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Is isolation of extensively drug resistant tuberculosis (XDR-TB) patients in South Africa ethically and legally justifiable?

Khumalo, Charmaine Slindile

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IS ISOLATION OF EXTENSIVELY DRUG RESISTANT TUBERCULOSIS (XDR-TB) PATIENTS IN SOUTH AFRICA ETHICALLY AND LEGALLY JUSTIFIABLE?

Name: Charmaine Slindile Khumalo

Student Number: 1714615

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Supervisor: Dr. Norma Tsotsi

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DECLARATION

I, Charmaine Slindile Khumalo, declare that this report is my work and has not been submitted or incorporated in another dissertation or thesis for any other degree.

DEDICATION

To my mother Ncamisile Khumalo. Thank you for being my inspiration. To my children, Thakasani and Masha'allah. My sisters: Slungile, Phindile, and Natasha, thank you for your endless support. My late father, Njabulo Khumalo, thank you for your spiritual presence.

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ABSTRACT

South Africa (SA) is reported as having one of the highest burdens of tuberculosis (TB) in the world. Drug resistant TB is a major global epidemic, with 500,000 cases occurring annually. In 2006, extensive drug resistant TB (XDR-TB) cases were first reported in SA. This particular strain of *Mycobacterium tuberculosis* has proven to be the most difficult to treat as it requires a more complex treatment regime. The prevention and treatment of XDR-TB are of paramount importance not only in SA, but worldwide. This study outlines the magnitude of the need to treat XDR-TB by isolation. Isolation requires legal and ethical analysis, as this is not a norm in the treatment of communicable diseases. The South African government's legal and moral responsibilities were critically analysed in this study. Several laws were analysed with relation to isolation as an intervention for XDR-TB treatment. The bioethical theories that were analyzed included deontology, utilitarianism, virtue ethics, communitarianism, and Ubuntu ethics. Isolation of XDR-TB patients was also examined through the four principles of bioethics: respect for patient autonomy and informed consent; beneficence; non-maleficence; and justice. The use of these bioethical perspectives illustrated the requirement for isolation as an intervention for the treatment of XDR-TB.

ACRONYMS

BOR	Bill of Rights
CDC	U.S. Centers for Disease Control and Prevention
FCHD	Fulton County Health Department
HPCSA	Health Professions Council of South Africa
MDR-TB	Multi Drug-Resistant Tuberculosis
NDoH	National Department of Health
NGO	Non-Governmental Organisation
NHA	National Health Act, 2003 (Act No. 61 of 2003)
	National Health Act, 2004 (Act No. 61 of 2003)
SA	South Africa
TB	Tuberculosis
USA	United States of America
UDHR	Universal Declaration of Human Rights
WHO	World Health Organization
XDR-TB	Extensively Drug-Resistant Tuberculosis

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CHAPTER 1

1.1 Introduction and Background

Tuberculosis (TB) is one of the leading causes of death worldwide, and affects 10.4 million people globally each year (WHO, 2018). In 1998, the first case of multi-drug resistant tuberculosis (MDR-TB) was diagnosed (Keshavjee and Farmer, 2012). MDR-TB affects about 500,000 new patients annually (Kanabus, 2017b). As a result of continued spread of multiple drug resistant strains of TB and patient noncompliance, extensively drug resistant tuberculosis (XDR-TB) began to occur (Kanabus, 2017b). The term XDR appears to have been used for the first time in March 2006. According to the World Health Organization, there are about 8,500 reported cases of XDR in the world, with Africa constituting 14% of these cases (2016). South Africa alone had over 1,000 cases of XDR-TB in Kwazulu-Natal between August 2011 and November 2014. These numbers point to the high burden of XDR in SA (Kanabus, 2017b).

Traditionally, treatment and management of XDR includes putting patients through a lengthy treatment regimen. Owing to the highly infectious nature of TB, management of XDR patients in many settings involves—but is not limited to—isolation of patients, a practice that bioethicists, civil rights activists, health care providers and policy makers have condemned and commended in equal measure.

This study examined the ethical and legal issues surrounding the isolation of XDR-TB patients in SA. This study examined the South African legal framework in terms of the laws surrounding treatment and control of XDR-TB as an infectious disease.

1.2 Literature Review

Tuberculosis (TB) is a highly contagious, infectious disease that is caused by the bacillus *Mycobacterium tuberculosis.* It usually affects the lungs (pulmonary TB) but is also able to affect other sites of the human body. The disease is spread by those who are sick with pulmonary TB by coughing, sneezing, or talking (WHO, 2016). This is not the only way that TB can spread in the body; Extrapulmonary TB spreads to different sites of the body and occurs in different forms which include: Lymphatic TB; Pleural TB; Skeletal TB; Meningeal TB; Peritoneal TB; and Genitourinary TB (Rockwood, 2007). A minute portion (5–15%) of the estimated 2–3 billion individuals that are infected with *M. tuberculosis* will go on to develop TB in their lifetime (WHO, 2016).

"XDR-TB is a disease that is caused by strains of *M. tuberculosis* that are resistant to isoniazid and rifampicin as well as any fluoroquinolone, and at least one of three injectable drugs; capreomycin, kanamycin or amikacin" (Raviglione and Smith, 2007). On the other hand, MDR-TB is a disease that is only resistant to isoniazid and rifampicin, which is what differentiates it from XDR-TB (Migliori *et al.*, 2007). Although MDR-TB is curable, it takes three times longer to treat when compared to ordinary TB (Selgelid, Kelly and Sleigh, 2008). Treatment of ordinary TB takes six to nine months while treatment of MDR-TB can take up to 30 months (Swindells, 2012). Treatment for MDR-TB is also more expensive due to the fact that more drugs are required for treatment. The medication used to treat MDR-TB is not as effective as the medication used to treat ordinary TB and results in greater toxicity (Selgelid, Kelly and Sleigh, 2008). Greater toxicity results in adverse side effects and include neurologic effects (convulsions and depression), renal toxicity, auditory toxicity, rashes, and hepatitis (Baghaei *et al.*, 2011).

According to Selgelid et al, (2008), there was an increase in the number of XDR-TB cases from 2006 to 2008. This increase was attributed to patients' failure to adhere to prescribed regimens, as a result of patients' inability to afford the cost of treatment and inability to get time away from work to collect drugs, among other factors (Selgelid, Kelly and Sleigh, 2008). Other structural factors included drug stockouts and the availability of low quality, substandard, expired or fake drugs in the market (ibid). Low quality medication is easier to obtain when there are drug stockouts, given that they are procured locally. Such medication is not quality assured or tested as it is not procured from the Stop TB Partnership's Global Drug Facility which supplies countries with second line drugs that have undergone extensive testing (Udwadia and Furin, 2019). It is estimated that 8,000 new cases of XDR-TB are diagnosed globally every year. Of these, about 1,000 cases occur in Africa (Kanabus, 2017b). The mortality rate associated with XDR is an estimated 60% out of these (Dall, 2017). In 2016, there was an estimated 967 new XDR-TB cases (WHO, 2016).

XDR-TB usually occurs because of amplified drug resistance due to insufficient treatment of MDR-TB. It can also be transmitted from one infectious individual to another individual (Lobue, 2009).Treatment of XDR-TB is very complex and requires trained professionals (Lobue, 2009). XDR-TB is also very expensive to treat and is four times more expensive than MDR-TB treatment. XDR is estimated to have used about 32% of the 2011 national TB budget in South Africa and yet still remained underfunded (Kanabus, 2017a).

There are different options for managing and treating XDR-TB. These include isolation and community-based treatment (Petersen *et al.*, 2017). Community-based treatments are carried out in community centres where it is more feasible for patients as they have to travel long distances for follow-up appointments and medication. The treatment is easily accessible and medication

adherence can be properly managed (Chaiyachati *et al.*, 2013). Isolation is used for separating individuals' who are known to have the disease from the community. It therefore assists in preventing further transmission of the pathogen. For this reason, the word isolation is usually used instead of quarantining in XDR-TB management (Fidler, Gostin and Markel, 2007).

Quarantine and isolation are sometimes used interchangeably but it should be noted that they are different. Both procedures are imposed upon patients on a voluntary basis. However, involuntary isolation may be imposed by the law as mandatory when it is necessary to protect the public's health. "Quarantine is the restriction of movement, or the separation of healthy individuals who have been exposed to a contagious disease, before it is known whether they will become sick. It usually takes place at home and may be applied at the individual level or even at the community level of the exposed individual" (Cetron *et al.*, 2004).

The current approach for the treatment of XDR-TB is primarily prevention. What is meant by this is that MDR-TB is managed in such a way that it should not give rise to XDR-TB. Prevention is the key to infection control as in most cases XDR-TB arises because of poor management of MDR-TB. The treatment of XDR-TB needs an individualised approach which is based on history of drug use in the particular patient and results from a drug susceptibility test. Due to this complexity, it is imperative that the treatment of XDR-TB should always be initiated under guidance of a clinical management team and review committees (National Department of Health, 2013). The 2013 policy guidelines note that on-going adherence, counselling and psychosocial support must be provided to patients and reinforced throughout treatment. The patients must also be educated about TB prevention and cough hygiene (ibid). This can help minimize the spread of the disease. "XDR-TB patients must be isolated in a well-ventilated side ward in a TB or district hospital, if space allows (ibid)." This statement is in support of isolation provided that the resources are available. If the

patients are at home, ‘they must be educated about cough hygiene and infection control at home (ibid).’

A decentralised and deinstitutionalised management programme approach has also adopted in SA after the success of the program. The 2019 policy framework provides guidance on how to treat patients closer to their homes. The results from the program showed an improvement in XDR-TB treatment outcomes. The policy noted that very sick patients need to be admitted and the admission should vary from 2 weeks to 2 months depending on the patient’s condition (National Department of Health, 2019). Isolation of XDR-TB patients is necessary in certain instances but in my view should be the last option. It is important to look at other options that do not infringe upon human rights and these should render better outcomes if not the best.

For the purposes of this study, the main focus was on the isolation of XDR-TB patients from the community in a hospital setting, whereby the patients are forced to undergo isolation. This type of isolation is of larger groups in a hospital setting and not of individual patient isolation. Mandatory isolation was solely implemented for application in infectious diseases control, which automatically includes TB and therefore XDR-TB. Mandatory isolation was critically assessed in this research report.

The key principles of isolation from a public health perspective include the following:

- “Isolation is used when sick individuals are infected with a highly dangerous and contagious disease
- The sick individuals are separated from their communities
- Care and required services are provided for the sick individuals
- The individual rights of the isolated individuals are protected

- Once the sick individuals are disease free, they are released to go home
- Mandatory isolation has to be the last resort in the treatment process" (Cetron *et al.*, 2004).

Isolation usually involves a specific form of treatment regime (Fidler, Gostin and Markel, 2007). The treatment regimen has to be an individualised plan; there are guidelines on how to construct such a regimen. It involves the use of a minimum of four drugs that are likely to be effective, but also the use of as many drugs that are likely to be tolerated by the individual. The individuals may be isolated from each other by being in separate rooms (Ndjeka *et al.*, 2014). As of 2016, WHO treatment guidelines for drug-resistant tuberculosis do not have recommendations specific to isolation and hospital infection control. The guidelines do however state that "Culture positive XDR-TB patients should always be in respiratory isolation." Respiratory isolation is particularly critical if an individuals has come into contact with an infected person, and requires the use of specialised N95 respirators. Respiratory isolation differs from ordinary isolation as the infected individuals are not isolated in negative pressure rooms in hospitals but rather in their own homes (Petersen *et al.*, 2017). The individuals receive treatment in their homes and not in a hospital setting (Fallow, 2008).

