



**USAID**  
FROM THE AMERICAN PEOPLE

# TB CARE II

## Ethics of Tuberculosis Prevention, Care and Control: A Training Curriculum

### Facilitator-Led Training Guide

July 2015

#### **DISCLAIMER**

*This training curriculum is made possible by the support of the American people through the United States Agency for International Development (USAID). The information provided in this guide is the sole responsibility of University Research Co., LLC and its partner the Global Tuberculosis Institute and do not necessarily reflect the views of USAID or the United States Government.*

## Acknowledgements

TB CARE II is funded by United States Agency for International Development (USAID) under Cooperative Agreement Number AID-OAA-A-10-00021. The project team includes prime recipient, University Research Co., LLC (URC), and sub-recipient organisations Jhpiego, Partners in Health, Project HOPE along with the Canadian Lung Association; Clinical and Laboratory Standards Institute; Dartmouth Medical School: The Section of Infectious Disease and International Health; Euro Health Group; MASS Design Group; and the Global Tuberculosis Institute at Rutgers, The State University of New Jersey.

This document was produced for review by the United States Agency for International Development by the Global Tuberculosis Institute at Rutgers, The State University of New Jersey.

The following individuals and organizations made significant contributions to the development of this Facilitator-Led Training Guide and accompanying the course materials:

- Nisha Ahamed, MPH, Consultant, Global Tuberculosis Institute at Rutgers, The State University of New Jersey
- Rajita Bhavaraju, MPH, Director of Curriculum and Assessment MPH, International Union Against Tuberculosis and Lung Diseases
- Jennifer K. Campbell, MPH, Training and Consultation Specialist, Global Tuberculosis Institute at Rutgers, The State University of New Jersey
- Robert Makombe, MD, Senior Regional Technical Advisor, University Research Co., LLC
- Refiloe Matji, MD, Vice President, University Research Co., LLC
- Nalini Naidoo, MD, Consultant
- Lee B. Reichman, MD, MPH, Senior Advisor, Global Tuberculosis Institute at Rutgers, The State University of New Jersey
- Alisha Smith-Arthur, University Research Co., LLC

The Ethics of TB Prevention Care and Control training was pilot tested in East London South Africa and the course materials were reviewed by content experts. Many thanks are due to the following for their significant contributions in review and pilot testing of these materials:

- Lindiwe Mvusi, MD, Director, National TB Program, South Africa
- The dedicated group of nurses, physicians and other health care workers from the Eastern Cape Province, OR Tambo and Buffalo City Metro Health Districts in South Africa who participated in pilot testing
- Mike Frick, MSc, Project Officer, Treatment Action Group
- Amera Khan, MPH, Training, Education, and Behavioral Studies Team Lead, Centers for Disease Control and Prevention, Division of TB Elimination
- Margaret Molefe, Training Advisor, TB CARE II South Africa
- Nokuthula Sopeseka: Senior Manager TB Programme Eastern Cape Province
- Thandeka Dayimani, National Expansion Coordinator, University Research Co., LLC
- Simphiwe Mayaphi TBHIV Provincial Coordinator, University Research Co., LLC

Some content for this facilitator guide was based on information in the *Effective TB Interviewing for Contact Investigation: Facilitator-Led Training Guide* produced by the United States Centers for Disease Control and Prevention, Division of Tuberculosis Elimination.

## Table of Contents

Acknowledgements.....	2
Foreword.....	6
1. Introduction .....	7
Overview of Facilitator-Led Training Guide .....	7
Sections .....	7
2. Description of <i>Ethics of Tuberculosis Prevention Care and Control</i> Training .....	9
Training Course Goal and Learning Objectives .....	9
Target Audience .....	9
Course Materials and Format.....	10
Class Size .....	10
3. Adult Learning Principles.....	11
4. Course Planning.....	13
The Planning Process.....	13
Logistics .....	13
Identifying Facilitators and Course Faculty .....	14
5. Pre-Course Arrangements.....	16
Facilitator/Presenter Preparation .....	16
Inviting the Delegates .....	17
Supplies .....	19
Classroom and Facility Arrangements.....	19
6. Group Facilitation and Training Delivery.....	20
Effective Training.....	21
Providing Effective Facilitation.....	21
Tips for Dividing Groups.....	23
Energisers.....	23
Providing Feedback .....	23
7. Evaluation.....	25
Immediate Evaluation .....	25
Change in Performance and Impact Evaluation.....	27
Facilitator Evaluation.....	28

8.	Course Activities.....	29
	Course Contents.....	29
	Format.....	29
	Activity Overview .....	29
	Activity Types .....	32
9.	Facilitating Each Module.....	33
10.	Module 1: Introduction.....	34
	Facilitation Guide for Module 1: Introduction.....	34
	Slide Kit for Module 1: Introduction .....	36
	Facilitator Instructions for Module 1 .....	40
11.	Module 2: Background on Tuberculosis.....	47
	Facilitation Guide for Module 2: Background on Tuberculosis.....	47
	Slide Kit for Module 2: Background on Tuberculosis .....	48
12.	Module 3: Overarching Goals and Ethical Values .....	52
	Facilitation Guide for Module 3: Overarching Goals and Ethical Values .....	52
	Slide Kit for Module 3: Overarching Goals and Ethical Values.....	53
13.	Module 4: Obligation to Provide Access to TB Services.....	62
	Facilitation Guide for Module 4: Obligation to Provide Access to TB Services.....	62
	Slide Kit for Module 4: Obligation to Provide Access to TB Services .....	63
14.	Module 5: Information, Counselling and the Role of Consent .....	78
	Facilitation Guide for Module 5: Information, Counselling and the Role of Consent.....	78
	Slide Kit for Module 5: Information, Counselling and the Role of Consent .....	80
15.	Module 6: Supporting Adherence to TB Treatment .....	88
	Facilitation Guide for Module 6: Supporting Adherence to TB Treatment.....	88
	Slide Kit for Module 6: Supporting Adherence to TB Treatment .....	90
	Facilitator Notes for Module 6 Plenary Discussion: Supporting Adherence to TB Treatment .....	96
16.	Module 7: Gap Between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment.....	97
	Facilitation Guide for Module 7: Gap Between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment .....	97
	Slide Kit for Module 7: Gap between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment .....	99
17.	Module 8: Health Care Worker Rights and Obligations.....	104
	Facilitation Guide for Module 8: Health Care Worker Rights and Obligations .....	104

	Slide Kit for Module 8: Health Care Worker Rights and Obligations .....	106
	Facilitator Instructions for Activity 4: Health Care Worker Rights and Obligations.....	111
18.	Module 9: Involuntary Isolation and Detention as Last-Resort Measures .....	113
	Facilitation Guide for Module 9: Involuntary Isolation and Detention as Last-Resort Measures ....	113
	Slide Kit for Module 9: Involuntary Isolation and Detention as Last-Resort Measures.....	114
	Facilitator Instructions for Activity 5: Involuntary Isolation and Detention as Last-Resort Measures .....	121
19.	Module 10: Research on TB Care and Control .....	123
	Facilitation Guide for Module 10: Research on TB Care and Control .....	123
	Slide Kit for Module 10: Research on TB Care and Control.....	124
20.	Module 11: Conclusion.....	131
	Facilitation Guide for Module 11: Conclusion.....	131
	Slide Kit for Module 11: Conclusion .....	132
	Facilitator Instructions for Activity 6: Ethics of TB Prevention, Care and Control Planning Tool .....	136
21.	Delegate Hand-outs .....	139
	Delegate Hand-out for Activity 2: Ethics Assessment Tool .....	140
	Delegate Hand-out for Activity 3: Obligation to Provide Access to TB Services .....	142
	Delegate Hand-out for Plenary Discussion: Supporting Adherence to TB Treatment.....	144
	Delegate Hand-out for Activity 4: Health Care Worker Rights and Obligations .....	145
	Delegate Hand-out for Activity 5: Involuntary Isolation and Detention as Last-Resort Measures...	146
	Delegate Hand-out for Activity 6: Ethics of TB Prevention, Care and Control Planning Tool .....	147
	Activity 6: Ethics of TB Prevention, Care and Control Planning Tool .....	149
22.	Resource List .....	151

## Foreword

Given the knowledge we have regarding the aetiology, mode of transmission, risk factors, diagnosis and effective treatment for tuberculosis (TB), it would seem that global elimination of TB would be within our grasp. However, management of TB today is increasingly complex; factors including HIV infection, drug resistance, poverty, and socioeconomic conditions impact all stages of TB prevention, care and control.

The key vulnerable groups most affected by TB include people living in poverty, ethnic minorities, women, children, people living with HIV (PLHIV), prisoners, homeless persons, migrants, refugees and internally displaced persons. Members of these groups are more likely to be exposed to conditions that are conducive to TB development and they are less likely to have the information, power and resources necessary to ensure access to health care.

TB contributes to poverty in many ways, for example, by preventing people from working and by imposing high costs related to treatment and care. People can also be subjected to arbitrary and harmful measures such as involuntary treatment, detention, isolation and incarceration. Finally, TB-associated stigma and discrimination—and overlapping discrimination based on gender, poverty, or HIV status—can affect people's employment, housing and access to social services.

The Global Fund to Fight AIDS, TB and Malaria has stated that: 'TB is a disease of poverty and inequality that particularly affects key vulnerable populations with little or no access to basic services. A human rights-based approach to TB prevention, treatment and care includes addressing the legal, structural and social barriers to quality TB prevention, diagnosis, treatment and care services.'

In some places, travelers may be barred from entering a country because of latent TB infection or TB history, and undocumented migrants may be deported before completion of TB treatment. Studies have shown that PLHIV, sex workers, transgender people and other marginalized groups are sometimes denied equal access to DOTS Centers (government clinics providing TB services).<sup>1</sup>

To mount an effective response, a TB control programme should therefore be informed by and harmonised with the protection of civil, political, economic, social and cultural rights. This training course focusing on the ethics of TB prevention, care and control, seeks to provide a human-rights, person-centred framework for the application of ethical values to the management of TB control programmes. It is based on the World Health Organization's *Guidance on the ethics of tuberculosis prevention, care and control*, published in 2010.

Experts in this field have contributed to the development of this curriculum and the training course. It is hoped that ethical guidance provided in this curriculum will help frontline health care workers, support staff, and TB programme managers consider how to more effectively provide prevention, treatment, care and support for people at risk of and those with TB using a human-rights-based approach.

<sup>1</sup> The Global Fund to Fight AIDS, Tuberculosis and Malaria, Global Fund Information Note: TB and human rights (February 2013)

# 1. Introduction

## Overview of Facilitator-Led Training Guide

This facilitator-led training guide provides all the background information, details and materials needed to plan and implement the two-day interactive training course, *Ethics of Tuberculosis Prevention, Care and Control*. All of these materials as well as the PowerPoint presentations and presentation handouts for delegates are also available online at:

<http://globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbethicscurriculum.html>

Many different people are involved in the planning and delivery of training courses. This guide includes information on working with the appropriate people for planning the course, background on effective training, and detailed information for those who will be facilitating and presenting at the course. This guide is designed for those who will be planning, coordinating, and facilitating the training. In many cases one individual may be responsible for all of these roles. In other cases, these roles may be carried out by more than one person. The guide or sections of the guide can be shared with others involved in planning and conducting the *Ethics of Tuberculosis Prevention, Care and Control* training course as needed.

## Facilitator-Led Training Guide Objectives

By reading, reviewing, and utilising this guide, the facilitator will be able to:

- Apply the principles of adult learning to training activities
- Conduct training on ethics of TB prevention, care and control that is relevant to participant needs
- Utilise local standards, sensitivities and culture to personalise the training
- Conduct short-term and long-term evaluation of the outcomes of the training

## Sections

This Facilitator's Guide contains the following sections:

1. Introduction
2. Description of *Ethics of Tuberculosis Prevention Care and Control* Training Course
3. Adult Learning Principles
4. Course Planning
5. Pre-Course Arrangements
6. Group Facilitation and Training Delivery
7. Evaluation
8. Course Activities
9. Facilitating Each Module
10. Module 1: Introduction
11. Module 2: Background on TB
12. Module 3: Overarching Goals and Ethical Values
13. Module 4: Obligation to Provide Access to TB Services
14. Module 5: Information, Counselling and the Role of Consent

15. Module 6: Supporting Adherence to TB Treatment
16. Module 7: Gap between Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment
17. Module 8: Health Care Worker Rights and Obligations
18. Module 9: Involuntary Isolation and Detention as Last-Resort Measures
19. Module 10: Research on TB Care and Control
20. Module 11: Conclusion
21. Delegate Hand-outs
22. Resource List

Prior to conducting the course, you should review each section in order to become familiar with all of the course's components. You may refer back to any section as necessary. You should also become familiar with the *Ethics of tuberculosis prevention, care and control slide kit*. This will ensure that you can answer participant questions and refer to sections with ease throughout the training.



## 2. Description of *Ethics of Tuberculosis Prevention Care and Control* Training

The *Ethics of Tuberculosis Prevention, Care and Control* training course focuses on the application of ethical values within tuberculosis (TB) control programmes. Global efforts to combat TB have raised questions about the need for a human rights-based approach to TB as well as the ethical management of treating people with TB and those at risk of contracting TB. The prevention, care and control of TB raise social and cultural concerns as well as ethical considerations around public health and medical ethics. These issues are explored in the *Ethics of Tuberculosis Prevention, Care and Control* training course. Course content is based on the World Health Organization's *Guidance on the ethics of tuberculosis prevention, care and control*, released in 2010.

### Training Course Goal and Learning Objectives

The overall goal of the *Ethics of Tuberculosis Prevention, Care and Control* course is:

- To sensitise and educate delegates on the application of ethical values to all aspects of TB prevention, care and control

The learning objectives of a training programme are its measurable outcomes. The objectives listed below are based on the activities provided in this guide.

The objectives of the *Ethics of Tuberculosis Prevention, Care and Control* training course are to:

- Discuss the relationship between ethical values and tuberculosis (TB) care
- Describe one main area of emphasis from the World Health Organization's *Guidance on ethics of tuberculosis, prevention control and treatment*
- Demonstrate an understanding of context-specific challenges in ethical management of TB
- Identify potential approaches for addressing challenges to ethical management of patients with tuberculosis

Objectives should be incorporated as part of the evaluation activities at the end of the course to gauge whether these were achieved. Specific objectives for each module are also included in this guide.

### Target Audience

The target audience for this training course includes:

- Frontline health care workers who provide care and support to patients at risk for TB , or those who have been diagnosed with TB
- Supervisors of these frontline staff
- Support staff who are responsible for ensuring that the TB programme can be effectively and efficiently implemented
- Local level, provincial or national TB programme staff who work to ensure better control, and eventually, elimination of TB

While health care workers in local, provincial or national TB programmes will certainly be a primary audience for this course, given the wide range of health care providers who are involved in diagnosing,

preventing and managing TB, delegates may come from a variety of settings, including primary care facilities and HIV programmes. Delegates should possess basic knowledge on TB and on the TB programme in their area.

### Course Materials and Format

In addition to this *Ethics of Tuberculosis Prevention, Care and Control: Facilitator-Led Training Guide*, this course utilises two further resources: the *Ethics of Tuberculosis Prevention, Care and Control Slide Kit*; and the *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes*. The *Ethics of Tuberculosis Prevention, Care and Control Slide Kit* provides key discussion points in PowerPoint presentation format, with Speaker Notes included. As noted earlier, all course material can be accessed at:

<http://globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbethicscurriculum.html>

Individuals have different ways in which they best learn and acquire information. Most adults learn best by participating in activities that reflect their experiences and are relevant to their work. People also grasp concepts best from varying media. For most, reading about and listening to information on a certain topic leads to some information retention. However, demonstration and practicing skills are among the best ways to learn and retain information.

The most effective way to learn about ethics of TB prevention, care and control is to learn about the issues and recommendations, consider the uses of the WHO guidance and practice its application in TB control. Therefore, this training course utilises varied training methods in order to meet the course objectives. A proposed agenda, with activities and timings can be found in the section on Course Activities Overview.

Interactive activities for this course consist of the following formats:

- Small group discussions
- Plenary discussions
- Case studies
- Individual activities

In the course of this guide, there are notations indicating where modifications can be made to account for local standards of practice, sensitivities to local norms and culture, roles and responsibilities, as well as spans of control and regulations. Adjustments can also be made to this course based on time available and number of participants being trained.

Participants will complete the above mentioned *Assessment Tool* at the beginning of the course. This will allow them to look at their own TB control programme in the context of the WHO ethics guidance. As the course progresses, the activities and discussions will help them consider how the ethical guidance can be applied to help strengthen their own TB control programme.

### Class Size

Because understanding application of the ethical guidance is a key component in this course, it is presented as an interactive learning experience. Using this style of teaching, the class size should be small. It is recommended that the class size be between 15 and 25 people.

### 3. Adult Learning Principles

Adult learning principles play a key role in delivering health care professional training. To conduct an effective training programme, facilitators need to be aware of the unique needs of the adult learner. Adults, unlike children, base their learning on past experiences and relevance to current or future experiences. The outcome of a training programme is important to the adult learner. This places a value on the learning activities. Therefore, understanding how a training experience applies to real-life scenarios is vital.

The opportunity to develop strategies and apply knowledge through exercises and activities is an important element of adult learning. The training materials contained in this manual, and the approaches described, are geared toward both practical education and developing a better understanding of ethical issues in TB. The information provided should be considered in relation to the delegate's role and be made relevant to the delegate's specific occupational needs. Any presentation using the materials provided in this manual must be relevant to the delegate's past and present experiences and job-related tasks.

Some effective teaching methods with adult learners include the use of examples and practice. Because learners also bring with them life and job experiences, participants should be allowed to actively participate in training, by asking questions related to specific and realistic situations. Brainstorming with colleagues about solutions to challenging situations should be encouraged as well. Training should also allow time to absorb ideas which may be a change to the delegates' current thinking. In turn, the facilitator should also respect differing opinions and exceptions to what may be taught.

Facilitators can learn from the course delegates in many ways. The delegates may have innovative ways of solving problems or different viewpoints. Adult learners are a unique learning resource for both the facilitator and one another.

Table 1 summarises how adults learn and provides some suggestions for running effective training programmes.

**Table 1: Training implications for adult learning**

How adults learn	What does this mean?	Suggestions for Training
Adults bring a lot of experience with them to training sessions, and they therefore have something to contribute and something to lose	<ul style="list-style-type: none"><li>• Adult learning is unique to each individual. Everyone learns at their own pace and in their own way</li><li>• Adults value their own experience and don't want to be treated as stupid or ignorant</li><li>• Adult cannot be forced to change</li></ul>	<ul style="list-style-type: none"><li>• Adults want to test what they learn with what they already know. Encourage them to answer questions from their own experience</li><li>• Don't just present information as 'truth'. Use people's different experiences to encourage questioning and discussion so that they can arrive at the truth for themselves</li><li>• Adults don't want to risk looking stupid. Treat everyone equally and respect their input and ideas. If someone makes a mistake treat it as a means to create discussion and so enable learning</li><li>• For learning to occur, material has to be provided in manageable steps. Adults need to understand as they learn and gradually come to master a task</li><li>• Adults want feedback on their progress and how they can improve. However, don't be overly critical, as positive reinforcement is also needed when a new task is being carried out for the first time</li></ul>
Adults prefer to focus on real life, immediate problems rather than on theoretical situations	<ul style="list-style-type: none"><li>• Adults see learning as a means to an end, rather than an end in itself</li><li>• Learning is voluntary. Adults only learn what they want to learn and do what they want to do. What they learn must have personal meaning and be of direct or immediate value</li></ul>	<ul style="list-style-type: none"><li>• Provide useful information that is relevant to their needs. Adults would rather focus on current issues, rather than material that may be useful in the distant future</li><li>• Tell adults about the purpose and benefits of the session, and about the process that will be followed. That way they will know what's in it for them</li><li>• Summarise and review regularly so they can see that progress is being made</li></ul>
Adults are accustomed to being active and self-directing	<ul style="list-style-type: none"><li>• The best learning is based on experience</li><li>• Most adults like to work with others. Aim for a cooperative process that supports sharing of experiences</li></ul>	<ul style="list-style-type: none"><li>• Participation needs to be encouraged, supported and expected. Don't embarrass them, but don't let them hide either</li><li>• For learning to occur, adults have to do things. They must get involved and work at tasks and exercises. They learn by doing and making mistakes and then discovering solutions for themselves</li><li>• Adults want to be consulted and listened to. Although trainers need to give direction at times, this should be the exception rather than the rule</li></ul>

## 4. Course Planning

This section covers issues that should be considered prior to conducting a training programme. These issues include formulating why training is being conducted, for whom it is targeted, and what skills need to be addressed.

### The Planning Process

Depending on who your intended audience is and where they are from, it is important to involve supervisory, provincial/state, and other staff in planning the training programme. These individuals will consider what outcomes they wish to see from a training programme, as well as make determinations on who should be trained and what staff capabilities exist. These issues may range from who is available from individual facilities/clinics to attend training, to a broad assessment of where poor performance indicators exist for TB outcomes.

A planning committee discussion should answer:

- Why a course on the Ethics of Tuberculosis Prevention, Care and Control is being conducted
- Who should attend the course, including job descriptions and titles, geographic locations (if not from the same health department located in one area), and levels of experience
- How will delegates be identified and invited to the course
- Who should provide the training, and who will provide support services before, during, and after the course
- Who should pay for the training
- Who should facilitate and present the training
- When to conduct the training
- Where to conduct the training

### Logistics

Along with your planning committee or the others who are assisting you, select a date and venue for the course. Since training should be a focused experience, free of distractions, choosing a location away from the health department or work setting is ideal. If possible, coverage should be arranged to provide an uninterrupted training experience for staff.

Try to schedule the course during regular work hours. This ensures that participants can be available for the entire course, without experiencing conflict with other responsibilities such as childcare, personal appointments, or other work. Also, continuity can be best achieved if the course is held over two consecutive days. Since this is a two day training course, delegates who will be traveling to the course from long distances will need accommodations; these delegates should arrive the day before the training course begins to ensure that they are present at the start of the course.

## Identifying Facilitators and Course Faculty

The best-qualified individual to facilitate this course is one with a background in health education and who is a skilled facilitator or trainer. That is, the facilitator should be:

- Knowledgeable about key elements of facilitation
- Comfortable in front of a group of people
- Able to navigate group discussions and draw out differing ideas and opinions
- Flexible with deviations from the course structure
- Able to provide constructive feedback
- Able to communicate and articulate her/his own and others ideas
- In possession of good listening skills; clarifies and probes for understanding
- Able to respond non-defensively to challenges
- Self-aware; can self-correct
- Able to put people at ease and create a comfortable learning environment
- Able to show respect for the ideas and opinions of others
- Non-judgmental

Additionally, since facilitating a course such as this requires time, commitment, and collaboration, other key facilitator characteristics include:

- Willingness to devote the time required to prepare for training
- Demonstrated success in working with groups as a leader or facilitator
- Ability to establish rapport with a wide variety of individuals at all levels
- Having credibility and respect
- Support for the training course and understanding of why it is important to the success of the TB programme

## Background

Given these requirements, facilitators for this course may include:

- Training or education staff from the national or regional level TB programme or other organisations working in TB Control
- Other national or regional level TB programme staff with experience in training and facilitation
- Other appropriately qualified Ministry of Health staff

While these materials provide the necessary information for one course facilitator to present the course content, it would be preferable to include presenters from different backgrounds, settings, and levels within the TB programme to bring a variety of perspectives and help keep activities lively. Since there may be a mixed audience in terms of professions, it may also be helpful to ensure that the course faculty reflects this, with a mix of physicians, nurses and others. When reviewing the course materials, consider who might be best suited to present the different modules based on expertise in specific topics or areas.

Specifically, it is recommended that someone who supports the TB control programme at a National or Provincial/State Department of Health level assist the facilitator or serve as faculty for this course. These individuals should be able to answer questions related to the TB programmes, and further advise delegates on varying approaches based on his or her experience, knowledge and expertise.

## **Experience**

The facilitator should have knowledge and understanding of TB prevention care and control and should also be familiar with the populations with which the delegates interact. He or she should also be comfortable with the fact that delegates may have difficult questions and sometimes have negative feelings about the communities with which they work, and the people with whom they interact. It is up to the facilitator to remain objective and non-judgmental.

While a specific background in ethics and human rights would be helpful, it is not necessary to serve as facilitator or faculty in this course since a great deal of detail and information is provided in this guide. However, sensitivity to the ethical challenges and principles involved in TB prevention, care and control is essential. It is also suggested that all facilitators and course faculty review the WHO document *Guidance on the ethics of tuberculosis prevention, care and control* prior to presenting at the course.

## **Delegate-Centred Training**

Just as TB prevention, care, support and control is person-centred, the facilitator should be committed to making the course delegate-centred. This means making the experience comfortable, encouraging delegates to critically think during the activities, and hearing and responding to delegates concerns.

## 5. Pre-Course Arrangements

In addition to preparing teaching materials and anticipating the delegates' needs, some logistical considerations should be part of course preparation. These include inviting and working with course presenters; inviting the delegates; arranging the classroom set-up; and preparing learning materials.

### Facilitator/Presenter Preparation

Every trainer has a personal style of preparation and delivery. A useful way to begin preparing for the course is to review the slide kits and the activities for this course.

As a facilitator you should become familiar with the concepts to ensure that you can respond to any questions or concerns that may arise during the course of training. You should also work with all presenters and faculty members to ensure that they are also comfortable with the material and activities.

To prepare for the course, facilitators and faculty should:

- Review slide sets with facilitator notes
- Review course activities
- Develop personal anecdotes or illustrative examples to contextualise a teaching point
- Plan to deal with special or sensitive issues

In addition, these suggestions may also assist you in facilitating this course:

- **Find out what duties the delegates have.** This information may be useful in helping you understand where the TB control programme fits into their overall roles and responsibilities, and the span of control delegates have within the TB programme. This information can be gathered during the course enrollment process
- **Anticipate different training groups.** Occasionally, there may be persons who are less familiar with concepts presented in the training. Certain terms and concepts may need to be reviewed to bring everyone to the same level
- **Form groups for small group discussions thoughtfully.** Give careful thought to which delegates should be placed together for activities, because these groupings can influence the dynamics and results of activities both positively and negatively. It may be helpful to obtain a list of how long each of the delegates has supported the TB programme. This way the groups can be mixed. Less experienced persons can learn from more experienced delegates. Some delegates may have experience from other disciplines or programmes that can also be factored into forming groups. Caution: just because they have supported the TB programme for a long time does not mean they are providing care and support based on a person-centred approach
- **Group delegates with people they do not know** as much as possible. While in groups with unknown individuals, delegates may be inclined to share more openly



## Inviting the Delegates

As noted earlier, delegates for this course should support the TB control programme as part of his or her job responsibilities. Potential participants could include front line health care workers or administrators at district, regional or national levels who are involved in TB prevention, care or control. The course delegates may be either pre-selected to attend, or have to 'apply' to participate in the training course. In either case, all delegates should be sent a letter of confirmation with any relevant course instructions including:

- Learning objectives
- Location and directions
- Course timings
- Prerequisites

A sample letter is shown in Figure 1. This letter may be modified to fit your course needs. The confirmation letter should be sent at least one month prior to the course to allow staff to make arrangements for workplace coverage.

**Figure 1: Sample confirmation letter**

*Print on letterhead*

<Date>

<Name of Delegate>

<Address>

Dear \_\_\_\_\_

I am pleased to confirm your enrolment in the training course, 'Ethics of Tuberculosis Prevention, Care and Control', which will be held on <day/date> from <start time> to <end time> in <city, province/state>. Directions to the course site are enclosed.

The objectives of the 'Ethics of Tuberculosis Prevention, Care and Control' Training Course are for the delegate to be able to:

- Discuss the relationship between ethical values and tuberculosis (TB) care
- Describe one main area of emphasis from the World Health Organization *Guidance on ethics of tuberculosis, prevention control and treatment*
- Demonstrate an understanding of context-specific challenges in ethical management of TB
- Identify potential approaches for addressing challenges to ethical management of patients with tuberculosis

Please note that during the course, we will ask you to complete the *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes* document. This assessment tool is based on the World Health Organization's recommendations for ensuring a person-centred approach and application of ethical values in the design and implementation of TB programmes. I am enclosing a copy of the assessment tool, in case you wish to review it prior to the course. Completion of the assessment tool will allow you to understand the specific areas within your TB programme that may be strengthened by the application of the ethical guidance that will be discussed during the training.

<The remainder of the letter can be devoted to other appropriate matters such as:

lodging, travel, expense reimbursement, dietary requirements or special needs, emergency message telephone number at course site, parking, etc.>

If you have any questions regarding the course, please feel free to call me at (    )

\_\_\_\_\_ - \_\_\_\_\_ or contact me by email at \_\_\_\_\_@\_\_\_\_\_. I look forward to your participation in the course.

Sincerely

<Course Facilitator>

## Assistance

If possible, you should secure a support person to help with registration, activities during the course and dealing with unforeseen problems that may arise. This person should not be a delegate and does not necessarily need to be someone who is part of the TB programme. The support person can act as a timekeeper and should keep a copy of the agenda with specific timings of each activity. A support person can assist with taking notes on a flip chart during plenary discussions and can also identify and try to address any unforeseen problems while the facilitator proceeds with the course activities. If the facilitator/trainer acts as the support person, he or she can also make observations during the course, which will assist in formulating future training.

## Supplies

Activities in this manual have a list of necessary supplies that you should have prepared and ready ahead of time. In addition, you should have the following items ready for the delegates before the start of the course:

- Handouts for participants:
  - Agenda
  - Slide set handouts formatted for delegates - available at
  - Delegate handouts for activities (Activities 2, 3, 4, 5, 6 and Module 6 Plenary Discussion Handout)
  - Copies of *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes*
  - Course evaluation

A folder or binder containing the agenda and slide set handouts can be prepared in advance and provided to delegates at the beginning of the course. All handouts are available at:

<http://globaltb.njms.rutgers.edu/educationalmaterials/productfolder/tbethicscurriculum.html>

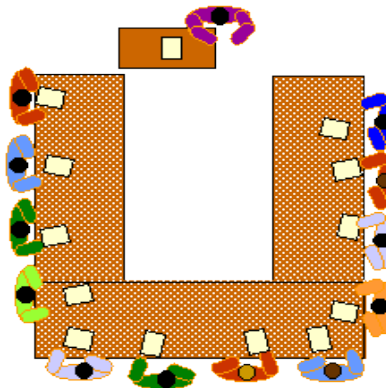
- Preprinted or prewritten nametags or signs (if not preprinted or prewritten, provide pens for writing) - The writing on the tags should be visible from the front of the room and all areas of the classroom set up. The facilitators and trainers should also have nametags
- Attendance Register - This should be a preprinted list of expected delegates' names with space for them to sign. Delegates may require verification of their attendance, and the attendance register can serve this purpose. Check if there is a required format from the local Department of Health office
- Computer, projector and electronic files with PowerPoint slides
- Extra pens and paper for participants' note taking
- Flip chart with extra paper and flipchart pens for activities
- Delegate certificates of completion – Providing certificates is a nice way of ending a course. Certificate paper can be inexpensively purchased and names printed or neatly handwritten. These may also serve as verification of attendance for required by supervisors. If this is not an option, certificates may be emailed to delegates after the course is completed

## Classroom and Facility Arrangements

The ideal arrangement for the classroom is to place tables in a 'U' shape with the opening of the 'U' at the front of the classroom and chairs for delegates around the outside of the table, as illustrated in

Diagram 1. In this arrangement, delegates can see each other for interactive purposes. The 'U' should remain open to allow the instructor to move about freely. However, this arrangement may not always be possible in the space available to you or if the chairs and tables cannot be moved easily.

**Diagram 1: U-shaped classroom setup**



Whatever the arrangement, there should be enough space for delegates to move about and form groups without disturbing one another. While much of the course involves small group activities, the seating arrangements help to facilitate discussion. Ideally, if several rooms are available, these can be used for small group activities.

