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An ethical reflection on the DOTS programme in South Africa: adherence, vulnerable populations, benefits, and burdens

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Chapter 1

The Global burden of Tuberculosis (TB)

1.1. Introduction

In this chapter, I will identify the burden of Tuberculosis (TB) globally, and highlight the problem of TB in developing countries such as those in sub-Saharan Africa focussing on South Africa. Because TB is a burden to all countries, it is very important to examine factors that contribute to the impact of TB on the public's health and to provide the necessary interventions in controlling TB. These include factors e.g. the relationship between HIV/AIDS and TB, poverty, displaced and homeless populations, and the economic burden of TB.

1.2. The global problem of TB

TB is one of the leading and most serious public health problems globally (Yudav *et al.* 2006:187). It is one of the most important infectious disease priorities that were identified by the Group of Eight (G8) countries in their July 2001 summit agreement (Gibson *et al.* 2005:932). It is estimated that one third of the population globally is

infected with *Mycobacterium tuberculosis*. (Yudav *et al.* 2006:187; Khan *et al.* 2006:211).

The World Health Organization (WHO) in its 13th annual TB report stated there were an estimated 9.27 million new cases of TB globally in 2007(WHO 2009). Even though this figure represents an increase from 9.24 million reported in 2006, the global population is on the increase. So the number of cases per capita is a more useful measure of the problem (Donald & Helden 2009:2393). Mainly developing countries account for 80% of the worldwide burden of TB. In 2007, the countries that were reported to have a very high prevalence rate of TB were India (2 million cases), China (1.3 million cases), Indonesia (530 000), Nigeria (460 000), and South Africa (460 000). Of the estimated 1.37 million TB-HIV related cases, 79% were in Africa and 11% in Asia (Donald & Helden 2009:2393).

What is of major concern is that globally there were approximately 500 000 cases of multidrug-resistant (MDR) TB in 2007 (including 289 000 new cases) reported (WHO 2009). Of these, 131 000 were reported from India, 112 000 from China, 43 000 from Russia, 16 000 from South Africa, and 15 000 from Bangladesh (Donald & Helden 2009:2393). Moreover, 55 countries in

2008 reported cases of extensively drug resistant (XDR) TB. Consequently, these figures are grounds for considerable concern and highlight a possible threat to many public health care systems' ability to diagnose, treat and manage TB; both in individual patients and in the context of a treatment programme such as Directly Observed Treatment Short-course (DOTS) (ibid 2009).

TB control worldwide has not received sufficient attention from policy-makers and health services researchers (ibid 2009:2394). TB, an airborne infectious disease, is one of the main causes of mortality and morbidity among adults in the world (Oza 2002:25). More, the irony of the situation is that this infectious disease is curable yet thus far, it remains one of the most prevalent and worsening calamities of our time.

Many public health officials have debated TB reduction strategies in developing and poor countries as a human rights issue that must be addressed immediately. Concerning this issue, as the WHO (2001) identifies, "TB is not (only) a health problem, it is a social, economic and political disease". TB manifests itself in areas where there is neglect, exploitation, illiteracy, and violation of human rights. It can argued that the real cause of TB

transmittance, especially of TB epidemics in specific populations, is not only due to the microbe but a complex set of socioeconomic and political factors outside the realm of human biology (ibid 2001). Ironically, the factors that affect people's vulnerability to being infected with TB also limit their access to treatment and cure.

Concerning the global TB crisis, "Looking toward the next millennium it is difficult to be optimistic" writes Oza (2002:26). According to WHO (2002) approximately one billion people will be newly infected with TB between the year 2002 and 2020 unless TB control is further strengthened globally.

