



**UNIVERSITY OF
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**INYUVESI
YAKWAZULU-NATALI**

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School of Law**

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RESEARCH DISSERTATION FOR MASTERS IN
MEDICAL LAW**

**The Health, Ethical and Legal implications of non-
adherence to treatment amongst patients infected**

with Tuberculosis.

(The HEAL Study)

**Jayneetha Maharaj
205522671**

Supervisor: Dr Donrich W Thaldar

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Table of Contents:

Declaration of original work iv
List of abbreviations and acronyms v
List of Tables vi
Abstract vii

Chapter 1: Perspectives on Tuberculosis, ethics and the law

1.1. Introduction 1
1.2. Rationale and research questions 2
1.3. Research outline 3
1.4. Literature review 4
1.5. Research design and methods 5

Chapter Two: Tuberculosis, non-adherence and public health implications

2.1. Introduction 7
2.2. Classification and treatment of TB..... 7
2.3. TB, MDRTB and public health8
 2.3.1. The impact in SA 8
 2.3.2. The global impact 9
2.4. The concept of non-adherence10
 2.4.1. Definition 10
 2.4.2. Factors contributing to non-adherence 11
 2.4.3. Impact of non-adherence 12
 2.4.4. Non -adherence strategies 13

Chapter Three: Ethical, legal and human rights considerations of TB care

3.1. Ethical considerations 16
 3.1.1. Equity and social justice 16

3.1.2. Solidarity	18
3.1.3. Beneficence	19
3.1.4. Autonomy	19
3.1.5. Effectiveness and efficiency	19
3.1.6. Privacy and confidentiality	19
3.1.7. Informed consent	20
3.1.8. Ethics and TB research	20
3.1.9. Justice	21
3.2. Human rights considerations	22
3.2.1. Prisoners and people in custody	22
3.2.2. People who use drugs	23
3.2.3. Healthcare workers	23
3.2.4. Migrants	24
3.2.5. Children	24
3.2.6. Moribund and terminally ill people	25
3.3. Non-adherence and coercive social distancing	26
3.3.1. The harm principle	26
3.3.2. Human rights principles	27
3.3.3. Principle of reciprocity	28
3.4. Legal considerations and case law in TB care	28
Chapter Four: The re-introduction of TB sanatoria	
4.1. Introduction	36
4.2. Historical perspective	36
4.3. Rationale for sanatoria	37
4.3.1. Benefits	37
4.3.2. Failure of current strategies	38
4.3.3. Socio economic challenges	39
4.4. Current attitudes of patients, HCW's and public individuals to sanatoria	41

Chapter Five: Conclusion	43
List of Cited Works	48
Appendix 1	59

Sincere gratitude to:

To Almighty God for making this possible, to my husband without whom this would not be achievable, and to my children for their constant support.

“The world has made defeating AIDS a top priority. This is a blessing. But TB remains ignored. We can't fight AIDS unless we do much more to fight TB as well”

Nelson Mandela, former President of South Africa

Declaration of Original Work

I, Jayneetha Maharaj (205522671), declare that:

(i) The research produced in this mini dissertation for the purposes of completing an LLM in Medical Law, except where otherwise indicated, is my original work.

(ii) This mini dissertation has not been submitted for any degree or examination at UKZN or any other university.

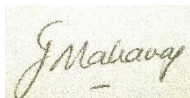
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ABBREVIATIONS AND ACRONYMS

AIDS - Acquired immunodeficiency syndrome

ART - Antiretroviral therapy

CRC - Convention on the Rights of the Child

FSW - Female sex worker

HCW - Health care workers

HIV - Human immunodeficiency virus

HRC - United Nations Human Rights Council

ICCPR - International Covenant on Civil and Political Rights

ICESCR - International Covenant on Economic, Social and Cultural Rights

MDR-TB - Multidrug-resistant tuberculosis

OHCHR - Office of the United Nations High Commissioner for Human Rights

PWUD - People who use drugs

SES - Socioeconomic status

TB - Tuberculosis

UN - United Nations

UNAIDS - Joint United Nations Programme on HIV/AIDS

UNDP - United Nations Development Programme

WHO - World Health Organisation

List of Tables

Table 1: Rationale for sanatoria: a tabulation	40
Table 2: Current attitudes of patients, HCW's and public individuals to sanatoria.....	41

ABSTRACT

Despite global efforts to eradicate tuberculosis (TB), it remains a significant cause of morbidity and mortality. In South Africa, healthcare represents the fourth highest area of annual expenditure, however the prevalence of TB, including drug-resistant TB and HIV-related TB remains amongst the highest in the world. The control of this infection is further compromised by patients who do not complete their treatment, thereby contributing to the development of resistant forms such as MDRTB and XDRTB. Although some success has been achieved in decreasing mortality, the eradication of TB remains challenging. A paradigm shift from the current focus on biomedical and pharmacological interventions must include ethical, human rights and legislative considerations, as the control of the disease is inextricably linked to social determinants and public health. Nonadherence to treatment extends beyond the research and development of newer drugs and requires input into the social determinants as well. Nonspecific legislation and generic policy guidelines may ultimately contribute to public health endangerment as authorities attempt to balance individual autonomy and public health rights in cases where infected persons wilfully default on treatment. More aggressive measures such as isolation and imprisonment have also not proven effective in countries that have enforced them. In this context, the dissertation explores the current impact of TB, the ethical issues, and the legislative constraints relating to the management of non-adherence to treatment. Modern-day sanatoria as a treatment umbrella for both nonadherence and social determinants is introduced, whilst ethical considerations such as social justice, equity and solidarity, are discussed within the existing legislative and policy framework. In support of the movement for sanatoria, the dissertation provides the reader with the findings of a pilot survey on the attitudes of current TB sufferers and health care workers towards this intervention. In the final analysis, it remains the collective duty of infected individuals, the general public, and both state and non-state actors to fulfil their respective roles in eradicating the disease.

Chapter 1: Perspectives on tuberculosis, ethics and the law

1.1. Introduction

Tuberculosis (TB) is caused by an infection with a bacterium called *Mycobacterium tuberculosis*.¹ The infection is spread by bacteria in the air and can be contracted when one breathes in infected air.² People who are in close contact with infected individuals are at increased risk of contracting infection, as the infected droplets can enter their lungs. Immunocompromised individuals, including those with HIV infection, diabetes mellitus, children, elderly and malnourished persons may develop serious complications such as lung collapse.³ TB is known to spread to other organs including the brain and bones and can result in significant morbidity and mortality.⁴ Globally, TB remains the leading cause of infectious mortality and the most common cause of drug resistance.⁵ Social determinants such as : (1) poverty, (2) malnutrition, (3) poor housing, (4) lack of sanitation, (5) gender inequality, (6) smoking, and (7) alcohol abuse contribute to the risk of infection, especially amongst those who are vulnerable.⁶ However, if the infection is diagnosed early, correct medication administered and adherence to treatment is followed, TB can be completely cured. To the contrary, non-adherence to treatment, *inter alia*, leads to complicated forms of TB, collectively referred to as ‘multi drug resistant (MDTB)’.⁷

Despite the vast efforts by healthcare and allied workers to eradicate the epidemic completely, the treatment success rate for TB was quoted as 86% in 2014, and treatment success rates of 54% and 30% were reported for MDR-TB and XDR-TB respectively.⁸ Extensively drug-resistant tuberculosis (XDR-TB) is a complicated form of TB which develops when bacteria become resistant to some anti-TB drugs, and follows the inappropriate management of multidrug-resistant TB (MDR-TB).⁹

¹ Centre for Disease Control and Infection ‘Tuberculosis (TB) Disease: Symptoms and Risk Factors’ (24 January 2019) available at <https://www.cdc.gov/features/tbsymptoms/index.html> , accessed on 7 June 2019.

² Tuberculosis bacteria are spread through droplets in the air, commonly referred to as ‘droplet spread’.

³ Ibid.

⁴ Ibid.

⁵ UNAIDS ‘Tuberculosis’ (2019) available at <https://www.unaids.org/en/topic/tuberculosis> , accessed on 7 June 2019.

⁶ Ibid.

⁷ Ibid.

⁸ World Health Organization ‘Global Tuberculosis control’ (2015) available at http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf , accessed on 7 June 2019.

⁹ Swendiman K and Jones N ‘Extensively Drug-Resistant Tuberculosis (XDR-TB): Emerging Public Health Threats and Quarantine and Isolation’ Congressional Research Service (2010) available at <https://fas.org/sgp/crs/misc/RL34144.pdf> , accessed on 12 September 2019.

In South Africa, infection control measures are not rigorous, and the responsibility of preventing spread to the general public lies with the infected patient, who is expected to adhere to treatment regimens after counselling.

In addition to treatment counselling, advice on infection control measures such as coughing away from people ¹⁰, the frequent washing of hands and avoiding crowded spaces, infected patients are further advised to limit their travel whilst they are infectious. Currently, no legislation exists to enforce adherence to treatment, restrict movement in public spaces or to enforce the practice of infection control measures. The spread of infection therefore impacts negatively on both individual and public health and contributes to the current economic, social and disease burden in the country.

The legal, ethical and existing policy framework therefore requires a ‘reappraisal’ in order to protect and maintain the human rights of the infected patients - as well as the general public. In this context, the dissertation explores the individual obligations of patients to avoid infecting others, including measures such as coercive social distancing, third-party notification, the duty of health workers to treat infectious patients (and limitations thereto), as well as certain aspects of social justice, amongst other issues. The need for legislative reform, empirical research, adherence to ethical principles, and rescue alternatives such as TB sanatoria are discussed further.

1.2. Rationale and research questions

South Africa is generally considered to have high rates of TB - the ‘Global TB Report’ suggested that in 2014, the country had the second-highest incidence globally.¹¹ According to the report, the incidence has also increased fourfold over the past decade.¹² Tuberculosis can be cured completely if treatment is strictly adhered to, however it continues to remain a foremost cause of death, particularly in those who have co-existing HIV infection.¹³ Further data also indicate a rise in multidrug resistant tuberculosis (MDRTB) cases, as well as the existence of extreme drug resistant tuberculosis (XDRTB).¹⁴ Patients who do not complete their treatment suffer a high risk of mortality, and hence

¹⁰ This entails coughing at a distance away from people, using a tissue or coughing into an elbow whilst turning away from people.

¹¹ World Health Organization ‘Global Tuberculosis control’ (2015) available <http://apps.who.int/>.pdf., accessed on 7 June 2019.

¹² Ibid.

¹³ Statistics South Africa. Mortality and causes of death in South Africa, 2014: Findings from death notification. Pretoria: Stats SA; 2015.

¹⁴ World Health Organization (see note 11 above).

contribute to mortality data for TB in general, including the rate of conversion from drug sensitive to drug resistant TB.¹⁵ In this context, the research questions relate to (1) the success of existing strategies, (2) the adherence to ethical guidelines, (3) the role of relevant legislation and (4) the need for an alternate strategy (5) the potential role of sanatoria to promote adherence.

1.3. Research outline

The body of the dissertation comprises of five chapters, including the introductory and conclusory chapters. In Chapter 1, a brief overview of the clinical and public health impact of TB is discussed as well as the need for adherence to treatment in order to prevent spread and control the disease. Ethical, legal and policy frameworks for the management of non-adherence is presented. A literature review of the key focus areas as well as an outline of the research methodology is also presented, leading into Chapter 2.

In Chapter 2, TB is discussed from a clinical practice perspective. The concept of ‘multi drug resistant TB’ is explained and the local and global impact of both types of TB are highlighted. The concept of ‘non-adherence’ and its implications is discussed further and strategies for dealing with non-adherence are explored. A review of the option of compulsory isolation is made through the investigation of secondary sources and relevant legal prescripts and policy guidelines.

In Chapter 3, the ethical, legal and human rights issues relating to TB care and control are highlighted. Individual ethical principles are discussed, followed by human rights considerations of both patients and healthcare workers. Specific attention is drawn to vulnerable groups where poor adherence to treatment poses a significant risk to global spread and complicated forms of the disease. In relation, the ethical and legal issues of coercive social distancing are also investigated. The chapter closes with a discussion of the general legal framework, including references to case law and a brief comparative analysis of TB legislation in other countries.

In Chapter 4, TB sanatoria are discussed from a historical perspective and treatment outcomes are presented. A rationale for the reintroduction of modern-day sanatoria is presented in the context of the failure of current strategies, socio-economic challenges and the potential benefits. This chapter concludes with a brief assessment of the current attitudes of healthcare workers, infected patients and the public towards the reintroduction of sanatoria to manage TB more successfully.

¹⁵Adane A, Alene K, Koye D, et al ‘Non-Adherence to Anti-Tuberculosis Treatment and Determinant Factors among Patients with Tuberculosis in Northwest Ethiopia’ (2013) 8(11) *PLoS One* 1.

In Chapter 5, key ethical, human rights and legislative aspects are synthesised and a rationale for the reintroduction of modern-day sanatoria is highlighted. The role of sanatoria as a treatment umbrella that embraces the health, ethical and legal aspects of TB care is presented to close this chapter.

1.4. Literature review

The literature reviewed in the dissertation includes sources that informs: (a) clinical and epidemiological aspects, (b) spread and public health implications of TB and MDRTB infection, (c) the juxtaposition of individual and public ethical positions, and (d) the legal prescripts and policy guidelines that relate to the management of TB locally and globally:

According to the WHO, the African continent has three times the disease burden for TB and related deaths for its population compared with other areas.¹⁶ It is also suggested that the incidence of tuberculosis in African countries increased twofold previously.¹⁷ Tuberculosis is predominantly a disease of the human respiratory system and is completely curable, however if left untreated it will result in the spread of the infection, and ensuing morbidity and mortality. Drug resistance may emerge when anti-TB medication is not used according to schedule, prescribed incorrectly by health professionals, are of substandard quality, and more commonly, when patients stop treatment before completion (non-adherent).¹⁸ According to the WHO, over half a million cases were identified with resistance to the most common and effective ‘first-line drug’ used for TB viz, rifampicin.¹⁹

The challenge faced by healthcare practitioners relates to (1) the enforcement of drug adherence whilst maintaining an ethical standard of practice, and (2) the legal recourse available to them to manage non-adherent patients. When prescribing treatment, HCW’s must also take cognisance of the informed choices made by their patients about treatment, including the exhaustive counselling required for those who opt out of a treatment plan. Informed consent is also important before treatment initiation and to promote adherence. The refusal of treatment by patients further poses a major challenge to the control of the TB epidemic. Healthcare providers therefore face the dilemma of respecting their patient’s choices or acting in the best interest of public health by enforcing adherence. The *Siracusa Principles*, which were adopted in 1984, have established conditions and criteria when restricting human rights

¹⁶ Chiasson RE and Martinson NA ‘Tuberculosis in Africa — Combating an HIV-Driven Crisis’ (2008) 358 (11) *NEJM* 1089.

¹⁷ Dockrell HM ‘Towards new TB vaccines: What are the challenges?’ (2016) 74(4) *Pathogens and Disease* 16.

¹⁸ Munro S, Lewin S, Smith H, et al ‘Patient Adherence to Tuberculosis Treatment: A Systematic Review of Qualitative Research’ (2007) 4(7) *Plos One* 238.