In SA, patients are subjected to a combination of strict infection control measures at the hospital and the individual's home. Patients from the XDR-TB outbreak in Tugela Ferry 2006, were treated at home and given the necessary resources required for treatment. This saw a drop in the number of cases in the Tugela Ferry region from 2005 to 2015. There are nurse delivering services through mobile clinics and vehicles in place to allow for systemic care which helps to prepare the families of infected individuals before they are discharged from hospitals and also doing follow ups at the individuals home after they have left the hospital (Petersen *et al.*, 2017). This indicates that isolation is done in different settings, not only in hospitals. There are 40 TB hospitals in SA, but

only nine offer treatment for MDR and XDR-TB patients (Bateman, 2007). XDR-TB patients pose a serious threat to public health (Boggio *et al.*, 2008).

1.3 Ethical and legal issues associated with XDR-TB in South Africa

Isolation does lead to loss of liberty (Fidler, Gostin, and Markel, 2007). The infected individuals are confined to one area until they are deemed free of the disease (ibid). This however conflicts with the patient's right to freedom of movement (ibid). Which is more important—the individual's right to freedom of movement, or the protection of society? If XDR-TB becomes too widespread, it would mean isolation in much larger scales (Selgelid, Kelly and Sleigh, 2008). During isolation, there is a loss of privacy as patients lose their rights. The community knows that a particular individual has XDR-TB as this knowledge is conveyed by the relevant authorities. This leads to stigmatization, as their community will know that they are infectious, and thus pose a danger to society (Fidler, Gostin and Markel, 2007). Their bodily integrity may be compromised as they are subjected to mandatory treatment and tests. This is addressed by the National Health Act (NHA), which allows for treatment without consent (*The National Health Act*, 2003; Fidler, Gostin and Markel, 2007).

From a public health perspective, isolation is a drastic measure. However, it does not mean that it is an inappropriate one.

> "Public health is primarily concerned with the health of the entire population, rather than the health of individuals. Its features include an emphasis on the promotion of health and the prevention of disease and disability; the collection and use of epidemiological data, population surveillance, and other forms of empirical quantitative assessment; a

> recognition of the multidimensional nature of the determinants of health; and a focus on the complex interactions of many factors—biological, behavioural, social, and environmental—in developing effective interventions" (Childress *et al.*, 2002).

If a person has XDR-TB, they are a threat to the public and this cannot be disputed. Therefore, isolation may be ethically justifiable, provided that it is the last resort and there is minimal harm in terms of justice and human dignity (Fidler, Gostin and Markel, 2007).

According to the Constitution of South Africa (1996) isolation is enshrined to bear a clear infringement to on an individual's Constitutional rights (Van Wyk, 2009). Van Wyk, further says that "These rights include, the right to dignity, freedom and security of the person, freedom of movement, the right to privacy and the right to equality." The sections applicable to the rights above are in Chapter 2, Bill of Rights of the Constitution.

Section 9 contemplates the rights to equality:

- "9 (1) Everyone is equal before the law and has the right to equal protection and benefit of the law
- 9 (2) Equality includes the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken."

The right to human dignity in Section 10 states, "Everyone has inherent dignity to have their dignity respected and protected." Section 12(1) states that, "Everyone has the right to freedom and security of the person, which includes the right:

- 12 (1) (a) not to be deprived of freedom arbitrarily or without just cause."

The right to privacy as contemplated in Section 14 states that, “Everyone has the right to privacy, which includes the right not to have

- 14(d) the privacy of their communications infringed.”

Yet, according to the Constitution, “these rights ought to be balanced against the legitimate needs of society and the constitutional rights of other members of society.” The Constitution further allows imposing limitations on these constitutional rights, in accordance with Section 36 (1a–e)” (*Constitution of the Republic of South Africa*, 1996; Van Wyk, 2009).

Is isolation justifiable in terms of reduction of the burden of XDR-TB? The rights that an individual has can be limited if there is a justifiable reason. This demonstrates that there are no absolute rights in this regard. A particular right can be more significant when decisions pertaining to an individual’s need to be finalised. What is in place in terms of the law and isolation? In SA, in terms of the law, an individual who has an infectious disease may be isolated, until the disease stops being a public health risk. The National Health Act (NHA) is such a law that supports isolation.

“XDR-TB is a notifiable medical condition according to the NHA and should be notified through written or electronic notification to the Department of Health within seven days of diagnosis by the health care provider as well as private and public health laboratories.” As per the NHA, *Government Gazette* of June 30, 2017, Chapter 3, Section 15 (2), “The head of a provincial department must apply to the high court for an appropriate court order, if a person who is a clinical or laboratory confirmed case, carrier or contact of a notifiable medical condition refuses to consent to isolation in order to prevent transmission” (*The National Health Act*, 2003). This does not explicitly make isolation mandatory, but spells out the fact that a court order may be issued if an

infected person who poses a risk to the public refuses to get treatment. The treatment however can be done without consent (Van Wyk, 2009).

1.5 Research Question

Is isolation of XDR-TB patients ethically and legally justifiable?

1.6 Rationale for the Study

There were 8000 new cases of XDR-TB that were reported worldwide in 2016. The reason for this study is because XDR-TB may lead to a number of deaths but also that it is not an easy disease to treat. XDR-TB diagnosis in SA increased from 85 patients in 2004 to 741 patients in 2010 (National Department of Health, 2013). Isolation is recommended to increase treatment adherence and to reduce infection, which is beneficial for public health. However, isolation violates individual rights, causes stigma, and denies family members access to their loved one. The South African Constitution, the NHA, the Regulations Relating to Communicable Diseases and the Notification of Notifiable Medical Conditions (R.2438) do not consider the violation of individual rights. This study looked at the legal and ethical issues related to XDR-TB that are associated with isolation in South Africa. The research will contribute towards the justification of isolating XDR-TB patients for the sake of public health.

1.7 Thesis Statement

In this study, I defended the position that it is ethically justifiable to isolate XDR-TB patients.

1.8 Aim and Objectives

Aim

To critically evaluate the morality of isolating XDR-TB patients.

Objectives

1. To analyse and describe the legal framework surrounding XDR-TB management with regards to the isolation of XDR-TB patients in SA.
2. To analyse the ethical issues surrounding XDR-TB management with regards to the isolation of XDR-TB patients in SA.
3. To analyse the ethical implications of isolating of XDR-TB patients in SA.

1.9 Research Design

This was a normative research study involving a review of existing legal and ethical guidelines on the management of XDR-TB patients.

Normative ethics is a branch of philosophy that, "is concerned with the articulation and justification of the fundamental principles that govern the issues of how we should live and what we normally ought to do" (Sugarman and Sulmasy, 2010). "Its most general concerns are providing an account of moral evaluation and, possibly, articulating a decision procedure to guide moral action" (Driver, 2009). The answers are presented critically and systematically in order to justify the replies (Sugarman and Sulmasy, 2010). In this study, the normative question was whether the isolation of XDR-TB patients in SA was ethically and legally justifiable.

The moral theory of utilitarianism was used to normatively argue for the isolation of XDR-TB patients in this study.

1.10 Research Methods

1.10.1 A normative study

The study was a purely normative study. There was no new data collected. Library and desktop-based research were utilised. The research methods that were employed in this study were philosophical and bioethical.

An ethical analysis of literature was done, with the literature being discussed further in the study. The legal framework and ethical issues related to the topic of the study were critically analysed. The review of the literature included the explanation of concepts and definitions, as well as the identification and criticism of the current conditions and practices applicable to this study. The theoretical frameworks were then evaluated after the interpretation and description thereof. The analysis of literature also included the development and defending of arguments. The sources of literature included, but were not limited to: research articles, books, Google Scholar, PubMed, government legislation, and other academic search engines.

1.10.2 Argumentative strategy

Whether a patient ought to be isolated in cases of XDR-TB include various legal and ethical concerns. Legal issues include the conditions where isolation must be undertaken, who gets isolated, and who governs the isolation of infected individuals. Ethical issues, furthermore, include informed consent, whether the conditions of isolation are justifiable, and whether patients ought to be forced to undergo treatment and confidentiality. It should be noted that respect for autonomy

can be overridden. Guidelines recommend isolation of XDR-TB patients to promote public health (Department of Health, 2011). None have comprehensively looked at isolation from the perspective of the ethical and legal issues. This leaves a gap in the ethical and legal issue implication of isolation. In this study, the normative approach to defend the position that isolation of XDR-TB patients is ethically and legally justifiable was utilised.

I argued in support of isolation of XDR-TB patients in SA in this study. Within the legal framework, local and international laws about the topic of this study were used to support my argument. The international laws included are the International Health Regulations as adopted by the WHO. The South African laws included the NHA and The Constitution of the Republic of South Africa. The regulations relating to communicable diseases of notifiable medical conditions (R.2438) were also reviewed and critiqued. The Siracusa Principles were also analysed and critiqued in relation to isolation.

This study provided an ethical framework for analysis by using four principles that are used in principlism: autonomy; beneficence; non-maleficence; and justice. In utilitarianism, respect for autonomy is overridden as the population takes precedence over the individual. The benefit of the individual and the population is also taken into consideration in terms of protection against infection. Whatever causes the least amount of harm is taken into consideration. This thesis' central argument, moreover, is based on the theory of utilitarianism, where isolation is for the greater good (i.e., the public rather than the individual) takes precedence. I further discuss theories of deontology, communitarianism, virtue, and Ubuntu ethics. Public health ethics was discussed with the introduction of an ethics framework for public health. I discussed the pros and cons of utilitarianism as a tool in public health ethics and how conflict arises between ethics and public health.

1.11 Ethics

An ethics waiver was approved. Reference W-CBP-180904-1.

1.12 Research Outcomes

The study will inform existing policies and guidelines on the management of XDR-TB patients and also contribute to existing literature. My intention is to contribute to public health literature by raising awareness of ethical issues and providing solutions to readers.

1.12.1 Recommendations

This thesis provides the reader with the following recommendations:

- Regulations and policies need to approved and implemented at a much quicker rate than they are currently implemented. The policies also need to be focused on XDR-TB management as there is currently more focus on MDR-TB in the policy documents. These regulations include, Regulations relating to communicable diseases and notifiable medical conditions and the Regulations relating to the surveillance and control of notifiable medical conditions. The policy documents that I am referring to are: Management of drug-resistant tuberculosis policy guidelines and Multi-drug resistant tuberculosis, a policy framework on decentralised and deinstitutionalised management for South Africa.
- The duration of isolation of the XDR-TB patients ought to be reduced from 18–24 months to 6–9 months, as this allows patients to more feasibly adhere to treatments.
- Approving and implementing strategies (National TB Strategies) needs to be enforced in an efficient manner by the government and public health practitioners

- The ethical aspects of isolation need to be considered when drafting and implementing laws related to isolation. The benefits need to be weighed against the harm as patients' well-being can be harmed during isolation, for example.

1.13 Limitations

The study was based on South African laws, as well as social context; they may not be generalizable, and may not be applicable in similar settings.

