Ethical Management of Patients with Complicated TB Disease

Adriana Vasquez, MD
UTHSCNE at TCID

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Adriana Vasquez, MD has the following disclosures to make:

- No conflict of interests
- No relevant financial relationships with any commercial companies pertaining to this educational activity
Agenda

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

• Ethical issues in tuberculosis prevention, care and control

• Lack of TB funding

• Palliative care and MDR/XDR-TB

PBS Frontline TB Silent Killer

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.
GLOBAL BURDEN

TB is one of the world's top health challenges:
MORE THAN 2 BILLION PEOPLE, equal to a QUARTER of the world's population are infected with TB.

Despite our best efforts...
...there is an unacceptable low rate of decline in incidence each year.

EACH YEAR
1.5 MILLION DEATHS
9 MILLION NEW CASES

EACH DAY
24,000 NEW CASES
4,000 DEATHS
8,000 MISSED

3.3 MILLION people are either not diagnosed or not treated.
The proportion of missed cases remains the same each year.

Among those missed are those most vulnerable:
Children and women
The very poor
Households of people with HIV/AIDS
Indigenous populations
The elderly

Many of those missed will either die, fall into unknown treatment but most will continue to infect others.

www.stoptb.org
Why Are TB Patients Missed

• No Access: Distance to care, poverty, stigma, limited facilities, financial barriers, conflict
• No Diagnosis: undertrained staff, inaccurate tests, lack of equipment
• No Documentation: weak reporting, lack of case notification
• No Treatment: Lack of meds and poor links between services
Why Invest In Finding The 3 million TB Patients Missed

• TB is Curable with a $30 USD six month treatment course
• TB Respects No Borders
• A $1 USD Investment in preventing TB provides a $30 USD Return to National Economies
• 1 Person with TB can infect up to 10 people a year

Restoring Hope in Swaziland: Helping Stop TB through Earlier Diagnosis

• The Kingdom of Swaziland
• World’s highest incidence of TB superimposed with high levels of co-infection with HIV.
• 47% of people with TB in the country are not detected or notified.
• Late detection of TB increases the risk of disease transmission, poor health outcomes and economic hardship

http://www.who.int/features/2013/swaziland_tb/en/
In Swaziland 70% of patients with tuberculosis are also co-infected with the HIV virus.

Why MDR-TB Develops?  
Factors Fuelling the Outbreak

- Inappropriate treatment regimens
  - Choice of drugs, dosage, and treatment duration

- Program factors
  - Lack of susceptibility testing
  - Lack of infection control and DOT
  - Irregular drug supply,
  - Incompetent health personnel
  - Expired medication

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

THE END TB STRATEGY

VISION
A world free of tuberculosis
- zero deaths, disease and suffering due to tuberculosis

GOAL
End the global tuberculosis epidemic

<table>
<thead>
<tr>
<th>INDICATORS</th>
<th>MILESTONES</th>
<th>TARGETS</th>
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<tr>
<td></td>
<td>2020</td>
<td>2025</td>
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<tr>
<td>Reduction in number of TB deaths compared with 2015 (%)</td>
<td>15%</td>
<td>75%</td>
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<tr>
<td>Reduction in TB incidence rate compared with 2015 (%)</td>
<td>20%</td>
<td>5%</td>
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<tr>
<td>Tuberculosis-related deaths and illnesses due to TB (%)</td>
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PILLARS AND COMPONENTS

1. INTEGRATED, PATIENT-CENTRED CARE AND PREVENTION
   A. Early diagnosis of tuberculosis including universal drug-susceptibility testing, and systematic screening of contacts and high-risk groups
   B. Treatment of all people with tuberculosis including drug-resistant tuberculosis, and patient support
   C. Collaborative tuberculosis/HIV activities, and management of co-morbidities
   D. Preventive treatment of persons at high risk, and vaccination against tuberculosis

2. BOLD POLICIES AND SUPPORTIVE SYSTEMS
   A. Political commitment with adequate resources for tuberculosis care and prevention
   B. Engagement of communities, civil society organizations, and public and private care providers
   C. Universal health coverage policy, and regulatory frameworks for case notification, vital registration, quality and rational use of medicines, and infection control
   D. Social protection, poverty alleviation and actions on other determinants of tuberculosis

3. INTEGRATED RESEARCH AND INNOVATION
   A. Discovery, development and rapid uptake of new tools, interventions and strategies
   B. Research to optimize implementation and impact, and promote innovations