There should also be space in the front of the room for a table on which to place teaching materials, including the computer. A podium for speakers may be helpful, but is not necessary, and has the potential to be a barrier to a facilitator working with a group of delegates. This will depend on the preferences of the speaker.

## 6. Group Facilitation and Training Delivery

## Effective Training

Effective training requires knowledgeable, skilled, organised, and enthusiastic facilitators. By taking the initiative to provide this training, you are ensuring that ethical values and principles are considered in the implementation of TB control programmes.

## Providing Effective Facilitation

During a course, the facilitator should:

- Encourage participants to share ideas and concerns
- Model effective communication by listening, checking for understanding, and asking questions
- Provide information to supplement what the participants bring with them to the course

Since this training may include a mixed group of delegates with different roles, work settings and job responsibilities, you should keep these differing roles and responsibilities in mind as you facilitate the course. There will also be a variation in their ability to apply guidance obtained from this course. This means that you will need to be aware of the impact of these factors as you plan and lead the delivery of the training. Senior level staff who have a wider span of control should be encouraged to support subordinates in applying ethical guidance in their day-to-day functions. A route to facilitate this could include:

- Create an enabling environment for staff to raise ethical concerns and seek guidance
- Empower staff to utilise a person-centred approach in patient care

Additionally, in some cases, there may be no clear-cut answers for ethical dilemmas or questions raised by delegates. As noted in the stated course goal, the intention of the training is to raise awareness on ethical values as applied to the management of TB, and to help delegates think about and develop approaches or strategies to make improvements to TB programmes. Thus, discussion of different dilemmas, perspectives, and potential approaches is itself useful, even if consensus is not reached during the course. These discussions may also be beneficial as they can identify ethical issues and challenges that require discussion, review and guidance at a higher level.

There are several concepts to keep in mind for effective facilitation.

- **Set ground rules for the course.** While adult learners should be treated as adults, there should be some basic rules of conduct during the course. These will be covered in the Course Activities section. These rules emphasise confidentiality, respect for others' opinions, and nonjudgmental behaviour. Both the facilitator and delegates can formulate these rules together, as people are more likely to adhere to rules that they have been part of formulating.
- **Create a safe learning environment.** Participating in discussions and sharing views and opinions can be intimidating for some delegates. Facilitators will want to lead these activities in ways that build confidence and strength in the areas that the delegates themselves have expressed as concerns. Facilitators can minimize the stress and maximise the value of learning together.
- **Encourage delegates to become acquainted during breaks.** During the breaks, at lunch, and at other appropriate times, encourage delegates to talk with each other and compare job responsibilities, policies, procedures, and 'tricks of the trade'. These interactions will help the delegates, and may well benefit later discussions in the group.

- **Help delegates review the content of each activity.** An important aspect of training is providing delegates with opportunities to focus on the 'big picture' of what they are learning. This evaluation will give delegates a chance to review the material that they have covered during the course and to raise questions or concerns they have about the content. Tips for summarising key learnings are included with each activity description.
- **Accommodate local laws, policies, and cultural norms and practices.** Any effective job-training course accommodates the circumstances in which the delegate works. You will want to pay attention to any relevant local laws and practices which impact on how one initiates or conducts an interview.
- **Facilitate question-asking by repeating questions.** Questions may not be heard or understood by all of the delegates. Therefore, when a question is asked, you should either repeat or paraphrase it to help others understand it clearly. It is acceptable to ask other participants to try to answer the question, so that delegates share and learn from each other.
- **Do not let a factual error in a delegate's statement go uncorrected.** Even if only a small point in an otherwise correct answer is wrong, that point should be quickly and tactfully clarified so that others are not left with an incorrect impression.
- **Be aware of the level of participation of each person in the course.** It is natural for some delegates to talk more than others. You should encourage those who seem to talk less than others to answer questions and share perspectives and experiences.
- **Apply active listening in all aspects of training.** You should be aware of what each person is saying and be able to paraphrase it if the point someone has made is relevant later in the course. This gives the delegates a sense of relevance, and it is helpful for them to hear important concepts reiterated in various contexts.
- **Take responsibility for keeping delegates on track.** Discussions may stray from the main point or lead into negative discussions and complaints about work. It is your job to move the discussions ahead which may involve interrupting after someone has finished a sentence or merely stating that others may have contributions to make, but you simply have to move on to adhere to time constraints. Also, during all small group activities, it is important to circulate throughout the room to catch problems and assist or encourage people as needed. You should alert participants to the amount of time remaining in each small group activity several minutes before the activity is to end.
- **Allow groups to work independently.** Within the course, there are activities that involve group work. The purpose of this is to promote incorporation of varying ideas and to enhance the flow of many ideas at once. As the facilitator, you should walk around the room to observe how groups' processes are progressing. However, try not to intervene unless a group is missing the purpose of the activity or is very far behind the time allotted for completion of the activity. By observing the group processes, you can assess how well the group was prepared for this activity and whether your instructions were clear. This is important for future training programmes.
- **Realise that there are different successful approaches.** While you may teach a particular approach, the course delegates may have other ways in which they accomplish certain tasks, which may also be acceptable approaches.

## Tips for Dividing Groups

As described, the interactive nature of this training course is grounded in the activities to facilitate learning. If little information is known about the delegates prior to the course, it will be necessary to find ways to form small groups quickly at the beginning of the activity. The activity write-ups provide mechanisms for dividing delegates into groups. Here are other suggestions, a few which require pre-planning, that can be used to divide delegates into groups:

- At the start of the training course, put a code on delegate's name badges, such as a colour, a number, and a letter; using 3 colours, 4 numbers and 5 letters. Then, at various times divide the group according to one of the categories
- Get delegates to change seats after the tea and lunch break so they are sitting next to different people. Then sort groups by counting off delegates where they sit
- Write delegates' name on pieces of paper and put the names into a hat or container. Pick names out of the hat or container to form groups
- For a mix of roles, ask delegates to find two others with different roles from their own
- Ask delegates to work with as many as possible of the delegates they know the least

## Energisers

An energiser is a quick activity that is intended to increase energy during training by engaging delegates in physical activity, laughter, or problem-solving. Given the short duration of this training course, energiser activities have not been included in the agenda. It would, however, be worthwhile including an energiser activity if you notice that energy levels are starting to drop or delegates are becoming quiet and not participating fully in the activities.

Here are some examples of quick energiser activities that you can use to revive the group should energy levels start to flag.

- Arrange delegates into two equal lines facing each other. One group turns around while the other group gets 30 seconds to change 10 things about them (switch jewelry, change hair style, untie shoelaces, switch watch to other arm, etc.) as long as they are all things in sight. The first group then turns around, and must identify the 10 changes within one minute. After they identify the changes, or time is up, they swap so the other team gets to make changes while they guess.
- Ask delegates to choose a particular spot in the room. They start the game by standing in their 'spot'. Instruct delegates to walk around the room and carry out a particular action, e.g., hopping, saying hello only to people wearing a particular colour, walking backwards, etc. When you say 'Stop', delegates must run to their original spots. The delegate who reached their spot first is the next leader and can instruct the group to do what they wish.

## Providing Feedback

Feedback is critical to skills building. Feedback is the process through which facilitators and delegates provide each other with comments and observations. Providing positive feedback is very important in building confidence. Negative feedback is also important, and should be constructive.

When providing feedback, mention positive aspects first and then gently ease into any negative aspects. Statements like 'I would have liked to see you....' can be helpful for providing feedback on areas for improvement. You can preface negative feedback with an acknowledgement of how difficult the situation can be, especially if someone is new or is dealing with a challenging patient or population.

During the course, there will be opportunities for both you and the participants to provide feedback to one another.



## 7. Evaluation

Course evaluation is the assessment of a training programme based on:

- Delegates' written and verbal comments and ratings
- Delegates' improvement in skills and knowledge both in the short- and long-term

Evaluation should measure whether the course objectives have been accomplished. There are several methods for completion of the course evaluation process for both immediate and long-term feedback. The performance of objectives is one measure for course evaluation (outcome evaluation); another is to determine how the course progressed (process evaluation). This will assist in planning future training.

### Immediate Evaluation

The best way to assess the course structure and participant satisfaction is through immediate evaluation. This can be done through a simple written form that participants should be required to complete at the end of the course.

The purpose of the immediate written feedback is to determine:

- The strengths and weaknesses of the course
- The delegates' self-reported satisfaction with their increase in learning and the skills built
- How the course's format helped or deterred from learning
- Other types of training that may be required
- The effectiveness of teaching style of the facilitators and trainers.

A sample evaluation tool for the course is shown in Figure 2. The written course evaluation form should be given to the delegates at the end of the course, during the designated evaluation completion time.

**Figure 2: Post-Course Self-Skills Evaluation Form**

### Ethics of TB Prevention, Care and Control Course Evaluation Form

Please respond to the following statements by circling the appropriate number for your response (from the rating scale below).

1 - Strongly Disagree    2 - Disagree    3 - Agree    4 - Strongly Agree

The objectives were clearly stated at the beginning of the course	1	2	3	4
The course objectives were satisfactorily met	1	2	3	4
The trainer(s) was (were) knowledgeable about the subject matter	1	2	3	4
[LIST TRAINERS NAMES INDIVIDUALLY]	1	2	3	4
The trainer(s) exhibited effective training skills during the course	1	2	3	4
[LIST TRAINERS NAMES INDIVIDUALLY]	1	2	3	4
The trainer(s) presentation was interactive	1	2	3	4
[LIST TRAINERS NAMES INDIVIDUALLY]	1	2	3	4
I was given enough opportunities to ask questions and express concerns	1	2	3	4
This course was long enough for me to understand the ethical concepts and how they can be applied in the TB programme	1	2	3	4
The course activities promoted finding ways to apply the ethical guidance into my day-today work in the TB programme	1	2	3	4
This training course met my expectations	1	2	3	4
I would recommend this course to others	1	2	3	4
My ability to provide improved TB prevention, care, support and control to patients at risk of or who have TB were enhanced by taking this course	1	2	3	4
The learning environment was comfortable	1	2	3	4
If any of the above ratings are 3 or 4, list which activities could have been improved and how				
What did you find most beneficial about this course?				
Suggest ways that we can check in with you at 1 month and 6 months respectively, to assess how far you are in implementing your plan				
What do you believe should be changed about this course?				
Do you have any other comments or suggestions on this course?				

### Change in Performance and Impact Evaluation

The more important, yet more challenging, type of evaluation is impact evaluation. This is a specific long-term evaluation of changes in interviewing performance over time. Impact evaluation measures the way in which the delegates' utilise content from the training to improve the level of care provided to patients at risk of or those with TB. This is challenging because you will have to analyse whether any changes were due to the course itself or to other external factors. Therefore, the best way to measure change is by conducting an evaluation process prior to the course and then again after the course. In this instance, the pre-evaluation process will be conducted in the form of delegates completing the *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes* document.

Figure 3 shows a sample post-evaluation form that can be utilised at 1 month and 6 months respectively to assess long-term impact of the training.

**Figure 3: Sample post-evaluation form**

<Name>

<Role>

<Facility/Clinic>

<District/Region>

<Province/State>

Area: <write in>				
Component: <write in>				
Actions taken	Challenges or Barriers	Successes or Helpful Factors	Progress made	Next steps

## Facilitator Evaluation

Finally, you and any co-facilitators should evaluate the training programme's effectiveness. This can be done not only from formal written and external observation, but also from your own reactions. Here are questions you may ask yourself about the quality of your training. Responses to these questions can be used to improve the next Ethics of tuberculosis prevention, care and control training course offering:

### **How did participants react to the course? (Process evaluation)**

Watch the delegates during the training. If they are uncomfortable or tense, try to determine the source of the problem and how to make people more comfortable. It helps to identify those who were uncomfortable in terms of experience levels and the format of the activity.

### **What did the participants learn from the workshop? (Outcome evaluation)**

Review the course learning objectives and assess whether you think these have been met.

#### **Ask yourself before each activity:**

- What makes this activity appropriate now and what will participants learn?
- What changes may be necessary to make certain activities appropriate at the time they are conducted?

#### **Ask yourself after each activity:**

- What have I learned from these activities?
- What have the participants learned from these activities?

Short-term and long-term evaluations can assist in improving future courses and can suggest refresher or additional training that can be done on a periodic basis.

## 8. Course Activities

### Course Contents

This section provides an overview of all the interactive activities for the *Ethics of Tuberculosis Prevention, Care and Control* training course. The agenda gives you an overview of the activities and approximately how long each activity takes. You may revise the agenda, taking note that all the modules will need to be completed by the end of the two-day training course.

### Format

Each activity is listed separately in the form of Facilitator Instructions. You will find the Facilitator Instructions for each activity in the relevant module in the next section, which is titled 'Facilitating Each Module'. These provide step-by-step instructions on how to conduct the activity. They are contained within a solid dark blue border to easily identify them. The activity descriptions in the Facilitator Instructions for each of the course modules comprise the following sections:

- Objectives
- Question
- Time allotted
- Procedure for running activity
- Materials needed – All of the activities have accompanying hand-outs, which require duplicating. For some, you may need additional items. The hand-outs are included immediately after each activity section.
- Tips

Review all the activities before deciding how to deliver the training. This will also assist you in preparing items you may need and in anticipating any questions that may arise.

All hand-outs may be duplicated and modified, as needed, for distribution.

### Activity Overview

Figure 4 shows an overview of the course activities associated with the course. This is not the formal agenda. Figure 5 provides an example of a formal agenda, which delegates should receive at the beginning of the course. It includes a list of the course modules along with allotted timings and additional items, including:

- **Check –In/Registration** – This is the period of time prior to the course in which delegates arrive, sign preprinted the attendance register, and receive course materials and name tags.
- **Breaks** – You should allow at least one 15-minute break in the agenda for every 2 hours of course time. This permits participants to relax for a few minutes, network with others, and also respond to any work-related tasks. Breaks may be negotiated if you wish. For example, if a course is moving along smoothly and in a timely fashion, delegates may choose to forego a break in order to leave the course early. Breaks can also be shortened if a course is behind schedule and time needs to be made up.

- **Meals** – Generally, 45-60 minutes should be allotted for a lunch break. If lunch is being provided as part of the course, the break can be shorter. However, if delegates need to go off-site to purchase their meal, this break time should allow for additional time.
- **Evaluation** – About 15 minutes at the end of the course should be allotted for participants to complete the written course evaluation form.

**Figure 4: Overview of course activities**

Module	Activity	Activity Format	Estimated Time
<b>1</b>	Activity 1a: Introduction – Icebreaker	Plenary discussion	30 minutes
	Activity 1b: Introduction - Setting Ground Rules	Plenary discussion	10 minutes
	Activity 2: Introduction - Ethics Assessment Tool	Individual activity Plenary discussion	60 minutes
<b>3</b>	Ethical dilemmas or questions related to autonomy	Plenary discussion	10 minutes
	Impact of ethical values on TB programme goals	Plenary discussion	10 – 15 minutes
<b>4</b>	Benefits to universal access to TB Care	Plenary discussion	10 minutes
	Practices around HIV Testing	Plenary discussion	5 – 10 minutes
	Do patients carry costs for TB Services?	Plenary discussion	5 – 10 minutes
	Activity 3: Obligation to Provide Access to TB Services	Small group discussion Plenary discussion	40 minutes
<b>5</b>	How do you provide relevant, appropriate and accurate information to patients?	Plenary discussion	5 minutes
	Refusal to participate in contact tracing	Plenary discussion	5 minutes
	Management of treatment refusal	Plenary discussion	10 minutes
<b>6</b>	Use of incentives and enablers to encourage adherence	Plenary discussion	10 - 15 minutes
<b>7</b>	Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment in different settings	Plenary discussion	15 minutes
	Managing the gap between availability of drug susceptibility Testing and access to treatment for drug resistant TB	Case Study: Plenary discussion	15 minutes
<b>8</b>	Activity 4: Health Care Workers' Rights and Obligations	Small group discussion Plenary discussion	25 minutes
<b>9</b>	Activity 5: Involuntary Isolation and Detention as Last-Resort Measures	Individual activity Plenary discussion	20 minutes
<b>11</b>	Activity 6: Conclusion – Ethics of TB Prevention, Care and Control Planning Tool	Individual activity Small group discussion Plenary discussion	75 minutes

DAY ONE		
Time	Topic	Faculty
08:30-09:00	Check-In/Registration	
09:00-11:00	Module 1: Introduction Completion of Ethics Assessment Tool	
11:00-11:15	BREAK	
11:15-12:15	Module 2: Background on TB Module 3: Overarching Goals and Ethical Values	
12:15-13:15	LUNCH	
13:15-15:15	Module 4: Obligation to Provide Access to TB Services	
15:15-15:30	BREAK	
15:30-16:30	Module 5: Information, Counselling and the Role of Consent	
16:30-16:45	Wrap-up and Review of Day One	
DAY TWO		
8:30-0900	Check-In/Registration	
09:00-09:15	Review of Day 2 Agenda and Questions from Day 1	
09:15-10:15	Module 6: Supporting Adherence to TB Treatment	
	BREAK	
10:30-11:15	Module 7: Gaps Between Availability of Drug-Susceptibility Testing and Access to MDR-and XDR-TB Treatment	
11:15-12:00	Module 8: Health Care Worker Rights and Obligations	
	LUNCH	
13:00-13:45	Module 9: Involuntary Isolation and Detention as Last-Resort Measures	
13:45-14:15	Module 10: Research on TB Care and Control	
	BREAK	
14:30-16:15	Module 11: Conclusion	
16:15-16:30	Feedback on Course and Completion of Evaluation Forms	

**Figure 5: Formal agenda**

## Activity Types

There are many approaches and activities to participatory learning. Table 2 provides summary for each of the different types of activities utilised in the *Ethics of Tuberculosis Prevention, Care and Control* training course.

**Table 2: Types of activities and their purpose**

Technique	Description	Purpose
Small group discussion	Dialogue between delegates in small groups of three to five people. Facilitator should remind delegates to keep the discussion relevant	Facilitates learning through discussion, active participation, feedback and reflection. Useful for deepening understanding and identifying differences and alternative options
Plenary discussion	Dialogue between all delegates, with facilitator posing questions to prompt discussion. Potential responses can be prepared in advance to guide delegates and link to learning objectives	Facilitates learning through discussion, active participation and sharing experiences from entire group. Useful for deepening understanding and identifying different options
Individual activity	Delegate works through a problem, issue or question on their own	Facilitates reflection. Useful for planning or evaluating performance
Case study	Delegate is presented with a problem, often based on a real-life situation, to work through. Designed to incorporate problems and issues associated with the relevant subject matter	Identifying differences and alternative options, practise and application of learning, problem-solving, decision-making, developing analytical skills, team work, process review, self-discovery

As facilitator, you play a key role in concluding all activities, irrespective of the format that the activity takes. As a result, it is important that you leave sufficient time to wrap up activities, summarise key points, and review and link the activity to the learning objectives. Finally, you need to make use of the opportunity to respond to questions and clarify misunderstandings.

For those modules where activities are assigned numbers, Facilitator Instructions and Delegate Hand-outs are available in the sections that follow in this Facilitator's Guide.



## 9. Facilitating Each Module

This section provides you with detailed instructions for facilitating each of the 11 modules in the training course. For each module, you are provided with the following resources:

- Facilitation Guide which comprises the following information:
  - Expected timing for the module
  - Overview of the module objectives
  - Techniques to be used for facilitating the module
  - Materials required
  - Key messages to be communicated during the module
  - Synopsis of the module content
  - Procedure for facilitating the module
- Slide kit which comprises:
  - PowerPoint slides
  - Speaker notes for each slide
- Where appropriate, Facilitator Instructions as described in the 'Course Activities' section above

In addition, Delegate hand-outs have been prepared for all activities, except Activity 1a and 1b. These are contained in the following section, titled 'Delegate Hand-Outs' in this Facilitator Guide. You should ensure that each delegate receives a Delegate Hand-out for each activity where one is required.

## 10. Module 1: Introduction

### Facilitation Guide for Module 1: Introduction

#### Time

- 2 hours

#### Objectives

- To set out the overall course goal which is to sensitise and educate delegates on the application of ethical values in all aspect of tuberculosis prevention, care and control
- To provide an opportunity for delegates to introduce themselves and to consider the role of ethics in their own environments
- To reach consensus from the group on ground rules for achieving optimal learning outcomes

#### Techniques

- Plenary discussion
- Individual activity

#### Materials

- PowerPoint slides
- *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes*
- Activity 2: Ethics Assessment Tool Delegate Hand-out
- Flip chart and pens

#### Key Messages

- Management of TB can raise complex issues around medical and public health ethics
- Active participation from all delegates will enhance the discussion and exploration around different aspects of ethics and TB prevention care and control




#### Synopsis of module

Global efforts to combat TB have raised questions about the need for a human rights approach and the ethical management of treating people with TB, as well as those at risk of contracting TB. A central ethical issue is balancing patients' rights and autonomy with the protection of the public's health. This course aims to sensitize and educate delegates on the application of ethical values in all aspects of TB, prevention, care and control. It will do this by providing an opportunity for delegates to interact with one another as they consider the role of ethics in their environments. The foundation material for the course will be drawn from recent work by the World Health Organization titled *Guidance on ethics of tuberculosis, prevention control and treatment*. Delegates will also complete *the Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes*. This tool will help identify ethical issues and challenges in their TB control programmes which will be explored in more detail during the course.

### Procedure for running Module 1


1. Ensure that you have printed a copy the *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes* and Activity 2: Ethics Assessment Tool Delegate Hand-out for each delegate which can be found in the Delegate Hand-out section
2. Present slides for the module, and follow the instructions and speaker notes in each slide
3. Use the Facilitator's Instructions below to run Activities 1a, 1b and 2

## Slide Kit for Module 1: Introduction

Slide 1	<div data-bbox="375 310 857 562"> <h1>Ethics of Tuberculosis Prevention, Care and Control</h1> <h2>MODULE 1: INTRODUCTION</h2> </div> <div data-bbox="321 573 906 646"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 657 906 720"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<h3>Background and rationale for the course</h3> <ul style="list-style-type: none"> <li>• The renewal of global efforts to combat TB raises issues about the just and humane treatment of people with TB</li> <li>• Tuberculosis (TB) control raises social and cultural concerns as well as ethical considerations about public health and medical ethics</li> <li>• Recognising the complexity of some of these issues, WHO released guidance on ethics in 2010</li> </ul>  <p>USAID TB CARE II PROJECT</p> <p>2</p>	<ul style="list-style-type: none"> <li>• Explain that since TB regained its alarming profile as the world's leading infectious killer, and was declared a global emergency by the World Health Organization, there have been renewed and concentrated efforts for its control</li> <li>• Key vulnerable groups most affected by TB include people living in poverty, ethnic minorities, women, children, people living with HIV, prisoners, homeless persons, migrants, refugees and internally displaced persons. Members of these groups are more likely to be exposed to conditions that are conducive to TB development and less likely to have the information, power and resources necessary to ensure their health</li> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<h3>Background and rationale for the course - 2</h3> <ul style="list-style-type: none"> <li>• Tuberculosis control raises several issues including stigmatisation of infected individuals, and the cultural and economic consequences of acquiring TB</li> <li>• One central ethical issue is balancing patients rights and autonomy with the protection of the public's health</li> <li>• What are the ethical implications of imposing a TB management strategy on a vulnerable population that may not be able to implement the strategy?</li> </ul> <p>USAID TB CARE II PROJECT</p> <p>3</p>	<ul style="list-style-type: none"> <li>• Explain that traditional medical ethics focuses on the physician-patient relationship, and the preservation of autonomy and human dignity, and is very strongly individualistic in perspective</li> <li>• Public health ethics, on the other hand, focuses on populations and the protection and promotion of health in communities</li> <li>• Given its nature and impact, TB is indeed a serious threat to communities, which deserve protection from exposure to TB and attention to the means to curtail its spread. Simultaneously, individuals within communities, particularly those in liberal democracies, have the right to personal autonomy and privacy</li> <li>• Achieving a balance between these seemingly conflicting goals can only result from an understanding of the underlying ethical</li> </ul>

		<p>principles</p> <ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Interventions such as directly observed therapy, detention and mandatory treatment entail a substantial reduction of autonomy not customarily found in clinical medicine.</li> <li>• On a larger scale, TB is also a human rights issue, raising important questions about equity regarding who suffers the most from disease, and the global imbalance with regard to disease burden as well as reciprocal social obligation to alleviate suffering</li> </ul>
Slide 4	<p>Some potential impacts of ethics on the management of TB</p> <ul style="list-style-type: none"> <li>• All patients have free universal access to TB testing, prevention and treatment</li> <li>• All patients are fully informed and consent to TB testing and treatment</li> <li>• Patients with TB are not detained or isolated, but are provided with treatment, care and support in and by the community</li> <li>• Needs of all patients, including those of socially vulnerable groups, are taken into consideration</li> </ul> <p>USAID TB CARE II PROJECT 4</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 5	<p>Course goal</p> <p>To sensitise and educate delegates on the application of ethical values in all aspects of TB prevention, care and control</p> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>• Review course goal</li> <li>• State that the ethics guidance published by World Health Organization in 2010 to assist programmes with the application of ethics on the management of TB forms the basis of this training; some of the nuanced issues described in the previous slide will be discussed</li> <li>• It is important to note that all of the elements and guidance provided during the training course may not be present in the TB programmes that delegates support</li> <li>• In addition, changing these elements may not be within their direct control</li> <li>• What is of importance, however, is that delegates gain a better understanding of the ethical guidance and its application with regard to the management of TB</li> <li>• Delegates should, consequently, try to bear in mind the prescripts within the guidance and apply what is possible within their roles and responsibilities</li> </ul>

Slide 6	<p><b>Learning objectives</b></p> <ul style="list-style-type: none"> <li>• Discuss the relationship between ethical values and tuberculosis (TB) care</li> <li>• Describe one main area of emphasis from the World Health Organization (WHO) Guidance on ethics of tuberculosis, prevention control and treatment</li> <li>• Demonstrate an understanding of context-specific challenges in ethical management of TB</li> <li>• Identify potential approaches for addressing challenges to ethical management of patients with TB</li> </ul> <p>USAID TB CARE II PROJECT 6</p>	<ul style="list-style-type: none"> <li>• State that learning objectives have been set so as to ensure that the course goal is achieved.</li> <li>• <i>Review slide content</i></li> </ul>
Slide 7	<p><b>Introduce yourself....</b></p> <p><b>PLENARY</b></p> <ul style="list-style-type: none"> <li>• Introduce yourself by providing the following information <ul style="list-style-type: none"> <li>• Your first and last name</li> <li>• The District, sub-District or Facility where you work</li> <li>• Your role in supporting the TB programme</li> <li>• How you understand ethics as a professional working in the health care sector</li> <li>• What you would like to learn from this training course</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>• See Activity 1 in the Facilitator Guide for guidance on how to run this activity</li> <li>• This is a plenary discussion, which should take approximately 30 minutes total</li> <li>• Introduce yourself and other faculty members</li> <li>• Spend the time getting each delegate to introduce themselves focusing on the points on the slide; allow yourself a few minutes to summarise</li> </ul>
Slide 8	<p><b>Group agreements</b></p> <p><b>PLENARY</b></p> <ul style="list-style-type: none"> <li>• Make a commitment to the course, including participating fully in activities</li> <li>• Respect different experience and skill levels in each other</li> <li>• Encourage fellow delegates who are less experienced</li> <li>• Keep information confidential</li> <li>• Do not be judgemental</li> <li>• Support delegates to share opinions in an open manner</li> <li>• Be back on time after breaks and lunch</li> <li>• Do not interrupt others while they are speaking</li> <li>• Turn off or place cell phones on silent mode during the sessions</li> <li>• Do not turn your computer on during the sessions</li> <li>• Others?</li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>• See Activity 1b in the Facilitator Guide for guidance on how to run this activity.</li> <li>• This is a plenary discussion, in which all delegates participate</li> <li>• Allocate 10 minutes for this activity</li> <li>• Explain that the training course is largely activity-based; as such, it is important, before the course commences, that delegates understand and adhere to the ground rules for participating in activities, thereby contributing to the learning process for all delegates</li> </ul>

<p>Slide 9</p>	<p><b>Ethics assessment tool</b></p> <p><b>INDIVIDUAL</b></p> <ul style="list-style-type: none"> <li>Complete <i>Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes</i> (40 minutes)</li> <li>The tool will help better understand the specific areas within your TB programme that may be strengthened by the application of the ethical guidance</li> <li>You may not be able to answer all the questions; complete the tool to the best of your ability, for the purposes of this course</li> <li>Participate in 15 minute group discussion after completion of the tool</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>See Activity 2 in Facilitator's Guide on how to run this activity</li> <li>The entire activity should take an hour, with 5 minutes for instructions, 40 for delegates to complete the tool, and 15 for summary group discussion</li> <li>Emphasise that delegates may not know the answer to all the questions on the tool, and that this is fine. They should complete the tool to the best of their ability, and skip questions they cannot answer</li> <li>The tool will not be handed in to their supervisors or the TB Programme. The purpose of completing the tool here is to allow delegates better understand the specific areas within their TB programme that may be strengthened by the application of the ethical guidance that will be discussed during the training</li> <li>However, delegates may choose to share the tool when they return to their work setting, or may choose to complete the tool more fully (possibly with other members of the TB programme) as described in the introduction to the tool itself</li> </ul>
<p>Slide 10</p>	 <p>USAID TB CARE II PROJECT</p> <p>10</p>	<ul style="list-style-type: none"> <li>Check if delegates have any questions and address these</li> <li>That ends our introduction to this course. Welcome again and let's move on to our first module: 'Background on TB'</li> </ul>

## Facilitator Instructions for Module 1

### Facilitator Instructions for Activity 1a: Icebreaker

#### Objectives

- Set a comfortable atmosphere
- Help delegates learn about each other
- Get delegates to think critically and holistically about their professional ethics and values and how these could impact on the manner in which they perform their roles within the TB programme they are part of
- Understand what key information delegates hope to learn during the training course
- Ensure that delegates learning expectation are aligned with the course objectives

#### Questions

- Introduce yourself by providing the following information to the members of your group:
  - Your first and last name
  - The District, sub-District or Facility where you work
  - Your role in supporting the TB programme
  - How you understand ethics as a professional working in the health care sector
  - What you hope to learn during this course

#### Time Allotted

30 minutes

- 5 minutes for instructions
- 25 minutes for plenary discussion

#### Materials Needed

Flip chart and pens to record group discussions

#### Procedure for running activity

1. Welcome the delegates to the training course
2. Introduce yourself and your co-facilitators
3. Inform delegates that the purpose of the training course is to sensitise and educate them to the application of ethics in the management of TB and that this training is based on the WHO *Guidance on ethics of tuberculosis prevention, care and control*, that was published in 2010
4. Ask each delegate, in turn, to respond to the questions:
  - a. Your first and last name
  - b. The District, sub-District or Facility where you work
  - c. Their role in supporting the TB programme
  - d. How they understand ethics as a professional working in the health care sector
  - e. What they hope to learn during the training course
5. Start on one side of the room and work your way through to the other side



6. Use a flip chart to record key information:
  - a. Job responsibility
  - b. Brief description of definition of ethics
  - c. Expectations for the course
7. Ensure that all delegates get an opportunity to state what they expect to learn
8. Use the opportunity to comment on delegate background, different perspectives on professional ethics and to clarify and reinforce the objective for the training course
9. Refer to the delegate expectations for the duration of the training course to ensure that these are being addressed

### Setting the scene

Traditional medical ethics focuses on the doctor-patient relationship, and the preservation of autonomy and human dignity, and is very strongly individualistic in perspective. Public health ethics, on the other hand, focuses on populations and the protection and promotion of health in communities.

Given its nature and impact, TB is a serious threat to communities, which deserve protection from exposure to TB and attention to the means to curtail its spread. Simultaneously, individuals within communities, particularly those in liberal democracies, have the right to personal autonomy and privacy. Achieving a balance between these seemingly conflicting goals can only result from an understanding of the underlying ethical principles.

Therefore, how do you understand ethics as a professional working within the health care sector and how do these ethics and associated values impact on how you perform your roles and responsibilities within the TB programme that you are part of?