CHAPTER 2: The Legal Framework

2.1 Introduction

Many health practitioners in SA are aware that SA has one of the highest rates of XDR-TB worldwide. Additionally, patients generally abscond from treatment, which leads to public health risks (Selgelid, Kelly and Sleigh, 2008). The following chapter will analyse the legal requirements under which isolation may take place. The right to health in SA is enshrined in the Constitution with the Bill of Rights elaborating further on them. The National Health Act, 2003 (Act 61 of 2003) addressed issues of treatment without consent but was lacking in the isolation of infected individuals. In the analysis, the following sources of law will be looked at:

- The Constitution of the Republic of South Africa
- The National Health Act, 2003 (Act 61 of 2003)
- Legislation in South Africa
- International legal frameworks
    - The Siracusa Principles
    - The International Covenant on Economic, Social and Cultural Rights (ICESCR)
    - The United Nations Universal Declaration of Human Rights (1948)

Two prominent cases will be analysed and critiqued according to the how law was applied in the court rulings. The South African case examined was the Minister of Health, Western Cape v Goliath 2009 2 SA 248 (C); internationally, Speaker vs. HHS and CDC 680 F.Supp.2d 1359, 1369–70 (N.D.Ga.2009) was examined as well.

2.2 The Constitution of Republic of South Africa

The South African Constitution in Section 7(1) acknowledges the Bill of Rights as "a cornerstone of democracy" (*Constitution of the Republic of South Africa*, 1996). This section begins with a definition of South Africa's constitution:

> A Constitution is a body of fundamental principles according to which a State is to be governed. It sets out how all the elements of government are organised and contains rules about what power is wielded, who wields it and over whom it is wielded in the governing of a country. It can be seen as a kind of contract between those in power and those who are subjected to this power. It defines the rights and duties of citizens, and the mechanisms that keep those in power in check. The Constitution of the Republic of South Africa is the supreme law of our country. It provides the legal foundation for the existence of the Republic, sets out the rights and duties of its citizens, and defines the structure of the Government (*Constitution of the Republic of South Africa*, 1996).

It has been called the "birth certificate" of a free and democratic South Africa (*Constitution of the Republic of South Africa*, 1996). The Constitution was passed by Parliament in 1996 (*Constitution of the Republic of South Africa*, 1996). Some of the values of the Constitution include human dignity, non-racialism and non-sexism. These values ensure that there is democracy and these are in line with many other democracies worldwide (*Constitution of the Republic of South Africa*, 1996).

Chapter 2 of the Constitution is the Bill of Rights (BOR). "The Bill of Rights is the cornerstone of democracy in South Africa. It enshrines the rights of people in our country and affirms the democratic values of human dignity, equality and freedom. The state must respect, promote and

fulfil the rights in the Bill. These rights can be limited in certain circumstances which are referred to in Section 36 or elsewhere in the Bill" (*Constitution of the Republic of South Africa*, 1996).

It is also important to define what a human right is, especially in this context. "Human rights may be described as entitlements that people have by virtue of being human beings. They take the form of social or material claims from society that are universal across cultures and settings and are codified in national and international laws. They are by nature intended to address fundamental needs, and originated in concerns to protect people from an abusive state by limiting the power of the state over individuals" (London, 2008). In simple terms, a human right is what you are born with. The state has a duty to deliver on this human right hence has an obligation to it (ibid).

Isolation is one of the components that runs contradictory to the Constitution and the BOR. It is an intervention whereby individuals are involuntarily removed from their communities to protect the health of rest of the population. It demonstrates that the state has a duty that to prioritize public health needs. This can be viewed as a trade-off pertaining to human rights versus public good (ibid). There is justification for the limitations that are placed on individuals in terms of their individual rights. Isolation is usually the last resort and it should not happen unless other avenues have already been explored (ibid). There needs to be proof that the individual is infected, risk of causing harm to uninfected individuals and could involuntary isolation actually be required (ibid).

The public health purpose for isolation is of substantial significance and the potential objectives for a policy for isolation of XDR-TB patients are highlighted below.

- "Prevent patient infecting others—others who are at risk;
- Prevent transmission in the population;
- Ensure adherence to treatment;

- Respond to public concerns." (London, 2008)

However, the above objectives are reactive measures and therefore would not be as effective as preventative measures, which is what the state should ideally aim for. Isolation is a more appropriate intervention compared to those that are community based or daily clinic visits. This is because of the nature of the treatment regimen which involves oral and injectable drugs over a lengthy period. Infection can be reduced if the patients are in a controlled setting—such as a hospital—rather than in a public setting. The hospitals are also equipped with the resources and infrastructure to facilitate treatment. There are trained health workers that are easily accessible to the patients in hospital, as opposed to having a nurse at a home attending to an individual patient. Patients will not easily abscond from treatment if they are being monitored in a hospital environment. The public will also be protected from transmission if patients are isolated (Department of Health, 2011; Matteelli, Roggi and Carvalho, 2014). The above scientific arguments for isolation can either be supported or undermined by legal and ethical arguments.

The Constitution is central to the development and implementation of health law and policy. The BOR primarily guides the content of all laws and policies, and is directly enforced by the courts (*The Constitution and Public Health Policy*, no date). The states duties are outlined in Section 7(2) of the Constitution. Section 7(2) states, "The state must respect, protect, promote and fulfil the rights in the Bill of Rights." This means that the government must:

- "Respect the right of access to health care services by not unfairly or unreasonably getting in the way of people accessing existing health care services, whether in the public or private sector
- Protect the right by developing and implementing a comprehensive legal framework to stop people who get in the way of the existing access to others

- Promote the right by creating a legal framework so that individuals are able to realise their rights on their own
- Fulfil the right by creating the necessary conditions for people to access health care, by providing positive assistance, benefits and actual health care services"

Section 9

Why has XDR-TB not been the center of ethical arguments? It is not easy to raise ethical issues relating to infectious diseases due to their very nature. Innocent individuals can be a threat to other innocent individuals, which makes it difficult to promote public health. The issues that arise include equality and discrimination. Invasion of privacy and confidentiality, as well as restriction to freedom is required in for the promotion of public good. The imposition of isolation may be necessary at times in order to protect the public from harm (Selgelid, Kelly and Sleigh, 2008).

Section 9 of the Bill of Rights of the Constitution of the Republic of SA affirms everyone's equality in terms of the law. The equality right is the first right that is listed in the Bill of Rights. In the context of isolation, Section 9(2), which states that "Equality included the full and equal enjoyment of all rights and freedoms. To promote the achievement of equality, legislative and other measures designed to protect or advance persons, or categories of persons, disadvantaged by unfair discrimination may be taken," will be discussed further. All people are equal and should be treated in the same way without any unfair discrimination. Provisions should be put in place in order to prevent any form of discrimination.

Other people can view isolation as discrimination. This may be because it does not fully demonstrate equality. It promotes inequality amongst the population, as the rights of those isolated individuals are limited in a sense. It may be seen as unfair discrimination to isolate individuals. On the other hand, it is not fair to put other people at risk of disease infection. This may lead to an

outbreak and more lives being affected by the disease. When Section 9(2) is closely analyzed it can be deduced that equality is not an absolute human right. The word ‘may’ gives an indication that the right can be restricted depending on the situation.

Section 10

“Everyone has inherent dignity and the right to have their dignity respected and protected,” as stated in Section 10 of the Bill of Rights of the Constitution of the Republic of SA. What does human dignity mean? Dignity is defined as “the state of being worthy of honour or respect.” “When this concept is associated with the adjective human, it is used to denote that all human beings possess equal and inherent worth and therefore ought to be accorded the highest respect and care, regardless of age, sex, socioeconomic status, health condition, ethnic origin, political ideas, or religion” (ten Have and Gordijn, 2014). This inherent trait must be protected and respected at all times. Public health usually overrides human dignity, as public health is more concerned about the health of societies and communities instead of that of individuals (Horn, 2015). Since isolation is viewed as a public health intervention, human dignity may be compromised, since the public’s interest is prioritized over the individual. It should be noted that the main objective of law is the wellbeing of society (Dingake, 2017).

Section 11

“Everyone has the right to life,” as stated in Section 11 of the Bill of Rights of the Constitution of the Republic of SA. Late testing of XDR-TB leads to drug resistance which then makes it virtually untreatable (Raviglione and Smith, 2007). Is it then fair to expose individuals to XDR-TB? Isolation is in place in order to reduce transmission to the population. It can also be viewed as a way to safeguard an individual’s life since proper treatment administration and adherence is

practiced in hospital settings. If an individual is isolated, not only is the public protected, but it also guarantees recovery since patients are monitored (ibid).

Section 12

The patient's freedom and security as stated in Section 12 of the Constitution of the Republic of South Africa may be violated when XDR-TB patients are isolated. Section 12 (1) states that, "Everyone has the right to freedom and security of the person, which includes the right:

- (1)(a) not to be deprived of freedom arbitrarily or without just cause."

In other words, there needs to be a valid reason for depriving a person of their freedom. It cannot be a decision based on opinion or hearsay. Isolation is considered when less restrictive means have been proven unsuccessful; as seen in the literature cited, it is a last resort. The deprivation of freedom needs to be justified in circumstances where public health is of paramount significance (Pieterse and Hassim, 2009).

Section 18

"Everyone has the right to freedom of association," as stated in Section 18 of the Bill of Rights of the Constitution of the Republic of SA. Everyone has the freedom to associate with whomever they want to associate with. The question that comes to mind in this section is how you ensure balance. The balancing of public health interest and civil liberties is vital in public health law. This is due to the sacrifice of individuals by isolating them from social contacts and disclosing their disease status (Verani *et al.*, 2016). Balance can be ensured by allowing patients to go home often or having their families come to visit them at the hospital. The patients are also allowed to go home once the risk to public health is insignificant; this is when the sputum culture tests are negative after three consecutive negative conversions, which are taken on a monthly basis (Van Wyk, 2009).

Section 24

Everyone has the right to, "an environment that is not harmful to their health or well–being," as stipulated in Section 24(a) of the Constitution. It justifies why XDR-TB patients should be isolated as they pose a real danger to the public. The hospital should ideally have measures in place to prevent airborne transmission of XDR-TB. Regulations for Hazardous Biological Agents 1390 stipulate:

> "Ideally place patients in a private room that has…monitored negative air pressure in relation to the surrounding areas, 6–12 air changes per hour, appropriate discharge of air outdoors or monitored high-efficiency filtration of room air before the air is circulated to other areas of the hospital. Where this is not possible, use a room with a simple extraction fan providing at least six air changes per hour, a room with an open window, and adequate ventilation (Verani *et al.*, 2016)."

This shows the provisions in place to ensure that isolation is in an environment conducive to treatment. Although Section 24 (b) addresses an ecological environment, this can also be applied in societal or hospital settings. Everyone, according to the Constitution, has the right to a healthy and safe environment.

Section 36

Even though the XDR-TB patients have all the rights mentioned in the above paragraphs, it is also apparent that there are limitations to these rights. The government needs to provide justifications for the limitation of rights. According to my understanding, limitations are restrictions that are put in place in order to prevent a certain action or actions from occurring. Section 36 (1) (a–e) of the

Bill of Rights of the Constitution of the Republic of SA, states as to when these limitations are imposed. Section 36 (1) (a–e) stipulates that, "The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic society based on human dignity, equality and freedom, taking into account all relevant factors, including:

- (a) The nature of the right;
- (b) The importance of the purpose of the limitation;
- (c) The nature and extent of the limitation;
- (d) The relation between the limitation and its purpose;
- (e) Less restrictive means to achieve the purpose."