¹⁹ World Health Organization ‘Global tuberculosis report 2017’. Geneva: WHO; 2017 available at http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf, accessed on 5 June 2019.

in order to avoid public health risk.²⁰ Guidelines on non-consensual medical treatment is contained in Article 12 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which provides that ‘every individual has a right to obtain the highest standards of mental and physical health including the right to be free from non-consensual medical treatment’.²¹ Similarly, ‘involuntary detention’ implemented to enforce treatment and prevent spread, not only breaches the right to privacy, but also breaches the freedom of movement of the individuals. However, the National Health Act 61 of 2003,²² recognises that there are situations when patients may be ‘admitted to a health facility without their consent if they pose a risk to themselves or the public’. Notwithstanding, more specific local policies and guidelines are therefore required to ensure the prevention of spread whilst ensuring that the rights of patients are not infringed. The reluctance of some countries such as Kenya and Canada to follow the *Siracusa Principles* and the ICCPR guidelines highlights the need for specific norms and standards, inclusive of ‘rights-restricting measures’ that address the threats to public health.²³ Legislation and practices that comply with existing human rights obligations in cases of detention, compulsory treatment, and other rights-restricting measures for TB therefore require further consideration.

1. 5. Research design and methods

The dissertation adopts a qualitative design based on desktop research involving primary and secondary sources of data. Primary sources include inter alia, but were not limited to, constitutional references locally and internationally, national legislature/policies/strategies, case and delict law references, statutory law references and empirical research in journal articles. Secondary sources included scholarly articles from journals, published papers, qualitative and quantitative research papers, commentaries, original reports and personal communication where available. Seminars, conference proceedings and press releases were included for supplementary background information and comparative purposes. Chapter 1 will introduce the topic in the dissertation. Chapters 2,3 and 4 includes the core areas of the topic.

²⁰ Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights Annex, UN Doc E/CN.4/1984/4 (1984).

²¹ International Covenant on Economic, Social and Cultural Rights (1966) Article 12.

²² National Health Act No 61 of 2003 s7.

²³ Todrys K, Howe E, and Amon J ‘Failing Siracusa: governments’ obligations to find the least restrictive options for tuberculosis control’ (2013) 3(1): *Public Health Action* 7.

Chapter 5 will be the conclusory chapter and include the rationale for the introduction of TB sanatoria as an intervention.

In concluding this chapter, it becomes evident that Tuberculosis presents not only a medical challenge but is inextricably linked to social determinants as well. Ethical and legal challenges present further boundaries to care and compliance. In Chapter 2, non-adherence to anti -TB therapy and public health implications are discussed further.

Chapter 2: Tuberculosis, non-adherence and public health implications

2.1. Introduction

TB has been widely recognised as a leading cause of death from a bacterial infection.²⁴ The evidence of TB can be traced to mummies in Egypt and dates as far back as 2400BCE.²⁵ The infection was initially referred to as ‘phthisis and consumption’ and later as ‘white death’, and the ‘great white plague’, before contemporary descriptions such as pulmonary and disseminated TB were utilised.²⁶ In the early years, TB reached epidemic proportions in Europe and North America, affecting mostly the lower socio-economic classes of that society.²⁷ Although the incidence of TB has declined globally, it remains a major public health issue, especially in poor resourced countries, as many deaths still currently occur in developing countries.²⁸ Non adherence to treatment for primary TB contributes to the development of more complicated forms of TB such as MDR TB and XDR TB which carry a higher mortality.

2.2. Classification and treatment of tuberculosis

TB can be classified according to the response of the bacilli to specific antibiotic drugs, and is known as either ‘drug sensitive’ or ‘drug resistant’, depending on the specific response shown.²⁹ Drugs that are initially prescribed, also known as ‘first line or core drug regimens’ include drugs such as rifampicin and isoniazid.³⁰ When the response to these first line drugs for initial TB infection is unsuccessful, a resistant form of TB called ‘MDRTB’ (multidrug resistant TB) develops, which requires the use of more toxic drugs such as fluoroquinolones, which are referred to as ‘second line drugs’.³¹ The development of resistance to second line drugs is classified as XDRTB (extensively drug resistant tuberculosis), for which novel, experimental and more toxic drugs are then prescribed.³²

²⁴ UNAIDS (see note 5 above).

²⁵ Barberis I, Bragazzi NL, Galluzzo L, et al ‘The history of tuberculosis: from the first historical records to the isolation of Koch’s bacillus’ (2017) 58(1) *J Prev Med Hyg.* 9.

²⁶ Ibid.

²⁷ Ibid.

²⁸ World Health Organisation ‘Tuberculosis’ (2018) available at <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>, accessed on 28 May 2019.

²⁹ Pinto L and Menzies D ‘Treatment of drug-resistant tuberculosis’ (2011) 4 *Infect Drug Resist* 129.

³⁰ Ibid.

³¹ World Health Organization. Anti-tuberculosis drug resistance in the world. Report no.4. WHO/HTM/TB/2008. 394.

³² Ibid.

More recently, tuberculosis bacteria that have become resistant to most of the available scheduled drugs have been identified in parts of the country, and have subsequently been classified as ‘TDR-TB’ (totally drug-resistant tuberculosis).³³ Although a small number of cases are thought to be extensively or totally drug resistant, they have been identified in India, Iran, Italy and South Africa.³⁴

2.3. TB / MDR-TB and public health

TB is a preventable disease and most cases can be cured when appropriate medicines are prescribed and taken correctly. Generally, the risk of serious illness amongst those with TB is low, especially if treatment is adhered to, however when the immune system is compromised by HIV, malnutrition or diabetes, the risk increases.³⁵ According to the WHO, patients with HIV infection have a 30% greater risk of contracting TB as a secondary infection.³⁶ Of concern, is that over half a million cases have developed resistance to rifampicin in 2017, noting that it remains the most effective initial drug currently used for TB.³⁷ Multidrug-resistant TB (MDR-TB) remains a growing public health crisis as long as the general public remains exposed to infection.

2.3.1. The impact in South Africa

It is widely accepted that South Africa has amongst the highest rates of TB globally, and TB remains the primary cause of mortality.³⁸ According to the ‘2018 WHO Global TB Report’, it is estimated that there were over 300 000 cases of active TB 2 years ago, and almost 80 000 people demised from infection.³⁹ It is further suggested that almost two thirds of infected persons have HIV infection.⁴⁰ Although more patients have been cured in the last decade, the rate of TB infection remains high, and

³³ World Health Organization ‘Totally Drug Resistant’ tuberculosis: a WHO consultation on the diagnostic definition and treatment options’ (2012) available at www.who.int/tb/areas-of-work/drug-resistant-tb/totally-drug-resistant-tb-faq/en/, accessed on 23 May 2019.

³⁴ Dheda K ‘Latest transmission patterns for drug resistant TB pose a new challenge’ (2017) available at <https://www.news.uct.ac.za>, accessed on 23 May 2019.

³⁵ World Health Organisation ‘Tuberculosis’(2018) available at <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>, accessed on 23 May 2019.

³⁶ Ibid.

³⁷ Ibid.

³⁸ World Health Organization (see note 11 above).

³⁹ World Health Organization ‘Global tuberculosis report 2018’. Geneva: WHO; 2018 available at http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf, accessed on 5 June 2019.

⁴⁰ World Health Organization (see note 35 above).

the number of MDR-TB cases has increased twofold up to 2012.⁴¹ In relation to drug resistant TB, it is estimated that South Africa has approximately a fifth of the MDRTB cases globally and the highest number of confirmed XDRTB cases as well.⁴² Of concern, is that in South Africa only over two thirds of people who were diagnosed with TB, were started on TB treatment.⁴³

2.3.2. The global impact

Although TB presents a healthcare challenge worldwide, it remains a leading cause of morbidity and mortality mostly in developing countries, as the overwhelming majority of infections and deaths are found in these countries.⁴⁴ The impact of the epidemic has led the World Health Organisation (WHO) to declare the disease a global health emergency.⁴⁵ Older data also show excessive global estimates for infection and approximately half a million deaths among those infected with HIV.⁴⁶ The association between poverty and TB is also well researched, and the highest rates of TB infection can be found amongst the poorest communities.⁴⁷ Data also shows that TB occurs frequently among people in the lower income bracket, those who live in overcrowded areas, and people who have poor schooling.⁴⁸ Poverty may result in poor nutrition which may be associated with alterations in immune function. Poverty can also result in overcrowded living conditions, poor housing with little ventilation, and poor hygiene, which collectively increase the risk of transmission of infection.⁴⁹ Globally, there are about half a million cases of MDR-TB, and in developing countries where poverty, malnutrition, migration and HIV infection are more common, MDR- TB is more prevalent.⁵⁰ Data also shows that over half

⁴¹ World Health Organization 'Global tuberculosis report 2017'. Geneva: WHO; 2017 available at http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf, accessed on 5 June 2019.

⁴² World Health Organisation (see note 39 above).

⁴³ Massyn N, Peer N, English R, et al. 'District Health Barometer' Durban Health Systems Trust (2015/16) available at www.hst.org.za/publications/Pages/HSTDistrictHealthBarometer.aspx, accessed on 25 May 2019.

⁴⁴ World Health Organisation (see note 28 above).

⁴⁵ Kochi A 'The global tuberculosis situation and the new control strategy of the World Health Organization' (1991) 71(1) *Tubercle* 1.

⁴⁶ World Health Organization. Global tuberculosis control 2009: epidemiology, strategy, financing: WHO report 2009. Geneva: World Health Organization; 2009. p303. (WHO/HTM/TB/2009.411).

⁴⁷ Davies PD 'Tuberculosis: the global epidemic' (2000) 98 (100) *J Ind Med Assoc* 2.

⁴⁸ Cantwell MF, Mckenna MT, McCray E, et al 'Tuberculosis and race/ethnicity in United States: impact of socioeconomic status' (1998) 157. *Am J Respir Crit Care Med* 1016.

⁴⁹ Spence DP, Hotchkiss J, Williams CSD, et al 'Tuberculosis and poverty' (1993) 307 *BMJ* 759.

⁵⁰ Kochi A (see note 45 above).

of those people who develop MDRTB eventually demise from the infection.⁵¹ According to Espinal et al, a multitude of factors that enhance the development of MDR have been identified, including : (1) non-adherence to therapy, (2) a lack of direct observed treatment, (3) limited or interrupted drug supplies, (4) poor quality of drugs, (5) the availability of over the counter TB drugs, (6) poor medical management, and (7) poorly-managed national control programmes.⁵²

2.4. The concept of non-adherence

2.4.1. Definition

Adherence to prescribed drug regimens includes aspects such as timing, dosage, type of medication, as well as the duration of treatment. According to Farmer, definitions of adherence are not specific, and range from the percentage of prescribed tablets consumed in a given timespan, to the classification of errors of dosage, omission, timing or purpose.⁵³ Farmer also suggests that adherence to anti-TB medication correlates closely with clinical outcomes such as cure rates.⁵⁴ A definition for medication adherence suggested by the WHO relates to ‘the extent to which an individual’s behaviour complies with the recommendations given by the relevant health care provider’.⁵⁵ Moodie suggests three types of non-adherence patterns that may be prevalent in TB treatment regimens : (a) total default (dropout); (b) irregularity of attendance (incomplete course); (c) and irregular (inconsistent dosage) medication.⁵⁶ According to the ‘The South African Tuberculosis Control Programme’, a person who defaults TB treatment may be considered as a ‘treatment defaulter’ if they have interrupted their prescribed treatment schedule for a period of two or more consecutive months.⁵⁷ Awofeso suggests that the successful cure of TB is achieved when patients have persistently high treatment adherence levels.⁵⁸

⁵¹ Rattan A, Kalia A, Ahmad N ‘Multidrug-resistant Mycobacterium tuberculosis: molecular perspectives’ (1998) 4 *Emerg Infect Dis* 195.

⁵² Espinal MA, Laserson K, Camacho M, et al ‘Determinants of drug-resistant tuberculosis: analysis of 11 countries’ (2001) 5 *Int J Tuberc Lung Dis* 887.

⁵³ Farmer KC ‘Methods for measuring and monitoring medication regimen adherence in clinical trials and clinical’ (1999) 21 *Clin Ther* 1074.

⁵⁴ Ibid.

⁵⁵ World Health Organisation ‘Defining adherence’ (2003) available at https://www.who.int/chp/knowledge/publications/adherence_Section1.pdf, accessed on 2 July 2019.

⁵⁶ Moodie AS ‘Mass ambulatory chemotherapy in the treatment of Tuberculosis in a predominantly urban community’ (1967) 95 *Am Rev Respir Dis* 384.

⁵⁷ The South African Tuberculosis Control Programme, Practical Guidelines 2004.

⁵⁸ Awofeso N ‘Antituberculous medication side-effects constitute major factor for poor adherence to tuberculosis treatment’ (2008) *Bulletin of WHO* 86.

2.4.2. Factors contributing to non-adherence

Other authors have suggested that a patient's behaviour towards drug therapy may be influenced by many factors including the social and cultural dynamics, socio-economic background, the anticipated health benefits, and the patient's perception of his/her illness.⁵⁹ Ideally, these factors need to be identified early in the management, to enable healthcare providers to take relevant measures to ensure patients continue treatment without interruption. Munro suggests that stigma may also have an impact on successful treatment adherence.⁶⁰ There is a relative paucity of data on the factors that contribute to nonadherence in TB treatment, as most literature emanates from a biomedical perspective on aspects of TB treatment. It is therefore suggested that further research be conducted into the social, ethical, and legal aspects of non-adherence in order to find effective solutions. Some studies suggest that women are more likely to be adherent to treatment, and the commonest age group in which most patients do not comply is from 35 years to 55 years, although reasons for this are unclear.⁶¹ Kulkarni proposes that low socio-economic status (SES), people who migrate or live in unstable conditions, female sex workers (FSW) and those with poor knowledge or education may also be predictors of non-adherence.⁶² He further rationalises that migration may result in a solitary lifestyle, hinder access to social support, or result in overcrowded and unhygienic living conditions.⁶³ It has also been proposed that non-adherence may be related to inattention and poor memory, as well as incorrect perceptions about medication.⁶⁴ The early improvement or resolution of symptoms may create the perception that the illness is cured and hence contribute to non-adherence, whilst patients still remain infectious.⁶⁵ It is proposed that a lack of education on the importance of adherence needs to be emphasised during the counselling process. This view is supported by Culqui et al who suggest that the correct information about TB and its treatment is likely to improve adherence to treatment.⁶⁶ Kumareson asserts that non-adherent patients are potential defaulters, and may have poor or no knowledge of TB.⁶⁷

⁵⁹ Esther S 'When TB treatment fails: A socio behavioural account of patient adherence' (1993) 147 *American Review of Respiratory Disease* 1311.

⁶⁰ Munro et al (see note 18 above).

⁶¹ Kulkarni PY, Akarte SV, RM Mankeshwar RM, et al 'Non-Adherence of New Pulmonary Tuberculosis Patients to Anti-Tuberculosis Treatment' (2013) 3(1) *Ann Med Health Sci Res* 67.

⁶² Ibid.

⁶³ Ibid.

⁶⁴ OECD 'Investing in medication adherence improves health outcomes and health system efficiency' (22 June 2018) available at <http://www.oecd.org/els/health-systems/health-working-papers.htm>, accessed on 2 July 2019.

⁶⁵ World Health Organisation (see note 55 above).