### Tip

Reinforce that there are no right or wrong answers. In addition, remind delegates that they should consider what is in their span of control as they work through the questions.

## Facilitator Instructions for Activity 1b: Setting Ground Rules

### Objective

- Set ground rules for the training course
- Help delegates understand what is expected of them during the training course
- Create a comfortable learning atmosphere

### Question

What are the ground rules that should guide how this training course is run?

### Time Allotted

10 minutes

### Materials Needed

- Flip chart and pens to record group agreements
- Prestick or tape to display flipchart sheets

### Procedure for running activity

1. Write out a summary of the ground rules for the training course on a flip chart page prior to the course
2. Read out the ground rules, emphasising the following points:
  - a. Delegates should participate fully in all activities since they are designed to reinforce the learnings from the course material and to allow delegates to understand the ethical dimensions of what they do professionally within the TB programme.
  - b. Participants should respect different experience and skill levels in one another.
  - c. Concerns they may have about classmates should not be raised outside of the classroom.
  - d. The activities throughout this course raise and address different issues. Therefore it is important not only to participate fully in every one, but also to be present for the entire course from start to finish. Since facilitators have built this time into the course structure, there is no reason for a delegate to leave early or not be present, unless, of course, there is an emergency. If someone needs to leave early, they should speak to the facilitator privately
3. Ask delegates to add any additional rules. Write the additional rules on the flip chart page that contains the ground rules
4. Ensure that the flip chart page is visible to all delegates during the training
5. Inform delegates that these ground rules should be adhered to
6. Mention locations of certain important places, such as bathrooms, where lunch will be served, etc.

## Ground Rules

- Make a commitment to the course, including participating fully in all activities
- Respect different experience and skill levels in each other
- Encourage fellow delegates who are less experienced
- Keep information confidential. Additionally, issues and concerns raised by fellow delegates should not be discussed outside of the training
- Do not be judgmental. Do not disapprove of views and observations that may be different from your own
- Support delegates to share opinions in an open manner
- Be on time at the beginning of each day, after breaks and lunch
- Do not interrupt others while they are speaking
- Turn off or place cell phones on silent mode during the sessions. If the call cannot be ignored, answer the phone outside of the training room
- Do not turn your computer on during the sessions. Use the time provided during breaks and lunch to respond to emails

## Facilitator Instructions for Activity 2: Ethics Assessment Tool

### Objectives

- Have delegates evaluate their TB programme in the context of the ethical guidance that will be discussed during the training
- Help delegates better understand the specific areas in their programmes that may be strengthened by the application of this guidance

### Question

- What was your experience completing the tool?
- Based on the tool, what are some challenges or strengths around ethical management of TB in your programme?

### Time Allotted

60 minutes

- 5 minutes for instructions
- 40 minutes for completion of the tool
- 15 minutes for plenary discussion

### Materials Needed

- Ethics Assessment Tool
- Activity 2: Ethics Assessment Tool Delegate Hand-out

### Procedure for running activity

1. Explain that the *Ethics of Tuberculosis Prevention, Care and Control: An Assessment Tool for National TB Programmes* was developed based on the previously mentioned WHO ethics guidance
2. Explain that the purpose of the ethics assessment tool is to help TB programmes assess themselves on topics covered in the WHO guidelines. The tool can assist programmes in identifying potential strengths and gaps in the ethical treatment of TB patients
3. Ask delegates to complete the assessment tool based on their knowledge of the TB control programme they support
4. Explain that the purpose of completing the tool at the beginning of this course is to allow delegates to better understand the specific areas within their TB programme that may be strengthened by the application of the ethical guidance that will be discussed during the training
5. Emphasise that delegates may not know the answer to all the questions on the tool, and that this is fine. Delegates should complete the tool to the best of their ability, and leave out the questions they cannot answer
6. Inform delegates that their completed tool will not be collected or provided to their supervisors. However, delegates may choose to share the tool when they return to their work setting, or may choose to complete the tool more fully (possibly with other members of the TB programme) as described in the introduction to the tool itself
7. Distribute ethics assessment tool and the hand-out called Activity 2: Ethics Assessment Tool Delegate Hand-out

8. Inform delegates that they have 40 minutes to complete the tool and that they will be asked to provide feedback in a plenary discussion
9. Provide a time check after 30 minutes, when they have 10 minutes remaining, and again when there are 5 minutes remaining. If delegates finish completing the tool early, you may choose to move on to the plenary discussion. If delegates are still working on the tool after 40 minutes, ask them to stop and indicate that they can complete the tool, during the break or over lunch
10. Facilitate a plenary discussion by asking delegates to share their experience completing the tool. Prompts can include:
  - a. What did delegates think about the process of completing the tool?
  - b. Did anyone have difficulty completing the tool? If so, what were the specific areas or challenges?
  - c. Thinking about the completed tool, are there any ethical gaps or challenges that they can identify in their TB programme?
  - d. What were the strengths or accomplishments regarding ethical TB management within their programmes?
11. Close the discussion by providing summary points from the Tips section

### Setting the scene

In some ways ethics around management of TB can seem simple and even 'common sense'. For example, clearly ethical principles would indicate that effective high quality diagnosis and treatment services should be available to all at no cost. However, in resource limited settings operationalising these simple concepts can sometimes be challenging. Further, with the ongoing TB/HIV epidemic, increase in drug-resistance, new ethical questions and challenges are emerging. Finally, some of the ethical dilemmas and challenges faced by TB programmes may not have clear or simple solutions. The purpose of the WHO ethics guidance, the assessment tool, and this course is to help gain a better understanding of issues, identify, share and discuss challenges and approaches and raise awareness of these issues within TB programmes.

Currently the WHO *Guidance on ethics of tuberculosis prevention, care and control* as well as the ethics assessment tool and this training course cover the following topics:

- Access to care
- Patient-centred care
- Information, counselling and consent
- Adherence
- Drug susceptibility testing and treatment of resistant disease
- Health care workers' rights and obligations
- Isolation and legal interventions
- Research

However, in 2015 WHO convened a working group to look at other emerging ethical issues around TB, so new guidance may be released. This is a reminder that as new diagnostic tools and treatments are made available, and drug resistant TB and TB/HIV situations continue to pose challenges for patients, communities, and TB control, an evolving ethics and human-rights based perspective should be applied to TB prevention, care and control activities.

#### Tip

Reinforce that completion of the ethics tool in this course is to help delegates better understand the specific areas within their TB programme that may be strengthened by the application of the ethical guidance that will be discussed during the training. During the next two days, delegates should be thinking about challenges and gaps identified from the completion of the tool. Some of the course discussions and activities over the next two days will help delegates to develop strategies for improvement. However, clearly delegates will not be able to address all of the gaps or challenges that they identify. Remind delegates to focus on strategies, approaches and actions that fit into their roles and responsibilities.

## 11. Module 2: Background on Tuberculosis

### Facilitation Guide for Module 2: Background on Tuberculosis

#### Time

- 15 minutes

#### Objectives

- Understand the global burden of TB-related disease
- Describe why a human-rights, person-centred approach should be applied in the management of TB

#### Techniques

- Lecture

#### Materials

- PowerPoint slides

#### Key Messages

- While TB morbidity and mortality may be declining, TB remains a significant public health issue
- A multi-dimensional cross-sectional method that focuses on social determinants of health is required to control TB
- A person-centred approach is vital in the management of TB

#### Synopsis of module

This module provides an overview to the state of TB prevention, care, treatment and control. TB still remains a significant public health problem globally. According to the WHO's Global tuberculosis report, 2014, while the mortality rate from TB is decreasing and there is a year-to-year decline in number of people who are infected with TB, a large number of lives are still being lost to a curable disease. In addition, TB is second only to HIV/AIDS as the greatest killer worldwide due to a single infectious agent.



Further, the WHO estimates that the risk of developing TB is between 26 and 31 times greater in people living with HIV than among those without HIV infection. This means that in countries that have a high incidence of HIV, TB remains a major concern.

There are many complicating factors that may contribute to the transmission of TB and the morbidity and mortality associated with the disease. These include high rates of poverty and associated challenges including crowded living conditions, poor access to health care facilities and a lack of information and education related to health, including TB. Each factor causes barriers, whether monetary, environmental or knowledge-based, which inhibits an individual's, community's and country's ability to implement effective TB control. Consequently, to ensure effective TB prevention, care, support and control, these barriers need to be addressed, while maintaining the individual at the centre of decision-making.

#### Procedure for running Module 2

1. Present slides for the module and follow the instructions and speaker notes in each slide

## Slide Kit for Module 2: Background on Tuberculosis

Slide 1	<div data-bbox="371 323 842 567"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <h4>MODULE 2: BACKGROUND ON TUBERCULOSIS</h4> </div> <div data-bbox="321 583 886 653"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 663 886 722"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>• Understand the global burden of TB-related disease</li> <li>• Describe why a human-rights, person-centred approach should be applied in the management of TB</li> </ul> <p>USAID TB CARE II PROJECT <span>2</span></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<h3>Background*</h3> <ul style="list-style-type: none"> <li>• Estimated 9 million people who developed TB in 2013 <ul style="list-style-type: none"> <li>• 56% in South-East Asia and Western Pacific Regions</li> <li>• 25% in African Region</li> </ul> </li> <li>• Between 1990 and 2013: <ul style="list-style-type: none"> <li>• 45% decrease in TB mortality rate</li> <li>• 41% decrease in TB prevalence rate</li> </ul> </li> </ul> <p><i>*WHO: Global Tuberculosis Report 2014</i></p> <p>USAID TB CARE II PROJECT <span>3</span></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that TB remains a major global health problem, responsible for ill health among millions of people each year. TB ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV)</li> </ul>



Slide 4	<p><b>Post 2015 Global TB Strategy</b></p> <p><b>VISION</b>  <b>A TB-free world</b>  Zero deaths, disease and suffering due to TB</p> <p><b>GOAL</b>  End the global tuberculosis epidemic</p> <p><b>MILESTONES FOR 2025</b>  75% reduction in TB deaths (compared with 2015)  50% reduction in TB incidence rate (less than 55 TB cases per 100 000 population)  No affected families facing catastrophic costs due to TB</p> <p><b>TARGETS FOR 2035</b>  95% reduction in TB deaths (compared with 2015)  90% reduction in TB incidence rate (less than 10 TB cases per 100 000 population)  No affected families facing catastrophic costs due to TB</p> <p><i>*WHO: Global strategy and targets for tuberculosis prevention, care and control after 2015. 2015</i></p> <p>USAID TB CARE II PROJECT 4</p>	<ul style="list-style-type: none"> <li>• State that the end of 2015 is significant, representing a transition between the Millennium Development Goals (MDGs) established in 2000 and a post-2015 development framework.</li> <li>• A set of 17 Sustainable Development Goals (SDGs) with targets set for 2030 had been proposed.</li> <li>• The third of these goals, which speak to ‘Ensure healthy lives and promote well-being for all at all ages’, includes a target to end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases and combat hepatitis, water-borne diseases, and other communicable diseases.</li> <li>• Within this broader context and contributing to the development of health-related SDGs, in 2012 WHO initiated the development of a post-2015 global TB strategy; the overarching goal of which is to end the global TB epidemic by 2035</li> <li>• <i>Review slide content</i></li> </ul>
Slide 5	<p><b>Principles of post-2015 Global TB Strategy</b></p> <ul style="list-style-type: none"> <li>• Government stewardship and accountability, with monitoring and evaluation</li> <li>• Strong coalition with civil society organizations and communities</li> <li>• <b>Protection and promotion of human rights, ethics and equity</b></li> <li>• Adaptation of the strategy and targets at country level, with global collaboration</li> </ul> <p><i>*WHO: Global strategy and targets for tuberculosis prevention, care and control after 2015. 2015</i></p> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise the bullet, ‘Protection and promotion of human rights, ethics and equity’</li> </ul>

Slide 6	<p><b>WHO Guidance on Ethics of TB Prevention, Care and Control</b></p> <ul style="list-style-type: none"> <li>• Can assist National TB Programmes (NTPs), TB service providers, policy makers, civil society and other stakeholders in implementing TB prevention, care and control efforts in an ethical manner</li> <li>• Addresses a broad range of ethical issues that arise in NTPs, ranging from informed consent and isolation to health care workers' rights and obligations, and clinical and epidemiological studies</li> <li>• Raises consciousness about ethics in TB control and in practice</li> </ul> <p>USAID TB CARE II PROJECT 6</p>	<ul style="list-style-type: none"> <li>• State that the 2010 WHO guidance on the ethics of TB prevention, care and control mentioned earlier remains important in the context of the current Stop TB strategy, in addition to the post-2015 Global TB strategy</li> <li>• <i>Review slide content</i></li> </ul>
Slide 7	<p><b>Goal of TB care and control programmes</b></p> <ul style="list-style-type: none"> <li>• Achieve universal access to high-quality diagnosis and patient-centred treatment</li> <li>• Reduce the human suffering and socioeconomic burden associated with TB</li> <li>• Protect public health, including protecting poor and vulnerable populations from TB, TB/HIV, and MDR-TB</li> <li>• Support development of new tools and enable their timely and effective use</li> <li>• Protect and promote human rights in TB prevention, care and control</li> </ul> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>• State that these are the goals outlined in the WHO's Stop TB Strategy</li> <li>• <i>Review slide content</i></li> <li>• Emphasise the last bullet, 'Protect and promote human rights in TB prevention, care and control'</li> </ul>
Slide 8	<p><b>Objectives for comprehensive TB strategy</b></p> <ul style="list-style-type: none"> <li>• Provide proper treatment of infected individuals</li> <li>• Ensure prevention of new infections <ul style="list-style-type: none"> <li>• Effective care and control programme</li> <li>• Infection control</li> <li>• Vaccination</li> <li>• Appropriate population screening</li> <li>• Improvement in socio-economic factors known to increase risk of TB</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that these objectives will ensure that the goals listed on the previous slide are achieved</li> </ul>

Slide 9



USAID TB CARE II PROJECT

9

- Check if delegates have any questions and address these
- Let's move on to our second module which is 'Overarching goals and ethical values'

## 12. Module 3: Overarching Goals and Ethical Values

### Facilitation Guide for Module 3: Overarching Goals and Ethical Values

#### Time

- 45 minutes

#### Objectives

- Explain ethical values
- Describe the relationship between ethical values and TB prevention, care and control

#### Techniques

- Lecture
- Plenary discussion
- Group discussion

#### Materials

- PowerPoint slides
- Flip chart and pens

#### Key Messages

- It is important to reflect on relevant ethical considerations in the context of different obligations
- Consider the patient's own circumstances, preferences and requirements in decision-making

#### Synopsis of module

The overarching goals and ethical values in the management of TB are complex and multidimensional. Ethically relevant concerns, such as socio-economic factors affecting vulnerable communities and obligations of government, in the control of communicable diseases in general, and TB in particular, are considered.

Malnutrition, poor sanitation, crowded living conditions and lack of access to education and health care, conditions particularly prevalent in impoverished communities, increase vulnerability to infectious diseases in general, and TB specifically. This closely relates to ethical issues around social justice.



When communicable diseases are considered, the ethical issues broached are generally assumed to be external to the patient. They are evaluated in terms of the individual's circumstances and environment. Many of the aggravating issues pertaining to individual rights relate to the way in which TB is transmitted and prevented. An individual can act as a vector by simply breathing and coughing. This brings into play issues around common good and the individual's right to autonomy.

These are just a few of the ethical issues that should be considered in the management of TB. This module further makes the point that this is a nuanced issue and a complete analysis of the ethical goals and values and the complex social, political, historic, and economic dynamics surrounding TB prevention, treatment, care and support is required.

#### Procedure for running Module 3

1. Present slides for the module and follow the instructions and speaker notes in each slide

## Slide Kit for Module 3: Overarching Goals and Ethical Values

Slide 1	<div data-bbox="378 325 860 577"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <h4>MODULE 3: OVERARCHING GOALS AND ETHICAL VALUES</h4> </div> <div data-bbox="321 592 906 661"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 661 906 730"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>• Explain what ethical values are</li> <li>• Describe the relationship between ethical goals and TB prevention, care and control</li> </ul> <p>USAID TB CARE II PROJECT 2</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<h3>Ethics and ethical values</h3> <ul style="list-style-type: none"> <li>• <b>Ethics</b> Deals with right and wrong conduct, with what we ought to do and what we should refrain from doing</li> <li>• <b>Medical ethics</b> How to handle moral problems arising out of the care of patients; often clinical decisions must consider more than just the patient's medical condition</li> <li>• <b>Ethical Values</b> Way we ought to live our lives, including: <ul style="list-style-type: none"> <li>• Actions, intentions, behaviour</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 3</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that ethical values refer to the way we ought to live our lives, including our actions, intentions, and our habitual behaviour</li> <li>• They can sometimes be the source of disagreement and conflict</li> <li>• However, through analysis and discussion, it is possible to arrive at a rough consensus as to which values ought to be seen as central</li> <li>• The approach taken here is to articulate the relevant ethical considerations as a complex web or network of different obligations</li> <li>• Such an approach allows us to accept the possibility of conflict between different values and interests both for individuals and between</li> </ul>

		<p>individuals and/or groups</p> <ul style="list-style-type: none"> <li>• This requires that situations will occur when some rights and obligations are held to be more important than others</li> <li>• It is therefore clear that concepts involving ethics, ethical values and their interpretation, may be subjective in nature</li> <li>• As such, the important consideration is that consensus is reached regarding which rights and obligations are held to be more important than others in the given situation</li> </ul>
Slide 4	<p>Ethics in public health</p> <ul style="list-style-type: none"> <li>• Focuses on design and implementation of measures to monitor and improve the health of populations</li> <li>• Considers structural conditions that promote or inhibit development of healthy societies</li> <li>• The protection and promotion of health in communities</li> </ul> <p>USAID TB CARE II PROJECT 4</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Mention that one of the ethical challenges is, for example, balancing individual patient rights with what is deemed to be common good. Cite the example of doctor-patient confidentiality</li> </ul>
Slide 5	<p>Human rights</p> <ul style="list-style-type: none"> <li>• Legal guarantees that protect individuals and groups against actions that interfere with fundamental freedoms and human dignity</li> <li>• Encompass the following: <ul style="list-style-type: none"> <li>• Civil</li> <li>• Cultural</li> <li>• Economic</li> <li>• Political</li> <li>• Social</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>• State that the history of the concept that human beings have rights is a long one and there have been many different approaches to and theories about human rights</li> <li>• <i>Review slide content</i></li> </ul>

Slide 6	<p><b>United Nations Universal Declaration on Human Rights</b></p> <hr/> <p>'Has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and <b>medical care</b> and necessary social services.'</p> <p><small>United Nations Human Rights. General Assembly Resolution 217 A (III). Universal Declaration on Human Rights. 1948</small></p> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>6</small></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that in 1948, the recognition of health as a human right took a great step forward when the UN adopted the Universal Declaration of Human Rights</li> <li>• Emphasise that TB, and the way in which TB care are provided impact multiple basic human rights, including health, housing, education etc</li> <li>• Explain that more specific information on human rights and health, in context of TB, will be provided during the course, especially in the next module, which addresses access to TB care</li> </ul>
Slide 7	<p><b>Link between ethical values and human rights principles</b></p> <hr/> <ul style="list-style-type: none"> <li>• Intimately interlinked in a dynamic way</li> <li>• Human rights form the concrete legal expression of ethical values</li> <li>• Human rights provide overarching ethical framework that should be respected</li> </ul> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>7</small></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Explain that health rights are integral component of human rights, and as such health rights are encompassed by the overarching ethical framework</li> </ul>
Slide 8	<p><b>Important ethical values in TB care and control</b></p> <hr/> <ul style="list-style-type: none"> <li>• Social justice/equity</li> <li>• Solidarity</li> <li>• Common good</li> <li>• Autonomy</li> <li>• Reciprocity</li> <li>• Effectiveness</li> <li>• Subsidiarity</li> <li>• Participation</li> <li>• Transparency and accountability</li> </ul> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>8</small></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that each of these will be discussed in more detail now and ask participants to keep these in mind over the next two days</li> </ul>


Slide 9	<p><b>Social justice/equity</b></p> <ul style="list-style-type: none"> <li>• Highlights: <ul style="list-style-type: none"> <li>• Underlying root causes</li> <li>• Societal inequalities</li> </ul> </li> <li>• May include redistribution of resources to compensate for existing inequalities</li> <li>• Address socio-economic factors that increase risk of TB</li> </ul> <p>Health equity is achieved when every person has the opportunity to 'attain his or her full health potential' and no one is 'disadvantaged from achieving this potential because of social position or other socially determined circumstances.'</p> <p>Health inequities are reflected in differences in life expectancy; quality of life; rates of disease, disability, and death; severity of disease; and access to treatment.</p> <p><small>Centers for Disease Control and Prevention</small></p> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Explain that given the role of socio-economic factors in increasing the risk of TB infection and progression of TB disease, social justice is a key component in TB control</li> </ul>
Slide 10	<p><b>Solidarity</b></p> <ul style="list-style-type: none"> <li>• Standing together (group, community, nation)</li> <li>• Strong community ties, resulting in cooperative action</li> </ul> <p>USAID TB CARE II PROJECT</p> <p>10</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that infectious diseases increase risk of harm for entire community and that such risks can be reduced through collective community action</li> </ul>
Slide 11	<p><b>Common good</b></p> <ul style="list-style-type: none"> <li>• Infectious diseases threaten health of individuals and whole populations</li> <li>• Removal or reduction of threat of infection benefits society</li> <li>• Important to consider: <ul style="list-style-type: none"> <li>• Mechanisms for transmission of TB</li> <li>• Prevention of TB</li> <li>• Community empowerment in the prevention, care and control of TB</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT</p> <p>11</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Mention that evidence shows individual health is shaped by the social environment, and as a result, everyone gains from a society with strong public health facilities to address TB control and treatment</li> </ul>




Slide 12	<p><b>Autonomy</b></p> <ul style="list-style-type: none"> <li>• Individuals guaranteed right to make decisions about their own lives, including health care <ul style="list-style-type: none"> <li>• Informed consent</li> </ul> </li> <li>• Patients generally should have right to choose among treatment options</li> </ul> <p>USAID TB CARE II PROJECT 12</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that autonomy should be considered in debates about ethical TB policy</li> <li>• Indicate that informed consent around treatment is an essential component of autonomy and will be discussed in more detail in the module focusing on Information, Counselling and the Role of Consent</li> <li>• Note that as discussed earlier, at times, an individual's right to autonomy may be in conflict with the need to protect the public's health</li> </ul>
Slide 13	<p><b>PLENARY</b> Share your experience.....</p> <ul style="list-style-type: none"> <li>• What ethical dilemmas or questions have you faced related to autonomy?</li> <li>• How have you addressed them: <ul style="list-style-type: none"> <li>• At District level</li> <li>• At Facility level</li> </ul> </li> </ul> <p><b>For example</b> What do you do when a patient tells you that the traditional health practitioner has recommended that the patient stop treatment?</p> <p>USAID TB CARE II PROJECT 13</p>	<ul style="list-style-type: none"> <li>• This is a plenary discussion, which should take no longer than 10 minutes</li> <li>• Ask group to share what type of ethical dilemmas or questions they have faced that relate to autonomy and how these were addressed. The example on the slide can be used to generate additional discussion or if delegates do not share dilemmas or questions</li> <li>• In the example provided, some mechanisms that could be employed include:</li> <li>• At District level <ul style="list-style-type: none"> <li>• Review policies regarding collaboration between facility staff and traditional health practitioners</li> <li>• If necessary, raise the issue of the need for collaboration with the District Management Team</li> <li>• Ensure that facility level staff are appropriately trained, including on Patient Rights</li> <li>• Utilise existing structures to meet and set up frameworks for collaboration with key individual and/or associations representing traditional health practitioners working in the District</li> </ul> </li> <li>• At Facility level <ul style="list-style-type: none"> <li>• Acknowledge the patient's right to seek medical care from a traditional health practitioner</li> <li>• Counsel the patient on the need to continue therapy</li> <li>• Ask the patient for permission to discuss the situation with the traditional health practitioner</li> </ul> </li> </ul>

Slide 14	<p><b>Reciprocity</b></p> <ul style="list-style-type: none"> <li>• Individuals who put themselves at greater risk of harm for the sake of others deserve benefits in exchange for running such risks</li> <li>• Obligation exists to: <ul style="list-style-type: none"> <li>• Minimise risks through appropriate infection control measures:</li> <li>• Provide appropriate treatment</li> <li>• Compensate when harm occurs</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 14</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that this principle applies equally to health care workers who provide care and support for patients at risk of or being treated for TB</li> <li>• Mention that minimising risks may be through appropriate infection control measures, including administrative, environmental and personal respiratory protection</li> <li>• Having appropriate policies is also very important</li> </ul>
Slide 15	<p><b>Effectiveness</b></p> <ul style="list-style-type: none"> <li>• Duty to avoid actions that are not working</li> <li>• Obligation to implement proven measures that are likely to succeed</li> <li>• Linked to efficiency (use of limited resources for maximum benefit)</li> </ul> <p>USAID TB CARE II PROJECT 15</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that evidence of effectiveness in TB programmes requires ongoing monitoring, surveillance and research</li> </ul>
Slide 16	<p><b>Subsidiarity</b></p> <ul style="list-style-type: none"> <li>• Decisions to be made as close to individuals and communities as possible</li> <li>• Community participation paramount to ensuring local interests, concerns, beliefs reflected</li> </ul> <p>USAID TB CARE II PROJECT 16</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• The principle of subsidiarity aims to bring people closer by guaranteeing that decisions are made with involvement from individuals and communities at the local level</li> <li>• It ensures that constant checks are made to verify that decisions are justified and in the interests of the community</li> <li>• However, the principle of subsidiarity does not however mean that decisions must always be taken at the local level</li> <li>• In some instances, decision-making at a district, provincial or national level may have greater impact, contingent on these decisions reflecting the local needs</li> <li>• As a result, community participation is key to ensure these perspectives are incorporated into the decision making process</li> </ul>

Slide 17	<p>Participation</p> <ul style="list-style-type: none"> <li>Community should have meaningful involvement in all steps of the decision-making process</li> <li>Community should be invited and encouraged to work with policy makers to help drive the decision-making</li> </ul> <p>USAID TB CARE II PROJECT 17</p>	<ul style="list-style-type: none"> <li>Review slide content</li> </ul>
Slide 18	<p>Transparency and accountability</p> <ul style="list-style-type: none"> <li>Decisions made in open manner</li> <li>Decision-making process is fair, responsive to community needs and evidence-based</li> </ul> <p>USAID TB CARE II PROJECT 18</p>	<ul style="list-style-type: none"> <li>Review slide content</li> </ul>
Slide 19	<p>Patient-centred care</p> <p>Involves viewing health care from the patient's perspective and then adapting care to more closely meet the needs and expectations of patients</p> <p>"Patient-centered care reflects a partnership among practitioners and patients to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care. Patient-centered approaches recognize that care is provided along a continuum of services"</p> <p><small>O'Donnell MR, Daffery AD, Frick M, Hirsch-Moverman Y, Amico KR, Serfaty M, Wolf A, Metcalfe JJ, Isaakidis P, Davis L, Bost JC, Nason N, Gurevitz M, Zahra J, Bangberg D, Padayatchi N, Freedberg G. Consensus statement on behalf of the attendees of the Re-inventing adherence: patient-centered care for drug resistant TB and HIV. March 19-20, 2015, Columbia Mailman School of Public Health, Columbia University, New York, NY, USA</small></p> <p>USAID TB CARE II PROJECT 19</p>	<ul style="list-style-type: none"> <li>Explain that the concept of patient-centred care which has long been a part of the Stop TB strategy (WHO Stop TB Partnership. Treatment of Tuberculosis; Guidelines, 4<sup>th</sup> Edition. 2010)</li> <li>Review slide content</li> </ul>

<p>Slide 20</p>	<p><b>Approach to person-centred care</b></p> <ul style="list-style-type: none"> <li>Many groups face risks from failure to diagnose and treat TB</li> <li>Person-centred approach promotes concept that it is equally important consider individuals infected with and affected by condition <ul style="list-style-type: none"> <li>Individual who is sick and receiving care</li> <li>Individual who is sick and not receiving care</li> <li>Family members and contacts</li> <li>Community at large</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 20</p>	<ul style="list-style-type: none"> <li><i>Review slide content</i></li> <li>State that the person-centred care builds on the concept of patient-centred care</li> <li>It goes on to recognise that that the direct beneficiary of TB care is the individual who is sick, and that strategies must therefore be designed with this individual's rights and welfare in mind. For example, TB patients have the right to receive advice and treatment that meets international quality standards, be free of stigmatisation and discrimination, establish and join peer support networks, and benefit from accountable representation</li> <li>Yet, person-centred care also recognises that patients are not the only individuals whose rights and interests must be protected</li> </ul>
<p>Slide 21</p>	<p><b>Shared responsibility for the care of the patient</b></p>  <p>USAID TB CARE II PROJECT 21</p>	<ul style="list-style-type: none"> <li>State that promoting these ethical values requires the active cooperation of multiple individuals and entities, who together share responsibility for caring for patients and helping to achieve the NTP goals</li> <li>Explain that:</li> <li>Initially, the responsibility for creating, sustaining, and continually improving TB care and treatment programmes rests with governments and the international community. All governments have a fundamental obligation to provide universal access to high-quality TB diagnosis and treatment, and to address the social determinants that are largely responsible for the spread of TB. The international community must provide financial and technical assistance to countries that lack the resources to satisfy this obligation on their own. TB has not yet been eradicated mostly because these responsibilities have been neglected.</li> <li>Local communities' role is also to support TB diagnosis and treatment and to monitor the equity of access to health care.</li> <li>Community organisations, families, and individual members should play a supportive part in TB prevention, identification, care and treatment, and provide a compassionate environment free of stigmatization and discrimination.</li> <li>The web of responsibilities also embraces individual patients. It is their duty to give complete and accurate personal and clinical</li> </ul>

		<p>information to providers, to alert them to any difficulties encountered in the treatment process, to follow prescribed treatment regimens, to encourage others to seek treatment, to show consideration for other TB patients and care providers, to act in ways that do not put others at risk, and, if they can do so safely, to notify their contacts of the need to seek diagnosis</p>				
Slide 22	<div><p>Let's discuss</p><p>PLENARY</p><table><thead><tr><th>Ethical Values</th><th>Consider</th></tr></thead><tbody><tr><td><ul style="list-style-type: none"><li>Social justice/equity</li><li>Solidarity</li><li>Common good</li><li>Autonomy</li><li>Reciprocity</li><li>Effectiveness</li><li>Subsidiarity</li><li>Participation</li><li>Transparency and accountability</li></ul></td><td><p>How do these ethical values impact on your ability to ensure that TB programme goals are met?</p><p>How do these ethical values make a contribution toward the effectiveness of the programme?</p></td></tr></tbody></table><p>USAID TB CARE II PROJECT 22</p></div>	Ethical Values	Consider	<ul style="list-style-type: none"><li>Social justice/equity</li><li>Solidarity</li><li>Common good</li><li>Autonomy</li><li>Reciprocity</li><li>Effectiveness</li><li>Subsidiarity</li><li>Participation</li><li>Transparency and accountability</li></ul>	<p>How do these ethical values impact on your ability to ensure that TB programme goals are met?</p> <p>How do these ethical values make a contribution toward the effectiveness of the programme?</p>	<ul style="list-style-type: none"><li>This is a plenary discussion that should take 10-15 minutes</li><li>Ask delegates to consider the questions one at a time</li><li>Write down the responses on the flipchart</li><li>In summary:</li><li>In many situations, multiple ethical considerations will be relevant and may point in different directions. An ethically acceptable decision depends on thinking about the full range of appropriate normative considerations, ensuring that multiple perspectives are taken account of and creating a decision-making process that will be considered fair and legitimate by the stakeholders involved.</li><li>Not all of the values discussed in the preceding presentation are suited to every situation, but they are all important, and ought to be protected and promoted in appropriate circumstances. Judgement must be used about which are relevant and how they can be used to articulate related obligations.</li><li>Remind delegates that there are no right or wrong answers to these questions</li></ul>
Ethical Values	Consider					
<ul style="list-style-type: none"><li>Social justice/equity</li><li>Solidarity</li><li>Common good</li><li>Autonomy</li><li>Reciprocity</li><li>Effectiveness</li><li>Subsidiarity</li><li>Participation</li><li>Transparency and accountability</li></ul>	<p>How do these ethical values impact on your ability to ensure that TB programme goals are met?</p> <p>How do these ethical values make a contribution toward the effectiveness of the programme?</p>					
Slide 23	<div><p>USAID TB CARE II PROJECT 23</p></div>	<ul style="list-style-type: none"><li>Check if delegates have any questions and address these</li><li>This is the end of the module on Overarching Goals and Ethical Values</li><li>Our next module that we'll consider is: 'The Obligation to Provide Access to TB Services'</li></ul>				

## 13. Module 4: Obligation to Provide Access to TB Services

### Facilitation Guide for Module 4: Obligation to Provide Access to TB Services

#### Time

- 2 hours

#### Objectives

- Describe a human-rights approach to TB prevention, care and control
- Discuss how a human-rights approach can be utilised for appropriate TB prevention, care and control that meets needs of patients

#### Techniques

- Lecture
- Plenary discussion
- Group discussion

#### Materials

- PowerPoint slides
- Activity 3: Obligation to Provide Access to TB Services Delegate Hand-out

#### Key Messages

- All individuals have a right to free access to effective high quality TB services and governments have an obligation to provide those services
- Person-centred approach should provide the framework for determining how TB services are provided

#### Synopsis of module



This module builds on two important principles. The first deals with obligation of governments to provide free access to effective high quality TB services to all, including members of vulnerable groups. This obligation is based on the overarching goals and ethical values discussed in Module 3, including the basic human right to health. The module lays out the services governments should provide and the ethical and practical rationale for this. As far as possible, link the specific ethical values discussed to the principle of obligation to provide access to TB services. This will help delegates frame the overarching goals of the TB control programmes they support with those advocated for in this training programme.

