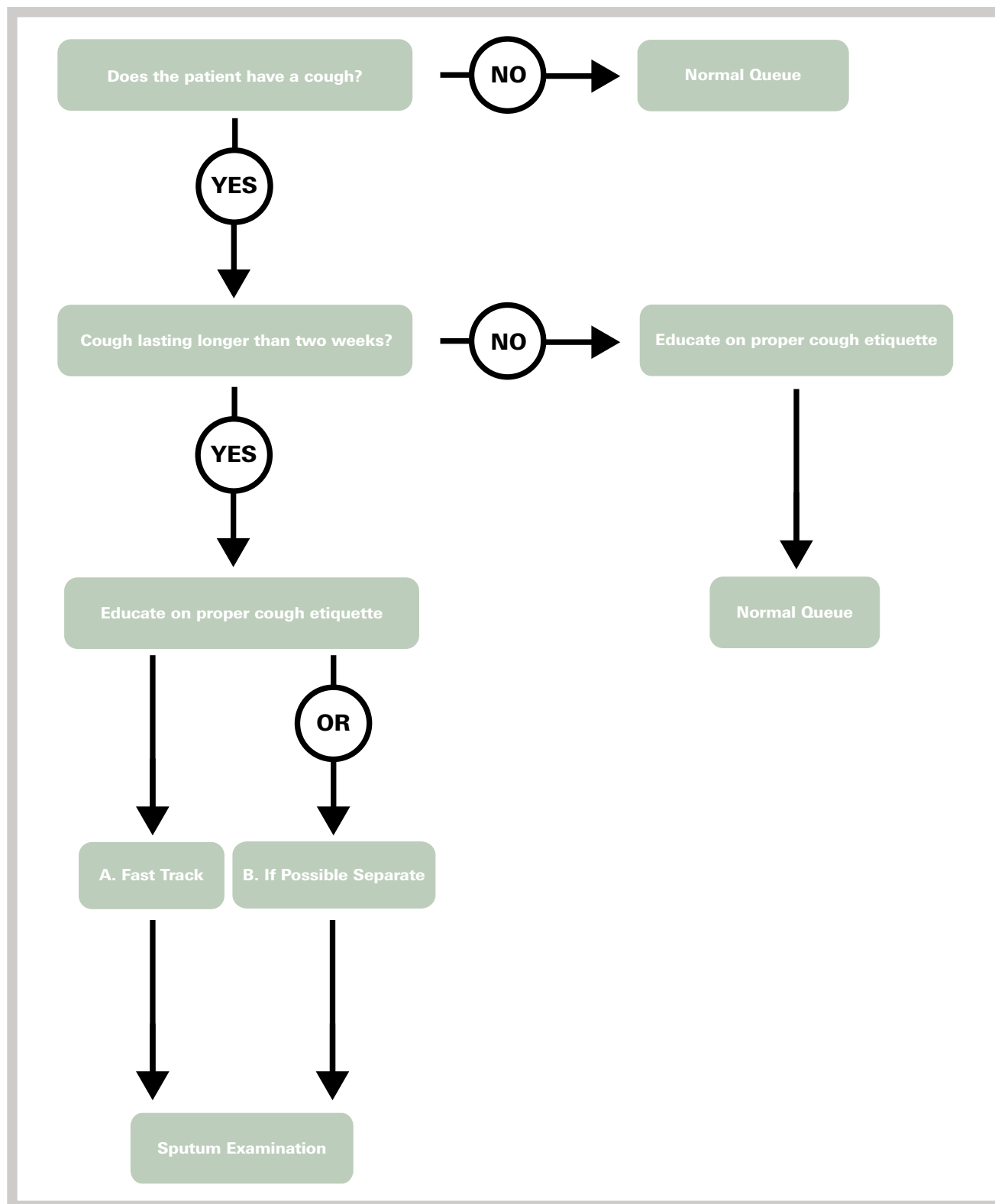
What should be implemented:

Raise awareness of possible TB with particular attention to cough while reducing risk of nosocomial infection to other patients and staff. Write a facility policy to this effect.

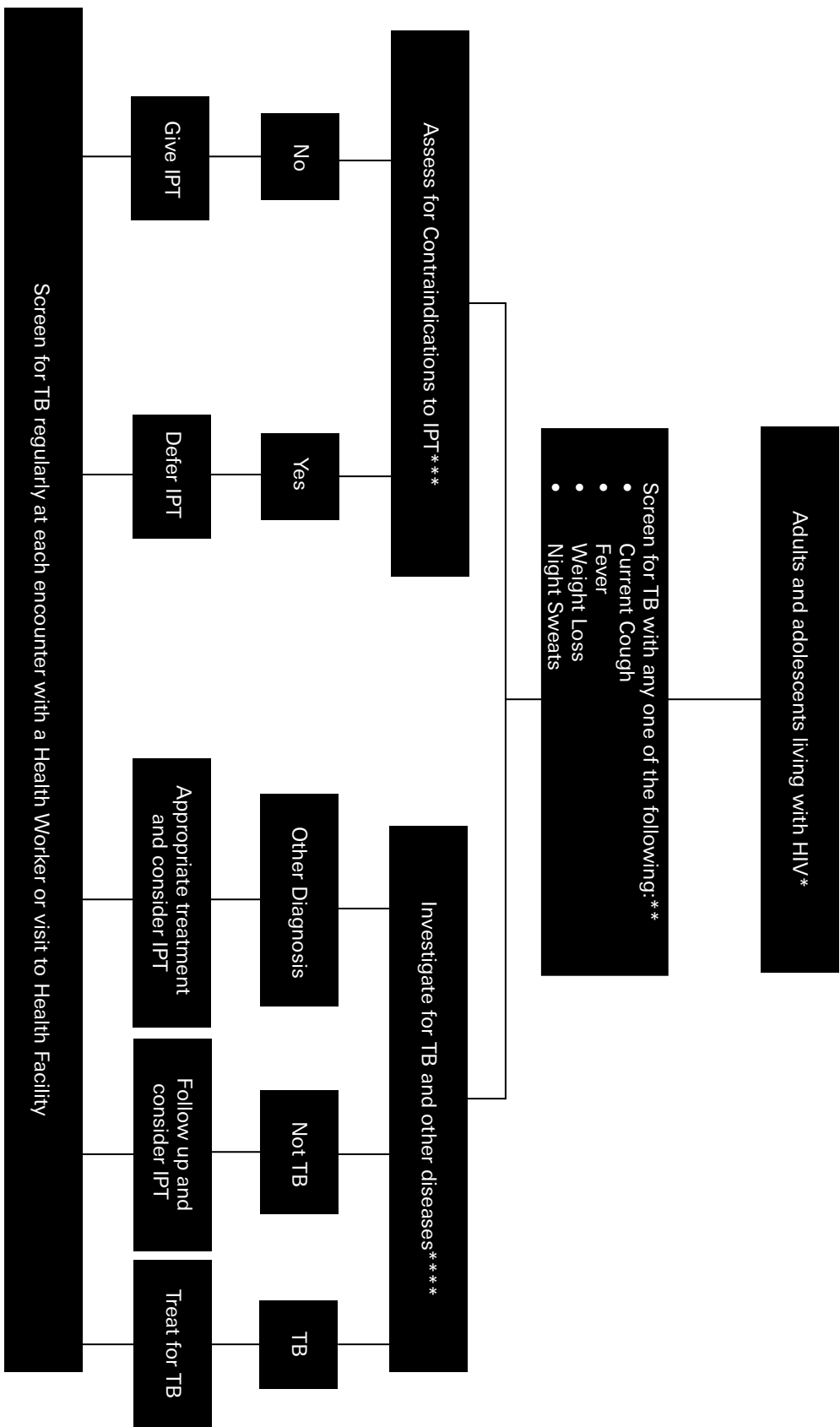
Recommended Actions:

Adopt appropriate actions for the different types of services offered at the facility and identify those workers responsible for identifying patients as they enter the facility.

1. Develop a standard triage procedure or checklist to uniformly identify potentially infectious patients as they enter the facility;
2. Assign responsible persons as "cough officers" for triaging;
3. Separate all coughing patients and then apply the TB screening tool to each coughing patient;
4. Develop a reporting form (if one is not provided) to document that this patient has met the criteria for triage;
5. During the screening process explain to the patients why they are being selected for special care;
6. Monitor the process to be sure that each coughing patient is screened, then monitor the percentage of suspects against total outpatients and diagnosed sputum positive TB patients seen in the facility. Better screening should show a significant increase in diagnosed TB patients.

Tool: TB Screening Flowchart (Source: Infection Prevention and Control Policy, Ghana)

Tool: Algorithm for TB screening in adults and adolescents living with HIV in HIV prevalent and resource constrained settings



Footnote for adult algorithm.

- * Every adult and adolescent needs to be evaluated for ART eligibility and infection control measures should be prioritized to reduce transmission of TB in all settings providing care.
- ** Chest radiography can be done if available, but it is not required to classify patients into TB and non-TB groups. In high HIV prevalent settings with a high TB prevalence among people living with HIV (e.g. greater than 10%), strong considerations must be given to adding additional sensitive investigations.
- *** Contraindications include: active hepatitis (acute or chronic) or regular and heavy alcohol consumption or symptoms of peripheral neuropathy. Past history of TB and current pregnancy should not be contraindications for starting IPT. Although not a requirement to initiate IPT, TST may be done as part of eligibility screening in some settings.
- **** Investigations for TB should be done in accordance with existing national guidelines.

Part 3: Healthcare Facilities – Administrative Controls – Separation**TOPIC:** Separate infectious patients

WHAT THE WHO POLICY STATES: Known and suspected infectious TB patients should be placed in a room or (outside) area separate from other patients. In particular, PLHIV or with strong clinical evidence of HIV infection, or with other forms of immune-suppression, should be physically separated from those with suspected or confirmed infectious TB. Patients with susceptible TB should be separated from those with MDR/XDR-TB to prevent transmission of a drug resistant strain.. Whenever possible a community-based treatment model should be encouraged.

What is the objective:

To ensure separation or isolation of known and suspected infectious TB patients from others, to reduce the risk of nosocomial infection.

Who should be involved:

Patients, staff and visitors.

What should be implemented:

Ensure the design or re-allocation of areas for the separation and isolation of patients. Distancing of known or potentially infectious TB patients reduces the risk of transmission. Write a facility policy to this effect.

Recommended Actions:

Adopt appropriate actions for the different services offered in the facility and identify staff responsible for those actions;

1. If possible, create a separate or isolation area, by dividing big areas in existing spaces into several smaller ones. The creation of an outside covered seating area is also a method used to safely isolate coughers until they can be seen by a care provider;
2. Develop a policy to separate known or suspected infectious TB patients as they first enter the facility;
3. Combine any separation/isolation with the highest quality of care. Ensure that any curtailing of individual freedoms happens as the absolute last resort and with great efforts to explain the process and reasoning for such actions.
4. Provide information to patients and visitors explaining the rationale for separation/isolation;
5. Inform patients and visitors by placing visible signage on entryway doors to the facility and to the doorways of restricted areas.

Example: Signage at University Teaching Hospital, Lusaka, Zambia



Example: Restricted area signage Chatty Clinic in South Africa (Source: V. Lipke)

A simple homemade sign placed in the hallways.



Part 3: Healthcare Facilities – Administrative Controls - Cough Etiquette**TOPIC:** Control the Spread of Pathogens with Cough Etiquette

WHAT THE WHO POLICY STATES: Every facility should at least have a poster on TB infection control and cough etiquette in the outpatient department waiting area, admissions area and casualty department. Patients, staff and visitors should be instructed to turn their head away from others and to cover their mouth and nose when coughing, with cloth such as an arm sleeve, scarf, handkerchief, clean rag, paper tissue or face mask. All staff are responsible for being a role model for cough etiquette and should work together to help patients, visitors and other staff adhere to this practice.

What is the objective:

To ensure patient, visitor and staff compliance with respiratory hygiene practice.

Who should be involved:

All patients, staff and visitors.

What should be implemented:

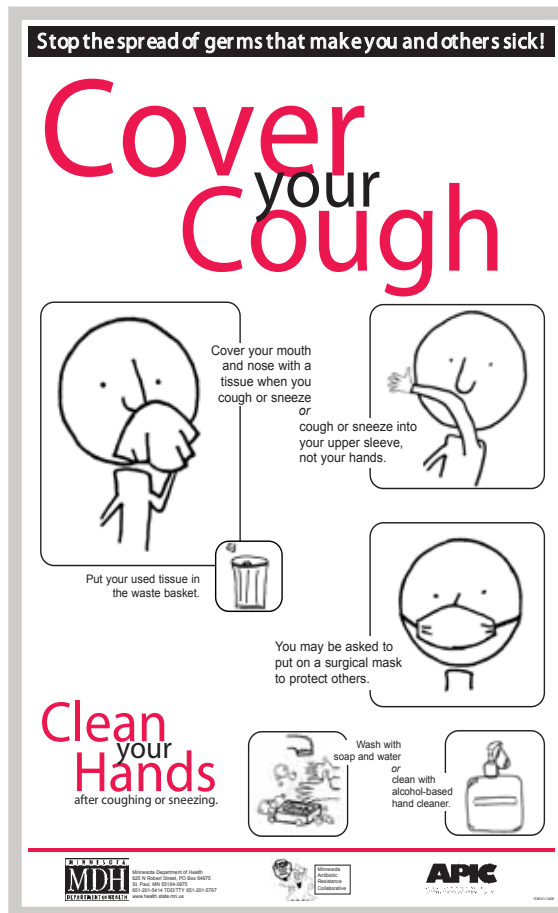
The concept that all staff must reinforce the behavioral change they would like to see, by using themselves as role models and instructing patient and visitors how to cover their cough. Write a facility policy to this effect.

Recommended Actions:

Adopt appropriate actions for different services offered at the facility and identify persons responsible for those actions:

1. Use and display IEC materials/posters on cough etiquette where patients cannot fail to see them (directly in front of them and not on a back wall) or on the front door as they enter the facility;
2. Provide daily health education on cough etiquette at all service delivery points;
3. Practice role playing with staff to strengthen verbal instruction and increase their comfort level when instructing others on cough etiquette;
4. Provide tissues, cloths, rags or (paper surgical) face masks for all known and suspected TB patients, especially MDR-TB and XDR-TB patients;
5. Remind non-adhering patients to comply with the respiratory hygiene policy of the facility;
6. Staff can help reduce the stigma of wearing (surgical) face masks by their own behavior regarding mask and N95 use.

Example: Old and New Posters Promoting Cough Etiquette



Example: Expert Views on Cough Etiquette (Source: Published by HIV & AIDS Treatment in Practice (HATIP))

Questions linger about the best way to encourage good cough etiquette. Face masks can help prevent the spread of Mtb from the patient wearing them to others — but many feel they stigmatize the patients who wear them.

“We are experimenting with the four possible ways of practising cough hygiene (hand /upper arm/ handkerchief or tissue /surgical mask). At present, using the hand is the most accepted,” according to Robin Smith, an Infection Control Practitioner working for Médecins Sans Frontières in Khayelitsha. “There is still a great deal of stigma attached to surgical masks. We have considered giving all patients surgical masks on entry into the clinic to overcome this.”

Good adherence to a less than optimal barrier may be better than poor adherence to a good one. However, using a handkerchief has generally been thought to be less effective than a face mask, but according to research by Prof. Mehtar “using a handkerchief or cloth to cover the mouth and nose was effective in reducing aerosol to 0.25m, and surgical masks effectively reduced aerosols to 0.5m.” As a result, Tygerberg is emphasizing using handkerchiefs and cloths.

Face masks may come in useful for patients who do not adhere to good cough etiquette or who have drug-resistant TB. Even then, it is impossible to force anyone to keep one on.

“I visited one of the smaller hospitals in Cape Town recently,” said Dr. Corbett, “with TB patients just mixed in with everyone else. One of the TB patients had a mask on because she’d been recognized as drug resistant. While we were there, her kids came in to see her and straight away she took her mask down and people laughed, but they didn’t do anything about it. So I think it’s very hard.”

Other HCWs working at very busy clinics in South Africa told HATIP that they were not currently teaching any cough hygiene to their clients. In contrast, Chris Green, a treatment educator at Spiritia Foundation in Jakarta, Indonesia told HATIP that face masks are insisted upon within their HIV community support groups:

“In our support group meetings, we encourage participants to discuss the probability of peer group members coming to a meeting with a cough. We note that if they are just excluded, or asked to wear a mask, they may feel discrimination - particularly if they have recently joined. We encourage groups to discuss this in advance, and develop a group rule, to be posted on a notice board, that anybody attending with a chronic cough will be asked to wear a mask and encouraged to visit a clinic. This will also increase awareness.”

He added that in some parts of Indonesia, they have another problem besides poor cough etiquette: “In Papua, many of the indigenous people chew betel-nut and spit out the residue. One can see the red marks of this all round the hospitals in Papua and betel is even sold just outside the wards. A recent report raised concerns that this is certainly contributing to TB infection in Papua New Guinea and the same is extraordinarily true in Indonesian Papua. I remember as a lad, the notices in the public conveniences in England: ‘Spitting causes Consumption’. I think those campaigns were effective; we urgently need to emulate them in Papua.”

At the Stop TB Partnership, TB/HIV Core Group Meeting in New York in April, both Dr. Jeroen van Gorkom of KNCV and Dr. Miller said similar campaigns around cough hygiene are needed.

“Even 80 years ago in the Netherlands - we had campaigns about cough hygiene, not spitting in public and so on,” said Dr. van Gorkom.

Dr. Miller said that within months, she would like to see cough etiquette and other TB-IC printed on posters and put up in thousands of clinics, as was done in the past.

Part 3: Healthcare Facilities – Administrative Controls - Time Spent in Facilities

TOPIC: Minimize Time Spent in Healthcare Facilities

WHAT THE WHO POLICY STATES: Hospital stay is generally not recommended for the evaluation of people suspected of having TB, except in cases that are complicated or have other medical conditions which require hospitalization, such as infectious drug-resistant TB. Community-based approaches for the management of pulmonary TB appear to be more cost effective than hospitalization and, if proper TB-IC measures are in place, the risk of TB transmission in the household should be minimal. By minimizing the time spent in any healthcare facility the risk of the transmission of TB decreases.

What is the objective:

To reduce the risk of TB exposure to other patients and HCWs by minimizing the time known and suspected TB patients are within the facility.

Who should be involved:

Patients, visitors and HCWs.

What should be implemented:

The prompt screening, evaluation by a clinician, diagnostic services and initiation of treatment to reduce the risk to others in the facility.

Recommended Actions:

Adopt appropriate actions for different services offered at the facility and identify persons responsible for those actions:

1. Move TB suspects to the front of the line/queue to separate them from other patients;
2. Reduce waiting and consultation time to keep them as short as possible, preventing further exposure;
3. Document in the patient's chart the time patients spend waiting, being evaluated, getting labs tests completed and receiving results and medications;
4. Evaluate delays in waiting times to receive care. Look for ways to improve turn-around times and streamline the process;
5. Introduce rapid diagnostic tests whenever possible to improve turn-around time;
6. Do not hospitalize infectious pulmonary TB patients longer than absolutely necessary.

Example: How to Measure and Compare Quality of Services / Time Spent in the Facility

Were patients with a cough lasting more than two weeks missed when entering the facility and only detected at a later time or in the examination room?

What were the time intervals from suspicion of TB to ordering sputum for AFB smears, from ordering to the collection of sputum, from the examination of the smear to the reporting of results and from the return of laboratory results to the initiation of treatment?

Source of information for the indices would be by reviewing the TB SUSPECT REGISTRATION FORMS / medical records of a sample of patients seen in a facility.

If the indices are known for a facility, standards could be defined and sample findings could be compared with set standards. Findings may also be compared with other facilities (benchmark) to evaluate performance.

TB Suspect Registration Form

Date	Cough > 2 weeks	Other symptoms* (w/f/ns)	Missed upon entry** (y/n)	Entry time	Time sputum ordered	Time sputum received	Time sputum examined	Time results received	Outcome*** (TB / not TB/ NS)	Time initiation treatment

*Other symptoms: weight loss=w; fever=f; night sweating=ns

**Missed upon entry: symptoms detected at a later time than upon entry to the facility; or after numerous visits while symptomatic yet undetected: y=yes; n=no

***Outcomes: TB diagnosed or confirmed=TB; TB ruled out after diagnostic investigation=not TB; Did not present to referral facility for investigation=NS (not seen).

Part 3: Healthcare Facilities – Administrative Controls – TB Prevention and Care for HCWs

TOPIC: Ensure provision of prevention and care interventions for HCWs that include HIV and TB testing, prevention, ART, IPT for HIV positive staff and TB medications if needed.

WHAT THE WHO POLICY STATES: All staff should be given information and encouraged to undergo TB diagnostic investigation if they have signs and symptoms suggestive of TB. Similarly, all staff should be given information and encouraged to undergo HIV testing and counselling. If diagnosed with HIV, they should be offered a package of prevention, treatment and care that includes regular screening for active TB and access to TB and HIV medications and to TB preventive therapy for those unlikely to have active TB disease. HIV positive staff should not be working with known or suspected TB patients and should be relocated to lower risk areas.

What is the objective:

To prevent staff from contracting HIV/TB and to support those who have contracted HIV/TB in compliance with international standards including occupational health and safety.

Who should be involved:

Staff, occupational healthcare workers, professional associations, regulatory bodies and unions.

What should be implemented:

Compassionate, non-stigmatizing and non-discriminatory workplace practices and procedures regarding TB prevention, treatment and confidential HIV testing and counseling for all staff.

Recommended Actions:

Adopt appropriate actions for the delivery of confidential testing and treatment for both TB and HIV at the facility and identify persons responsible for those actions:

1. Create or annually update the workplace practices and policies regarding the Three 'I's for HIV/TB (IPT, ICF, IC) and ART to decrease the burden of TB among staff living with HIV and decreasing the burden on HIV in staff with TB (HIV testing and counseling, HIV prevention, CPT, HIV care and support, ART);
2. Involve regulatory bodies, unions and professional associations if appropriate;
3. Cross-check the national OHS regulations to ensure that the workplace practice and policies conforms with those regulations;
4. Educate staff on the signs and symptoms of TB/HIV, encourage early care seeking and support the employee whilst on therapy;
5. Provide Free periodic and symptomatic screening for HIV and TB;
6. Offer staff with HIV an opportunity to transfer to work sites that have the least risk of TB transmission;
7. Maintain a confidential employee screening register by location.

Example: The Basic Principle of Workplace Policy (Source: ILO-WHO)**Recognition of TB as a Workplace Issue:**

TB is a workplace issue because it affects the health of workers and the productivity of enterprises. The workplace has a role to play in broader global efforts to limit the spread and effects of TB. Workplace programs should be gender-sensitive, taking into account women's greater vulnerability to TB and its impact as a result of higher levels of poverty, the burden of care and the increasing incidence of HIV among women.

Non-discrimination:

No one should experience discrimination on the basis of their TB status, whether in terms of continuing employment relationships or access to health insurance, occupational safety and healthcare schemes. Employees with TB should be entitled to work for as long as they are medically fit and appropriate work is available.

Confidentiality:

Neither job applicants nor employees should be asked to disclose information on the basis of their perceived TB or HIV/AIDS status. Access to personal data should be bound by the rules of confidentiality and be in accordance with the ILO code of conduct on the protection of worker's personal data.

Healthy Work Environment:

The work environment should be healthy and safe, as far as practicable, in order to prevent the transmission of TB. This includes the responsibility for employers to provide information and education on TB transmission, appropriate environmental measures and protective clothing where relevant.

Care and Support:

Workplaces should provide access to health services which fulfil the needs of male and female employees with TB and related illnesses, or should refer workers to treatment and care services in the community. The DOTS approach is preferred. Measures to accommodate and support workers with TB should be made through flexible leave arrangements, rescheduling of working times and arrangements for return to work.