1.3. The burden of TB in the sub-Saharan regions and South Africa

The enormity of the TB problem is often skewed towards developing countries where the impact of the disease is very large or out of control (Walker & Stevens 2003:359). This is attributed to poor living conditions and less developed public health systems than in the developed world. Yet, even when these factors are taken into consideration, the mortality rate due to TB is unjustifiably high as TB can be cured with relatively inexpensive drugs

(Walker & Stevens 2003:360). There are three important reasons entwined with poor healthcare systems and poverty for the high mortality rates: 1) a low propensity to seek medical help when sick, 2) poor diagnosis upon seeking healthcare and 3) high levels of non-adherence to medical treatment when diagnosed. Not every individual with TB actually starts treatment, and of those who start treatment less individuals complete it (ibid 2003).

In the sub-Saharan Africa only, approximately two million cases of TB are reported, making it the single leading microbial killer of adults (Naidoo *et al.* 2008:1 & Peabody *et al.* 2005:347). The prevalence rate of TB infection is very important especially in countries like South Africa with a high HIV infection rate because those who are HIV infected are at a high risk of developing TB (Dye 1999:680).

“Inevitably, the burden of TB-HIV co-infection is increasing as HIV spreads” writes Corbert (2003:1016). Co-infection prevalence rates have reached tremendously high levels in African countries such as Botswana, Zimbabwe, and South Africa. The seriousness of the TB/HIV epidemic was confirmed by WHO (June of 1996) when South Africa was found to have one of the

worst recorded TB epidemics globally due to the rising rates of HIV and the emergence of multidrug resistance (Kandel *et al.* 2008:47a).

According to WHO's (2009) global report, TB in South Africa is a major public health problem. South Africa is ranked fifth by WHO on the list of 22 countries in the world with a high-burden of TB. South Africa in 2007 had nearly 460 000 new TB cases (WHO 2009). Furthermore, with an incidence rate of an estimated 948 cases per 100 000 population, and this is major increase from 338 cases per 100 000 population in 1998. On the same matter, more than 400 000 cases of TB require treatment annually, and more than 50% of these cases never receive treatment, which reflects the classic mistake of identifying cases but not treating them adequately (Weyer 2007:391).

The causal factors for the worsening TB epidemic in South Africa are varied (Weyer 2007:391). In the past, there was a legacy of neglect, poor management of TB patients and fragmented and unequal healthcare services. Again, barriers related to effective TB control in South Africa are the same as those experienced in other sub-Saharan countries. These barriers include HIV/AIDS co-infection, deteriorating socioeconomic conditions

among already vulnerable populations and constraints on human resources in the healthcare sector. In this section below, I will limit my discussion to the threats posed by HIV/AIDS, poverty, homelessness, and displaced populations.

1.3.1. The relationship between TB and HIV

In South Africa, the progress in respect to control of the TB epidemic is likely to be constrained over the next few years as a result of the HIV/AIDS epidemic (USAID 2009). Furthermore, the TB-HIV co-infections rate is very high, with an estimate of 73% of new TB cases co-infected with HIV. Further still, approximately 31% of all TB-HIV co-infection in Africa are in South Africa. The emergence of Multidrug-resistant (MDR) TB due to non-adherence to the treatment regimen or inappropriate drug regimen is also fuelling the epidemic (USAID 2009).

The two epidemics have a symbiotic relationship: HIV also fuels the TB epidemic, and consequently, TB is increasing the HIV mortality rates (WHO 2001). Furthermore, HIV positive individuals have a 50% risk of developing active TB. Of those who are HIV negative, the risk is only 5-10%. Globally, TB is the most common

cause of mortality in individuals who are HIV positive. The HIV virus acts by weakening an individual's immune system, and consequently, making him/her less able to fight off the TB infection (HST 2000). Because of their weak immune system, HIV + individuals are 30 times more likely than is the general population to acquire TB (NTBCP 2003). Thus in countries such as South Africa with an increasing prevalence rate of HIV we can see that tackling the problem of TB becomes a matter of urgency both locally and globally (Yudav *et al.* 2006:187).