The second relates to what a person-centred approach entails. It focuses on the individual; promotes independence and autonomy rather than control; and encourages individuals to actively participate in decision-making. The relationship between the individual and frontline health care provider is pivotal to the experience of good quality person-centred care and support.

#### Procedure for running Module 4

1. Ensure that you have printed a copy of Activity 3: Obligation to Provide Access to TB Services Delegate Hand-out for each delegate which can be found in the Delegate Hand-out section
2. Present slides for the module, and follow the instructions and speaker notes in each slide
3. Use the Facilitator's Instructions to run Activity 3

## Slide Kit for Module 4: Obligation to Provide Access to TB Services

Slide 1	<div data-bbox="378 325 857 573"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <h4>MODULE 4: OBLIGATION TO PROVIDE ACCESS TO TB SERVICES</h4> </div> <div data-bbox="321 590 906 659"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 659 906 730"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>Describe a human-rights approach to TB prevention, care and control</li> <li>Discuss how the human-rights approach can be utilised for appropriate TB prevention, care and control that meets needs of patients</li> </ul> <p>USAID TB CARE II PROJECT</p> <p>2</p>	<ul style="list-style-type: none"> <li>Review slide content</li> </ul>
Slide 3	<h3>Human rights</h3> <ul style="list-style-type: none"> <li>Grow out of the basic equality and human dignity shared by all human beings</li> <li>Found in international human rights treaties that set out the obligations that governments have to: <ul style="list-style-type: none"> <li>Citizens</li> <li>International community</li> </ul> </li> <li>Individual citizens required to respect the rights of others</li> </ul> <p>USAID TB CARE II PROJECT</p> <p>3</p>	<ul style="list-style-type: none"> <li>Review slide content</li> <li>Explain that, as discussed in the first section on Overarching Goals and Ethical Principles, human rights are a set of legal rights that grow out of the basic equality and human dignity shared by all human beings</li> </ul>

Slide 4	<p><b>Human rights - 2</b></p> <ul style="list-style-type: none"> <li>• United Nations International Covenant on Economic Social and Cultural Rights (Adopted and opened for signature, ratification and accession by General Assembly resolution 2200A (XXI) of 16 December 1966, entry into force 3 January 1976)</li> <li>• Article 12: "Right of everyone to the enjoyment of the highest attainable standard of physical and mental health"</li> <li>• Calls on governments to take steps necessary for "the prevention, treatment and control of epidemic, endemic, occupational and other diseases"</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• Explain that since the Universal Declaration on Human Rights was ratified, additional legal documents outlining human rights, including some that specifically speak to the right to health</li> <li>• <i>Review slide content</i></li> <li>• Emphasise that the right to health as defined in Article 12 relates to TB and TB control</li> </ul>
Slide 5	<p><b>Human rights - 3</b></p> <ul style="list-style-type: none"> <li>• General Comment 14 issued by the United Nations Committee on Economic, Social and Cultural Rights in 2000</li> <li>• Legally binding interpretation of the human right to health</li> <li>• Defines and describes the minimum core obligations of the human right to health</li> <li>• Components include availability, accessibility, acceptability and quality</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• General Comment 14 is another key legal document outlining human rights, including the right to health</li> <li>• <i>Review slide content</i></li> <li>• Explain that these 4 components of the right to health are often referred to as '3AQ' and will be discussed in detail in the following slides</li> </ul>
Slide 6	<p><b>Human rights- General Comment 14 - 1</b></p> <ul style="list-style-type: none"> <li>• <i>Availability</i>: Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity</li> <li>• <i>Accessibility</i>: Health facilities, goods and services must be accessible to all</li> <li>• This includes non-discrimination, physical, economic, and information accessibility</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise that that any discussion of ethical TB services must incorporate these concepts</li> </ul>



Slide 7	<p><b>Human rights- General Comment 14 - 2</b></p> <ul style="list-style-type: none"> <li>• <b>Acceptability:</b> Health facilities, goods and services must be respectful of medical ethics &amp; culturally appropriate; respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements, respect confidentiality and improve the health status of those concerned</li> <li>• <b>Quality:</b> Health facilities, goods and services must be scientifically and medically appropriate and of good quality. This requires skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe and potable water, and adequate sanitation</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 8	<p><b>Human rights approach to TB care - 1</b></p> <ul style="list-style-type: none"> <li>• Addresses legal, structural and social barriers to quality TB prevention, diagnosis, treatment and care services</li> <li>• Emphasises: <ul style="list-style-type: none"> <li>• <b>Appropriate treatments</b> that meet patients' needs to prevent development of drug resistance</li> <li>• Patients' right to be <b>free from discrimination</b></li> <li>• Patients' right to be <b>free from forced or coerced treatment</b></li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>• Reiterate that TB is a disease of poverty and inequality that particularly affects key vulnerable populations with little or no access to basic services</li> <li>• A human rights-based approach should be utilised in TB prevention, treatment and care</li> <li>• This includes addressing the legal, structural and social barriers to quality TB prevention, diagnosis, treatment and care services</li> <li>• The 3 AQ concepts mentioned in the previous slide are clearly applicable to TB prevention diagnosis and treatment</li> <li>• This section sets out obligations under these human rights standards and the priority areas where measurable progress can be made to eliminate barriers to service access and ensure meaningful participation of people living with and affected by the disease</li> <li>• <i>Review slide content</i></li> </ul>
Slide 9	<p><b>Human rights approach to TB care - 2</b></p> <ul style="list-style-type: none"> <li>• For drug-resistant TB, consider <b>community-based</b> treatment options <ul style="list-style-type: none"> <li>• Respect for patients' rights</li> <li>• Excellent treatment completion rates</li> <li>• Protect public health</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 9</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>

Slide 10	<p><b>Access to TB care</b></p> <ul style="list-style-type: none"> <li>• Strong association exists between TB incidence and a country's gross domestic product per capita</li> <li>• Strong socio-economic gradient also found: <ul style="list-style-type: none"> <li>• Within countries</li> <li>• Within cities</li> <li>• Across households</li> </ul> </li> <li>• Poorest individuals, families, communities, countries have highest risk of TB</li> </ul> <p>USAID TB CARE II PROJECT 10</p>	<ul style="list-style-type: none"> <li>• State that further there is increasing knowledge about how social determinants of health, such as childhood conditions, urbanisation, living conditions and employment conditions influence all stages of TB pathogenesis</li> <li>• This leads to inequities related to exposure to infection, progression to active disease, and delayed or incorrect diagnosis, as well as health outcomes.</li> <li>• <i>Review slide content</i></li> </ul>
Slide 11	<p><b>Optimal conditions for uptake of TB services</b></p> <ul style="list-style-type: none"> <li>• No discrimination</li> <li>• No exposure to other risks</li> <li>• Confidentiality maintained</li> <li>• Access to information</li> <li>• No coercion into accepting services without consent</li> </ul> <p>USAID TB CARE II PROJECT 11</p>	<ul style="list-style-type: none"> <li>• Explain that providing these quality TB services will help achieve optimal conditions for the uptake of prevention, testing, treatment and care services,</li> <li>• In order to provide quality services in TB prevention, treatment and care, it is necessary to reduce such human rights barriers through programmes that enable access to services.</li> <li>• People are more likely to use health services in the conditions detailed on this slide, which relate back to the Accessibility component of General Comment 14</li> <li>• <i>Review slide content</i></li> </ul>
Slide 12	<p><b>Obligation of governments</b></p> <ul style="list-style-type: none"> <li>• Provide universal access to TB care (Availability Accessibility, Acceptability)</li> <li>• Grounded in governments' duty to fulfil human right to life</li> <li>• Resource-limited countries which cannot fulfill these obligations completely should apply principle of progressive realisation</li> <li>• Move as expeditiously and effectively as possible towards achieving these critical goals</li> <li>• Regulate care in line with internationally accepted quality standards (Quality)</li> </ul> <p>USAID TB CARE II PROJECT 12</p>	<ul style="list-style-type: none"> <li>• The WHO Constitution states that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'</li> <li>• Similarly, as noted earlier, the International Covenant on Economic, Social and Cultural Rights specifically calls on State Parties (governments) to take steps necessary for 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases'</li> <li>• <i>Review slide content</i></li> <li>• The obligation to provide universal access to TB care includes a duty to ensure the quality of that care. Thus, governments have an ethical obligation to regulate this care to ensure that it is consistent with internationally accepted quality standards. This includes both TB diagnosis and treatment</li> </ul>

Slide 13	<p>Premise for universal access</p> <ul style="list-style-type: none"> <li>As noted in human right frameworks, everyone has right to a minimum standard of health care</li> <li>Access to TB care should receive high priority: <ul style="list-style-type: none"> <li>Usually curative</li> <li>Prevents spread of disease</li> <li>Prevents development of drug-resistant strains</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 13</p>	<ul style="list-style-type: none"> <li>Explain that as stated above, governments' have an obligation to provide universal access to TB care.</li> <li><i>Review slide content</i></li> <li>In addition to the clear responsibility to provide universal access based on a human rights approach, providing universal access is also inexpensive and cost effective for governments</li> </ul>
Slide 14	<p>PLENARY Consider and share ...</p> <p>What do you believe are the benefits to universal access to TB care?</p> <p>USAID TB CARE II PROJECT 14</p>	<ul style="list-style-type: none"> <li>Ask delegates to provide responses to the question</li> <li>Spend 10 minutes obtaining and collating the responses</li> <li>Write down the responses on the flipchart</li> <li>Tick off the responses as you discuss the subsequent slide</li> </ul>
Slide 15	<p>Benefits of universal access</p> <ul style="list-style-type: none"> <li>Prevents significant morbidity and mortality</li> <li>Slows the spread of infectious disease</li> <li>Reduces development of drug-resistant strains</li> <li>Inexpensive and highly cost-effective</li> <li>Decreases vulnerability to poverty</li> </ul> <p>USAID TB CARE II PROJECT 15</p>	<ul style="list-style-type: none"> <li>Explain that even when resources are limited, there are several reasons why governments should give high priority to providing universal access to TB care as part of their commitment to fulfilling the human right to health</li> <li><i>Review slide content</i></li> <li>Link the delegates' responses to the points listed on the slide as part of the review of the slide content</li> </ul>

<p>Slide 16</p>	<p><b>Universal access to MDR- and XDR-TB care</b></p> <p>Achieve universal access to diagnosis and treatment of multidrug-resistant (MDR-) and extensively drug-resistant (XDR-) tuberculosis as part of the transition to universal health coverage, thereby saving lives and protecting communities</p> <p><small>World Health Assembly Resolution 62.15</small></p> <p><small>USAID TB CARE II PROJECT</small> 16</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that providing universal access to TB care is important not only for drug-susceptible TB but also MDR and XDR-TB, which have had a particularly pernicious impact on vulnerable populations</li> </ul>
<p>Slide 17</p>	<p><b>International Standards for TB Care</b></p> <p>'All providers who undertake evaluation and treatment of patients with tuberculosis must recognise that, not only are they delivering care to an individual, they are assuming an important public health function.'</p> <ul style="list-style-type: none"> <li>• Basic principles of care for persons with, or suspected of having TB: <ul style="list-style-type: none"> <li>• Prompt and accurate diagnosis</li> <li>• Standardised treatment regimens of proven efficacy</li> <li>• Appropriate treatment support and supervision</li> <li>• Monitoring of treatment response</li> <li>• Carrying out of essential public health responsibilities</li> </ul> </li> </ul> <p><small>International Standards for TB Care, Third Edition, 2014</small></p> <p><small>USAID TB CARE II PROJECT</small> 17</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Prompt, accurate diagnosis and appropriate treatment are the most effective means of interrupting transmission of <i>M. tuberculosis</i>.</li> <li>• Thus, as well as being essential for good patient care, they are the foundation of the public health response to tuberculosis</li> </ul>
<p>Slide 18</p>	<p><b>Free TB care</b></p> <ul style="list-style-type: none"> <li>• Meets government obligation to protect public's health: <ul style="list-style-type: none"> <li>• Ease burden of unaffordable costs</li> <li>• Treatment benefits extend to society as a whole</li> </ul> </li> </ul> <p><small>USAID TB CARE II PROJECT</small> 18</p>	<ul style="list-style-type: none"> <li>• State that governments have an obligation to provide TB care for free</li> <li>• <i>Review slide content</i></li> <li>• Explain that the WHO's Stop TB Strategy states that, 'anti-TB drugs should be available free of charge to all TB patients, both because many patients are poor and may find them difficult to afford, and because treatment has benefits that extend to society as a whole (cure prevents transmission to others)'</li> <li>• Remind delegates that the second of these reasons reflects the ethical principle of reciprocity, which states that, when individuals undergo burdens for the benefit of the community, society has an obligation to provide 'something in return'.</li> </ul>

Slide 19	<p><b>Costs of not providing free care</b></p> <ul style="list-style-type: none"> <li>• Barrier to obtaining or completing a full course of TB treatment</li> <li>• Individuals who are infectious are never cured</li> <li>• Additional people exposed</li> <li>• Development of dangerous drug-resistant strains</li> </ul> <p>USAID TB CARE II PROJECT 19</p>	<ul style="list-style-type: none"> <li>• Explain that the obligation to provide free TB care also reflects pragmatic considerations</li> <li>• <i>Review slide content</i></li> <li>• Thus, ensuring that TB care is freely available is essential to governments' ability to protect the public's health, and likely to prove the less expensive option in the long run</li> </ul>																														
Slide 20	<p><b>Free diagnosis and other services</b></p> <ul style="list-style-type: none"> <li>• Free access to diagnostic measures for drug susceptible and drug resistant TB <ul style="list-style-type: none"> <li>• Prevents patients from receiving ineffective treatment to which they are resistant</li> <li>• Ensures patients are cured</li> <li>• Prevents additional spread of infection</li> <li>• Prevents further development of drug-resistance</li> </ul> </li> <li>• Free access to preventive therapy <ul style="list-style-type: none"> <li>• Minimise the overall burden of disease</li> </ul> </li> <li>• Remove non-TB-specific financial barriers</li> </ul> <p>USAID TB CARE II PROJECT 20</p>	<ul style="list-style-type: none"> <li>• State that all aspects of TB care should be provided free of charge</li> <li>• <i>Review slide content</i></li> <li>• It is also important to remove non-TB-specific financial barriers to accessing the health-care system, such as: <ul style="list-style-type: none"> <li>• User fees which prevent poor people from receiving health-care services</li> <li>• Charges imposed on TB patients for the care of related conditions, e.g. HIV</li> </ul> </li> </ul>																														
Slide 21	<p><b>PLENARY Consider</b></p> <p>Do patients carry costs related to the services and tests involved in TB prevention, diagnosis, treatment, care and support?</p> <table border="1"> <thead> <tr> <th>Item</th><th>Yes</th><th>No</th></tr> </thead> <tbody> <tr><td>Sputum test</td><td></td><td></td></tr> <tr><td>Drug susceptibility test</td><td></td><td></td></tr> <tr><td>TB medicines</td><td></td><td></td></tr> <tr><td>Treatment for side effects</td><td></td><td></td></tr> <tr><td>Treatment for related conditions</td><td></td><td></td></tr> <tr><td>Transport costs</td><td></td><td></td></tr> <tr><td>Loss of wages</td><td></td><td></td></tr> <tr><td>Food costs (while queuing at facility)</td><td></td><td></td></tr> <tr><td>Other</td><td></td><td></td></tr> </tbody> </table> <p>USAID TB CARE II PROJECT 21</p>	Item	Yes	No	Sputum test			Drug susceptibility test			TB medicines			Treatment for side effects			Treatment for related conditions			Transport costs			Loss of wages			Food costs (while queuing at facility)			Other			<ul style="list-style-type: none"> <li>• Ask delegates to determine if patients in their TB programme carry costs for the items listed on the slide, using a flip chart to record the responses</li> <li>• Ask delegates to add other items that patient may have to pay for as part of receiving care and support in the TB programme</li> <li>• Spend 5-10 minutes obtaining and discussing the responses</li> <li>• Remind delegates that costs, either direct or indirect, impact on access to TB care and potentially adherence to treatment, thereby compromising the ethical values of social justice, equity and common good</li> </ul>
Item	Yes	No																														
Sputum test																																
Drug susceptibility test																																
TB medicines																																
Treatment for side effects																																
Treatment for related conditions																																
Transport costs																																
Loss of wages																																
Food costs (while queuing at facility)																																
Other																																

Slide 22	<p><b>Root causes of MDR- and XDR-TB</b></p> <ul style="list-style-type: none"> <li>• Improper treatment regimens</li> <li>• Failure to ensure that patients complete the whole course of treatment</li> </ul> <p><small>WHO: Guidelines for the programmatic management of drug-resistant tuberculosis. Emergency update, 2008</small></p> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>22</small></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• State that as WHO recognised, these causes of root causes of drug-resistant TB may be due to lack of appropriate diagnostics or treatment</li> <li>• Resources directed to solving these problems will enable governments to avoid the financial burdens associated with treating MDR- and XDR-TB</li> </ul>
Slide 23	<p><b>Free access to MDR- and XDR-TB treatment</b></p> <ul style="list-style-type: none"> <li>• Even stronger case for ensuring free access to treatment of drug-resistant TB</li> <li>• High costs underscores the importance of providing adequate resources to support basic TB care and control: <ul style="list-style-type: none"> <li>• Infection control</li> <li>• DOTS</li> <li>• Community-based care programmes</li> </ul> </li> </ul> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>23</small></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• If MDR- and XDR-TB cases are not appropriately treated, a self-sustaining and potentially devastating epidemic of drug-resistant TB will be the inevitable result, due to human suffering and significantly higher morbidity and mortality</li> </ul>
Slide 24	<p><b>International community obligations</b></p> <ul style="list-style-type: none"> <li>• Provide financial and other assistance to countries that cannot offer universal access to care on their own</li> <li>• Grounded in a number of different ethical principles: <ul style="list-style-type: none"> <li>• Humanitarian</li> <li>• Redistribution of wealth</li> </ul> </li> </ul> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>24</small></p>	<ul style="list-style-type: none"> <li>• State that it is undeniable that the expense of providing universal access to TB care, particularly MDR- and XDR-TB care, poses a significant burden for resource-poor countries</li> <li>• As noted above, these governments have an obligation to move as expeditiously and effectively as possible to scaling up their treatment capacity</li> <li>• For example, an argument based on humanitarian principles such as beneficence, solidarity, etc. that fellow human beings require relatively cheap interventions that could easily and dramatically improve their lives</li> <li>• The argument could be grounded in the idea that justice requires a redistribution of wealth because the present actual distribution might be at least partly due to past unfairness</li> </ul>


Slide 25	<p>Another compelling reason for universal access</p> <ul style="list-style-type: none"> <li>• Growing drug resistance</li> <li>• Only a matter of time before it impacts upon one's own country</li> </ul> <p>USAID TB CARE II PROJECT 25</p>	<ul style="list-style-type: none"> <li>• Explain that there is another compelling reason that obligations regarding TB care and control should be taken seriously</li> <li>• <i>Review slide content</i></li> <li>• Even if governments find moral arguments unconvincing, they have a strong prudential reason to be concerned about diseases such as TB, in light of the growing drug resistance</li> <li>• If the situation deteriorates elsewhere in the world, it is likely to be only a matter of time before it impacts upon one's own country</li> </ul>
Slide 26	<p>Quality of TB drugs</p> <ul style="list-style-type: none"> <li>• Substandard drugs: <ul style="list-style-type: none"> <li>• Harm individual patients</li> <li>• Contribute to the development, spread, and amplification of drug-resistant strains</li> </ul> </li> <li>• <b>Governmental level obligation to:</b> <ul style="list-style-type: none"> <li>• Assure quality of TB drugs</li> <li>• Ensure infrastructure for and sustainability of drug supply</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 26</p>	<ul style="list-style-type: none"> <li>• Explain that it is ethically unacceptable for national TB programmes to provide drugs that are not quality-assured</li> <li>• The Stop TB Partnership's Global Drug Facility has identified infrequent and poor quality drug supplies as the main barrier to preventing and eliminating TB</li> <li>• <i>Review slide content</i></li> <li>• Individual providers are simply not equipped to evaluate the quality of drugs on a case-by-case basis</li> </ul>
Slide 27	<p>HIV Testing: Share your practice</p> <ul style="list-style-type: none"> <li>• Are all patients with HIV being counselled and offered TB testing? <ul style="list-style-type: none"> <li>• What are the barriers to counselling and offering patients who are HIV-positive TB tests?</li> <li>• What encourages you to counsel and offer TB tests to patients who are HIV-positive?</li> </ul> </li> </ul> <p>HIV testing recommended in all patients with TB</p> <p>USAID TB CARE II PROJECT 27</p>	<ul style="list-style-type: none"> <li>• Ask delegates to consider if all patients who are HIV-positive are counselled and offered testing for TB</li> <li>• Ask delegates to share what drives their decision-making regarding which patients who are HIV-positive are counselled and offered TB testing</li> <li>• Spend 5-10 minutes on the discussion</li> <li>• State that whether or not a patient is tested for TB should not depend on the type of patient or the provider</li> </ul>

Slide 28	<p>Unfulfilled government obligations</p> <ul style="list-style-type: none"> <li>Healthcare providers actions: <ul style="list-style-type: none"> <li>Consider risks and benefits to both patient and public</li> <li>Consult with patient and other health-care providers</li> <li>Notify the national government</li> <li>Advocate for urgent rectification</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 28</p>	<ul style="list-style-type: none"> <li>Explain that when governments do not satisfy their obligation to make quality-assured TB drugs available, health care providers making decisions for individual patients face difficult ethical dilemmas</li> <li>In some cases, they may reasonably conclude that it would be ethically preferable to give a patient drugs of unknown quality rather than forego treatment entirely</li> <li><i>Review slide content</i></li> </ul>
Slide 29	<p>Ethical considerations for promotion of better access to TB care and treatment</p> <ul style="list-style-type: none"> <li>Patient-centred treatment approach</li> <li>Community-based care</li> <li>Patients as part of larger communities</li> <li>Social justice and equity</li> </ul> <p>USAID TB CARE II PROJECT 29</p>	<ul style="list-style-type: none"> <li>State that many of the key ethical considerations relevant to promoting access to TB prevention, care and treatment are already part of WHO's Stop TB Strategy</li> <li><i>Review slide content</i></li> <li>The following four slides will examine each of these considerations in greater detail</li> </ul>
Slide 30	<p>Ethical considerations: Patient-centred treatment approach</p> <ul style="list-style-type: none"> <li>Treatment should be accessible, acceptable, affordable, and appropriate</li> <li>Patients should have choices about location of treatment</li> <li>When directly observed therapy is used, patient should have choice about individuals who will be doing observing</li> </ul> <p>USAID TB CARE II PROJECT 30</p>	<ul style="list-style-type: none"> <li>The first ethical consideration in developing strategies to promote better access to TB care and treatment is utilising a patient-centred treatment approach</li> <li>This was discussed earlier on in the section focussed on Overarching Goals and Ethical Principles</li> <li><i>Review slide content</i></li> </ul>



Slide 31	<p><b>Ethical considerations: Promoting community-based care</b></p> <ul style="list-style-type: none"> <li>• Achieves comparable results to hospitalisation and, in theory, may result in decreased nosocomial spread of the disease when provided by trained lay and community health workers</li> <li>• Reduces burdens on health-care facilities</li> <li>• More cost effective than facility-based treatment</li> <li>• Enables governments with limited resources to serve greatest proportion of those in need</li> </ul> <p>USAID TB CARE II PROJECT 31</p>	<ul style="list-style-type: none"> <li>• State that the next ethical consideration deals with community-based care</li> <li>• Promoting community-based care which is accessible, well-accepted by patients, and promotes adherence</li> <li>• <i>Review slide content</i></li> </ul>
Slide 32	<p><b>Ethical considerations: Focus on patients as part of larger communities</b></p> <ul style="list-style-type: none"> <li>• Patients should be encouraged to form support groups</li> <li>• Patients should be encouraged to work with their communities to address the social determinants of TB</li> </ul> <p>USAID TB CARE II PROJECT 32</p>	<ul style="list-style-type: none"> <li>• State that the third ethical consideration when designing strategies to promote better access to TB care and treatment involves focusing on patients as part of their larger communities</li> <li>• <i>Review slide content</i></li> </ul>
Slide 33	<p><b>Ethical considerations: Promoting social justice and equity</b></p> <ul style="list-style-type: none"> <li>• TB programmes should take into account the needs of all patients</li> <li>• Interventions should be gender sensitive</li> <li>• Interventions should address different types of vulnerabilities: <ul style="list-style-type: none"> <li>• Individuals who face increased risk of becoming infected and developing active disease</li> <li>• Individuals who face challenges of accessing and fully utilising services</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 33</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Indicate that specific vulnerable groups that must be considered are identified in the following slides</li> </ul>

Slide 34	<p>Promoting social justice and equity: Special considerations for vulnerable groups</p> <ul style="list-style-type: none"> <li>• Special consideration for needs of: <ul style="list-style-type: none"> <li>• Women</li> <li>• Children</li> <li>• People co-infected with HIV</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 34</p>	<ul style="list-style-type: none"> <li>• Review slide content</li> </ul>
Slide 35	<p>Promoting social justice and equity: Special considerations for vulnerable groups - 2</p> <ul style="list-style-type: none"> <li>• Specific tailored interventions for vulnerable groups including: <ul style="list-style-type: none"> <li>• People living in extreme poverty</li> <li>• Indigenous populations</li> <li>• Refugees</li> <li>• Asylum seekers</li> <li>• Migrants</li> <li>• Mine workers</li> <li>• Prisoners</li> <li>• Substance users, including those who use alcohol</li> <li>• Homeless people</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 35</p>	<ul style="list-style-type: none"> <li>• Review slide content</li> <li>• Indicate that these interventions should be developed and implemented proactively</li> </ul>
Slide 36	<p>GROUP Let's discuss...</p> <ul style="list-style-type: none"> <li>• Divide into groups, based on the facilitator's instructions</li> <li>• Move to the place designated for your group</li> <li>• Spend 20 minutes discussion time in the following way: <ul style="list-style-type: none"> <li>• 5 minutes reading through the question and information provided in Obligation to Provide Access to TB Services: Activity 3 Delegate Hand-out and noting: <ul style="list-style-type: none"> <li>— Most critical barrier that limits access to TB services in the community you serve, with specific regard to vulnerable groups,</li> <li>— What you currently do or what you can do in your role to address this barrier</li> </ul> </li> <li>• 5 minutes each: <ul style="list-style-type: none"> <li>— Discussing the barrier, as well as the solutions (current or proposed)</li> <li>— Soliciting feedback from group members regarding the solutions</li> <li>— Asking group members, who may have similar experience to share their solutions</li> </ul> </li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 36</p>	<ul style="list-style-type: none"> <li>• Ask delegates to refer to the slide for instructions on how the activity will be run</li> <li>• Inform them that the instructions are also available in the Obligation to Provide Access to TB Services: Activity 3 Delegate Hand-out and that they should refer to it</li> <li>• Ensure that delegates understand the instructions and clarify any misunderstanding</li> </ul>

Slide 37	<p>Activity: Group Discussion</p> <p>GROUP</p> <ul style="list-style-type: none"> <li>For the community you serve, what is the most critical barrier that limits access to TB services, particularly for vulnerable groups?</li> <li>What actions would you propose to remove these barriers in order to ensure the ethical obligation to provide access to TB services is upheld?</li> </ul> <p>USAID TB CARE II PROJECT 37</p>	<ul style="list-style-type: none"> <li>See Activity 3 in the Facilitator Guide for guidance on how to run this activity</li> <li>This is a group discussion, which should take approximately 40 minutes</li> <li>Tell delegates to separate into groups of 4-5 people</li> <li>Ensure that each group has the material needed for the activity</li> <li>Set aside 20 minutes for the small group discussion</li> <li>Spend 15 minutes on getting feedback from the groups and the plenary discussion, allowing yourself 2-3 minutes to summarise</li> <li>State that prevention, diagnosis, care and treatment of TB, both drug-susceptible and drug-resistant TB, raise important ethical and human rights issues that must be addressed.</li> <li>For example, TB particularly affects poor and vulnerable populations, and therefore social justice and equity must be at the heart of the response</li> <li>TB can be a lethal infectious disease which in the absence of proper treatment, and care of patients and control of the epidemic raises questions on how to ensure balance of individual responsibilities, rights and liberties of those affected by the disease with the protection of those who are at risk of infection</li> </ul>
Slide 38	 <p>USAID TB CARE II PROJECT 38</p>	<ul style="list-style-type: none"> <li>Check if delegates have any questions and address these</li> <li>This is the end of the module on 'Obligation to Provide Access to TB Services'</li> <li>Next, we'll be focusing on 'Information, Counselling and the Role of Consent'</li> </ul>

## Facilitator Instructions for Activity 3: Obligation to Provide Access to TB Services

### Objective

To assist delegates to critically and holistically assess their TB programme on the basis of the ethical values described to determine how the level of care can be improved

### Questions

- For the community you serve, what is the most critical barrier that limits access to TB services, particularly for vulnerable groups?
- What actions would you propose to remove these barriers in order to ensure the ethical obligation to provide access to TB services is upheld?