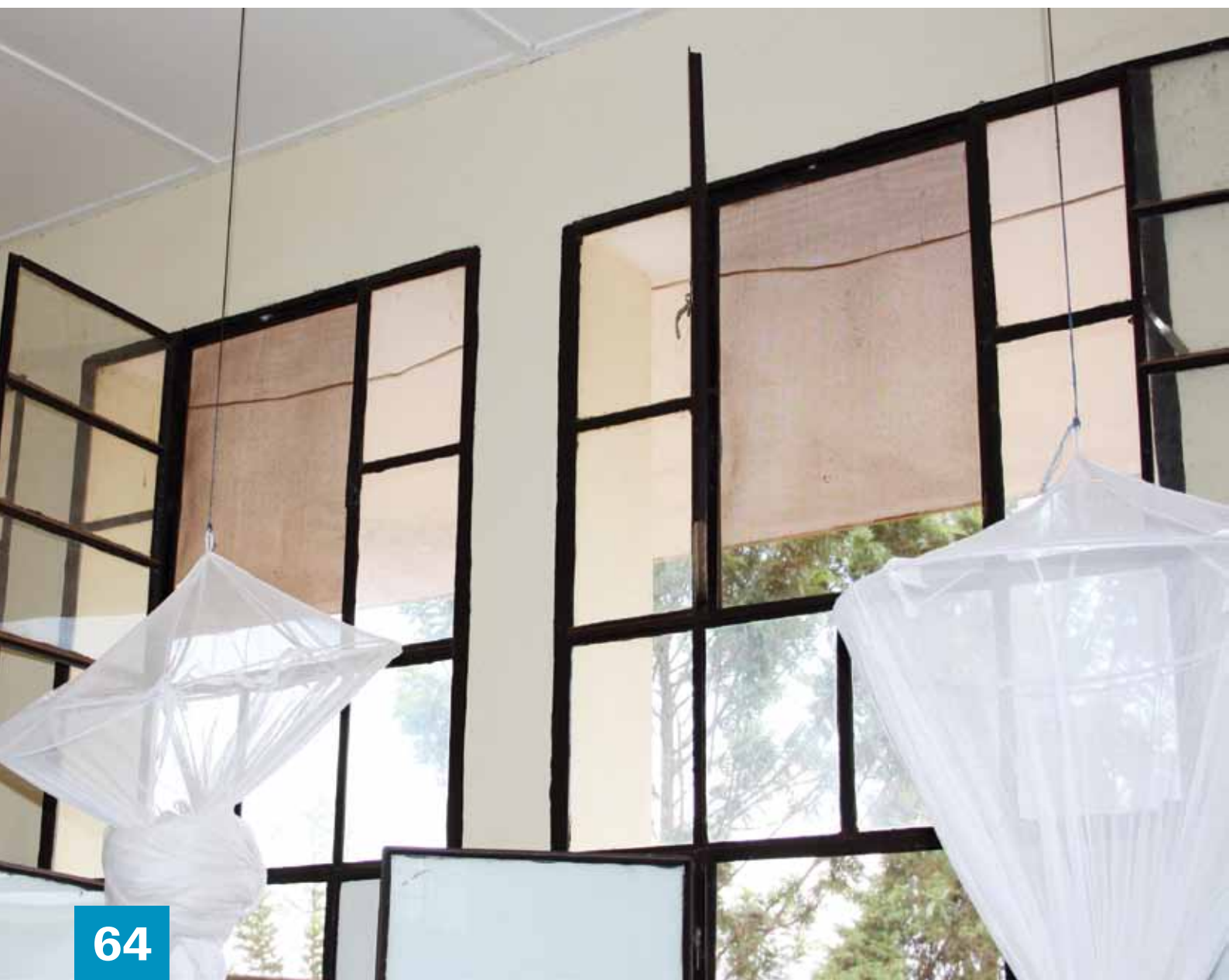
Social Dialogue:

Control and management of TB in the workplace is more effective when planned and implemented on the basis of collaboration between managers and the workforce. A workplace health and safety committee with broad representation should be responsible for overseeing implementation.

Part 4

Healthcare Facilities

Environmental Controls



Part 4: Healthcare Facilities – Environmental Controls – Ventilation Systems: Natural, Mixed-mode and Mechanical

TOPIC: Use Ventilation Systems

WHAT THE WHO POLICY STATES: In choosing a ventilation system (i.e. natural, mechanical, or mixed-mode) for healthcare facilities, it is important to consider local conditions, such as building structure, climate, building byelaws and regulations, culture, cost and outdoor air quality. Any ventilation system must be monitored and maintained on a regular basis/schedule. Adequate resources (budget and staffing) for maintenance are critical. The current WHO ventilation standard for an airborne precaution room is at least 12 ACH. This is equivalent to 80 l/s/patient for a room of 24 m³.

What is the objective:

To ensure sufficient air exchange and control airflow direction to reduce the risk of TB exposure.

Who should be involved:

Architects, engineers, maintenance officers, facility administration, HCWs and governmental or independent accreditation and licensing bodies.

Explain to patients, staff and visitors the importance of adequate fresh air in reducing risk and ask them not to close windows and doors without permission.

What should be implemented:

Ensure that airborne infection control is considered in the healthcare facility master planning.

Recommended Actions:

Adopt appropriate actions for different climates and local contexts where service is being delivered and identify the workers who will do those actions and monitor them daily.

1. Position windows and doors in opposite walls of wards and rooms. Keep windows and doors open to maximize cross ventilation. Maintain openings in or above entrance doors to improve cross ventilation where doors cannot be left open;
2. Procure equipment i.e. vaneometers, ventilation smoke tube kits (incense/mosquito coils are a cheaper alternative), measuring tape, and if applicable anemometers, to measure the effectiveness of the different ventilation systems;
3. Conduct periodic air exchange measurements and identify areas with insufficient air exchanges falling below 12 ACH;
4. Ask for engineers to assess, design, select, install and maintain (mixed-mode) mechanical ventilation systems. Ensure that the staff knows how to report failures promptly;
5. Place fans strategically to obtain adequate dilution when natural ventilation alone cannot provide sufficient ventilation rates. Consider installation of wind driven extraction fans such as “Whirly Birds” or electric extractor fans to ensure that air from within the facility is removed;
6. Designate responsible staff members to check ventilation equipment and open windows/doors according to a daily time schedule. Report and repair deficiencies immediately. Keep a log of both your daily ventilation checks and a log for equipment repairs;
7. Incorporate preventive maintenance procedures into existing facility maintenance programs;
8. Consider closed mechanical ventilation systems only in well established settings with a constant power supply, where trained maintenance staff are guaranteed and there is easy access to parts.

Example: Signage on Window to Remind Patients and Staff that 'This Window Should be Kept Open' (Source: CDC, Global AIDS Program SA)

Open this window!
Fresh air fights TB



This sticker was developed by the U.S. Centers for Disease Control & Prevention, Global AIDS Program, South Africa through funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)



Example: Signage on Door to Remind Patients and Staff that 'This Door Should Be Kept Open' (Source: CDC, Global AIDS Program SA)

**Open
this
Door!**

Fresh air fights TB



This sticker was developed by the U.S. Centers for Disease Control & Prevention, Global AIDS Program, South Africa through funding from the U.S. President's Emergency Plan for AIDS Relief (PEPFAR)

Fact Sheet: Ventilation and TB Infection Control (Source: RHRU, HIV Management Cluster, South Africa)

Fact Sheet: Ventilation and TB Infection Control



Why is ventilation important in the implementation of infection control ?

Tuberculosis is spread by airborne route. Infectious particles (droplet nuclei) are suspended in the air and infection with TB is acquired by inhalation of infectious particles. Breathing clean air (air free of TB particles) will not lead to TB infection; therefore keeping air clean is critically important. This can be achieved by ensuring good ventilation.

What is 'ventilation'?

Ventilation refers to the removal of old, stale or 'diseased' air, and replacing it with new, fresh or 'clean' air. This has the effect of removing infectious particles, and diluting those that remain, so that the chances of inhaling infectious particles are kept to a minimum. Ventilation can also control the direction of air flow so that air flows from less contaminated to more contaminated areas.

What is 'air mixing'?

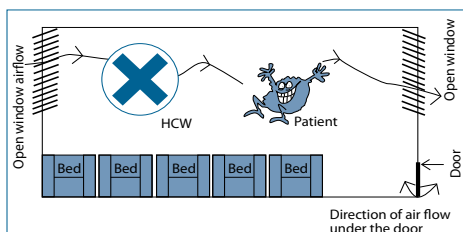
Air mixing refers to the mixing of existing air within an environment so that infectious particles are evenly mixed within an environment and pockets of air with high concentrations of infectious particles are evenly distributed. This will mean that all infectious particles have an equal chance of being removed or diluted by ventilation. Air mixing is essential if ventilation is to be effective. If air is not mixed properly, ventilation may not remove enough infectious particles.

How can I mix the air?

Air can be mixed by using fans (standing fans or extraction fans) or by opening windows and taking advantage of wind or natural flow patterns of air within an environment.

What is 'directional air flow' and how can I use this to keep health care workers safe?

Air should flow from low concentration of infectious particles, towards a high concentration. The HCW should always be 'upwind' of the patient – ie clean air should flow from behind the HCW towards the patient.



How can I measure ventilation rates?

Ventilation rates are measured by 'air changes per hour' (ACH). This is calculated by dividing room ventilation rate (m^3/hr) by the room volume (size, in m^3). Ventilation rate for naturally ventilated spaces are difficult to calculate (refer National TB Infection Control Guidelines). However one can 'feel' if air is moving within the environment, and confirm this using the smoke test (refer to Section 4). Air-conditioners usually have fixed or variable settings which can be read on the unit. An air-conditioning technical specialist can assist.

How does natural ventilation compare with mechanical ventilation (air conditioning)?

Natural ventilation is almost always more effective than mechanical ventilation. A study in Peru showed that natural ventilation achieved more than 17-40 air change per hour (ACH), while well functioning air conditioning in isolation rooms achieved 12 ACH.

What are recommended ventilation rates for health care facilities?

The CDC recommends 12 air change per hour (ACH) for respiratory isolation rooms and areas where suspected TB patients are managed. In South Africa, we do not have resources for isolation rooms. When considering TB infection control issues, all persons attending health care facilities should be managed as TB suspects.

If I cannot open windows, or if mechanical ventilation is used in my facility, how can I ensure that ventilation rates are adequate?

Consult an air conditioning technical expert and present the problem and the requirements.

Maintain air conditioning units regularly, according to a schedule

Ensure that air mixing is taking place in the facility and in high risk consulting rooms

Keep the direction of air flow correct to minimize risk to health care workers, especially in the consulting rooms.

Did you know?
Air MIXING is essential
if ventilation is to be
effective

Example: Equipment to Measure ACH Using a Vaneometer



Example: Calculation formula of ACH

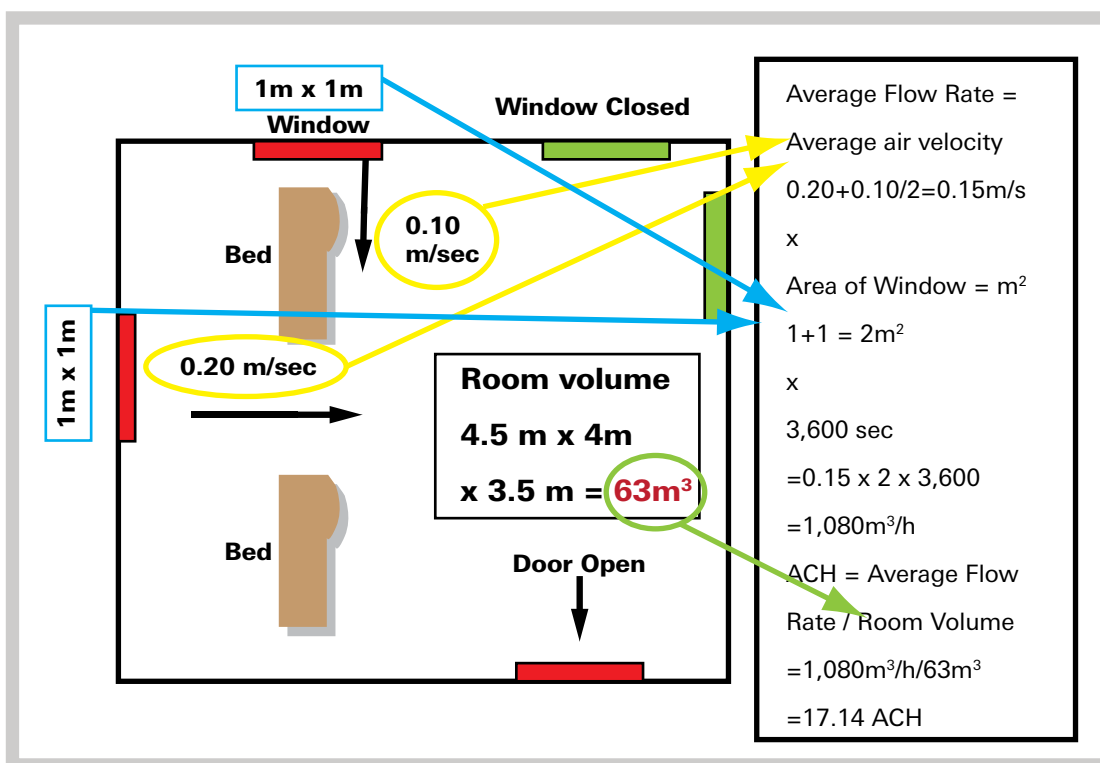
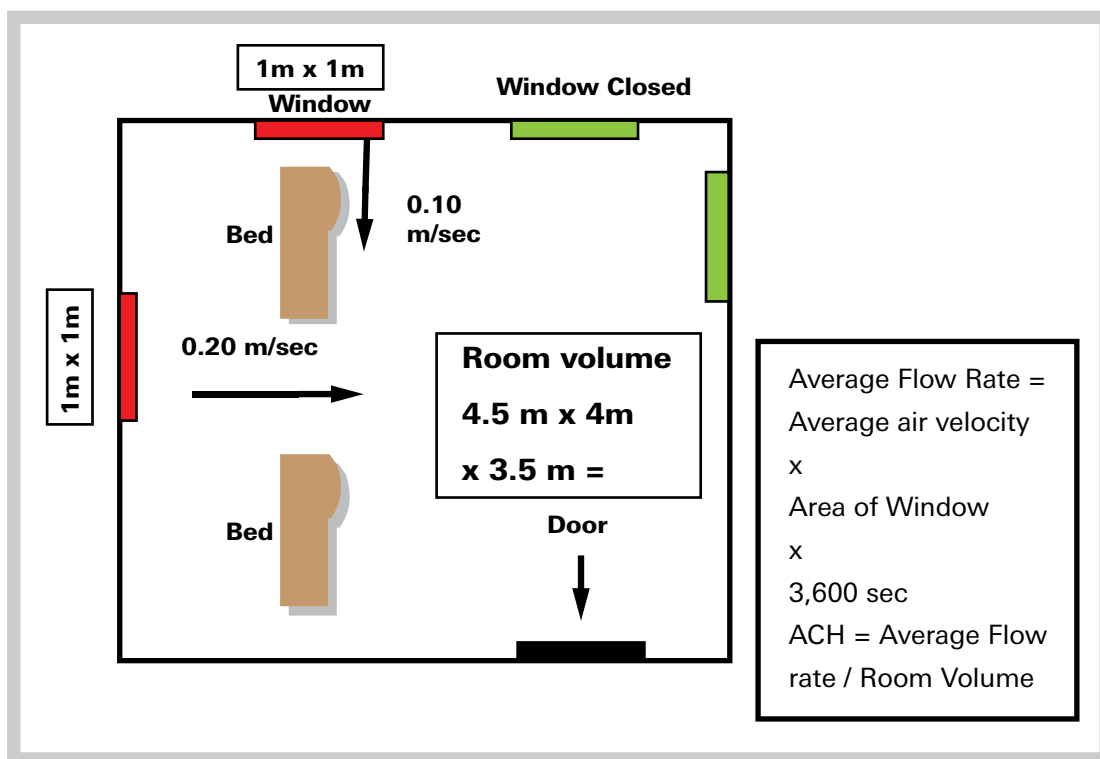
Calculation of ACH

$ACH = \text{Average Flow Rate} / \text{Room Volume}$

Average Flow Rate = ____ m^3 /Hour

Room Volume = ____ m^3

Example: ACH Calculation in a Room



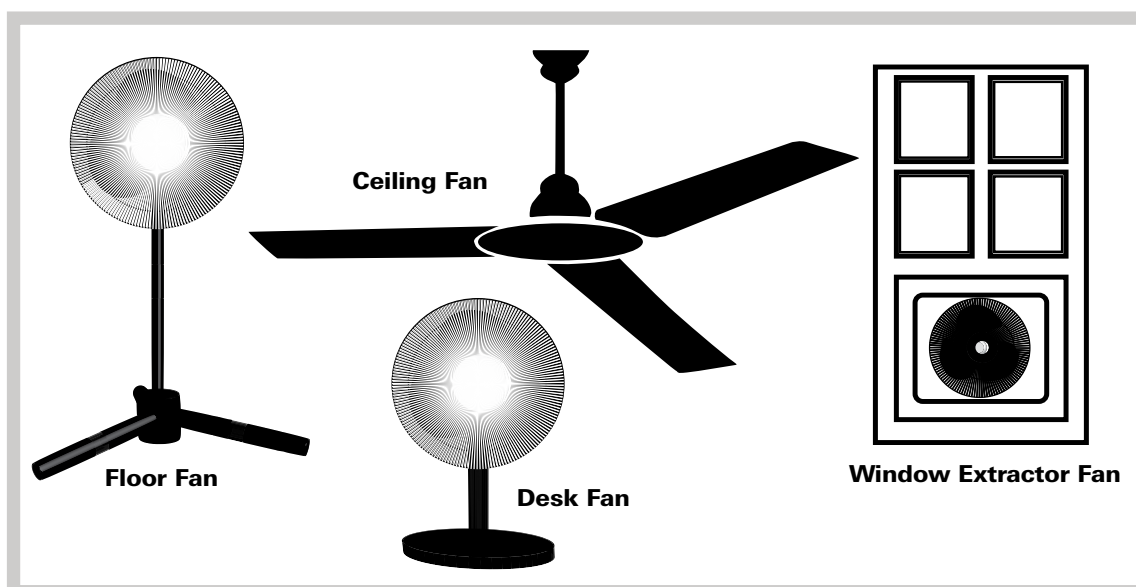
Picture: Wind driven turbines:

These devices pull warmer air from the ceiling and push it outside enhancing ventilation and without any electricity.



Example: Propeller Fans

Remember that propellor fans only mix the air within the room and only extractor fans move room air from within the building to the outside.



Tool: TB Infection Control Equipment Maintenance Log (Source: RHRU HIV Management Cluster, South Africa)

Name: will be responsible for maintenance of TB infection control equipment.

The following TB infection control equipment is used at our facility: (this should include fans, UVGI fittings, air conditioning units situated in the facility:

Name of Equipment	Situation in the facility	Name of maintenance company	Contact details of maintenance company

Equipment Maintenance and Cleaning Log:

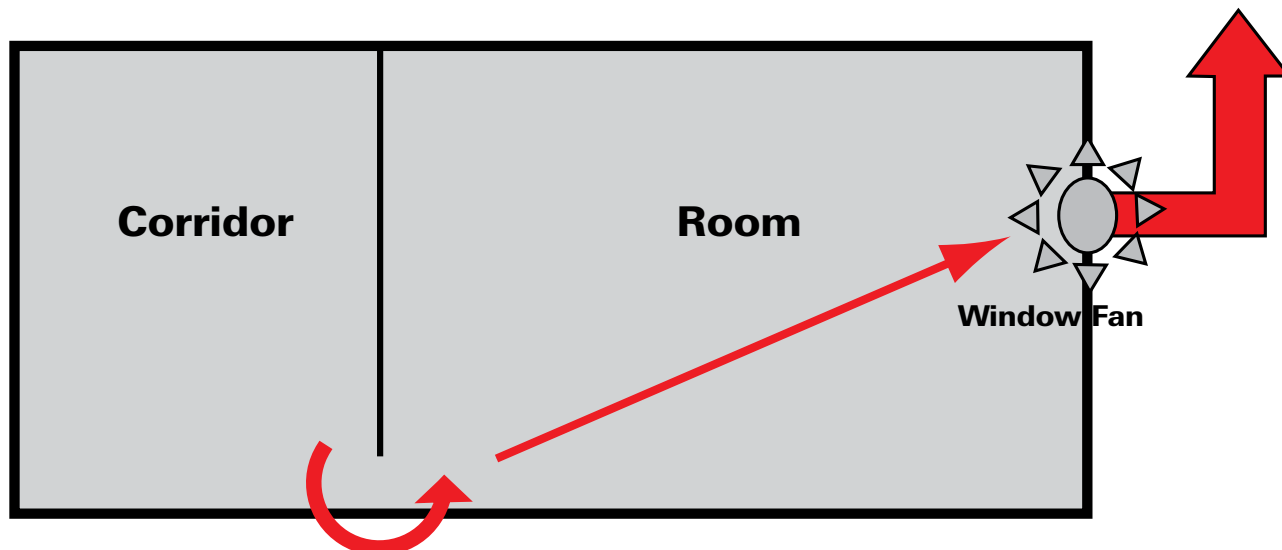
Name of Equipment:		
Description of maintenance required:		
Date:	Type of Service Done:	Next Service Required On:

Name of Equipment:		
Description of maintenance required:		
Date:	Type of Service Done:	Next Service Required On:

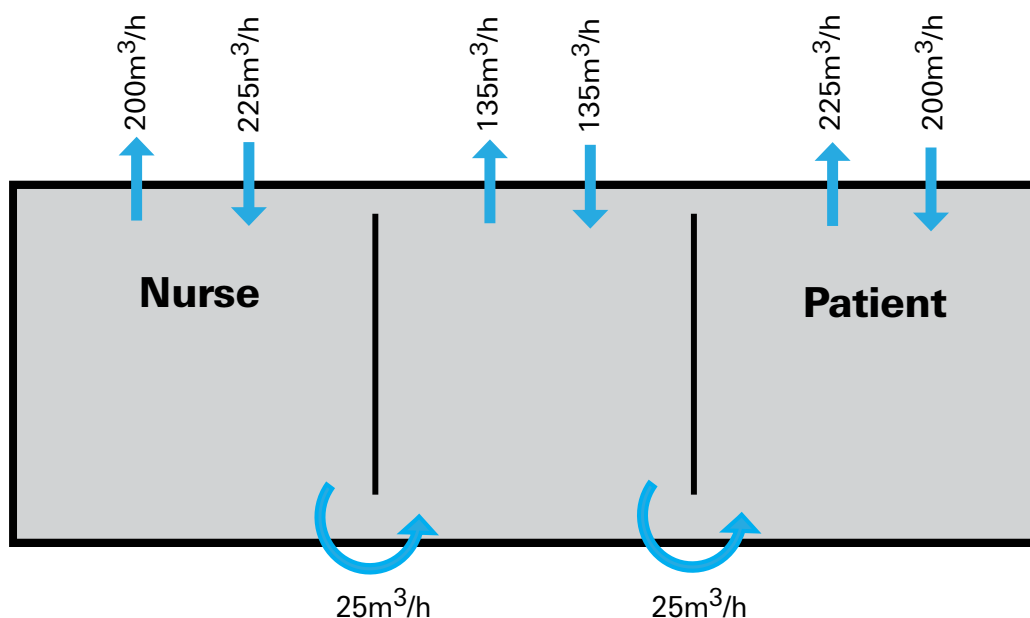
Name of Equipment:		
Description of Maintenance Required:		
Date:	Type of Service Done:	Next Service Required On:

Example: Negative Pressure

Airflow with window extractor fan



Example: Negative Pressure in "Mechanical ventilation"



Extractor fan directs/ensures air flow from the clean corridor to the contaminated room and then to the outside.

Supply and extraction of air in each room creates a gradient and directs airflow from clean rooms to the contaminated patient room.

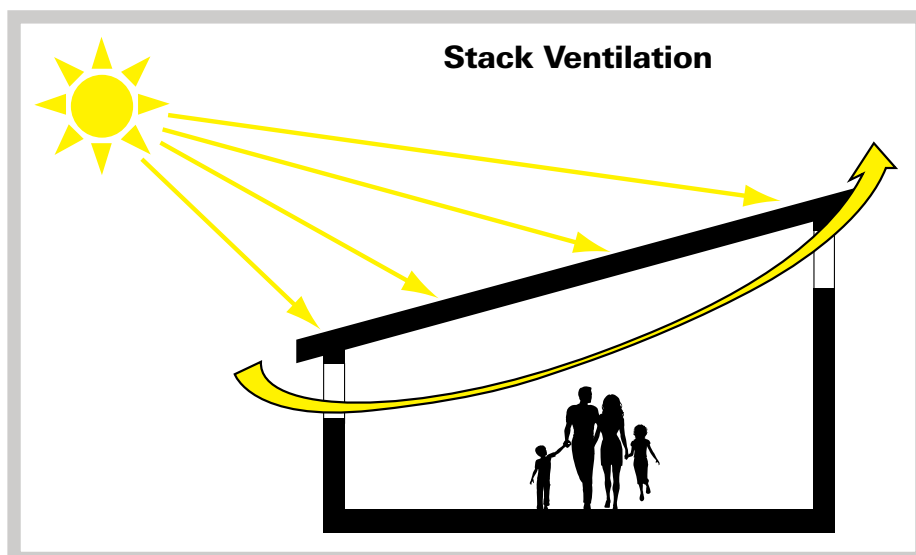
Example: Mechanical Ventilation Equipment Room of Closed Mechanical Ventilation System, MDR-TB ward, University Medical Centre St Radboud, The Netherlands
(Courtesy of Dr W. de Lange)



Closed mechanical ventilation systems are costly to install and maintain. These systems require qualified personnel to maintain the correct volume of air movement between hallways, the patients' room and cooling, heating and filtering systems. Costing of such systems must include continuous adequate maintenance and engineering personnel and upkeep supplies.

Example: Stack Ventilation

This model shows that a building with a slant roof can facilitate air movement when openings allow the free movement of air near the ceilings.



Part 4: Healthcare Facilities – Environmental Controls – Ultraviolet Germicidal Irradiation (UVGI)

TOPIC: Use of Upper Room or Shielded Ultraviolet Germicidal Irradiation Fixtures

WHAT THE WHO POLICY STATES: UVGI devices do not replace ventilation systems, rather they should be considered as an additional and effective intervention if risk cannot be reduced by ventilation. Properly designed and installed, upper room UV is associated with little or no hazards for room occupants.

What is the objective:

To decontaminate room air using UVGI fixtures.

Who should be involved:

Engineers, maintenance officers, facility administration, staff, patients, manufacturers and their local agencies.

Explain to patients, staff and visitors that UV lamps must remain switched on at all times and warn them not to look directly into the UV lamps.

What should be implemented:

UVGI should be used in priority areas in healthcare facilities for example emergency rooms, large waiting areas, homeless shelters, and other enclosed spaces where neither mechanical nor natural ventilation can be adequately protective or if extra protection is needed. UVGI is the ideal companion to natural ventilation when windows are closed at night and in cold weather conditions.