⁶⁶ Culqui D, Munayco E, Grijalva CG, et al 'Factors associated with the non-completion of conventional anti-tuberculosis treatment in Peru' (2012) 48(5) *Arch Bronconeumol* 150.

⁶⁷ Kumareson J, Tuberculosis: Epidemiology and Control In: Narayan JP, ed (1st ed. New Delhi 2002)16.

Geethakrishnan emphasises the role of education in improving knowledge, creating awareness and improving the behaviour of patients towards their treatment.⁶⁸ This finding is supported by Kulkarni et al, who further demonstrated that those who at least achieved high school education were all adherent to treatment.⁶⁹ They noted further that non-adherence decreases in relation to an increasing level of education. In a separate study involving SES, Bhatia et al showed a relationship between non-adherence and low socio-economic status, where treatment adherence increased as social class rose.⁷⁰ Other authors have indicated that the absence of ‘family and social support’ may also contribute to poor treatment adherence.⁷¹ Batista has suggested that substance abuse such as smoking and excessive alcohol consumption may also play a role in contributing to poor treatment adherence.⁷²

2.4.3. The impact of non-adherence

Strict adherence may facilitate the eradication of the disease whilst poor adherence can lead to treatment failure, relapse, the emergence of drug resistant strains, prolonged illness, disability and death. The WHO has estimated that a one individual with active and untreated infection may potentially infect 10-15 people in a single year.⁷³ Patients who default TB treatment remain infectious and can spread the disease to their family members and members of the public with whom they are in close contact. Such patients require prolonged and costly admission to specialised TB hospitals dedicated to the treatment of resistant forms of TB, in order to provide ‘barrier nursing’ and reduce ‘nosocomial spread’ of resistant TB. Barrier nursing involves the use of gloves, masks, and gowns to prevent contact between sources of infection and staff caring for infected patients. These patients are also advised to restrict and limit their movement in the public domain and face self-imposed travel restrictions, which implies general lifestyle limitations. Another subset of people who have a greater chance to contract TB or MDRTB due to high exposure are the healthcare workers. Exposure to infectious patients, high HIV rates and a lack of ventilation in facilities are some of the reasons healthcare workers in South Africa

⁶⁸ Geetakrishnan K ‘Case-holding and treatment failures under a TB clinic operating in rural setting’ (1990) 37(3) *Indian Journal of Tuberculosis* 145.

⁶⁹ Kulkarni PY (see note 61 above).

⁷⁰ Bhatia S, Landier W, Shangguan M, et al. ‘Nonadherence to oral mercaptopurine and risk of relapse in Hispanic and non-Hispanic white children with acute lymphoblastic leukemia: A report from the Children’s Oncology Group’ (2012)30 *J Clin Oncol* 2094.

⁷¹ Pablos-Méndez A, Knirsch CA, Barr RG, et al ‘Nonadherence in tuberculosis treatment: predictors and consequences in New York City’ (1997) 102 *Am J Med* 164.

⁷² Batista J, Albuquerque M, Ximenes R, et al ‘Smoking increases the risk of relapse after successful tuberculosis treatment’ (2008) 37(4) *Int J Epidemiol* 841.

⁷³ World Health Organization ‘The Global Plan to Stop TB 2006-2015: actions for life towards a world free of tuberculosis’. Geneva: WHO. 2006 available at http://www.who.int/tb/features_archive/global_plan_to_stop_tb/en/, accessed on 3 June 2019.

have amongst the highest rates of tuberculosis (TB) infection globally.⁷⁴

2.4.4. Non-adherence strategies

The failure to complete the prescribed TB treatment increases the period of infectiousness, relapse of infection, resistance to drugs and the chances of death.⁷⁵ It has been suggested that as many as half of TB patients do not complete treatment within a 24 month period.⁷⁶ Incomplete treatment poses a serious risk for the individual patient, as well as the community, and contributes to failure in eradicating the disease globally. Several intervention strategies have been employed to improve compliance - however, TB remains a global concern.

A strategy of 'patient reminders' has been implemented; however, data shows conflicting outcomes. Paramasivan (1993) showed that written and telephonic reminders were beneficial for patients in India, even amongst those who were illiterate.⁷⁷ Similar findings were demonstrated by Tanke (1997) in the USA.⁷⁸ Similarly, these findings are consistent with those of Macharia (1992), who demonstrated that reminders were useful in preventing defaults in scheduled appointments in various settings in the USA.⁷⁹ However, in contrast Tulsy *et al*, in a subsequent study in California showed little or no benefit towards the completion of treatment after an assessment conducted at 6 months.⁸⁰

Monetary incentives have been shown in some studies to be an effective method for improving adherence. Malotte (1998), showed that after money was provided as an incentive to a cohort of homeless men and drug users in the USA, their appointment -keeping rate improved significantly.⁸¹

⁷⁴ Green A 'SA's healthcare workers hard hit by TB infections' (24 October 2016) available at <https://www.health-e.org.za>, accessed on 5 June 2019.

⁷⁵ Cuneo WD and Snider DE 'Enhancing patient compliance with tuberculosis therapy' (1989) 10 *Clin Chest Med* 375.

⁷⁶ *Ibid*.

⁷⁷ Paramasivan R, Parthasarathy RT, Rajasekaran S 'Short course chemotherapy: A controlled study of indirect defaulter retrieval method' (1993) 40 *Indian J Tub* 185.

⁷⁸ Tanke ED, Martinez CM, Leirer VO 'Use of automated reminders for tuberculin skin test return'. 1997;13(3) *American Journal of Preventive Medicine* 189.

⁷⁹ Macharia WM, Leon G, Rowe BH, et al 'An overview of interventions to improve compliance with appointment keeping for medical services' (1992) 267(13) *JAMA* 1813.

⁸⁰ Tulsy JP, Pilote L, Hahn J, Zolopa AJ, et al 'Adherence to isoniazid prophylaxis in the homeless' (2000) 160 *Arch Intern Med* 697.

⁸¹ Malotte CK, Hollingshead JR, Larro M 'Incentives vs outreach workers for latent tuberculosis treatment in drug users' (2001) Feb 20(2) *Am J Prev Med* 107.

Similar findings were elucidated by Pilote (1996) in studies in the same country.⁸² In contrast, a study conducted by White amongst people in California who were recently discharged from prison, was inconclusive.⁸³ The use of money or similar financial incentives to induce compliance to complete treatment is linked with many ethical and moral implications. It must be remembered that the highest burden of TB is in resource-poor countries where monetary incentives may not be sustainable. Likewise, in developed countries the monies may be inadequate to cover the necessary costs for indigent patients. Further research on the use of financial incentives is required in these circumstances.

The evidence for the impact of health education independently, is also inconclusive. Sanmarti *et al*, suggest some benefit from their study in Spain, however the study design did not adequately compare the control group.⁸⁴ Further studies by Morisky *et al* in the USA, were confounded by the effects of a monetary incentive that was used in conjunction with an educational intervention, requiring a bivariate analysis.⁸⁵

More restrictive interventions include: Directly Observed Treatment Short course (DOTS), involuntary detention, incarceration, isolation and quarantine. DOTS is part of the World Health Organisation's DOTS strategy,⁸⁶ however studies on its benefits are heterogenous in nature. In a local randomised controlled trial conducted in Cape Town, South Africa, Zwarenstein *et al* showed no difference between 'clinic-based supervision' by nurses and 'self-supervision' in relation to treatment adherence.⁸⁷ In a larger study from Thailand, direct observation by a supervisor chosen by the patient was associated with higher cure rates.⁸⁸ Similarly, Clarke *et al* showed that DOTS which used lay health care workers was

⁸² Pilote L, Tulskey JP, Zolopa AR, *et al* 'Tuberculosis prophylaxis in the homeless: A trial to improve adherence to referral' (1996) 156 *Arch Intern Med* 161.

⁸³ White M, Tulskey, J, Reilly P, *et al* 'A clinical trial of a financial incentive to go to the tuberculosis clinic for isoniazid after release from jail' (1998) 2 (6) *The International Journal of Tuberculosis and Lung Disease* 506.

⁸⁴ Sanmarti L, Megias JA, Gomez MN, *et al* 'Evaluation of the efficacy of health education on the compliance with antituberculous chemoprophylaxis in school children: A randomized clinical trial' (1993) 74 *Tubercle and Lung Disease* 28.

⁸⁵ Morisky DE, Malotte CK, Choi P, *et al* 'A patient education program to improve adherence rates with antituberculosis drug regimens' (1990) 17(3) *Health Education Quarterly* 253.

⁸⁶ World Health Organisation 'What is DOTS' available at http://www.searo.who.int/tb/topics/what_dots/en/, accessed on 7 June 2019.

⁸⁷ Zwarenstein M, Schoeman JH, Vundule C, *et al* 'Randomised controlled trial of self-supervised and directly observed treatment of tuberculosis' (1998) 352 *Lancet* 1343.

⁸⁸ Kamolratankul P, Sawert H, Lertmaharit S, *et al* 'Effectiveness of directly observed therapy, short course (DOTS) in the treatment of pulmonary tuberculosis in Thailand' (1999) 93 *Transactions of the Royal Society of Tropical Medicine and Hygiene* 552.

superior to standard TB care in South Africa.⁸⁹ Studies on DOTS are confounded by differences in the frequency of home visits by health workers, level of training of health workers, monitoring schedules, tablet counting and urine testing, accessibility to patients, and other factors.

Quarantine applies to individuals who have been exposed to a communicable disease but who may not necessarily be ill. It is suggested that people who have latent TB do not pose any risk of transmission and quarantine is therefore an inappropriate disease control measure for TB. The aim of isolating a patient or infected person, is to separate him/her from others who are healthy, and further restrict free and widespread movement in order to contain the spread of infection. Public health officials globally are guided by legal prescripts, and may within reason, isolate individuals with TB disease if they pose a threat to the public's health. In Israel, 'recalcitrant patients' were taken to court and hospitalised under a court order, either in prison, or in a prison hospital.⁹⁰ Similarly, cases of detention have been reported in New York⁹¹, England and Wales.⁹² In Australia, public health detention orders for TB carriers have also been issued,⁹³ and in Kenya, a court issued an order for the imprisonment of TB patients for purposes of administration of TB treatment.⁹⁴

In concluding, it becomes evident that primary TB as well as complicated forms such as MDR TB and XDRTB are associated with significant morbidity, mortality, and cost to the country. Moreover, strategies discussed earlier in the chapter aimed at promoting adherence, have limited success globally. In Chapter 3, pertinent legal, ethical and human rights issues are discussed further and their impact on compliance is highlighted.

⁸⁹ Clarke M, Dick J, Zwarenstein M, Lombard CJ, et al 'Lay health worker intervention with choice of DOT superior to standard TB care for farm dwellers in South Africa: a cluster randomised control trial' (2005) 9(6) *Int J Tuberc Lung Dis* 673.

⁹⁰ Weiler-Ravella A, Leventhal RJ, Coker D, et al 'Compulsory detention of recalcitrant tuberculosis patients in the context of a new tuberculosis control programme in Israel' (2004) 118 *Public Health* 323.

⁹¹ Gasner M, Mae KL, Feldman G, et al 'The use of legal action in New York City to ensure treatment of TB' 340 (5) *NEJM* 359.

⁹² Coker RJ 'Public Health Impact of Detention of Individuals with Tuberculosis: Systematic Literature Review' (2003) 117(4) *Public Health* 281.

⁹³ Senanayake SN and Ferson MJ 'Detention for tuberculosis: public health and the law' (2004) 180 (11) *Med J Aust* 573.

⁹⁴ Mburu G, Restoy E, Kibuchi E, et al "Detention of People Lost to Follow-Up on TB Treatment in Kenya- The Need for Human Rights-Based Alternatives' (2016) 18(1) *Health Hum Rights* 43.

Chapter 3: Ethical, legal and human rights considerations in TB care

3. I. Introduction: Ethical considerations

The prevention, treatment and control of TB/MDRTB are associated with several ethical issues. The management of TB and the success of control programmes are influenced by the equitable distribution of limited public health resources, protection of vulnerable people, respect for patient autonomy about treatment options and the role of affected communities during outbreaks. The World Health Organisation's 'End TB Strategy'⁹⁵, as well as the 'Sustainable Development Goals' (SDGs)⁹⁶ have emphasized aspects such as equity, human rights and ethical standards in the care and control of TB.

3.1.1. Equity and Social justice

Social justice, as applied to healthcare includes concerns about inequalities, access to care, the fair distribution of resources and neglect of vulnerable people. The predisposition to TB and its association with inequalities in society are linked with these and other aspects of social justice.⁹⁷ Farmer asserts that TB affects mainly those who are marginalised in society and is associated with poverty and disadvantaged people in society.⁹⁸ Systematic interventions aimed at controlling the spread of infection should ideally extend beyond clinical and biomedical parameters, and include socio-economic and political factors that are directly linked to high levels of infection amongst marginalised people. In recognition of the social justice issues that predispose vulnerable people to TB infection, the WHO implemented the End TB Strategy as a global intervention in 2006 (see above). The focus areas included in this strategy are aimed at achieving social justice, and include: increasing access to care for vulnerable groups; the unabating TB/HIV, MDR-TB epidemic; the socioeconomic and healthcare needs of those who are poor and vulnerable; strengthening existing health systems; the involvement of health-care providers; the empowerment of people and communities at risk; and relevant research.⁹⁹

⁹⁵ World Health Organisation 'End TB Strategy- Global strategy and targets for tuberculosis prevention, care and control after 2015' (2019) available at https://www.who.int/tb/post2015_strategy/en/, accessed on 3 June 2019.

⁹⁶ United Nations Development Plan 'Sustainable Development Goals' available at <http://www.un.org/sustainabledevelopment/news/communications-material/>, accessed on 4 June 2019.

⁹⁷ Gostin LO and Powers M 'What does social justice require for the public's health? Public health ethics and policy imperatives (2006) 25(4) *Health Aff* 1053.

⁹⁸ Farmer P. *Infections and Inequalities: The Modern Plagues*. Berkeley, CA: University of California Press; 1999.

⁹⁹ WHO (see note 95 above).

In 2016, the Global Tuberculosis Report revealed inequalities in societies with regard to access to cost-effective diagnostic screening and relevant treatment options necessary to achieve a decline in TB.¹⁰⁰ Of concern is that almost 2 years later, the WHO 2018 Report highlighted that many new cases of TB were still associated with malnourishment, HIV/AIDS, smoking, diabetes mellitus and excessive alcohol consumption.¹⁰¹ The data suggests that insufficient progress has been made to address extreme poverty and the other social ills that contribute to the high incidence of TB.

Some authors suggest that large scale politics in the recent past have impacted on the health sector in general and promoted co-payments, health insurance, input directed payments, and the rationalisation of medical services. Bond and Homedes suggest that the unethical treatment of healthcare as a commodity and commercialisation along business lines may encourage providers to limit their services to healthy people.¹⁰² These authors suggest that the commercialisation of health services influences its utilisation by the wealthy as well as the poor, with the poorest having the highest risk of limited access and therefore poorer care. Rasanathan *et al* make an association with poverty, low socio-economic status and poorer treatment outcomes, and attribute the latter to limited access to quality care available to the poor.¹⁰³ Hart suggests that an ‘inverse care law’ applies, where the poor are inversely affected by the unavailability of much needed medical and social care.¹⁰⁴ It is therefore proposed that the current ‘macro-level approach’ i.e. diagnose at local clinic and attend hospital for treatment, is inadequate and should be combined with ‘micro-level initiatives’ that address socio-economic disparities. Relevant programmes that are targeted at individuals and the community at large should also be developed. Sagbakken *et al*, also suggest the implementation of relevant community programmes that incorporate community interaction and empowerment programmes for affected patients.¹⁰⁵ A focus on the individual needs of patients and their specific life situation is necessary in order to achieve social justice, as social determinants may change over the duration of the disease.¹⁰⁶

¹⁰⁰ World Health Organization ‘Global tuberculosis report 2016’. Geneva: WHO; 2016 available at http://apps.who.int/iris/bitstream/10665/191102/1/9789241565059_eng.pdf, accessed on 5 June 2019.

