Ethics of Tuberculosis Prevention, Care and Control

MODULE 10: RESEARCH IN TB CARE AND CONTROL

[INSERT SPEAKER NAME
DATE &
LOCATION HERE]

Insert country/ministry logo here

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TB CARE II

Objectives

Upon completion of this module, you will be able to:

- 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

Research: A critical component of TB care and control

- Drugs, vaccines, treatment regimens, and diagnostic measures
- Social and structural determinants of disease and ways to prevent them
- Effectiveness of the following:
  - Infection control measures
  - Adherence strategies
  - Drug delivery mechanisms
  - Bio-medical interventions
- Social, cultural, and anthropological studies about individuals and communities

Who is involved in research or has research projects running at your site?

WHO Post 2015 global strategy and targets for TB prevention, care and control

- Intensified research and innovation through:
  - Discovery, development and rapid uptake of new tools, interventions and strategies
  - Research to optimise implementation and impact, and promote innovations

*WHO: Global strategy and targets for tuberculosis prevention, care and control after 2015. 2015

General ethical principles to govern research: Respect

- Respect for autonomy
  - Those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination
- Protection of persons with impaired or diminished autonomy
  - Those who are dependent or vulnerable be afforded security against harm or abuse

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002

General ethical principles to govern research: Beneficence

- Ethical obligation to maximise benefit and to minimise harm
- Gives rise to norms requiring that:
  - Risks of research be reasonable in light of expected benefits
  - Research design be sound
  - Investigators be competent both to conduct research and to safeguard welfare of research subjects
- Further proscribes deliberate infliction of harm on persons
  - Non-maleficence (do no harm)

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002

General ethical principles to govern research: Justice

- 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
- Refrain from practices that are likely to worsen unjust conditions or contribute to new inequities
- Leave low-resource countries or communities better off than previously or, at least, no worse off
- Responsive to the health conditions or needs of vulnerable subjects

Council for International Organizations of Medical Sciences (CIOMS) in collaboration with WHO. International Ethical Guidelines for Biomedical Research Involving Human Subjects. 2002

Important considerations when designing ethical research strategy - 1

- **Full stakeholder participation**, including community and civil society, in generation of research questions and design and implementation of studies
  - ***Good Participatory Practice Guidelines for TB Drug Trials* -** Critical Path to TB Drug Regimens Stakeholder and Community Engagement Workgroup, 2012

Important considerations when designing ethical research strategy - 2

- **Communication** of research findings and application of these findings to participants
- Populations in which research is carried out should stand to **benefit from results**
- **Technology transfer**, whenever applicable, for benefit of affected population
- Ultimately helps low- and middle-income countries **develop capacity** to do research themselves
- Protocols should consider how **findings will be translated into public health policy**, as applicable

Important considerations when designing ethical research strategy - 3

- Research ethics committees should determine that:
  - **Risks reasonable** in relation to anticipated benefits
  - Adequate process in place for obtaining participants' **informed consent**
- With significant third-party risks:
  - **Appropriate infection control measures** should be implemented as part of the research protocol
  - Importance of **informing third parties** about such risks (and possibly obtaining their consent) considered

Are these ethical considerations applied at your site?

Did you indicate that you are involved with research or have research projects/trials being conducting at your site?

If so, how are the ethical considerations described above applied in these projects?

Public health surveillance activities

- Refers to **ongoing, systematic collection, analysis, interpretation, and dissemination of data** regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health
- Intended to provide evidence basis needed for governments to **monitor prevalence of disease** and **measure impact of prevention and treatment programmes**
- Essential to advocates' ability to **call attention to problems** requiring reform

Application of ethical considerations to routine public health surveillance activities - 1

- Inform individuals when information taken in clinical contexts will be used
- Individuals and communities should be given information about:
  - Type of data being gathered
  - Purpose for which data will be used
  - Outcome of the surveillance

Application of ethical considerations to routine public health surveillance activities - 2

- Confidentiality of information generated should be protected to maximum extent possible
- Individuals should be informed of any circumstances in which information obtained may be disclosed to third parties
- Informed consent may be necessary in some circumstances:
  - Records or samples retain identifying information
  - May be linked with identifying information with a code

Application of ethical considerations to routine public health surveillance activities - 3

- Informed consent can be waived:
  - Research involves minimal risk
  - Obtaining informed consent would be impracticable
  - Protections for confidentiality and other rights are provided.
- Decision on appropriateness of waiving consent should rest with research ethics committee
- Research with records or samples for which identifying information has been permanently removed may also require review by research ethics committee

Circumstances in which biomedical research trials should not be performed – 1

- Capacity to conduct independent and adequate scientific and ethical review does not exist
- Voluntary participation and freely decided consent cannot be obtained
- Conditions affecting potential vulnerability or exploitation may be so severe that risk outweighs the benefit of conducting the trial in that population

Circumstances in which biomedical research trials should not be performed - 2

- Agreements have not been reached among all research stakeholders on access to medical care and treatment
- 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