Recommended Actions:

Adopt appropriate actions for different high-risk areas of the facility and identify the workers responsible for the maintenance and monitoring of UVGI equipment.

1. Hire an engineer trained in UVGI, to design the type and placement of the units. They should also inspect the installation of the units to avoid costly mistakes;
2. Ensure that there is adequate air mixing so that the mycobacterium is exposed and sterilized.
3. Develop a UVGI procurement and maintenance plan; the budget should include both handling/ shipping costs and import taxes;
4. Have an agreement with suppliers or with district/provincial hospital engineers to measure lamp performance and maximum exposure at least yearly;
5. Establish a cleaning and lamp replacement schedule based on manufacturer guidelines. Bulbs do lose their efficiency over time and must be replaced yearly;
6. Keep a cleaning, replacement and maintenance log with dates and locations for all sites where UVGI is used in the facility;
7. Incorporate UVGI preventive maintenance procedures into existing facility maintenance programs.
8. Staff need to be educated about use, safety and maintenance of UVGI.

Example: Upper-room shielded UVGI fixture



Picture: Different types of Ceiling, Corner and wall-mounted upper-room UVGI fixtures



Figure: Electromagnetic Spectrum

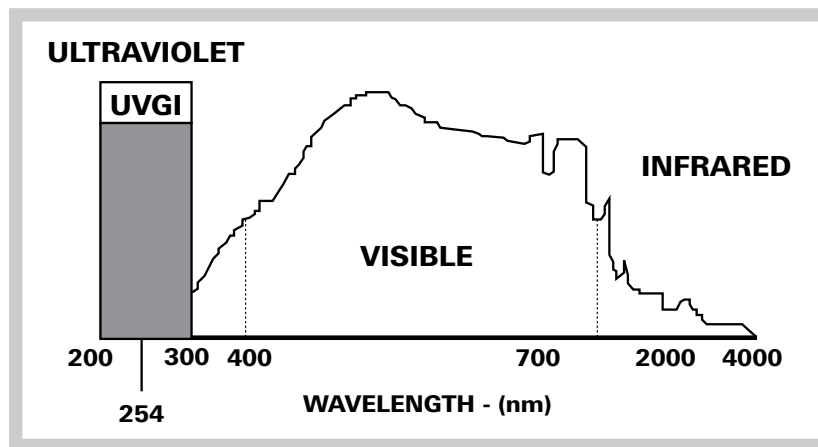


Figure: The TB Killing Zone length as projected from a UVGI wall unit above the patient's and staff's heads

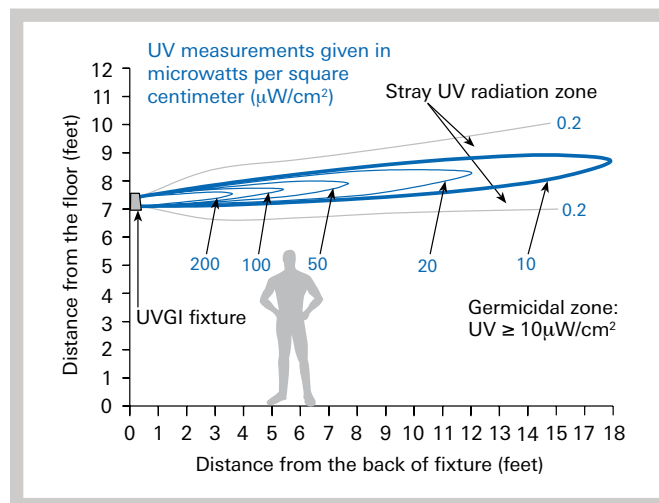
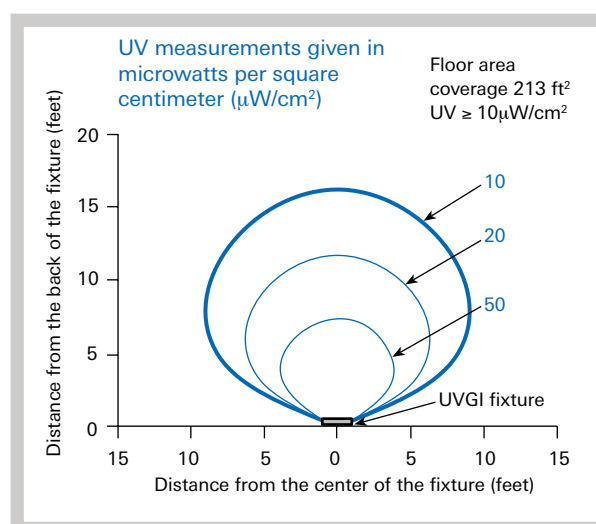
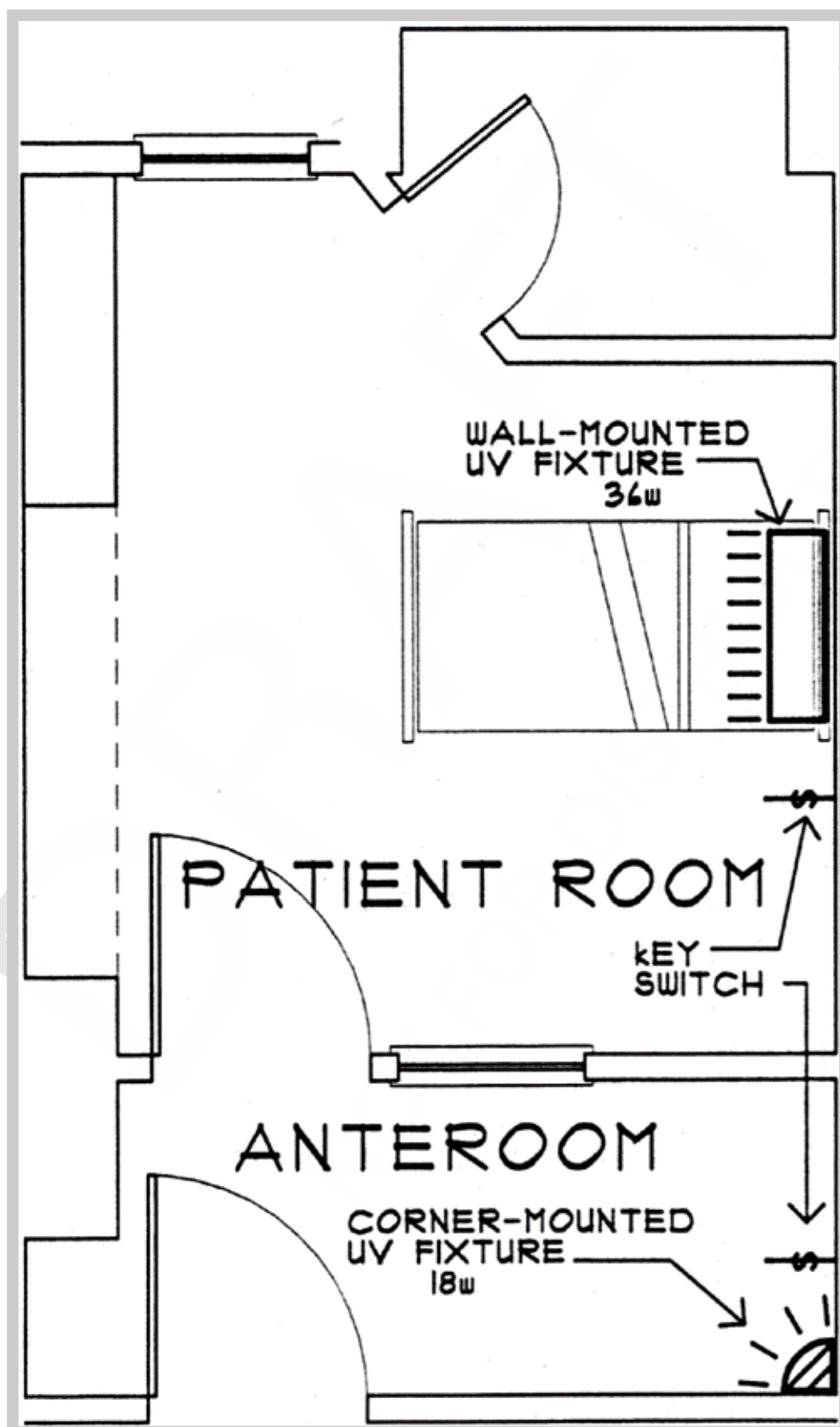


Figure: The TB killing zone width as projected from a UVGI wall unit above the patient's and staff's heads



Example: Design for corner and wall-mounted upper-room fixtures in a patient- and ante-room (Source: Guidelines for the Application of Upper-Room Ultraviolet Germicidal Irradiation for Preventing Transmission of Airborne Contagion—Part II: Design and Operation Guidance, Melvin W. First, Sc.D., P.E, Edward A. Nardell, M.D., William Chaisson, P.E. Richard Riley, M.D.)



Part 5 Healthcare Facilities

Personal Protective Equipment



Part 5: Healthcare Facilities – Personal Protective Equipment (PPE)**TOPIC:** Use of Particulate Respirators

WHAT THE WHO POLICY STATES: Use particulate respirators for HCWs when caring for patients suspected or known to have infectious TB, in particular drug-resistant TB patients. Visitors should also wear particulate respirators when in enclosed spaces with infectious cases. Particulate respirators must meet or exceed the N95 standards set by the United States Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) or the FFP2 standards that are CE certified. Particulate respirators are not to be worn by patients

What is the objective:

To reduce the inhalation of infectious particles by breathing air that has been effectively filtered to 0.3 microns.

Who should be involved:

Nurses, doctors, cleaners, ambulance drivers, radiology, laboratory staff, ancillary staff, community workers, visitors and immune compromised care takers.

What should be implemented:

A respirator program for staff members working in high risk areas or performing high risk procedures.

Recommended Actions:

Adopt appropriate actions for the different services offered at the facility and identify the staff responsible for those actions.

1. Select and procure different models/sizes of respirators in adequate amounts to ensure an uninterrupted supply;
2. Determine those staff working in high risk facilities/areas, in particular staff caring for known or suspected MDR or XDR-TB patients or performing high risk procedures, for example aerosol-generating procedures;
3. Create a site specific policy detailing whom should wear a respirator and where and when they should be worn;
4. Train staff on when and how to wear the respirators safely;
5. Keep a register on fit test results (name, date of fit test, results, respirator type and size, date of next yearly test);
6. Supervise staff on the proper use and storage of respirators and counsel those workers who are not in compliance with your respiratory policy, emphasizing positive reinforcement and rewarding good behavior;
7. Put up signs indicating where high risk areas are being entered and reminding staff to wear respirators when entering the area;
8. Inform patients as to why staff wear respirators and patients use tissues, cloths or wear surgical/face masks.

Fact sheet: N95 Respirators (Source: RHRU, HIV Management Cluster, South Africa)

Fact Sheet: N95 Respirator/Masks

What is an N95 respirator/mask and how does it work to prevent transmission of TB?

Masks placed in front of and around the mouth and nose can act as filters, to capture infectious particles and prevent them from being inhaled. In this way, infection with TB can be prevented. Masks in this context can be called 'particulate filter respirators.' Droplet nuclei that have potential to transmit TB infection are 1-5µm in diameter. Masks that are able to prevent TB infection must capture particles this size and larger.

N95 respirator/masks meet specifications required by the United States National Institute for Occupational Safety and Health (NIOSH) which include:

- Filter size of 1µm in size
- Filter efficiency = 95%
- Tight facial seal.

The letter 'N' in N95 refers to the fact that the mask/filter is 'Not resistant to oil'.

How well do the N95 respirator/masks prevent TB infection?

No-one has been able to measure this! Some guidelines don't even recommend the use of these masks! But one thing is for certain – they will NOT work if:

- They are not properly fitted
- If the wearer has facial hair (beard) preventing a proper fit
- They are damaged or crushed
- They are saturated (reused until the filter capacity has been exceeded)
- They get wet (even if they dry again).

Can I re-use N95 respirator/masks?

N95 respirator/masks are expensive. It is helpful to re-use them. New masks can be issued after 2 weeks of use. General guidelines to facilitate reuse include:

- Each staff member should re-use their own mask (it is helpful to write the staff member's name on the mask)
- Keep the mask dry and clean.
- Replace masks if they are damaged, or get wet
- Never use the mask 'inside out' or reversed.

Who should use ordinary surgical masks?

Surgical masks are very different from N95 respirator/masks. They have only 50% filter efficiency and lack a tight facial seal. Infectious patients should use ordinary surgical masks because these reduce the numbers of infectious particles in the air. Surgical masks are useful to catch larger respiratory droplets and prevent droplet nuclei from forming.

Who should use N95 respirator/masks, and when?

HCW (and visitors) should use N95 respirator/masks in specific high-risk areas only ¹. These could include

- Areas where administrative and environmental controls probably will not protect persons from inhaling infectious airborne droplet nuclei. This would include the clinic rooms where TB suspects are seen, hospital casualty facilities, MDR TB treatment facilities.
- When dealing with patients with suspected or confirmed infectious TB (i.e. pulmonary TB, not TB meningitis)
- When cough-inducing procedures are performed on patients with suspected or confirmed TB disease;
- XDR or MDR treatment points or facilities.

Masks are NOT a substitute for administrative and environmental controls. Masks will improve personal protection when administrative and environmental controls are functioning optimally.

Which TB patients are most infectious?

TB suspects with the following symptoms or conditions are more likely to be infectious:

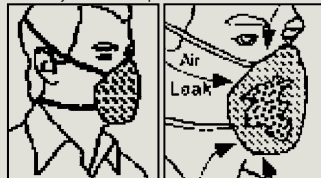
- Cough
- Cavitation on chest x-ray;
- Positive AFB sputum smear result;
- Respiratory tract disease with involvement of the lung or airways, including larynx;
- Failure to cover the mouth and nose when coughing;
- On TB treatment for less than 2 weeks.

Fitting an N95 respirator/mask

A mask will provide no protection if it is not properly fitted, as air will flow through 'gaps' between the mask and the wearer's skin. Fit-tests should be done when selecting the type of mask that your facility uses as variability in facial structure can mean that different types of masks fit better. Any facial hair, such as beards or long sideburns, may prevent the respirator from fitting properly. An informal way to test the fit of your mask is as follows:

- Fit the mask according to manufacturer's instructions.
- Once the mask is in place, inhale sharply. The mask should be drawn in towards your face, indicating that a negative pressure has been generated.
- If the mask does not draw in towards your face, or you feel leakage at the edges, adjust straps by pulling back along the sides and/or reposition respirator.
- Repeat until mask is sealed properly.

Figure 1. (A). N95 respirator/mask (B) Air leaks on an incorrectly fitted N95 respirator/mask.



Example: Components of a Respirator Fit Test Program

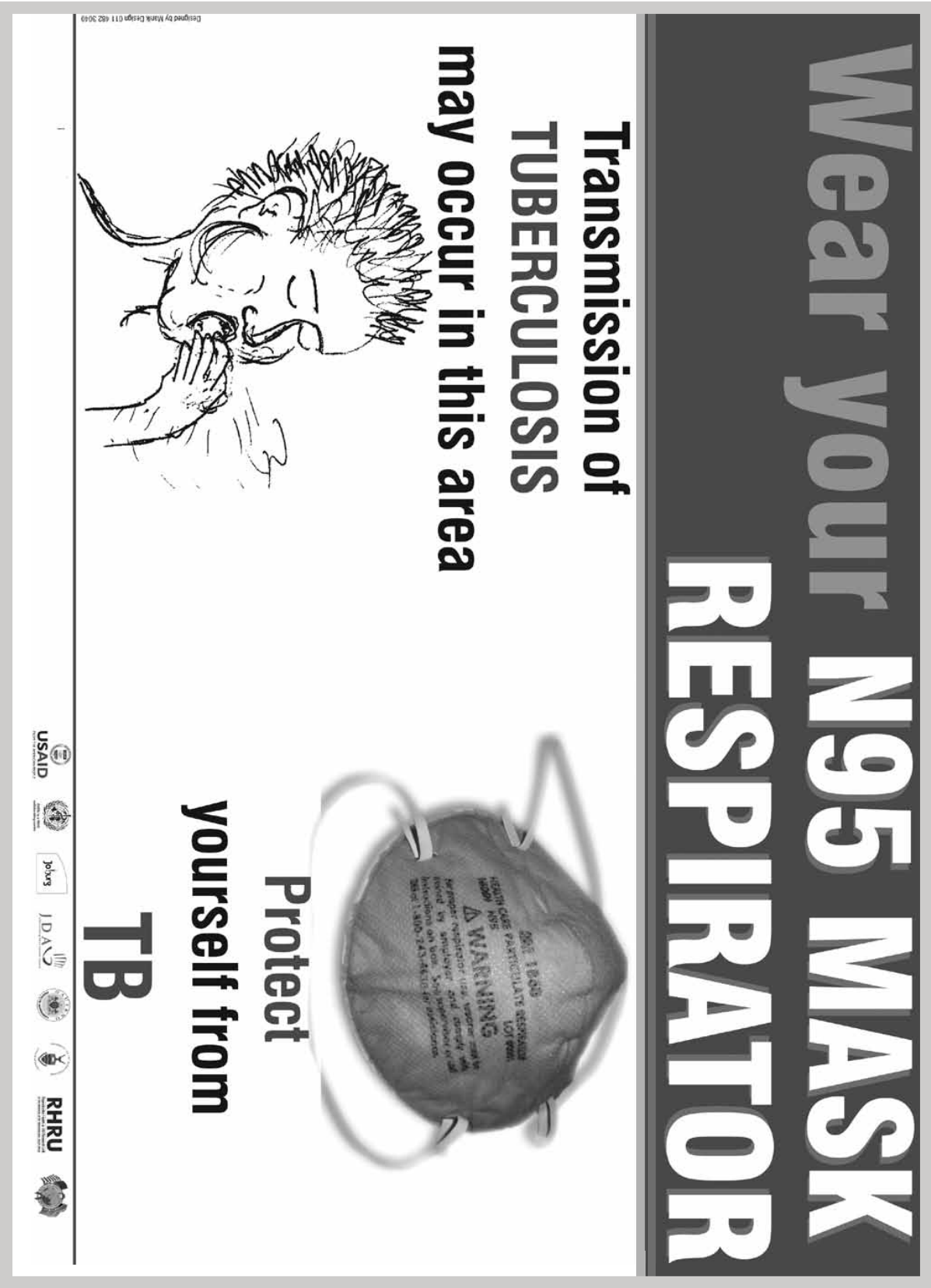
A respirator program ideally consists of the following components:

1. Selection of different types of respirators.
2. Formation of a pool of respirator-fit-testers.
3. Procurement of qualitative respirator fit test kits.
4. Adoption of a medical evaluation fit test form and fit-test-certificate and fit-test-register.
5. Qualitative fit testing of staff attending to TB patients.
6. Procurement of selected N95 or FFP2 respirators.
7. Development of a SOP on the use and storage of respirators*.
8. Distribution of the respirators.
9. IEC materials (poster, pamphlets and signage).
10. Evaluation of the program after one year.

* See Annex: Respiratory Protection Information Brochure for Staff of KNCV Tuberculosis Foundation Page 125

Picture: Fit Test Kit

Example: Signage for staff on wearing respirator (Source: RHRU HIV Management Cluster, South Africa)



Tool: Respirator Medical Evaluation Form (Modified from Occupational Safety and Health Administration, US Department of Labor #1910, Appendix C, Respirator Medical Evaluation Form - V. Lipke)

Respirator Medical Evaluation

This questionnaire is used in determining whether or not you have a medical condition that may affect your ability to wear a respirator. Fit test is also required. All medical information is considered confidential.

All information must be completed for respirator approval.

Name:	Date:	Employee Number # or EID:
Job/Title:	Unit/Department:	Manager:
Work Phone:	Home Phone:	
Work Location:		

	Yes	No
Have you ever used a respirator mask before?		
Have you ever had problems wearing a respirator?		
Do you have medical problems which may interfere with respirator use?		
Are you short of breath at rest?		
Do you get short of breath when walking?		
Do you get chest pain with certain activities?		
Do you have claustrophobia?		

Has a doctor ever told you, that you have one of the following?

	Yes	No		Yes	No
Angina			Diabetes		
Heart Attack			Lung Disease		
Heart Disease			Asthma		
Epilepsy or Seizure			High Blood Pressure		

Smoking History:

Smoke: _____ Ex-Smoker: _____ Never Smoker: _____

Are you currently taking any medications?

If yes please list: _____

Since facial hair may interfere with the respirator face piece seal, gentlemen need to be clean shaven while wearing any tight-fitting respirator. This includes disposable filtering face piece respirators such as N95s. Fit testing should be repeated if you have a weight change of 20 pounds (9.07kg) or more, significant facial scarring in the area of the face piece seal, significant dental changes (i.e. multiple extractions without prosthesis, or acquiring dentures), reconstructive or cosmetic surgery, or any other condition which may interfere with face piece sealing. I understand the above, and will schedule a new fit test with Employee Health if indicated.

Employee Signature _____ Date: _____

Approved _____ Denied _____

Restrictions/Remarks _____

Tool: Respirator Fit Test Procedure Form (Modified from the Occupational Safety and Health Administration, US Department of Labor Manual on TB Fit Testing - V. Lipke)

Employees should pass an appropriate qualitative fit test or quantitative fit test:

Prior to initial use,

Whenever a different respirator (size, type, model or make) is used,

Periodically thereafter,

Additional fit test whenever changes in physical condition or job description that could affect respirator fit are noticed or reported.

Observe if the HCW applies the respirator in a correct manner.

Name of employee: _____

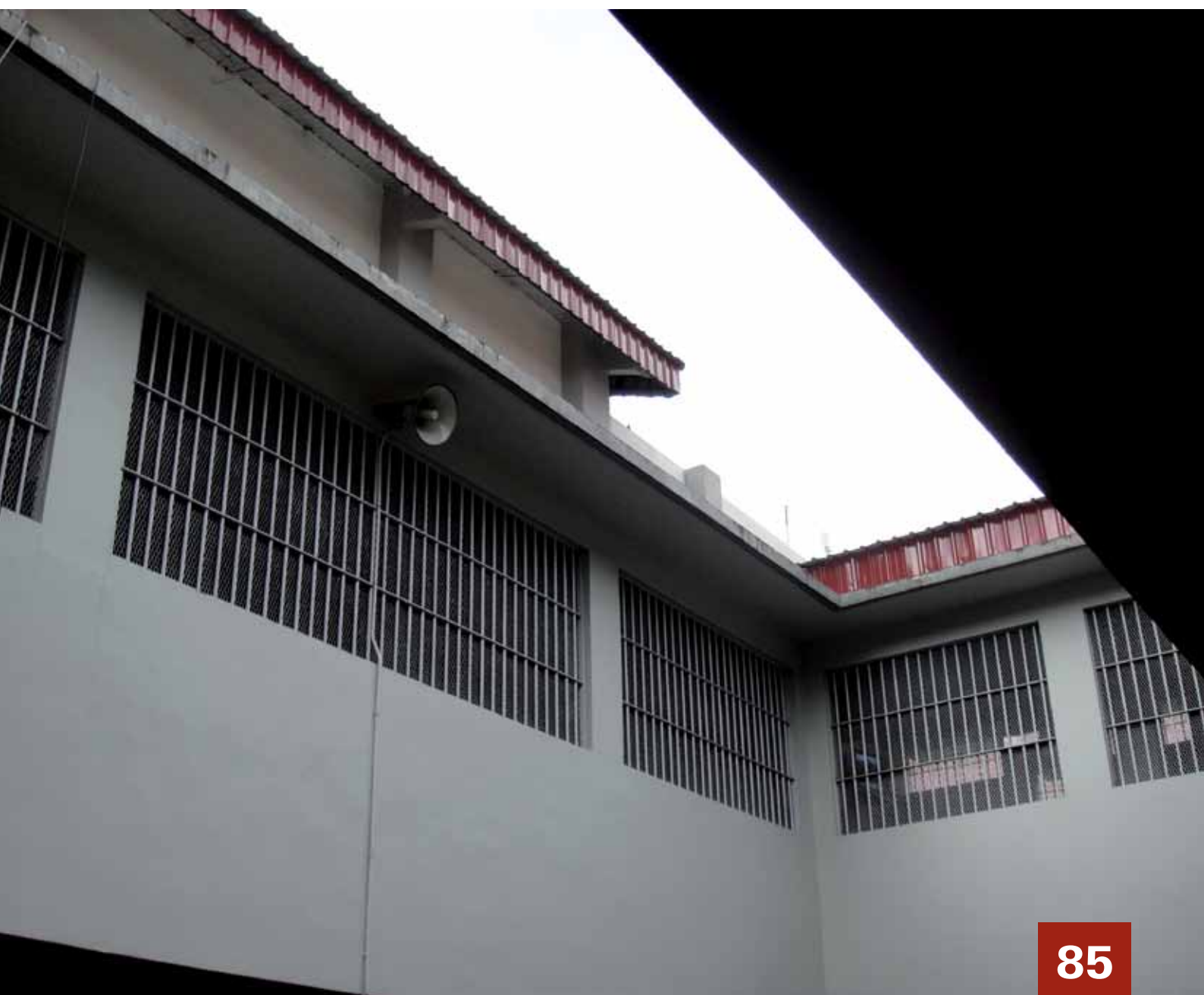
Place of work (Name of facility/Department): _____

Date of fit test: _____

Respirator (Type and size): _____

Steps	Activity	Y	N
Step 1	Respirator Medical Evaluation		
Sensitivity Test			
Step 2	Use sensitivity solution to establish if health worker tastes test agent		
Application of Respirator			
Step 3	Find center of nose piece and bend		
Step 5	Open respirator		
Step 5	Place straps on back of head		
Step 6	Place respirator on face		
Step 7	Pull top strap over head		
Step 8	Place top strap on crown of head		
Step 9	Pull lower strap over head		
Step 10	Pinch metal clip or foam cuff around nose		
Step 11	Pull respirator over chin		
Step 12	Check for major leaks		
Fit Test			
Step 13	Cover head with hood with opening in front		
Step 14	Squeeze nebulizer 5-10 times with fit test solution		
Step 15	Normal breathing 1 minute		
Step 16	Deep breathing 1 minute		
Step 17	Move head side-to-side 1 minute		
Step 18	Move head up-and-down 1 minute		
Step 19	Talk non-stop 1 minute		
Step 20	Jogging or walking in place 1 minute		
Step 21	Normal breathing 1 minute		
Step 22	Remove straps one by one from behind over the head		
Administration / Comments			
Date of next fit test:		Name:	

Part 6 Congregate Settings



Part 6: Congregate Settings

TOPIC: TB-IC measures should be assessed and implemented in prisons and other settings where people have a higher risk of TB transmission due to a confined setting.