### Time Allotted

40 minutes

- 5 minutes for instructions and dividing delegates into groups
- 20 minutes of small group discussion
- 15 minutes for plenary discussion

### Materials Needed

- Activity 3: Obligation to Provide Access to TB Services Delegate Hand-out
- Flip chart and pens to record plenary discussion

### Procedure for running activity

1. Remind delegates that the ground rules established for the first activity still apply
2. Separate the delegates into groups of 4 or 5 people; ask delegates to find other people who work at different facilities or clinics
3. Ask them to go to the designated areas
4. Provide each delegate with a hand-out called Activity 3: Obligation to Provide Access to TB Services Delegate Hand-out
  - a. Give the groups 20 minutes to discuss the questions and instruct them to designate someone to report back in the plenary discussion
  - b. Each group member should share the most critical barrier they face in terms of providing access to TB services, with specific regard to vulnerable groups, such as the poor or children, and actions they propose or that they currently use to address this barrier
  - c. Other members of the group should provide comment or feedback and suggest alternate solutions, based on the experience of other group members in similar circumstances
5. Provide a time check to the groups when they have 5 minutes and then 2 minutes remaining
6. Facilitate a plenary discussion, asking delegates to share solutions that were discussed to the barriers they face
7. Provide summary points from under the Tips section

### Setting the Scene

Prevention, diagnosis, care and treatment of TB, both drug-susceptible and drug-resistant TB, raise important ethical and human rights issues that must be addressed. For example, TB particularly affects poor and vulnerable populations, and therefore social justice and equity must be at the heart of the response. TB can be a lethal infectious disease which, in the absence of proper treatment, and care of patients and control of the epidemic, raises questions on how to ensure balance of individual responsibilities, rights and liberties of those affected by the disease, with the protection of those who are at risk of infection.\*

*\*Companion Handbook to the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis. Geneva: World Health Organization; 2014. 21, Ethics in programmatic management of MDR-TB.*

### Tip

Treatment should be accessible, acceptable, affordable, and appropriate. Delegates should be reminded to consider the question, based on their span of control and roles and responsibilities. They should also consider the role they can play in advocating for changes in the TB programme so as to continue to improve the quality of care provided.

Use the opportunity to check the delegates' understanding of the ethical values and clarify any misunderstandings.

## 14. Module 5: Information, Counselling and the Role of Consent

### Facilitation Guide for Module 5: Information, Counselling and the Role of Consent

#### Time

- 1 hour

#### Objectives

- Describe the ethical justification for providing patient counselling
- Explain the role and meaning of informed consent

#### Techniques

- Lecture
- Plenary discussion

#### Materials

- PowerPoint slides
- Flip chart and pens

#### Key Messages

- In addition to being ethically justified, providing full and accurate information helps individuals understand the need TB testing and treatment
- Individuals have a right to be informed about contact notification and should be encouraged to participate in the identification and notification of contacts
- Informed consent ensures patients are engaged and can actively partner with health care providers in decision-making regarding their treatment, care and support

#### Synopsis of module

This module considers the following four principles underpinning information, counselling and consent.

1. The ethical justification for counselling and providing information to patients about the tests that they are being asked to undergo
2. The kind of information about TB tests and treatment that patients are given
3. What TB patients should be told about contact notification
4. How the concept of 'informed consent' is applicable to TB testing and treatment.

Individuals undergoing TB testing and treatment have a right to receive complete and accurate information about the risk, benefits and alternatives available to them. They need to know what is being done to their bodies, how TB is spread and the treatment options available to them, as well as providing full information about TB treatment can help instill trust in the national TB programme (NTP). Trust is particularly important for NTPs to succeed.

Information and education provided to individuals undergoing TB testing should inform them about why they are being tested and the nature of TB. They should be informed about the risks and benefits to both themselves and their community, as well as be counselled as to why it is important to complete the full course of treatment.



Contact notification is often required in many countries upon a diagnosis of infectious TB. In this case, the health care worker should explain this requirement to patients and enlist their help in both identifying and potentially notifying their contacts. However, contact notification can be carried out without disclosing the name of the patient. If a patient is currently on treatment in a supportive patient-centered environment, it is extremely unlikely that they would not participate in the contact identification process. Identification of contacts to patients who are not on treatment and are unwilling to participate in contact identification can sometimes present an ethical dilemma to both health care workers and public health officials since they would have to balance the non-disclosure of a patient's health status to a third party with the rights of third parties; i.e. the right to life. Health care workers have duties to their patients, but also have an obligation to protect the lives of others. Thus, TB programmes and public health officials should develop clear policies on how to manage the non-consensual disclosure of a patient's TB status, which should happen only in very rare cases. These policies should be aimed at protecting patients and their contacts from stigmatisation and of course, patients should be notified before non-consensual disclosure is carried out. Where case reporting and contact notification is not a statutory requirement, patients are encouraged to notify their contacts themselves

Ethical consent engages patients as partners in their treatment process by giving them relevant information and an opportunity to make decisions for themselves. This process of ensuring that their decisions are voluntary and informed should not be confused with legal mechanisms such as consent forms that may be construed as threatening by patients. For TB treatment, when drug susceptibility testing is offered in the absence of treatment, care should be taken to inform patients of the risks and benefits of testing and they should be specifically asked for their consent especially when treatment is not available to them. Where patients refuse to consent to TB treatment, they should be counselled about the risks to themselves and their community. In addition, health care workers should work with the patient in order to understand their concerns and to find ways to address these concerns. In those rare cases where patients continue to refuse treatment after counselling, they should be advised that while they have the right to refuse treatment, if they have active TB and do not complete the full course of treatment, it is possible that they may be subjected to involuntary isolation or detention.

#### [Procedure for running Module 5](#)

Present slides for the module and follow the instructions and speaker notes in each slide

## Slide Kit for Module 5: Information, Counselling and the Role of Consent

Slide 1	<div data-bbox="375 327 852 569"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <h4>MODULE 5: INFORMATION COUNSELLING AND THE ROLE OF CONSENT</h4> </div> <div data-bbox="321 583 894 653"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 657 894 726"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>Describe the ethical justification for providing patient and counselling</li> <li>Explain the role and meaning of informed consent</li> </ul> <p>USAID TB CARE II PROJECT <span>2</span></p>	<ul style="list-style-type: none"> <li>Review slide content</li> </ul>
Slide 3	<h3>Ethical justification for providing information</h3> <ul style="list-style-type: none"> <li>People have the right to know what is being done to their bodies and why</li> <li>Helps patients understand TB, how it is spread, and the options for treating it, making it more likely that individuals will adhere to treatment</li> <li>Providing full information about TB treatment helps instill trust in system, leading to higher level of respect in community</li> </ul> <p>USAID TB CARE II PROJECT <span>3</span></p>	<ul style="list-style-type: none"> <li>There are several reasons to ensure that individuals undergoing TB testing and treatment receive complete and accurate information about the risks, benefits, and alternatives available to them.</li> <li>Explain that there is strong ethical justification for giving individuals information and counselling about tests and treatments they are being asked to undergo</li> <li>Review slide content</li> <li>Providing information about testing and treatment shows respect for basic individual rights</li> <li>Understanding this information is particularly important for patients who must undergo significant burdens to complete treatment, such as taking time off from work to travel to a clinic</li> <li>Finally, it is widely acknowledged that trust in the</li> </ul>



		public health system is essential for the system to succeed
Slide 4	<p>Kind of information provided</p> <ul style="list-style-type: none"> <li>• TB Testing <ul style="list-style-type: none"> <li>• Basic information about the nature of TB and why they are being tested</li> </ul> </li> <li>• Individuals offered TB treatment <ul style="list-style-type: none"> <li>• Information about the risks and benefits of the proposed interventions, including the role of traditional medicine</li> <li>• Importance of completing the full course of treatment</li> <li>• Infection control measures</li> <li>• Available support to help patients complete the full course</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 4</p>	<ul style="list-style-type: none"> <li>• State that it is the patient's right to expect and receive appropriate information about TB testing and treatment</li> <li>• <i>Review slide content</i></li> </ul>
Slide 5	<p>Ensuring provision of appropriate information</p> <ul style="list-style-type: none"> <li>• Work with peer advocates and community leaders</li> <li>• Suitable for individuals from diverse backgrounds: <ul style="list-style-type: none"> <li>• Linguistic</li> <li>• Educational</li> <li>• Cultural</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>• Explain that it is as important to provide relevant information, and that this ties back into the human rights concept of information accessibility included in General Comment 14, described earlier</li> <li>• <i>Review slide content</i></li> </ul>
Slide 6	<p>Consider...</p> <p><b>PLENARY</b></p> <p>How do you provide relevant, appropriate and accurate information to patients?</p> <p>USAID TB CARE II PROJECT 6</p>	<ul style="list-style-type: none"> <li>• This is a plenary discussion, in which all delegates participate</li> <li>• Assign 5 minutes for the discussion</li> <li>• Record responses on a flipchart</li> <li>• Suggest that delegates consider how their own perceptions may influence the type of information provided to patients</li> <li>• At the end, summarise the discussion and point out areas of convergence and divergence with the lesson content</li> </ul>

<p>Slide 7</p>	<p><b>Informed consent</b></p> <ul style="list-style-type: none"> <li>• Process of engaging patients as partners in the treatment process by giving them relevant information and an opportunity to make decisions for themselves</li> <li>• Ethical aspect should not be confused with legal mechanisms</li> <li>• <b>Fundamental ethical requirement of engaging patients as partners by ensuring that their decisions are voluntary and informed</b></li> </ul> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Explain that as an ethical concept, informed consent refers to the process of engaging patients as partners in the treatment process by giving them relevant information and an opportunity to make decisions for themselves</li> <li>• Legal mechanisms, such as consent forms, that some health-care providers and researchers use to document patients' decisions are sometimes criticised as adding unnecessary administrative complexity, or as being threatening to patients who fear they are being asked to sign away their legal rights</li> <li>• Whatever the merits of these objections, they do not undercut the importance of adhering to the fundamental ethical requirement of engaging patients as partners by ensuring that their decisions are voluntary and informed</li> </ul>
<p>Slide 8</p>	<p><b>Elements of informed consent</b></p> <ul style="list-style-type: none"> <li>• Nature of the decision or procedure</li> <li>• Reasonable alternatives to proposed intervention</li> <li>• Relevant risks, benefits, and uncertainties related to each alternative</li> <li>• Assessment of patient understanding</li> <li>• Acceptance of the intervention by patient</li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
<p>Slide 9</p>	<p><b>Informed consent in TB testing and treatment</b></p> <ul style="list-style-type: none"> <li>• Usually no need for a specific process of informed consent to TB diagnosis</li> <li>• Providers should seek the patient's informed consent to TB treatments</li> <li>• No obligation for written consent forms or consent to treatment in writing</li> </ul> <p>Providers must provide relevant information and seek the patient's agreement to undergo treatment</p> <p>USAID TB CARE II PROJECT 9</p>	<ul style="list-style-type: none"> <li>• State that there is usually no need for a specific process of informed consent to TB diagnosis, which is implicit in general consent to undergo a medical examination</li> <li>• <i>Review slide content</i></li> <li>• As noted above, the core ethical obligation is to provide relevant information and seek the patient's agreement; there is no inherent ethical obligation to do this by using a written form</li> <li>• <b>It is important to remember that the goal of the process is to show respect for the patient and enhance the likelihood that treatment will be completed; it should not be implemented in a manner that creates barriers to achieving these fundamental goals</b></li> </ul>

Slide 10	<p><b>Consent around diagnosis in absence of treatment</b></p> <ul style="list-style-type: none"> <li>For TB testing, a specific consent process is generally not required</li> <li><b>However, implicit consent for diagnostic testing is premised on availability of treatment</b></li> <li>In absence of treatment for drug resistant TB, consent is required for drug susceptibility testing: <ul style="list-style-type: none"> <li>Inform patient of risks and benefits of testing</li> <li>Specifically ask about willingness to consent in the absence of treatment</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 10</p>	<ul style="list-style-type: none"> <li>State that an exception to implicit consent for diagnostic testing is situations where drug susceptibility testing is offered to patients when treatment for drug-resistant TB is not available</li> <li><i>Review slide content</i></li> <li>Because patients' implicit consent to testing is premised on the assumption that treatment will be offered for any conditions that are diagnosed, it cannot reasonably be applied to tests for conditions when no treatment is available</li> <li>Explain that this since access to care is a human right, all effort should be made ensure that both diagnosis treatment for drug resistant TB is available and this gap should not exist on a long-term basis</li> <li>This will be discussed further in the section dealing with the gap between the availability of drug-susceptibility testing and access to MDR- and XDR-TB treatment</li> </ul>															
Slide 11	<p><b>When explicit informed consent is needed</b></p> <table border="1"> <thead> <tr> <th>Areas</th><th>Yes</th><th>No</th></tr> </thead> <tbody> <tr> <td>TB Testing</td><td></td><td>✓</td></tr> <tr> <td>TB Treatment</td><td></td><td>✓</td></tr> <tr> <td>Drug-susceptibility testing in the absence of treatment</td><td>✓</td><td></td></tr> <tr> <td>Research</td><td>✓</td><td></td></tr> </tbody> </table> <p>World Health Organization. Guidance on ethics of tuberculosis prevention, care and control. 2010</p> <p>USAID TB CARE II PROJECT 11</p>	Areas	Yes	No	TB Testing		✓	TB Treatment		✓	Drug-susceptibility testing in the absence of treatment	✓		Research	✓		<ul style="list-style-type: none"> <li>Ask delegates whether consent is necessary in these cases (answers will appear on mouse click)</li> <li>State that, in summary:</li> <li>A specific informed consent process is not required for TB testing or treatment as the potential benefits to the patient are clear</li> <li>If an active TB case is missed, the disease can be fatal, but upon diagnosis, a complete cure and curtailment of transmission are usually possible</li> <li>Moreover, TB testing and screening are not especially risky</li> <li>Informed consent for drug susceptibility testing in the absence of treatment for drug-resistant TB should be obtained</li> <li>The rationale for requiring informed consent in these situations is that, in the absence of available treatment for drug-resistant TB, drug susceptibility testing offers few direct benefits to the individuals being tested</li> <li>The main direct benefit is the provision of information that can help patients make informed life planning decisions</li> <li>Finally informed consent is required when conducting research. This will be discussed in greater detail in the module on Research on TB Care and Control</li> </ul>
Areas	Yes	No															
TB Testing		✓															
TB Treatment		✓															
Drug-susceptibility testing in the absence of treatment	✓																
Research	✓																

Slide 12	<div>Disclosure about process for contact notification: Mandatory case-reporting system</div> <div><ul style="list-style-type: none"><li>Notification may trigger a public health intervention</li><li>Determine identity of close personal contacts</li><li>Contacts are notified of their risk of infection</li></ul></div> <div><div>Healthcare worker responsibility:<ul style="list-style-type: none"><li>Explain process to patients</li><li>Seek to enlist patient's cooperation in identification and notification of contacts</li></ul></div></div> <div>USAID TB CARE II PROJECT12</div>	<ul style="list-style-type: none"><li>Explain that in many countries, a diagnosis of infectious TB must be reported to public health officials</li><li>Review slide content</li></ul>										
Slide 13	<div>Disclosure about process for contact notification: No case-reporting or contact tracing system</div> <div><ul style="list-style-type: none"><li>Patients should be encouraged to notify their contacts themselves</li><li>TB programmes should provide assistance and support to patients</li></ul></div> <div>USAID TB CARE II PROJECT13</div>	<ul style="list-style-type: none"><li>Review slide content</li><li>State that in countries that do not have case-reporting systems, or where case reporting does not lead to the identification and notification of contacts by public health authorities, patients should be encouraged to notify their contacts themselves</li><li>TB programmes should provide assistance and support to patients who undertake to notify their contacts</li></ul>										
Slide 14	<div>PLENARYThink about...</div> <div>Explore the reasons why a patient with TB would not want to participate in the process of contact identification and notification and generate possible solutions</div> <div><table><tr><th>Reason</th><th>Possible Solution</th></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr><tr><td></td><td></td></tr></table></div> <div>USAID TB CARE II PROJECT14</div>	Reason	Possible Solution									<ul style="list-style-type: none"><li>This is a plenary discussion, in which all delegates participate</li><li>Assign 5 minutes for the discussion</li><li>Record responses on a flipchart</li><li>At the end, summarise the discussion and point out areas of convergence and divergence with the lesson content</li><li>Ask delegates to share their opinions/current practice regarding patients who do not want to participate in the contact identification and notification process</li><li>Suggest that they consider it from both the perspective of the individual patient as well as the patient's contacts</li><li>Ask what they believe the reasons could be that patients may not want to participate in the process</li><li>Ask them to think about what they can do to help the patients overcome their fears and concerns regarding contact identification and notification</li></ul>
Reason	Possible Solution											

Slide 15	<div data-bbox="354 237 716 266" data-label="Section-Header"> <h3>Non-disclosure of patient status</h3> </div> <ul data-bbox="354 291 857 558" style="list-style-type: none"> <li>• Ethical and human rights standard is to protect the confidentiality of the patient</li> <li>• Contact identification and notification CAN be carried out without disclosing name of the patient</li> <li>• Non-consensual disclosure of the patient's health status to a third party interferes with right to confidentiality</li> <li>• Disclosure of status can have significant impact on patient due to stigma and can impact patient's relationship with health care providers</li> <li>• However: <ul style="list-style-type: none"> <li>• Third party's right to life may be seriously threatened if patient has infectious TB, especially if it is a drug-resistant strain</li> <li>• Consider rights of the individual patient vs. rights of the patient's contacts/public</li> </ul> </li> </ul> <div data-bbox="341 596 496 611" data-label="Text"> <p>USAID TB CARE II PROJECT</p> </div> <div data-bbox="786 585 800 598" data-label="Text"> <p>15</p> </div>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise that if a patient is currently on treatment in a supportive patient-centered environment, it is extremely unlikely that they would not participate in the contact identification process, especially if reassured that confidentiality can be maintained</li> <li>• In rare cases, identification of contacts to patients who are not on treatment and are unwilling to participate in contact identification can sometimes present an ethical dilemma to both health care workers and public health officials since they would have to balance the non-disclosure of a patient's health status to a third party with the rights of third parties; i.e. the right to life</li> <li>• Research has shown that in some communities a TB diagnosis may also be assumed to be a diagnosis of HIV, and thus disclosing TB diagnosis has other ramifications to patient, and can be considered a further violation of confidentiality by the health care system</li> <li>• Indicate that additionally, if a patient is receiving treatment, disclosure of his or her status can have very harmful impacts on his relationship with his health care providers and may jeopardize continued TB treatment -thus every effort MUST be made to protect patient confidentiality</li> <li>• However, health care workers may be in a unique position to protect the lives of others, which they also have obligation to do</li> </ul>
Slide 16	<div data-bbox="354 1358 850 1386" data-label="Section-Header"> <h3>Justification for non-consensual disclosure*</h3> </div> <div data-bbox="363 1436 863 1486" data-label="Text"> <p>*Non-consensual disclosure: informing a third party about a patient's status without his or her consent</p> </div> <ul data-bbox="354 1497 857 1665" style="list-style-type: none"> <li>• Guided by obligation to protect the lives of others</li> <li>• Viewed as a last-resort option</li> <li>• Only when there is a significant risk of infection to others if status is not disclosed and limited to those who need to know in order to protect their own health or health of others</li> <li>• Public health authorities and TB programmes should develop clear policies governing non-consensual disclosure</li> <li>• Patient notification to take place before any non-consensual disclosure is carried out</li> </ul> <div data-bbox="341 1717 496 1732" data-label="Text"> <p>USAID TB CARE II PROJECT</p> </div> <div data-bbox="786 1707 800 1719" data-label="Text"> <p>16</p> </div>	<ul style="list-style-type: none"> <li>• State that in exceptional cases, the obligation to protect the lives of others may justify disclosure of patients' TB status without their consent</li> <li>• The non-consensual disclosure of a patient's TB status should be considered only after all reasonable efforts to engage the patient's cooperation have failed</li> <li>• <i>Review slide content</i></li> <li>• Standards and procedures around non-consensual disclosure should be aimed at protecting patients and their contacts from stigmatisation and other social harms associated with TB in many settings</li> </ul>

Slide 17

Provider obligations with treatment refusal

- Counsel about risks to both themselves and community
- Seek to understand the reasons for reluctance about treatment
- Work together to identify methods for overcoming concerns
- Should treatment refusal persist:
  - Inform patient that that they could be subject to involuntary isolation or detention

USAID TB CARE II PROJECT17

- Review slide content
- Explain that it is rare that patients persist in refusing treatment when appropriate counselling is provided
- If such cases arise, patients should be informed that, while they have the right to refuse care, if they have active TB and do not complete the necessary course of therapy, it is possible that they could be subject to involuntary isolation or detention
- Inform delegates that this issue will be discussed further under the section titled Involuntary Isolation and Detention

Slide 18

PLENARY

What is your current practice in dealing with patients who have refused treatment?

Reason for Refusal	Potential Solution

USAID TB CARE II PROJECT18

- This is a plenary discussion, in which all delegates participate
- Ask delegates to share their experiences when dealing with patients who have refused treatment
- Probe to explore under what circumstances treatment was refused and how it was dealt with
- Spend 10 minutes on the discussion
- Record responses on a flipchart
- Summarise the discussion and point out/comment divergent or out-of-norm practices

Slide 19


Possible solutions for dealing with refusal to be treated

PLENARY

Reason for Refusal	Potential Solution
Concerns regarding disclosure	Reassure patient that all information is confidential Assess strength of family and social support Inform patient of need for contact tracing Encourage patient to discuss TB diagnosis and treatment with support structure
Misconceptions relating to treatment	Assess patient's knowledge, beliefs, and attitudes about TB and TB treatment Assess strength of family and social support Encourage patient to discuss TB diagnosis and treatment with support structure
Concerns regarding adherence	Discuss ability to take responsibility for adhering to TB treatment Assess strength of family and social support Encourage patient to discuss TB diagnosis and treatment with support structure

USAID TB CARE II PROJECT19

- State that there may be additional reasons for patients to refuse treatment
- Review slide content

Slide 20	 <p>USAID TB CARE II PROJECT 20</p>	<ul style="list-style-type: none"> <li>• Check if delegates have any questions and address these</li> <li>• This is the end of the module on 'Information, Counselling and the Role of Informed Consent' and the end Day One of this training</li> </ul>
Slide 21	<p>Day One Summary – 1</p> <ul style="list-style-type: none"> <li>• Topics discussed today <ul style="list-style-type: none"> <li>• Introductions: who we are, and our beliefs and practices round ethics and TB</li> <li>• Ethics assessment tool: examining our TB Programmes using an ethical perspective</li> <li>• Overview of ethical values and human rights</li> <li>• Obligation to provide access to TB services</li> <li>• Information counselling and the role of consent</li> <li>• Questions or comments?</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Thank participants for their attention and sharing their experience and perspectives on these topics</li> </ul>
Slide 22	<p>Day One Summary – 2</p> <ul style="list-style-type: none"> <li>• Topics for tomorrow <ul style="list-style-type: none"> <li>• Review of any outstanding questions</li> <li>• Supporting adherence</li> <li>• Gaps between testing and treatment for drug resistant TB</li> <li>• Health care worker rights and obligations</li> <li>• Involuntary isolation and detention</li> <li>• Research on TB care and control</li> <li>• Putting it all together: developing strategies and approaches for improving ethical challenges or gaps in TB care: <b>Bring your completed Assessment Tool!</b></li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Indicate that if delegates have any questions that were not addressed today, they can write them on a piece of paper and leave by the door (or other place as appropriate). The questions will then be addressed at the beginning of the session tomorrow</li> <li>• Remind participants that the concluding activity tomorrow will build on the discussions we had today, and the information and challenges they identified from completing the ethics assessment tool</li> </ul>

## 15. Module 6: Supporting Adherence to TB Treatment

### Facilitation Guide for Module 6: Supporting Adherence to TB Treatment

#### Time

- 1 hour

#### Objectives

- Identify strategies for promoting adherence to treatment
- Discuss ethical issues around adherence to treatment

#### Techniques

- Lecture
- Plenary discussion

#### Materials

- PowerPoint slides
- Supporting Adherence to TB Treatment Plenary Discussion Delegate Hand-out
- Flip chart and pens

#### Key Messages

- Partnership between the patient and their health care provider is key in developing a treatment adherence strategy
- Ethical obligations to and rights of both the patient and the community in which they live and work should be considered when addressing issues relating to treatment adherence

#### Synopsis of module

The most essential aspect of TB treatment is to take TB medications as prescribed in order to protect the health of patients and prevent further spread of the disease. While people with TB have an ethical duty to complete their course of treatment, health care workers have an ethical obligation to both the patient and the public at large to support patients and their ability to adhere to treatment.

It is therefore ethically justified to use directly observed therapy (DOT) to ensure treatment to adherence. When used as part of a patient-centred approach to care, it can be seen as a process that provides support, motivation and understanding to patients. Similarly, the use of ‘enablers’, mechanisms or resources that facilitate patients’ ability to adhere to treatment, are ethically justifiable as they help mitigate the impact of the social determinants of TB, including poverty, all of which can make it difficult for patients to complete a full course of therapy. Enablers also empower patients to take an active role in their care, promoting the ethical value of individual autonomy. Some programmes offer financial or other incentives to patients in exchange for taking TB treatment. While not inherently inappropriate, it should be part of a well-designed and respectful person-centred approach to TB care. It speaks to the ethical principle of reciprocity when individuals accept burdens for the benefit of the community and receive something in return.

Programmes have an ethical obligation and duty of care toward patients who have problems with adhering to treatment. Follow up with patients and the efforts to promote adherence should always be consistent with the patient-centred care approach. For example, TB programmes and health care

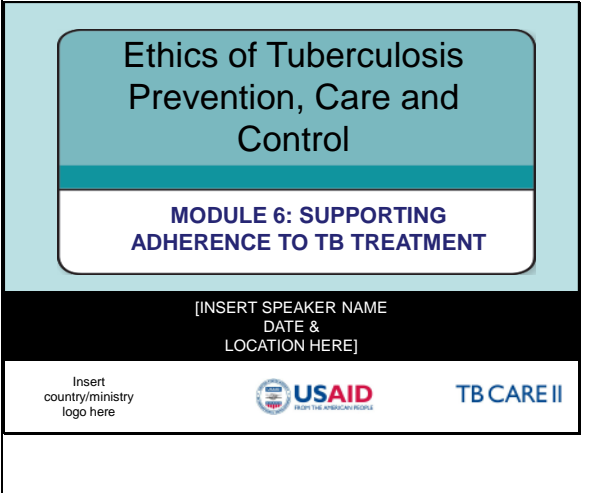


workers should ensure that intrusions into the patient's space are kept to a minimum during follow-up. It is not ethically acceptable to refuse to treat a particular patient because it appears that he/she may not adhere to treatment. Finally, there is an ethical obligation not to abandon patients on TB care. In those situations when all curative treatments have been attempted and the patient is still not responsive, then the obligation of non-abandonment requires the provision of palliative care, the details of which need to be worked out after an individualised risk assessment.

#### Procedure for running Module 6

1. Ensure that you have printed a copy of Supporting Adherence to TB Treatment Plenary Discussion Delegate Hand-out for each delegate, which can be found in the Delegate Hand-out section
2. Present slides for the module, and follow the instructions and speaker notes in each slide
3. Use the Facilitator's Notes below to run the plenary discussion

## Slide Kit for Module 6: Supporting Adherence to TB Treatment


Slide 1		
Slide 2	<p><b>Objectives</b></p> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>Identify strategies for promoting adherence to treatment</li> <li>Discuss ethical issues around adherence to treatment</li> </ul> <p>USAID TB CARE II PROJECT 2</p>	<ul style="list-style-type: none"> <li>Review slide contents</li> </ul>
Slide 3	<p><b>Ethical basis for promoting adherence to TB treatment</b></p> <ul style="list-style-type: none"> <li>Providers have obligations to patient and public to support patient's ability to adhere to treatment</li> <li>People with TB have ethical duty to complete therapy</li> <li>However, completing TB treatment can be difficult for patients: <ul style="list-style-type: none"> <li>Lost wages and impacts (food, supporting family etc.)</li> <li>Stigma</li> <li>Side effects</li> </ul> </li> </ul> <p>Partnership is key to success!</p> <p>USAID TB CARE II PROJECT 3</p>	<ul style="list-style-type: none"> <li>Explain that taking TB medications as prescribed is the most essential aspect of TB treatment</li> <li>As discussed previously, adherence to TB treatment: <ul style="list-style-type: none"> <li>protects the patient's own health</li> <li>prevents the further spread of the disease</li> <li>prevents the development of drug-resistant strains</li> </ul> </li> <li>Review slide content</li> <li>Emphasise the need for partnership between providers, patients, and others who can assist in ensuring treatment completion</li> <li>In addition to challenges listed on slide, there are also some costs to patients, as discussed previously in module on access to care (transportation etc.)</li> </ul>

Slide 4	<p><b>Patient-Centred Care</b></p> <p>“Patient-centred care reflects a partnership among practitioners and patients to ensure that decisions respect patients’ wants, needs, and preferences and that patients have the education and support they need to make decisions and participate in their own care. Patient-centered approaches recognise that care is provided along a continuum of services”</p> <p><small>O'Donnell MB, Doherty AD, Fick M, Hirsch-Movsarian Y, Jernicek KR, Sentillogram M, Wolf A, MacCallie JZ, Isaakidis P, Davis L, Ernst JCM, Naidoo N, Garnettson M, Zelnick JR, Bangsberg D, Padayatchi N, Friedland G. Consensus statement on behalf of the attendees of the “Re-inventing adherence: patient-centered care for drug-resistant TB and HIV”, March 19-20, 2015, Columbia Mailman School of Public Health, Columbia University, New York, NY, USA</small></p> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• Note that this definition was provided earlier, but is important to frame the discussion around supporting adherence</li> <li>• Utilising the approach outlined here, as well as creating a partnership with the patient and others is essential in supporting patient adherence</li> <li>• Note that some of the strategies discussed in this presentation should be implemented in a patient centered manner</li> </ul>
Slide 5	<p><b>Directly observed therapy (DOT)</b></p> <ul style="list-style-type: none"> <li>• May improve adherence to treatment</li> <li>• Benefits of DOT can include: <ul style="list-style-type: none"> <li>• Minimising the burden of care on patient</li> <li>• Reducing indirect costs of care, such as time lost from work</li> <li>• Providing encouragement and support for patients</li> <li>• Opportunity for early detection and management of side effects</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Note that there is discussion and debate about this topic, as for diseases such as HIV, DOT is not incorporated</li> </ul>
Slide 6	<p><b>Directly observed therapy (DOT) - 2</b></p> <ul style="list-style-type: none"> <li>• Ethically justifiable when done as part of a patient-centred approach to care: <ul style="list-style-type: none"> <li>• Take steps to avoid the stigmatisation of patient</li> <li>• Give patient choices about who will observe them and where observation will take place</li> <li>• Clearly explain what will happen if patient is non-adherent</li> <li>• Implement mechanisms to promote early detection and proper management of side-effects</li> </ul> </li> </ul> <p>DOT should be process for providing support, motivation, and understanding to patients</p> <p>USAID TB CARE II PROJECT 6</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Provide examples of these approaches:</li> <li>• Avoiding the stigmatisation of patients, for example, through community education on TB</li> <li>• Giving patients choices about who will observe them (and where); the person chosen to do the observation must assume responsibility to ensure that the therapy is completed or, if it is not, to notify the patient's health-care provider;</li> <li>• Clearly explaining what will happen if the patient is non-adherent (e.g. defaulter tracing);</li> <li>• Implementing mechanisms to promote early detection and proper management of side-effects</li> <li>• Directly observed therapy should be seen as a process for providing support, motivation, and understanding to patients. It is a necessary part of TB care, but is not intended to be a method for ‘forcing’ patients to do something against their will</li> </ul>

Slide 7	<p>Promoting adherence through use of incentives and enablers - 1</p> <ul style="list-style-type: none"> <li>Enablers refer to mechanisms or resources that facilitate patients' ability to adhere to treatment</li> <li>Examples include: <ul style="list-style-type: none"> <li>Taxi/bus fare</li> <li>Food baskets</li> </ul> </li> <li>Incentives refer to small rewards to encourage patients to adhere to TB treatment by motivating them with something they want or need</li> <li>Examples include: <ul style="list-style-type: none"> <li>Cash payment</li> <li>Clothing</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>Review slide content</li> </ul>
Slide 8	<p>Promoting adherence through use of incentives and enablers - 2</p> <ul style="list-style-type: none"> <li>Use of incentives and enablers can help mitigate the impact of the social determinants of TB</li> <li>Create opportunities to stay in touch with health care workers or DOT supporters</li> <li>Empower patients to take an active role in their care</li> <li>Promote ethical value of autonomy</li> <li>Should be chosen according to patient's needs and interests</li> <li>Must be provided in an equitable and non-discriminatory way</li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>Review slide content</li> <li>Emphasise that the impacts of social determinant such as poverty may make it difficult to complete a full course of treatment (e.g need to work to provide for family. Enablers can help to counter this by providing food or meeting other needs</li> <li>Note that enablers should be considered carefully in light of ethics: Rather than providing a meal to mothers at the clinic, provision of a food basket will allow her to provide food for her children and family as well</li> <li>Note that learning as much as possible about patients will help to identify their needs and interests and better motivate them to complete treatment. This can help to identify personalised items, which will be of value to the patient</li> </ul>
Slide 9	<p>Promoting adherence through use of incentives and enablers -3</p> <ul style="list-style-type: none"> <li>When to offer: <ul style="list-style-type: none"> <li><b>Enablers:</b> May be vital to the initiation of treatment and should be provided as soon as treatment starts</li> <li><b>Incentives:</b> Best time to begin using incentives is after a good relationship has been established with patient</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 9</p>	<ul style="list-style-type: none"> <li>Review slide content</li> <li>Emphasise that the impacts of social determinant such as poverty may make it difficult to complete a full course of treatment (e.g need to work to provide for</li> </ul>

