M/XDR-TB AND THE LAW: South African Context

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Background to South African situation

- HIV pandemic & spiraling epidemic of TB, with associated ↑ in M/XDR-TB
- Collectively throughout all 9 SA provinces, among highest #s of XDR-TB worldwide
- MDR-TB accounts for ~3% of all TB cases (± 6000 MDR-TB cases documented a year)
- Strong public health interventions are required to protect highly-susceptible, as well as immune-competent, individuals who are at high risk
- Defaulting [>30% d/t long duration of Rx, S/E of anti-TB drugs, prolonged hospitalization], treatment failures, etc. => chronic M/XDR-TB failures & pose serious PH risk
The South African Reality

THE STATUS QUO
Gauteng’s hospitals of neglect

[Hospitals had] “become the gates which lead to death”
Thomas Lightfoot (1850): London Medical Times

Why was my sister left to rot to death?
Killer bugs strike hospitals
One in seven patients at risk of picking up life-threatening infection

SA’s deadly new plague
Top doctor warns that hospital infections could soon rival Aids and malaria

Hospital diagnosis is no comfort to bereaved parents

Worldwide alarm at virulence of bacteria
Misuse of antibiotics spawns bugs immune to every weapon in medicine’s arsenal
Tuberculosis: An Infection Control Perspective

- Community to Hospital

- Nosocomial transmission
  - patient-to-patient
  - patient-to-HCW

- Hospital to Community:
  - Intrafamilial spread in 4 families of MDR-TB from patients treated at Sizwe Hospital

Woolf M, 1988, Presented at ID Congress, Sandton, South Africa
Tuberculosis: An Infection Control Perspective

- Nosocomial transmission:
  - patient-to-patient:
  - patient-to-HCW:
    - Balt E, et al. Nosocomial transmission of TB to HCWs in Mpumalanga. SAMJ

7 HIV positive patients
Initial hospital admission: sensitive MTB (6 pts)
Nosocomial acquisition of MDRTB - 6 drug resistance
Atypical clinical presentation  Rapidly fatal
## SIZWE MDRTB OUTBREAK ‘97 - ‘98

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- **Sensitive**
- **Resistant**
The issues

- Outbreak responses REACTIVE rather than PROACTIVE
- Surveillance systems WEAK. Delay in outbreak detection -> increased cases, increased loss of lives. Costs (direct + indirect) inestimable
- Education, staffing, infrastructure and political support often neglected
- INFECTION CONTROL OFTEN NOT PRIORITISED!
- Whose responsibility is it? And accountability?
Principlistic ethical conflicts emerge giving rise to ethical & legal dilemmas

- **Infringements** of not only the patient’s autonomy, but also of individuals including HCWs at high risk of acquiring the disease

- **Beneficence & non-maleficence**: rationale for treating patients is good, but how can no harm be done if some drugs are either painful when administered &/or linked with toxic S/Es

- **Justice**: (i) resource allocation to a man-made problem, and (ii) exposure of unsuspecting individuals to a potentially life-threatening disease
South African legal framework

- The Constitution of the Republic of South Africa Act 108 (1996) is supreme law of the nation – all legislation, including that relevant to PH – must be contextually & legally aligned with the Bill of Rights.

- Bill of Rights (Chapter 3 of the SA Constitution) defines rights of all South Africans & affirms values such as human dignity, equality, autonomy (which includes informed consent), self-determination & freedom – these must be respected, protected & enforced by the State.

- However, and potentially conflicting with the SA Constitution, are public health interventions, within the current SA legal framework aimed at containing serious PH hazards such as M/XDR-TB.

- The Bill of Rights spells out the parameters within which the DoH is required to operate.

- Effective PH procedural safeguards within existing legislation are lacking.
SA Legislation pertaining to rights of HCWs & allied health practitioners

- OHS Act 85 of 1993 and its HBA regulations (21 December 2001)
- Compensation of Occupational Injuries Act 130 of 1993
- Employment Equity Act 55 of 1998
- Labour Relations Act 66 of 1995
- Basic Conditions of Employment Act 75 of 1997
SA: The rights of HCWs & allied health professionals

- TB (& therefore M/XDR-TB) listed occupational disease
- Employer has a legal responsibility to provide safe measures or alternative employment for HCWs (e.g. HIV-infected) at greater risk to acquire TB in workplace
- HBA regulations clearly spell out responsibilities of both Employer and Employee to take all measures to limit & control exposures to dangerous biological agents
The Healthcare Worker

