TB Intensive
San Antonio, Texas
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Ethical Management of Patients with Complicated TB Disease
Adriana Vasquez, MD
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TB Intensive
Ethical Management of Patients with Complicated TB Disease

Adriana Vasquez, MD
UTHSCT at TCID
November 2014

Agenda

• Awareness of the limited number of patients with MDR/XDR-TB who access to appropriate diagnosis and treatment

• Ethical issues in tuberculosis prevention, care and control

• TB as a neglected topic in bioethics

• Palliative care and MDR/XDR-TB
PBS Frontline TB Silent Killer


Fragile Progress in MDR-TB

• Globally in 2013, about 480 000 people developed MDRTB
• The number of people diagnosed with MDRTB tripled between 2009 and 2013
  – Introduction of rapid diagnostics
• 97 000 patients were started on MDR-TB in 2013, three fold increase compared with 2009
• Key challenges
  – 39 000 patients were on the waiting list for treatment
  – Gap between diagnosis and treatment widened between 2012 and 2013
  – Poor treatment outcomes due to inadequate regimens, weak health systems and insufficient funding

WHO Global TB Report 2014
Proportion of TB Cases with Drug Resistance

- Increasing diagnosis of MDR TB
  - Xpert MTB/RIF available in 108 countries in 2013
- 3.5% of new TB cases in the world have MDR
- 20.5% cases with prior TB treatment have MDR
- 9% of MDRTB cases in the world have XDR-TB
- 100 countries have reported at least one case of XDRTB by the end of 2013

World Tuberculosis Day - 24 March 2014
The "missed" 3 million

- In 2014, the slogan for World Tuberculosis Day is "Reach the 3 million".
- TB is curable, but current efforts to find, treat and cure everyone who gets ill with the disease are not sufficient. Of the 9 million people a year who get sick with TB, a third of them are "missed" by health systems. Many of these 3 million people live in the world’s poorest, most vulnerable communities or are among marginalized populations such as migrant workers, refugees and internally displaced persons, prisoners, indigenous peoples, ethnic minorities and drug users.
Challenges

• 3 out of 4 MDR-TB cases still remain without a diagnosis

• Provision of antiretroviral therapy (ART) for TB patients known to be living with HIV needs to increase to meet WHO’s recommendation that all TB patients living with HIV promptly receive ART.

http://www.who.int/campaigns/tb-day/2014/event/en/
TB Case: Mr. R.L.

- 53 y/o Caucasian male with
  - No prior TB treatment
  - Alcohol dependent

- Prior TB exposure
  - Father diagnosed with susceptible TB in 1985
  - Acquired untreatable TB within 8 years, due to poor treatment regimens in TX
  - Went home and died under the care of his family

- Twelve years later, son was diagnosed with TB
  - Son helped taking care for his dying father

What Type of TB Do You Think Mr. R.L. Had?

- XDR – TB

He was treated at TCID for 2 years with daily medications and was cured
Why MDR-TB Develops?
Factors Fuelling the Outbreak

• Inappropriate treatment regimens
  – Choice of drugs, dosage, and treatment duration

• Program factors
  – Irregular drug supply, incompetent health personnel
  – Expired and even counterfeit medication
  – Lack of susceptibility testing
  – Lack of infection control and DOT

• Patient’s factors
  – Poor adherence, malabsorption, inability to travel to clinic


Can XDR-TB Patients be Cured?

• Likelihood of success is much smaller than treatment of MDR-TB or drug susceptible TB

• Cure rates depend on
  – Extent of drug resistance and disease
  – Co-morbidities
  – Early, accurate diagnosis and appropriate treatment

Five Priority Actions to Address the Global MDR-TB Crisis

1. Prevent the development of drug resistance through high-quality treatment of drug-susceptible TB
2. Expand rapid testing and detection of drug-resistant TB cases
3. Provide immediate access to effective treatment and proper care
4. Prevent transmission through infection control
5. Increase political commitment with financing

WHO Global TB Report 2014

Guidance on Ethics of Tuberculosis Prevention, Care and Control

Based on the work of a WHO Task Force on Addressing Ethical Issues in TB Care and Control Programs, and broad consultations with other experts and stakeholders, the World Health Organization (WHO) published a guidance document entitled "Guidance on Ethics of TB Prevention, Care and Control" in December 2010.