The rights stated as per section 36(1) (a–e) may be limited only "in terms of law of general application." There is currently no general description of the abovementioned law of general application. The nature of the right is not to be seen as the same as the importance of the right. "It is a measure of the ability of a right to be limited." Even though no rights are absolute as considered by law, there are rights that are unable to be limited or have specific ways in which they can be limited. The context in which the right is being applied in plays a pivotal role in the limitation thereof. "The emphasis should not be on the importance of the right, but rather on the importance of the values that a particular right advances in the context in which that right is sought to be applied" (Iles, 2007). Isolation, which restricts the rights stated in Sections 9–12, 18, and 24, is only used when it is absolutely necessary to do so. The justification for isolation is for the protection of the public against infection from deadly communicable diseases; it is not about the right itself, but about the end goal. This restriction is also time based; and will be lifted when clinical tests are shown to be negative, with the patient no longer being infectious.

The Constitution, moreover, “does not regard the limitation of a constitutional right as justified unless there is a substantial state interest requiring the limitation.” This demonstrates that there has to be an important reason as to why a right, needs to be limited. The public interest served needs to be reviewed carefully by the court in order to determine the weight that the purpose should carry. The limitation must be of some sort of importance to the state. It is again emphasised that the limitation has to be justified. The nature and extent of the limitation is basically the, “assessment of the manner in which the limiting law limits the right and the extent to which the limitation curtails enjoyment of the right” (Iles, 2007). How is the right limited? The scope of isolation is reviewed as to what degree of it will be carried out.

The court needs to consider whether there is a correlation between the limitation and its purpose, when looking into a limitation. In terms of the limitations, there always needs to be a least restrictive means that has at least been tried in order to achieve the desired end goal (Rautenbach, 2014). This is because the aim is to have minimal harm when limiting these rights. The nature and extent of the right as well as its purpose has to be well understood in order to accomplish these least restrictive means (Rautenbach, 2014). The process steps should explicitly show that the least restrictive means failed and that isolation was indeed the last resort. There needs to be evidence of such and the courts need to request it. The treatment that is administered isolation has several side effects that make it an unattractive regime. If there is another way whereby treatment is less harmful then that should be used instead of isolation.

In terms of Section 36 (1) (a–e) of the Bill of Rights of the Constitution of the Republic of SA, the benefits should outweigh the harm. In the case of the isolation of XDR-TB patients, these benefits would include becoming disease free and promoting public health, as there would be minimal risk of transmission (Carstens, 2009). In the end this is what the government needs to accomplish as

the Constitution is in place to protect the population. The reasons for the use of isolation as an intervention are valid, and given the risk of disease transmission, isolation is justifiable. Its main goal is to protect the lives of those who are at risk of the disease and that in itself is justifiable. The Constitution offers some guidance pertaining to challenging isolation as an intervention or contesting the limitations that are imposed. This is stated in section 38 of the Bill of Rights of the Constitution of the Republic of SA where it states;

"Anyone listed in this section has the right to approach a competent court, alleging that a right in the Bill of Rights has been infringed or threatened, and the court may grant appropriate relief, including a declaration of rights. The persons who may approach a court are:

- Anyone acting in their own interest;
- Anyone acting on behalf of another person who cannot act in their own name;
- Anyone acting as a member of, or in the interest of, a group or class of persons;
- Anyone acting in the public interest; and
- An association acting in the interest of its members."

A person who is isolated due to XDR-TB and feels that their rights have been infringed upon, they have the right to challenge the decision of isolation in a court of law. If the courts conclude that the isolation was not justified then the person can be released.

2.3 The National Health Act

"The National Health Act (Act 61 of 2003) sets out the structure of the national, provincial and district health care system. It is designed to create the framework for delivering health care services, including the duty to 'promote the inclusion of health services in the socio–economic development plan of the Republic.' The National Health Act, 2003 (Act 61 of 2003) was passed

by Parliament to give effect to the right of everyone to have access to health care services. This right is guaranteed by Section 27 of the Constitution of the Republic of South Africa, which placed obligations on the state to progressively realise rights of access to health care services within its available resources" (*The National Health Act*, 2003).

Section 27 of the Constitution states the following:

"Health care, food, water and social security

- Everyone has the right to have access to—
    - Health care services, including reproductive health care;
    - Sufficient food and water; and
    - Social security, including, if they are unable to support themselves and their dependents, appropriate social assistance
- The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights; and
- No one may be refused emergency medical treatment"

All the rights in the Constitution are interrelated, indivisible and mutually supporting. In other words, it is important to achieve the realization of some rights in order to enjoy other rights; all rights are interconnected. From the above description, it can be seen that the NHA is of great significance. It is an extension of the Constitution of the Republic of SA and therefore forms a link between the two statutes.

Chapter 1 of the NHA states the objectives of the Act. Amongst others there are:

- "Protecting, respecting, promoting and fulfilling the rights of:

- The people of South Africa to the progressive realisation of the constitutional right to access to health care services, including reproductive health care;
- The people of South Africa to an environment that is not harmful to their health or well–being;"

The objects above are linked to Section 27 and Section 24 of the Constitution of the Republic of South Africa. Progressive realisation is described as the State's obligation towards the fulfilment and improvement in the enjoyment of socio–economic rights to the maximum extent possible, even if there are resource constraints. The performance of the State in terms of progressive realisation would depend on socio–economic rights enjoyed by people at any given moment as well as the society's capacity of fulfilment (Chenwi, 2013).

The environment must not be harmful meaning that it must be safe for all South Africans. Isolation ensures that the public is in a safe environment as they are protected from exposure to XDR-TB. The health of the population is not at risk when the infectious individuals are isolated.

Consent is addressed by certain portions of the NHA, predominantly in the second chapter. In short, involuntary isolation is legally permissible. This can be in the form of a court order when failure to treat the infected individual will result in a public health risk. The NHA refers to the person receiving health treatment as the 'user'; in the context of isolation, the user would be the XDR-TB patient.

Chapter 2 of the NHA states the rights and duties of users and health care personnel. Section 6 of this chapter, states that "the user should have full knowledge of everything pertaining to his or her health status. Every health care provider must inform a user of:

- The user's health status except in circumstances where there is a substantial evidence that the disclosure of the user's health status would be contrary to the best interests of the user.
- The range of diagnostic procedures and treatment options generally available to the user
- The benefits, risks, costs and consequences generally associated with each option and;
- The user's right to refuse health services and explain the implications, risks and obligations of such refusal."

This section gives the user the right to question the medical treatment before administration. The user is informed of the treatment cost and what treatment they are eligible for. The pros and cons of the treatment are weighed out and the consequences of refusing the treatment are explained.

Furthermore, in Chapter 2 of the NHA, Section 7 states the conditions for consent of the user. "Section 7(1) of the NHA states that a health service may not be provided to a user without the user's informed consent, unless:

- The user is unable to give informed consent and such consent is given by a person;
    - Mandated by the user in writing to grant consent on his or her behalf; or
    - Authorised to give such consent in terms of any law or court order;
- The user is unable to give informed consent and no person is mandated or authorised to give such consent, and the consent is given by the spouse or partner of the user or, in the absence of such spouse or partner, a parent, grandparent, an adult child or a brother or a sister of the user, in the specific order as listed;
- The provision of a health service without informed consent is authorised in terms of any law or a court order;

- Failure to treat the user, or group of people which includes the user will result in a serious risk to public health; or
- Any delay in the provision of the health service to the user might result in his or her death or irreversible damage to his or her health and the user has not expressly, implied or by conduct refused the service."

According to the NHA, there are limitations placed on consent; these limitations give provisions to service without consent in certain cases, as seen above. The courts can issue a court order for the user in question to allow for service provisions without informed consent. If the failure to treat the user will result in a risk to public health then service provision without consent would also be acceptable. This illustrates that isolation is approved by legislative authority.

Section 7(2) of the NHA states that a health care provider must take all reasonable steps to obtain the user's informed consent. The health care provider is required to inform the user of the risks involved in the health service that is to be provided. They need to have some form of understanding of the treatment before making a decision. The health care provider sheds more light onto the service.

Section 7(3) of the NHA states, "that for the purposes of this section 'informed consent' means consent for the provision of a specified health service given by a person with legal capacity to do so and who has been informed as contemplated in Section 6." This section gives a description informed consent in the context of the NHA. The user needs to be aware of what service is being offered and be able to make an informed decision based on the information given by the health care provider.

In the interpretation of the NHA shows that a lot has gone into understanding the requirements for treating XDR-TB patients. South African law looks not only at protecting the public, but at ensuring that the patient receives treatment. The issue of consent is also addressed, with the legal responsibilities and ethical considerations being highlighted. The limitations of informed consent are also highlighted which is important in terms of isolation of XDR-TB patients, so as not to endanger the public. The Constitution and the NHA are aligned with regards to the requirements that need to be enforced on individuals. This is shown by the issue of limitations being addressed in both the Constitution and the NHA. They both have sections that are of relevance to isolation and also highlight the point of protecting the public from the risk of infection. The rights in the Constitution support each other as they allow the individual to have their freedom only to a certain extent whereby it can be justified to have their right to freedom infringed upon. The emphasis is not only placed on what the individual requires but also looks at the entire population.

2.4 Legislation on Communicable Diseases

South Africa has some laws that pertain to communicable diseases. Legislation is defined as "a specific act or statute passed by the legislative or parliamentary branch of government to help implement the broad mandates of the constitution." The constitutional right to health is realised by the Ministry of Health due to legislation. "Legislation builds on broader constitutional principles and aims by creating public health structures; creates entities such as a ministry of health and positions such as a minister of health and establishes requirements, objectives and processes and prohibits practices" (Verani *et al.*, 2016).

"Regulations are issued after legislation by a legislatively authorised entity or official. They provide greater operational detail to guide additional policies, programmes and practice." Isolation

is an example of an intervention that is authorised by South African regulations (Verani *et al.*, 2016).

Regulations on communicable diseases assist in answering questions pertaining to issues that arise in terms of the infected individual;

- "They state the duties of all provincial and national departments
- Set amongst others, the standards for infection control
- They also clarify as to when and where a court order could forcibly isolate a patient" (Bateman, 2014).

Communicable diseases fall under policy documents and guidelines as stated in Appendix B of the NHA. The policies and guidelines cover several aspects of health care and disease management and were developed by the Department of Health.

Regulations in SA, R.2438 on October 30th 1987, relate to communicable diseases and notifiable conditions regarding communicable diseases but are still in draft form and regulations relating to the surveillance and control of notifiable medical conditions are from the 2017 *Government Gazette,* No.41330, Vol 630 (*Regulations relating to communicable diseases and notification of notifiable medical conditions*, 1987), (*Regulations relating to the surveillance and the control of notifiable medical conditions*, 2017). All of these regulations have different sections pertaining to isolation.

In R.2438 sections 2, 8, 14, 17 and 19 mainly focus on the isolation of individuals with communicable diseases. It states that the following:

- "Individuals can be placed in hospitals or a place of isolation if they are suffering from a communicable disease.