¹⁰¹ WHO (see note 39 above).

¹⁰² Bond P and Dor G ‘Uneven health outcomes and political resistance under residual neoliberalism in Africa’ 2003;33(3) *Int J Health Serv.* 607.

¹⁰³ Rasanathan K, Sivasankara A, Jaramillo E, *et al* ‘The social determinants of health: key to global tuberculosis control’ (2011)15 (2) *Int J Tuberc Lung Dis.*15.

¹⁰⁴ Hart JT ‘The Inverse Care Law’ (1971) 27(1) *Lancet* 405.

¹⁰⁵ Sagbakken M, Frich JC, Bjune GA, *et al* ‘Ethical aspects of directly observed treatment for tuberculosis: a cross-cultural comparison (2013) 14(25) *BMC Medical Ethics* 1.

¹⁰⁶ Rice DP, Thomas A, Hodgson TA, Andrea N *et al* ‘The economic costs of illness: A replication and update’ 1985 7(1) *Health Care Financ Rev.* 61.

In South African programmes such as Directly Observed Treatment (DOT), soup kitchens, fund raising initiatives, awareness campaigns and other activities are conducted in affected communities.¹⁰⁷ In the United Kingdom, similar social justice interventions such as DOT is provided for alcoholics and other vulnerable people where authorities may consider potential failure as being more likely.¹⁰⁸ In the USA, some DOT clinics offer comprehensive services, including individual support, meals, monetary assistance and other forms of assistance, including input from counselling services and social workers.¹⁰⁹ It is suggested that ongoing social justice interventions are likely to improve health service uptake amongst vulnerable persons who are affected by TB.

3.1.2. Solidarity

Houtepen and Ter Meulen suggest that solidarity can be viewed in various ways, from the context of ‘symmetrical relationships’ in which people are considered equal: e.g. brotherhood to ‘asymmetrical relationships’, characterised by an unequal relationship to each e.g. charity.¹¹⁰ Although the concept of solidarity can be defined differently, it is suggested that it reflects a type of social relationship which exists in a community or population group.¹¹¹ In the context of TB care and control, it is proposed that solidarity can be viewed in both global and local contexts, where the former includes inputs from international players such as organisations, wealthy nations and political formations, and the latter involves local communities and groups. The concept of ‘global solidarity’ was intensified by the UN in 2014, with the aim of consolidating resources to address the funding shortfalls needed for TB care and control.¹¹² It is suggested further that solidarity amongst communities may also be achieved by the transfer of knowledge and skills among individuals, involvement of the community in research and development, and their inclusion in vaccine development strategies. This view is supported by the African Union, which has made a request for global solidarity to be able to enhance development and facilitate the implementation of newer technologies, antibiotics, and diagnostic tools.¹¹³ At a regional

¹⁰⁷ Macq JC, Theobald S, Dick J, et al ‘An exploration of the concept of directly observed treatment (DOT) for tuberculosis patients: from a uniform to a customized approach’ (2003) *7 Int J Tuberc Lung Dis*. 103.

¹⁰⁸ Ibid.

¹⁰⁹ Sagbakken (see note 105 above).

¹¹⁰ Houtepen R and Ter Meulen R (2000) 8 ‘New types of Solidarity in the European Welfare State’ *Health Care Analysis* 329.

¹¹¹ Solidarity relates to social cohesion based upon the interdependence of individuals in societies, which is like the concept of Ubuntu in African culture, which refers to the capacity to express compassion, reciprocity, dignity, justice and mutual caring. See Mechtraud 1955 *Philippine Sociological Review* 3(3) 23. Also see Metz 2007 *The Journal of Political Philosophy* 15(3) 323.

¹¹² United Nations ‘Resolution adopted by the General Assembly’ (25 September 2015) available at <https://www.un.org>, accessed on 2 June 2019.

¹¹³ African Union ‘Roadmap on shared responsibility and global solidarity for AIDS, TB and malaria response in Africa’ (2012) available at <http://carmma.org/download/file/fid/767>, accessed on 29 May 2019.

level, Maher et al. conducted research in 6 African countries and demonstrated that solidarity practiced in communities that were involved in district TB programmes was effective and was associated with improved rates of treatment and reduced costs.¹¹⁴

3.1.3. Beneficence

Beneficence embraces the general idea that one's actions should promote good. TB is highly infectious and has the potential to harm the community through the spread of airborne bacteria. Efforts by all stakeholders to eradicate the disease will be of mutual benefit to infected individuals and the general population. The benefit of eradicating TB extends beyond health improvement and includes social and financial benefits for society at large.

3.1.4. Autonomy

The concept of autonomy may be considered *inter alia* as respect and upholding of the right of individuals to make decisions about their own lives, including their own health care needs.¹¹⁵ In the context of TB care, respect for the autonomy of a patient implies that he/she should have the right to choose to be screened, treated, admitted to hospital or, to default on treatment in favour of alternative or natural therapies, or no treatment at all. Non-adherence to treatment is discussed elsewhere in this dissertation. Nevertheless, it remains the duty of health care workers (HCWs) to inform patients of the risks and consequences of their decision, and provide counselling with a multidisciplinary team, including family members and religious leaders in whom they have trust.

3.1.5. Effectiveness and efficiency

Achieving effectiveness in the control of TB infection requires a commitment from health care providers to practice diligence, implement proven intervention measures, ensure effective drug treatments, and keep abreast of ongoing research. It is the ethical duty of HCWs to monitor adverse outcomes from highly toxic, poorly tested and ineffective drugs, and to stop treatment in these circumstances. To promote efficiency, available resources should be used productively, and existing TB programmes should be subject to regular surveillance and research audits.

3.1.6. Privacy and confidentiality

Privacy and confidentiality are essential tenets of the 'doctor-patient relationship' in any illness. Ensuring the confidentiality of information about TB patients may also reduce the stigma associated with TB and help ensure the trust of patients. However, an ethical dilemma exists relating to third-party

¹¹⁴ Maher D 'The role of the community in the control of tuberculosis' (2003) 83(1-3) *Tuberculosis* 177.

¹¹⁵ American Medical Association 'Fundamental elements of the patient-physician relationship. Code of Medical Ethics' (1990) 264(24) *JAMA* 3133.

notification i.e. whether to inform close contacts of infected patients, especially when patients themselves may not have informed close contacts or fail to take necessary precautionary measures. In this context, it can be argued that disclosure would violate the patient's rights to confidentiality and autonomy, however current legislation places emphasis on public health safety.¹¹⁶ Beauchamp and Childress suggest that the 'implicit or explicit promise is that information regarding his/her health will be held in confidence'.¹¹⁷ Noting that third party disclosure would involve breaking such a promise, physicians are guided by the policy of the Department of Health, which includes all forms of TB as a notifiable medical condition, through the utilisation of a notification register.¹¹⁸ 'Notifiable medical conditions' are diseases that are considered to be of concern to the health of the public at large as they are likely to pose a public health risk and can affect communities through outbreaks or epidemics.

3.1.7. Informed Consent

The management of TB ranges from the sputum testing to invasive procedures such as pneumectomy (the removal of an entire lung). Individuals have a right to bodily integrity, therefore comprehensive and accurate information concerning risks, benefits and alternatives should be made available to them by healthcare professionals. The screening for TB after obtaining verbal consent may not require a further specific informed consent process, however when objections are raised to testing, then extensive counselling should be conducted. In all other related aspects, such as the usage of drugs and other surgical procedures, a full informed consent process (including written consent) is mandatory.

3.1.8. Ethics and TB research

Ongoing research into TB is essential for new drugs and vaccine development. It is suggested that the best available treatment should be provided to participants, and patient wellbeing be considered with the aims and objectives of the research. These precepts are provided in the '*Declaration of Helsinki*' of the World Health Organization (WHO), which is widely regarded as the basis for the fundamental principles of research involving human subjects.¹¹⁹ It is also suggested, that in order to maintain an

¹¹⁶ The National Health Act (s6) and the South African Constitution (s36), place emphasis on public health safety, after which confidentiality and patient autonomy are considered. Tuberculosis has been declared a notifiable disease.

¹¹⁷ Beauchamp and Childress, *Principles of Biomedical Ethics*, Fourth Edition. Oxford. 1994.

¹¹⁸ KZN DOH 'Notifiable medical conditions' available at <http://www.kznhealth.gov.za/cdc/notifiable.htm>, accessed on 24 April 2019.

¹¹⁹ Declaration of Helsinki, 64th WMA General Assembly, Fortaleza, Brazil, October 2013 available at <http://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/experimentation>, accessed on 03 May 2020.

ethical standard in research, it is imperative that it is conducted in accordance with international and institutional guidelines for clinical research. Moreover, research outcomes should be shared with all stakeholders in order to facilitate early policy changes that may benefit affected people.

3.1.9. Justice

The provision of justice in the management of TB extends across local, national, global and government initiatives. The TB epidemic raises many issues that relate to distributive justice, due to its association with poverty in many developing countries. Adequate resources for health improvement initiatives are limited in poor resourced countries. This creates a moral obligation for wealthy nations to increasingly assist poor countries to improve their health care.¹²⁰ Apart from a humanitarian and social perspective, wealthy nations and large corporates (Big Pharma) can increase access to existing medication and promote research and development initiatives for drugs and diagnostics which are needed for newer forms of resistant TB. Currently, large pharmaceutical companies are downscaling their TB and anti-infective research programs in general, in favour of new treatments, including vaccines and drugs for chronic medical conditions such as diabetes and hypertension.¹²¹ As a consequence, budget allocations for TB research from corporates dropped significantly, and overall spending for TB research and development has declined over the last decade.¹²² It is therefore suggested that as more private-sector companies pull out of TB research, the responsibility falls increasingly on public institutions and governments to conduct relevant research.

Garrett argues that financial aid from donor countries should be utilised to improve the health care infrastructure and general health issues in poor resourced countries rather than spending on infective conditions such as AIDS and TB.¹²³ It is suggested that funding should address both aspects as they are mutually inclusive. Moreover, governments have an ethical responsibility to ensure free and universal access to diagnosis, treatment and care of TB. Similarly, justice for HCW's must be ensured by the providing support and a safe working environment to enable them to fulfil their responsibilities. Not only does TB treatment improve the health condition of affected individuals but eradicating widespread infection is ethically and morally justifiable as it benefits the broader community.

¹²⁰ Selgelid MJ 'Ethics, Tuberculosis and Globalization' (2008) 1(1) *Public Health Ethics* 10.

¹²¹ Frick M 'Tuberculosis Research and Development: 2014 Report on Tuberculosis Research Funding Trends' (2015) available at <http://www.treatmentactiongroup.org>, accessed on 6 June 2019.

¹²² Ibid.

¹²³ Garrett L 'The Challenge of Global Health' (2007) available at <http://www.hsrc.ac.za>, accessed on 9 June 2019.

3.2. Human rights considerations

Human rights in the context of TB are present in the relationship between infected individuals, the general public and the state, but also include obligations for private and non-governmental players.¹²⁴ Human rights are enshrined *inter alia* in the Constitution,¹²⁵ Article 25 of the Universal Declaration of Human Rights¹²⁶, Article 12 of the International Covenant on Economic, Social and Cultural Rights¹²⁷ and the African Charter on Human and People's Rights which is intended to promote and protect human rights and basic freedoms in the African continent.¹²⁸ The right to health, articulated as 'the highest attainable standard of physical and mental health', is considered as a basic right of all citizens.¹²⁹ Individuals therefore reserve the right to receive treatment for TB whilst governments have the responsibility to take steps to control the TB epidemic. The following categories are discussed here:

3.2.1. Prisoners and persons in state custody: Prisoners and people in detention are at increased risk of TB due to overcrowding, poor ventilation in prison cells and a lack of access to health services like that available in hospitals. Stuckler *et al.* demonstrated in European and central Asian countries that the incarceration of large numbers of people increases the risk for TB and multidrug-resistant TB.¹³⁰ The rights of prisoners must be respected by governments and authorities alike, and TB services in prison should be consistent with all national TB treatment and control programmes. Moreover, ethical norms such as autonomy, informed consent, privacy and confidentiality should be respected in the prison environment and reassurance should be provided to prisoners that adherence to TB treatment remains independent of the conditions related to their sentences.

¹²⁴ World Health Organisation 'Ethics guidance for the implementation of the End TB strategy' (2010) available at <https://apps.who.int/>, accessed on 23 April 2019.

¹²⁵ Constitution of the Republic of South Africa, 1996.

¹²⁶ United Nations, 1948, Universal Declaration of Human Rights, Article 25, General Assembly Resolution 217A available at <http://www.un.org/en/universal-declaration-humanrights>, accessed 10 February 2017.

¹²⁷ ICESCR (see note 21 above).

¹²⁸ African Commission on Human and Peoples' Rights (1986), African Charter on Human and Peoples' Rights available at www.achpr.org, accessed 22 May 2020.

¹²⁹ Constitution of the World Health Organization, 1946 available at www.ncbi.nlm.nih.gov/pmc/articles/PMC2567705, accessed on 12 September 2019.

¹³⁰ Stuckler D, Basu S, McKee M, King L. Mass incarceration can explain population increases in TB and multidrug-resistant TB in European and central Asian countries. *Proceedings of the National Academy of Sciences* 2008;105(36):13280.

3.2.2. People who use drugs (PWUD): Getahun suggests that people who use recreational drugs are at an increased risk of acquiring TB, which may be further complicated by co-infection with HIV.¹³¹ Data reveals that the ‘criminalisation’ of minor drug offences still remains part of drug legislation in many countries.¹³² In China, the government has implemented a tracking system for those considered to be drug addicts, which has resulted in the reluctance of drug users to present to government institutions for treatment.¹³³ More drastic measures for those with drug-related convictions have been incorporated into federal law in the United States, such as the denial of housing, withdrawal of nutritional support, removal of cash transfers, and subsidies for education.¹³⁴ Restrictions on welfare benefits has also been imposed, as a lifelong punitive measure.¹³⁵ It is suggested that discriminatory laws and policies deny drug users of their human rights and increases their vulnerability, further exacerbating the spread of TB. In contrast, UNAIDS proposes that the human rights of drug users must be ensured, and access to justice provided, including the provision of legal representation.¹³⁶ They propose further that the aim of drug abuse management is to promote health and wellbeing, including the provision of security of individuals, which are fundamental human rights.¹³⁷

3.2.3. Health care workers (HCWs): Health care workers have an ethical obligation to provide care to patients by virtue of their profession, although exposure to infected patients poses an inherent risk to themselves and ultimately to their families. However, it has been argued that there are limits to the extent of risk they should be subjected to.¹³⁸ It is suggested that it is unethical for HCWs to assume continued risks in an environment where inadequate safety conditions exist to provide care. Furthermore, HCWs who are at increased risk of acquiring TB, such as those cases who are HIV positive,

¹³¹ Getahun H, Baddeley A, Raviglione M ‘Managing tuberculosis in people who use and inject illicit drugs’ (2013) 91 *Bulletin of the World Health Organization* 154.