Governments Have a Responsibility to Provide Free and Universal TB Services

- Including diagnosis and treatment of M/XDR-TB

- Treatment significantly improve the health condition of individuals and the community by
  - Stopping the spread of a highly infectious disease.

http://www.who.int/tb/publications/ethics_in_tb_factsheet_28jan11rev.pdf?ua=1

Patients Need to Be Fully Informed and Counseled about their Treatment

- Informed consent is important when diagnosis is offered although no treatment can be provided

- Patients undergoing TB testing and treatment should receive comprehensive information about the risks, benefits and alternatives

http://www.who.int/tb/publications/ethics_in_tb_factsheet_28jan11rev.pdf?ua=1
Health Care Workers Have Obligations to Provide Care, but also a Right to Adequate Protection

• Health care workers have an ethical obligation to care for their patients

• Governments and health care institutions must provide a safe working environment

• Health-care workers who are at height risk of contracting TB themselves, such as those who are HIV positive, may be exempted from their duty to care

http://www.who.int/tb/publications/ethics_in_tb_factsheet_28jan11rev.pdf?ua=1

Involuntary Isolation is Rarely Justified and Should be a very Last Resort

• TB treatment should be provided on a voluntary basis
  – If a patient refuses treatment, this is likely to be due to insufficient counseling or lack of treatment support

• Involuntary isolation should always be used as a very last resort, and
  – It is essential that the manner in which it is implemented complies with applicable ethical and human rights principles

http://www.who.int/tb/publications/ethics_in_tb_factsheet_28jan11rev.pdf?ua=1
TB Programs and Practitioners Have a Duty not to Abandon their Patients

- There is a fundamental ethical obligation to provide
  - Palliative care to all patients in need
  - Patients should never be abandoned, even when all available curative treatments fail

- It is unacceptable to deny treatment based on predictions about non-adherence by particular patients

http://www.who.int/tb/publications/ethics_in_tb_factsheet_28jan11rev.pdf?ua=1
Research on TB is Necessary and Should Be Conducted in an Ethical Manner

• There is a need for further research on TB prevention, diagnosis and treatment

• Research should be guided by the ethical principles articulated in international guidelines

• Research should always ensure the dignity of the research subjects
  – Results should lead to a benefit for the affected population

http://www.who.int/tb/publications/ethics_in_tb_factsheet_28jan11rev.pdf?ua=1

Edendale Hospital, KwaZulu Natal, South Africa
TB is the Most Important Neglected Topic in Bioethics

- PubMed search conducted in 2007 for the terms
  - “Ethics” and “AIDS” yielded 2998 entries
  - “Ethics” and “TB” yielded 179 entries

- With the exception of AIDS, bioethics discussion of infectious disease remains in its infancy

The Spread of XDR-TB May Be More Significant than AIDS

- Being airborne, TB can be contracted via casual contact and is much more contagious
  - Behavioral modification (IV drug use, sexual contact) can prevent AIDS

- The risk to ‘innocent individuals’ and public health in general is greater in the case of TB
Ethical Challenges in TB Control in the Era of XDR-TB

- Distribution of health care resources
  - Unlike TB, AIDS requires lifelong treatment and no cure exists
    - Full course of TB medication cost $20 dollars vs. $100 per year for AIDS medications in developing countries
  - 20 million clinical trials for TB drugs vs. 300 million clinical trials for HIV drugs (2007)

- Advocacy for AIDS is greater than TB

Tuberculosis Research and Development, 2009–2012

- The U.S. government must increase its support for research to develop new tools to fight TB.
- TB vaccine was introduced in 1921 and offers limited protection to adolescents and adults.
- Only two new drugs to treat TB were developed over the last 40 years.
- This pales in comparison with the speed of research to tackle two closely related diseases:
  - HIV and hepatitis C. Advances in drug discovery have transformed hepatitis C, once a chronic condition, into a curable infection, and the U.S. Food and Drug Administration has approved 36 drugs or combinations of drugs to treat HIV since 1987.
- The development of drug-resistant TB has now outpaced the speed of drug discovery and approval

http://www.treatmentactiongroup.org/tbrd2014/usg
Challenges in TB Funding

• Estimated US $ 8 billion per year is required for a full response to the TB epidemic in low and middle income countries (excluding research and developing)