- The infected individuals are also obligated to stay in their place of isolation until they are no longer infectious and hence no longer a threat to the public.
- A written order from the court can be issued in order to have the infected individual put into isolation.
- The reporting of an infected individual has to be done orally with written confirmation sent to the relevant authorities within 24 hours."

The public health issue is continuously being emphasised with the law coming into play if the infected individuals do not agree to voluntary isolation. This highlights the significance of a communicable disease with the quick turnaround time in terms of reporting. It puts a sense of urgency and relays the high risk of having such a disease. The abovementioned regulation does not refer to TB specifically but refers to communicable diseases.

The draft regulations, R.2438, were never fully implemented and they remained in draft format for a long period of time. They were however used in a case involving XDR-TB patients in 2008 which will be discussed further in Section 2.6. The sections that are pertinent to XDR-TB and isolation are sections 5 and 6 of Chapter 3, Section 7 of Chapter 4, Section 10 of Chapter 5 and Section 16 of Chapter 7.

As per the *Government Gazette* notice of 2017, no.41330, "The Minister may, after consultation with the National Health Council, declare by notice in the *Government Gazette* any Notifiable Communicable Diseases. This is carried out if in his or her opinion:

- such a disease poses a serious threat to an entire or part of a population of a particular province or the Republic;

- may require immediate, appropriate and specific action by the national department, one or more provincial departments and/or one or more municipalities;
- In certain instances, conditions and diseases that may be regarded as a public health emergency of international concern or a public health risk."

XDR-TB is a serious threat to public health. The *Government Gazette* 2017 notice also emphasizes the reporting of communicable diseases, which should be within 24 hours. It also states that court orders may be issued to individuals who refuse voluntary isolation. Fundamentally, a person who is suspected of having XDR-TB can be ordered by the court to get tested and get treatment in a hospital by means of isolation or any other available intervention. In this regard preventing the infection of innocent individuals and protecting the public.

Section 10(1) of the 2017 notice states "A healthcare provider may apply to the high court for an order, if a person who is a carrier or susceptible contact or ill because of a communicable disease as listed in this document or who is diagnosed with MDR or XDR-TB and does not voluntarily consent: a) to a medical examination, b) to be admitted to a health facility, c) mandatory isolation for infected persons as per the list in the abovementioned document and persons with MDR or XDR-TB who willfully refuse treatment." There are conditions that need to be met in order for mandatory court orders. These include the following:

- "It is a confirmed communicable disease that is hazardous to the public (XDR-TB).
- Other measures, which may prevent the occurrence or spread of the disease, must have been tried.

- An overall evaluation has been made that this is clearly the most justifiable course of action in relation to the risk of the disease being transmitted and to the stress and the compulsory measure is likely to entail.
- It is highly probable that other persons will otherwise be infected.
- The head division of the department in which the person is isolated is authorised to annul the decision as soon as the conditions for mandatory action is no longer present, or the person convert to voluntary interventions."

Criteria are in place in order to have fairness when there is a mandatory measure that is imposed as in the treatment of XDR-TB. This shows that there has been a lot of work put into drafting these processes and the implementation of such. Infected individuals are also given a chance to appeal if they feel that the order of isolation is too harsh.

The 2017 notice of the regulations relating to the surveillance and control of notifiable medical conditions, shares similarities with R.2438. These include the fact that a court order may be issued if an individual with XDR-TB refuses isolation, the reporting time that must be within 24 hours of a positive diagnosis and that XDR-TB is seen as a public health risk. There is one difference which is in Section 20 of the 2017 notice, which specifies that if a patient knows that they are suffering from XDR-TB but choose not to inform the relevant authorities, they are liable to a prison term, not exceeding 10 years; or both imprisonment and a fine determined by a court of law. This difference can be viewed as a flaw as it would be difficult for the patient to prove that they knew about their illness and hence would not be able to inform the relevant health authorities.

These regulations are of great significance in guiding the health sector as to the treatment of XDR-TB patients. If there is nothing in place, then it will result in an outbreak and unnecessary deaths. If they are not clear enough then they can be incorrectly used or even poorly implemented.

2.5 International Legal Framework

The Siracusa Principles and Limitation of Rights

The Siracusa Principles were adopted by the UN Economic and Social Council in 1984, in order to allow for the limitation of individual rights as a means to deal with "a serious threat to the health of the population or individual members of the population" (Amon J, Girard and Keshavjee, 2009; Mburu *et al.*, 2016). They state, "that limitations of individual rights may only occur when such limitations are:

- Provided for and carried out in accordance with the law
- Directed towards a legitimate objective of general interests
- Strictly necessary in a democratic society
- The least restrictive and intrusive in severity and duration to achieve the objective
- Based on scientific evidence and neither drafted nor imposed arbitrarily nor in a discriminatory manner" (Mburu *et al.*, 2016).

In the context of these limitations, the WHO views isolation of individuals that have communicable diseases such as XDR-TB as legitimate under international human rights law, provided that it is the last resort. It is justifiable only if other measures have been taken prior but were deemed unsuccessful. In relation to this study this supports isolation of XDR-TB patients and the limitation of the infected individuals' rights. However, the WHO does explicitly state that isolation can be carried out provided that other avenues have been explored (Mburu *et al.*, 2016). This is also in line with Section 36 of the BOR which states when limitations to patient rights are imposed. The Constitution in Section 9 of Chapter 2, outlines that a health service can be given without the individuals' consent. This is done, subject to

applicable law, where the user is admitted to a health establishment without his or her consent. It can be evidenced that the isolation of XDR-TB patients is justifiable in terms of the law as the limitations imposed are articulated in the Siracusa Principles, the Constitution and the NHA. The individual can be held against their will, provided that specific requirements are met.

2.6 Case Law

Case law is important in the context of isolation as it gives guidance as to what the outcome of an isolation case should be. Case law looks at past decisions that may either support or not support a court of law's final decision. There are two significant cases relating to XDR-TB and isolation of patients that will be discussed. The first case occurred in the United States of America (USA); the second in Cape Town, South Africa (Ruger, 2010; Bateman, 2014).

Andrew Speaker v. Centers for Disease Control and Prevention (CDC)

Andrew Speaker was a lawyer who diagnosed with MDR-TB, XDR-TB, and MDR-TB once more. Speaker was initially diagnosed with MDR-TB and was told by the Fulton County Health Department (FCHD) not to travel internationally. Speaker had decided to travel to different countries against the FCHD's instructions. It was only later on that samples from Speaker that were tested by the CDC and confirmed that he actually had XDR-TB. Speaker was put in an isolated ward after he was located, where he underwent more tests to determine the status of his infection. Speaker underwent the first federal quarantine order since 1963, which highlighted the issue of involuntary isolation. Speaker did not have an issue with being isolated but noted that his confidentiality had been breached. The right to privacy and confidentiality was infringed upon as the public was informed about his illness and isolation. Speaker decided to sue the state for the

way that his case was handled; his case was later dismissed by the courts. The decision by the courts was in line with the Public Health Service Act (Congress, 1944). In Part G the Act states,

> (a) The Surgeon General, with the approval of the Secretary is authorized to make and enforce such regulations as his judgement are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or position into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgement may be necessary. (b) Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General.

Minister of Health of the Western Cape v. Goliath and others, No. 13741/07

The abovementioned case involved four XDR-TB patients who ran away from the Brooklyn Chest Hospital in Cape Town, and then legally contested their compulsory readmission and continued isolation; they lost (Bateman, 2014). The main question in the case was whether compulsory admission and isolation was justifiable from a legal point of view. The court ordered the respondents to go back to the Brooklyn Chest Hospital and abide by the hospital's rules of behaviour. "A *rule nisi*—a court order that does not have any force unless a particular condition is met—was issued by the court to this effect." There was a counter application by the respondents,

whereby they stated that their detention infringed on their right to freedom as per Section 12 of the Constitution. In the judgement, there were a number of factors that were considered, including:

- The seriousness of XDR-TB as a disease, relating it to its clinical manifestations.
- The difficult and length treatment regimen for XDR-TB.
- The fact that it is associated with a higher mortality rate when compared to other strains of TB.

The medical evidence presented clearly showed that XDR-TB is a highly infectious disease and a global health problem. The court concluded that the four XDR-TB patients must be hospitalised and it is preferred that this is done at the MDR-TB referral centres where there would be additional control measures such as isolation. The Brooklyn Chest Hospital met the criteria as observed by the court (Carstens, 2009).

The treatment and hospitalization period, which can continue even after the patient no longer needs to be isolated lasts for a minimum of 18 to 24 months. The guidelines used by the court stipulated that all XDR-TB patients, "should have their treatment initiated in hospital because of the toxicity of the drugs, the monitoring and management of side effects, and protection from indiscriminate prescribing to avoid further and even more resistant strains of tuberculosis." It was also discovered that the majority of the XDR-TB patients did not adhere to taking their medication and this raised another issue of the objectives of the guidelines not being met (Carstens, 2009).

The court used the Constitution, Section 36(1) which states that:

- "The rights in the Bill of Rights may be limited only in terms of law of general application to the extent that the limitation is reasonable and justifiable in an open and democratic

> society based on human dignity, equality and freedom, taking into account all relevant factors."

This was used to justify the limitation on freedom of movement. It also relied on other evidence from abroad. The article by Singh, Upshur and Padayatchi "XDR-TB in SA" (2007) was also used to support the outcome.

> "The successful containment of XDR-TB in South Africa and elsewhere carries human rights and ethical implications. An important question that we must come to terms with is the extent to which judicially sanctioned restrictive measures should be employed to bring about control of what could develop into a lethal global pandemic (Singh, Upshur and Padayatchi, 2007)."The abovementioned article supports a very utilitarian argument and therefore supports that isolation should be in the interest of public health. "Health workers and human rights advocates in South Africa and elsewhere must be reminded that although a country's Bill of Rights may bestow a range of human rights on individuals, these rights can usually be restricted if doing so is reasonable and justifiable (ibid)."

The restrictions can only come into effect if non-coercive measures have failed (ibid). As much as we all have rights, there is also a need to protect the public from any risk of contracting XDR-TB. The isolation of XDR-TB patients was justified by the law as certain conditions of regulations, the Constitution, and the NHA were met. The safety to public health is much more significant than the harms to XDR-TB patients.

In a South African context, the law applied legislation that was already in place. The two documents that played a key role in the conclusion of the case were the Constitution and NHA. As long as there is some form of legal document in place, it will be used in such cases. I support the

decision that was made by the court in this instance. The defendants absconded from their treatment and this would have made them to pose an even greater threat to public health.

The two cases discussed above share similarities in that the court did not rule in favour of the defendants, relevant guidelines and policies were used to make a judgement, individual liberty was not taken into account and hence the public health risk held more significance. It can be noted that isolation is supported by international and South African laws but only under certain circumstances. It is deciding what justifiably these circumstances are, that separates out the legal from the ethical and why a consideration of ethical arguments is necessary.