¹³² Open Society Foundations ‘Tuberculosis and Human Rights’ (24 September 2018) available at <http://www.opensocietyfoundations.org>, accessed on 4 June 2019.

¹³³ Lembke A, Zhang N ‘A qualitative study of treatment-seeking heroin users in contemporary China’ (2015) 10 *Addict Sci Clin Pract.* 23.

¹³⁴ Collateral consequences: denial of basic social services based upon drug use. New York: Drug Policy Alliance (2003) available at http://www.drugpolicy.org/docUploads/Postincarceration_abuses_memo.pdf, accessed 6 April 2019.

¹³⁵ A lifetime of punishment: the impact of the felony drug ban on welfare benefits. Washington, DC: The Sentencing Project (2013) available at <http://sentencingproject.org/doc/publications.pdf>, accessed 6 April 2019.

¹³⁶ UNAIDS ‘Health, Human Rights and people who use drugs’ (2015) available at <http://www.unaids.org> accessed on 23 April 2019.

¹³⁷ Ibid.

¹³⁸ Ethical considerations in developing a public health response to pandemic influenza. Geneva: World Health Organization (2007) available at http://whqlibdoc.who.int/hq/2007/WHO_CDS_EPR_GIP_2007.2_eng.pdf, accessed 8 February 2019.

should be exempted from this exposure and placed in a lower risk environment due to their increased susceptibility to acquire infection. Governments and healthcare institutions have the responsibility to provide the necessary infrastructure including basic infection prevention and control measures to ensure a safe working environment. Similarly, HCW's should reciprocate their obligations to health care institutions and patients by providing an efficient and appropriate standard of medical and nursing care.

3.2.4. Migrants: Migrants may lack legal documentation, and be subjected to discrimination in their daily lives, including poor access to health services.¹³⁹ It has been suggested that some groups of migrants may have increased risk for acquiring TB and may remain undiagnosed for the reasons outlined, whilst their own TB status may also affect their movement and social status.¹⁴⁰ These groups may not enjoy political representation, suffer marginalisation in society or face harassment from police or community members, further deterring them from attending TB screening clinics. For such groups, solidarity is necessary, regardless of foreigner or legal status, to advocate for TB screening and care. It is suggested that this will be consistent with the principles of equity and justice, by providing care to those with the greatest need. Providing optimum health to migrant populations enhances their human rights and other life choices. It is proposed that a collective effort should be made by governments, communities and health providers alike, to reduce the stigma, and protect the dignity, privacy and confidentiality of migrants.

3.2.5. Children: According to the '2016 WHO Global TB Report', over a million children worldwide suffer from TB, and thousands die from TB annually.¹⁴¹ It is argued that childhood TB may not have been prioritised in same way as adult TB, thereby contributing to the current limitations in childhood TB drugs, treatment and care. Laventhal *et al* suggest that inadequate enrolment of children into TB research, mainly due to ethical, legal and informed consent issues, have contributed to inadequate diagnostics and paediatric medication.¹⁴² It must be remembered that instruments such as The UN Convention on the Rights of the Child have established that 'the best interests of the child

¹³⁹ The International Organization for Migration considers a migrant to be any person who is moving or had moved across an international border or within a state away from his/her habitual place of residence, and his/her children, regardless of: (i) a person's legal status, (ii) whether the movement is voluntary or involuntary, (iii) what the causes of movement are, (iv) or what the length of stay is.

¹⁴⁰ Stop TB Partnership. Key populations brief: Mobile populations. Geneva, 2016.

¹⁴¹ WHO (see note 100 above).

¹⁴² Laventhal N, Tarini B, Lantos J 'Ethical issues in neonatal and paediatric clinical trials' (2012) 59 *Pediatr Clin North Am* 1205.

shall be the primary consideration' in all actions concerning children.¹⁴³ Moreover, The UN Committee on the Rights of the Child has suggested that 'best interests must be the basis of all decision-making about providing, withholding or terminating treatment, and should aid the resolution of conflict of interest between parents and health workers'.¹⁴⁴ Furthermore, section 28 of the Constitution¹⁴⁵ and section 9 of the Children's Act¹⁴⁶, also state that a child's best interest is of paramount importance in every matter including care, protection and well-being. It is further suggested that research in childhood should be guided by legal and ethical prescripts and incentives from pharmaceutical companies should be subjected to rigorous institutional evaluation.

3.2.6. Moribund and terminally ill people

Palliative care is generally administered to terminally ill patients to improve their quality of life through pain relieving medications. The access to palliative care for TB sufferers is therefore a core component of their right to health. The ICESCR has declared that state parties are obliged to provide equal access to palliative health services for all persons if needed.¹⁴⁷ State parties are further obliged to respect the right to health and provide necessary medications, even to the moribund and terminally ill, as guided by the WHO Action Programme on Essential Drugs.¹⁴⁸ The Health Professions Council of South Africa (HPCSA) has consolidated the integration of palliative care into health service delivery and provides clinical guidelines to registered medical practitioners.¹⁴⁹ Most palliative care in South Africa is provided by NGOs, and care provided by hospices takes place mainly within the patient's home.¹⁵⁰ An ethical argument can be made to stop therapy when there is no proven prospect of success, when side effects outweigh benefits or become life-threatening, or when drugs become ineffective. It is suggested that palliative care should be integrated with existing TB services and be continued at the point of care.

¹⁴³ United Nations 'Convention on the Rights of the Child' (1990) available <http://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx>, accessed 24 February 2017.

¹⁴⁴ United Nations Committee on the Rights of the Child. (17 April 2013) General Comment No. 15. (Art. 24), U.N. Doc. CRC/C/GC/15.

¹⁴⁵ The Constitution of the Republic of South Africa (1996) s28.

¹⁴⁶ The Children's Act No.38 of 2005 s9.

¹⁴⁷ ICESCR (see note 21 above).

¹⁴⁸ Iversen PB 'Action Programme on essential drugs' (1998) available at <http://apps.who.int/medicinedocs/pdf/s2237e/s2237e.pdf>, accessed on 7 June 2019.

¹⁴⁹ Health Professions Council of South Africa (2019) Ethical Guidelines on Palliative Care (Booklet 19) available at <https://www.hpcsa.co.za> accessed on 22 May 2020.

¹⁵⁰ Drenth C, Sithole Z, Pudule E, et al 'Palliative Care in South Africa' (2018) 55(2) *Journal of Pain and Symptom Management* 170.

3.3. Nonadherence and coercive social distancing

The development of resistant forms of TB i.e. MDR-TB and XDR-TB has been linked to non-adherence (also referred to as treatment interruption or non-compliance) to the first line therapy for primary TB, the low cure rates that result, and co-morbid HIV infection.¹⁵¹ Almost half of adults in South Africa with primary TB, also known as drug sensitive TB, are cured annually, however better resourced countries have higher cure rates.¹⁵² Beresford has indicated that approximately fifteen percent of patients default on the initial prescribed treatment, and almost a third of patients default on 'second-line treatment'.¹⁵³ Patients with both MDRTB and XDRTB, and the newest category of 'TDRTB' contribute directly to high rates of mortality amongst the public once they default treatment and spread the infection. Serious public health concerns provide the ethical justification for the limitation of certain rights in such cases, as well as the utilisation of restrictive measures. However, restrictive measures such as involuntary isolation and the enforcement of therapy for non-adherent patients is inextricably linked to complex ethical considerations, human rights and legal issues. Involuntary isolation may be regarded as unethical as it infringes on an individual's rights to freedom of movement, freedom of association, and the right to liberty. The commencement of immediate treatment after diagnosis, as well as associated complementary measures such as counselling and the use of masks remains an effective strategy, however these measures do not ensure that the patient adheres to the prescribed treatment schedule. The need for ethically justifiable and judicially sanctioned restrictive measures to prevent an impending public health crisis therefore becomes a national and global imperative. Restrictive measures that are used to control the spread of TB includes quarantine, isolation in specific facilities, detention and travel restrictions.

3.3.1. The Harm Principle

In principle, it is ethically justifiable that the least restrictive measures, such as wearing a TB mask should be utilised on a regular basis to prevent harm. In addition, such measures should include counselling and social support to address the social determinants that contribute to non-adherence. It can be argued that the involuntary isolation of non-compliant infected persons is a justifiable option, as it based on the need to protect others from harm. This highlights the 'harm principle', a pillar of public health that justifies restrictive measures during disease outbreaks with certain infectious organisms.¹⁵⁴

¹⁵¹ Singh JA, Ross Upshur R, Padayatchi N 'XDR-TB in South Africa: No Time for Denial or Complacency' 2007 4(1) *PLoS Med.* e50.

¹⁵² Beresford B 'Call to isolate TB victims' (8 September 2006) available at <http://www.mg.co.za/article>, accessed on 23 May 2019.

¹⁵³ Ibid.

¹⁵⁴ Mill JS 'Freedom of Speech' (17 April 2008) Stanford *Encyclopaedia of Philosophy*, accessed on June 2019.

Most health care professionals are likely to encourage compliance in their practice, however when counselling efforts fail and a patient persistently refuses to take treatment, the WHO has considered ‘involuntary isolation’ to a limited extent, using the least restrictive means as a last resort.¹⁵⁵ It is suggested that isolation should not be considered as a form of punishment, and should include information on the right to appeal. The prevention of harm and protection of public health as legitimate ethical expectations have also been supported by Kass,¹⁵⁶ Childress¹⁵⁷ and Upshur¹⁵⁸ in the USA and Canada. It is proposed that the limitation of human rights is justifiable to prevent harm to the public, however it should be conducted in a respectful manner, follow extensive counselling and have clear evidence of failure of other measures.

3.3.2. Human Rights principles

Apart from constitutional provisions, the protection of the general public from harm through the enforcement of restrictive measures such as isolation is also guided by human rights and expert guidance documents such as the Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights.¹⁵⁹ Section 25 of the Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights holds: ‘Public health concerns may be invoked for limiting certain rights to allow a state to deal with a serious threat to public health or individual members of the population’.¹⁶⁰ Limitations on the rights and freedoms are further emphasised in the ‘limitation clause’ (Article 4) of the ICCPR.¹⁶¹ Restrictions are further guided by paragraph 29 CG 14 which clarifies that : ‘the least restrictive measures should be utilised , be of a limited period and subject to review’.¹⁶² Similarly, in accordance with the Universal

¹⁵⁵ WHO ‘Guidance on Ethics of tuberculosis prevention, care and control’ (2010) available at http://www.who.int/tb/features_archive/ethics/en/index.html , accessed 23 April 2019.

¹⁵⁶ Kass N ‘An ethics framework for public health’ (2001) 91 *Am J Public Health* 1776.

¹⁵⁷ Childress JF, Faden R, Gaare RD, et al. ‘Public health ethics: Mapping the terrain’ (2002) 30 *J Law Med Ethics* 170.

¹⁵⁸ Upshur R ‘Principles for the justification of public health intervention’ (2002) 93 *Can J Public Health* 101.

¹⁵⁹ The Siracusa Principles (see note 20 above).

¹⁶⁰ Ibid (Article 25).

¹⁶¹ ICESCR (see note 21 above; Article 4).

¹⁶² ICESCR (see note 21 above; GC14 Paragraph 29).

Declaration of Human Rights, freedom of movement (Article 13)¹⁶³ and the right to peaceful assembly (Article 20)¹⁶⁴ may be limited for the sake of promoting and protecting public health. This compares favourably to the provisions and limitations in section 36(1) of the Constitution which requires that the limitation of rights be reasonable and justifiable, based on dignity, equality and freedom, and the consideration of all relevant factors.¹⁶⁵ It is suggested that isolated individuals should be provided with legal counsel if required and authorities should be appointed to manage and review such cases on an on-going basis. Restrictive measures such as isolation should not be viewed as punishment, and appropriate counselling should be provided to affected persons before isolation, including the right to appeal it.¹⁶⁶ From a human rights perspective, it is proposed that there should be evidence of serious infectious risk and failure of the alternative strategies employed, as it may be argued that prolonged isolation required for the completion of treatment does not represent the least restrictive means to achieve this goal.

3.3.3. The Principle of reciprocity

When the human rights or freedoms of individuals are restricted for the purpose of protecting public health, such as the spread of TB, it is expected of stakeholders to provide support and compensation where applicable to individuals who have to remain isolated. It is suggested that when restrictive measures are applied to control the spread of TB, both government and broader society have the duty to reciprocate by providing resources such as food and water, as well as counselling and emotional support. Applying the principle of reciprocity in these cases ensures that restricted individuals are not left unassisted, but are supported by the state, healthcare workers, family and the community. In support of the principle of reciprocity, Harris and Holm suggest that those with communicable diseases are responsible not to infect others, however they can only do so if they are supported in this regard.¹⁶⁷ It can be argued further that a failure of reciprocal input can compromise the success of restrictive measures and ultimately cause harm. Reciprocity also includes the State, who have the obligation to ensure protection and safe working environments for their HCWs.

3.4. Legal considerations in TB control

According to the United Nations, relevant legislation remains a powerful form of protection for people with TB, as it can be specific, address individual and public health issues and may protect the rights

¹⁶³ Universal Declaration of Human Rights (1948) Article 13.

¹⁶⁴ Ibid (Article 20).

¹⁶⁵ The Constitution of the Republic of South Africa (1996) s36.

¹⁶⁶ Open Society Foundation (see note 132 above).

¹⁶⁷ Harris J and Holm S 'Is there a moral obligation not to infect others?' (1995) 311 *BMJ* 1215.

of people who are infected with TB.¹⁶⁸ However, in a recent audit of legislation in 22 countries with high rates of TB infection, only two countries were found to have laws that were specific to TB.¹⁶⁹ Although numerous policies, regulations and other nonspecific legislation exists for the care and control of TB in South Africa, they are not specific, legally binding or enforceable. In South Africa, the legislative mandate of the Department of Health is derived largely from the National Health Act, 61 of 2003,¹⁷⁰ and the Constitution.¹⁷¹

The Constitution states: ‘that everyone has the right to equality, and obliges the state to realise socio-economic rights and access to health care’, including TB treatment.¹⁷² Section 27 states that ‘everyone has the right to access to food, water, and social security’,¹⁷³ which are the determinants of successful compliance in TB treatment. Moreover, the National Health Act 61 of 2003 requires a system of decentralised health service management in each health district, where TB patients may access treatment at their closest clinics.¹⁷⁴ The other statutory provisions that guide TB care include inter alia: Children’s Act 38 of 2005,¹⁷⁵ which provides for basic health care and well-being of children, the Occupational Health and Safety Act 85 of 1993,¹⁷⁶ which provides for a safe working environment for employees, the Compensation for Occupational Injuries and Diseases Act 130 of 1993,¹⁷⁷ providing for compensation for TB contracted by employees in the course of their employment, and for death resulting from such injuries or disease. TB care and control in SA is further guided by policy prescripts including the National Strategic Plan on HIV, STIs and TB,¹⁷⁸ HIV& AIDS and TB management policy for the public service,¹⁷⁹ policy on multidrug resistant TB,¹⁸⁰ and management protocols in the South

¹⁶⁸ UNDP ‘Legal Environment Assessments for Tuberculosis’ (2017) available at <http://www.stoptb.org>, accessed on 25 April 2019.