<div>Slide 10</div>	<div><div>Let's discuss incentives and enablers .....</div><div><div>PLENARY</div><div><ul style="list-style-type: none"><li>What, if any enablers or incentives have you employed to encourage adherence?</li><li>For each of these, what are the trust or ethical concerns identified, and how can these be managed?</li></ul></div></div><div><div>USAID TB CARE II PROJECT</div><div>10</div></div></div>	<ul style="list-style-type: none"><li>This is a plenary discussion, in which all delegates participate</li><li>Refer to the Facilitator Notes for background for this discussion</li><li>Assign 10-15 minutes for the discussion</li><li>Ask that they answer the question, based on their experience</li><li>Remind delegates that there are no right or wrong answers and that all views and opinions should be respected</li><li>Record responses on a flipchart</li><li>At the end, summarise the discussion and point out areas of convergence and divergence with the lesson content and hand out the Supporting Adherence to TB Treatment: Plenary Discussion Delegate Hand-out</li></ul>								
<div>Slide 11</div>	<div><div>Use of incentives for completing treatment: Summary</div><div><table><tr><th>Benefits</th><th>Risks</th></tr><tr><td>Society provide something in return for individual who accepts burden for benefit of community (ethical principle of reciprocity)</td><td>Could seem inappropriate, even insulting, attempt to buy the patient's cooperation</td></tr><tr><td rowspan="3"><div>Provision of incentives should be based on:<ul style="list-style-type: none"><li>Expected efficacy of practice</li><li>Sensitivity to local norms</li></ul></div></td><td>May overlook broader, and ultimately more valuable efforts to address root causes of non-adherence]</td></tr><tr><td>May undermine important efforts in other areas of public health</td></tr><tr><td>May prevent full disclosure of patient concerns, issues due to fear of losing incentives</td></tr></table><div><div>USAID TB CARE II PROJECT</div><div>11</div></div></div></div>	Benefits	Risks	Society provide something in return for individual who accepts burden for benefit of community (ethical principle of reciprocity)	Could seem inappropriate, even insulting, attempt to buy the patient's cooperation	<div>Provision of incentives should be based on:<ul style="list-style-type: none"><li>Expected efficacy of practice</li><li>Sensitivity to local norms</li></ul></div>	May overlook broader, and ultimately more valuable efforts to address root causes of non-adherence]	May undermine important efforts in other areas of public health	May prevent full disclosure of patient concerns, issues due to fear of losing incentives	<ul style="list-style-type: none"><li>The process of treatment involves significant burdens that patients undergo not only for their own benefit but also for the benefit of the community</li><li>According to the ethical principle of reciprocity, when individuals accept burdens for the benefit of the community it is appropriate for society to provide something in return</li><li>Review slide content</li><li>Note that if incentives are offered, it is important to ensure that they are managed carefully. For example, mechanisms should be established to ensure that they are not provided to individuals who do not actually need TB treatment</li><li>In addition, they should not be allocated in a discriminatory or inequitable manner</li></ul>
Benefits	Risks									
Society provide something in return for individual who accepts burden for benefit of community (ethical principle of reciprocity)	Could seem inappropriate, even insulting, attempt to buy the patient's cooperation									
<div>Provision of incentives should be based on:<ul style="list-style-type: none"><li>Expected efficacy of practice</li><li>Sensitivity to local norms</li></ul></div>	May overlook broader, and ultimately more valuable efforts to address root causes of non-adherence]									
	May undermine important efforts in other areas of public health									
	May prevent full disclosure of patient concerns, issues due to fear of losing incentives									
<div>Slide 12</div>	<div><div>Ethical considerations regarding non-adherence - 1</div><div><ul style="list-style-type: none"><li>Ethical obligation to follow up with patients who are having problems with adherence</li><li>Demonstrates commitment to:<ul style="list-style-type: none"><li>Promoting the individual patient's best interests</li><li>Need to protect others in the community from the risks of untreated TB</li></ul></li></ul></div><div><div>USAID TB CARE II PROJECT</div><div>12</div></div></div>	<ul style="list-style-type: none"><li>Review slide content</li></ul>								

Slide 13	<p><b>Ethical considerations regarding non-adherence - 2</b></p> <ul style="list-style-type: none"> <li>• Efforts to contact patients must be carried out in a way that minimises intrusions</li> <li>• At initiation of treatment, patients should be: <ul style="list-style-type: none"> <li>• Informed that they will be contacted if they do not keep appointments</li> <li>• Given a choice about the process by which communication will take place</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 13</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise that efforts to contact patients who do not show up for treatment create a risk of intruding on individuals' privacy and autonomy. These efforts need to be carried out in such a way that minimises intrusions. For example, if health care workers visit TB patients at home, they should not arrive in vehicles that can be identified as belonging to the TB programme</li> <li>• When patients start treatment, they need to be told that they will be contacted if they do not show up for their appointments. The programme will either call them or visit them at home, depending on which method is likely to be effective</li> </ul>
Slide 14	<p><b>Response to non-adherence</b></p> <ul style="list-style-type: none"> <li>• Try a different approach</li> <li>• Try to identify most effective methods and best practices to promote adherence</li> <li>• Reconsider overall approach to treatment, especially if non-adherence is on large scale <ul style="list-style-type: none"> <li>• This may indicate system issues that must be improved</li> </ul> </li> <li>• *Remember the ethical principle of autonomy*</li> </ul> <p>USAID TB CARE II PROJECT 14</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise that if existing strategies for encouraging patients' adherence to treatment do not work, the first response should be to try a different approach. For example, scheduling treatments at a different time, relying more heavily on directly observed therapy, or addressing any possible complicating factors such as drug or alcohol use</li> <li>• Clarify that formal research is not required to determine the most effective methods to promote adherence. Providers can ask patients what would help them, and can also document which methods are most successful</li> <li>• Explain that programmes that frequently experience problems with adherence should reconsider their overall approach to treatment. While isolated cases of non-adherence may reflect patient-specific factors, on a larger scale it suggests that the system has failed to adequately implement a person-centred approach to care</li> <li>• In very rare instances, if all reasonable efforts to promote adherence have failed and the patient still remains infectious, involuntary isolation or detention may be considered, following a clearly defined procedure with approvals and safeguards to protect patient's rights and autonomy. This possibility is discussed below in the section on Involuntary Isolation and Detention</li> </ul>

Slide 15	<p><b>Denying treatment to individuals based on predictions about non-adherence</b></p> <ul style="list-style-type: none"> <li>• No evidence that non-adherence can be accurately predicted</li> <li>• Specific reasons that may impede adherence should be addressed as part of initial discussions about treatment</li> <li>• Distinguish from situations in which conditions in a particular setting are inadequate to support TB programme at all</li> </ul> <p>USAID TB CARE II PROJECT 15</p>	<ul style="list-style-type: none"> <li>• State that it is <b>not</b> ethically acceptable for health care workers to refuse to initiate TB treatment because they think a patient will not adhere to treatment</li> <li>• <i>Review slide content</i></li> <li>• Emphasise that any attempt to predict adherence is likely to be based on inappropriate stereotypes and is inherently unethical</li> <li>• Denying treatment to individual patients based on predictions about non-adherence should be distinguished from situations in which conditions in a particular setting are inadequate to support a TB programme at all, such as settings in which basic needs of adequate water, food, shelter and sanitation cannot be met</li> </ul>
Slide 16	<p><b>Provider's ethical obligations when treatment fails</b></p> <ul style="list-style-type: none"> <li>• Fundamental ethical obligation to avoid abandoning patients for who treatment is not working</li> <li>• Obligation of non-abandonment requires provision of palliative care</li> <li>• Location of care based on an individualised risk assessment <ul style="list-style-type: none"> <li>• Individual's degree of infectiousness</li> <li>• Willingness and ability to comply with infection-control precautions</li> <li>• Presence of children in the home</li> <li>• Preparation and training of community care providers</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 16</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise that the obligation of non-abandonment requires the provision of both chronic and terminal palliative care as needed). The fact that curative treatment is not working does not absolve the provider of responsibility for optimising the patient's comfort and well-being</li> <li>• State that isolation or detention should only be considered as very last resort and will be discussed in detail later in the course</li> </ul>
Slide 17	 <p>USAID TB CARE II PROJECT 17</p>	<ul style="list-style-type: none"> <li>• Check if delegates have any questions and address these</li> <li>• This is the end of the module on 'Supporting Adherence to TB treatment'</li> <li>• Next, we'll be focusing on 'Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment'</li> </ul>

## Facilitator Notes for Module 6 Plenary Discussion: Supporting Adherence to TB Treatment

### Setting the scene

Simply offering a Directly Observed Therapy (DOT) programme is not enough. Patients must agree to participate in taking their medicine and continue to adhere to the treatment regimen through the full course of treatment. Incentives and enablers may help them do this. **Incentives** are small rewards given to patients to encourage them to either take their own medicines or keep their clinic or field DOT appointments. **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties. Incentives and enablers may help patients adhere to and complete treatment.

Incentives and enablers should be chosen according to the patients' special needs and interests, or the patients may not care if they receive them. For example, if the health care worker knows that transportation is a problem, he or she could offer bus or taxi fare as an enabler. If transportation is not a problem, then he or she should offer something that is needed. Learning as much as possible about patients will help to identify their needs and interests and better motivate them to complete treatment. The best time to begin using incentives is after a good relationship has been established with a patient. Enablers, however, may be vital to the initiation of treatment and should be provided when treatment begins. Always start by talking with patients to learn about their needs.

Though many programmes have shown success using incentives and enablers, some health care workers disagree about whether or not incentives should be used. The attitude one has about incentives is important. Some health care workers do not like using incentives because they think patients should want to get well and should consider it their duty to take their medicine. They believe that incentives are bribes. The use of enablers or incentives may draw into the question the patient's motivation for seeking and agreeing to treatment.

At times, patients may also feel that the health care worker is trying to bribe them into accepting treatment. When incentives are used with an attitude of caring and concern for the patient, the patient will be less inclined to question the health care worker's motives. The reason for using incentives is to motivate the patient to complete treatment. Above all, incentives and enablers are not a substitute for a high-quality relationship with patients based on trust, effective communication, and mutual respect.

### Facilitator summary

Incentives may work, but one has to account for several factors before using them. There should be a supportive environment for the use of incentives and enablers to be seen in context. Part of this context is an understanding of and sensitivity to local norms and customs and how one should observe these if incentives and enablers are to be used. Ethical considerations should also be taken into account.

### Tip

Remind delegates that there are no right or wrong answers. In addition, delegates should consider what is in their span of control as they participate in the discussion.

After the plenary discussion, distribute the Supporting Adherence to TB Treatment Delegate Handout.



## 16. Module 7: Gap Between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment

### Facilitation Guide for Module 7: Gap Between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment

#### Time

- 45 minutes

#### Objectives

- Discuss reasons for and challenges with gap between diagnosis and treatment of drug-resistant TB and need to close this gap
- Explain the benefits of drug susceptibility testing in the absence of drug-resistant TB treatment
- Demonstrate why education and counselling forms an essential component of patient care in the absence of drug susceptibility testing and appropriate treatment for drug-resistant TB

#### Techniques

- Lecture
- Plenary discussion
- Case study plenary discussion

#### Materials

- PowerPoint slides
- Flip chart and pens

#### Key Messages

- Appropriate patient education and counselling is necessary in ensuring that patients are empowered to provide informed consent
- Drug susceptibility testing plays an important role, even in the absence of drug-resistant TB treatment

#### Synopsis of module



It is highly desirable and necessary that every country should have point of care rapid diagnostic methods at the outset of the TB diagnostic process *and* the ability to provide appropriate treatment for patients with drug resistant TB. However, drug susceptibility testing is ethically acceptable and appropriate as an interim measure, even when no second or third line drug treatment is available. TB In those locales and countries where capacity to supply rapid drug susceptibility testing is being scaled up, treatment decisions should be made on an individualized basis and should be a consultative process involving multiple practitioners and a patient advocate, if available. It is necessary that education and counselling be provided to patients. It is particularly important that patients provide informed specific consent to diagnostic testing in the absence of treatment. It is important to note that diagnostic testing for drug-resistant TB in the absence of treatment should only be a temporary situation. In these cases it is important to examine why this is case, how long it will continue, and what needs to occur to in order to change the situation.

The discussion in module should be linked to the ethical considerations discussed in Module 5 dealing with Information, Counselling and the Role of Consent.

#### Procedure for running Module 7


1. Present slides for the module and follow the instructions and speaker notes in each slide.

## Slide Kit for Module 7: Gap between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR-TB Treatment

Slide 1	<div style="text-align: center;"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <p><b>MODULE 7: GAP BETWEEN AVAILABILITY OF DRUG SUSCEPTIBILITY TESTING AND ACCESS TO MDR-TB AND XDR-TB TREATMENT</b></p> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<p><b>Objectives</b></p> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>• Discuss reasons for and challenges with gap between diagnosis and treatment of drug-resistant TB and need to address this gap</li> <li>• Explain the benefits of drug susceptibility testing in the absence of drug-resistant TB treatment</li> <li>• Demonstrate why education and counselling forms an essential component of patient care in the absence of drug susceptibility testing (DST) and appropriate treatment for drug-resistant TB</li> </ul> <p>USAID TB CARE II PROJECT <span style="float: right;">2</span></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<p><b>Gap between diagnosis and treatment</b></p> <ul style="list-style-type: none"> <li>• Point-of-care rapid diagnostic methods at the outset of the diagnostic process can revolutionise the treatment of MDR- and XDR-TB by enabling the use of a tailored drug therapy</li> <li>• Countries should ensure that patients diagnosed through these measures are provided access to the most appropriate drugs</li> <li>• Scaling up and providing treatment, including treatment for MDR-TB and XDR-TB is an essential element of providing ethical TB care (universal access to care)</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• Explain that new diagnostic tests such as GeneXpert can confirm TB and drug resistance incredibly rapidly. Since WHO has endorsed the use of these tests for diagnosis of TB, they are being widely implemented globally</li> <li>• However, these tests provide information on drug resistance, and in some cases treatment for MDR-TB may not be available, although the test is being used</li> <li>• <i>Review slide content</i></li> </ul>

Slide 4	<p><b>Gap between diagnosis and treatment -2</b></p> <ul style="list-style-type: none"> <li>While countries are in the process of scaling up treatment for MDR/XDR-TB, the use of drug susceptibility testing may be appropriate</li> <li>May be used as an <b>interim measure</b> even where: <ul style="list-style-type: none"> <li>Second- or third-line drug treatment is not available</li> <li>The only available treatment is substandard</li> </ul> </li> <li>Patients <b>MUST</b> be asked to provide informed consent for diagnostic testing in absence of treatment</li> <li>Countries, TB Programmes and providers should focus on ensuring adequate treatment is available for all who are diagnosed with drug-resistant TB</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li><i>Review slide content</i></li> <li>Emphasise that countries that implement diagnostic testing in the absence of treatment should do so only as a temporary measure, and should establish a timetable for when treatment for MDR- and XDR-TB will be made available</li> </ul>
Slide 5	<p><b>Ethical approach to scaling up MDR/XDR-TB treatment</b></p> <ul style="list-style-type: none"> <li>3 AQ Principles should be incorporated as universal access to care for drug resistant is implemented in countries is scaled up and implemented</li> <li><b>Availability:</b> Facilities, goods and services and programmes are available in sufficient quantity</li> <li><b>Accessibility:</b> Facilities, goods and services are accessible to all (non-discrimination, physical, economic, and information accessibility)</li> <li><b>Acceptability:</b> Respectful of medical ethics, culturally appropriate, respect of confidentiality</li> <li><b>Quality:</b> Scientifically and medically appropriate and of good quality; skilled medical personnel, scientifically approved and unexpired drugs and hospital equipment, safe water, sanitation</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>State that as countries implement rapid testing for drug resistant TB and then implement treatment on a large scale it is important to consider ethical components and approach, especially the 3 AQ principles discussed earlier</li> <li><i>Review slide content</i></li> <li>Emphasise that all of these elements must be considered when providing MDR-TB care. Though countries may feel urgency to offer this treatment to all at the local level, it is essential to consider mechanisms for providing this treatment in an ethical and respectful way</li> <li><b>For example, in order to provide acceptable quality care for drug-resistant TB at the local or primary care level, adequate training must be provided for health care workers at who will be involved</b></li> </ul>
Slide 6	<p><b>Benefits of offering drug susceptibility testing in absence of treatment</b></p> <ul style="list-style-type: none"> <li>Provide evidence of a high prevalence of MDR- and XDR-TB</li> <li>Ensure that individuals with M/XDR-TB are not inappropriately treated with regular TB drugs</li> <li>Guide decisions about segregating TB patients being cared for in a closed environment</li> <li>Help individuals make life plans, diminish impact of disease on family members, and inform important behaviour regarding infection control</li> </ul> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>State there are benefits to offering drug-susceptibility testing, even when treatment is not currently available</li> <li><i>Review slide content</i></li> </ul>

Slide 7	<p>What happens in your setting?</p> <p><b>PLENARY</b></p> <ol style="list-style-type: none"> <li>1. Is there access to drug susceptibility testing for patients? <ul style="list-style-type: none"> <li>• If no, why not, what can be done to change this?</li> </ul> </li> <li>2. Is treatment available for MDR-/XDR-TB? <ul style="list-style-type: none"> <li>• If no, Why not and what can be done to change this (especially in cases where DST IS available?)</li> <li>• If yes, how do you manage and treat patients?</li> </ul> </li> <li>3. If MDR-/XDR Treatment is available, is it provided in a way that is accessible to patients? (in light of human rights context of non-discrimination, physical, economic, and information accessibility) <ul style="list-style-type: none"> <li>• If no, why not, what can be done to change this?</li> <li>• If yes what have been the challenges in providing this access and how were they addressed?</li> </ul> </li> </ol> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>• This is a plenary discussion, in which all delegates participate</li> <li>• Allow 15 minutes for this discussion</li> <li>• Start with the first question and ask delegates to answer based on their work setting. Proceed through the questions if appropriate, based on answers from delegates</li> <li>• Remind delegates that there are no right or wrong answers and that all views and opinions should be respected</li> <li>• Record responses on a flipchart</li> <li>• At the end, summarise the discussion</li> </ul>
Slide 8	<p>Making ethically appropriate treatment decisions in absence of DST</p> <ul style="list-style-type: none"> <li>• Ideally all patients should undergo rapid drug-resistance testing in order to ensure provision of appropriate treatment regimens</li> <li>• Approach benefits to both patients and community <ul style="list-style-type: none"> <li>• Reduces risk of further spread of TB</li> <li>• Reduces development of drug-resistant TB strains</li> </ul> </li> <li>• For resource-constrained countries that cannot meet obligation to provide drug susceptibility testing on their own <ul style="list-style-type: none"> <li>• International community should provide financial and other support, in keeping with the ethical principles of social justice and equity</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>• As emphasised previously in the section on the Obligation to provide Access to TB Services, countries and TB programmes should provide universal, free access to drug susceptibility testing</li> <li>• <i>Review slide content</i></li> </ul>
Slide 9	<p>Making ethically appropriate treatment decisions in absence of DST</p> <p>For countries that are still scaling up their capacity</p> <ul style="list-style-type: none"> <li>• Treatment decisions should be made on an individualised basis based on: <ul style="list-style-type: none"> <li>• Local epidemiology</li> <li>• Patient specific factors</li> </ul> </li> <li>• Decisions should ideally be made in consultative process involving: <ul style="list-style-type: none"> <li>• Multiple practitioners</li> <li>• Patient advocate (when available)</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 9</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>

Slide 10	<p><b>Making ethically appropriate treatment decisions in absence of DST</b></p> <p>For patients</p> <ul style="list-style-type: none"> <li>• Education and counselling should be offered; this will ensure that:             <ul style="list-style-type: none"> <li>• Patients are fully informed</li> <li>• Informed consent has been provided prior to testing</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 10</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 11	<p><b>CASE STUDY</b> Let's discuss.....</p> <p>A 29 year old patient, who lives in a community where there is a high prevalence of drug-resistant TB has just been diagnosed with TB. She has three children, aged 7, 4 and 18 months. Her husband works in the mines and lives in the mining hostel. He returns home once every quarter. He has been losing weight and has not been able to work. She last had an HIV test when she was pregnant with her youngest child (which was negative). Her mother-in-law and her husband's niece, who is 16, lives with her. Presently, there are no drug susceptibility testing facilities available at the hospital.</p> <ul style="list-style-type: none"> <li>• What steps would you take for the treatment, care and support of the patient?</li> <li>• How would you counsel the patient?</li> </ul> <p>USAID TB CARE II PROJECT 11</p>	<ul style="list-style-type: none"> <li>• NOTE: You may choose to modify this case study in advance of this course so it reflects the current situation in your country</li> <li>• Inform delegates that this case study will take the form of a plenary discussion, which should last no longer than 15 minutes</li> <li>• Ask for a volunteer to read the case study out loud, then use the questions to lead the discussion</li> <li>• Record the discussion using the flip chart</li> <li>• At the end, summarise the discussion and point out areas of convergence and divergence with the lesson content</li> <li>• <b>Remind delegates that the patient should be at the centre of the decision-making</b></li> <li>• Appropriate education and counselling should be provided to the patient</li> </ul>
Slide 12	 <p>USAID TB CARE II PROJECT 12</p>	<ul style="list-style-type: none"> <li>• Check if delegates have any questions and address these</li> <li>• This is the end of the module on the 'Gap Between the Availability of Drug Susceptibility Testing and Access to MDR- and XDR- TB Treatment'</li> <li>• Next, we'll be focusing on 'Health care Workers' Rights and Obligations'</li> </ul>



## 17. Module 8: Health Care Worker Rights and Obligations

### Facilitation Guide for Module 8: Health Care Worker Rights and Obligations

#### Time

- 45 minutes

#### Objectives

- Discuss the ethical obligations health care workers have to care for patients at risk of or those with TB
- Describe the rights of health care workers who care for patients at risk of or those with TB

#### Techniques

- Lecture
- Group discussion

#### Materials

- PowerPoint slides
- Activity 4: Health Care Worker Rights and Obligations Delegate Hand-out
- Flipchart and pens

#### Key Messages

- There is an obligation to provide a safe working environment for health care workers who care for patients at risk of or those with TB
- Health care workers have the right to expect effective policies, practices and high quality care to protect their health

#### Synopsis of module

Health care workers have an ethical obligation to provide care to patients, even if doing so involves some degree of risk. But there are limits on the degree of risk that they can reasonably be expected to take. Further, any consideration of health care workers' obligations to provide care must consider the reciprocal obligations of governments and health care facilities to provide at least minimum standards of safety. With these standards in place, and with reasonable training, supplies, equipment, infrastructure, support and access to proven methods of care and treatment, it is not reasonable for health care workers to refuse to look after patients with TB. An exception to this expectation may be health care workers who are at higher risks of contracting TB because, for example, they are HIV positive. The duty to care for patients is based partly on the duty of health care systems to fulfil their reciprocal obligations to health care workers and patients. Should these not be met, the workers could face significant risks from interacting with patients. As a result, they are not acting unethically should they decide not to work..



The discussion in this module should be linked to the ethical considerations discussed in Module 5 dealing with Information, Counselling and the Role of Consent.



### Procedure for running Module 8

1. Ensure that you have printed a copy of the Activity 4: Health Care Worker Rights and Obligations Delegate Hand-out for each delegate, which can be found in the Delegate Hand-out section
2. Present slides for the module and follow the instructions and speaker notes in each slide
3. Use the Facilitator's Instructions below to run Activity 4

## Slide Kit for Module 8: Health Care Worker Rights and Obligations

Slide 1	<div data-bbox="378 325 865 577"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <h4>MODULE 8: HEALTH CARE WORKER RIGHTS AND OBLIGATIONS</h4> </div> <div data-bbox="321 594 917 667"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 667 917 741"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<div data-bbox="358 846 482 877"> <h4>Objectives</h4> </div> <div data-bbox="358 909 878 1060"> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>• Discuss the ethical obligations health care workers have to care for patients at risk of or those with TB</li> <li>• Describe the rights of health care workers who care for patients at risk of or those with TB</li> </ul> </div> <div data-bbox="342 1213 501 1228"> <p>USAID TB CARE II PROJECT</p> </div> <div data-bbox="800 1203 808 1213"> <p>2</p> </div>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<div data-bbox="358 1350 771 1381"> <h4>International Standards for TB Care</h4> </div> <div data-bbox="358 1413 833 1501"> <p>Emphasises responsibility of providers:</p> <ul style="list-style-type: none"> <li>• Be aware of individual and population risk factors</li> <li>• Reduce diagnostic delay</li> </ul> </div> <div data-bbox="342 1717 501 1732"> <p>USAID TB CARE II PROJECT</p> </div> <div data-bbox="675 1675 857 1686"> <p><small>International Standards for TB Care, Third Edition, 2014</small></p> </div> <div data-bbox="800 1707 808 1717"> <p>3</p> </div>	<ul style="list-style-type: none"> <li>• State that everyone has right to a minimum standard of health care</li> <li>• The addition of the new standard in the 2014 edition of the International Standards for TB Care further emphasises the responsibility of providers</li> <li>• <i>Review slide content</i></li> </ul>

Slide 4	<p>Ethical principles and health care worker obligations to care for TB patients - 1</p> <ul style="list-style-type: none"> <li>• Ethical obligation to provide care to patients</li> <li>• Limits to degree of risk that can be reasonably expected</li> <li>• May have multiple obligations that must be balanced against their job-related duties</li> </ul> <p>USAID TB CARE II PROJECT 4</p>	<ul style="list-style-type: none"> <li>• Review slide content</li> </ul>
Slide 5	<p>Ethical principles and health care worker obligations to care for TB patients - 2</p> <ul style="list-style-type: none"> <li>• Should not be expected to assume risks: <ul style="list-style-type: none"> <li>• That can be avoided by the adoption of basic infection control measures</li> <li>• When there is no reasonable possibility of benefit for those for whom they are providing care</li> </ul> </li> <li>• Obligations must also consider <b>reciprocal obligations</b> of governments and health care facilities to provide minimum standards of safety</li> </ul> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>• Review slide content</li> </ul>
Slide 6	<p>Risks vs. responsibilities</p> <p>Legitimate expectation for health care worker to care for patients with TB when provided with:</p> <ul style="list-style-type: none"> <li>• Reasonable training</li> <li>• Supplies</li> <li>• Equipment</li> <li>• Infrastructure</li> <li>• Support</li> <li>• Access to proven methods of care and treatment</li> </ul> <p>Governments have an obligation to ensure that support is provided</p> <p>USAID TB CARE II PROJECT 6</p>	<ul style="list-style-type: none"> <li>• State that in general, risks associated with caring for patients with TB are not sufficiently great to absolve health care workers of their duty of care</li> <li>• Review slide content</li> </ul>

Slide 7	<p><b>Dealing with greater risks</b></p> <ul style="list-style-type: none"> <li>• Expectations may not be appropriate if health care workers' risk of contracting TB infection high <ul style="list-style-type: none"> <li>• Unless working conditions adequately protect from TB exposure</li> </ul> </li> <li>• If at heightened risk of danger: <ul style="list-style-type: none"> <li>• Attempt to ensure that patients are not abandoned</li> <li>• Transfer patient responsibilities to other providers</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>• Explain that some health care workers have a higher risk of contracting a TB infection, such as those who are HIV positive</li> <li>• <i>Review slide content</i></li> </ul>
Slide 8	<p><b>GROUP</b> <b>Let's discuss...</b></p> <p><b>What potential gaps and challenges could prevent HCWs from being protected when managing people at risk of or those with TB?</b></p> <ul style="list-style-type: none"> <li>• Divide into groups, based on instructions</li> <li>• Move to the place designated for your group</li> <li>• Nominate a spokesperson, note-taker and timekeeper for the group</li> <li>• Read through the question and information provided in the section titled 'Setting the Scene' in the Health Care Worker Rights and Obligations: Activity 4 Delegate Hand-out</li> <li>• Discuss the question in your small group</li> <li>• Prepare a group response in preparation for the plenary discussion</li> </ul> <p>USAID TB CARE II PROJECT 8</p>	<ul style="list-style-type: none"> <li>• See Activity 4 in the Facilitator Guide for guidance on how to run this activity</li> <li>• This is a group discussion, which should take approximately 25 minutes</li> <li>• Ask delegates to refer to the slide for instructions on how the activity will be run</li> <li>• State that health care workers work under extremely difficult conditions as a result of the challenges facing the health care system, including amongst others the shortage of health care workers across the board, increasing population, the high burden of disease especially human immuno-deficiency virus (HIV) and tuberculosis (TB), and deteriorating health care infrastructure</li> <li>• Ask delegates to discuss the gaps and challenges that prevent health care works from being protected when they care for patients who are at risk of TB or who have TB</li> <li>• Inform them that the instructions are also available in the Health Care Worker Rights and Obligations: Activity 4 Delegate Hand-out and that they should refer to it</li> <li>• Ensure that delegates understand the instructions and clarify any misunderstanding</li> <li>• Ask delegates to separate into groups of 4-5</li> <li>• Set aside 10 minutes for the small group discussion</li> <li>• Spend 10 minutes on getting feedback from the groups and the plenary discussion, allowing yourself 2-3 minutes to summarise</li> </ul>

Slide 9	<p><b>Reciprocal obligations to health care workers</b></p> <ul style="list-style-type: none"> <li>• Provide training, equipment, and protection</li> <li>• Give skills and information necessary to assess risks so that proper precautions may be taken</li> <li>• Provide access to TB diagnosis, including TB screening, for those living with HIV</li> <li>• Identify and treat those with active TB, using the best proven treatment</li> </ul> <p>USAID TB CARE II PROJECT 9</p>	<ul style="list-style-type: none"> <li>• State that the duty of care does not exist in a vacuum</li> <li>• Rather, it depends on the provision of goods and services by governments and health-care institutions</li> <li>• If these important reciprocal obligations are not fulfilled, provision of appropriate TB care may not even be possible</li> <li>• Review slide content by linking to the key outcomes from the discussion</li> <li>• Health care workers who are not themselves in good health will not be able to properly look after their patients</li> <li>• For these reasons, health care systems have obligations to health care workers who provide care to patients with TB</li> </ul>
Slide 10	<p><b>Reciprocal obligations to health care workers (continued)</b></p> <ul style="list-style-type: none"> <li>• Clearly articulate: <ul style="list-style-type: none"> <li>• Expectations about the working conditions</li> <li>• Specific roles they are expected to assume</li> <li>• Risks inherent in those situations</li> </ul> </li> <li>• Appropriately compensate for services: <ul style="list-style-type: none"> <li>• Danger pay and insurance for themselves and their families</li> <li>• Disability pay for those who become infected</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 10</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 11	<p><b>Health care worker obligations when reciprocal obligations are unfulfilled</b></p> <ul style="list-style-type: none"> <li>• Not unethical to decide not to work</li> <li>• System, not the individual worker, that is ethically responsible</li> <li>• Appeal to those in a position to make changes</li> <li>• Governments and health care systems have an obligation to ensure that care can be provided safely</li> </ul> <p>USAID TB CARE II PROJECT 11</p>	<ul style="list-style-type: none"> <li>• Explain that the duty to care is based partly on the duty of health systems to fulfill their reciprocal obligations</li> <li>• If these are not met and, as a result, health care workers would face significant risks from interacting with patients, they do not act unethically by deciding not to work</li> <li>• <i>Review slide content</i></li> </ul>

Slide 12



USAID TB CARE II PROJECT

12

- Check if delegates have any questions and address these
- This is the end of the module on 'Health Care Workers' Rights and Obligations'
- Next, we'll be focusing on 'Involuntary Isolation and Detention as Last-Resort Measures'

## Facilitator Instructions for Activity 4: Health Care Worker Rights and Obligations

### Objective

To inform health care workers, particularly those providing TB prevention, testing, treatment, care and support to patients at facility level, that they too have the right to expect a minimum standard of care

### Question

What potential gaps and challenges could prevent health care workers from being protected when managing people at risk of or those with TB?