WHAT THE WHO POLICY STATES: TB is spread more readily in congregate settings than in healthcare facilities because of the longer duration of potential exposure, crowded environment, poor ventilation, and limited access to healthcare services. Any clinic or infirmary within these settings should implement TB-IC measures, as in any other healthcare facility.

What is the objective:

To apply appropriate TB-IC measures in congregate settings such as prison cells, homeless shelters, barracks, refugee camps, dormitories, nursing homes, work sites such as factories, mine shafts and settings which provide services for PLHIV. Communities have the right to a work place and community space without being at risk of acquiring a life threatening infection like TB.

Who should be involved:

Policy makers, Coordinating bodies, Ministries and Non-governmental organizations responsible for congregate settings, detainees, patients, management and staff of prisons, jails, factories and mines where workers have high burden of TB, AIDS support organizations and other congregate settings.

What should be implemented:

All sites where people with high burden of TB are gathered need to incorporate appropriate TB-IC to reduce the risk of transmission.

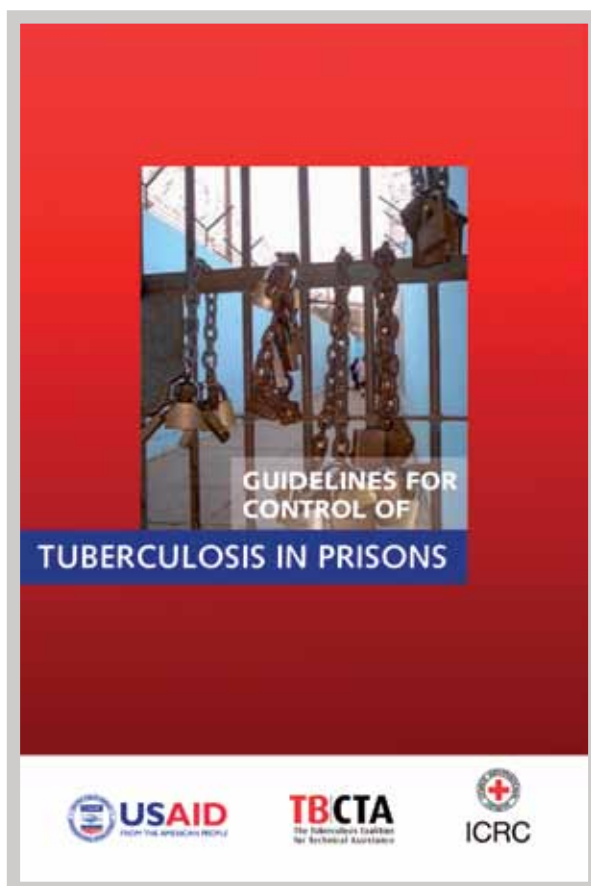
Recommended Actions:

Adopt appropriate actions for the different congregate settings and identify those responsible for those actions (Start with items that can be easily incorporated first).

1. Train people in charge of congregate settings where people with a high burden of TB work, access services, or congregate for other reasons;
2. Conduct a facility assessment;
3. Provide TB screening for all persons accessing the congregate spaces when doing intake and at regular intervals;
4. Focus on bringing educational materials and TB-IC activities into prisons, other correctional institutions and other settings;
5. Support the early identification of coughers and the use of cough etiquette by supplying tissues or cloths. Help create group agreements and culture of the congregate setting where people who have cough (lasting more than two weeks) are identified and encouraged to seek services without stigmatizing them;
6. People suspected of having TB or diagnosed with TB should be encouraged to start therapy as quickly as possible and to stay on treatment until cured;
7. Separate infectious TB patients away from those that don't and, if possible, isolate them in an adequately ventilated area, until sputum conversion;
8. Separate people suspected of or having drug-resistant TB, from other inmates (including other TB patients) or refer them for proper treatment;
9. Give information and encourage staff and people residing in congregate settings to undergo HIV Testing & Counseling and refer them for treatment;
10. If diagnosed with HIV, offer a package of prevention, care and treatment which includes periodic and symptomatic screening for TB.

Example: TB-IC Measures in Prisons (Source⁷: Guidelines for Control of Tuberculosis in Prisons, 2009, TBCTA and International Committee of the Red Cross)

1. Preventing the spread of infection from community to prison.
 - Using intensified TB screening for new or transferred prisoners.
 - Preparing adaptation blocks or rooms (to be used for two to four weeks) for new or transferred prisoners.
2. Preventing TB infection among prisoners (from one TB prisoner to other prisoners) or to prison's staff.
 - Conducting a contact investigation for TB suspects and cases.
 - Improving infection control (i.e. implementing managerial, administrative, and environmental interventions) in prisons.
 - Using IEC for prisoners.
3. Preventing infection of family members and the community by released prisoners or prison staff.
 - Examining prisoners before release.
 - Examining prison staff regularly.



Guidelines for the Control of Tuberculosis in Prisons - January 2009

Masoud Dara, Malgosia Gremiska, Michael E. Kimerling, Herman Reyes, Andrey Zagorskiy

⁷ This publication can be downloaded here:
http://www.tbcta.org/Uploaded_files/Zelf/GuidelineTBPrisons1252321251.pdf

Part 7 Households



Part 7: Households

TOPIC: TB-IC activities and measures also apply to household settings.

WHAT THE WHO POLICY STATES: Reduction of transmission of TB in particular MDR-TB in households is necessary because the household members are at high risk of becoming infected and consequently developing TB. Whether a patient is treated on an outpatient basis or admitted to a healthcare facility appears to have little impact on household transmission, provided the patient is treated effectively. Patients with MDR-TB usually convert later than those with drug-susceptible TB. This may prolong the risk of transmission in the household. MDR-TB increases the risk of morbidity and mortality, particularly in people living with HIV. Additional infection control measures should therefore be implemented for the management of MDR-TB patients at home.

What is the objective:

To ensure TB-IC measures are carried out in household settings reducing the likelihood of TB transmission to others in the household.

Who should be involved:

Policy makers, management and staff of community-based organizations, health facilities with home-based care services, community leaders, patients and their family members and close contacts.

What should be implemented:

The promotion of early diagnosis of cases, adherence to treatment and implementation of proper TB-IC practices in the household, before and after the diagnosis of TB.

Recommended Actions:

Adopt appropriate actions for the differing audiences and identify those who can offer the greatest influence in improving household compliance to TB-IC practices. Start with the easier ones first and then add other actions.

1. Engage community leaders and representatives as champions for TB prevention activities especially in areas with a high burden of TB and MDR/XDR-TB;
2. Create community awareness on the early signs and symptoms of TB, prompt treatment until cured and risk reduction strategies for the home such as openings windows, sleeping away from the patient and use of IPT in children and if family members are HIV positive;
3. Minimize stigma related to TB-IC specific measures as the wearing of face masks. Be the role model for good TB-IC;
4. Develop and display posters and other IEC materials which feature natural ventilation and cough hygiene;
5. Train community health workers and volunteers on TB-IC and how to conduct home visits;
6. Educate household members on TB-IC measures, in particular adherence to treatment and cough etiquette;
7. Conduct contact investigations of all household members and close contacts who may have been exposed to the patient;
8. Offer HIV Testing and counselling to all household members;
9. Offer preventive treatment in particular to children and HIV-positive household members;
10. Whenever possible, wear respirators whilst attending to MDR-TB patients at home;
11. Encourage household members and the person(s) with TB disease to participate in a facilitated support group.

Example: How to Reduce Exposure in Households

Houses should be adequately ventilated, particularly rooms where people with infectious TB spend considerable time (natural ventilation may be sufficient to provide adequate ventilation).

Anyone who coughs should be educated on cough etiquette and should follow such practices at all times.

While smear positive, TB patients should spend as much time as possible outdoors, sleep alone in a separate, adequately ventilated room and spend as little time as possible in public places or in public transport.

While smear or culture positive, MDR-TB patients who cough should always practice cough etiquette (including use of face masks) when in contact with people.

Ideally, health service providers should wear respirators when attending patients in enclosed spaces.

Ideally, family members living with HIV, or family members with strong clinical evidence of HIV infection, should not provide care for infectious MDR-TB patients. If there is no alternative, HIV-positive family members should wear respirators.

Children below five years of age should spend as little time as possible in the same living spaces as culture-positive MDR-TB patients. Such children should be followed up regularly with TB screening and, if positive, drug-susceptibility testing.

When conditions do not exist to minimize risk of TB infection in a household, XDR-TB patients should be admitted to a specialized healthcare facility.

Household members of any TB patients should be encouraged to get screened for HIV and TB and be given appropriate (preventive) therapy.

If possible, HIV-positive family members, or family members with a strong clinical evidence of HIV infection, should not share a household with culture positive XDR-TB patients.

If possible, renovation of the patient's home should be considered, to improve ventilation (e.g. building of a separate bedroom, or installation of a window or wind catcher – "Whirly bird" – or both)*.

* Annex SOP 201: TB Infection Control Community-based Guidelines (Page 150)

Part 8 References



References/Websites

International Federation of Infection Control:
<http://www.theIFIC.org/>

Tuberculosis Coalition for Technical Assistance:
<http://www.tbcta.org/>

Global Health Delivery Online:
<http://www.ghdonline.org/ic/>

International Union Against Tuberculosis and Lung Disease:
<http://www.theunion.org/>

Centers for Disease Control and Prevention:
<http://www.cdc.gov/>

The World Health Organisation:
<http://www.who.int/en/>

The World Health Organisation - Tuberculosis:
<http://www.who.int/tb/en/>

The World Health Organisation - Infection Prevention and Control in Health Care:
http://www.who.int/csr/bioriskreduction/infection_control/en/index.html

Association for Professionals in Infection Control and Epidemiology:
<http://www.apic.org/>

United States Agency for International Development:
<http://www.usaid.gov/>

The Stop TB Partnership:
<http://www.stoptb.org/>

KNCV Tuberculosis Foundation:
<http://www.kncvtbc.nl/>

The Lilly MDR-TB Partnership:
<http://www.lillymdr-tb.com/>

The Francis J. Curry National Tuberculosis Center:
<http://www.nationaltbcenter.edu/>

International Hospital Federation:
<http://www.ihf-fih.org/>

HIV/AIDS Treatment in Practice:
<http://aidsmap.com/hatip>

Part 9

Glossary of Terms



Glossary of Terms

The terms listed below have been defined or adapted for the purpose of this document.	
Air Changes per Hour	Under ideal conditions – in which droplet nuclei are evenly distributed and room air is uniformly mixed – the proportion of infectious particles eliminated with each air change or one “equivalent air change” is 63%. A second air change removes 63% of what remains, and so on. One air change has occurred when the volume of air entering or exiting a room is equal to the volume of the room. Subsequent increases in air changes leads to an exponential reduction in droplet nuclei.
Advocacy Communication and Social Mobilization	In this context, the aim of advocacy is to secure financial resources and change policies, guidelines or procedures by influencing groups such as politicians, decision makers and journalists. The aim of communication is increase awareness, influence social norms, change behavior (in individuals or sub-populations) and improve communication and counselling between people with TB, their families and providers. The aim of social mobilization is to change norms, improve services, expand community support and solve social problems, often by bringing groups together to act at the community level.
Adequately Ventilated Room	A room with at least 12 air changes per hour (ACH).
Aerosol	Liquid or solid particles dispersed in air, that are of fine enough particle size (0.01 to 100 micrometers) to remain airborne for a period of time.
Airborne Precautions	Precautions that apply to patients or suspects with airborne infections and are used in addition to Standard Precautions (see below); these include use of respirators by health workers, patient placement in a separated well-ventilated area and use of medical mask on patient for transportation outside patients isolation area. These precautions are generic for all airborne infections but they also contribute to reduce the spread of TB.
Anemometer	A hot wire device that measures the air velocity commonly used in laboratories when testing the performance of a biological safety cabinet.
Community Involvement	Community involvement in TB means the involvement of people with TB and their communities in the design, implementation, monitoring and evaluation of health promotion, TB preventive and curative services. Home-based care and community-based approaches for management of TB are part of community involvement in TB control.
Congregate Settings	A mix of institutional settings where people live in close proximity to each other such as correctional facilities e.g. prisons, jails, homeless shelters, refugee camps, military barracks, dormitories and nursing homes. For the purpose of this document, healthcare facilities are considered separately, even though these are settings where people congregate.
Control	Measures used to minimize the risk of spreading TB within populations.
Droplet Nuclei	Airborne particles that carry Mtb; droplet nuclei are generated after people who have pulmonary or laryngeal TB disease cough, sneeze, shout, or sing. The particles are approximately 1–5 µm; normal air currents can keep them airborne for prolonged periods and spread them throughout a room or building. Droplets are generally >5 µm in diameter. Droplets settle faster than a droplet nucleus and will not reach the alveoli.
Extensively Drug Resistant	XDR-TB is defined as resistance to at least rifampicin and isoniazid from among the first-line anti-TB drugs (which is the definition of MDR-TB) in addition to resistance to any fluoroquinolones, and to at least one of three injectable second-line anti-TB drugs used in TB treatment (capreomycin, kanamycin, and amikacin).
Fit Testing	The use of a protocol to select the best fit of a respirator on a person.
Healthcare Facility	Any establishment that is engaged in direct patient care on site.

Healthcare Facilities	Clinical context where healthcare is provided (e.g. hospital, outpatient clinic, home).
Health Care Workers	Health care workers are all people, in public and in private services, in the health sector and other sectors, whose main activities are aimed at enhancing health. They include the health service providers – for example doctors, nurses, pharmacists, laboratory technicians – and the health management and support workers for example financial officers, cooks, drivers and cleaners.
Infection Control Assessment	An assessment of the implementation of managerial activities (including risk assessment), administrative controls, environmental controls, and respiratory protective equipment in a setting, in the context of local epidemiological, climatic and socioeconomic conditions.
Infectious Case	Smear-positive cases are the most infectious and most likely to transmit TB. Smear-negative but culture- positive cases can also transmit TB.
Isolation Room	Patient room (ideally single) where infectious TB patients should be isolated from other patients.
HIV Prevalent Settings	HIV-prevalent settings are defined as countries, sub-national administration units (e.g. districts, counties) or selected facilities (e.g. referral hospitals, drug rehabilitation centers) where the adult HIV prevalence rate among pregnant women is more than or equal to 1% or HIV prevalence among TB patients is more than or equal to 5%.
Measures	These include the set of managerial activities, administrative controls, environmental controls and personal protective equipment for TB infection control.
Mechanical Ventilation	Mechanical ventilation is created by using a supply and/or an exhaust fan to force air exchange and to drive airflow. It works by generating negative or positive pressure in the room to drive air changes. To be effective, all doors and windows must be kept closed with controlled air leakage into or out of the room.
Mixed-mode Ventilation	A ventilation system that combines the use of both mechanical and natural ventilation. It provides the opportunity to choose the most appropriate ventilation mode based on the circumstances.
Multidrug-Resistant TB (MDR-TB)	TB caused by strains of M. Tuberculosis, which are resistant to both isoniazid and rifampicin with or without resistance to other drugs.
Natural Ventilation	Ventilation created by the use of external natural forces such as wind and temperature. Control of airflow direction cannot be achieved by simple natural ventilation and is dependent upon sufficient wind speed or direction, or temperature differential.
Negative Pressure	Permits the control of the air-flow direction so the room with negative pressure has a lower pressure than adjacent areas, which keeps air from flowing out of the room and into adjacent rooms or areas. It is the relative air pressure difference between two areas in a healthcare facility.
Nosocomial Transmission	An infection occurring in a patient in a hospital or other health facility in whom the infection was not present or incubating at the time of admission. This includes infections acquired in the hospital but appearing after discharge, and also occupational infections acquired by staff working at the facility.
Particulate Respirators	Special type of closely-fitted mask with the capacity to filter particles to protect from inhaling infectious droplet nuclei. The N95 respirator has filter efficiency level of 95% or greater against particulate aerosols free of oil when tested against 0.3 µm particles. The "N" denotes that the mask is not resistant to oil; the "95" refers to 95% filter efficiency. The FFP2 respirator has a filter efficiency level of 94% or greater against 0.4 µm particles and is tested against both an oil and a non-oil aerosol.
People suspected of having TB or people with TB symptoms	Any person who presents with symptoms or signs suggestive of TB.

Personal Protective Equipment	Personal protective equipment for eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers, which should be provided, used, and maintained in a sanitary and reliable condition wherever it is necessary by reason of hazards of processes or environment, biological hazards, chemical hazards, radiological hazards, or mechanical irritants encountered in a manner capable of causing injury or impairment in the function of any part of the body through absorption, inhalation or physical contact.
Public Health Surveillance	The ongoing, systematic collection, analysis, interpretation and dissemination of data regarding a health-related event, for use in public health action to reduce morbidity and mortality, and to improve health. Data disseminated by a public health surveillance system can be used for taking immediate public health action, planning and evaluating programmes, and formulating research hypotheses.
Risk Assessment	The risk assessment includes analysis, collection and review of surveillance data and in-depth facility description.
Separation	Placing patients infected or colonized with the same known pathogen in a designated unit (one that has the same space and staff), to which patients without the pathogens are not admitted.
Smoke Tube	Device used to generate visible, non-hazardous smoke which can be used to monitor proper airflow direction and assist in assessing the proper function of ventilation systems.
Standard Precautions	The basic infection control precautions in healthcare that are intended to minimize spread of infection associated with patient's blood, body fluids, secretions and non-intact skin. Examples of such precautions include hand hygiene (possibly by hand rubbing with alcohol based formulations or hand washing using soaps and clean water), respiratory hygiene, cleaning and disinfection, waste management and – based on infection control assessment – use of personal protective equipment (e.g. gloves, facial protection, gowns).
Surgical or Face Mask	Cloth or paper mask that prevents the spread of micro-organisms from the wearer to others by capturing the large wet particles near the source (mouth); it may not provide protection from inhaling infectious droplet nuclei, such as M. Tuberculosis.
Triage (in relation to TB)	A system for identifying TB suspects based on cough, used in fast-tracked TB diagnosis and further separation when necessary.
UVGI	Radiation at 254 nm, produced within the UV-C region of the electromagnetic spectrum. UVGI prevents microbial replication by inactivating both bacterial and viral DNA. The most practical and effective application uses wall or ceiling-mounted UVGI fixtures to create a upper room air disinfection zone. Good mixing of air between the upper and lower room is required to allow effective disinfection of air in the lower part of the room where people breathe (the breathing zone).
Vaneometer	A device that measures the velocity of air with a moving replaceable vane inside. Commonly used during facility assessments to calculate the ACH.

Part 10 Annexes



Annex: TB Infection Control as One of the 12 Collaborative TB/HIV Activities

In 2008 nearly a third of TB deaths were HIV related. The relative risk of TB among PLHIV ranges from 20-37 fold higher compared with that among persons not infected with HIV.

WHO has issued the WHO TB/HIV policy recommending twelve collaborative activities as part of core HIV and TB prevention, care and treatment services. This includes interventions which reduce TB morbidity and mortality in PLHIV in addition to the provision of ART, ICF, IPT, and IC for TB, which are also branded as Three 'I's for HIV/TB, which should be primary responsibilities of National AIDS programs and HIV stakeholders.

Ensure that the Three 'I's for HIV/TB are implemented by those providing care to PLHIV in order to protect them from TB infection, help prevent active disease from developing, identify active TB disease early, improve the chances of cure and prevent transmission, as part of TB-IC.

WHO recommended collaborative TB/HIV activities**Establish mechanisms for communication**

1. Set up a coordinating body for TB/HIV activities effective at all levels
2. Conduct surveillance of HIV prevalence among TB patients.
3. Carry out joint TB/HIV planning.
4. Conduct monitoring and evaluation.

Decrease the burden of TB in people living with HIV (the Three 'I's for HIV/TB)

1. Establish Intensified TB case-finding.
2. Introduce Isoniazid prevention therapy.
3. Ensure TB Infection control in healthcare and congregate settings.

Decrease the burden of HIV in TB patients

1. Provide HIV testing and counseling.
2. Introduce HIV prevention methods.
3. Introduce cotrimoxazole preventive therapy.
4. Ensure HIV care and support.
5. Introduce antiretroviral therapy.

Annex: ICAP TB Infection Control Practices: Facility Assessment**ICAP TB Infection Control Practices: Facility Assessment**

The purpose of this survey is to assess the current TB infection control practices in the facility, through observation and discussion with the sister in charge.

Facility name: _____ Region/District: _____
 Completed by: _____ Designation: _____
 Information supplied by: _____ Designation: _____
 Date form completed (dd/mm/yyyy) ____/____/____

TB Infection Control Plan

1. Does the facility have a written infection control plan that is kept on site? ☐ Yes ☐ No
2. If YES, is TB infection control
 - ☐ Included in this plan
 - ☐ Maintained in a separate plan
 - ☐ Not available
 - ☐ Not sure

If there is a TB infection control plan, obtain a copy for review (see last page to review the plan in detail)

Patient Triage and Management

3. Observe whether there a staff member who screens patients for prolonged (longer than 2 weeks) duration of cough immediately after they arrive at the facility. ☐ Yes ☐ No
 If NO, go to question # 7
4. If YES, who is this person (designation)?

5. Where does the screening take place (describe)?

6. Are tissues, pieces of cloth, or face masks available for patients who are coughing? ☐ Yes ☐ No
7. Is there an enclosed waste basket where used tissues and face masks can be discarded? ☐ Yes ☐ No
8. Is there a separate waiting area for patients with suspected infectious TB? (Indicate this area on the facility plan on the last page.) ☐ Yes ☐ No
9. Observe and tick the appropriate boxes as to what happens to a patient who is coughing while waiting in the queue and describe further observations regarding this:

- ☐ They are asked whether they have a history of TB and/or TB treatment
- ☐ They are asked about the duration of their cough
- ☐ They are asked to wait in a separate waiting area
- ☐ They are placed in the front of the queue
- ☐ They are educated about cough etiquette and respiratory hygiene
- ☐ They are provided with tissues or face masks to cover their mouth and nose
- ☐ They are requested to produce sputum specimens
- ☐ They continue to wait in the normal queue until it is their turn to be attended to by the nurse or doctor as for any other patient
- ☐ They are sent for a chest x-ray before sputum specimens are taken
- ☐ They are sent home

Other observations:

10. Is there a symptom checklist in place to screen patients for TB? ☐ Yes ☐ No
 If NO, go to question # 15

11. If YES, what items are included in this checklist?

- ☐ Cough > 2 weeks
- ☐ Weight loss
- ☐ Night sweats > 2 weeks
- ☐ Fever > 2 weeks
- ☐ Close contact with someone with TB in the past year
- ☐ History of TB treatment

☐ Other - specify:

12. Who completes/administers the checklist (tick all that apply)?

- ☐ Data clerk
- ☐ Nurse
- ☐ Medical Officer
- ☐ Other - specify:

13. How often is the checklist administered?

- ☐ At enrollment only
- ☐ Every 6 months
- ☐ At every visit
- ☐ Other - specify:

14. Where is a TB diagnosis typically made? ☐ on-site ☐ off-site
15. If OFF-SITE, describe the process by which referral information and results of the diagnostic workup are transferred between the facility and the referral site.
-
-
16. Is there a designated area away from other patients and staff where patients can produce sputum specimens? ☐ Yes ☐ No
17. If YES, describe (inside, unventilated toilet, exam room, waiting room, outside, etc.)
-
- Indicate the area on the facility plan on the last page.
18. Does a staff member advise the patient who is asked to produce a sputum specimen on how to produce a good specimen? ☐ Yes ☐ No
19. Does a staff member observe the patient who is asked to produce a sputum specimen on site? ☐ Yes ☐ No
20. Do staff use any personal respiratory protection when observing a patient produce sputum?
- ☐ No
- ☐ Yes, surgical mask
- ☐ Yes, personal respirator (N95 or FFP2 mask)
- ☐ Yes, other - please specify:
-
21. Is a TB suspect register kept in the facility? ☐ Yes ☐ No
- If NO, go to question # 25
22. If a TB suspect register is available, record the following numbers, for the HIV care and treatment clinic only, for the previous calendar year:
- How many TB suspects were identified?
- How many TB suspects had sputum smear sent?
- How many TB suspects had sputum culture sent?
- For how many TB suspects were smear results available?
- For how many TB suspects were culture results available?
- How many TB suspects had a positive smear?
- How many TB suspects had a positive culture?
- How many suspects with positive smears were started on TB treatment?
- How many suspects with positive cultures were started on TB treatment?