CHAPTER 3: The Ethical Framework

3.1 Introduction

There are a number of ethical issues that are raised by isolation. There are several ethical issues and dilemmas including that XDR-TB only happens as a result of many failures and not all of these are patient related. System failures due to lack of resources and weak healthcare infrastructure. The fact that the illness is often very difficult to treat with a highly mortality rate and hence often terminal. There could also be drug stockouts that occur due to lack of funding. Drug resistance could be promoted by the incorrect strain diagnosis. A lack of health education could lead to infected individuals living with the disease and hence progression which leads to death. The issue of public health ethics is the most prominent one when it comes to isolation. The ethical theories that will be discussed in this chapter include deontology, virtue ethics, utilitarian, communitarianism, and Ubuntu. Deontology and virtue ethics present arguments against isolation, and hence do not support my argument. It is however important to contrast these two theories with those that support arguments in favour of isolation, such as utilitarianism supported by communitarianism and Ubuntu ethics. The four bioethical principles will also be analysed. These four principles stem from principlism and include: autonomy; beneficence; non-maleficence; and justice. They will be discussed apropos the ethical theories mentioned.

3.2 Ethical Theories

Deontological theory

The view of a Kantian deontologist in terms of the XDR-TB dilemma would stem from the requirement to respect the dignity of individuals (Anthony, 2009). People must never be treated as a means to an end but rather as ends in themselves, as per one of the duties we have in the view of

a Kantian ethicist (Tsotsi, 2009). “To treat people ‘as an end’ means, on the most superficial level, treating them well. We must promote their welfare, respect their rights, avoid harming them and generally endeavour, so far as we can, to further the ends of others” (Rachels, J & Rachels, 2010). The moral importance of the risk of harming others would only be apparent if what is causing that harm was done on purpose and with complete awareness. An individual who has no knowledge of XDR-TB cannot be blamed or even liable for harming others. This is however not applicable to individuals who are fully aware that they have XDR-TB and in turn put the lives of innocent people at stake. Kantians would hold the individual accountable for their actions and let them face the consequences. Is isolation, whereby the treatment can be up to a period of two years, “merely the means to some other end”, and also against the autonomous interests of an individual (Anthony, 2009)? “The basis of a deontological approach is respect for persons, and as a person you are born with basic human rights which entail dignity and respect (ibid)”.

The deontological theory is one of, “duty, holding that some features of actions other than or in addition to consequences make actions right or wrong (Rachels, J & Rachels, 2010).” Kantian deontology is derived from what Kant called the categorical imperative. This principle was given different formulations by Kant but he expressed it in this way at a certain point; “Act so that you treat humanity, whether your own person or in that of another, always as an end and never as a means only (ibid)”. My interpretation of the categorical imperative is that it is something that an individual must do. It is a rule in a sense that must be adhered to in a particular situation. He further stated, “To treat people ‘as an end’ means, on the most superficial level, treating them well. We must promote their welfare, respect their rights, avoid harming them and generally endeavour, so far as we can, to further the ends of others (ibid).” A good example of this would be of research that benefitted many individuals but would be unethical if voluntary informed consent was not

obtained. Isolation can be viewed in the same light as it is beneficial to the population but at the same time the individuals' suffering from XDR-TB can be isolated without their informed consent.

The deontology theory comprises a number strengths and weaknesses. Persons are treated as equals, as an individual cannot exempt themselves or get special treatment in a given situation. This would not be seen as a moral act if an individual gives themselves special privileges. The theory is also based on respect for autonomy as persons must not be treated as a means only. There is also the basic obligation to respect a person's decision. It also does not support any form of harm or pain towards the individual. In terms of the weaknesses, the theory places emphasis on the individual as opposed to society (Beauchamp & Childress, 2013). The choices can be beneficial for an individual but not produce a positive outcome for the society (Mandal, Ponnambath and Parija, 2016). This is one of the reasons why this theory would not fit in with isolation. Isolation is a public health intervention and is not driven by individual requirements. The theory also places more emphasis on the law in terms of duties and obligations that an individual has to abide by. It is also not based on virtue and emotion as these do not have any moral worth. The actions are performed from duty as these actions have moral worth (Beauchamp & Childress, 2013).

As per parts of the Goliath case reviewed in this thesis' previous chapter, the isolated XDR-TB patients failed to see that this was for their own best interests, as they tried to escape, and complained about their living arrangements. According to Kant, we are all morally obligated to act in accordance with a certain set of principles and rules regardless of the outcome. In other words, some acts are always wrong, even if such acts lead to an admirable outcome. Thus, we should always judge actions independently of their outcome because an act can be morally bad but may unintentionally lead to a favourable outcome. Kantians would therefore see isolation as ethically unjustifiable. They would still expect individuals to be responsible enough to get

treatment in order to limit the risk of exposure to others, as this would be the right thing to do. Above everything, Kantian ethics put the autonomy of the individual first (Hamilton, 2015).

Virtue ethics

Virtue ethics refers to the level of significance of an action. It does not inform us of what to do, unlike deontology and utilitarianism (Hamilton, 2015). It is interested in the actors themselves and not the consequences or actions (Ofunne, 2019). Virtue ethics places emphasis on an individual's character instead of following a set of rules in order. In many ways, it can be seen as a structure of moral readiness (Hamilton, 2015). It encourages individuals to behave in a virtuous manner in any circumstance and to have high moral standards (ibid). As a theory, virtue ethics does not support isolation as an intervention for the treatment and control of XDR-TB as it looks more into the individual and not the collective.

Utilitarian theory

Several authors have argued that public health programs and interventions are strongly supported by utilitarian ethics. They include the likes of Rothstein, 2004; Holland, 2007; and Royo-Bordonada & Roman-Maestre, 2015 (Bellefleur and Keeling, 2016). "Public health is in essence paternalistic because it tends to use the power of the State to intervene on behalf of the health of individuals (even where this has not been requested), and utilitarian because it seeks to preserve the health status (something that contributes to the well–being of persons) of the maximum number of individuals possible, ideally the entire population" (Royo-Bordonada and Román-Maestre, 2015). Utilitarian ethics, as referred to by these authors, is suitable for justifying and assessing the morality of public health interventions and programs (Bellefleur and Keeling, 2016). The utilitarian perspective is completely different from that of a deontologist. The action should be for

the greater good and promote happiness. This perspective has led to a number of public health policies being ethically justifiable. This rationale can be carried over to XDR-TB management. It can be argued that isolation is required in order to prevent harming others and that a small number of individuals will suffer in order for the larger population to be safe and not at risk of infection.

Jeremy Bentham and John Stuart Mill were two famous utilitarians that focused on social and legal reform (Driver, 2009). "Bentham proclaimed the principle of utility as the standard of right of action on the part of governments and individuals. Actions are approved when they are such as to promote happiness, or pleasure, and disapproved of when they have a tendency to cause unhappiness, or pain (Bentham, 1970)." The government and individuals have their part to play in terms of utility where happiness is the end goal and actions that cause pain or unhappiness are unwarranted.

John Stuart Mill was a follower of Bentham who admired his work (Driver, 2009). Mill believed that, 'legitimate state-sponsored interventions that interfere with the lives of individuals,' should actually be permissible as they would prevent harm to others (Anthony, 2009). The consequences are what drives the utilitarian argument in terms of what intervention is acceptable or not acceptable. The rights of the individual are not taken into consideration nor the nature of the intervention (Anthony, 2009). Mill and Bentham saw it befitting to use utilitarianism to support interventions that are not focused on the individual only but also on other people.

It is not feasible to always get your way when living a social environment. There are other individuals to consider when making certain decisions. The individual interests have to be weighed up against those of the population at large. "Society prohibits autonomous actions that may harm others and also limits the choices offered to individuals in order to share resources fairly among everyone" (Anthony, 2009).

In my opinion, the utilitarian theory should be adopted in public health for a number of reasons. There are four utilitarian characteristics that are aligned to public health; the maximization of the presence of a good, whereby special attention is paid to the consequences, the focus is at the population level while the justification for government-led public health actions come from an impartial perspective (Bellefleur and Keeling, 2016). The good that is maximised in this context is the populations' health. Public health analyses risks versus benefits pertaining to the health of the population. Factors to take into consideration are the effectiveness and efficiency of the programs, interventions and actions implemented in terms of public health and for the utilitarian. The consequences of the action are taken into consideration both in public health and utilitarianism (ibid). The consequences of the intervention, which in this case is isolation would be taken into consideration when making the decision of promoting public health. This also relates the fact that utilitarianism is also referred to as a consequentialist theory. Public health and utilitarianism aim to be effective at the same level which is at a population level (ibid). They do not focus on the individual and this is possibly because some individuals react adversely to interventions while the collective react in a positive manner hence promoting the health of the population. Justification for state-led public health interventions are based on an impartial point of view just like utilitarianism. The decisions are based on how it affects the population and not the person. These characteristics assist in seeing as to why a utilitarian approach is preferred in the scope of public health (ibid).

There are however some weaknesses to the utilitarian theory and these have been noted in literature. Utilitarianism is viewed as being too demanding. Personal relationships are not taken into consideration and individuals have to prioritise strangers (Bellefleur and Keeling, 2016; Levin *et al.,* 2019). This can be seen in public health where the infected individual has to be isolated in

order to protect the public, which comprises of people that they do not know. The end cannot justify all means. It is not all means that can be justified as some can be lies or stigmatization. The use of these certain or undesirable means cannot be justified by the need to maximize utility. These means infringe upon other crucial ethical principles (Bellefleur and Keeling, 2016). Utilitarianism fails to recognize virtue evaluation. Mill argued that virtue is part of the good life and that a person without virtue will not be able to promote good (Driver, 2009). The weaknesses are apparent but in my opinion do not outweigh the advantages of using utility as a public health tool.

Communitarianism

Communitarianism is the process whereby fellow citizens engage with regards to an issue that involves common good. It is a systemic method of approaching ethical issues as opposed to utilising a set of defined principles to be applied to ethical issues (Cheyette, 2011). The restriction of autonomy in order to benefit the community at large would be fit from the perspective of a communitarian. The interests of the individual are not the priority and in this regard isolation would be acceptable. Isolation as practised in SA would be on par with a communitarian perspective without it being the perspective of the community.

Ubuntu

> *Ubuntu* is a term derived from the Bantu Nguni languages of Zulu, Xhosa, Swati and Ndebele. Ubuntu forms the core of most traditional African cultures. It embraces a spirit of caring and community harmony and hospitality, respect and responsiveness. It is further described as the capacity for compassion, reciprocity and dignity. The hallmarks of Ubuntu are harmony and continuity. It is about understanding what it means to be connected to one

> another. Ubuntu expresses an African view of the world anchored in its own person, culture and society which is difficult to define in a Western context (Ncube, 2010).

Ubuntu on the other hand would not apply as it requires solidarity, respect and sympathy for others. The infected individuals who escaped from isolation would definitely not have had any feelings of unity with any communal compulsion with regards to their treatment, as they went on to free themselves. This is where the law came into play, which is the manner in which the public health intervention of isolation is achieved (Anthony, 2009). Ubuntu is rooted in the honest interest in other individuals in terms of their wellbeing (Behrens, 2013). Furthermore, I believe that Ubuntu would only apply from a public health perspective with regards to isolation as the community or public is being protected from harm or infection.

It has been argued that communitarianism allows for a better foundation in the development of infectious diseases control policies. This is due to the fact that these diseases raise questions entailing ethical obligations that we owe to perfect strangers. This is somewhat a socially embedded framework and thus could be better when it comes to social issues involving communicable diseases (Cheyette, 2011). In my opinion, deontology supports Western ways which are commonly expressed as individualistic ethic (West, 2014). Ubuntu, however, contrasts with Western society as it does not follow an individualistic approach. Public health is a Western way that is supported by communitarianism where the interest of the individual is not prioritised, the same as utilitarianism.