¹⁶⁹ Ibid.

¹⁷⁰ National Health Act No. 61 of 2003.

¹⁷¹ Constitution of the Republic of South Africa (1996) s27.

¹⁷² Ibid.

¹⁷³ Ibid.

¹⁷⁴ National Health Act No. 61 of 2003 s29.

¹⁷⁵ Children’s Act No. 38 of 2005.

¹⁷⁶ Occupational Health and Safety Act, 85 of 1993.

¹⁷⁷ Compensation for Occupational Injuries and Diseases Act 130 of 1993.

¹⁷⁸ National Department of Health. National Strategic Plan on HIV, STIs and TB (2012-2016) available at <http://www.doh.gov.za/docs/stratdocs/2012/NSPiull.pdf>, accessed 14 April 2019.

¹⁷⁹ National Department of Health. HIV& AIDS, STI and TB Management Policy available at <http://www.dpsa.gov.za>, accessed on 4 June 2019.

¹⁸⁰ National Department of Health. Management of drug-resistant tuberculosis: Policy guidelines. Available at http://www.tbonline.info/media/uploads/documents/mdr-tb_sa_2010.pdf, accessed 4 May 2019.

African National TB Guidelines.¹⁸¹ However, none of these guidelines provide directives to HCWs on enforcement measures for non-compliant patients. Compulsory isolation restricts the right of freedom of movement; however, it is suggested that such individual rights are subject to limitations in situations where it can be shown to be ‘justifiable or applied within reason’. It is therefore necessary to reflect on relevant case law in this context:

The *Goliath case*¹⁸² is widely discussed as a seminal case that reflects the conflict between the principle of a person’s right to autonomy with the rights of larger society. A more detailed analysis of this case is presented hereunder:

The issue in the case: Tuberculosis is transmitted in the air and is caused by *Mycobacterium tuberculosis*, which may be transmitted through infectious droplets.¹⁸³ Multi-drug resistant tuberculosis (MDR-TB) is a form of TB that is resistant to initial treatment, whilst XDR-TB is resistant to additional newer drugs.¹⁸⁴ XDR-TB is invariably associated with a higher mortality rate than the other types.¹⁸⁵ Poor adherence to treatment contributes to the development of MDR TB and XDR TB, as organisms may develop resistance to drugs that are taken incompletely. XDR-TB is a highly infectious and life-threatening to infected persons themselves and the public at large.¹⁸⁶ Involuntary detention for the purpose of ensuring that an infected individual complies with the treatment regimen also decreases the risk of spread to the general public. However, it can be argued that involuntary detention for this purpose tramples on the rights of individuals to enjoy freedom of movement and make decisions about their own health.

The parties in the case : In 2008, Goliath and 3 others (applicants) took the Minister of Health of the Province of Western Cape (respondent) to the High Court of South Africa Cape of Good Hope Provincial Division to challenge their compulsory isolation at Brooklyn Chest Hospital for a period of three consecutive months, until they fulfilled the criteria for negative sputum culture conversion for XDR tuberculosis.¹⁸⁷

¹⁸¹ Department of Health ‘South African National TB Guidelines’ (2014) available at www.mic.uct.ac.za, accessed on 7 May 2019.

¹⁸² *Minister of Health of the Province of the Western Cape v Goliath and Others* (2009) (2) SA 248 (C).

¹⁸³ *Goliath* (n173) 24.

¹⁸⁴ *Goliath* (n173) 25.

¹⁸⁵ *Ibid.*

¹⁸⁶ *Goliath* (n173) 26.

¹⁸⁷ *Goliath* (n173) 17.

The relevant facts:

The applicants were diagnosed with extensively drug-resistant (XDR- TB) and were voluntarily admitted to Brooklyn Chest Hospital for treatment.¹⁸⁸ However, during their hospitalisation, the applicants refused to be treated or isolated and absconded frequently, alleging that the hospital conditions were unsatisfactory, and that they had financial and family responsibilities to be attended to.¹⁸⁹ They asserted that they should not be isolated, as Section 12 of the Constitution guaranteed their rights to freedom and security.¹⁹⁰

The legal question:

Did the State violate the Applicants rights to personal freedom by enforcing hospital admission and subsequent isolation to ensure treatment?

*Important issues considered in the judgement :*¹⁹¹

- compulsory detention imposes a restriction of rights, especially to free movement.
- XDR TB is known to be a highly infectiousness and life-threatening infection.
- the spread of XDR TB is a public health concern and isolation may be reasonable to protect the public.
- inadequate reliable data exists on the treatment and cure of XDR TB to better inform the court on less restrictive measures.
- the Department of Health Guidelines state that a patient with XDR TB must be treated in hospital.¹⁹²

Constitutional and statutory law, conventions, principles, and guidelines considered by the court in making a judgement:

Constitution of South Africa (S12),¹⁹³ Constitution of Ghana S14 (1),¹⁹⁴ ICCPR (Article 12),¹⁹⁵ Siracusa Principles on the Limitations and Derogation Provisions in the ICCPR (Article 25) ¹⁹⁶, and European Convention on Human Rights (Article 5).¹⁹⁷

¹⁸⁸ *Goliath* (n173) 33.

¹⁸⁹ *Ibid.*

¹⁹⁰ Constitution of the Republic of South Africa (1996) s12.

¹⁹¹ *Ibid* (see note 182 above).

¹⁹² Department of Health (see note 181 above).

¹⁹³ *Ibid* (see note 190 above).

¹⁹⁴ Constitution of Ghana (1992) Section 14(1).

¹⁹⁵ International Covenant on Civil and Political Rights (Article 12).

¹⁹⁶ Siracusa Principles Art 25 (see note 20 above).

¹⁹⁷ European Convention on Human Rights (1950) Article 5.

The Court's decision/ judgement in the case: In summary, the Court acknowledged the deprivation of the right to freedom, but legitimately countenanced the decision for compulsory detention based on valid public health concerns. This judgement is therefore supported, as it was not 'arbitrary or without just cause'. In quoting s 36(1) of the Constitution,¹⁹⁸ the court stated that 'in principle, the limitation on the freedom of movement of patients with infectious diseases is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom'.¹⁹⁹ The Court therefore held that the State *did not* violate the Applicants' right to freedom and security and the Applicants' were ordered to be readmitted and isolated until they became sputum negative.²⁰⁰

Application of legal prescripts and guidelines in relation to the facts in the case: In applying Section 12 of the Constitution,²⁰¹ the Court found that the 'involuntary isolation amounted to a deprivation of freedom'. In applying Section 7 of the NHA 2003,²⁰² which states that 'health services should not be provided to users without their informed consent, unless failure to treat the user, or group of people which includes the user, will result in a serious risk to public health', consideration was given to public health risk.

The judgement also considered constitutional prescripts applied in other countries, such as S 14(1) of the Constitution of Ghana,²⁰³ which states that 'limitations to the right of liberty may apply to persons with infectious/ contagious diseases for their treatment or the protection of the community'. Guidance from international conventions and principles as outlined above were also applied, which collectively permit limitations of the right of movement to protect public health, and lawful detention of persons for the prevention of the spread of infectious diseases.

The circumstances under which the court may have reached a different judgement:

If XDR TB was not of serious public health concern, the Court may not have ruled in favour of detention and treatment, but rather in favour of the respect of the right to freedom of movement and choice of treatment. If more robust clinical data was available, the Court judgement may have stipulated a shorter period of isolation as guided by such data. If alternatives to hospital were available, such as TB sanatoria, the Courts may have ruled in favour of this option, as it is less restrictive in nature.

¹⁹⁸ South African Constitution s36(1).

¹⁹⁹ *Goliath* (n173) 42.

²⁰⁰ *Goliath* (n173) 88.

²⁰¹ *Ibid* (see note 190 above).

²⁰² National Health Act (Section 7).

²⁰³ *Ibid* (see note 194 above).

Case commentary:

It is suggested that the judgement upheld by the Court in this case is appropriate, and that the State did not violate the Applicants 'rights to personal freedom without just cause by enforcing hospital admission and isolation to ensure treatment. This view is based on the following issues:

- The right to dignity and freedom are enshrined in the Constitution and hence involuntary isolation was a violation of their rights.
- Although there is no legal basis to consider non- adherence to treatment as the commission of a crime punishable by isolation, the spread of life-threatening infection to the general public is of serious concern and hence the protection of public health constitutes 'just and reasonable cause'.
- Subject to section 7 of the NHA,²⁰⁴ provision is made for mandatory medical examination, isolation and quarantine of carriers, contacts and sufferers of specified communicable diseases.
- International legal instruments such as: Article 12 of the ICCPR,²⁰⁵ Article 25 of the Siracusa Principles ²⁰⁶, Article 5 of the European Convention on Human Rights (1950) ²⁰⁷ and Article 6 of the African Charter on Human and Peoples' Rights (1981/1986),²⁰⁸ collectively support the limitation of the right to liberty of movement by necessary restrictions provided by law to protect public health.
- Other comparative legislation such as the Ontario Health Protection and Promotion Act ²⁰⁹ in Canada, and s 14(1) of the 1992 Constitution of Ghana ²¹⁰, similarly advocate limitations to the right to the liberty of persons suffering from an infectious disease for the purpose of his or her care or treatment or the protection of the community.
- There is room for the application of restrictive measures if more ethically and legally justifiable strategies such as The WHO strategy of voluntary cooperation prove to be ineffective.²¹¹

²⁰⁴ National Health Act No. 61 of 2003 s7.

²⁰⁵ ICCPR (see note 195 above).

²⁰⁶ Siracusa Principles on the Limitation and Derogation of Provisions in the International Covenant on Civil and Political Rights UN Doc E/CN.4/1984/4 (1984) (Article 25).

²⁰⁷ European Convention on Human Rights (see note 197 above).

²⁰⁸ African Charter on Human and Peoples' Rights (1981/1986) Article 6.

²⁰⁹ Ontario Health Protection and Promotion Act.

²¹⁰ Ibid (see note 194 above).

²¹¹ World Health Organisation (see note 19 above).

- The ‘Regulations relating to Communicable diseases and the Notification of Notifiable medical conditions’²¹² in terms of the NHA provide for the compulsory medical examination, hospitalisation or treatment of persons suffering from a communicable disease.

The judgement in this case is consistent with comparative case law. For example, a similar decision was taken by the court in the interest of public health in *Toronto (City Medical Officer of Health) v Deakin*²¹³, where a detention and treatment order for continuation of TB treatment was extended by the court without consent, despite objections that it violated the patient’s ‘constitutional liberty rights’. In the *Goliath case*, the court acknowledged the violation of the patient’s rights, but concluded that it was justified to protect public health. Cases described in the literature also highlight the suitability of the environment for isolation. Isolation in prison is not necessarily a conducive environment for the enforcement of TB treatment. This issue is highlighted in *Lee v Minister of Correctional Services*,²¹⁴ where prison authorities allegedly failed to take preventative measures causing the applicant to be infected with TB. The High Court held that the responsible authorities’ omission(s) constituted a ‘negligent breach of its constitutional and statutory duty to protect the applicant’s rights’. However, the Constitutional Court noted that it would not be possible to prove that omissions relating to suboptimal prison conditions were the direct cause of infection. Nevertheless, clinical researchers suggest that the risk of TB transmission within our prison system is unacceptably high, and prisons predispose prisoners and hence the general population to TB infection.²¹⁵ Johnstone-Robertson confirmed a high risk of TB in prisons using a ‘transmission modelling analysis of probabilities of TB transmission’ in Pollsmoor correctional facility, Cape Town.²¹⁶ He demonstrated that congestion, poor living conditions and ineffective TB control programmes in prison contributed to high transmission rates.²¹⁷ These authors suggest that cases should be actively pursued, and national minimum standards and international environmental standards should be implemented, which could reduce transmission significantly.²¹⁸

Occupational risks for the development of TB and the responsibility of employers in infection control

²¹² GN R.485 of 23/4/199.

²¹³ *Toronto (City, Medical Officer of Health) v Deakin* (2002) O.J. No. 2777.

²¹⁴ *Lee v Minister of Correctional Services*. (2013) (1) SACR 213 (CC).

²¹⁵ Van Niekerk JP ‘Lock up and stay: South Africa’s sick prisons’ (2005) 95(5) *SAMJ* 281.

²¹⁶ Johnstone-Robertson S ‘Tuberculosis in a South African prison - a transmission modelling analysis’ (2011) 101(11) *SAMJ* 809.

²¹⁷ *Ibid.*

²¹⁸ *Ibid.*

and prevention is noted in the *Nkala v Harmony Gold Mining Company*²¹⁹ case, where a class action on behalf of mineworkers who contracted silicosis or TB was instituted. A settlement was reached to compensate all workers who are suffering from infection, and the families of deceased miners. This case demonstrates the responsibility to be taken by private employers and corporates, to ensure effective infection prevention measures in the workplace as well.

In conclusion, the issues outlined in the cases described in this chapter suggest that existing strategies are ineffective in ensuring adherence, and a new legislative framework needs to be developed. It is anticipated that the government will promulgate regulations in their communicable disease programmes and provide clarity on the circumstances when a court order should be sought to forcibly isolate a patient. The responsibility to ensure prevention and control of TB lies with infected individuals themselves, as well as government and the private sector. In Chapter 4, the role of sanatoria for the purpose of improving adherence is discussed, and the chapter includes a pilot survey of the attitudes of healthcare workers, patients and people from the general public towards the role of sanatoria.

²¹⁹ *Nkala v Harmony Gold Mining Company Limited* (2018/44060) [2018] ZAGPJHC 657.

Chapter 4: The re-introduction of TB sanatoria

4.1. Introduction

A sanatorium (aka sanitarium or sanitorium) is a medical facility used for the holistic management of chronic illnesses, and has been used for the treatment of tuberculosis (TB) since the late 1800's.²²⁰ Sanatoria are used for specific treatments such as the administration of medications, and are usually combined with supportive regimens such as proper diet, sunlight and exercise. They may also serve as institutions for rest and recuperation of the chronically ill and debilitated, in a private setting with space and open-air. The use of sanatoria as part of the treatment of TB was promoted by medical professionals as it offered more space and fresh air, a secluded environment, improved hygiene, discipline among patients, and opportunities for education and support, in a non-urban environment.²²¹ 'Open-air sanatoria' facilitated the complete treatment of infected individuals, and were therefore successful in preventing spread.²²² In the recent past, South African experts have proposed that modern day sanatoria may be necessary, given the persistently high rates of non-adherence and rapidly developing resistant forms of the disease.²²³

4.2. Historical perspective

Supportive measures such as fresh air, good nutrition and exercise for the cure of TB were promoted by Hippocrates, widely considered as the 'father of medicine'.²²⁴ Many years later, German physician Brehmer opened one of the first sanatoria with supportive measures in Poland, under his personal supervision.²²⁵ Thereafter, less upmarket establishments were built to treat more infected people from the lower socioeconomic classes.²²⁶ Although serious infection still resulted in mortality in some cases, treatment in sanatoria was shown to be beneficial for patients with less severe disease.²²⁷

²²⁰ Murray JF, Schraufnagel D, and Hopewell P 'Treatment of Tuberculosis. A Historical Perspective' (2015) 12 (12) *Annals of the American Thoracic Society* 1.