23. What was the total adult head count (patient-visits) for the clinic?

24. How are TB suspects evaluated? Observe consultations and describe in as much detail as possible (include details on route and time between entry to evaluation, including sputum collection, to departure):

25. Where are sputum specimens kept?

26. What is your impression of the amount of time it takes for the following steps in processing a sputum specimen?

Event

Time for transport of sputum specimen from clinic to lab

Time required by lab to process sputum specimen for AFB smear microscopy

Time required by lab to process sputum specimen for TB culture

Time to report results by lab once processed

Time to transport results from lab to clinic

Time to get results back to the clinician

Time to get results from clinician to patient

Time from diagnosis to starting patient on treatment

Estimated	
Hours	Days

27. Is there a specimen tracking system?

☐ Yes ☐ No

28. Which laboratory is used for sputum smears and cultures?

Sputum Smears: ☐ Off-site ☐ On-site Lab name: _____

TB Cultures: ☐ Off-site ☐ On-site Lab name: _____

29. Review the charts for 5 TB patients seen in the last 3 months to determine the # days between sputum collection and initiating TB treatment.

Patient # 1.....

Patient # 2.....

Patient # 3.....

Patient # 4.....

Patient # 5.....

Date sputum collected	Date result received	Date treatment started

TB Treatment and Referrals

30. Where do patients from this facility receive TB treatment (tick all that apply)?

☐ On-site

☐ Off-site

☐ BOTH on-site AND off-site

If ON-SITE ONLY, go to question # 33; If OFF-SITE ONLY, go to question # 37

31. If BOTH on-site and off-site, what are the criteria to refer them off-site?

32. If ON-SITE, is directly observed therapy (DOT) available?

☐ Yes ☐ No

If NO, go to question # 36

33. If YES, for what duration?

☐ First 2 months of therapy

☐ Entire course of therapy

Other - specify:

34. What is the frequency of DOT?

☐ 7 days/week

☐ 5 days/week

☐ 3 days/week

☐ Other - specify

35. What systems are in place to ensure adherence/follow-up of TB patients?

36. If OFF-SITE, describe the process by which referral information and information on treatment progress are transferred between the facility and the referral site.

37. Does the HIV care and treatment unit have a TB register?

☐ Yes ☐ No

38. If NO, where are TB patients registered? Tick the appropriate boxes.

☐ In the TB unit of the same facility

☐ In the clinic the patient is referred to (local clinic)

☐ TB patients treated in the HIV care and treatment unit are not registered

☐ Elsewhere - specify:

39. If a TB register is available, record the following numbers for the most recent calendar year:

How many TB patients (all types of TB) were registered?

How many Pulmonary TB patients (PTB) were registered?

How many PTB patients had a sputum smear or culture result at diagnosis?

How many PTB patients had a positive sputum smear result at diagnosis?

How many PTB patients had a positive sputum culture result at diagnosis?

How many smear positive PTB patients became smear negative after 3 months of treatment?

How many smear positive PTB patients were moved out to another facility?

How many smear positive PTB patients were cured?

How many smear positive PTB patients completed treatment without proof of cure?

How many smear positive PTB patients died?

How many smear positive PTB patients defaulted (no follow-up for more than 2 months)?

How many smear positive PTB patients were smear positive at the end of treatment (treatment failures)?

How many smear positive PTB patients were identified as MDR-TB patients?

How many smear positive PTB patients were identified as XDR-TB patients?

Time intervals from Arrival to Departure

40. Observe 5 patients who were identified as TB suspects to monitor how long they are at the facility.

Patient # 1

 Patient # 2

 Patient # 3

 Patient # 4

 Patient # 5

Time Arrived	Time Identified as TB suspect	Time Departed

Environmental Infection Control Measures

41. Describe the natural ventilation (tick all that apply):
- ☐ open windows on opposite walls, unrestricted airflow
 - ☐ high ceiling height (>3m)
 - ☐ standard ceiling height
 - ☐ windows on one wall, restricted airflow
 - ☐ vents, windows
 - ☐ no windows
42. Are windows kept open:
- | | | |
|-----------------------|------------------------------|-----------------------------|
| during the day | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| at night | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| during the summer | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| during the winter | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| during the wet season | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| during the dry season | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| during windy seasons | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
43. Is there electricity at the facility? ☐ Yes ☐ No
If NO, go to question #49
44. IF YES, are fans used to increase air mixing? ☐ Yes ☐ No
Describe
-
45. Is there mechanical ventilation? ☐ Yes ☐ No
46. If YES, describe
- ☐ Enclosed room with re-circulating air conditioner
 - ☐ Extraction system
 - ☐ Single pass heating, ventilation, and air conditioning (HVAC)
 - ☐ Recirculating HVAC/Air Conditioning system
 - ☐ Recirculating room air cleaners
 - ☐ Other: (specify)
-
47. What air-cleaning methods are used?
- ☐ None
 - ☐ Ultraviolet germicidal irradiation (UVGI)
 - ☐ HEPA filtration
48. How often are environmental controls checked and maintained?
-
-

Personal Respiratory Protection

49. Are staff involved in sputum induction procedures? ☐ Yes ☐ No

If NO, go to question # 51

50. Do staff use any personal respiratory protection when doing sputum induction?

- ☐ No
☐ Yes: surgical mask
☐ Yes: N95 or FFP2 mask (personal respirator)
☐ Yes: other - please specify:

51. Are N95 or FFP2 masks available? ☐ Yes ☐ No

52. If YES, describe the situations in which N95 or FFP2 masks are used in the facility (confirm through observation):

Patient Education and Awareness

53. Are patients taught about:
 TB signs and symptoms ☐ Yes ☐ No
 Cough etiquette and respiratory hygiene ☐ Yes ☐ No

54. If YES, where, how often, and by whom?

55. Are patients given educational materials (observe)? ☐ Yes ☐ No

56. If YES, describe the materials and keep a copy for review:

57. Are posters displaying cough etiquette and respiratory hygiene prominently displayed? ☐ Yes ☐ No

Staff Capacity Building

58. Is initial training provided for new staff members about TB infection control practices? ☐ Yes ☐ No

59. IF YES, what groups of employees are included in this training?

60. Is ongoing training provided for HCWs about TB infection control practices? ☐ Yes ☐ No

61. If YES, what groups of employees are included in the training?

62. How often is training done?

63. Is it mandatory? ☐ Yes ☐ No

64. Are records kept of training sessions? ☐ Yes ☐ No

65. If YES, review documentation of when trainings were held and who attended the trainings and summarize below.

Staff Protection

66. Are staff members screened for TB? ☐ Yes ☐ No

67. If YES, describe procedures used and frequency of screening:

68. Do you know of any staff member who developed active TB in the past 2 years? ☐ Yes ☐ No

If YES, please provide more details (category of staff, workplace, type of TB etc.):

69. Are staff offered confidential voluntary HIV counseling and testing? ☐ Yes ☐ No

70. What is the recommended action for HIV-infected workers?

71. What are the policies for reassignment if an HIV-infected worker requests it?

72. What HIV-related care and treatment is available on-site for infected staff members?

73. Is isoniazid (INH) preventive treatment (IPT) available for HIV-infected staff members? ☐ Yes ☐ No

TB Infection Control Plan Review

74. Review the infection control plan to determine whether the plan includes a policy regarding:
- | | | |
|--|------------------------------|-----------------------------|
| a. The availability and functioning of an infection control team | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Screening patients for TB disease | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. Cough etiquette and respiratory hygiene | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Identifying patients under investigation or treatment for TB | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Placing TB suspects and cases in a separate waiting area | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Triaging TB suspects and placing them at the front of the queue | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. Access of TB suspects to TB diagnostic services | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Use of personal respiratory protective equipment | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| i. Laboratory turnaround time for sputum smears | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| j. Communication of sputum smear results with facility staff | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| k. Access/referral of confirmed TB cases to TB treatment/TB treatment facilities | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| l. Maintaining a TB suspect register and a TB case register (according to national guidelines) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| m. Ensuring adherence and completion of treatment of TB cases | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| n. Using, monitoring and maintaining environmental control measures | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| o. Staff education on TB, TB control and the TB infection control plan | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| p. Educating staff on risks of TB infection, including specific risks for HIV-infected staff | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| q. Provision of confidential TB services to HCWs and staff | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| r. Provision of confidential HIV services to HCWs and staff | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| s. Monitoring the infection control plan | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

75. Who are the members of the infection control team (name, designation, responsibilities)?

76. How often does the team meet?

Does the team have a budget?

☐ Yes ☐ No

If YES, what is the budget? _____ per annum

Elaborate on the different policies addressed in the infection control plan:

a. TB screening:

b. Cough etiquette:

c. Triaging of TB suspects:

d. TB diagnosis:

e. TB treatment:

f. Environmental controls:

g. Personal respiratory protective equipment

h. Staff education:

i. TB and HIV services for staff:

j. Additional information/remarks:

TB Screening Data

79. Collect the following data elements from the HIV care register and/or patient folders (whichever is the PRIMARY SOURCE); include all patients enrolled in the past calendar year, or if no information in the register, between July and December of the last calendar year.

Collect the following data elements from the HIV care register and/or patient folders (whichever is the PRIMARY SOURCE); include all patients enrolled in the past calendar year, or if no information in the register, between July and December of the last calendar year.

Source: _____

Time period: From (mm/yy) ____/____ to ____/____

Number of patients enrolled in HIV care (HIV care register)

Number of patients screened for TB at their FIRST visit (at enrollment)

Number of patients screened positive

Number of patients evaluated for TB (with sputum smear or other investigations)

Number of patients diagnosed with TB

Number of patients diagnosed with smear positive PTB

Number of patients diagnosed with extra-pulmonary TB

Number of patients started on TB treatment

Number of patients screened for TB at their LAST visit

Number of patients screened positive

Number of patients evaluated for TB (with sputum smear or other investigations)

Number of patients diagnosed with TB

Number of patients diagnosed with smear positive PTB

Number of patients diagnosed with extra-pulmonary TB

Number of patients started on TB treatment

Facility Layout

80. Draw a diagram with measurements of the HIV care and treatment facility, indicating waiting areas, consultation rooms, procedure rooms, dispensary, laboratory and offices. Include windows, doors, environmental control measures (fans, UV light, etc.) and airflow. Indicate where patients are screened for TB and how 1) a TB suspect and 2) a patient not suspected of TB flows through the facility during a typical visit. Include photographs if possible.

Annex: Template of a (Simple) Facility TB-IC Plan (Source: RHRU, HIV Management Cluster, South Africa).

Name of Facility/Clinic:	Manager of Facility/Clinic:
Plan adopted or modified by on (date): <ul style="list-style-type: none"> • This plan includes the following sections: • The Infection Prevention and Control Committee. • An overview of the facility's infection control strategy. • Infection control in Reception area. • Infection control in waiting and consultation areas. 	

Name:	Position:	The committee will meet
	Chair:	When:
	Secretary (minute taker):	Where:
		Person responsible for baseline assessment and ongoing audit of TB infection control.
		Person responsible for ongoing in-service TB infection.
		Control training.
		Person responsible for review of staff risk for TB.
		Person responsible for the maintenance of TB infection control fittings.
		Person responsible for ordering tissues, N95 respirator/masks and the appropriate waste disposal bins.
		Person responsible for the daily opening of facility windows.

Management of patients within this facility will proceed as follows, in order to reduce generation of infectious TB particles (describe the flow of patients through the facility, indicating how and where the triage of patients according to cough will be done and where waiting areas will be):

Floor plan of facility showing client movements and air flow directions:**TB infection control at facility reception area:**

The following TB infection control practices will be implemented at reception into our facility	Name of Person Responsible:
• Posters about TB infection control will be displayed.	
• The queuing system will be explained to all clients.	
• All clients will be asked if they are coughing.	
• Clients who cough will be asked to cough into tissues or a mask.	
• Clients who cough will be given tissues or a mask.	
• Clients who cough will be asked to dispose of tissues or mask using bins provided.	
• Clients who cough will be directed to a special waiting area.	

Area Description:	Name of Person Responsible:
• Posters about TB infection control will be displayed	
• The professional nurse (or nurse staffing the service) will periodically scan the queue for coughing clients.	
• Coughing clients will be seen first.	
• Direction of air flow in each consultation room will be established and marked with a sign. HCW should sit with the clean air moving from behind them towards the client.	
• N95 respirator/masks will be available in consultation rooms for HCW.	
• Tissues and masks will be displayed in a prominent position in the waiting area.	
• Bins or appropriate receptacles for disposal of tissues/masks will be placed in a prominent position in the waiting area.	
• Windows or doors will be opened to ensure maximum air flow.	
• Appropriate arrangement of professional nurse/doctor and patient in consultation room will be maintained according to airflow direction.	
• N95 respirator/masks will be available in consultation rooms for HCWs.	
• Fans will be located in appropriate areas (consultation rooms and/or waiting areas) and be operational.	

Annex: TB-IC Plan: Policies & Activities (Source Zaria NTP)

Goal: Provide high quality care with adequate safety for all.

Team members:

- | | |
|----|----|
| 1. | 5. |
| 2. | 6. |
| 3. | 7. |
| 4. | 8. |

TOR:

- Conduct basic risk assessment
- Develop a work plan and budget
- Conduct quarterly assessment on adherence to IC
- Organize training for staff
- Conduct quarterly meetings to discuss issues on IC

Policy Issues Are:**A. Administrative:**

1. The facility will be using two separate GOPDs (GOPD 1 for only new comers and GOPD 2 for patients on follow-up).
2. Daily health education will be provided on cough etiquette and HIV/AIDS prevention in the 2 GOPDs at 8.30am.
3. Patients will be triaged at the GOPD 1 daily (see patients with severe cough first).
4. All patients visiting the facility will be provided with HIV Testing and Counseling at all service points.
5. Hawking and visitations by children to wards are prohibited and signage must be put in place.
6. Respiratory protection will only be used in the BL2, BL3 and MDR ward of the facility.
7. TB and TB/HIV co-infected patients are to be admitted in different wards in the facility.
8. Appropriate IEC materials must be displayed at the different service points.
9. Facility staff will have regular training on IC 10. All patients on admission must adhere to cough etiquette (having sputum container with disinfectant and a hand tissue).
10. Staff will be encouraged to know their HIV status and take necessary actions.
11. The management will provide adequate N95 respirators and surgical masks as required.
12. Strict adherence to SOPs in all service points.
13. Staff with accidental injuries should be managed based on national guidelines.

B. Environmental Measures:

1. Natural ventilation must be ensured in all service points
2. Facility attendants should ensure all windows are open at all times.
3. Additional mechanical ventilation (extractor fans) will be added to the wards, lab and MDR wards.
4. Industrial fans will be installed in all waiting areas (GOPDs, pharmacy, X-ray unit and VCT sites).
5. Electricity will be supplied during the working hours and for two hours at night.
6. UV light should be added to the MDR ward, lab and GOPDs.

C. Respiratory Protection

1. N95 respirators will be used in the laboratory and MDR ward.
2. Patients who are smear positive for TB will use surgical masks whilst in ART, lab, X-ray unit or at the nursing station.

D. Waste Disposal

1. All waste from the lab must be disinfected appropriately before leaving the lab.
2. All service points must have an appropriate dustbin (sharp object in its disposing containers).
3. All service points must use the incinerator.
4. Protective hand gloves will be provided appropriately (lab, nurses, clinicians, HCT and specific for the attendants).
5. Laundry should be done using the appropriate disinfectant.

Activities and Responsibilities:**...will be responsible for:**

- Coordination of all activities and liaising with the management;
- Carrying out periodic supervision;
- Conducting the quarterly meeting;
- Organizing trainings where necessary.

...will ensure:

- Health education is provided in the GOPDs daily;
- IEC materials are available and placed appropriately;
- Treatment supporters are supported in triaging patients in GOPD 1.

...will ensure:

- That security officers direct patients to appropriate GOPDs;
- No hawking takes place within the GOPD, Lab and the wards;
- Children less than 6 years old are prohibited from visiting relations in the wards.

...will ensure:

- Strict adherence to SOPs in the lab;
- Patients use designated waiting areas and the sputum collection site;
- Timely release of sputum examination results;
- Any positive un-claimed results are communicated;
- Patients are tested for HIV at GOPDs;
- Waste management is done appropriately.

...will ensure:

- Patients are regularly educated on cough etiquette whilst in the wards;
- Patients are tested for HIV at GOPDs and lab.

...will ensure:

- All windows in the wards are open at all times;
- Patients adhere to cough etiquette;
- Patients use dustbins appropriately;
- Dustbins are emptied daily in the incinerator.

...will ensure:

- Weekly monitoring of the facility;
- Regular maintenance of all windows, doors and electrical fittings;
- Regular supply of electricity as agreed.

...will ensure:

- Monitor all service points monthly;
- Document and report challenges.

Annex: Strategic Human Resource Development for TB Infection Control

Strategic Human Resource Development for TB Infection Control

Vision:

By the year 2020 all countries have effective TB-IC programs to minimize the risk of TB transmission in healthcare facilities, congregate settings and households.

Goals:

A sufficient number of HCWs of all categories involved in TB infection control (IC) are available at the international, national and local levels of the health system, including congregate settings⁸. HCWs, trained in TB-IC, have the skills, knowledge and attitudes necessary to successfully implement and sustain TB infection control interventions.

There are support systems, to ensure continuous sustainable provision of high quality services by consultants and HCWs, trained in TB-IC, to meet the TB-IC needs at all levels.

Implementation framework:

As a basis for developing the implementation strategies, the Human Resource for Health Action Framework (See figure below) was used to design strategies to achieve an effective and sustainable (TB-IC) health workforce. This Figure is applied to the situation of TB-IC and strategies are categorized in six areas, some of them are already being implemented as part of TB programs or general IC interventions.

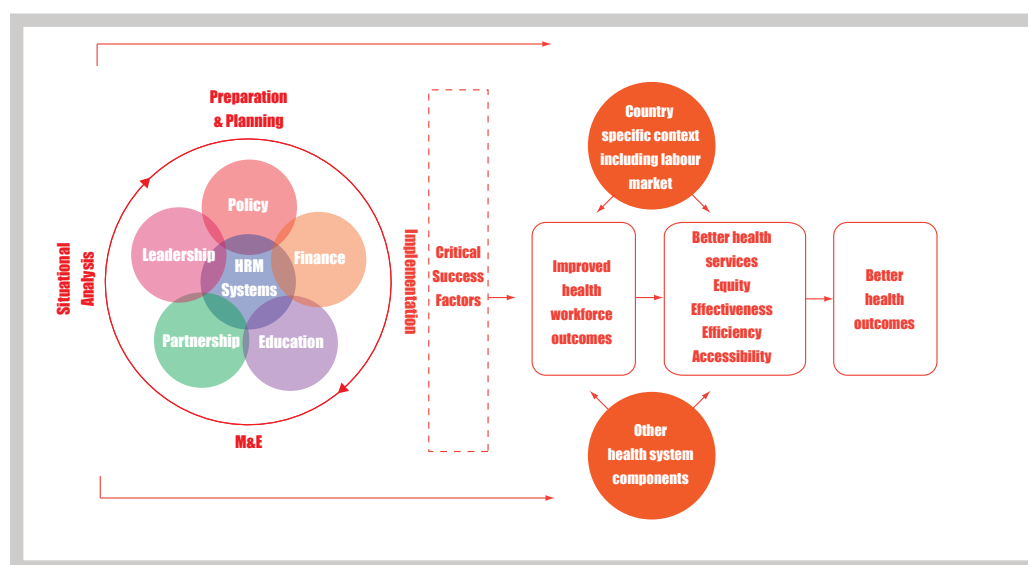


Figure: Human Resource for Health Action Framework

Below policy statements are outlined and implementation strategies are presented together with concrete success factors. The strategies are to be elaborated further and translated into activities.

Policy Statements, Strategies and Success Factors

Policy

1. There is a need to streamline TB-IC into the general IPC policies at all levels.
2. There is need to align, integrate and enforce the implementation of national HR policies in relevant programs and relevant public sectors with congregate settings.

⁸ Based on the long-term goals for HRD, Implementing the WHO STOP TB Strategy, a handbook for national TB control programs.

TB-IC is part and parcel of Infection Prevention and Control; specifically part of the prevention of air borne infections. Especially in the areas with the proliferation of HIV and other epidemics, Infection Prevention and Control is extremely important in healthcare facilities to protect patients, workers and visitors, but also in other congregate settings of the society and even in the private domain i.e. the homes of patients. Hence, the group of stakeholders which should be involved is considerable and much wider than the government health sector alone.

Other new or existing policies may have positive or negative consequences on the risks of TB transmission in the population if the potential attributed risk is not recognized, assessed and monitored in the process of the development, implementation and review of other policies. When appropriate, TB-IC policy guidelines should be aligned and integrated with other policies, in particular with guidelines addressing the prevention of air borne infections in different congregate settings.

Strategies with regard to Policy:

- a. To strengthen coordination in policy development and review involving all stakeholders.
- b. To align, monitor and evaluate policy implementation in a coordinated systemically manner.

Policy Success Factor:

- A coordinated process of national policy development, implementation and review.

Finance

3. TB specific funds shall be used to support the IPC efforts, which include TB-IC measures, but also the national health budget and other (external) funds.
4. Since IPC and TB-IC activities are facility centered, facilities should allocate funds from their internally generated funds to IPC and TB-IC related HR activities so as to ensure sustainability. Ownership of program is key to sustainability.

Adequate budget provision for HR related TB-IC interventions at all levels implies planning and budgeting in accordance with the procedures and regulations of the national budget preparation and approval system and of other available external funds in accordance with specific procedures and regulations as stated in the applicable Requests For Proposal.

Depending on a country's system of (multi-)annual planning and budgeting HR related TB-IC activities shall be budgeted. HR related TB-IC activities are: supervision, technical assistance, training courses. The source of funding for budget allocations must be identified. The following sources shall be considered: MOH budget, NTP budget, GFATM, World Bank, TB CAP, OGAC and project funds from other specific donor partners and facility internally generated funds.

Strategies with regard to Finance:

- c. To integrate planning and budgeting of HR related TB-IC activities into the existing planning and budgeting processes at all levels.
- d. To integrate planning and budgeting of TB-IC activities into the existing planning and budgeting processes of external (project) funds and loans.

Success factor with regard to: Finance:

- Adequate funding for HR related TB-IC activities addressing the identified priority gaps to implement TB-IC at all levels and in various settings.

Education

5. Training curricula shall be aligned with the 2009 WHO TB-IC policy and TB-IC shall be integrated into training on general IPC.

The regional training centers can be geared towards supporting scale-up of TB-IC at country level

within their geographical region. Eventually all countries should be able to organize national training courses in their local most common language – regional training centers could support this endeavor. TB-IC should be a part of the updated TB curricular at pre-service and in-service training institutions.

Strategies with regard to Education:

- e. To introduce IC curricular and TB-IC TOT in regional training centers to ensure access to continuous education and skills upgrade.
- f. To introduce TB-IC as part of the updating of the general TB/IPC curricular in pre-service, postgraduate, in-service training.

Success factor with regard to Education:

- TB-IC is integrated into the general IPC training curricular; Sustainable and quality assured training capacity on TB-IC established in regional training centers and in the countries.

Partnerships

6. Ensure linkages with other governmental, private and non-governmental non-for-profit organizations as well as patient networks to support scaling up of the (TB) IPC activities at community, facility/local, (sub-) national and international levels.

Since the list of stakeholders is long and extends to other public and private sectors than the health sector alone, as stated in the previous paragraph, it is of paramount importance to involve and link all stakeholders in a meaningful manner and also to lay down the terms of reference for the collaboration in a memorandum of understanding or form of contractual arrangement. A partner network can accelerate the scaling up of TB-IC by expanding coverage as well as speeding up activities.

Strategies with regard to Partnerships:

- g. To promote the establishment of coordinating bodies and technical working groups with wide representation of stakeholders.
- h. To describe the terms of reference precisely of coordinating bodies and technical working groups.
- i. To enhance and formalize collaborative partnerships by signing a contractual arrangement between partners.

Success factor with regard to Partnership:

- A coordinating body and/or technical working group (including an HR focal point) responsible for IPC including TB-IC with representation of all relevant stakeholders, overseeing the implementation of TB-IC including HR related activities.

Leadership

7. The general/health system IPC program should lead the implementation of IPC/TB-IC activities urged on by the NTP, HIV & Influenza programs (with advocacy & financial support) to ensure sector wide acceptance and sustainability.
8. There is a need to accelerate the scaling-up of TB-IC interventions as part of TB/HIV activities and programmatic management of drug resistant TB.
9. There is a need for advocacy for the integration of TB-IC into general IPC policies, training and other activities.
10. There is need for advocacy for the implementation of TB-IC controls in other congregate settings and local communities in accordance with the 2009 WHO TB-IC policy.

TB-IC control measures are made complex by having to deal at different levels as well as in different areas ranging from managerial activities to administrative, engineering and respiratory protection controls. Due to this complexity effective advocacy is required. The aim of the advocacy efforts is to put TB-IC on the agenda and achieve strong governance to (re-)direct the implementation of TB-IC. It is important to recognize and make use of the opportunities that may result from collaboration with big

well funded programs to prevent the spread of HIV and Influenza.