### Time Allotted

25 minutes

- 5 minutes for instructions and dividing delegates into groups
- 10 minutes of small group discussion
- 10 minutes for plenary discussion

### Materials Needed

- Activity 4: Health Care Worker Rights and Obligations Delegate Hand-out
- Flipchart and pens to record small group and plenary discussions

### Procedure for running activity

1. Remind delegates that the ground rules established for the first activity still apply
2. Separate the delegates into groups of 4 or 5 people
3. Ask them to go to the designated areas
4. Tell the groups that they will have to provide feedback in a plenary discussion and that they should nominate a spokesperson, note-taker and time-keeper
5. Inform the groups that the note-taker should summarise the group's discussion in preparation for the plenary discussion
6. Provide each delegate with a hand-out called Activity 4: Health Care Worker Rights and Obligations Delegate Hand-out
7. Give the groups 10 minutes to discuss the questions posed
8. Provide a time check to the groups when they have 5 minutes and then 2 minutes remaining
9. Ask the spokesperson from each group to provide feedback, based on the responses
10. Facilitate a plenary discussion and ask for suggestions on how these gaps and challenges might be addressed or what actions health care workers could take in these situations
11. Provide summary points from Tips section

### Setting the Scene

Health care workers play an essential role in the provision of health care services. Their core role is to care for the sick and injured. They are often viewed as 'immune' to injury or illness, as they are called upon to put patients first. This places them at much higher risk of exposure to viruses, bacteria and parasites, which can be transmitted through the air or through body fluids such as TB, HIV and Hepatitis B.

Their risk of exposure to TB specifically may be increased by less than optimal working conditions such as overcrowding, poor ventilation, inadequate infection control measures and insufficient personal protective equipment.

It is recognised that protecting health care workers also contributes to quality care. Some of the same measures to protect patients from infections should be instituted to protect health care workers.

Consider what minimum requirements you believe should be met for you to effectively care for patients who are risk of TB or who have TB.

### Tip

Some of the issues that may be raised through the discussion include:

- Refusal of health care workers to provide care for infectious patients, especially when there are concerns relating to MDR- or XDR-TB
- Compensation for contracting TB
- Extended sick leave should TB be contracted
- Expected administrative, environmental, social protection

Remind delegates that they should raise issues relating to their safety and concerns with their supervisory and management structures should they believe that adequate protection is not provided.



## 18. Module 9: Involuntary Isolation and Detention as Last-Resort Measures

### Facilitation Guide for Module 9: Involuntary Isolation and Detention as Last-Resort Measures

#### Time

- 45 minutes

#### Objectives

- Describe how a person-centred approach will help patients understand the benefits of TB treatment to themselves, their families and communities
- Discuss the specific ethical principles and criteria to be utilised in situations where involuntary isolation is being considered

#### Techniques

- Lecture
- Individual activity

#### Materials

- PowerPoint slides
- Activity 5: Involuntary Isolation and Detention as Last-Resort Measures Delegate Hand-out
- Flip chart and pens

#### Key Messages

- Engaging patients in decisions around treatment increases their adherence to treatment
- Involuntary isolation or detention should only be employed as a last resort measure and in compliance with ethical and human rights principles

#### Synopsis of module



TB treatment should be provided on a voluntary basis, with the patient's informed consent and co-operation. There are, however, exceptional cases where patients will not adhere to the prescribed course of treatment or may be unwilling or unable to comply with infection control measures. Detention should never be a routine component of TB programmes. In these cases it may be justifiable, in order to safeguard the community, to isolate or detain the patient involuntarily, following an established protocol developed to balance the need to protect the health of the public and the individual rights of patients. Patients who decline treatment and pose a risk to others should be made aware in advance that their continued refusal may result in compulsory isolation or detention. When implemented, programmes should ensure that it takes place in adequate settings with reasonable social support provided to isolated patients. As well, the ethical and human rights principles (Siracusa Principles and 2010 WHO guidance on treatment of tuberculosis) should be applied in such cases. Patients in isolation should be offered treatment but not be compelled to accept it. Their informed refusal should be respected since in isolation they are no longer a public health risk and as a practical matter, it would be impossible to provide effective treatment without the patient's co-operation.

The discussion in this module should be linked to both the ethical values discussed in Module 3 dealing with Overarching Goals and Ethical Values, as well as the role of information and counselling described in Module 5.

#### Procedure for running Module 9

- Ensure that you have printed a copy of the Activity 5: Involuntary Isolation and Detention as Last-Resort Measures Delegate Hand-out for each delegate, which can be found in the Delegate Hand-out section
- Present slides for the module and follow the instructions and speaker notes in each slide
- Use the Facilitator's Instructions below to run Activity 5

Slide Kit for Module 9: Involuntary Isolation and Detention as Last-Resort Measures

Slide 1	<div data-bbox="378 218 854 468"> <h1>Ethics of Tuberculosis Prevention, Care and Control</h1> <h2>MODULE 9: INVOLUNTARY ISOLATION AND DETENTION AS LAST RESORT MEASURES</h2> </div> <div data-bbox="321 478 898 625"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<div data-bbox="326 730 898 1119"> <h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>Describe how a person-centred approach will help patients understand the benefits of TB treatment to themselves, their families and communities</li> <li>Discuss the specific ethical principles and criteria to be utilised in situations where involuntary isolation is being considered</li> </ul> <p>USAID TB CARE II PROJECT</p> <p>2</p> </div>	<ul style="list-style-type: none"> <li>Review slide contents</li> </ul>
Slide 3	<div data-bbox="326 1224 898 1612"> <h3>Let's discuss...</h3> <div> <div> <h4>INDIVIDUAL</h4> </div> <div> <h4>Instructions</h4> <ul style="list-style-type: none"> <li>Read through the information provided in the section titled 'Setting the Scene' in the Involuntary Isolation and Detention as a Last-Resort Measure: Activity 5 Delegate Hand-out</li> <li>Spend 5 minutes thinking about and writing down your answers to the questions in the space provided in the Delegate Hand-out</li> <li>Hand over your completed Hand-out to the facilitator</li> </ul> </div> <div> <h4>Think about</h4> <ul style="list-style-type: none"> <li>Is involuntary detention of patients ever acceptable?</li> <li>If so, under what conditions?</li> </ul> </div> </div> <p>USAID TB CARE II PROJECT</p> <p>3</p> </div>	<ul style="list-style-type: none"> <li>Ask delegates to refer to the slide for instructions on how the activity will be run</li> <li>Inform them that the instructions are also available in the Involuntary Isolation and Detention: Activity 5 Delegate Hand-out and that they should refer to it</li> <li>Ensure that delegates understand the instructions and clarify any misunderstanding</li> <li>State that:</li> <li>TB control programmes operate within a complex legal framework that balances the civil rights of individuals with society's need for protection.</li> <li>A dialogue between medical and legal professionals is necessary to ensure that whatever legal steps are taken to address patient non-adherence strike the appropriate balance with modern constitutional guarantees of privacy, liberty, and non-discrimination. These issues are the same whether a patient has drug-susceptible or drug-resistant TB</li> </ul>

		<ul style="list-style-type: none"> <li>For those few patients who, for whatever reasons, continue to pose a risk to the public despite all efforts to address their barriers, ethical and legal options are needed to ensure that these patients do not continue to put others in the community at risk</li> </ul>
Slide 4	<p><b>Engaging the patient about treatment decisions</b></p> <ul style="list-style-type: none"> <li>TB treatment should be provided on a voluntary basis, with the patient's informed consent and cooperation</li> <li>Utilising a person-centred approach, incorporating education, counselling and support: <ul style="list-style-type: none"> <li>Shows respect</li> <li>Promotes autonomy</li> <li>Improves likelihood of adherence</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 4</p>	<ul style="list-style-type: none"> <li><i>Review slide content</i></li> <li>State that non-adherence is often the direct result of failure to engage the patient fully in the treatment process</li> </ul>
Slide 5	<p><b>Community-based care and treatment - 1</b></p> <ul style="list-style-type: none"> <li>Treating TB patients at home with appropriate infection measures generally imposes no substantial risk to other household members <ul style="list-style-type: none"> <li>When diagnosis is made, household contacts have already been exposed</li> <li>Risk of infection is reduced once effective treatment is initiated</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 5</p>	<ul style="list-style-type: none"> <li>Explain that for patients who are willing to undergo treatment, isolation and detention are usually neither necessary nor appropriate</li> <li>Community-based care should <b>always</b> be considered before isolation or detention is contemplated</li> <li><i>Review slide content</i></li> </ul>

Slide 6	<p><b>Community-based care and treatment - 2</b></p> <ul style="list-style-type: none"> <li>• Successfully implemented in a number of different settings, including for patients with MDR- and XDR-TB</li> <li>• Important to institute services and support structures to ensure that community-based care is as widely available as possible</li> </ul> <p>USAID TB CARE II PROJECT 6</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> <li>• Emphasise that countries and TB programmes should put in place services and support structures to ensure that community-based care is as widely available as possible</li> <li>• Remind participants that this approach is consistent with the 3AQ principles discussed earlier</li> </ul>
Slide 7	<p><b>Ethical acceptability of involuntary isolation and detention</b></p> <ul style="list-style-type: none"> <li>• Detention should NEVER be a routine component of TB programmes</li> <li>• Interests of community members may justify efforts to isolate or detain patient involuntarily if patients: <ul style="list-style-type: none"> <li>• Do not adhere to the prescribed course of treatment</li> <li>• Are unwilling or unable to comply with infection control measures</li> </ul> </li> <li>• Involuntary isolation and detention must be carefully limited and used only as very last resort, in certain specific conditions only after all voluntary measures to isolate such a patient have failed</li> </ul> <p>USAID TB CARE II PROJECT 7</p>	<ul style="list-style-type: none"> <li>• State that while there has been a great deal of publicity about isolated cases of TB patients unwilling to undergo treatment, it is important to remember that these cases are highly infrequent occurrences</li> <li>• Individuals who have been properly counseled about the risks and benefits of TB treatment rarely refuse care, and adherence is not usually a problem if appropriate support is provided</li> <li>• The reason many countries are struggling with high rates of TB infection is not that a few individuals refuse to take their TB medications, but rather that access to high-quality TB diagnosis and treatment is too often unavailable</li> <li>• <i>Review slide content</i></li> <li>• Reinforce that any programme that experiences frequent refusals of care, or significant problems with adherence, should take a hard look at whether it is doing everything it can to implement the person-centred approach described during this training</li> </ul>

Slide 8	<p><b>Ethical acceptability of involuntary isolation and detention -2</b></p> <ul style="list-style-type: none"> <li>• Safeguards should be applied to the manner in which involuntary isolation or detention is implemented</li> <li>• Applicable ethical and human rights principles must be considered and applied in the very rare cases where involuntary isolation and detention is being considered</li> <li>• Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights, 1985 <ul style="list-style-type: none"> <li>• Should be used to examine whether the necessary protections exist to restrict individual rights (i.e. detention)</li> </ul> </li> </ul> <p><small>United Nations Economic and Social Council, Siracusa principles on the limitation and derogation of provisions in the International Covenant on Civil and Political Rights, U.N. Doc. E/CN.4/1985/4, Annex, 1985</small></p> <p><small>USAID TB CARE II PROJECT</small></p>	<ul style="list-style-type: none"> <li>• Review slide content</li> </ul>
Slide 9	<p><b>Siracusa Principles</b></p> <ul style="list-style-type: none"> <li>• Restriction is provided for and carried out in accordance with the law</li> <li>• Restriction is in the interest of a legitimate objective of general interest</li> <li>• Restriction is strictly necessary in a democratic society to achieve the objective</li> <li>• There are no less intrusive and restrictive means available to reach the same objective</li> <li>• Restriction is based on scientific evidence and not drafted or imposed arbitrarily i.e. in an unreasonable or otherwise discriminatory manner</li> </ul> <p><b>Each of these criteria must be met and restrictions should be of a limited duration and subject to review and appeal</b></p> <p><small>USAID TB CARE II PROJECT</small></p>	<ul style="list-style-type: none"> <li>• Review slide content</li> </ul>
Slide 10	<p><b>Summary: Applying ethical principles in involuntary isolation or detention -1</b></p> <p>Limited to exceptional circumstances when an individual:</p> <ul style="list-style-type: none"> <li>• Is <b>known</b> to be <b>contagious</b>, <b>refuses treatment</b>, and all reasonable measures to ensure adherence have been attempted and proven <b>unsuccessful</b></li> <li>• Is <b>known</b> to be <b>contagious</b>, has <b>agreed to ambulatory treatment</b>, but <b>lacks capacity to institute infection control</b> in home</li> <li>• Is <b>highly likely</b> to be <b>contagious</b> (based on symptoms and evidence of epidemiological risk factors) but <b>refuses</b> to undergo <b>assessment</b> of his/her infectious status</li> </ul> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>10</small></p>	<ul style="list-style-type: none"> <li>• Review slide content</li> </ul>

Slide 11	<p>Summary: Applying ethical principles in involuntary isolation or detention - 2</p> <ul style="list-style-type: none"> <li>Follow ethical and human rights principles (Syracusa Principles)</li> <li>Limit scope of government authority</li> <li>Provide due process protections for individuals whose liberty may be restricted</li> <li>Develop clear criteria and procedures for the use of non-voluntary measures, with involvement from TB patients and civil society</li> </ul> <p>USAID TB CARE II PROJECT 11</p>	<ul style="list-style-type: none"> <li>Review slide content</li> </ul>
Slide 12	<p>Summary: Applying ethical principles in involuntary isolation or detention - 3</p> <ul style="list-style-type: none"> <li>In rare event that isolation or detention is to be used: <ul style="list-style-type: none"> <li>Ensure adequate settings (other rights, eg health, food, housing must be maintained)</li> <li>Apply appropriate infection control measures</li> <li>Provide reasonable social supports to isolated patients and their dependents</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 12</p>	<ul style="list-style-type: none"> <li>Emphasise that these principles are not just legal obligations; they also reflect important ethical values</li> <li>Other ethical values, such as reciprocity, should also be respected</li> <li>Review slide content</li> </ul>
Slide 13	<p>Compelling treatment over patient objections</p> <ul style="list-style-type: none"> <li>NEVER appropriate to compel treatment <ul style="list-style-type: none"> <li>Violates ethical principal of autonomy</li> </ul> </li> <li>Address risks to public through isolation</li> <li>Informed refusal of treatment in isolated patients should be respected</li> </ul> <p>Practically, not possible to provide effective treatment without the patient's cooperation</p> <p>USAID TB CARE II PROJECT 13</p>	<ul style="list-style-type: none"> <li>Review slide content</li> <li>Explain that while persons with infectious TB who do not adhere to treatment or who are unable or unwilling to comply with infection control measures can pose significant risks to the public, those risks can be addressed by isolating the patient</li> <li>Patients who are isolated should be offered the opportunity to receive treatment, but if they do not accept, their informed refusal should be respected, as the isolated patient no longer presents a public health risk</li> <li>Forcing these patients to undergo treatment over their objection would require a repeated invasion of bodily integrity, and could put health care providers at risk</li> </ul>

Slide 14



USAID TB CARE II PROJECT

14

- Check if delegates have any questions and address these
- This is the end of the module on 'Involuntary Isolation and Detention as Last-Resort Measures'
- Next, we'll be focusing on 'Research on TB Care and Control'



## Facilitator Instructions for Activity 5: Involuntary Isolation and Detention as Last-Resort Measures

### Objective

To sensitise health care workers to the ethical concerns regarding involuntary isolation and detention of patients

### Question

Is involuntary detention of patients ever acceptable? If so, under what conditions would it be acceptable?

### Time Allotted

20 minutes

- 5 minutes for instructions
- 5 minutes for individual activity
- 10 minutes for plenary discussion

### Materials Needed

- Flip chart and pens to record plenary discussion
- Activity 5: Involuntary Isolation and Detention as Last-Resort Measures Delegate Hand-out

### Procedure for running activity

1. Provide delegate with hand-out called Activity 5: Involuntary Isolation and Detention as Last-Resort Measures Delegate Hand-out
2. Inform them that they have 5 minutes to fill in the answers in the Delegate Hand-out
3. Collect the completed Hand-outs
4. Spend a few minutes collating the responses. If you have a co-facilitator, ask him/her to collate and group the responses. These should be written up on a flipchart
5. Facilitate a plenary discussion based on the responses captured
6. Provide summary points from under Tips section

### Setting the Scene

TB control programmes operate within a complex legal framework that balances the civil rights of individuals with society's need for protection.

A dialogue between medical and legal professionals is necessary to ensure any legal steps taken to address patient non-adherence, strike the appropriate balance with modern constitutional guarantees of privacy, liberty, and non-discrimination. These issues are the same whether a patient has drug-susceptible or drug-resistant TB.

For those few patients who, for whatever reasons, continue to pose a risk to the public despite all efforts to address their barriers to initiating and adhering to treatment, ethical and legal options are needed to ensure that these patients do not continue to put others in the community at risk.

Tip

Isolation or detention should never be implemented as a form of punishment. Patients who decline treatment and who pose a risk to others should be made aware in advance that their continued refusal may result in compulsory isolation or detention.

Reinforce that, with appropriate support, adherence to treatment is not usually a problem.

## 19. Module 10: Research on TB Care and Control

### Facilitation Guide for Module 10: Research on TB Care and Control

#### Time

- 30 minutes

#### Objectives

- Demonstrate how the application of ethical principles in research protects patients in general and vulnerable populations in particular
- Describe the ethical considerations around public health surveillance activities

#### Techniques

- Lecture

#### Materials

- PowerPoint slides

#### Key Messages

- While research in TB care and control is of vital importance, it should be grounded in and governed by ethical principles
- Individuals and communities involved in public health surveillance should be informed about these activities and any potential issues that could negatively impact on maintaining patient confidentiality

#### Synopsis of module


A greater commitment to research on TB prevention and treatment and improving the standard of care is required. These greater research efforts should be informed by relevant principles of research ethics articulated by organisations such as the WHO and Joint United Nations Programme on HIV/AIDS. Amongst others, these principles set out guidance for designing ethical research strategies which include considerations such as involving all stakeholders in the design and implementation of studies, keeping participants informed of research findings and the application of the findings, amongst others. Further, investigators doing epidemiological research on TB which involves the use of medical records and blood samples need to be aware of the ethical considerations such as informed patient consent. In the case of public health surveillance, participation in surveillance activities is not optional for individuals. In these cases, it is desirable to inform individuals when information taken in clinical contexts will be used for public health surveillance. To the extent that it is possible, individuals and communities involved in public health surveillance should be informed about these activities, how the data will be used and also of any potential issues that could negatively impact on maintaining patient confidentiality.

The discussion in this module should be linked to both the ethical values discussed in Module 3 dealing with Overarching Goals and Ethical Values, and information and counselling, described in Module 5.

#### Procedure for running Module 10

1. Present slides for the module and follow the instructions and speaker notes in each slide

## Slide Kit for Module 10: Research on TB Care and Control

Slide 1	<div data-bbox="378 325 857 573"> <h3>Ethics of Tuberculosis Prevention, Care and Control</h3> <h4>MODULE 10: RESEARCH IN TB CARE AND CONTROL</h4> </div> <div data-bbox="324 590 901 657"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="324 667 901 730"> <p>Insert country/ministry logo here</p>  <p>TB CARE II</p> </div>	
Slide 2	<h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>• Demonstrate how the application of ethical principles in research protects patients in general and vulnerable populations in particular</li> <li>• Describe the ethical considerations around public health surveillance activities</li> </ul> <p>USAID TB CARE II PROJECT 2</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<h3>Research: A critical component of TB care and control</h3> <ul style="list-style-type: none"> <li>• Drugs, vaccines, treatment regimens, and diagnostic measures</li> <li>• Social and structural determinants of disease and ways to prevent them</li> <li>• Effectiveness of the following: <ul style="list-style-type: none"> <li>• Infection control measures</li> <li>• Adherence strategies</li> <li>• Drug delivery mechanisms</li> <li>• Bio-medical interventions</li> </ul> </li> <li>• Social, cultural, and anthropological studies about individuals and communities</li> </ul> <p>Who is involved in research or has research projects running at your site?</p> <p>USAID TB CARE II PROJECT 3</p>	<ul style="list-style-type: none"> <li>• There is an urgent need to develop an enhanced evidence base for TB prevention and treatment, and to improve the standard of care. Achieving these goals will be impossible without a greater commitment to research. Further research is particularly important</li> <li>• <i>Review slide content</i></li> <li>• The international community should cooperate to develop incentives to encourage this kind of research and development. It is also important to ensure that, as evidence is developed, it is made publicly available and integrated into practice</li> <li>• Ask delegates how many of them are involved in research</li> </ul>

Slide 4	<p><b>WHO Post 2015 global strategy and targets for TB prevention, care and control</b></p> <ul style="list-style-type: none"> <li>Intensified research and innovation through: <ul style="list-style-type: none"> <li>Discovery, development and rapid uptake of new tools, interventions and strategies</li> <li>Research to optimise implementation and impact, and promote innovations</li> </ul> </li> </ul> <p><small>*WHO: Global strategy and targets for tuberculosis prevention, care and control after 2015. 2015</small></p> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>4</small></p>	<ul style="list-style-type: none"> <li>Mention that the WHO's End TB Strategy has listed, as part of the post-2015 global strategy, the need for intensified research and innovation as one of its three central pillars</li> <li><i>Review slide content</i></li> </ul>
Slide 5	<p><b>General ethical principles to govern research: Respect</b></p> <ul style="list-style-type: none"> <li>Respect for autonomy <ul style="list-style-type: none"> <li>Those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination</li> </ul> </li> <li>Protection of persons with impaired or diminished autonomy <ul style="list-style-type: none"> <li>Those who are dependent or vulnerable be afforded security against harm or abuse</li> </ul> </li> </ul> <p><small>Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002</small></p> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>5</small></p>	<ul style="list-style-type: none"> <li>State that guidelines for research on TB should draw on principles of research ethics already articulated in other documents</li> <li>These include guidelines by WHO and UNAIDS on research on HIV, although it is important to recognize that TB and HIV do not always raise identical issues</li> <li>For example, the risks to third parties may be greater in TB research because the disease can be transmitted through casual contact</li> <li>The example of general ethical principles governing research on the slide have been drawn from guidance provided by the Council for International Organizations of Medical Sciences in collaboration with the WHO</li> <li><i>Review slide content</i></li> <li>We will review the additional principles in the subsequent slides</li> </ul>
Slide 6	<p><b>General ethical principles to govern research: Beneficence</b></p> <ul style="list-style-type: none"> <li>Ethical obligation to maximise benefit and to minimise harm</li> <li>Gives rise to norms requiring that: <ul style="list-style-type: none"> <li>Risks of research be reasonable in light of expected benefits</li> <li>Research design be sound</li> <li>Investigators be competent both to conduct research and to safeguard welfare of research subjects</li> </ul> </li> <li>Further proscribes deliberate infliction of harm on persons <ul style="list-style-type: none"> <li>Non-maleficence (do no harm)</li> </ul> </li> </ul> <p><small>Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002</small></p> <p><small>USAID TB CARE II PROJECT</small></p> <p><small>6</small></p>	<ul style="list-style-type: none"> <li><i>Review slide content</i></li> </ul>

Slide 7	<p><b>General ethical principles to govern research: Justice</b></p> <ul style="list-style-type: none"> <li>• Ethical obligation to treat each person in accordance with what is morally right and proper and to give each person what is due to him or her</li> <li>• Refrain from practices that are likely to worsen unjust conditions or contribute to new inequities</li> <li>• Leave low-resource countries or communities better off than previously or, at least, no worse off</li> <li>• Responsive to the health conditions or needs of vulnerable subjects</li> </ul> <p><small>Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002</small></p> <p><b>USAID TB CARE II PROJECT</b></p> <p>7</p>	<ul style="list-style-type: none"> <li>• Emphasise the following: This ethical principle refers primarily to distributive justice, which requires the equitable distribution of both the burdens and the benefits of participation in research</li> <li>• One cannot hold the sponsors of research or investigators accountable for unjust conditions where the research is conducted. However, they must refrain from practices that are likely to worsen unjust conditions or contribute to new inequities</li> <li>• Research projects in low-resource countries or communities should leave them at best better off or at least no worse off. Any product developed there should be made reasonably available to them, and as far as possible leave the population in a better position to obtain effective health care and protect its own health</li> <li>• This principle of justice requires the research to be responsive to the health conditions or needs of vulnerable subjects. Subjects should be the least vulnerable necessary to meet the research needs</li> </ul>
Slide 8	<p><b>Important considerations when designing ethical research strategy - 1</b></p> <ul style="list-style-type: none"> <li>• <b>Full stakeholder participation</b>, including community and civil society, in generation of research questions and design and implementation of studies</li> <li>• <b>Good Participatory Practice Guidelines for TB Drug Trials</b> - Critical Path to TB Drug Regimens Stakeholder and Community Engagement Workgroup, 2012</li> </ul> <p><b>USAID TB CARE II PROJECT</b></p> <p>8</p>	<ul style="list-style-type: none"> <li>• Explain that certain considerations are particularly important in designing an ethical research strategy</li> <li>• <i>Review slide content</i></li> <li>• Emphasise that in collaborative international research, local investigators should be involved in development of research questions, design, and implementation and that it should be conducted in a manner that ultimately helps low- and middle-income countries develop the capacity to do research themselves</li> <li>• The <i>Good Participatory Practice Guidelines for TB Drug Trials</i>: produced in 2012 by the Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens can be useful tool for understanding and implementing the community and civil society into TB Research</li> </ul>

Slide 9	<p>Important considerations when designing ethical research strategy - 2</p> <ul style="list-style-type: none"> <li>• <b>Communication</b> of research findings and application of these findings to participants</li> <li>• Populations in which research is carried out should stand to <b>benefit from results</b></li> <li>• <b>Technology transfer</b>, whenever applicable, for benefit of affected population</li> <li>• Ultimately helps low- and middle-income countries <b>develop capacity</b> to do research themselves</li> <li>• Protocols should consider how <b>findings will be translated into public health policy</b>, as applicable</li> </ul> <p>USAID TB CARE II PROJECT 9</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 10	<p>Important considerations when designing ethical research strategy - 3</p> <ul style="list-style-type: none"> <li>• Research ethics committees should determine that: <ul style="list-style-type: none"> <li>• <b>Risks reasonable</b> in relation to anticipated benefits</li> <li>• Adequate process in place for obtaining participants' <b>informed consent</b></li> </ul> </li> <li>• With significant third-party risks: <ul style="list-style-type: none"> <li>• <b>Appropriate infection control measures</b> should be implemented as part of the research protocol</li> <li>• Importance of <b>informing third parties</b> about such risks (and possibly obtaining their consent) considered</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 10</p>	<ul style="list-style-type: none"> <li>• Further, as with other types of research involving human participants, research ethics committees should determine that the risks are reasonable in relation to the anticipated benefits and that there is an adequate process in place for obtaining participants' informed consent. Research ethics committees should consider how the impact of research on individuals other than the research participants, e.g. family members and other close contacts, affects the assessment of risks and benefits and the process of informed consent</li> <li>• Ask delegates who indicated that they were involved with research or those who have research projects/trials being conducting at their site how the ethical considerations described above are applied in these projects</li> </ul>
Slide 11	<p>Are these ethical considerations applied at your site?</p> <div> <p>Did you indicate that you are involved with research or have research projects/trials being conducting at your site?</p> <p>If so, how are the ethical considerations described above applied in these projects?</p> </div> <p>USAID TB CARE II PROJECT 11</p>	<ul style="list-style-type: none"> <li>• Ask delegates who signaled that they were involved in research projects or were aware of research projects being conducted at their site to consider if the ethical considerations described in the previous two slides are applied in these research projects</li> </ul>

Slide 12	<p>Public health surveillance activities</p> <ul style="list-style-type: none"> <li>Refers to <b>ongoing, systematic collection, analysis, interpretation, and dissemination of data</b> regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health</li> <li>Intended to provide evidence basis needed for governments to <b>monitor prevalence of disease</b> and <b>measure impact of prevention and treatment programmes</b></li> <li>Essential to advocates' ability to <b>call attention to problems</b> requiring reform</li> </ul> <p>USAID TB CARE II PROJECT 12</p>	<ul style="list-style-type: none"> <li>Explain that routine public health surveillance is not the same as epidemiological research</li> <li>Public health surveillance <i>is</i> generally authorised by legislators and carried out by public health officials. Unlike research, surveillance is not intended to generate or contribute to generalisable knowledge</li> <li>Review slide content</li> </ul>
Slide 13	<p>Application of ethical considerations to routine public health surveillance activities - 1</p> <ul style="list-style-type: none"> <li>Inform individuals when information taken in clinical contexts will be used</li> <li>Individuals and communities should be given information about: <ul style="list-style-type: none"> <li>Type of data being gathered</li> <li>Purpose for which data will be used</li> <li>Outcome of the surveillance</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 13</p>	<ul style="list-style-type: none"> <li>State that in order for surveillance to be effective, the data must be comprehensive</li> <li>For this reason, individuals are generally not given the right to opt out of having their information used for purposes of surveillance</li> <li>Because participation in surveillance activities is not optional, it would be misleading to ask the subjects to provide informed consent. Nonetheless, it is desirable to inform individuals when information taken in clinical contexts will be used for purposes of public health surveillance</li> <li><i>Review slide content</i></li> </ul>
Slide 14	<p>Application of ethical considerations to routine public health surveillance activities - 2</p> <ul style="list-style-type: none"> <li>Confidentiality of information generated should be protected to maximum extent possible</li> <li>Individuals should be informed of any circumstances in which information obtained may be disclosed to third parties</li> <li>Informed consent may be necessary in some circumstances: <ul style="list-style-type: none"> <li>Records or samples retain identifying information</li> <li>May be linked with identifying information with a code</li> </ul> </li> </ul> <p>USAID TB CARE II PROJECT 14</p>	<ul style="list-style-type: none"> <li><i>Review slide content</i></li> </ul>



Slide 15	<p>Application of ethical considerations to routine public health surveillance activities - 3</p> <ul style="list-style-type: none"> <li>• Informed consent can be waived: <ul style="list-style-type: none"> <li>• Research involves minimal risk</li> <li>• Obtaining informed consent would be impracticable</li> <li>• Protections for confidentiality and other rights are provided.</li> </ul> </li> <li>• Decision on appropriateness of waiving consent should rest with research ethics committee</li> <li>• Research with records or samples for which identifying information has been permanently removed may also require review by research ethics committee</li> </ul> <p>USAID TB CARE II PROJECT 15</p>	<ul style="list-style-type: none"> <li>• Explain that there are specific ethical issues that apply to epidemiological research on TB, including research with medical records and stored blood samples</li> <li>• <i>Review slide content</i></li> </ul>
Slide 16	<p>Circumstances in which biomedical research trials should not be performed – 1</p> <ul style="list-style-type: none"> <li>• Capacity to conduct independent and adequate scientific and ethical review does not exist</li> <li>• Voluntary participation and freely decided consent cannot be obtained</li> <li>• Conditions affecting potential vulnerability or exploitation may be so severe that risk outweighs the benefit of conducting the trial in that population</li> </ul> <p>USAID TB CARE II PROJECT 16</p>	<ul style="list-style-type: none"> <li>• As much as research on the various aspects of TB care and control is necessary, there are circumstances/conditions in which biomedical research trials should not be performed</li> <li>• <i>Review slide content</i></li> </ul>
Slide 17	<p>Circumstances in which biomedical research trials should not be performed - 2</p> <ul style="list-style-type: none"> <li>• Agreements have not been reached among all research stakeholders on access to medical care and treatment</li> <li>• Agreements have not been reached on responsibilities and plans to make trial products that prove to be safe and effective, available to communities and countries where they have been tested, at an affordable price</li> </ul> <p>USAID TB CARE II PROJECT 17</p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>

Slide 18



- Check if delegates have any questions and address these
- This is the end of the module on 'Research on TB Care and Control'
- This brings us to the final module, which is the 'Conclusion'

## 20. Module 11: Conclusion

### Facilitation Guide for Module 11: Conclusion

#### Time

- 1 hour 45 minutes

#### Objectives

- Discuss emerging ethical issues in TB prevention care and control
- Identify strategies and approaches to improve ethical TB management practices within your work setting

#### Techniques

- Lecture
- Individual activity
- Group discussion
- Plenary discussion

#### Materials

- PowerPoint slides
- Activity 6: Ethics of TB Prevention, Care and Control Planning Tool Delegate Hand-out
- Completed Ethics of TB Prevention, Care and Control Assessment Tool
- Flip chart and pens

#### Key Message

- Reflect on actions you can take to align your TB control programme with the guidance provided during this training programme

#### Synopsis of module



This course set out to sensitise and educate delegates on the application of ethical values in all aspect of TB, prevention, care and control. In doing so, it has raised a number of ethical issues in TB prevention care and control for delegates to consider and note. Additionally, new ethical issues around TB prevention care and control continue to emerge.