²²¹ Collins J 'Life in the Open Air: Place as a Therapeutic and Preventative Instrument in Australia's Early Open-air Tuberculosis Sanatoria' (2012) 22(2) *The Journal of the Society of Architectural Historians, Australia and New Zealand*. 208.

²²² Ibid.

²²³ Dheda (see note 34).

²²⁴ Frith J 'History of Tuberculosis- sanatoria and the discoveries of the Tubercle Bacillus' (2014) (22) 2 *Journal of Military and Veterans' Health* 36.

²²⁵ Daniel TM. 'Hermann Brehmer and the origins of tuberculosis sanatoria' (2011) 15(2) *Int J Tuberc Lung Dis* 161.

²²⁶ Ibid.

²²⁷ Herzog H 'History of Tuberculosis' (1998) 65 *Respiration* 5.

Thereafter, ‘tuberculosis sanatoria’ became an important long-term treatment option globally. In the USA, a widely known sanatorium was built by Trudeau, a physician and TB sufferer and thereafter, sanatoria could be found throughout Europe and some other countries.²²⁸ In South Africa, the Nelspoort Sanatorium, and first tuberculosis hospital dates back to 1925.²²⁹ However, as research and development resulted in the discovery of effective antibiotics, treatments became cheaper and more effective than conventional treatment in sanatoria. Most sanatoria were therefore closed by the authorities towards the mid-1960s, after which emphasis shifted to antimicrobial therapies.²³⁰

4.3. Rationale for sanatoria

4.3.1. Benefits

In reviewing the history of sanatoria, Bates was able to show a decrease in the rate of TB cases around the time sanatoria were introduced.²³¹ She noted further that despite the high incidence of TB at that time, there was an appreciable decline in the number of deaths resulting from TB. Newsholme found that when patients with an advanced stage of lung TB were treated separately, it was associated with reduced mortality from TB in England, Wales, Scotland, Prussia, and New York.²³² His analyses also indicated that appropriate nutrition, an upliftment in living conditions and other supportive measures were associated with fewer deaths from TB in Great Britain.²³³ In a separate analysis of the general tendency of deaths from TB in England and Wales, Wilson found a decrease in the rate of TB infection relative to programs that were directed to separation and medical care.²³⁴ He demonstrated the same trend in New York, and Minnesota, where there was a decline in TB infection rates relative to separation

²²⁸ Murray JF, Schraufnagel D, and Hopewell P ‘Treatment of Tuberculosis. A Historical Perspective’ (2015) 12 (12) *Annals of the American Thoracic Society* 1.

²²⁹ Kruger, D.W. (ed) (1972). *Dictionary of South African Biography*, Cape Town: Human Sciences Research Council (5) 9.

²³⁰ Schatz S, Bugle E, Waksman S ‘Streptomycin, a substance exhibiting antibiotic activity against gram-positive and gram-negative bacteria’ (1944) 55 *Exp Biol Med* 66.

²³¹ Bates B, *Bargaining for life: A social history of tuberculosis 1876-1938* (1992) Philadelphia: University of Pennsylvania Press.

²³² Newsholme A ‘An Inquiry into the Principal Causes of the Reduction in the Death-Rate from Phthisis During the Last Forty Years, with Special Reference to the Segregation of Phthisical Patients in General Institutions’ 1906 (6) *Journal of Hygiene* 336.

²³³ *Ibid.*

²³⁴ Wilson LG ‘The Historical Decline of Tuberculosis in America: Its Causes and Significance’ (1990) 45 *Journal of the History of Medicine and Allied Sciences* 366.

and ‘contact tracing’, particularly close members of the patient’s family.²³⁵ Similarly, Fairchild and Oppenheimer confirmed the benefit of segregation of individuals that were suffering with pulmonary TB over prolonged periods.²³⁶ In contrast however, a study in Madras did not show an appreciable difference in clinical outcomes or infection control rates amongst household members when treatment in sanatorium was compared with treatment at home.²³⁷ It is suggested that outcomes from studies involving TB care and control are influenced by variables like social dynamics, education, poverty and cultural issues which differ between countries. There is a paucity of more recent local and global comparative data on sanatoria due the closure of sanatoria after the success of newer medications.

4.3.2. Failure of current strategies

Despite global efforts to improve treatment and care, TB remains the leading infectious cause of death globally.²³⁸ Despite the interventions instituted in SA to control the disease, it still has amongst the highest rates of TB when compared to similar countries where TB is common.²³⁹ The current modalities available to ensure compliance of treatment range from the least restrictive to most restrictive, including self-administered therapy (SAT), directly observed therapy (DOT), court mandated therapy and imprisonment. Karumbi and Garner conducted a large systematic review of many countries, including South Africa, and found that the completion of treatment and cure in both ‘SAT’ and ‘DOT’ groups were low, implying that these modalities were ineffective in ensuring adherence.²⁴⁰ Similarly, despite ‘court mandated enforcement of detention and imprisonment’ to ensure compliance, non-adherence to treatment still remains an challenging healthcare issue. More recently, local researchers showed high death rates after 5 years despite treatment with a maximum number of newer drugs, and more concerningly, new forms of resistant bacteria have been identified, and more recently been referred to as

²³⁵ Wilson (see note 234 above).

²³⁶ Fairchild A and GM Oppenheimer GA ‘Public health nihilism vs pragmatism: history, politics, and the control of tuberculosis’ (1998) 88(7) *Am J Public Health* 1105.

²³⁷ Tuberculosis Chemotherapy Centre ‘A concurrent comparison of home and sanatorium treatment of pulmonary tuberculosis in South India’ (1959) 21 *Bull World Health Organ* 51.

²³⁸ Tharakan SM ‘Global Trends: Tuberculosis (2018) Congressional Research Service’ (2018) available at www.crs.gov, accessed on 26 April 2019.

²³⁹ Churchyard GJ, Mametja L D, Mvusi L et al (2014) 104(3) *South African Medical Journal* 244.

²⁴⁰ Karumbi J and Garner P ‘Directly observed therapy for treating tuberculosis’ (2015) Cochrane Database of Systematic Reviews, Issue 5. Art. No.: CD003343. DOI: 10.1002/14651858.CD003343.pub4.

“Total Drug Resistant TB” (TDRTB).²⁴¹ Healthcare professionals also express concern that those patients suffering with drug-resistant TB in South Africa are being sent back into the community when their treatment fails, where they may invariably spread the disease to the community.²⁴² It is suggested that hospitals in the country do not have the capacity to admit and treat all infected patients on a long-term basis, which exacerbates the situation further.

4.3.3. Socio-economic challenges

Sadler suggests that the lower rates of TB in high income countries may be associated with better living conditions, appropriate nutrition, and the advances associated with industrialisation.²⁴³ In contrast, Harling suggests that social constraints such as poverty, overcrowding, migration, diseases, and malnutrition have been associated with the rise in TB and poor rates of treatment adherence.²⁴⁴ Homelessness and AIDS have been shown to be strongly associated with the development of TB drug resistance in the USA.²⁴⁵ Similarly in the UK, Spence *et al*, analysed many districts and found a strong correlation between poverty and the high rates of TB.²⁴⁶ In Mongolia, Myanmar, Tanzania and Viet Nam, Siroka *et al*, also demonstrated that the lowest socio-economic conditions were associated with a higher risk of acquiring TB.²⁴⁷

In South Africa, Doolan *et al* have shown that a higher frequency of diseases is prevalent among lower socio-economic group (SES) groups.²⁴⁸ Similar findings were made by Bradshaw *et al* in a local study.²⁴⁹ It has been suggested that in South Africa an ‘inverse care law’ can be identified, where the lowest socio-economic groups suffer the largest burden of ill-health but have access to the lowest level

²⁴¹ Boseley S ‘Experts call for new drugs and return of sanatoriums to halt TB in South Africa’ (17 January 2014) available at <https://www.theguardian.com>, accessed on 3 May 2019.

²⁴² Ibid.

²⁴³ Sadler AT ‘Socio-economic Determinants of Tuberculosis and of Risk Taking Behaviour’ (2013) available at <https://pdfs.semanticscholar.org>, accessed on 7 June 2019.

²⁴⁴ Harling G, Ehrlich R, Myer L ‘The social epidemiology of tuberculosis in South Africa: a multilevel analysis’ (2008) 66(2) *Soc Sci Med*. 492.

²⁴⁵ Selgelid (see note 120 above).

²⁴⁶ Spence et al (see note 49 above).

²⁴⁷ Siroka A, Law J, Macinko K, et al. ‘The effect of household poverty on tuberculosis’ (2016) 20(12) *Int J Tuberc Lung Dis* 1603.

²⁴⁸ Doolan K, Ehrlich R, Myer L ‘Experience of violence and socioeconomic position in South Africa: a national study (2007) 2 *Plos One* 1290.

²⁴⁹ Bradshaw D, Steyn K, (Eds.) *Poverty and chronic diseases in South Africa*. Cape Town: South African Medical Research Council; 2001. 6 (also see Harling et al note 244 above).

of health services.²⁵⁰ Harling also showed that in SA, TB is most common amongst the poorest people, and noted a high correlation with cigarette smoking, high alcohol consumption, low levels of education, high unemployment rates and poverty.²⁵¹ It is suggested that as the economy of SA faces challenges, unemployment and low socio economic levels are likely to persist, further contributing to the spread of the disease. It is therefore proposed that modern day sanatoria be considered and reintroduced, as many of the social determinants that contribute to nonadherence can be addressed, treatment can be supervised, and improved care and control can be achieved.

Table 1: Rationale for sanatoria: a tabulation

Category	Comment	Proposed benefits of sanatoria over hospitals
Persistent high rates of TB	SA still has the highest TB burden globally despite existing standard hospital treatment.	Trained and dedicated staff (specific to TB) to ensure better compliance.
Failure of existing strategies	Hospital treatments and other interventions have not eradicated the epidemic.	Data shows good outcomes associated with treatment in sanatoria.
Comprehensive care	Current hospital treatment does not adequately address allied and complementary care.	Onsite medical and allied health providers are dedicated to TB patients compared with hospitals overburdened with general patients.
Social determinants	Treatment in hospitals do not address issues such as exercise, overcrowding and substance abuse adequately.	Sanatoria provide appropriate ventilation, open air gymnasiums, counselling and tranquility in an adequately spaced environment.
Monitoring of therapy	Challenges exist with implementing DOTS in hospitals – e.g. staff shortages	Sanatoria staff only monitor TB therapy compared with the overwhelming burden of monitoring of general medications in hospitals.
Ethical/Legal	Voluntary treatment in sanatoria conforms to ethical and legal prescripts - court orders may also apply in certain cases.	Voluntary and non-coercive admission to sanatoria is more likely if presented as a wellness centre with holistic care.
Social and psychological support	Current treatment is more pharmacologically driven in hospitals.	Sanatoria allow room for motivation, encouragement, guidance and spiritual development.
Research and Development	Hospitals are burdened with other health priorities for research and development.	Sanatoria allow research dedicated to biomedical and psychosocial aspects specific to TB.

²⁵⁰Ataguba J, McIntyre D ‘Financing and benefit incidence in the South African health system: Preliminary results’ (2009) Health Economics Unit, University of Cape Town Working Paper 09-1.

²⁵¹ Harling et al (see note 244 above).

4.4. Current attitudes of patients, HCW's and public individuals to sanatoria

Most data, including personal experiences of patients in sanatoria, emanate from earlier literature. A paucity of data on sanatoria is noted from around 1940 onwards, due to the closure of most sanatoria by this time. Moreover, relevant data emanates largely from Europe and the USA, where cultural and socioeconomic factors differ significantly from SA. With this background, attitudes towards sanatoria were assessed amongst randomly selected categories of participants: patients, HCWs and public individuals (Ethics Protocol Ref No: HSS/1356/018M). HCWs and MDRTB patients at KDH MDRTB unit, as well as members of the general public were included to ascertain their attitudes to sanatoria.

Table 2: Current attitudes of a pilot sample of (1) patients, (2) HCW's and (3) public individuals towards sanatoria

Question	MDRTB patients <i>n=10 (%)</i>		HCW's <i>n=10 (%)</i>		Public <i>n=10 (%)</i>	
1. Do you know what a sanatorium is?	Yes 50	No 50	Yes 100	No 0	Yes 60	No 40
2. Do you think it is a good option for non-adherence?	Yes 90	No 10	Yes 100	No 0	Yes 90	No 10
3. Should all patients be admitted or non-adherent patients only	All patients 40	Defaulters 60	All patients 70	Defaulters 30	All patients 40	Defaulters 60
4. Do you think it is a cost-effective option for non-adherent patients	Yes 90	No 10	Yes 100	No 0	Yes 90	No (no response)
5. Do you think it will eliminate non-adherence?	Yes 80	No 20	Yes 100	No 0	Yes 50	No 50
6. Do you think a patient may heal faster?	Yes 100	No 0	Yes 100	No 0	Yes 90	No 10
7. Do you think that the spread of infection from non-adherent patients will be reduced	Yes 100	No 10	Yes 100	No 10	Yes 90	No 10
8. Do you think it will make a difference to the TB epidemic?	Yes 100	No 0	Yes 100	No 0	Yes 100	No 0
9. How long do you think a patient should stay in a sanatorium?	Until non-infectious 50	Until treatment is complete 50	Until non-infectious 70	Until treatment is complete 30	Until non-infectious 40	Until treatment is complete 60

10. If you are unable to adhere to treatment, would you choose to be admitted in a sanatorium?	Yes 90 No 10	Yes 100 No 0	Yes 90 No 10
11. Do you think a non-adherent patient should have restricted movement in public?	Yes 80 No 20	Yes 100 No 0	Yes 70 No 30

n= total number

The findings show an overwhelming agreement amongst all persons assessed that sanatoria are a feasible option to address non-adherence. Many HCW's felt that all TB patients (including primary TB), and not only those with MDRTB, should be managed in a sanatorium. This may be attributed to their direct knowledge of the impact of non-adherence on the epidemic and the possibility that sanatoria may address the contributing factors such as nutrition and overcrowding more successfully than existing home or hospital treatment. Although most respondents felt that sanatoria are a cost-effective option, more detailed studies are required on this. Most respondents also held the view that patients may heal sooner in sanatoria and that the spread of infection will be reduced. This may be attributed to their awareness that sanatoria offer "multi modal supervised therapy". Although half the number of patients felt that treatment should be completed in a sanatorium, it must be remembered that non - infectious patients are not at risk of spreading the infection and may not require prolonged stay. A non-infectiousness patient may however revert if they are non-adherent to subsequent treatment, and extensive counselling is therefore required. Importantly, most patients themselves, HCW's and the public respondents were willing to be admitted to a sanatorium if they themselves were unable to adhere to treatment. This suggests that people may not view sanatoria as a form of incarceration and punishment but as an extension of the health facility to facilitate cure. The overall agreement on the restriction of movement of non-adherent patients suggest their knowledge of the risk of spread when in close contact with an infectious patient, and public health concerns.

In conclusion, it is suggested that sanatoria may have a beneficial role in enhancing adherence strategies, which are currently limited to counselling on adherence and follow up at TB clinics. In the short term, the establishment of multiple sanatoria may be expensive to initiate but may prove cost effective in the long term as the disease prevalence gets lower, however this will require future research. Notwithstanding that the small sample size in the pilot survey presented, the results generally indicate a positive attitude towards sanatoria. Chapter 5 is a conclusory chapter and aims to provide a synthesis of the ethical, legal and human rights issues related to non-adherence amongst TB patients.