Strategies with regard to Leadership:

- j. To lobby for an integrated response and benefit from leveraging the resources (including funding opportunities) together with other infection prevention control programs.
- k. To convince politicians, governors and general managers of relevant public and private sectors of the importance of TB-IC for the community at large and their constituencies in particular.

Success factor with regard to Leadership:

- Integration of TB-IC with existing health system with support from HIV and Influenza infection prevention programs.

Human Resource Management

Personnel management

- 11. Staffing needs for TB-IC need to be assessed and a strategy developed to ensure the most suitable (health) workers receive skills upgrade to be able to satisfy the need for TB-IC advice and activities.
- 12. There is a need to mainstream conditions of service and occupational health and safety policies.

Performance management

- 13. Strategies shall be developed to scale up human resources for TB-IC at local, national and international levels. Tasks and responsibilities for IC, as well as corresponding competencies need to be defined at various levels and per professional category, so as to cover the whole spectrum of TB-IC.
- 14. Training and capacity building at local, national and international level should be coordinated, where feasible, to avoid duplication of training efforts, promote congruence of training curricula and facilitate exchange of information.

TB-IC health workforce development is one of the strategies under the Human Resource Management and is based on the stages of health workforce development (WHO, 2006). TB-IC health workforce development implies activities to forecast the need for TB-IC professionals at all levels, to recruit and (if necessary) provide them with in-service training and continuing education. To ensure the TB-IC professionals perform well, i.e. are available, competent, responsive and productive, their performance has to be sustained and enhanced.

Strategies with regard to Human Resource Management:

- l. To have TB-IC integrated into country-level policies, so that it is a part of national workforce planning, training and development;
- m. To describe desirable and essential competencies of different cadres of healthcare workers from (inter-)national TB-IC consultants and trainers to the workforce on the ground;
- n. To describe objective criteria for measuring these competencies, make sure adequate system (including formal training) to acquire and maintain the necessary competencies is available;
- o. To maintain the lists of consultants and the list of competencies for international consultants and facilitators in an internationally accessible database.

Success factor with regard to Human Resource Management:

- TB-IC is integrated into country-level policies, different cadres of HCWs are trained.

Developed by: Nonna Turusbekova & Max Meis

Annex: Menu of TB-IC Indicators for Healthcare Facilities

Input	
1	Budget for coordinating body consisting of collaborative Ministries and partner organizations (expenses as numerator and allocation as denominator)
2	Budget for workshops, review and dissemination of national guidelines (expenses as numerator and allocation as denominator)
3	Budget for development of TOT curriculum and training materials, trainers costs and training costs (expenses as numerator and allocation as denominator)
4	Budget for national capital investment plan/renovations (expenses as numerator and allocation as denominator)
5	Budget for operational research (expenses as numerator and allocation as denominator)
6	HF with IC team/focal person (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
7	Budget for IEC (expenses as numerator and allocation as denominator)
8	HF with smear microscopy and/or C/DST laboratory services (number by type of facility as numerator and total or targeted number, by type of facility as denominator)
9	HF with separate waiting area(s) (number, by type of facility as numerator and total number, by type or targeted number as denominator)
10	Budget for procurement and maintenance of UVGI fixtures and tubes (expenses as numerator and allocation as denominator)
11	Budget for installation and maintenance of mechanical and mixed-mode ventilation (expenses as numerator and allocation as denominator)
12	Budget for procurement and maintenance of BSCs (expenses as numerator and allocation as denominator)
13	Budget for particulate respirators (expenses as numerator and allocation as denominator)
Process/Output	
14	Meetings of coordinating body (number of meetings held as numerator and number of meetings planned as denominator)
15	HF where at least a baseline TB-IC risk assessment was done using the national adopted assessment checklist (number, by type of facility as numerator and total or targeted number, by type of facility number as denominator)
16	HF with IC focal person or team (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
17	HF with TB-IC facility implementation plan based on a facility assessment (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
18	HF with written procedures on i) TB/HIV screening of staff, ii) triage, iii) patient movement, and iv) cough hygiene (number, by type of facility as numerator and total or targeted number, by type as denominator)
19	HF with at least 3 HCW trained on TB-IC in last 12 months (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
20	HF constructed and upgraded (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
21	HF with isolation rooms (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)

22	HF that display IEC messages on TB-IC (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
23	HF that record, collect and report national core indicators (number, by type of facility as numerator and total number, by type of facility or targeted number as denominator)
24	HF that engage in operational research projects on TB-IC (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
25	TB suspects identified and missed (numbers identified and missed, by type of facility as numerators and total number of outpatients as denominator)
26	TB suspects and diagnosed TB patients separated/isolated (numbers suspected and diagnosed as numerators against total number of admissions as denominator)
27	HCW screened for TB disease (or TB infection), by cadre, by type of facility (number, by cadre, by type of facility as numerator and total or targeted number of staff, by cadre, by type of facility as denominator)
28	Turn-around-time of sputum smear microscopy results < 24 hours (number of specimen results reported in less than 24 hours as numerator and total number of specimen results reported)
29	HF with certified UVGI (number, by type of facility as numerator and total number of facilities with UVGI as denominator)
30	HF with maintenance logs for mechanical or mixed-mode ventilation equipment (number, by type of facility and total number, by type of facility with ventilation equipment as denominator)
31	HF with certified BSCs (number, by type of facility as numerator and total number, by type of facility with BSCs as denominator)
32	HF supplied with particulate respirators according to distribution plan (number, by type as numerator and total number targeted, by type of facility as denominator)
Outcome	
33	HCW on IPT, TB treatment, CPT, ART (number of HCW as numerator and total number known HIV + HCWs as denominator)
34	HF that educate and enforce wearing of face masks (not particulate respirators) by TB suspects and –patients (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
35	HF with decline in time spent in the facility from identification as TB suspect to departure - for outpatients - (number, by type of facility measuring decline in time spent by outpatients as numerator and total number, by type measuring time spent by outpatients as denominator)
Impact	
36	TB disease incidence among different cadres of HCWs (number of HCWs employed in healthcare facilities who develop TB in one year as numerator and total number of HCWs employed in healthcare facilities during that same year as denominator)

Annex: Menu of TB-IC Indicators for Congregate Settings

Input	
1	Budget for national capital investment plan (expenses for construction, renovation and procurement of TB-IC equipment as numerator and allocation as denominator)
2	CS with IC focal person (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
3	CS with intensified TB/HIV screening policy of new-comers (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
Process / Output	
4	CS where at least a baseline TB-IC risk assessment was done using the national adopted assessment checklist (number, by type of facility as numerator and total or targeted number, by type of facility number as denominator)
5	CS with TB-IC facility implementation plan (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
6	CS with written procedures on i) TB/HIV screening of staff, ii) triage, iii) patient movement, and iv) cough hygiene (number, by type of facility as numerator and total or targeted number, by type as denominator)
7	CS with staff, by type of facility trained on TB-IC in last 12 months (number trained, by type of facility as numerator and total or targeted number, by type of facility as denominator)
8	CS constructed and upgraded (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
9	CS with isolation rooms (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
10	CS with separate communal area(s) and TB isolation ward (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
11	CS that display IEC messages on TB-IC (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)
12	People living in congregate setting screened upon arrival for TB/HIV (number of people screened by type of facility as numerator and total number of people screened by type of facility as denominator)
13	TB suspects identified and missed (numbers identified and missed, by type of facility as numerators and total number of clinic attendees as denominator)
14	TB suspects and diagnosed TB patients separated/isolated (numbers suspected and diagnosed as numerators against total number of residents as denominator)
15	Staff screened for TB disease (or TB infection), by cadre, by type of facility (number, by cadre, by type of facility as numerator and total or targeted number of staff, by cadre, by type of facility as denominator)
16	CS with maintenance logs for mixed-mode ventilation equipment (number, by type of facility and total number, by type of facility with ventilation equipment as denominator)
Outcome	
17	Staff on IPT, TB, CPT, ART (number against total number)
18	CS that educate and enforce wearing of face masks (not particulate respirators) by TB suspects and –patients (number, by type of facility as numerator and total or targeted number, by type of facility as denominator)

Impact

19	TB disease incidence among population (staff and residents) of congregate settings (number of staff employed and residents in congregate settings, by type of facility who develop TB in one year as numerator and total number of staff and residents in congregate settings, by type of facility during that same year as denominator)
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Annex: Menu of TB-IC Indicators for Households and Community Settings**Input**

1	Community-based healthcare organizations programs with written procedure and assessment checklist for initial home assessment for MDR-TB patients (number, by type of facility as numerator and total or targeted number as denominator)
2	Community-based healthcare organizations with SOP for intensified screening of household members for TB/HIV (number of organizations as numerator and total or targeted number as denominator)
3	Budget for face masks for MDR-TB patients in community (expenses as numerator and allocation as denominator)
4	Budget for small renovations of homes and procurement of fans (expenses as numerator and allocation as denominator)
5	Budget for particulate respirators (expenses as numerator and allocation as denominator)

Process / Output

6	Homes assessed of MDR/XDR-TB patients (number of homes assessed as numerator and total number of homes as denominator)
7	Households educated of MDR/XDR-TB patients (number of households educated as numerator and total number of households as denominator)
8	Households of MDR/XDR-TB patients, in which members were screened for TB(HIV) (number of household members screened as numerator and total number of household members as denominator)
9	Households of MDR/XDR-TB patients supplied with facial masks (number of households supplied as numerator and total number of households as denominator)
10	Homes of MDR/XDR-TB patients upgraded or supplied with fan (number of homes as numerator and total or targeted number of homes as denominator)
11	Community health workers supplied with respirators according to distribution plan (number of community health workers as numerator and total number as denominator)

Outcome

12	Ambulatory MDR-TB patients wearing face masks when mixing with others (number of compliant patients as numerator and total number of patients as denominator)
13	Household members with MDR/XDR-TB, infected by index case, detected and treated (number of household members as numerator and total number of household members as denominator)

Impact

14	TB disease incidence among household members of MDR/XDR-TB patients (number of household members who develop TB in one year as numerator and total number of household members during that same year as denominator)
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Annex: Respiratory Protection Information Brochure for Staff of KNCV Tuberculosis Foundation

Preamble

At the request of the management team of KNCV Tuberculosis Foundation, this brochure was developed to inform KNCV staff on respiratory protection as one of the measures for TB infection control and personal protection while visiting high TB risk healthcare services and congregate settings. It is noteworthy that wearing a respirator does not provide complete protection but decreases significantly the relative risk of TB infection. As new evidences arises, it may be necessary to update or revise the information provided in this document. For any additional information or clarification please contact any of the KNCV TB-IC appointed consultants. The guidance provided in this document does not carry any legal obligation for its authors, nor KNCV Tuberculosis Foundation.

Introduction

TB infection control is a combination of measures aimed at minimizing the risk of TB transmission within populations, particularly in the healthcare services and congregate settings. The foundation of such infection control is early diagnosis and the effective treatment of TB patients. At national and facility level, appropriate packages of managerial, administrative, environmental and personal protection are needed to control TB infection. Respiratory protection is only one of the possible interventions. The reader is advised to refer to the relevant guidelines and references provided at the end of this text for more comprehensive information on TB infection control.

Respirators versus Masks

A respirator is a protective face piece, hood or helmet that is designed to protect the wearer against a variety of harmful airborne agents. For practical reasons including light weight and relatively low cost, we recommend disposable respirators and not the full-face models with replaceable filters. For effective protection against TB infection, respirators should filter out at least 95% of particles of at least 0.3 microns. Therefore particulate respirators must meet or exceed the NIOSH-certified N95, or CE-certified FFP2 standards. In addition proper wearing of respirators is extremely important. If the respirator is not fitted correctly, infectious droplet nuclei can easily enter a person's airways, potentially resulting in infection.

Please note that a surgical mask is not a respirator. Masks are provided to patients in order to limit the spread of droplets or droplet nuclei (aerosols) by patients.



Considerations for Selection of Respirators

The overall effectiveness of respiratory protection is affected by:

1. The level of respiratory protection selected (e.g. the assigned protection factor).
2. The fit characteristics of the respirator model.
3. The care in using the respirator.
4. The adequacy of the training and fit-testing program.

Respirator Fit Testing

Respirators are available in different sizes (at least three) and shapes. It is recommended that staff be “fit tested” to ensure selection of the appropriate respirator. Qualitative fit testing involves the use of a harmless aerosol which may be “tasted”. If the staff “tastes” the aerosol (usually bitter-tasting liquid Bitrex or sweet saccharin), the respirator must be adjusted (i.e. the nose clip) and retested. If the staff fails the test a second time, a different size or brand respirator should be tested. Beards, facial hair and heavy make-up may not allow proper sealing of respirators to the face. Any leak between the face and the respirator is a potential entry point for infectious droplet nuclei.



Some respirators have an exhalation valve which makes it easier to exhale. In addition the voice of wearer can be better heard through the valve, the valve closes with inhalation.

When to Wear Respirators

Because the widespread and constant use of respirators is not practical, they should be used on a limited basis in specified high risk areas and in conjunction with other administrative and environmental control measures such as but not limited to: while visiting TB hospitals or ambulatory TB facilities with poor TB infection control e.g. poor natural ventilation or whilst interviewing

or examining TB patients indoors; visiting congregate settings with high TB rate; visiting mycobacteriology laboratories conducting culture and Drug Susceptibility Testing with unknown biosafety measures, while observing sputum induction or other cough-inducing procedures; bronchoscopy or autopsy; spirometry rooms; or surgery on potentially infectious TB patients.

For a visit to an outpatient and well ventilated facility with TB patients who are on continuation phase, one may not need to use respirators, however visiting a MDR-TB or TB ward without a respirator particularly if other infection control measures are not in place may pose a considerable risk.

Duration of Use

There is little documented evidence on the length of time a respirator may be worn with acceptable efficiency. The filter material used in respirators may remain functional for weeks or months; however fitting may decrease with frequent wearing. Respirators classified as disposable may be reused by the same staff as long as they are not wet and do not have loosened straps. However, before each use, the outside of the filter material should be inspected. If the filter material is physically damaged or soiled or the straps are loosened then the respirator should be discarded. The manufacturers advise single use of disposable respirators, however fit testing exercises have shown that if properly stored, a respirator may be used multiple times. Staff are advised to use common sense in either discarding or re-using the respirator. In addition to conditions which respirator has been used, duration of use per visit, appropriate storage, weather condition and the quality of the straps tightening respirators all play an important part, which makes it difficult to recommend how many hours or days a respirator may be used. For example, should a staff wear a respirator extensively during a mission of 6-7 days, the respirator may be discarded, however if the respirator has been worn for only a few hours or 2-3 times in a mission, one may keep the respirator for up to 2-3 similar missions.

How to Wear a Respirator (donning)

- 1. Find center of nose piece and bend**
- 2. Open respirator**
- 3. Place straps on back of hand**
- 4. Place respirator on face**
- 5. Pull top strap over head**
- 6. Place top strap on crown of head**
- 7. Pull lower strap over head**
- 8. Place strap at base of head**
- 9. Pinch metal clip around nose**
- 10. Pull respirator over chin**

Maintenance and Storage of Respirators

The main factors responsible for the deterioration of respirators are humidity, dirt and crushing.

Respirators should be stored in a clean dry location.

Storing the respirator in a plastic sealable bag after use is not a good practice. The respirator may be damp after use and sealing prevents drying and encourages microbial growth.

A bad practice is storing respirators in one's pocket. Respirators can be crushed during work activities.

It is recommended to fold a light towel around the respirator (being careful not to crush the respirator) or store the respirator in a thin paper envelope.

Can I Disinfect My Respirator?

Disposable respirators cannot be disinfected, therefore they can only be assigned for use to a single individual and cannot be shared. Instead, each respirator should be examined between each use. By using respirators in high TB risk areas, mycobacterium TB if present will be trapped in the filter which won't be released with shaking or other physical movements, therefore it is not necessary to disinfect respirators. In addition, using ultraviolet or other measures of disinfection will damage respirator straps or the filter.

Ethical Issues

Wearing respirator is a personal protection measure. It may be difficult to wear respirators while staff of the facility don't have access to them. We advise that you carry a few additional respirators with you to share with national colleagues who do not have access to respirators, or if possible visit sputum smear positive patients outdoors where the risk of infection is very low. Having said that, most countries are in the process of procuring respirators, therefore this may be less of a problem in the future. Most countries have access to different grants and therefore may procure their own respirators.

Discarding Respirators

Respirators can be disposed of in normal garbage and do not need to be disinfected before being discarded or incinerated.

Reference Materials

1. WHO policy on TB infection control in healthcare facilities, congregate settings and households. 2009, Stop The Department in collaboration with Epidemic and Pandemic Alert and Response Department HIV Department World Alliance for Patient Safety WHO, Geneva, Switzerland 2009.
2. Frequently Asked Questions and Answers, CDC <http://www.cdc.gov/niosh/tb-iv.html>
3. Guidelines for Tuberculosis in Health care facilities in resource-limited settings, WHO, 1999.
4. Respiratory Protection in Health Care Settings; Fact Sheets: Last Updated: April 2006, CDC <http://www.cdc.gov/tb/publications/factsheets/prevention/rphcs.htm>

For KNCV Tuberculosis Foundation, April 2009
Dr. Masoud Dara
Ieva Leimane

Annex: Tuberculosis Infection Control Operational Research Protocols

Study questions:

1. Do IGRA conversions among HCWs have a stronger association with risk factors for recent TB exposure than TST conversions?
2. Does the introduction of a minimum TB-IC package decrease transmission of TB from patients to HCWs?
3. Does reducing delays in the diagnosis and treatment for TB reduce the risk for transmission of TB to HCWs?
4. Does voluntary re-assignment of HIV-infected HCWs, allowing for other factors including ARVs, IPT, infection control measures, significantly reduce TB disease among HIV infected HCWs?

Surveillance protocol for latent TB infection

OR Appendix 1 includes recommended procedures, definitions and a standardized questionnaire to collect the appropriate information for on-going surveillance for latent TB infection among HCWs. These protocols can be modified to fit the local context; however, the more standardized the procedures the more comparable the results will be to similar studies. This protocol may be utilized to address study questions 1-4.

Surveillance protocol for active TB disease

OR Appendix 2 includes recommended procedures, definitions and a standardized questionnaire to collect appropriate information for on-going surveillance for active TB disease among HCWs. These protocols can be modified to fit the local context; however, the more standardized the procedures the more comparable the results will be to similar studies. This protocol may be utilized to address study questions 2-4.

Assessing minimum TB-IC requirements and supplementary TB-IC measures in healthcare facilities

OR Appendix 3 includes a questionnaire to assess whether minimum TB-IC requirements are in place in health facilities. Also includes a section with additional supplementary measures which can be tailored to the health facility's additional measures. Assessment of this minimum package should be done at least on a bi-annual basis to acquire a standardized snapshot of selected important TB-IC measures in healthcare facilities.

Assessing risk levels for HCWs of physical and functional areas in a health facility

OR Appendix 4 includes a conceptual framework on how to categorize low versus high risk TB transmission areas and functions within a facility. This categorization can be modified, if needed, to fit the facility-specific risk assessment.

Operational Research Study 1: Tuberculin skin testing (TST) versus interferon-gamma release assays (IGRA) for measuring the annual risk of TB infection (ARTI) in HCWs.

Context: Traditionally, the tuberculin skin test (TST) has been used for estimating the ARTI in HCWs (Ref 1 page 147). HCWs with TST conversions are considered recently infected and at risk for progressing to TB disease. It is therefore recommended that they be offered isoniazid preventive therapy. However, the TST has limitations in accuracy and reliability.

(Ref 2 page 147). Interpretation of TST boosting, conversions and reversions is challenging. (Ref 3 page 147). Newly available IGRAs are more specific than TST and are not affected by prior BCG vaccinations (Ref 4 page 147). Because these assays are ex-vivo, boosting is not a concern with repeated IGRA testing. Although IGRAs may be useful for diagnosing TB infection, there is considerable uncertainty around their use in serial testing (Ref 5 page 147). IGRA conversions

and reversions are documented (Ref 6-8 page 147), and there is no consensus on how to define conversions with IGRAs. Prognosis of IGRA conversions and reversions are unknown. In medium to high burden settings, it is not clear if IGRAs are better for measuring ARTI than TST.

Hypothesis: IGRAs are better capable of identifying new TB infection due to occupational exposure than TST.

Study design: Prospective serial testing design. All consenting HCWs will be screened by two-step TST at baseline and one of the commercially available IGRAs. A questionnaire will be used to collect data such as demographics, prior TB disease, HIV status, BCG status, and occupational exposure profile of the HCWs at baseline (e.g. duration of employment, direct contact with TB patients, nature of work). After 12 months, the HCWs will undergo repeat TST and IGRA to document conversions (new infections). A repeat questionnaire will be used to ascertain TB exposure between the baseline and year 1 testing.

Study setting: A healthcare facility which manages patients with TB.

Study outcomes: TST and IGRA conversion rates will be used to estimate ARTI in HCWs. Analysis will focus on whether the ARTI estimates differ substantially for the two tests, and whether IGRA conversions have a stronger association with recent TB exposure than TST conversions.

Study population and methods:

Study tools: A surveillance system for latent TB infection (OR Appendix 1) should be utilized for data collection.

Inclusion criteria: Ideally, all HCWs will be included. If this is not feasible because of large numbers, then HCWs working in locations that are considered high risk for TB exposure (e.g. internal medicine, infectious diseases, pulmonology, microbiology, radiology, nursing, TB or DOTS clinic) can be preferentially included. HCWs include trainees who are at risk of TB exposure (e.g. nursing students, residents, interns).

Exclusion criteria: Any HCW who had positive prior TST, or a major adverse reaction to the TST, or bacteriologically confirmed history of TB disease.

Estimated number of participants and sampling: All HCWs in the healthcare facility will be invited to participate. However, to precisely estimate ARTI, a sample size of at least 500 HCWs will be ideal. Assuming an ARTI of 5%, if 500 HCWs are serially tested, then the ARTI will be estimated with a 95% CI of 3 - 7%.

Enrollment procedure: If a periodic (annual or more frequent) TST screening program is already ongoing for detection of LTBI, then HCWs can be enrolled via the occupational health and safety/ employee health program. Otherwise, all HCWs will be invited to participate in the study, which will involve (bi-)annual screening using TST and IGRA for detection of LTBI and administration of (bi-) annual, standardized questionnaire (OR Appendix 1) over the study period.

Data analysis: Analyses will involve: a) estimation and comparison of conversion rates with both TST and IGRA; and b) association between TB exposure factors - as collected with the questionnaire - and test results. Logistic regression will be used to study association between TST or IGRA conversion (using various definitions for conversions), and between TST/IGRA and the exposure/risk factors. If IGRA conversion correlates more strongly with the exposure gradient, that should be seen in the magnitude of the odds ratios and the c-statistic (area under the receiver operating curve (ROC) for the model, which is a measure of diagnostic accuracy). A secondary analysis can be done to assess factors associated with discordant conversion results (e.g. TST conversion, but no conversion with IGRA).

Minimum duration: 1 year

Requirements: 1) a trained person who can place and read the TST; 2) a phlebotomist for blood draw; 3) a laboratory that is capable of performing the IGRA assays.

Clinical follow-up: All HCWs with TST conversions must be offered IPT, after ruling out active TB disease. All HCWs with TB symptoms must be worked up for active TB disease. HIV testing can also be offered to HCWs found to have active TB.

Potential limitations and challenges:

A major challenge will be to include and follow-up of the required number of HCWs, and ensuring that repeat tests are done as per schedule. If a healthcare facility employs only a small number of HCWs, then ARTI estimates are likely to be highly imprecise. To some extent, this may be overcome by doing a multi-center study with more than one healthcare facility included in the same area or region. If a multi-center study is done, then care should be taken to follow the same protocol and testing procedures at all sites (training and standardization will be required, and, ideally, IGRA testing should be done in one central laboratory). Another limitation is the lack of consensus on how to define IGRA conversions - so, one of the study objectives is to explore which conversion definition has the best correlation with markers of TB exposure. Lastly, if HCWs do not agree to get HIV tested, then the impact of HIV on TST and IGRA results will not be determined.

Operational research study 2: Effects of a minimum TB-IC package on TB in HCWs

Context: The risk of getting TB is increased in HCWs in low and middle income countries (LMIC) compared to the general population. In high TB incidence settings, this poses a significant occupational health problem. In many healthcare facilities in LMIC, it is not feasible to implement expensive technology, such as negative pressure isolation rooms. However, also affordable and relatively easy to implement TB-IC measures are expected to reduce TB transmission considerably already. In this light, we define a minimum TB-IC package, which is based on grade of evidence and feasibility of implementation in LMIC:

1. Implementation of outpatient triage for cough,
2. Collection of sputum outdoors or in separate, sufficiently ventilated rooms,
3. Adequate ventilation in other consultation/examination areas, waiting areas and TB wards,
4. Cohorting or isolation of TB patients in separate inpatient TB wards.

Hypothesis: the introduction of a minimum TB-IC package compared to the situation where this minimum package is not available will decrease transmission of TB from patients to HCWs.

Study design: Prospective, multi-center pre- and post-intervention study (quasi-experimental). The primary study outcomes (TB infection and TB disease in HCWs) will be assessed before and after a minimum TB-IC package is implemented in healthcare facilities. If health facilities already have routine screening of and a registration system in place for TB infection and TB disease in health workers, this registration system can be used to compare the study outcomes in different time period. If such a routine screening and registration system is not in place, these data should be collected before implementation and compared to after implementation. However, usually the duration of time before implementation will be too small in a single HCF to reach sufficient statistical power to be able to show an effect. Therefore, a multi-center study should be implemented. This may also give the possibility to assess effects of differences in additional TB-IC measures besides the minimum package.