HIV infection can also be a contributing factor that can affect the TB patient's adherence to TB medications. Kandel *et al.* (2008:47b) write that when there is a reappearance of TB (largely as a result of the HIV epidemic) there is concurrently an alarming rate of TB treatment interruption. In addition, to achieve TB control in countries with a high prevalence of HIV will require more than wide-scale implementation of the DOTS programme. Clearly, any effort to manage the TB epidemic must take HIV into account (WHO 2001). It is also important to note that TB in HIV-infected individuals is both treatable and preventable (Corbert 2003:1018).

The HIV virus increases the risk of progression from latent TB infection to active disease (Schiffer & Sterling

2007:229). So, patients who are co-infected with TB-HIV/AIDS have a high annual incidence of mortality and opportunistic infections, and this makes TB accelerates HIV disease progression, and vice versa (Naidoo *et al.* 2008:1 & Schiffer & Sterling 2007:229).

Since the global burden of TB is closely associated with the prevalence of HIV epidemic, this epidemic presents a massive challenge to global TB control (Schiffer & Sterling 2007:229; Corbett 2003:1009). In countries such as South Africa where HIV is common, the TB burden has increased. Furthermore, “not only does HIV increase the risk of reactivating latent TB infection, it also increases the risk of rapid TB progression soon after infection or re-infection with TB.” Still, in individuals who are infected with TB only, the lifetime risk of developing TB is in the range of between 10% and 20%. While, in individuals co-infected with TB and HIV, the annual risk is above 10%. In addition to the increase of an individual being easily affected by TB following HIV infection, it is possible that the transmittance of TB at community level will increase also (Corbett 2009:1009).

Therefore, preventing the spread of HIV and TB, extension of WHO DOTS programmes, and a focused attempt to curb HIV-related TB in areas of high HIV

prevalence are matters of great urgency (Corbert 2003:1019). Additionally, there is an urgent need also to employ a strategy of extended scope that combines intensified TB case finding and treatment, HIV prevention, and identification and treating latent TB in co-infected patients. So, to control HIV-related TB will entail an enormous local and global effort.

South Africa lost an early opportunity for effective HIV intervention, and this brought the weaknesses in TB control into sharp focus (Weyer 2007:391). Furthermore, dreadful predictions of the impact of HIV on TB and MDR-TB were first made in South Africa in 1999, and sadly, what had been mere predictions at the time have now happened. Substandard care, fertile conditions for transmission and the rapidly progressing HIV epidemic are all barriers in the ability of South Africa to meet the required targets for TB control (ibid 2007). Moreover, these are also contributing factors in the spread of drug-resistance.

Therefore, a dynamic and extremely strong partnership between HIV and TB control programmes is needed to avert major HIV-associated epidemics of drug-resistant TB (ibid 2007). Failure to be involved in such partnerships is bound to have devastating consequences.

1.3.2. Socioeconomic factors contributing to TB

A greater number of TB infections are in the developing countries as opposed to the developed[1] ones, and TB is seen as the disease of the poor (Oze 2002:26). There are many environmental and social factors, for example, over populated living areas and crowded working conditions, inadequate sanitation, greater occupational hazards such as sex workers, that contribute to TB found in poorer populations. Moreover, malnutrition, stress, overwork, inadequate, inaccessible, or non-existent health care are some of the factors that can affect the patient's recovery and worsen the disease. Other factors that exacerbate the TB problem in poor countries (or amongst poor people) are health systems that are defective and thus cannot cope. This is often related to either a lack of funding and human resources or dysfunctional politics (Donald & Helden 2009:2393).

Diseases of poverty such as TB, malaria and HIV manifest the dynamic relationship between poverty and

[1] In developed countries, there was a substantial reduction in the incidence of TB between the mid-19th and mid-20th centuries, before the advent of drug treatment (WHO 2001). This was due to factors that reduced transmission, improved working conditions, and also there was less overcrowding.

poor health. Although these diseases are a consequence of poverty, they also perpetuate and worsen impoverishment by exhausting personal, national health and financial resources (WHO 2001).