Chapter 5: Conclusion

The World Health Organisation (WHO) has declared the TB epidemic as a global health emergency.²⁵² Currently, approximately a third of the world's population is infected with the latent form of TB, which may develop into active disease during the course of their lifespan.²⁵³ The WHO has suggested that over 10 million people had contracted TB as recently as 2017, and many children have died from the disease.²⁵⁴ Multidrug-resistant TB (MDR-TB) remains a public health crisis, as many new cases have developed resistance to rifampicin - widely considered as an effective 'first-line' drug.²⁵⁵ Although many strategies have been developed and interventions implemented over the past years, TB remains a leading cause of death worldwide.²⁵⁶ The biomedical management of TB is inextricably linked to ethical and legal aspects, as TB is influenced by a variety of social determinants, legal and policy prescripts.

Renowned microbiologist Rene Dubos wrote: 'TB is a social disease - social and economic factors must be considered as much as the tubercle bacilli itself'.²⁵⁷ The association of TB with poverty has been shown, as well as the importance of the social aspect of tuberculosis in achieving successful treatment.²⁵⁸ Attaining social justice through poverty eradication is an ethical imperative, however it can be argued that it will not eliminate tuberculosis entirely. It can also be argued further that the association of tuberculosis with poverty may be a driver of 'stigma' in communities. Nevertheless, the ethical and moral imperatives of infection prevention and its impact on public health must be addressed in concert with research, development and biomedical interventions such as vaccine development. Healthcare professionals, ethicists, policymakers and community activists therefore share a combined responsibility in eradicating the disease.

Coercive restriction remains a moral and ethical dilemma and relates to the type of restriction and the extent to which restriction of movement is ethically justifiable for the protection of public health. It is suggested that patients who are non-infectious pose no immediate danger to others and should not be restricted. However, in other more infectious categories, restrictive measures should be based on

²⁵² WHO Global Tuberculosis Programme. (1994). TB: a global emergency, WHO report on the TB epidemic. World Health Organization available <http://www.who.int/iris/handle/10665/58749>, accessed on 6 June 2019.

²⁵³ Ibid.

²⁵⁴ WHO (see note 19).

²⁵⁵ Ibid.

²⁵⁶ UNAIDS (see note 5).

²⁵⁷ Dubos RJ and Dubos J. *The white plague: tuberculosis, man, and society* Little, Brown, Boston, MA; 1952.

²⁵⁸ Isaakidis P, Smith S, Majumdar S, et al. 'Calling tuberculosis a social disease—an excuse for complacency?' (2014) (384) 9948 *The Lancet* 1095.

evidence of public health risk, as associated with each case. A similar view is supported by Coker, based on the confinement of uncooperative patients in New York.²⁵⁹ Singh et al propose the use of quarantine for those people in whom infection is suspected, pending further confirmation of infection.²⁶⁰ However, it is suggested that infrastructure and logistic challenges in the healthcare system may render this option impractical.

HCW's also face the challenge of informing contacts about infected or suspected patients, especially when patients do not disclose to friends and family. It can be argued that disclosure by a HCW violates a patient's right to confidentiality, however the right to life of exposed individuals will be endangered. In the Common law exception based on endangered third parties in the *Tarasoff case*, the courts classified the HCW/patient relationship as affirmative responsibility, implying that they had the duty to act responsibly and prevent harm to the public when evidence existed.²⁶¹ According to Beauchamp and Childress, when a patient presents to health care workers, a promise exists that information regarding their health will be kept in confidence.²⁶² In this scenario, informing the third party would therefore involve 'breaking' such a promise. Healthcare workers therefore face the dilemma of balancing their ethical duty of non-maleficence to their patients, with their duties to save the lives of others who are at risk. However, The International Health Regulations, 2005 (IHR),²⁶³ the National Health Act No. 61 Of 2003,²⁶⁴ and the Regulations Relating to the Surveillance and Control of notifiable medical conditions (NMC) ²⁶⁵ in South Africa, stipulate the rapid detection of public health risks, early notification, as well as a prompt risk assessment and response to these risks. HCW's are therefore guided by the 'NDoH Standard Operating Procedures on the reporting of NMC', requiring TB to be 'notified to the Department of Health promptly' by healthcare providers as well as private and public health laboratories.²⁶⁶

²⁵⁹ Coker RJ *From Chaos to Coercion: Detention and the Control of Tuberculosis* (2000). New York: St. Martin's Press.

²⁶⁰ Singh JA, Ross Upshur R, Padayatchi N 'XDR-TB in South Africa: No Time for Denial or Complacency 2007 4(1) *PLoS Med.* e50.

²⁶¹ *Tarasoff v Regents of University of California* (1976) Cal.3d 425 [S.F. No. 23042].

²⁶² Beauchamp and Childress (see note 117).

²⁶³ WHO. Fifty-eighth World Health Assembly Resolution WHA58.3: revisions of the International Health Regulations. (23 May 2005) available at http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf, accessed 10 June 2019.

²⁶⁴ National Health Act No.61 of 2003.

²⁶⁵ Regulations relating to the surveillance and the control of notifiable medical conditions. Government Notice No.1434 of 2017.

²⁶⁶ National Department of Health 2018 Standard Operating Procedures: Reporting of Notifiable Medical Conditions (NMC) available at <http://www.nicd.ac.za>, accessed on 1 June 2019.

A further ethical challenge facing HCW's, is their duty to care for infectious TB patients even when this poses a danger to themselves and ultimately to their families. In this regard, Huber and Wynia, remind us that such duties of HCW's date back to Hippocrates; and the duty has historically been written into professional ethics guidelines.²⁶⁷ It is argued that this represents a biased view - even if HCW's have a professional duty to treat, it should be considered in terms of the type and level of risk they should face. Their 'right to refuse' should be respected and their 'right to autonomy' protected in dangerous circumstances. If the risks are exceptionally high in the context of XDR-TB, then it is imperative that the safety of working conditions must be improved. The Constitution ²⁶⁸, the National Health Act,²⁶⁹ and the Occupational Health and Safety Act ²⁷⁰ collectively stipulate that establishments must implement measures to minimise injury to HCW's or damage to their property. They must also be protected from physical harm and have a safe working environment. In keeping with the principle of reciprocity HCW's should also be compensated for adverse outcomes suffered.

From a legal perspective, a lack of specific legislation and policy prescripts exists to guide the enforcement of treatment of non-adherent TB patients. Whilst it is appreciated that it is impractical to have 'disease specific legislation', collective guidelines for life threatening diseases are necessary. Currently HCW's are guided by case law and need to obtain court orders to enforce treatment. In CESCRC GC No.14, paragraph 16 maintains that 'a right to health includes the right to control the spread of infectious diseases through a variety of control measures, some of which are restrictive'.²⁷¹ However, the use of restrictive measures such as quarantine, isolation, and travel prohibitions, restrict or limit basic human rights prescribed by the Universal Declaration of Human Rights e.g. 'freedom of movement (Article 13)' and 'right to peaceful assembly (Article 20)', for the sake of protecting and promoting the health of individuals and communities.²⁷² Limitations on rights and freedoms are also guided by the International Covenant on Civil and Political Rights (ICCPR),²⁷³ although it remains non-binding. In applying the Siracusa principles, the limitations include being in accordance with existing laws; the

²⁶⁷ Huber, S. J. and Wynia, M. K. 'When Pestilence Prevails...Physician Responsibilities in Epidemics' (2004) 4(1) *The American Journal of Bioethics* available at: <http://www.bioethics.net/journal/articles>, accessed 10 June 2019.

²⁶⁸ The Constitution of the Republic of South Africa, 1996.

²⁶⁹ National Health Act No.61 of 2003.

²⁷⁰ Occupational Health and Safety Act No.85 of 1993.

²⁷¹ ICESCR (1966) GC14 (Paragraph 16).

²⁷² Universal Declaration of Human Rights (1948) Articles 13;20.

²⁷³ International Covenant on Civil and Political Rights (ICCPR), G.A. Res. 2200A (XXI) (1966) available at <http://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx>, accessed 10 June 2019.

existence of a legitimate objective; that it is required in a democratic society; is the least restrictive means available; it is not arbitrary or unreasonable, nor discriminatory.²⁷⁴ Similarly, Section 36 of the Constitution provides for a limitation of the Bill of Rights in terms of law of general application and states that ‘limitations must be reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom’.²⁷⁵ Any limitation should therefore be reasonable, made for a good cause and should also be less restrictive. It is suggested that the restrictive measures undertaken in the recent Ebola virus disease (EVD) outbreak highlights the limitations enshrined in the Siracusa Principles.²⁷⁶ Notwithstanding that the Siracusa Principles can be applied in ‘legitimising’ restrictive measures for TB, it is suggested that it is unlikely to curb the spread of MDRTB resulting from non-adherence, as it remains multifactorial.

It is further suggested that in addition to DOTS-based treatment, governmental obligations include appropriate counselling on the risks of non-adherence; nutritional supplements to mediate the side effects of the medicine; and the option of limited in-patient treatment rather than detention and treatment in a prison setting. The education of the general public about TB is also necessary, as it has been shown that poor adherence is common and significantly associated with lack of knowledge about TB transmission.²⁷⁷ The imprisonment of non-adherent TB patients may not be practical currently and may affect those individuals with the least education and social support. Moreover, similar to detention in other overcrowded prisons in Africa,²⁷⁸ the conditions that exist in South African prisons may not be conducive to achieve the desired effect, from the perspective of providing an appropriate treatment environment for detained patients or preventing the spread of the disease.²⁷⁹ Against the background of these challenges, a strong argument is therefore made for the introduction of modern-day sanatoria as a middle road option for the management of non-adherence in TB. In SA, long-term outcomes in patients with XDR TB are unsatisfactory, and as appropriate chronic or palliative care facilities are inadequate, large numbers

²⁷⁴ Gostin LO ‘When terrorism threatens health: How far are limitations on human rights justified?’ (2003) 31(4) *The Journal of Law, Medicine & Ethics* 524.

²⁷⁵ Constitution s36 (1).

²⁷⁶ Diego S, Maxwell J, Smith MJ ‘Commentary: Limiting Rights and Freedoms in the Context of Ebola and Other Public Health Emergencies: How the Principle of Reciprocity Can Enrich the Application of the Siracusa Principles’ 17(1) (2015) *Health and Human Rights* 1.

²⁷⁷ Muture B N, Karaka M N, Kimuu P K, et al. Factors associated with default from treatment among tuberculosis patients in Nairobi Province, Kenya: a case control study (2011) 11 *BMC Public Health* 696.

²⁷⁸ International Centre for Prison Studies. World prison brief: Kenya. London, UK: ICPS (undated); http://www.prisonstudies.org/info/worldbrief/wpb_country.php?country, accessed on 6 June 2019.

²⁷⁹ Johnstone-Robertson et al (see note 216 above).

of patients with active XDR are sent home from hospitals, becoming more likely to infect the wider community.²⁸⁰ Researchers worldwide agree that a co-ordinated strategy is needed for highly infectious patients, including home-based or community care, and multidisciplinary teams in modern-day sanatoria. Boseley,²⁸¹ Bateman²⁸² and Greenhalgh²⁸³ support the role of sanatoria, whilst Dheda suggests greater emphasis on safety by the national health department and the creation of user-friendly and supervised TB patient-triaging policies.²⁸⁴

The pilot assessment included in the dissertation further demonstrates that the attitudes of patients, HCW's and lay persons towards sanatoria is largely acceptable. It is proposed that admission should be voluntary, and treatment should be maintained until patients are non-infectiousness. The concept of voluntariness is consistent with both ethical and legal prescripts and facilitates in house research with improved follow up and evaluative outcomes, which is currently lacking. It also allows for the management of other determinants of TB such as nutrition, exercise and substance abuse management, which collectively enhance the prospect of complete treatment. Court orders for involuntary detention in sanatoria may still apply when patients become public health risks, however if sanatoria are marketed as "wellness centres" rather than hospitals, where free movement is allowed in a destigmatised and caring environment, voluntary uptake is more likely.

The limitations in the study relate to the paucity of more recent research and reliable data on sanatoria, noting the closure of most sanatoria after the control of the epidemic. Older data from international studies remain heterogenous and inconsistent and are population specific. The research therefore highlights the gaps in the literature and reflects on the need for future research. A further limitation in the study lies in the comparative appraisal of international legal prescripts, which differs in countries. Moreover, TB treatment regimens, monitoring, evaluation and quality improvement programmes differ between countries, making direct comparisons difficult. Nevertheless, the current burden of TB indicates the critical need for the South African health system to keep abreast with the advances in TB care and control and consider evolving strategies. Concerted government efforts, within the health sector and other social and economic sectors, is therefore needed to address the TB epidemic in South Africa.

²⁸⁰ Pietersen E, Ignatius E, Streicher EM, et al 'Long-term outcomes of patients with extensively drug-resistant tuberculosis in South Africa: a cohort study' 383(9924) *The Lancet* 1230.

²⁸¹ Boseley (see note 241 above).

²⁸² Bateman C 'Defusing the new drug-resistant TB time bomb' (2014) 104(8) *S African Medical Journal* 528.

²⁸³ Greenhalgh I, AR Butler 'Sanatoria revisited: sunlight and health' (2017) 47(3) *I Journal of the Royal College of Physicians of Edinburgh* 1.

²⁸⁴ Dheda et al (see note 34 above).

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Appendix 1.



2 October 2018

Dr Jayneetha Maharaj 205522671
School of Law
Howard Campus

Dear Dr Maharaj

Protocol Reference Number : HSS/1395/018M

Project title: The health ethical and legal implications of non-adherence to treatment amongst patients infected with tuberculosis - HEAL study

Approval Notification – No Risk / Exempt Application

In response to your application received on 2 August 2018, the Humanities & Social Sciences Research Ethics Committee has considered the abovementioned application and the protocol has been granted **FULL APPROVAL**.

Any alteration/s to the approved research protocol i.e. Questionnaire/Interview Schedule, Informed Consent Form, Title of the Project, Location of the Study, Research Approach and Methods must be reviewed and approved through the amendment/modification prior to its implementation. In case you have further queries, please quote the above reference number.

PLEASE NOTE: Research data should be securely stored in the discipline/department for a period of 3 years.

The ethical clearance certificate is only valid for a period of 3 years from the date of issue. Thereafter Recertification must be applied for on an annual basis.

I take this opportunity of wishing you everything of the best with your study.

Yours faithfully

Professor Sheruka Singh (Chair)
Humanities & Social Sciences Research Ethics Committee

/pm

Cc Supervisor: Dr Dorrich Thaldar
cc Academic Leader Research: Drv Shannon Bosch
cc School Administrators: Mr Pradeep Ramsewak

Humanities & Social Sciences Research Ethics Committee

Dr Sheruka Singh (Chair)

Westville Campus, Govan Mbeki Building

Postal Address: Private Bag 354001, Durban 4300

Telephone: +27 (0) 31 200 3360/3360/3667 Facsimile: +27 (0) 31 200 4809 Email: hssc@ukzn.ac.za ethics@ukzn.ac.za ethics@ukzn.ac.za ethics@ukzn.ac.za

Website: www.ukzn.ac.za



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