THE GLOBAL STRATEGY AND TARGETS FOR TUBERCULOSIS PREVENTION, CARE AND CONTROL AFTER 2015, WERE ENDORSED BY ALL MEMBER STATES AT THE 2014 WORLD HEALTH ASSEMBLY.
Guidance on Ethics TB Care and Prevention

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 MDR/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

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
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

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
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

M.J. Selgelid IJTBLD 12(3);231-235 2008

Person with MDR-TB

• 33 year old Hispanic male from Peru
  – History of successful treatment in Peru for pan-susceptible TB, while in jail

• TB exposure
  – History of incarceration in Peru for 12 years
  – 3 cell mates died from MDR-TB

• Patient was diagnosed with MDR-TB 15 months after he immigrated to the US

• Poor infection control leads to spread of MDR-TB
• Sewri, largest TB hospital in Mumbai, 1200 beds, average 6 TB patients die a day
• 69 employees has been diagnosed with TB since 2011
  – 12 had died while 28 had been cured.
• Staff continue to work at the hospital long after being infected
• Workers like house keepers leave work after they get sick
  • "We don't know if they're alive with the disease or dead. Nobody tracks them. That's why I said the actual number would be much higher."
• Weak infection controls, infrequent checks on HCW, staff failed to wear N-95 where
• 40 patients attempted and 12 committed suicide in 3 years, fed up with painfully long treatments and lack of family support
  – Only one of 5 counsellor positions could be filled

Reuters October 11, 2015
Ethical Challenges in TB 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

M.J. Selgelid IJTBLD 12(3);231-235 2008
Global Control of TB: From XDR to Untreatable Tuberculosis

- Large number of untreatable TB, more than 100 patients, culture positive after 12-18 months of intensive inpatient treatment discharged into the community in South Africa since 2008
  - 33% smear positive
- Median time to death in the community after discharge was just under 2 years
- Lack of infection control in their homes and community, lead to spread of untreatable TB
- Great need for long term care facilities and palliative care

Global Control of TB: From Extensively Drug-Resistant to Untreatable TB

- KwaZulu-Natal more than 300 HCW diagnosed with MDR/XDR-TB, rate 6 times higher than in the community, suggesting nosocomial transmission
- Fears about contracting TB could exacerbate HCW shortage
- HCW should be screened at least annually with
  - TB symptom questionnaire, CXR
- Appropriate environmental and personal protection should be available and implemented
- HCW with MDR/XDR-TB should be appropriately managed

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
Initial Chest X Ray 5 months after MDR-TB Treatment Initiation

September 2012

February 2013

Respiratory Failure

• Worsening hypoxia, requiring intubation
  – Required 8 L oxygen

• Patient died of MDR-TB after 5 months hospitalization, leaving two orphaned children
WHO: What is Palliative Care

Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening

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
WHO: What Palliative Care Provides

- Relief from pain and other distressing symptoms
  - nausea, vomiting, malnutrition, hemoptysis, dyspnea
- Integrates the psychological and spiritual aspects of patient care
- Offers a support system to help the family cope during the patients illness
- Uses a team approach
- Enhance quality of life

WHO - The “Total” Pain Concept

**Emotional**
- Lost of function
- Coping abilities

**Spiritual**
- Guilt
- Why me?
- Life closure issues

**Physical**
- From disease
- From treatment

**Financial**
- Direct costs
- Indirect costs

WHO Global atlas of palliative care 2014
The Time is Now

- Each year nearly 500,000 people become sick with MDRTB
- By 2050 if we do not act, more than 2.6 million will die from MDRTB every year
- Costing the global economy a collective $17 trillion in loss productivity

cdc.gov/globalaids

ELIMINATING MDRTB WORLDWIDE

We are at a critical tipping point in the fight against MDR TB. The resistant strains are spreading and growing more resistant. If left unchecked, this may lead to a future where TB is no longer curable and TB deaths rise substantially. To contain this emerging crisis, we must act now to:

- Find and cure all existing cases of MDR TB
- Develop better tools to find and cure all forms of TB
- Strengthen basic TB control programs to prevent drug-resistant strains from developing

"Imagine a future where everyone with TB was diagnosed quickly, started on effective treatment - a regimen lasting only a few weeks - and a cure was nearly universal. By pairing global efforts to improve public health response capabilities with proven interventions to strengthen TB control, we can improve the lives of people with TB and avert the suffering and cost associated with this deadly disease."

Dr. Tom Frieden
Director, Centers for Disease Control and Prevention
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 global TB Report 2015

Thanks for your Attention!!!!

Questions?