Public Health Ethics

"When bioethics first emerged it confronted a tradition of medical practice and research within which paternalism still commanded both loyalty and impassioned defence (Bayer and Fairchild,

2004).” “Bioethics helps health professionals and public policymakers recognize moral dilemmas in health care and biomedical research and provides principles and moral rules with which to navigate through these dilemmas (Kass, 2001).” The most recent perspectives of public health ethics started to develop in the early 2000s and the field is now well developed. Early but particularly influential pieces include the works of Nancy Kass, Childress et,al, Bayer and Fairchild, Powers and Faden and lastly Tannahill. I will be discussing some aspects of the abovementioned authors works in the next paragraph.

In ‘An Ethics Framework for Public Health’, Nancy Kass writes, ‘codes of medical and research ethics generally give high priority to individual autonomy, a priority that cannot be assumed to be appropriate for public health practice.’ She noted that a framework of ethics analysis developed for public health was required. Kass then developed such a framework which I will be describing below (ibid). The ethics framework comprises of 6 steps. These steps include the following:

“1. What are the public health goals of the proposed program?

2. How effective is the program in achieving its stated goals?

3. What are the known or potential burdens of the program?

4. Can burdens be minimized? Are there alternative approaches?

5. Is the program implemented fairly?

6. How can the benefits and burdens of a program be fairly balanced?”

The goals need to orientate towards improvement of health by reducing death and disease burden (ibid). It would not make sense to have a program that did not have a purpose in improving people’s lives. In my opinion this would be unjustified and unethical. Data is required in order to show the

effectiveness of a program. Although proposed programs or interventions are based on specific assumptions, existing data is imperative when making decisions. However in public health, data-based programs are often neglected. Thus what needs to be significance is the burden created by that particular program (ibid). “As a rule of thumb, the greater the burdens posed by a program, the stronger the evidence must be to demonstrate that the program will achieve its goals (ibid).” These decisions lie with the government or public health practitioners to prove that the proposed end goal will be achieved. The burdens and harms need to be identified in a particular program. The majority of the harms and burdens fall under the following three categories: “risks to privacy and confidentiality, risks to liberty and self-determination and risks to justice (ibid).” In terms of communicable diseases, it is the reporting that raises concerns and the infringement of privacy and confidentiality. This can lead to stigmatization when confidentiality is breached which then translates to harm. In public health however, certain harms and burdens cannot be avoided as this would lead to the public population being vulnerable. I believe that there needs to be justification of a particular harm or burden caused and that the benefit should outweigh them (ibid). The intervention that is least harmful or with fewer risks should always be chosen. This should be done keeping in mind that the benefits should not be significantly reduced (ibid). I strongly agree with this as the purpose of an intervention is to cause the least amount of pain. Fair distribution of benefits and burdens needs to be established. This is in line with distributive justice. It is more imperative to have fairness in programs whereby restrictions are imposed. In doing so harms and burdens are reduced (ibid). Benefits and burdens can be fairly balanced in a program when data is used as a means to justify the burden and the least harmful program is utilized. There should also be a limit to coercive programs in that they need not be implemented if there is a less restrictive program that can achieve similar goals (ibid). According to Kass, ‘An ethics analysis must always

be conducted, both because bringing the truth, fairness, and respect to our work is right in itself and also because from a more utilitarian perspective, public health will be more effective if we do (ibid).' This is in support of using utility as an approach to public health.

Bayer and Fairchild also concur with using the least restrictive means in order to enhance public health. They also mention that compulsion and coercion are central to public health but efforts to elicit voluntary measures is more preferable. The aim is to promote public health without burdening liberty and privacy (Bayer and Fairchild, 2004). In 'Public Health Ethics: From foundations and frameworks to justice and global public health,' Kass reiterates the fact that voluntary approaches are ethically preferable to compulsory ones. She also mentions however that purely voluntary interventions do not always work (Kass, 2004).

Childress et al outlined 9 general moral considerations that are relevant to public health. These included: 'producing benefits; avoiding, preventing and removing harms; producing the maximal balance of benefits over harms and other costs (often called utility); distributing benefits and burdens fairly (distributive justice) and ensuring public participation, including the participation of affected parties (procedural justice); respecting autonomous choices and actions, including liberty of action; protecting privacy and confidentiality; keeping promises and commitments; disclosing information as well as speaking honestly and truthfully (often grouped under transparency); and building and maintain trust (Childress *et al.*, 2002)'. These moral considerations resonate with the public health ethics framework proposed by Kass and the work done by Bayer and Fairchild. Childress et al also noted that there is conflict between public health and the moral considerations. This conflict has also been apparent in work done by other scholars that I have already mentioned. The main theme that does come across from my analysis is that voluntary measure are preferred as they would avoid if not reduce conflict.

Andrew Tannahill described 10 possible ethical principles for health promotion, public health and health improvement. They included the following: ‘Do good, do not harm, equity, respect, empowerment, sustainability, social responsibility, participation, openness and accountability.’ He also proposed a decision making triangle which could be used for policies, programs, services or activities agreed against the set of ethical principles (Tannahill, 2008). It is evident that over the years there has been considerable work done in improving public health ethics.

Faden and Powers however, did not agree with utilitarian arguments. They argued that considerations of justice and not utilitarian aims are most foundational for public health. They state that, ‘ Utilitarianism is in our view the main competitor among theoretical alternatives discussed among public health theorists and practitioners (Faden and Powers, 2008).’ Their theory of social justice, ‘defends the view that considerations of justice provide the moral foundation for public health. For us, social justice is concerned with human well-being, which is best understood as involving plural, irreducible dimensions, each of which represents something of independent moral significance. Health is one of these distinct dimensions of well-being, as is personal security, the development and exercise of cognitive capacities for reasoning, living under conditions of social respect, developing and sustaining deep personal attachments and being able to lead a self-determining lives (ibid).’ Their theory is more focused on distributive outcomes which are only considered indirectly by utilitarians (ibid). From my point of view, this theory places some form of accountability on the individual to actually improve their own well-being and this in a way that will translate into social justice. In the case of an individual suffering from XDR-TB, a utilitarian approach would be seen as a serial and systemic injustice because of the limitations imposed. In this sense, the infected individual would disagree with utilitarian arguments.

3.3 Respect for Patient Autonomy and Informed Consent

According to Beauchamp and Childress, "respect for autonomy is a norm for respecting and supporting autonomous decisions" (2013). It is understood in layman's terms as a self-governance process by which man can express himself. It is in his own hands to choose how he behaves, choose who he wants to be and does what he wants to do (Anthony, 2009). Autonomy has two fundamental conditions: liberty and agency. Liberty is the freedom to choose what you as an individual want to do regardless of other controlling influences. Agency is the capacity to act as an individual (ibid). "An autonomous agent has the right to make their own decisions according to what they believe in and also to act in a manner that supports those views and beliefs. Respect for autonomy is a standard whereby the individual's choice is respected provided they have the capacity to make such decisions" (Dhai, 2017). "Autonomy will therefore determine the norms and standards that should be in place where an individual uses self-determination to make decisions."

The concept of autonomy in the medical world is enshrined by the process of informed consent, which gives way for patients to have the freedom to choose between different therapeutic options. The patients' choices can however not be in line with the medical practitioners' views and this is where conflict arises in terms of what is of benefit to the patient. Nevertheless, the medical practitioner cannot go against the patient's wishes (Anthony, 2009).

There are illnesses whereby interventions are exercised against the individuals without their consent as is the case with XDR-TB and the isolation of the infected patients. This intervention leads to the infringement of the individuals' autonomy. Upon looking at autonomy from this point of view it can be said that it is a form of freedom that has set conditions and limitations. "Respect for autonomy as a *prima facie* principle of medical ethics is an injunction to respect the dignity of

other human beings and serves to promote the freedom of others to choose what may happen to them." Personal autonomy can be restricted by means of infringement, denial and violation (Anthony, 2009).

The intervention used to control XDR-TB is a public health area in which the interests of the community surpass individual interests. XDR-TB management through isolation has led to a number of ethical issues, with the patients' autonomy being one of them. Patients have in the past tried to escape from detention and have been brought back by use of court orders (Bateman, 2014).

Isolation is an extreme measure and begs the question as to how far are we willing to go in terms of having the community's interest more significant at the cost of the autonomous individual (Anthony, 2009).

Another group of public health experts who are against isolation believe that hospitals can also spread XDR-TB. They say that the hospitals are sometimes poorly ventilated, overcrowded, and have in part been the reason for the rise in XDR-TB infections (Anthony, 2009). There is also the issue of lack of facilities and bed space, leading to the discharge of patients into the community (Olayanju *et al.*, 2018). If there is regular monitoring and contagion-control measures for family members, then why not have the patients treated in their own homes? People would not want to get tested for XDR-TB if they know what will happen to them if they have positive results as they would be discouraged by the fact that they would be detained against their will. "It is much better to know where the patients are and treat them where they are happy," as Dr. Tony Moll—the chief medical officer at the Church of Scotland Hospital in Tugela Ferry—observed (Anthony, 2009).

Autonomy, however, is not absolute and can be overridden by justice, beneficence, and non-maleficence. An autonomous individual can act freely and choose what they desire regardless of

the rules in place. Autonomy may also be diminished as well as constrained. In the coercive institutionalisation of XDR-TB patients, their autonomy is constrained as they are forcibly isolated (Beauchamp & Childress, 2013). There are conditions whereby autonomy does not take precedence, as long it is justifiable and the principle features of autonomy are not obscured or neglected (ibid).

The definition of informed consent states that, "Informed consent refers to conformity to the social rules of consent that require professionals to obtain legally or institutionally valid consent from patients or subjects before proceeding with diagnostic, therapeutic or research procedures. In this context it refers only to an institutionally or legally effective authorisation, as determined by prevailing social rules" (ibid). The above definition describes societal needs where the law takes preference in the requirement or non-requirement of consent. It also includes the institutional and professional ethical requirement of physicians to provide informed consent to patients.

Patients can still go to court to fight against isolation when they feel that it is not justifiable. Therefore, patients can refuse treatment hence not giving informed consent but this can be overruled by the mere fact that society needs to be protected from infectious diseases in line with public health, XDR-TB.

The question still remains though, "is it ever justifiable to restrict the autonomy and freedom of the individual in order to serve the interests of the community by protecting it from the risk of communicable disease?" The policy of isolating XDR-TB patients was defended by Beresford in an article written in the Mail and Guardian in 2006. He said, "The only way to prevent the spread of XDR-TB is to isolate carriers" (Anthony, 2009).

3.4 Beneficence and Non-maleficence

Beneficence is defined as, "the positive promotion of the welfare of others" (Anthony, 2009). Non-maleficence is seen as, "refraining from harming others whereas deeds that prevent and remove harm may be seen as good acts performed in favour of other people and are commonly grouped with other positive acts as examples of beneficence" (ibid). In terms of philosophy, beneficence is viewed as the foundation of the theory of utilitarianism. This theory, "seeks the greatest balance of welfare or happiness among people as the single principle from which right or wrong may be adduced" (ibid). In simple terms, an action is morally right as long as it benefits the majority. I will expand more on the theory of utilitarianism in the next chapter.