According to Kim *et al.* (2005:848), two hundred years ago, TB affected wealthy and poor countries alike, but in this age, rates of TB infections have become telling indicators of a society's wealth or poverty. Moreover, as Kim *et al.* (ibid) report, TB is not only a matter of infection; it is an indication of patterned resource distribution. So, understanding social inequalities in the developing countries (as well as social theory) is central to the understanding of the persistence and re-emergence of TB.

While the poorest spheres of society are more vulnerable to TB, any person living in a TB region can also be affected (Kim *et al.* 2005:849). The truth is that a significant number of individuals infected are literate, have considerable education, and earn a good income (CMEH 2002). Yet poverty increases the risk of such individuals to develop TB. This infectious disease catastrophically undermines the earning power of individuals and the society (STOP TB 2000). According to Kim *et al.* (2005:848), TB is, in every sense, both the

source and the consequence of poverty. What Kim *et al.* is saying here is that “the poor are precisely those who will never enjoy health particularly in settings in which common, treatable diseases remain untreatable.”

WHO (2001) stated that TB is deep-rooted in populations where human rights and dignity are not realised. Even though any person can be infected with TB, the disease thrive on the most vulnerable, that is, the marginalised, populations that are discriminated against, and the poor (ibid). The circumstances that increase vulnerability to TB have been identified as poverty, homelessness, displaced populations, substance abuse, psychological stress, poor nutritional status, and overcrowding. These factors also increase vulnerability to HIV (ibid). TB and the HIV/AIDS epidemics record their highest rates of infection among populations that are naturally disadvantaged or marginalised in their own communities.

1.3.2.1. The Homeless people

Homeless people are vulnerable to TB, have increased default rates in TB control programmes and poor prognosis (including mortality) when compared to the general public (Figueroa-Muniz & Ramon-Pardo

2008:734). In many developed countries, TB among the homeless is approximately 20 times higher than the general public, and this may be attributable to ongoing transmission in shelters (ibid). The provision of housing and social services may decrease hospital utilisation and improve adherence to treatment (ibid: 735). In addition, it is reported that supervised housing may be effective and increase treatment adherence, and resulting in significant cost savings.

1.3.2.2. Displaced populations

TB is increasingly the root cause of morbidity and mortality in refugees and displaced populations, especially during the post-acute phase of complex emergencies (Rodger *et al.* 2002:451). Until recently, little has been done to resolve this problem, mainly because of the difficulties of implementing TB control programmes where patients are unable to remain at a site for a relatively long time e.g. to undertake the full six months course of TB therapy. Moreover, drug supplies are often irregular, and donors may choose to spend limited resource they have on short-term programmes with immediate benefits such as re-locating. In addition, there

remains a lack of concise guidelines for the control of TB among refugees.

Globalisation has resulted in a significant impact on refugee migration patterns and health care issues (Figueroa-Muniz & Ramon-Pardo 2008:734). For example, the arrival of a large number of refugees in South Africa from countries such as Zimbabwe, Mozambique, and Somalia has resulted in an increased healthcare workload and disease burden. Many of these people live in poor conditions and overcrowded refugee settlements and therefore the risk of contracting TB is increased.

South Africa normally attracts people from across Southern African Development Community (SADC) and beyond. The annual number of people arriving from other SADC countries has increased from one million in the early 1990's to over five million in 2004 (SACU 2010:15). Moreover, the countries from which these migrants come often have experienced political upheaval and disruption of health care services. Thus, many of the migrants may already have TB and or HIV. On the same matter, the South African mining industry, despite having good HIV and TB treatment programmes, unintentionally contributes to the transmission of HIV, TB and drug-

resistant TB through its employment of such migrant workers (SACU 2010:15). Overall, this will increase the burden of HIV-TB on the public health system which is already under stress due to lack of human resources and political will to address the problem of TB.

Migrant workers and refugees have special health needs. They often experience obstacles when accessing healthcare due to language barriers, stigmatisation, poor cultural awareness, and psychological distress, disruption of families and social networks, and economic difficulties (Figueroa-Muniz & Ramon-Pardo 2008:735).