Intervention: The intervention should be a multi-tiered approach aimed to introduce TB-IC measures in the healthcare facilities. The first step is to install an IC committee which will make a TB-IC plan. Assessment of whether the minimum set of TB-IC measures is in place, should be done utilizing OR Appendix 3.

Study setting: Health care facilities which manage TB patients in settings with medium or high burden of TB.

Study outcomes: As study outcome parameters the following impact indicators will be used:

- Incidence of TB infection in health workers
- Incidence of TB disease in health workers

Study population and methods:

Study tools: A surveillance system for latent TB infection and active TB disease (OR Appendix 1 & 2) as well as the minimum TB-IC assessment (OR Appendix 3), should be utilized for data collection for this study.

Inclusion criteria: Ideally, all HCWs will be included. If this is not feasible because of large numbers, then HCWs working in locations that are considered high risk for TB exposure (e.g. internal medicine, infectious diseases, pulmonology, microbiology, radiology, nursing, TB or DOTS clinic) can be preferentially included. HCWs includes trainees who are at risk for TB exposure (e.g. nursing students, residents, interns).

Exclusion criteria: Any HCW who had positive prior TST or had a major adverse reaction to the TST.

Estimated number of participants and sampling: All health workers in the healthcare facility will be invited to participate. However, to be able to show a reduction in annual risk of infection (ARTI) from 6% to 3%, 750 health workers need to be included both before and after implementation of the minimum TB-IC package. The TB disease endpoint will need more HCWs than the infection endpoint. If 1% of HCWs get TB disease per year; one will need 5000 HW in both the pre-intervention and post-intervention period to show a reduction to 0.5%.

Enrollment procedure: If a periodic (annual or more frequent) TST screening program is already ongoing for detection of LTBI, then HCWs can be enrolled via the occupational health and safety/employee health program. Otherwise, all HCWs will be invited to participate in the study, which will involve (bi-)annual screening using TST for detection of LTBI (for those already undergoing TST through occupational health and safety/employee health, enrollment would enable access to records) and administration of (bi-)annual, standardized questionnaires over the study period.

Data analysis: The effect of the minimum TB-IC package on conversion rates and TB disease rate will be analyzed by comparing ARTI's and TB disease rates among HCW before and after implementation of the entire minimum TB-IC package with the chi-square test. Also, conversion and TB disease rates can be compared with survival analysis. Exclude those with TB disease history as well for measurement of TB infection

Minimum duration: two periods of one year, the first period before and the second period after implementation of the minimum TB-IC package. As it is not ethical to delay implementation because a baseline measurement is required, screening should be implemented as a first step. TST conversion rates and TB disease rates among HCW during and after implementation can then be compared.

Requirements: full-implementation of active screening for TB infection and disease among HCWs. A study coordinator should be appointed and have the capacity to collect, enter, analyze and report findings on the TB-IC situation in the facilities over time, and TB infection and TB disease among HCW in a systematic manner.

Clinical follow-up: HCWs with conversion by TST should be considered for preventive therapy.

Potential limitations and challenges:

A major challenge will be to include and follow-up of the required number of HCWs, and ensuring that repeat tests are done as per schedule. If a healthcare facility employs only a small number of HCWs, then ARTI estimates are likely to be highly imprecise. To some extent, this may be overcome by doing a multi-center study with more than one healthcare facility included in the same area or region. If a multi-center study is done, then care should be taken to follow the same protocol and testing procedures at all sites (training and standardization will be required).

Operational research study 3: Impact of reduction of diagnostic and treatment delays among patients with TB/MDR-TB on transmission among HCWs.

Context: A delay in the diagnosis and treatment of patients with active TB prolongs the period of infectiousness and thereby increases the risk of exposure to persons with whom the infected person comes into contact. Diagnostic delays are a result of both patient delay, the time from which the person initially experiences symptoms consistent with TB to the time he or she presents to the healthcare system; and healthcare system delay, the time from which the person initially presents to either an informal or formal healthcare provider to the time the person is diagnosed with active TB disease. Once diagnosed, patients may experience additional delays between the time of diagnosis and the time at which appropriate treatment for TB disease is initiated, often due to availability of medicines or in the case of drug-resistant or MDR-TB, awaiting laboratory results for drug susceptibility testing. Patients who experience extended delays are at risk for increased morbidity and mortality from TB, and patients with more severe disease may be more likely to transmit disease to others. HCWs in settings with a high prevalence of TB are at an increased risk for acquiring infection through occupational exposure. Patient delay, healthcare system delay, and treatment delay all have the potential to further amplify this risk, since patients who experience such delays are more likely to be un- or inadequately treated and in the late and more infectious stages of disease. In inpatient settings it is possible that a delayed diagnosis of TB in a patient admitted for other reasons may jeopardize the health of HCWs, particularly if infection control measures for respiratory protection are not utilized. Further, if a person with TB presents repeatedly to an outpatient setting without receiving a proper diagnosis, HCWs are at risk of repeated interactions with an infectious case.

Hypothesis: Reductions in diagnostic delays for TB patients will translate to less risk for the acquisition of TB infection and TB disease among HCWs.

Study Design: Prospective, multi-center, pre- post- intervention study (quasi-experimental). The primary study outcome, incidence of TB infection and TB disease among HCWs, will be assessed before and after an intervention aimed to reduce diagnostic delays for TB patients, after adjusting for level of occupational and non-occupational/community TB exposure, relevant socio-demographic and health characteristics of HCWs, and infection control measures.

Intervention: The intervention should be a multi-tiered approach aimed at reducing the diagnostic delays of TB patients serviced by the healthcare facilities and treatment delays within the healthcare facilities. The intervention would likely include community outreach and education to increase awareness in community members; education and collaboration with private practitioners, traditional healers, and other non-public settings where patients may initially seek healthcare; educating and utilizing tools to improve timely, accurate diagnosis of TB in public health settings; improving access to accurate, timely TB and DR-TB diagnostics (i.e. by improving turn-around times); strengthening communications between laboratories and clinicians; and providing clinicians with clear guidance for the management of TB patients.

Study Setting: Health care facilities which manage patients with TB, in a setting with a medium or a high burden of TB.

Study Outcomes: As study outcome parameters the following impact indicators will be used:

- Incidence of LTBI in health workers
- Incidence of TB disease in health workers

Study Population and methods:

Study tools: A surveillance system for latent TB infection and active TB disease (OR Appendix 1 & 2) as well as the minimum TB-IC assessment (OR Appendix 3), should be utilized for data collection for this study. The following additional information to questionnaires in OR Appendix 1-2 should be collected based on medical records of TB patients at the healthcare facilities:

- TB symptoms.
- DST results.
- Onset (date) of symptoms consistent w/ TB disease.
- Date(s) and details about previous healthcare encounters (both formal and informal – incl. traditional healers, private physicians) for current episode of symptoms.
- Number of outpatient visits to facility during period with TB symptoms.
- Dates of admission to and discharge from facility.
- Date of start of treatment.
- Dates of smear examination and results (quantitative) (to assess infectiousness and estimate time of smear conversion) If the facilities do not typically ask patients about onset of symptoms and seeking care prior to the visit when TB is diagnosed, then this study may involve having to implement procedures at the facility to routinely ask patients about this.

To attempt to control for potential changes in community exposure, surveillance data on smear-positive TB cases from the study catchment area should be analyzed in the models e.g. quarterly, biannual or annual incidence rates.

Inclusion criteria: Ideally, all HCWs will be included. If this is not feasible because of large numbers, then HCWs working in locations that are considered high risk for TB exposure (e.g. internal medicine, infectious diseases, pulmonology, microbiology, radiology, nursing, pediatrics, TB or DOTS clinic) can be preferentially included. HCWs includes trainees who are at risk for TB exposure (e.g. nursing students, residents, interns).

Exclusion criteria: HCWs that have a previously positive TST indicating LTBI or previous TB disease.

Estimated number of participants and sampling: All health workers in the healthcare facility will be invited to participate. However, to be able to show a difference in annual risk of infection (ARTI) from 6% to 3%, 750 health workers need to be included both before and after implementation of the intervention measures to reduce diagnostic delays. The TB disease endpoint will need more HCW than the infection endpoint. If 1% of HCW get TB disease per year; one will need 5000 HW in both the pre-intervention and post-intervention period to show a reduction to 0.5%.

Enrollment procedure: If a periodic (biannual or more frequent) TST screening program is already ongoing for detection of LTBI, then HCWs can be enrolled via the occupational health and safety/employee health program. Otherwise, all HCWs will be invited to participate in the study, which will involve (bi-)annual screening using TST for detection of LTBI (for those already undergoing TST through occupational health and safety/employee health, enrollment would enable access to records) and administration of (bi-)annual, standardized questionnaires over the study period.

Data analysis: The impact of the intervention aimed to reduce diagnostic delays will be assessed by comparing rates of TB infection and TB disease among HCWs before and after the intervention, after controlling for HCW and patient characteristics, occupational and non-occupational exposures, and infection control measures.

For all - calculate time from diagnosis to initiation of TB treatment

For DR-TB: time from diagnosis/sputum collection to initiation of appropriate therapy (based on DST results, if available).

Minimum duration: Two periods of one year, the first period before and the second period after implementation of the intervention aimed at reducing diagnostic delays.

Requirements: full-implementation of active screening for TB infection and disease among HCWs, and measurement of diagnostic delays before and after the intervention. A study coordinator should be

appointed and have the capacity to collect, enter, analyze and report findings on the TB-IC situation in the facilities over time, and TB infection and TB disease among HCW in a systematic manner.

Potential limitations and challenges: A major challenge will be to minimize losses to follow-up among HCWs enrolled, particularly if there is a high rate of staff turnover over the period of study. It will be necessary to ensure that standardized procedures and forms are used to collect data from all sites. One of the other key challenges is that the intervention may not effectively reduce diagnostic delays, and therefore would compromise the primary objective of the study. Previous studies demonstrating effective interventions for reducing diagnostic delays for TB patients is limited, and the reasons for diagnostic delays are both multi-factorial and differ according to the public health infrastructure, and the political, geographic, and cultural context. Before the current study is implemented, it is critical that any intervention implemented to reduce diagnostic delays be piloted to establish effectiveness. To control for potential changes in community transmission, local surveillance data on smear-positive cases may be placed in the model; however, if the quality of the data is unreliable e.g., data analysis of this factor will be less meaningful. Finally, because the study time will take place over 2-3 years, there is the potential that other interventions or temporal changes may be implemented that may impact rates of TB infection and TB disease in HCWs (e.g. enhanced infection control measures, changes in policies/guidelines, new diagnostics, media, etc). It will be critical to try to capture all potentially relevant factors throughout the study. Analytic techniques can be used to account for these factors to some extent, but it is likely that any major temporal changes will have effects that are unmeasured and unknown.

Operational research study protocol 4: Effect of opting out of high TB risk work environments on TB disease incidence among HIV-infected HCWs.

Context: Persons living with HIV/AIDS who are also dually infected with Mtb have exponential rates of TB incidence compared to HIV-uninfected and latently infected persons. Rapid progression of nosocomial hospital epidemics with high case fatality rates have been observed among HIV-infected persons. Isoniazid preventive therapy is now recommended for HIV-infected persons by WHO and has been shown to reduce the risk of progression to active TB disease among HIV-infected persons; however, the uptake in middle-high TB burden and low-middle income countries has been sub-optimal to date. The provision of anti-retrovirals to HIV-infected persons and concomitant immunoreconstitution has also shown an effect of reducing TB disease but not to the level of HIV un-infected persons. Infection control measures have also been able to reduce TB transmission in healthcare facilities. One potential administrative measure for further reducing risk of infection or re-infection among HIV-infected HCWs is by reducing their exposure via voluntary re-assignment of tasks and/or ward. This potential intervention has not been evaluated in a systematic way for its effectiveness in reducing TB incidence among HIV-infected HCWs. While ideally HIV+ workers would be safer to be limited to work in low risk areas, the reality in many high burden TB and HIV settings is that this is not feasible due to high proportion HIV+ HCWs in combination with a general HCW shortage, individual human rights of HIV+ workers to make informed decisions of the occupational risks they are willing to take in balance with employers' obligations to make the best efforts to protect them, potential perceived or real threat by HIV+ HCWs for unjust professional demotion or dismissal in some highly stigmatized settings, and HIV stigma that averts HIV testing and HIV disclosure in a work setting. This study attempts to evaluate how to best minimize risk of TB disease among HIV+ HCWs controlling for practical realities in many healthcare facilities.

Hypothesis: The introduction of voluntary re-assignment to lower risk work settings for HIV-infected HCWs compared to the situation where voluntary re-assignment is not offered or not taken up will significantly decrease TB incidence among HIV-infected HCWs

Study design: Prospective, multi-center cohort study. Evaluation of TB disease incidence rates among HIV-infected HCWs who voluntarily re-assign to lower risk areas. Over a 3 year study period,

multiple centers should actively screen all HCWs in their facilities for latent TB infection and active TB disease on a biannual basis and collect information on HIV, TB exposure, IPT, ART use and immunosuppression. Staff working in high risk TB areas who are HIV-infected should be offered voluntary re-assignment to other lower TB risk working areas. Incidence of TB disease among cohorts of HIV-infected HCWs (with and without voluntary re-assignment) will be compared to cohorts of HIV negative workers, controlling for potential TB exposure in the facilities and in the community as well as infection control measures within the facilities.

Study Setting: Health care facilities which manage patients with TB, in a setting with a medium or a high burden of TB and a medium or high burden of HIV

Study outcomes: As study outcome parameter the following impact indicator will be used:

- TB disease among any person working in a healthcare facility

Study Population and Methods:

Study tools: A surveillance system for latent TB infection and active TB disease (OR Appendix 1 & 2) as well as the minimum TB-IC assessment (OR Appendix 3), should be utilized for data collection for this study. In addition, for this particular study the following will be required for routine collection:

- Information on relocation of HCW from areas from higher to lower exposure to infectious TB. This list is not exhaustive of all physical and functional areas (such as housekeeping or physiotherapy) and procedures in a health facility, but the main risk areas and procedures of most health facilities are likely included here. These classifications may be changed based on a study site specific risk assessment (see OR Appendix 4 on physical and functional area risk assessment) specific to HCW risk (excluding potential risk to patients and visitors). For the purposes of an analytic framework for potential risk to HCWs:
 - Very high risk location and procedures could include, for example,: MDR-XDR-TB wards, TB culture, DST and molecular testing facilities, sputum induction areas, indoor sputum collection areas;
 - Higher risk locations and procedures could include, for example, TB wards (inpatient and outpatient), intensive care and internal medicine inpatient wards, respiratory therapy departments, intubation areas, bronchoscopy service areas;
 - High-medium risk includes, for example, x-ray service departments, outpatient department (waiting room and consultation room), emergency/urgent care departments, ARV clinics;
 - Medium-low risk may include pediatric wards (physically separated from adult patients), maternity wards (with average stay that is short e.g., 1-2 days), maternity and pediatric outpatient services, surgery departments (unless known TB patients or suspects have chest surgery), administrative areas with limited patients;
 - Lower risk includes, for example, administrative areas where no patients are located and AFB sputum microscopy centers (where sputum collection is not conducted inside the laboratory, sputum is not centrifuged, and no culture, DST nor molecular testing are conducted for TB).
- Local quarterly surveillance data on new smear-positive cases detected in the study catchment area for inclusion in the statistical model to control for potential fluctuations in community transmission.

Inclusion criteria: HCW working in HCF

HCW is defined as any worker regardless of profession within a healthcare facility

Exclusion criteria: HCW unwilling to participate in screening for TB infection and disease

Estimated number of participants and sampling: To compare the risk of TB disease among HIV+ HCW during and outside assignment in high TB risk areas, assuming 1. That 33% of HIV+ HCW work in high risk areas (i.e. ratio low:high=0.5:1), 2. An annual risk of TB disease to be 2.5% in those working

in high risk areas (i.e. median time to TB disease=52 months), 3. An accrual time during which individuals are recruited of 12 months, 4. Follow-up time of 2 years after recruitment, and 5. a hazard ratio of 1.5, one would need to include at least 525 HIV+ HCW to be able to determine a difference in TB disease risk at 95% confidence level and with 80% power.

Enrollment procedure: If a periodic screening is ongoing and routine, participants can be enrolled into the study via the occupational health and safety program or employee health clinic. If such a periodic screening does not exist, it will be necessary to set this up for the purposes of the study. The occupation health and safety program or other identified staff health program should also offer voluntary re-assignment to HIV-infected workers who are working in high risk TB areas.

Consent: Written informed consent will be required from all HCWs.

Data analysis:

This study should be analyzed with survival analysis. HCWs will be followed over time based on their IPT, HIV, ART, CD4 status, occupation within the facility, re-assignment status, and other factors. They will be censored either if they develop TB, they discontinue working at the facility for reasons other than TB disease, they die, or they reach the end of the study period without developing active TB disease. HIV unknown HCWs should be analyzed separately. If a HCW converts HIV status, they should be switched to the HIV positive follow-up group within the context of statistical analysis. In a high HIV and TB prevalent setting, the minimum number of participants in the study to achieve adequate statistical power is estimated to be 525 HIV+ staff enrolled. However, because the prevalence of HIV infection and TB disease is highly variable between countries, a power sample size calculation should be done specific for each study.

Minimum duration: 2-3 years

Requirements: Full-implementation of active screening for latent TB infection and TB disease among HCWs, preferably including HIV screening and monitoring among HIV-positive HCWs. A work reassignment program should be in place, which provides an opportunity for HIV+ HCW for relocation from positions where exposure to untreated TB is high to a lower risk position. A study coordinator should be appointed and have the capacity to collect, enter, analyze and report findings in a systematic manner.

Clinical follow-up: Clinical decisions for treatment of TB (both preventive and active disease) will be based on national protocols or clinic specific protocols.

Potential Limitations and Challenges:

Due to stigma, many HCWs may not uptake voluntary HIV testing and counseling within their health facility workplace. If such results are largely missing, this will limit the power of the study. However, missing value imputations i.e. special analyses for predicting HIV status when missing and sensitivity analyses may be utilized when evaluating the potential missing data for HIV status. Unknown HIV status should be analyzed separately. Some HCWs may opt-out of working in high risk settings while others may choose to remain. The acceptability of opting out among HIV+ HCWs and the feasibility of opting out in countries with high HIV prevalence and a shortage of HCWs is not assessed in this proposal; however, this may be a useful expanded study in parallel with the measurement from this proposal of the effectiveness of opting out. Undiagnosed infectious TB cases may be in any setting in a healthcare facility making the concept of high risk vs. medium-low risk blurry. However, the literature suggest that some areas of healthcare facilities have higher rates of transmission and the definition of high risk vs. medium-low risk areas is therefore a logical surrogate for potentially prolonged exposure than exceptional periodic exposure. Local analyses specific to the study catchment area may also be utilized to further define high vs. medium-low risk areas including a TB risk assessment. Further, the statistical model may include a variable regarding which departments the HCW was located. This study will be limited by the availability and completeness of the study data set. Further, some bias may be introduced by utilizing multiple healthcare facilities for comparison, particularly if the burden of TB is higher in some health care facilities and the extent of implementation of a minimum infection control package is different in distinct facilities. The proposed statistical analysis, however, can also control for this factor to an extent.

OR Appendix 1: Protocol and Questionnaire for surveillance of latent TB infection – (Modify for specific study setting as needed).

The questionnaire can be utilized for operational research protocols 1-4. For each protocol utilizing this questionnaire, the following standard procedures and definitions are recommended:

Procedures

Enrollment Procedure: If a periodic TST screening program is already ongoing, then HCWs can be enrolled via the occupational health and safety (or employee health clinic) program. If not, then special arrangements will have to be made to recruit HCWs. Clinical decisions about IPT will be made on the basis of serial TST results (because it is considered standard of care).

Consent: Written informed consent will be required from all HCWs before screening for TB infection.

Database: If not available, a database should be set up to record results of (bi-)annual screening of health workers for TST conversion and the questionnaire information.

TST: Participants will undergo TST using the Mantoux method. 2 TU of PPD RT23 (tuberculin bioequivalent to 5 TU of PPD-S) will be injected in the volar aspect of the forearm. 48 to 72 hours later, the transverse diameter of the induration will be demarcated using the ballpoint pen method and measured in millimeters by trained readers. Participants whose initial TST is positive (10 mm+) will be referred for medical evaluation. Participants whose initial TST is negative (0-9 mm), will undergo a second TST, 1 - 2 weeks later on the opposite forearm, using the same testing protocol to elicit the booster phenomenon [two-step TST protocol].

For Operational Research Protocol 1 Only (See page 127):

IGRA: Two commercial IGRAs are available: QuantiFERON-TB Gold In Tube (Cellestis, Carnegie, Australia) and T-SPOT.TB (Oxford Immunotec, Abingdon, UK). Whichever assay is selected, it should be performed according to the manufacturer's recommendations.

Definitions

TST conversions: baseline TST <10 mm and follow-up TST of >10 mm, with an increase of 10 mm over the baseline induration size (ATS/CDC/IDSA definition) (Ref 2 page 147).

For Operational Research Protocol 1 Only (See page 127):

IGRA conversions: a baseline negative IGRA result which becomes positive at repeat testing; however, this definition has been shown to result in a high conversion rate. More stringent definitions have been proposed 6-8 and will be explored in the study.

Questionnaire Administration

Each participants will have a questionnaire completed by a HCW or a data manager on demographics (age, sex, race, education, etc.), medical history (e.g. diabetes, HIV, immunosuppressive conditions), treatment for previous LTBI/disease, non occupational (e.g. household contact) and occupational TB exposure (e.g. work location, job title, year of training, duration of employment, contact with TB patients). HIV testing is at the discretion of participants and their healthcare providers (VCT and confidentiality must be ensured and HIV+ patients will need to be referred for evaluation). During repeat testing, participants will complete short questionnaires on exposures since the previous survey. The medical information on TST results should be filled in by the healthcare provider or data manager.

Potential Additional Resources

Administrative Records from facility on all HCWs, their hire dates, if and when they left the organization or died, transferred to another department, changed positions.

----- To be filled once -----

Health Facility:		Date: / /20	
<i>Staff Member Details</i>			
Name:		Written informed consent: <input type="checkbox"/> Yes <input type="checkbox"/> No	
Date of birth: / /19		Personal unique number (e.g. staff number):	
Gender:	<input type="checkbox"/> Male	<input type="checkbox"/> Female	
Job title:	<input type="checkbox"/> Medical Doctor	<input type="checkbox"/> Nurse	<input type="checkbox"/> Other, namely:.....
Total number of years of formal education:			
Of which total number of years of formal medical training:			
Employed in this facility since: / /19			
Total number of years working in <u>any</u> healthcare facility, including employment at this facility:			
Type of employment: <input type="checkbox"/> administrative <input type="checkbox"/> custodial <input type="checkbox"/> laboratory <input type="checkbox"/> patient-care			
Current work location(s):.....			
(if more than one, which is the main location:))			

----- to be filled every follow-up appointment and compiled with previously filled forms -----

Date:			
Personal Unique Number:			
Name:			
Change in work location within facility:		<input type="checkbox"/> Yes <input type="checkbox"/> No	If yes, current location(s):
Date of employment termination at this health facility (if applicable): / /20			
<i>Medical History</i>			
Diabetes:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Other immunosuppressive condition:	<input type="checkbox"/> Yes <input type="checkbox"/> No -> which condition:		
History of TB prophylaxis:	<input type="checkbox"/> Yes <input type="checkbox"/> No -> in which year:		
History of bacteriologically confirmed TB disease:	<input type="checkbox"/> Yes <input type="checkbox"/> No -> in which year:		
Direct contact with TB patients inside work-place:			
<input type="checkbox"/> Yes <input type="checkbox"/> No		-> <input type="checkbox"/> daily:	

in last 6 months		-> <input type="checkbox"/> weekly
		-> <input type="checkbox"/> monthly
		-> <input type="checkbox"/> less than monthly
Direct contact with TB patients outside workplace:		
<input type="checkbox"/> Yes <input type="checkbox"/> No	-> <input type="checkbox"/> in own household	
in last 6 months		-> <input type="checkbox"/> outside household
Use of N95 / FFP2 respirators:	<input type="checkbox"/> No	
	<input type="checkbox"/> Yes, during specific duties only	
	<input type="checkbox"/> Yes, always	

--- also fill out other side ---

Date of latest HIV test: / /20			
Latest HIV test result:			
If never tested or negative: offer voluntary counselling and testing			
		Date of HIV test: / /	
		HIV test result:	<input type="checkbox"/> Negative <input type="checkbox"/> Positive
If positive:			
		Date of latest CD4-count: / /20	
		CD4 count result: / /20	
		Current ART use:	<input type="checkbox"/> Yes <input type="checkbox"/> No
BCG vaccination status			
		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	
		If yes, visible scar observed:	<input type="checkbox"/> Yes <input type="checkbox"/> No
Date of TST testing: / /20			
Date of TST reading: / /20			
TST test result (in mm):			
If initial TST and negative result (0-9 mm), 2nd TST 1-2 weeks later in the opposite forearm:			
		Date of 2nd TST testing: / /20	
		Date of 2nd TST reading: / /20	
TST test result (in mm):			
For Operational Research Protocol 1 Only(See page 129):			
Date of blood drawing for IGRA: / /20			
IGRA test results quantitative:			
IGRA test result qualitative:		<input type="checkbox"/> Positive	<input type="checkbox"/> Negative

OR Appendix 2: Protocol and Questionnaire for Surveillance of Active TB disease (modify for specific study setting as needed).