The principle of beneficence in certain instances may surpass the individuals preferred choices. In these instances, beneficence and paternalism are demonstrated. Paternalism is when an individual's known preference is intentionally overlooked in order to benefit others, or to avoid harm to the individual themselves. This in turn violates the individual's autonomy (Anthony, 2009). This would arguably be the case in isolation of XDR-TB patients as they don't have the power to decide if they want to be isolated or not. Paternalism is not only evident in terms of public health measures, but also in the day to day management of individual patients.

When a person is harmed it suggests that their wellbeing has been violated. This may be in terms of, "physical harm, pain, psychological duress, loss of liberty, loss of privacy, loss of reputation, loss of property and loss of life (Anthony, 2009)." There are three major forms of harm in bioethics: pain, death, and disability (ibid). In the treatment of XDR-TB, there is apparent harm as the antibiotics that are administered have some level of toxicity. Studies have shown that approximately two thirds of infected patients have had to stop one antibiotic on a temporary basis

or even permanently due to adverse drug reactions (Ndjeka *et al.*, 2014). An adverse drug reaction is "one type of adverse event, defined as any outward medical occurrence that may present during treatment with a pharmaceutical product, but does not necessarily have a causal relationship with this treatment" (ibid). The severity of adverse drug reactions varies from patient to patient with very severe reactions leading to disabilities such as hearing loss (ibid).

However, a study published this year showed good results with a bedaquiline- and linezolid-based regimen used in XDR-TB patients. All of the patients in the study were admitted to Brooklyn Chest Hospital, which is specifically designed to treat XDR-TB patients (Olayanju *et al.*, 2018). The number of patient deaths was also reduced significantly (ibid).

3.5 Justice

There are different views on what justice means in different settings. It broadly refers to the fair, equitable and proper treatment of an individual with regards to what is owed or due to them (Dhai, 2017). It is about the individual being treated fairly. There are different types of justice and these include distributive and social justice (ibid).

In the context of XDR-TB and isolation I will look more closely at social justice. Social justice was inspired by the work done by John Rawls pertaining to justice as well as what was done by Amartya Sen on inequality. Rawl's position was that the interpretation of justice is linked to public reasoning. He wrote,

> "We do not look at the social order from our situation but take up a point of view that everyone can adopt on an equal footing. In this sense we look at society and our place in it objectively: we share a common standpoint along with others and do not make our judgements from a personal slant (Rawls, 1993, 2009)."

It relates to fair distribution of societal pros and cons as well as the equity in thereof. In order for public health requirements to be met, social justice has to be considered as it has a lot of significance in the ethical framework (Zwerling *et al.*, 2017).

The issue of social justice is raised as it is mostly in impoverished communities that XDR-TB is more prevalent. The infected individuals are already disadvantaged and this is even worsened when their liberty is infringed upon (Anthony, 2009). The patients are faced with not having employment during detainment which shows an injustice in the system. The argument still remains as to the rights of an individual versus those of society. In this context, justice is clearly not applied when the patients are isolated. In the above paragraphs I have discussed the four principles of bioethics. These principles can be weighed or balanced according to Beauchamp and Childress's method. These authors did in fact adapt their principles to public health. The general moral considerations that have been mentioned earlier on comprise of two major dimensions. "One is their meaning and range or scope; the other is their weight or strength. The first determines the extent of conflict among them – if their range or scope is interpreted in certain ways, conflicts may be increased or reduced. The second dimension determines when different considerations yield to others in cases of conflict (Childress *et al.*, 2002)." The way that I interpret this in terms of the four principles is that none of them are absolute and no principle is of more significance than the other. It all depends on the context on whether autonomy trumps justice for example. In public health and hence isolation, respect for autonomy is not absolute, nor are the other three principles. "Each principle may conflict with another and each may have to yield in some circumstances (ibid)." Conflicts do arise in public health and these need to be balanced accordingly. Weights cannot be determined prior to or in advance. In the context of isolation, respect for autonomy does not carry that much weight as informed consent can be overridden, for example.

The ethical theory of utilitarianism supports isolation of XDR-TB patients. It is not concerned with patients' respect or autonomy. This is a consequentialist theory that is based on the best consequences for all. Deontology fails in this regard because it is concerned about the respect and autonomy of an individual, which is not taken into consideration when isolation is imposed. Communitarianism is more of a social issue as decisions are made having in mind what the community requires. The principlism approach which is based on the four principles of justice, beneficence, non-maleficence, and autonomy is not applicable with regards to isolation. There is no regard for autonomy and informed consent. The treatment regime that the patients undergo results in harm as the drugs have a certain level of toxicity. In terms of justice, I find it hard to see where there is any form of such as the patients are kept away from society against their will. Is there justice for the society if patients are isolated? I would argue that there is, as society is protected from infection. Their needs are prioritised against those of the individual. Isolation is necessary in the condition of XDR-TB. There is justification for the act of isolation.

4. CHAPTER 4

4.1 Concluding Remarks

The number of XDR-TB cases have increased by ten times in the past ten years (Shah *et al.*, 2017). The Constitution presents a broad range of human rights that individuals have but these rights are also limited provided there is justification for such. Furthermore, the law has the right to issue orders for involuntary isolation and therefore treatment against the wishes of an individual, provided that it is of benefit to the public. This is a last resort though, where other non-coercive measure has been exercised (Maboko, 2011).

Isolation is a violation of human rights, with the infringement of the individuals' liberty that can only be justified when harm to others is minimised. The risk of harm to others has to outweigh individual consent. In terms of XDR-TB, the reason for isolation was driven by the government by putting laws in place that favour isolation. The extreme measure had to come into place as this is a public health issue. The policy is a harsh one indeed but it allows for the prevention of further transmission which in turn protects the public.

The main reason for isolation is to ensure that patients are monitored so that they can complete their course of medication. Isolation is due to patient failure to adhere to their medication. XDR-TB is not easy to manage as compared to MDR-TB, with it being a bit more difficult to treat.

The South African government has an obligation to its people whether as individuals or as a collective. They have a unique function in public health with their role encompassing taking care of the population and not individuals. What is very important though is that they take care of vulnerable groups, which relates to XDR-TB and isolation. In a sense the policies in place are there to take care of the population, as they aim to protect the public from infectious diseases. The

government should strive for interventions that are based on the law as well as ethics. Public health seems to rely very heavily on the law, as seen in Chapter 2 of this report. There are a number of policies, regulations and laws in place for the isolation of not only XDR-TB patients but also those with other communicable diseases. The respect for individual autonomy should also be taken into consideration, provided that the autonomy does not result in others being harmed.

SA has adopted a model similar that of Lesotho. The model focuses on decentralised and deinstitutionalised management of XDR-TB. Lesotho uses community-based treatment of XDR-TB, which does not involve any form of isolation and it has been very successful so far, and is much cheaper to implement (Amon J, Girard and Keshavjee, 2009; National Department of Health, 2019). In the Lesotho model, treatment is provided primarily at the community level by trained health workers. The health workers visit the patients' homes twice a day and provide medication, support, counselling of family members and accompanying of very sick patients to hospitals. Only patients requiring immediate, acute clinical care are hospitalized (Amon J, Girard and Keshavjee, 2009). In the South African model, treatment is provided in decentralised units or in the community using mobile teams. It is the general condition of the patient that is used to decide whether or not they should be admitted. The patients are also treated closer to their homes with the treatment success rate being 40% to 55% within the same period (National Department of Health, 2019). Having mentioned that though, patients should also adhere to medication so that they don't have to be isolated from their families. They should put their health first and think about the rest of the population. There is no easy way of managing any disease and it's even more difficult to manage one as infectious as XDR-TB.

Isolation can be justified by using consequentialist reasoning. This is because the disease does not spread if the infected individuals are isolated hence benefits the masses. A Kantian deontologist

would not see it the same way a utilitarian does because there is harm caused to the patients. The Kantian would only justify isolation if it is part of the norm in society, whereby the norm is applied to everyone equally. It is not easy to justify isolation in a Kantian sense, since this is not a general practice people abide by (and ergo, not a "rule" per se).

4.2 Recommendations

In this report the legal and ethical frameworks were analysed and critiqued with regards to isolation of XDR-TB patients. The legal requirements, stating the laws that are currently in place have been described. Cases involving XDR-TB patients were also referred to, pointing out that the ultimate decision of whether or not to isolate patients lies with the courts. The regulations and policies need to be approved and implemented at a much quicker rate as it takes long periods of time to do so. From a legal point of view there are regulations and policies in place for the management of XDR-TB. They also mandate that XDR-TB patients should be isolated if required. The government does play a huge role in disease control with there being routes like the *Government Gazette* to report any deviations in communicable diseases. What is lacking is the approval and implementation of the strategies. Provided that this is in place and done at an efficient timeframe, there would be greater success in not only treating XDR-TB but also in the eradication thus preventing new resistant strains from arising. The duration of isolation should be reduced to 6-9 months in order for patients to not spend a significant amount of time (18-24 months) away from their families. It might be easier to get patients to adhere to treatments if they have hope of going home sooner.

The legal aspects of XDR-TB isolation are very extensive and there is a lot of government support. When it comes to the ethical aspects, there is unfortunately a lot lacking. The utilitarian theory supports isolation but the four principles of autonomy, beneficence, non-maleficence, and justice

are barely apparent. These principles are not applied extensively or on the same level to how the law is applied.

There is a need to respect individual autonomy but this is overridden when public health is threatened. There are inequalities that arise as isolation looks at the best interest of the population. It can also be argued that patients also benefit as they receive treatment, but at what cost do they receive this treatment? They are away from their families and friends and also suffer stigmatisation and discrimination. There needs to be more weight put on the issues that arise from isolation.

Is isolation of XDR-TB patients justifiable? Yes, I believe it is.

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APPENDICES

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG | HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL

Human Research Ethics Committee (Medical)

Research Office Secretariat:
Faculty of Health Sciences, Phillip Tobias Building, 3rd Floor, Office 301/2/4, 29 Princess of Wales Terrace, Parktown, 2193
Tel +27 (0)11-717-1252 /1234/2656/2700
Private Bag 3, Wits 2050
Office email: HREC-Medical.ResearchOffice@wits.ac.za
Website: www.wits.ac.za/research/about-our-research/ethics-and-research-integrity/

Ref: W-CBP-180904-1 04/09/2018

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical)

Investigator: Miss Charmaine Khumalo (student no. 1714615 Staff no. A0060839)

Supervisor: Dr Norma Tsotsi

Department: Clinical Medicine – Steve Biko Centre for Bioethics

Project title: Is isolation of extensively drug resistant tuberculosis (XDR TB) patients in South Africa ethically and legally justifiable?

Reason: The study is purely normative in nature. No human participants will be involved in the study.

Professor CB Penny
Chairperson: Human Research Ethics Committee (Medical)

Copy – HREC (Medical) Secretariat: Rhulani Mkansi and Zanele Ndlovu.

Appendix 1: Research Ethics Committee Waiver

Appendix 2: Plagiarism Declaration Form

I, _Charmaine Slindile Khumalo_____

(Student number: __1714615_____)

am a student registered for__MSc (Med) Bioethics and Health Law_____ in the year ___2020_____.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above course is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

Signature: __Charmaine Slindile Khumalo_____

Date: __23 February 2021_____