The government of South Africa should ensure that there is ample and open access to healthcare for refugees. This will make possible early detection and treatment of TB. On this view, migrants, and refugees should not be discriminated against when they seek healthcare. This is both a legal and a moral requirement. Although in South Africa migration may be one of the sources of TB infection – especially if migrants originate from highly disease- burdened African countries – migrants have a right to access to healthcare. Even pragmatically, it is imprudent to deny them care particularly if they have an infectious disease.

1.3.3. The burden of TB on the economy

The burden of TB is borne not only by infected individuals but it can also affect the economy of developing countries The high TB burden needs to be attended to as soon as possible by governments both in the developing countries. If not attended to, the consequences of a highly diseased population will result in very serious economic disruption and can hinder the progress of these countries.

TB has a great economic impact on patients and their families through spending on diagnosis and treatment, transport to get to healthcare facilities, and the time lost from work (WHO 2006). Households incur much higher direct costs for TB (and HIV/AIDS) treatment than for any other disease (Russell 2004:148). Direct costs are the 1) household expenses related with seeking treatment which includes non-medical expenses such as transport or special foods whilst 2) indirect costs are the loss of household productive labour time for patients and healthcare givers (Russell 2004:148).

Furthermore, the TB burden on households may impose cost burdens of 8-20% of a family's annual income in

already impoverished settings. Again, if productive youths and adults contract TB, their productivity is lowered which may lead to an increase in poverty in their families and their communities. This is because these individuals will be cared for by their families, and some will depend on the government for grants. When a large number of people are not employed and depend on the government for grants, it means less people are paying taxes. The financial burden is thus carried by only a few which influences negatively on the social and economic development of the country (Russell 2004:148).

According to Singh *et al.* (2007:20-21) ten (10) million South Africans, that is, one (1) in four (4) citizens - are benefiting from government social welfare grants. Furthermore, approximately 27% of South Africans are unemployed, and consequently, social grants often constitute the primary income of many households. This is not a good picture as the burden of TB can be catastrophic on the economy of the country.

Laxminarayan *et al.* (2007:4) states that lifting the TB disease burden is one of the UN's Millennium Development Goals, the main aim is to reverse the incidence of TB by the year 2015. Furthermore, the

STOP TB partnership goes further and aims to halve TB morbidity and mortality rates by 2015.

The strategy that was found to be effective is DOTS. According to Laxminarayan *et al.* (2007:14-17) determining the benefits of achieving these goals starts with quantifying the economic costs of not achieving the goals; what are the economic costs of TB on society? What is the economic burden of not doing what is supposed to be done to prevent and treat TB?

- *Is financing of TB programmes sustainable?*

The financial crisis in South Africa due (currently) in part to the global economic recession threatens the sustainability of HIV and TB programmes (SACU 2010:14). In addition, also the global market has had an effect on future external financial resource flows. Furthermore, the International Monetary Fund (IMF) expects that tighter global funding will have a noticeable consequence on countries such as South Africa. Further still, South Africa's economy experienced its sharpest downturn in 17 years, shrinking from 3.7% growth in 2008 to 1.8% in 2009. Consequently, the output was radically decreased by lack of demand for goods and other

exports, which in turn, increased an already serious unemployment rate (SACU 2010:14).

Unemployment[2] rate which is already high in the sub-Saharan Africa especially amongst young people remains a pressure point, and can trigger more risky behaviour (SACU 2010:17). Again, the arrival of "economic refugees" from neighbouring countries such Zimbabwe, Mozambique, Somalia, and the Democratic Republic of the Congo to South Africa increases the number of individuals who require HIV and TB services. Consequently, this puts more strain on treatment programmes.

[2] Unemployment rate among young people in the year 2000-2006 was 39.6% Botswana, 44.8% in Namibia, and 60.1% in South Africa (World Bank 2009).