The questionnaire below can be utilized for operational research protocols 2-4. For each protocol utilizing this questionnaire, the following standard procedures and definitions are recommended:

Procedures

Enrollment procedure: If a periodic TB disease screening program is already ongoing, then HCWs can be enrolled via the occupational health and safety (or employee health clinic) program. If not, then special arrangements will have to be made to recruit HCWs. Clinical decisions about treatment of active TB disease should be made in consideration of national TB guidelines. All positive TSTs, dependent on the study specific study protocol, will be referred for a full screening for active TB disease (including symptom screening, sputum collection and testing).

Consent: Written informed consent will be required from all HCWs before screening for TB disease.

Database: If not available, a database should be set up to record results of (bi-)annual screening of health workers for TB disease and the questionnaire information.

Definitions

TB disease: should be defined utilizing standard WHO definitions.

Questionnaire administration

Each participant will have a questionnaire completed by an appointed healthcare provider or data manager on demographics (age, sex, race, education, etc.), medical history (e.g. diabetes, HIV, immunosuppressive conditions), treatment for previous LTBI/disease, non occupational (e.g. household contact) and occupational TB exposure (e.g. work location, job title, year of training, duration of employment, contact with TB patients). HIV testing is at the discretion of participants and their healthcare providers (VCT and confidentiality must be ensured and HIV+ patients will need to be referred for evaluation).

Potential additional resources

Administrative records can be utilized from facility on all HCWs, their hire dates, if they left the organization or died, transferred to another department, changed positions.

National TB register (individualized) can be utilized to match against for employees during the study period who may not have revealed their TB disease status to the health facility.

Quarterly surveillance data on new smear positive TB cases for study catchment area: this could be utilized to measure potential fluctuations in TB transmission rates in communities during the study period which can be controlled for.

----- To be filled once -----

Use of N95 / FFP2 respirators:	<input type="checkbox"/> No
	<input type="checkbox"/> Yes, during specific duties only
	<input type="checkbox"/> Yes, always

--- also fill out other side ---

Date of latest HIV test:				
Latest HIV test result:				
If never tested or negative: offer voluntary counseling and testing				
		Date of HIV test: / /		
		HIV test result:	<input type="checkbox"/> Negative	<input type="checkbox"/> Positive
		If positive:		
		Date of latest CD4-count: / /20		
		CD4 count result: / /20		
		Current ART use:	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Date of TB disease evaluation:		/ /20		
Sputum smear positive:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	
Date of sputum collection:		/ /20		
Culture positive:	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown	<input type="checkbox"/> Not Done
Date of specimen collection for culture:		/ /20		
Source of culture specimen:		<input type="checkbox"/> Sputum	<input type="checkbox"/> Blood	<input type="checkbox"/> Other: specify.....
Date of chest radiograph:		/ /20		
Result:	<input type="checkbox"/> Normal	<input type="checkbox"/> Cavitory	<input type="checkbox"/> Infiltrate	<input type="checkbox"/> Other <input type="checkbox"/> Not done
Does the employee have active TB disease:		<input type="checkbox"/> No	<input type="checkbox"/> No	If Yes, answer questions below
Site of active TB disease (choose 1):		<input type="checkbox"/> PULMONARY only		
		<input type="checkbox"/> Extra-pulmonary only		
		<input type="checkbox"/> Both pulmonary and extra-pulmonary		
Does the employee have bacteriologically confirmed MDR-TB?:		<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Unknown

OR Appendix 3: TB infection control assessment on minimum requirements and supplementary measures.

Health Facility:	Date: / /20
Date of most recent Previous Assessment:	Date: / /20
Minimum requirements for the purpose of the study	
1. Infection control committee with a health facility TB-IC plan?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Implementation of outpatient triage for cough?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Collection of sputum outdoors or in separate, sufficiently ventilated rooms?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Adequate ventilation in other consultation/examination areas, waiting areas and TB wards?	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Are smear-positive TB patients physically separated from non-infectious patients?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Some countries may already have additional measures in place and may want to measure there effect as well. The following questions are examples of additional questions that can be tailored to a countries' specific circumstances.	
Supplementary beyond the minimum infection control package as potentially defined by a specific study protocol in a specific setting	
6. Is there a designated focal point for TB-IC at the health facility?	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Is there evidence of TB-IC information, education and communication at the facility for cough etiquette i.e. posters and videos?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Are patients routinely directed to utilize outdoor waiting areas and spaces?	<input type="checkbox"/> Yes <input type="checkbox"/> No

OR Appendix 4: Assessment Tool: Assessing risk levels for HCWs by physical and functional areas in a healthcare facility

This risk assessment classification should be used as a conceptual guideline for each facility TB-IC focal point, team and/or study coordinator to distinguish between low and very high risk settings and procedures. This list is not exhaustive of all physical functional areas (such as housekeeping or physiotherapy) and procedures in a health facility, but the main risk areas and procedures of most health facilities are likely included here. If a particular facility TB-IC focal point or team has evidence that this general framework of risk classification does not fit their functional area or procedure, they should consult with the study coordinator to address this in the study design. This tool, for the purposes of the study, disregards potential risk to vulnerable patients and visitors e.g. infants, young children and immune-compromised persons.

Physical functional areas and procedures

Assuming limited existing TB-IC controls are in place, risk of active transmission of TB infection and disease in a particular setting within a health facility is defined by the following factors: the likelihood of TB suspects or TB patients producing infectious TB droplet nuclei e.g. smear-positivity, in this particular setting or with this particular procedure, the potential duration of exposure, the potential number of TB suspects and TB cases in this area, and the potential for multi-drug resistant TB (MDR-TB) or extensively drug resistant TB (XDR-TB) exposure. TB exposure can happen anywhere in a health facility or in a community; however, some settings have higher risks because of the aforementioned factors. Administrative controls will be effective to reduce TB transmission in the whole facility. Due to limited human and financial resources, it is more efficient and cost-effective to strategically target areas of higher risk in a health facility with environmental controls and respiratory protection. Based on these assumptions and factors, the risk for infectious TB exposure within a facility has been classified as low, medium, high and very high risk as follows:

→ **Low risk area or procedure:**

An area or procedure within the health facility which has a limited likelihood of exposing staff to TB suspects or patients or to TB droplet nuclei from infectious TB patients or TB specimens. The primary risk in this area is a rare exposure to a staff, patient or visitor with TB.

→ **Medium Risk Area or Procedure:**

An area or procedure in the health facility which has a moderate likelihood of exposing staff, patients and visitors to TB suspects or patients or to TB droplet nuclei from infectious TB patients or TB specimens. TB cases or medium risk procedures may be present in these settings but for short durations or with few such incidents likely.

→ **High Risk Area or Procedure:**

An area or procedure within the health facility which has a high likelihood of exposing staff to TB suspects or patients or to TB droplet nuclei from infectious TB patients or TB specimens. High risk areas settings and procedures are where many infectious TB suspects (undetected) or many known infectious TB patients may be present or subject to high risk procedures. These settings may also have high concentrated numbers of MDR-TB suspects or patients.

→ **Very High Risk Area or Procedure:**

An area or procedure within the health facility which has a very high likelihood of exposing staff TB suspects or patients or to TB droplet nuclei from infectious TB patients or TB specimens. Very high risk areas and procedures are where many infectious TB suspects (undetected) or many known infectious TB patients may be present or subject to high risk procedures. These settings may also have high concentrated numbers of XDR-TB suspects or patients.

Location at Health Facilities	Low Risk	Medium Risk	High Risk	Very High Risk
Administrative Areas (with no patient or suspect contact e.g. separate building than patients)				
Administrative areas (with limited patient or suspect contact or air exchange from patients)				
Maternity and Pediatric Wards				
ARV Outpatient Clinic				
Outpatients Department (waiting room and consultation room)				
Emergency Rooms				
Intensive Care and Internal Medicine Wards (inpatients)				
TB Outpatient (DOT) Clinics				
TB Inpatient Wards				
MDR-TB Wards				
XDR-TB Wards				

Administrative Areas:

The risk of TB infection in these areas is generally considered low. However, the risk for this area is generally considered medium risk if TB patients and suspects infrequently visit these administrative areas. If the administrative area were in the same air space as infectious TB patients e.g. on a TB ward, then the risk would be considered high; however, this situation is generally unlikely for most health facilities. Further, it is important to note that the administrative employees who frequently visit high risk areas in the facility, without proper TB-IC measures, are at higher risk of TB infection or disease but this is not attributable to the administrative area but to the high risk areas that they visit. Further, if a staff sitting in these administrative areas develops infectious TB and exposes other staff in this area then the risk of TB in this area, due to that exposure, would be higher than normal.

Maternity and Pediatric Wards:

The risk of TB infection in these areas is generally considered medium to HCWs. The maternity wards generally include very short stays and pediatric patients (unless they are over 14 years old) are unlikely to have infectious TB. However, pregnant women may develop active and potentially infectious TB as a result of immunosuppression from pregnancy, if they are already infected with TB. Further, visitors with infectious TB in the maternity and pediatric wards could potentially infect others.

ARV Clinics (outpatient):

Outpatient ARV clinics are generally considered medium risk to HCWs. The duration of exposure is generally short in these outpatient settings. However, while many people co-infected with HIV and TB develop non-infectious TB disease, some will develop infectious TB disease and potentially expose others. Possibly poor ventilation and lack of cough etiquette practices, if there is an infectious TB patient there who has not been screened, pose higher risk for others exposed in these settings including staff. Visitors accompanying the persons seeking ARVs may have infectious TB (undetected or detected) and expose staff in these areas.

Outpatients Department (waiting rooms and consultation rooms):

Outpatient departments are generally considered medium risk as the duration of exposure is short. However, there are several factors which may make them higher risk. First, long waiting times and poor ventilation in waiting areas and consultation rooms pose high risk if undetected infectious cases of TB or known infectious TB cases visit them without proper screening, ventilation or cough etiquette. Second, persons with infectious TB are likely to visit these waiting areas and consultation rooms because they are increasingly more ill and seeking medical attention. Third, people living with HIV are likely to also have other non-TB illnesses for which they seek medical attention in these settings. Fourth, visitors accompanying the persons seeking medical advice may themselves have infectious TB (undetected or detected) and expose others in these areas.

Emergency Rooms:

Emergency rooms are generally considered medium risk as the duration of exposure is short. However, there are several factors which may make them higher risk. First, long waiting times and poor ventilation in waiting areas and consultation rooms pose high risk if undetected infectious cases of TB or known infectious TB cases visit them without proper screening, ventilation or cough etiquette. Second, persons with infectious TB are likely to visit these waiting areas and consultation rooms because they are increasingly more ill and seeking medical attention. Third, visitors accompanying the persons seeking medical advice may themselves have infectious TB (undetected or detected) and expose others in these areas.

Intensive Care and Internal Medicine Wards (inpatients):

Inpatient internal medicine and intensive care wards are generally considered high risk. First, the duration of exposure is generally longer than in outpatient settings. Second, lack of TB screening of patients upon admission may result in unknown infectious TB exposures to others for days or even weeks resulting in infection of others. Infectious TB patients are likely to be admitted as they can

be very ill and be hospitalized for this reason. Third, potentially poor ventilation and lack of cough etiquette practices, if there is an infectious TB patient there, pose higher risk for health staff. Fourth, visitors accompanying the persons seeking medical advice may themselves have infectious TB (undetected or detected) and expose others in these areas for prolonged periods.

TB Outpatient (DOT) Clinics:

TB outpatient (DOT) clinics are considered high risk. First, while the duration of exposure is generally short in these outpatient settings, the patients have active TB and some of them are infectious. Second, if the area is not properly ventilated, workers may be infected or re-infected by the infectious TB patients. Third, it is possible that the TB patients, even if on appropriate 1st line treatment, may have infectious MDR-TB or even XDR-TB that has not yet been detected.

TB inpatient wards:

TB inpatient wards are considered high risk. First, there is a concentration of potentially infectious TB cases in this setting. Second, the duration of exposure from infectious TB could be prolonged, from several days to many weeks. Third, if appropriate TB infection control measures are not in place, workers may be at high risk to be infected or re-infected by the infectious TB patients. If smear-negative patients and smear-positive TB patients are not separated, the risk for staff infection increases because the wards will be bigger and require more staff. It is possible that a TB patient, even if on appropriate 1st line treatment, may have infectious MDR-TB or even XDR-TB that has not yet been detected. MDR-TB and XDR-TB cases are very difficult to treat, require prolonged treatment with injectable drugs and other drugs which have many side effects, are expensive to treat, and have poor cure rates compared to non-MDR and non-XDR-TB.

MDR-TB wards:

MDR-TB inpatient wards are considered high to very high risk. First, there is a concentration of potentially infectious MDR-TB cases in this setting. Second, the duration of exposure from infectious MDR-TB could be prolonged, often several months, before their 2nd line drugs render them non-infectious. Third, if the area does not have appropriate infection control measures in place, will be at higher risk of being infected or re-infected by the infectious MDR-TB patients. Fourth, if smear-negative TB patients and smear-positive MDR-TB patients are not separated, the staff exposed to the infectious TB increases because the wards will be bigger and require more staff. MDR-TB cases are very difficult to treat, require prolonged treatment with injectable drugs and other drugs which have many side effects, are expensive to treat, and have poor cure rates compared to non-MDR and non-XDR-TB. It is possible that the MDR-TB patients, even if on appropriate 2nd line treatment, may have infectious XDR-TB that has not yet been detected.

XDR-TB wards:

XDR-TB inpatient wards are considered very high risk. First, there is a concentration of potentially infectious XDR-TB cases in this setting. Second, the duration of exposure from infectious XDR-TB is likely to be prolonged, often many months, before the 2nd line drugs render them non-infectious. Third, if appropriate infection control measure are not in place, workers will be at a higher risk of being infected or re-infected by the infectious XDR-TB patients. Fourth, HIV infected staff in this setting may rapidly develop XDR-TB. Fifth, if smear-negative XDR-TB patients and smear-positive XDR-TB patients are not separated, the persons exposed to the infectious XDR-TB increases because the wards will be bigger, the wards will require more staff. Sixth, XDR-TB cases are very difficult to treat, require prolonged treatment with injectable drugs and other drugs which have many side effects, are expensive to treat, and have poor cure rates compared to non-MDR and non-XDR MDR-TB. Seventh, in some cases, XDR-TB may be considered untreatable.

Procedure at health facilities	Low Risk	Medium Risk	High Risk	Very High Risk
Smear-microscopy				
Surgery (unless performing chest surgery on a TB patient or suspect)				
X-ray services				
Respiratory therapy e.g., spirometry				
Intubation				
Bronchoscopy services				
Culture and DST procedures of TB specimens				
Molecular testing with live Mtb specimen processing				
Sputum collection				
Sputum induction				

Surgery (unless performing chest surgery on a TB patient or suspect):

Surgery is usually considered to be a low risk procedure unless the operation is on an infectious TB patient. If the operation is on an infectious TB patient, the surgery would be considered moderate to high risk either due to exposure to the TB patients infectious cough or by potentially aerosolizing M. Tuberculosis bacilli from the surgery, particularly surgery involving the lungs or other infected organs.

X-ray Services:

X-ray technicians and others visiting the x-ray services may be at moderate to high risk of TB infection. While the duration of exposure is short, infectious TB patients (undetected or detected) usually have lung abnormalities and often receive diagnostic chest X-rays.

Respiratory Therapy:

If a patient is receiving such therapy to measure their lung capacity e.g. Spirometry and they have active infectious TB (detected or undetected), the procedure may put workers, visitors and other patients at high risk for exposure to infectious TB.

Intubation:

This procedure may induce cough in an infectious TB patient (undetected or detected) and expose workers, visitors and other patients to infectious TB.

Bronchoscopy Services:

This procedure may induce cough in an infectious TB patient (undetected or detected) and, without proper TB-IC controls in place, expose workers, visitors and other patients to infectious TB. [It is also theoretically possible to infect patients with the tubes by placing non-sterilized contaminated tubes into the next patients' lungs].

Culture and DST procedures of live Mtb specimens:

These procedures, without proper laboratory infection controls in place, are high risk for TB infection. However, the specimens may also be handled by HIV infected workers and potentially be MDR-TB or XDR-TB specimens, and therefore can be very high risk.

Molecular testing with live Mtb specimen processing:

These procedures, without proper laboratory infection controls in place, are high risk for TB infection. However, the specimens may also be handled by HIV infected workers and potentially be MDR-TB or XDR-TB specimens. Therefore, this procedure can be very high risk.

Sputum Collection:

This procedure, without proper ventilation, is high risk for TB infection. Further, if the specimen is collected in an enclosed area without proper ventilation, the next persons (including people living with HIV) who enter the enclosed area could be infected. The specimens may also be collected in the presence of HIV infected workers and potentially be MDR-TB or XDR-TB patients (detected and undetected). Therefore, this procedure can be very high risk.

Sputum induction: This procedure, without proper ventilation and respiratory protection, is high risk for TB infection. Further, if the specimen is collected in an enclosed area without proper ventilation, the next persons (including people living with HIV) who enter the enclosed area could be infected. The specimens may also be collected in the presence of HIV infected workers and potentially be MDR-TB or XDR-TB patients (detected and undetected). Therefore, this procedure can be very high risk.

Other Procedures: autopsies of TB patients are considered high risk procedures as the Mtb bacilli may still be alive and be aerosolized by the procedure, particularly from infected lungs or other organs, even though the patient has passed away.

Operational Research Reference Materials:

1. Centers for Disease Control and Prevention. Guidelines for preventing the transmission of Mycobacterium tuberculosis in health-care settings, 2005. MMWR. 2005;54(No.RR-17):1-141.
2. American Thoracic Society (2000) Targeted tuberculin testing and treatment of latent tuberculosis infection. Am J Respir Crit Care Med 161: S221-247
3. Menzies D (1999) Interpretation of repeated tuberculin tests. Boosting, conversion, and reversion. Am J Respir Crit Care Med 159: 15-21.
4. Pai M, Zwerling A, Menzies D (2008) Systematic review: T-cell-based assays for the diagnosis of latent tuberculosis infection: an update. Ann Intern Med 149: 177-184.
5. Pai M, O'Brien R (2007) Serial testing for tuberculosis: can we make sense of T cell assay conversions and reversions? PLoS Med 4: e208.
6. Pai M, Joshi R, Dogra S, Mendiratta DK, Narang P, et al. (2006) Serial testing of health care workers for tuberculosis using interferon-gamma assay. Am J Respir Crit Care Med 174: 349-355.
7. van Zyl-Smit RN, Pai M, Peprah K, Meldau R, Kieck J, et al. (2009) Within-subject Variability and Boosting of T Cell IFN-g Responses Following Tuberculin Skin Testing. Am J Respir Crit Care Med 180: 49-58.
8. Pai M, Joshi R, Dogra S, Zwerling AA, Gajalakshmi D, et al. (2009) T-cell assay conversions and reversions among household contacts of tuberculosis patients in rural India. Int J Tuberc Lung Dis 13: 84-92.

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Annex: SOP 201: TB Infection Control Community-based Guidelines (Source: Collaborative TB/HIV Services, Standard Operating Procedures for Implementation of TB Activities at HIV/AIDS Service Delivery Sites, Family Health International, October 2009)

I. Key Concepts:

- The community-based health worker has a unique opportunity to help prevent the spread of TB by teaching and monitoring proper implementation of infection control measures practiced in the home during home visits.
- Infection control (IC) goal: to minimize the risk of TB transmission by detecting patients with TB disease early, isolating them promptly and treating people with TB disease quickly to prevent spread of TB to others.
- Implement IC along with universal or standard precautions (Part I SOP 105).
- Any pulmonary TB (PTB) patient during the first two weeks of treatment is considered infectious; PTB patients may spread TB to others via airborne transmission.
- HIV-infected HCWs are at increased risk of TB infection and active disease due to frequent exposures to TB suspects and undiagnosed individuals with TB disease.
- A TB patient is considered non-infectious after:
 - Having 2-3 consecutive negative sputum smears on 2 different days.
 - Completing at least two weeks of anti-TB therapy.
 - Completing a diagnostic evaluation or full TB treatment course.
- The reference to “TB” in this and other SOPs refers to the spread of Mtb, or TB bacilli, which the recommended TB-IC measures are meant to prevent.

II. Key Personnel: Community health workers (CHWs), RN, patient, family members and administrative staff

III. Materials: Paper tissues, disposable cloth scraps, container with lid and face masks (if available)

IV. Procedures:

A. Managerial control measures for administrative staff and all CHWs

1. Develop a TB-IC committee.

- a. Identify a person with expertise in IC to lead the committee at the community based site.
- b. Carry out a risk assessment to identify risk of TB transmission to PLHIV at the site.
- c. Develop a TB-IC implementation plan based on findings from the risk assessment.
- d. Include clinic management and staff in creating the IC plan.

2. Develop policies and procedures to ensure proper implementation of plan.

- a. Rethink the use of available spaces and consider renovation of health site.
 - i. Design waiting areas and examination rooms with the most natural ventilation possible.
 - ii. Place educational posters about IC measures in outpatient waiting areas, as well as in procedure rooms and other areas where they can be seen and easily read by patients and staff.
- b. Work with local coordinating bodies.
- c. Participate in research efforts.

3. Monitor the TB-IC implementation plan.

- a. The lead IC team member regularly supervises and monitors the IC plan; the TB-IC steering committee meets annually to assess the plan.

- b. Include civil society involvement, behavioral change campaigns, and reinforcement of a positive message for health workers, patients and visitors.

4. Schedule annual all-staff training about TB, TB infection control, and the clinic's TB-IC implementation plan.

B. Administrative control measures for administrative staff and all CHWs

1. Promptly identify potential and known infectious cases of TB; separate and treat them with minimal delay.

- a. Explain to patients that safety without stigma is the goal of IC and that screening for, and prevention of TB transmission is part of providing quality care. At the site, the community-based site RN screens all patients in a well-ventilated area and identifies people with a cough lasting > 2 weeks as soon as possible upon arrival to the site.
- b. If symptomatic, initiate TB-IC measures.
 - i. If a face mask is available, give to TB suspect to wear over their mouth and nose.
 - ii. Place the person in a separate, well-ventilated area well away from other HIV infected patients.
 - iii. Refer patient immediately for TB testing at the primary health clinic (PHC).

2. Offer a rapid screening referral mechanism for potential contacts of TB suspects, such as symptomatic patients and visitors accompanying TB suspects.

3. Encourage proper cough hygiene.

- a. Talk with TB suspects and people diagnosed with active TB disease about how they can adhere to proper cough hygiene and etiquette.
- b. Ask the coughing person to cover their mouth and nose when they cough or sneeze and practice hand washing.
- c. Provide tissues or disposable cloth scraps and instruct patient to cover their mouth and nose when coughing or sneezing.

4. Encourage safe management of sputum.

- a. Instruct patient to not clear their throat and then spit on the street or on the ground.
- b. Give patient a container with a lid for receiving sputum (if available) and instruct patient to spit sputum only into the container provided.
- c. If a plastic bag is used to receive sputum, always tie the opening.
- d. Dispose of sputum in a toilet or burn it.

5. If possible, encourage the TB patient to sleep in a separate bedroom from other family members, especially during the first 2-3 weeks of TB treatment while the cough is still present.

6. Promote proper eating hygiene

- a. Encourage family to use serving spoons during a meal with family and friends.
- b. Ask patient to not share drinking glasses with others.

7. Provide all staff intensified screening for TB.

- a. Periodically screen staff for symptoms of active TB disease.
- b. Schedule all-staff TB testing twice a year (e.g., TST, CXR) in high TB and HIV-prevalence areas.
- c. Document results in the staff member's occupational file.

8. In high-burden TB and HIV settings, test all HCWs for HIV in addition to TB.

- a. Offer staff voluntary, confidential HIV counseling/testing, and annual repeat testing if HIV-negative on previous occasions.
- b. Refer for assessment of and preferential access to ART.

9. If possible, do not assign HIV-infected CHWs to work in high-prevalent TB settings, including:

- a. Where patients are assessed for but not yet diagnosed with TB (e.g, health site waiting area)
- b. Performing sputum collection procedures

C. Environmental control measures for all CHWs

1. Environmental control measures combined with patient practices further reduce TB transmission.
2. Remind patients that sunlight is a free anti-bacterial disinfectant.
 - a. Advise patients and household members to open the doors and windows to their bedrooms, allowing the sun to reach inside.
 - b. Encourage patient and household members to regularly:
 - i. Wash pillowcases and bed sheets and dry them in sunlight.
 - ii. Place their mattresses in the sun.
3. Work with the family to lower the concentration of TB particles in room air, or to move air in the home and replace it with air from outside.
 - i. Natural ventilation
Keep doors and windows on opposite sides of the home open to bring in air from the outside.
 - ii. Mechanical ventilation
 - a. Use propeller fans, if available, mounted in ceilings or in a window opening to distribute and direct airflow.
 - b. Ensure that the air flows past household members first, then past the coughing patient and out the opposite window.

D. Respiratory control measures for administrative staff and all CHWs

1. Do not use a face mask as a TB prevention method when working with TB suspects.
 - a. Face masks only reduce transmission from symptomatic persons to others.
 - b. The best prevention of TB transmission occurs when TB suspects are diagnosed promptly with TB and started immediately on the correct TB drugs, and when the drugs are taken by patients exactly as prescribed. In these cases, patients usually become non-infectious in a week or two.