• Funding in 2014 is about US$6.3 billion

• Increase funding is required to close the gap up to US$2 billion per year

WHO Global TB Report 2014

Figure 1. USG investments in TB R&D as a proportion of the global total, 2009–2012
Ms. Z.A.: Patient with MDR-TB

- 38 y/o Mexican female with DM, married, 2 children - 9 and 15 years old

- Admitted to TCID with extensive, very advanced, cavitary MDR-TB

- Oxygen dependent throughout hospitalization

- Required mechanical ventilation for respiratory failure, successfully extubated

Initial Chest X Ray

September, 2012
5 months after MDR-TB Treatment Initiation

February 2013

MDR-TB with Anxiety, Depression

• Required prolonged AFB isolation
  – Three hours away from family, missed her kids
  – Requested to go home

• Developed GI and psychological intolerance to TB medications, depression, anxiety
  – Nausea, vomiting, refused to take medications by mouth, meds switched to IV

• Unable to take SSRI’s for depression
  – SSRI’s contraindicated with linezolid
Recurrent Respiratory Failure

• Worsening hypoxia,
  – Required 8 L oxygen

• Transferred to acute care hospital
  – Physicians discussed her poor prognosis with family
  – Husband agreed with comfort care

• Patient died of MDR-TB after 5 months hospitalization, leaving two orphaned children

Declaration on Palliative Care and MDR/XDR-TB Geneva, 19 Nov 2010

• Access to palliative care for individuals with MDR-TB is a human right and promotes dignity

• Palliative care in the context of MDR/XDR-TB should be integrated into the management of MDR/XDR-TB from the time of diagnosis until patient reaches cure or the end of life

• Palliative care definition by WHO is very appropriate for patients with resistant TB
Palliative Care and MDR TB

- Palliative care should be available to all people with potentially life-limiting illness like MDR TB
- Palliative care should be delivered to the patient and their family in the setting where they are receiving care
- Provides relief of pain and other distressing symptoms
  - Nausea, vomiting, cachexia, hemoptysis, dyspnea, fatigue

Palliative Care Association of South Africa

- Strongly recognizes that TB affects the entire household
  - Delivers palliative care in inpatient settings with isolation rooms and in homes
  - Recognizes the risk of infection to staff
- Improves quality of life, pain symptom control
- Provides compassionate end of life care

http://www.hospicepalliativecaresa.co.za
Conclusions

• MDR/XDR-TB is a serious global health threat

• Need to achieve universal access to diagnosis and patient centered treatment

• Palliative care should be available to all people with potentially life-limiting illness, including MDR-TB

• Robust research is needed to identify better ways to care for patient with MDR-TB
Conclusions

• Need to reduce the human suffering and socioeconomic burden associated with TB
  – Ensure treatment with dignity and compassion

• Numerous ethical reasons for wealthy nations to do more to help improve health care in poor countries.

• Infectious diseases fail to respect boundaries
  – Inadequate health care systems in poor countries threatens global public health

“Stop the stigma, discrimination and negligence”

Brenda, a TB Photovoice participant: “We need to put an end to stigma, discrimination, negligence and indifference. We have the science, the medication and everything it takes to STOP TB. What is keeping us from doing this?”
LINKS AND DOCUMENTS

• WHO’s STOP TB website:
  http://www.who.int/tb/en/
• WHO’s Ethics and Health website:
  http://www.who.int/ethics/en/
• WHO’s activities on Ethics & TB:
  http://www.who.int/tb/challenges/mdr/ethics/en/
• WHO global TB Report 2014
  http://www.who.int/tb/publications/factsheet_global.pdf?ua=1

Thanks for your Attention!!!!

Questions?
Rachel, a TB Photovoice participant: “Burning this mask was very important to me. I wore it for several months and it was very painful. My peers didn’t know what my face and smile looked like. When I burned the mask, it was like getting rid of the stigma (associated with Tuberculosis). I felt free.”