1.3.4. Conclusion

This chapter looked at the burden of TB in globally, with emphasis on the burden of TB in the sub-Saharan and South Africa. Factors such as HIV/AIDS, poverty, displaced, homeless, and migrant populations each in their own way contribute to the impact of TB on public health. I identified that the problem of TB is complex and far-reaching. Related to this I discussed that in countries where a high percentage of the population is unemployed and receiving social grants, the economic situation does not bode well for the economy, much less for programmes designed to diagnose and treat TB. The next chapter will concentrate on the South African DOTS programme

Chapter 2

The DOTS Strategy

2.1. Introduction

In this chapter, I will focus mainly on the South African DOTS strategy. TB is an infectious disease which requires that the patient adhere to the DOTS programme thus reducing TB. This also helps to diminish the risk of a patient developing drug-resistant TB. DOTS treatment involves the TB patient having to take, under direct supervision, multiple medications for a minimum period of six months. Many patients in some communities in South Africa consistently fail to report to the DOTS centres for treatment, thus TB spreads.

2.2. The DOTS strategy

Despite many countries' attempt to diagnose and treat TB, the numbers of TB cases are increasing rapidly (Walley *et al.* 2001:1). Furthermore, some of the increases in the number of TB cases are related to the increasing HIV epidemic, and some are due to the failures in existing treatment strategies for TB. Effective

treatment of TB is needed for individuals, their families, and society. If untreated the patient will be a danger of spreading TB to their families and the community.

2.2.1. Why the DOTS strategy was recommended

The reasons why WHO (1991) recommended the DOTS strategy which targets, among other things, treatment adherence to TB medication was an attempt to control the global problem of TB. With DOTS therapy, during the initial phase of therapy, patients take their medication daily under direct observation of the healthcare worker or the designated person. Therefore, completion of the TB medication is a vital benchmark of cure. The DOTS strategy can be used for treatment of new TB cases, people who have relapse, people who in the past have received treatment, but failed to complete it, and those who need retreatment (Walley *et al.* 2001:1).

- *Initial phase of DOTS*

Treatment under the DOTS strategy consists of a combination of drugs taken over a period of over six to eight months (Walley *et al.* 2001:3; Whittier 2007:3-4).

In the first two months, four drugs are taken together. The reason for this is to ensure that as many TB bacilli are eliminated and prevent the development of drug-resistance.

- *Continuation phase of DOTS*

This phase continues for four to six months, and a smaller amount of drugs are taken (Walley *et al.* 2001:3, 5). This is to ensure that individuals with TB are completely healed and they do not relapse. Therefore, if the patient is following the treatment consciously, then ideally pulmonary TB will stop being infectious within a period of two to six weeks.

The doctor or head of the TB treatment facility should categorize the individual with TB and the treatment should be prescribed according to the relevant TB guidelines.[3] Because it is important to respect one's patient as an individual, counselling for TB patients should focus on:

- TB treatment and its possible side-effects,

[3] HERE GIVE THE REFERENCE FOR THE SOUTH AFRICAN AND WHO DOTS PROGRAMME GUIDELINES

- The importance of adhering to the treatment until it is complete, and
- How to disclose their TB and or HIV/AIDS status to family members and to encourage them to disclose.

The problem with TB treatment is that if drugs are not available patients discontinue the treatment (Walley *et al.* 2001:5; Khatri & Frieden 2002:460). It is vital, therefore, that TB drugs be made available at all healthcare facilities at all times. TB drugs should be free and an uninterrupted supply must be maintained. Research has shown that if patients have to buy TB medications, then they will stop treatment when their TB symptoms are gone in order to save some money (I will discuss disruption of drug-supply in 2.2.2.4). In most instances, it is the vulnerable groups such as the poor who are the most affected by disruptions of drug-supply.

2.2.2. Five elements of the DOTS strategy

The DOTS strategy involves much more than direct observation of treatment, as many factors are needed to ensure adequate and accessible TB care (Walley *et al.* 2001:1; WHO 1994).

The involves aspects of programme design such as 1) political commitment with increased and sustained financing, 2) case detection through quality-assured bacteriology, 3) standardised treatment, with supervision and patient support, 4) an effective drug-supply and management system, and 5) monitoring and evaluation system, and impact management. These five elements are discussed below.