- Administrative, infrastructural & other controls
  - Legal rights
  - Responsibility of Healthcare Facility Administrator to:
    - Educate Staff
    - Offer VCT for HIV: inform of risks & provide options
    - Staff monitoring
    - Building design (engineering controls) – ID high-risk areas
    - Provide appropriate PPE & handwashing
SA: The rights of HCWs & allied health professionals

- HCW counseling about risks of working with TB and M/XDR-TB patients, taking all necessary precautions, right to work in a safe workplace, understanding the substantially increased risks if they are/become HIV +ve
- VCT should be offered but not compulsory – if HIV +ve HCW wants to be transferred to a safer working environment, option provided to do so
- Disclosure of HCW HIV status is voluntary & must be held in strictest of confidence
- Compensation claims can be lodged in terms of COIDA where TB presumed to be contracted during working hours & in workplace in which significant exposures are deemed to have taken place
- HCWs contracting TB through work cannot be dismissed on the basis of either incapacity or expiry of paid sick leave: a fair procedure, validity of which will be tested on a case-by-case basis in our courts, must be followed
Current legal framework regarding rights of the community vs. those of the patient

- State required ethically and by law to protect communities from being exposed to, and acquiring, potentially dangerous IDs

- Health Act ‘empowers’ PH authorities to implement interventions to contain those IDs that are a PH threat. BUT these must be carefully balanced with rights of the patient as an individual. Furthermore, in SA Constitution provision is made for restriction of individual rights under strict circumstances

- Constitutionally, however, all South Africans are entitled to a safe and healthy environment, including right to be protected from infection
Current legal framework regarding rights of the community vs. those of the patient

- Ethical & PH dilemmas include:
  - Issues of disclosure of an individual’s M/XDR-TB status to close contacts & the community
  - Infectious patients continuing employment
  - Discharge of chronic infectious patients back into the community
- PH authorities are constitutionally required to operate within the context of the Bill of Rights
- Violations of individual patient rights include violation of rights to: (i) freedom & security of person, (ii) life, (iii) healthcare services & emergency medical treatment, (iv) privacy, (v) justice, and (vi) those that, consequent to enforced hospitalization and isolation, impact on human dignity, freedom of movement & residence, and freedom of trade, occupation and from enforced detention
Recommendations (legal – subject o the use of lawful procedures, not ethics-based) proposed by the SAMRC  

Weyer K et al, MRC Policy Brief on Managing MDR-TB, No.1, January 2006

- Provision for enforced commitment to hospitalization/isolation – *seriously infringes on the right to freedom & security of person.* Enforced hospitalization justifiable only as a last resort.

- Treatment of M/XDR-TB patients cannot be enforced without patient’s consent – *invasion of right to freedom, security of person, & bodily integrity*

- Hence, informed consent (written) is required for Rx of M/XDR-TB patients

- Disclosure of patient’s status (except for notification) is not permissible – *infringes on patient’s confidentiality*

- Termination of Rx by HCW justifiable if: (i) Rx default – *provided that individual be heard before such action is taken*, (ii) consent for further Rx withdrawn by patient, (iii) negligible chance of therapeutic success, (iv) interruption & re-institution of Rx results in unacceptable risk of amplification of M/XDR-TB
Conclusions 1:

- Emergence of XDR-TB is a sober reminder of SA public health system to fail to control TB
- Knowledge needed of existing legislation / regulations in each country we operate in before appropriate recommendations are made
- PH interventions for IDs, with aim to contain infection, that have to resort to quarantine or detention of affected individuals will come at a cost of individual rights (particularly those concerning freedom and privacy)
Conclusions 2:

- Although Constitutional safeguards & PH legislation makes provision to overrule individual rights in the interest of PH, bioethicists – often in conflict with legal principles – will closely be monitoring & safeguarding human rights of individuals in just and open democratic societies.

- Ethically, utilitarianism will be challenged by the humanitarian approach.

- Major challenge in SA is to develop an ethically justifiable framework for Mx of M/XDR-TB that is based on sound legal principles.

- Test cases in South African courts are urgently needed to provide legal guidance that is acceptable within the context of both public health effectiveness & the individual rights of South Africans.
Are we going to see THE END OF TB in our lifetimes?

A call from the millennium children of the Eastern Mediterranean Region
Thank you!