This final module will help delegates synthesize what they have learned during the course. At the beginning of the course delegates completed an Ethics of TB Prevention, Care and Control Assessment Tool that could help them areas for improvement within their TB programme. The final activity, use of a Planning Tool, will build on issues identified through the Assessment Tool and the discussion and activities in the course to help delegates develop strategies and approaches that could improve ethical TB management practices within their work settings.

#### Procedure for running Module 11


1. Ensure that you have printed a copy of the Activity 6: Ethics of TB Prevention, Care and Control Planning Tool Delegate Hand-out for each delegate(this is in the Delegate Hand-out section)
2. Present slides for the module and follow the instructions and speaker notes in each slide
3. Use the Facilitator's Instructions below to run Activity 6

## Slide Kit for Module 11: Conclusion

Slide 1	<div data-bbox="365 325 862 581"> <h1>Ethics of Tuberculosis Prevention, Care and Control</h1> <h2>MODULE 11: CONCLUSION</h2> </div> <div data-bbox="321 598 909 672"> <p>[INSERT SPEAKER NAME DATE &amp; LOCATION HERE]</p> </div> <div data-bbox="321 682 909 745"> <p>Insert country/ministry logo here</p>   </div>	
Slide 2	<h3>Objectives</h3> <p>Upon completion of this module, you will be able to:</p> <ul style="list-style-type: none"> <li>• Discuss emerging ethical issues in TB prevention care and control</li> <li>• Identify strategies and approaches to improve ethical TB management practices within your work setting</li> </ul> <p>USAID TB CARE II PROJECT <span>2</span></p>	<ul style="list-style-type: none"> <li>• <i>Review slide content</i></li> </ul>
Slide 3	<h3>Emerging Issues</h3> <ul style="list-style-type: none"> <li>• Palliative/end of life care in infectious, untreatable patients</li> <li>• Treatment when safety profile of drugs is unclear</li> <li>• Monotherapy in the era of non-treatable TB</li> <li>• Compassionate use of TB drugs</li> <li>• Catastrophic expenditures in TB patients</li> </ul> <div data-bbox="354 1633 844 1705"> <ul style="list-style-type: none"> <li>• Have you seen the impacts of these in your setting?</li> <li>• What other emerging ethical issues have you noted?</li> </ul> </div> <p>USAID TB CARE II PROJECT <span>3</span></p>	<ul style="list-style-type: none"> <li>• State that these emerging issues raise serious ethical and moral concerns</li> <li>• <i>Review slide content</i></li> </ul>

<div>Slide 4</div>	<div><div>What does this training mean for you?</div><div><table><tr><th colspan="2">Conflict in Ethical Principles</th></tr><tr><td>Individual Autonomy</td><td>Risks to Public Health</td></tr><tr><td>Rights to privacy</td><td>Transmission of TB</td></tr><tr><td>Rights to liberty and self-determination</td><td>Risk of spread of drug-resistant TB</td></tr></table></div><div><div>USAID TB CARE II PROJECT</div><div>4</div></div></div>	Conflict in Ethical Principles		Individual Autonomy	Risks to Public Health	Rights to privacy	Transmission of TB	Rights to liberty and self-determination	Risk of spread of drug-resistant TB	<ul style="list-style-type: none"><li>State that among other characteristics, TB is a disease the treatment of which asks people to consider and make decisions regarding individual autonomy and the public common good and that there are instances when these considerations are divergent</li><li>It is a condition that puts into stark focus the rights of the individual and those of the public at large</li><li>This raises ethical dilemmas for health care workers who support TB programmes, who have to strike a balance between what is right for the individual patient vs. what is right for the broader community</li><li>This training has aimed to make you aware of the ethical considerations in the prevention, testing, treatment, care and support of TB</li><li>It is hoped that this training as well as the WHO guidance on ethics of TB prevention, care and control will assist navigating these complex issues</li><li>Some of these issues are identified on this slide</li><li>Review slide content</li></ul>
Conflict in Ethical Principles										
Individual Autonomy	Risks to Public Health									
Rights to privacy	Transmission of TB									
Rights to liberty and self-determination	Risk of spread of drug-resistant TB									
<div>Slide 5</div>	<div><div>Applying your training.....</div><div>Instructions</div><div><div>INDIVIDUAL</div><div>GROUP</div><div>PLENARY</div></div><div><ul style="list-style-type: none"><li>Using the <i>Ethics of TB Prevention, Care and Control Assessment Tool</i> that you completed for your TB programme, select the area which you believe will be most improved by applying the ethical values and guidance</li><li>Use Activity 6 Planning Tool in the Delegate Hand-out to plan actions you will take to achieve improvement in the area you selected and identify ways in which you can address gaps to achieve improvement in the following timeframes:<ul style="list-style-type: none"><li>Immediately</li><li>At 1 month</li><li>At 6 months?</li></ul></li><li>Review the barrier that you identified in Obligation to provide access to TB services: Activity 4 Delegate Hand-out to assist with the identification of the component where you can have the greatest impact to assist you</li></ul><div>Consider issues that you can directly impact on so that you can continue to improve the TB service you provide</div><div><div>USAID TB CARE II PROJECT</div><div>5</div></div></div></div>	<ul style="list-style-type: none"><li>Ask delegates to refer to the slide for instructions on how the activity will be run.</li><li>Inform them that the instructions are also available in the Ethics of TB Prevention, Care and Control Planning Tool: Activity 6 Delegate Hand-out and that they should refer to it</li><li>Ensure that delegates understand the instructions and clarify any misunderstanding</li><li>This is an individual activity, followed by work in small groups and a plenary discussion that will take a total of 1 hour and 15 minutes</li><li>Set aside 5 minutes for giving instructions<ul style="list-style-type: none"><li>20 minutes to work on their own</li><li>20 minutes in small groups of 3</li><li>25 minutes for a plenary discussion</li><li>5 minutes summarising and wrapping up the training course</li></ul></li><li>Ask delegates to work by themselves in order to identify the priority area in their TB programme, where application of the ethical guidance discussed during the training will enable them to provide individuals at risk of and those with TB more effective care and support</li><li>Thereafter, they need to create a plan that will</li></ul>								

		<p>address the gaps they've identified</p> <ul style="list-style-type: none"> <li>• Tell delegates when they have 5 minutes remaining for individual work</li> <li>• Tell delegates when to start working in their small groups and when they have 5 minutes remaining</li> <li>• Thereafter, facilitate a plenary discussion</li> <li>• Using each of the areas listed in the Planning Tool, ask delegates who have identified that particular area to volunteer to share the challenge, as well as the interventions they believe will address gaps in the short, medium and long term</li> <li>• Indicate that as delegates listen to others share their plans, they may feel free to amend or add other actions that they want to implement to their Planning Tool</li> <li>• Ask other delegates to volunteer their opinions and views if they have identified different challenges and potential actions within the same area</li> <li>• Ensure that challenges and potential actions to address these challenges in all eight areas listed in the Planning Tool are discussed</li> <li>• Remind delegates to focus on issues that are within their span of control; in other words, issues that their actions will have an impact on</li> </ul>
Slide 6	<p><b>Next Steps</b></p> <ul style="list-style-type: none"> <li>• Return to your work setting with the completed Activity Planning Tool and actions that can be taken: <ul style="list-style-type: none"> <li>• Immediately</li> <li>• Within 1 month</li> <li>• Within 6 months</li> </ul> </li> <li>• Discuss key outcomes and planned actions with your line manager and others in programme as appropriate to garner support</li> <li>• Continue to think critically and carefully about ethical TB prevention, care and control in your job!</li> </ul> <p>Advocate for the importance of addressing ethics, human rights, equity and social dimensions in TB programmes</p> <p>USAID TB CARE II PROJECT</p>	<ul style="list-style-type: none"> <li>• Thank delegates for their active participation over the last 2 days</li> <li>• Mention that the Ethics of TB prevention, care and control Training Course Evaluation Form asks for input into how delegates would like to report back regarding progress with implementation of planned actions</li> </ul>

<p>Slide 7</p>	<p>References and Resources</p> <ul style="list-style-type: none"> <li>World Health Organization. Guidance on ethics of tuberculosis prevention, care and control. 2010</li> <li>World Health Organization. Global Tuberculosis Report. 2014</li> <li>World Health Organization. Global strategy and targets for tuberculosis prevention, care and control after 2015. 2015</li> <li>United Nations Human Rights. General Assembly Resolution 217 A (III): Universal Declaration on Human Rights. 1948</li> <li>International Standards for TB Care, Third Edition, 2014</li> <li>Zungu M, Malotie M. Do we know enough to prevent occupationally acquired tuberculosis in healthcare workers? Occupational Health Southern Africa. <a href="http://www.occhealth.co.za/?viewArticle=1263">http://www.occhealth.co.za/?viewArticle=1263</a>. Accessed on 11 May 2015</li> <li>United Nations Economic and Social Council. Siracusa principles on the limitation and derogation of provisions in the International Covenant on Civil Political Rights. U.N. Doc. E/CN.4/1985/4, Annex. 1985</li> <li>Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002</li> <li>World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Oct 2009</li> <li>Sagbakken et al. BMC Medical Ethics 2013, 14:25. <a href="http://www.biomedcentral.com/1472-6939/14/25">http://www.biomedcentral.com/1472-6939/14/25</a>. Accessed on 9 May 2015</li> <li>Public Health Leadership Society. Principles of the Ethical Practice of Public Health. 2002</li> <li>World Health Organization. Guidelines for the programmatic management of drug-resistant tuberculosis. 2011 update</li> <li>World Health Organization. Towards universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis by 2015</li> <li>World Health Organization. Tuberculosis, ethics and human rights. WHO Regional Office for Europe Report of a regional workshop. Copenhagen, Denmark 16 October 2013</li> <li>Companion Handbook to the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis. Geneva: World Health Organization; 2014. 21. Ethics in programmatic management of MDR-TB</li> <li>World Care Council/International Standards for TB Care. Patients' Charter for Tuberculosis Care. 2006</li> </ul> <p>USAID TB CARE II PROJECT</p> <p>7</p>	<ul style="list-style-type: none"> <li>State that the list of resources and references on the slide will provide delegates with additional material on this important topic</li> </ul>
<p>Slide 8</p>	 <p>USAID TB CARE II PROJECT</p> <p>8</p>	<ul style="list-style-type: none"> <li>Check if delegates have any final questions and address these</li> <li>State that this is the conclusion of the course</li> <li>Thank the delegates for being receptive and engaged</li> <li>State that you hope the group has found the material of use and hopefully it will also be also valuable for when delegates return to their regular posts.</li> <li>Indicate that at the very least, you hope that the course has brought you a different and positive insight into the valuable work that delegates do daily</li> <li>State that you (and other presenters and facilitators) now need them to tell you how you did by completing an evaluation form</li> <li>Ask delegates to complete form and return it and thank them for their participation and their feedback</li> </ul>

## Facilitator Instructions for Activity 6: Ethics of TB Prevention, Care and Control Planning Tool

### Objective

Consider and identify approaches and strategies for addressing one critical aspect of the TB programme that can be strengthened in light of guidance on ethics of TB prevention, care and control

### Task/Question

- Identify which area of the TB Programme should be prioritised for strengthening ethical considerations
- Select components within the identified area where application of the ethical guidelines would have the most impact
- Identify mechanisms for short, medium and long term interventions for improvement

### Question

The delegates should review the Ethics of TB Prevention, Care and Control Assessment Tool they've completed for the TB programme they support. Using the tool they should identify the one main area in their TB programme, where application of the ethical guidance discussed during the training will enable them to provide individuals at risk of and those with TB more effective care and support. Delegates will then prepare a plan on how to address these gaps.

### Time Allotted

75 minutes

- 5 minutes for instructions
- 20 minutes of individual work
- 20 minutes for small group work
- 25 minutes for plenary discussion
- 5 minutes for a summary and wrap up

### Materials Needed

- Completed Ethics of TB Prevention, Care and Control Assessment Tool from the previous day
- Activity 6: Ethics of TB Prevention, Care and Control Planning Tool Delegate Hand-out
- Flip chart and pens to record plenary discussion

### Procedure for running activity

1. Provide the delegates with Activity 6: Ethics of TB Prevention, Care and Control Assessment Tool Delegate Hand-out
2. Inform delegates that they will start out working by themselves and at the end of 20 minutes, will be required to work in groups of 3
3. Ask delegates to work by themselves in order to review their completed Ethics of TB Prevention, Care and Control Assessment Tool and to create a plan that will address the gaps they've identified, using Activity 6: Ethics of TB Prevention, Care and Control Planning Tool Hand-out.



4. Delegates should:
  - a. Review their completed Ethics of TB Prevention, Care and Control Assessment Tool
  - b. Identify one area in their TB programme, where application of the ethical values and guidance will have the greatest impact on providing TB infected individuals or those at risk of being infected, with more effective care and support
  - c. Review the barriers that they identified in Activity 3: Obligation to Provide Access to TB Services to assist with the identification of the component where they can have the greatest impact
  - d. Within the selected area and its components, using the Activity 6: Planning Tool, consider and identify mechanisms that they can implement to address barriers to the provision of ethical TB care in the following time frames:
    - i. Immediately
    - ii. At 1 month
    - iii. At 6 months
5. Tell delegates when the 20 minutes of individual work time has elapsed, with a time check when 5 minutes are remaining
6. In their small groups of three, delegate should each share the area they selected and the components and proposed activities they noted on their hand-out
7. Inform them that they should use this time to share their decisions and plans, provide feedback and suggestions to each other, and amend individual plans if necessary
8. Facilitate a plenary discussion
9. Using each of the areas listed in the Activity 6: Planning Tool, ask delegates who have identified that particular area to volunteer to share their challenge, as well as the interventions they believe will address gaps in the short, medium and long term
10. Indicate that as delegates listen to others share their plans, they may feel free to amend or add other actions that they want to implement to their Activity 6: Planning Tool
11. Ask other delegates who have identified different challenges and potential actions within the same area to share their opinions and views
12. Ensure that challenges and potential actions to address these challenges in all eight areas listed in the Activity 6: Planning Tool are discussed
13. Provide summary points from under Tips section

### Setting the Scene

Through this training course, delegates will have learned the importance of ethical values and principles in TB prevention, care and control and how the application of ethical values and principles can positively contribute to the management of the TB control programme.

During this course, some of the major ethical issues discussed included:

- Obligation to provide care to all, including social support in adhering to treatment
- Provision of information, counselling and the role of consent
- Obligation not to abandon patients, including when treatment fails
- Gap between the diagnosis and treatment of MDR and XDR-TB
- Exposure of health-care workers to TB infection and their rights to adequate protection

Also, the human-rights-based approach to TB should be considered:

- Put the individual at the centre of any health policy
- Identify and support the most marginalised and vulnerable groups
- Address the related socioeconomic determinants and their implications for human rights
- Overcome institutional constraints
- Capacity gaps preventing individuals and groups from fulfilling their rights

Using this experience delegates are now asked to select the key areas that they believe will benefit most from application of the ethical guidance to provide more effective care and support.

#### Tip

Remind delegates that they should focus on issues within their span of control. For example, if the delegate is working at facility level, it would be worth them concentrating on issues that they can impact at the facility, such ethical practice in contact tracing. Delegates working at the district level could consider advocacy for policies and policy changes that continue to promote ethical practice.

In addition, remind delegates that they should complete the Hand-out with actions that they will take immediately, within one month and within six months. Due to time constraints, delegates were only asked to think through and plan out activities in one of the areas included on the planning tool below.

Delegates should return to this planning tool when they return to their work setting and should add additional planned activities in other areas of the plan. It may be helpful to consider how other colleagues could contribute to strengthening additional areas laid out in the planning tool. Encourage delegates to share their draft plan (and the Assessment Tool if they wish) with others in their work setting including their supervisor, and discuss ways to utilise these tools to make improvements to ethical TB prevention, care, and control.

## 21. Delegate Hand-outs

This section provides copies of the delegate hand-outs. You will need to ensure that, for activities where a hand-out has been prepared, you distribute a copy of the hand-out to each delegate prior to commencing with the activity. To help distinguish them from the Facilitator Instructions, the delegate hand-outs are marked with a dashed green border. Consider providing delegates with a folder for the handouts you are distributing.

Delegate hand-outs are available for the following activities:

- Module 1: Introduction: Activity 2
- Module 3: Overarching Goals and Ethical Values: Activity 3
- Module 6: Supporting Adherence to TB Treatment: Plenary Discussion
- Module 8: Health Care Worker Rights and Obligations: Activity 4
- Module 9: Involuntary Isolation and Detention as Last-Resort Measures: Activity 5
- Module 11: Conclusion: Activity 6

The Delegate Hand-outs for each of the above activities follow in the subsequent pages.

## Delegate Hand-out for Activity 2: Ethics Assessment Tool

### Instructions

- Follow the instructions of the facilitator and read through the questions and information provided in the section below titled 'Setting the Scene'
- Briefly review pages 2 and 3 of the Ethics Assessment Tool that you received from the facilitator
- Spend up to 40 minutes completing pages 4-24 of the Assessment Tool and then briefly answer the two questions below
- Complete the tool to the best of your ability; if you don't know the answers to some of the questions, just leave them blank. (The tool is intended to help you better understand the specific areas within your TB programme that may be strengthened by the application of the ethical guidance that will be discussed during the training, and you will not be judged on your responses)
- If you cannot finish the tool in the allotted time, you may complete it during the breaks or lunch
- Participate in the plenary discussion

### Setting the Scene

On the surface, ethics around management of TB may appear simple and even 'common sense'. For example, clearly, ethical principles would indicate that effective high quality diagnosis and treatment services should be available to all at no cost. However, in resource limited settings operationalising seemingly straightforward ethical concepts can sometimes be challenging. Prevention, diagnosis, care and treatment of TB, both drug-susceptible and drug-resistant TB, raise important ethical and human rights issues that must be addressed. For example, TB particularly affects poor and vulnerable populations, and therefore social justice and equity must be at the heart of the response.

Further, with the ongoing TB/HIV epidemic, increase in drug-resistance, new ethical questions and challenges are emerging. Finally some of the ethical dilemmas and challenges faced by TB programmes may not have clear or simple solutions. The purpose of the WHO ethics guidance, the assessment tool, and this course is to help gain a better understanding of issues, identify, share and discuss challenges and approaches and raise awareness of these issues within TB programmes.

### Questions and Responses

1. What was your experience completing the tool?

---

---

---

---

---

---

---

---

---

---

2. Based on the tool, what are some challenges or strengths around ethical management of TB in your programme?

---

---

---

---

---

---

---

---

---

---

## Delegate Hand-out for Activity 3: Obligation to Provide Access to TB Services

### Questions

- For the community you serve, what is the most critical barrier that limits access to TB services, particularly for vulnerable groups?
- What actions would you propose to remove these barriers in order to ensure the ethical obligation to provide access to TB services is upheld?

### Instructions

- Divide into groups, based on the facilitator's instructions
- Move to the place designated for your group
- Read through the questions and information provided in the section below titled 'Setting the Scene'
- Designate someone who will report back in the plenary discussion
- Spend the 20 minute discussion time in the following way:
  - Each group member should share the most critical barrier they face in terms of providing access to TB services, with specific regard to vulnerable groups, such as the poor or children and actions they propose or that they currently use to address this barrier
  - Group members should provide comments or feedback to each other and suggest alternate solutions, based on their own experiences in similar circumstances
  - Note your barrier and potential solutions on this hand-out
- Participate in the plenary discussion

### Setting the Scene

Prevention, diagnosis, care and treatment of TB, both drug-susceptible and drug-resistant TB, raise important ethical and human rights issues that must be addressed. For example, TB particularly affects poor and vulnerable populations, and therefore social justice and equity must be at the heart of the response. TB can be a lethal infectious disease, which in the absence of proper treatment and care of patients and control of the epidemic, raises questions on how to ensure a balance of individual responsibilities, rights and liberties of those affected by the disease, with the protection of those who are at risk of infection.\*

*\*Companion Handbook to the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis. Geneva: World Health Organization; 2014. 21, Ethics in programmatic management of MDR-TB.*

### Questions and Responses

1. For the community you serve, what is the most critical barrier that limits access to TB services, particularly for vulnerable groups?

---

---

---

---

---

- 
- This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

## Delegate Hand-out for Plenary Discussion: Supporting Adherence to TB Treatment

### Setting the scene

Offering a Directly Observed Therapy (DOT) programme is not enough. Patients must agree to participate in taking their medicine and continue to adhere to the treatment regimen through the full course of treatment. **Incentives** are small rewards given to patients to encourage them to either take their own medicines or keep their clinic or field DOT appointments. **Enablers** are those things that make it possible or easier for the patients to receive treatment by overcoming barriers such as transportation difficulties. Incentives and enablers may help patients adhere to and complete treatment.

Incentives and enablers should be chosen according to the patients' special needs and interests, or the patients may not care if they receive them. For example, if the health care worker knows that transportation is a problem, he or she could offer bus or taxi fare as an enabler. If transportation is not a problem, then he or she should offer something that is needed. Learning as much as possible about patients will help to identify their needs and interests and better motivate them to complete treatment. The best time to begin using incentives is after a good relationship has been established with a patient. Enablers, however, may be vital to the initiation of treatment and should be provided as soon as treatment begins. Always start by talking with patients to learn about their needs.

Some health care workers disagree about whether or not incentives should be used. The attitude one has about incentives is important. Some health care workers do not like using incentives because they think patients should want to get well and should consider it their duty to take their medicine. They believe that incentives are bribes. The use of enablers or incentives may raise questions about the patient's motivation for seeking and agreeing to treatment.

At times, patients may also feel that the health care worker is trying to bribe them into accepting treatment. When incentives are used with an attitude of caring and concern for the patient, the patient will be less inclined to question the health care worker's motives. The reason for using incentives is to motivate the patient to complete treatment. Above all, incentives and enablers are not a substitute for a high-quality relationship with patients based on trust, effective communication, and mutual respect. Nevertheless, it is worth noting that many programmes have shown success using incentives and enablers.



## Delegate Hand-out for Activity 4: Health Care Worker Rights and Obligations

### Question

What potential gaps and challenges could prevent health care workers from being protected when managing people at risk of or those with TB?

### Instructions

- Divide into groups, based on the facilitator's instructions
- Move to the place designated for your group
- Nominate a spokesperson, note-taker and timekeeper for the group
  - The note-taker will be responsible for writing down the responses provided by the group members
  - The spokesperson will be responsible for providing feedback from the group during the plenary discussion
  - The timekeeper will ensure that the discussion is kept on track
- Read through the question and information provided in the section below titled 'Setting the Scene'
- Participate in group and plenary discussions

### Setting the Scene

Health care workers play an essential role in the provision of health services. Their core role is to care for the sick and injured. They are often viewed as 'immune' to injury or illness, as they are called upon to put patients first. This places them at much higher risk of exposure to viruses, bacteria and parasites, which can be transmitted through the air or through body fluids, such as TB, HIV and Hepatitis B.

Their risk of exposure to TB specifically may be increased by less than optimal working conditions such as overcrowding, poor ventilation, inadequate infection control measures and insufficient personal protective equipment.

It is recognised that protecting health care workers also contributes to quality care. Some of the same measures to protect patients from infections should be instituted to protect health care workers.

### Question

What potential gaps and challenges could prevent health care workers from being protected when managing people at risk of or those with TB?

### Response

---

---

---

---

---

---

## Delegate Hand-out for Activity 5: Involuntary Isolation and Detention as Last-Resort Measures

### Question

- Is involuntary detention of patients ever acceptable?
- If so, under what conditions would it be acceptable?

### Instructions

- In the time allotted, do the following:
  - Read through the questions and information provided in the section below titled 'Setting the Scene'
  - Complete the Activity 5 Delegate Hand-out
- Hand in your completed hand-out to the facilitator
- Participate in the plenary discussion

### Setting the Scene

TB control programmes operate within a complex legal framework that balances the civil rights of individuals with society's need for protection.

A dialogue between medical and legal professionals is necessary to ensure any legal steps taken to address patient non-adherence, strike the appropriate balance with modern constitutional guarantees of privacy, liberty, and non-discrimination. These issues are the same whether a patient has drug-susceptible or drug-resistant TB.

For those few patients who, for whatever reasons, continue to pose a risk to the public despite all efforts to address their barriers to initiating and adhering to treatment, ethical and legal options are needed to ensure that these patients do not continue to put others in the community at risk.

### Questions and Responses

1. Is involuntary detention of patients ever acceptable?

---

---

---

---

2. If so, under what conditions would it be acceptable?

---

---

---

---

---

---

## Delegate Hand-out for Activity 6: Ethics of TB Prevention, Care and Control Planning Tool

### Task/Question

- Identify which area of the TB Programme should be prioritised for strengthening ethical considerations
- Select components within the identified area where you can have the most impact by ensuring application of the ethical guidelines
- Identify mechanisms for short, medium and long term interventions for improvement

### Instructions

- In this final activity, you will work on your own, then in a small group of 3 people, which will be followed by a plenary discussion:
  - 20 minutes individual work
  - 20 minutes small group activity
  - 30 minutes plenary discussion
- Review the Ethics of TB Prevention, Care and Control Assessment Tool that you completed at the beginning of this course. Select the one area within your programme where application of ethical values and guidance discussed during this training will have the greatest impact on providing TB infected individuals or those at risk of being infected, with more effective care and support
- Review the barriers that you identified in Activity 4: Obligation to Provide Access to TB Services to assist you in identifying the components in your selected area where you can have the greatest impact
- Consider issues that you can directly impact on so that you can continue to improve the TB service you provide
- Using the Activity 6: Planning Tool, indicate what actions you will take to achieve improvement in the area you selected, and identify ways in which you can address gaps to achieve improvement in the following timeframes:
  - Immediately
  - At 1 month
  - At 6 months
- Keep in mind that you have 20 minutes for your individual work in this activity, and focus on the issues you feel are most important in strengthening your TB programme. Remember to focus on issues that are within your span of control, in other words, issues you can directly impact on
- After 20 minutes of individual work, convene in your small group of 3 and share your plan to improve ethical practices in management of TB in the area you selected (area, components and proposed activities from your completed hand-out)
- Each group member will share their plan for their selected area, provide feedback and suggestions to each other, and amend individual plans if necessary
- After 20 minutes of working in your small group, participate in the plenary discussion

## Setting the Scene

Through this training course, we have discussed the importance of ethical values and principles in TB prevention, care and control and how the application of ethical values and principles can positively contribute to the management of the TB control programme.

During this course, some of the major ethical issues discussed included:

- Obligation to provide care to all, including social support in adhering to treatment
- Provision of information, Counselling and the role of consent
- Obligation not to abandon patients, including when treatment fails
- Gap between the diagnosis and treatment of MDR and XDR-TB
- Exposure of health-care workers to TB infection and their rights to adequate protection

Also, the human-rights-based approach to TB should be considered:

- Put the individual at the centre of any health policy
- Identify and support the most marginalised and vulnerable groups
- Address the related socioeconomic determinants and their implications for human rights
- Overcome institutional constraints
- Capacity gaps preventing individuals and groups from fulfilling their rights

Using this experience, select the key area that you believe will benefit most from application of the ethical guidance to provide more effective care and support. To ensure effective implementation, you should focus on issues in your selected area that are within your span of control.

Through this training course, you will have been shown how the application of ethical values and principles can positively contribute to the management of the TB control programme. Using this experience you are now asked to apply the ethical guidance to your TB programme.

Due to time constraints, you were only asked to think through and plan out activities in one of the areas included on the planning tool below. Begin with the ones that you think are the most important. However, when you return to your work setting, please consider other areas of the plan and add additional planned activities in those areas. You should share your draft plan (and your completed assessment tool, if you wish) with your supervisor and others in your work setting. Discuss ways to utilise these tools to make improvements to ethical TB prevention, care and control within your TB programme.

## Activity 6: Ethics of TB Prevention, Care and Control Planning Tool

ea	Component	Actions		
		Immediate	1 month	6 months
Access to Treatment				
Patient-Centred Care				
Information, Counselling and Consent				
Adherence				

Area	Component	Actions		
		Immediate	1 month	6 months
Drug Susceptibility Testing and Treatment of Resistant Disease				
Health Care Workers' Rights and Obligations				
Isolation and Legal Intervention				
Research				

## 22. Resource List

This resource list may be useful to facilitators when preparing for the course, but may also provide additional information to delegates who wish to deepen their understanding of the issues.

- World Health Organization. Guidance on ethics of tuberculosis prevention, care and control. 2010
- World Health Organization. Global Tuberculosis Report. 2014
- World Health Organization. Global strategy and targets for tuberculosis prevention, care and control after 2015. 2015
- United Nations Human Rights. General Assembly Resolution 217 A (III): Universal Declaration on Human Rights. 1948
- International Standards for TB Care, Third Edition, 2014
- Zungu M, Malotle M. Do we know enough to prevent occupationally acquired tuberculosis in healthcare workers? Occupational Health Southern Africa.  
<http://www.occhealth.co.za/?/viewArticle/1263>. Accessed on 11 May 2015
- United Nations Economic and Social Council. Siracusa principles on the limitation and derogation of provisions in the International Covenant on Civil Political Rights, U.N. Doc. E/CN.4/1985/4, Annex. 1985
- Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002
- World Medical Association. Declaration of Helsinki. Ethical Principles for Medical Research Involving Human Subjects. Oct 2008
- Sagbakken et al. BMC Medical Ethics 2013, 14:25. <http://www.biomedcentral.com/1472-6939/14/25>. Accessed on 9 May 2015
- Public Health Leadership Society. Principles of the Ethical Practice of Public Health. 2002
- World Health Organization. Guidelines for the programmatic management of drug-resistant tuberculosis. 2011 update
- World Health Organization. Towards universal access to diagnosis and treatment of multidrug-resistant and extensively drug-resistant tuberculosis by 2015
- World Health Organization. Tuberculosis, ethics and human rights. WHO Regional Office for Europe Report of a regional workshop. Copenhagen, Denmark 16 October 2013

- Companion Handbook to the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis. Geneva: World Health Organization; 2014. 21, Ethics in programmatic management of MDR-TB
- World Care Council/International Standards for TB Care. Patients' Charter for Tuberculosis Care. 2006
- Centers for Disease Control and Prevention. Division of Tuberculosis Elimination. Effective TB Interviewing for Contact Investigation: Facilitator-Led Training Guide