2.2.2.1 Political commitment with increased and sustained financing

Effective responses in support of TB control require political commitment with increased and sustained financing (WHO 2001). Furthermore, there should be clear and sustained political commitment by the South African government for the full implementation of the DOTS programme and also the STOP TB strategy. Moreover, the government should ensure that resources for the fight againt TB are adequate. It must be said that even if adequate financing is sufficient, there is a problem of human resources in the public health sector. This alone hinders progress in the implementation of the DOTS strategy (WHO 2001). Experience has shown that prevention of diseases is possible, though admittedly

difficult under particular conditions (UNESCO 2008). In spite of difficulties, and while aware that a policy of TB prevention has to work in several directions at the same time, nonetheless, to not prioritise the TB epidemic, is economically and socially dangerous. Lack of political commitment towards the eradication of TB in communities may lead to the re-emergence of the disease in areas were it had previously been eradicated (Selgelid *et al.* 2008:243).

TB and related eradication programmes also raises the issue of distributive justice. On this view, even though there is lack of resources for improvement of healthcare particularly in poor communities, there are numerous powerful moral (the egalitarian and utilitarian) and self-interested reasons for governments, such as in South Africa, to do more towards the eradication of TB (ibid 2008:243).

The egalitarian principle (or theory), for example, emphasizes the distribution of resources among persons equally or the distribution of healthcare services / health, equally among different population groups (Macklin 2004:5).

Ngwena and Cook (2005:111) say that egalitarians refer to equity as developing a healthcare system that is

responsive to the needs of the people rather than based on an individual's ability to pay for healthcare services. So, from the egalitarians' point of view equity means more governmental interference in the provision of healthcare, with the government assuming primary responsibility for the provision of healthcare to all the people - including vulnerable populations.

The primary goal of the government must be the reduction of disparities in health status among these population groups (Macklin 2004:5). In application of the egalitarian theory, it then requires that that all groups and categories of patients have equal access to the DOTS programme. On the same matter, the egalitarian principle in this case is very relevant to providing equitable access to the DOTS programmes for vulnerable groups. The reason for this is that these groups of people have been historically underserved by the health care system. Sometimes they have been denied healthcare altogether as a result they suffer in general the worst health status of a given population (Macklin 2004:5).

Economically poor and vulnerable groups, cultural/ethnic minorities, migrant populations, substance abusers, homeless persons, etc, are all at high risk of contracting TB. Again, these groups of people are likely to

experience a worse TB prognosis than the general population (Figueroa-Munoz & Ramon-Pardo 2008:734). Moreover, “their complex needs are often overlooked and they experience barriers to access routine healthcare.” Hence, additional considerations are required in order to make the case for determining priority of access to health care.

On the other hand, the utilitarian principle’s aim is to maximise utility by focusing on achievement of the greatest possible collective benefit (Calman 2008:8). So, this means that actions or rules are generally measured by the extent to which they reduce pain and suffering, and also promote overall happiness and wellbeing. Therefore, socio-economic practices which afford the greatest good or pleasure to the largest components of the society should be the purpose of governmental policies (Iseman 2000:95).

Another important factor that may be considered the government’s responsibility concerning TB treatment and adherence is patient education (Whittier 2007:5). Education may be considered ‘external’ to the TB patient but it is related as it is difficult for patients without any education to comprehend the cause and mode of TB spread. Without education, patients may rely on

superstition and local traditional healers for a ‘cure’. It also prevents the patient’s access and acquisition of TB medication. When uneducated, patients should not be blamed for lack of educational resources or information that is supposed to be provided to them through school educational programmes.

The fact that patient default from the DOTS programme when overt symptoms cease could also be considered an issue of educational and informational shortcoming (Whittier 2007:5-6). It must be noted that this type of behaviour is not necessarily due to the lack of knowledge on the part of the patient as many well educated and informed patients may decide to discontinue with TB medication even when the healthcare worker has properly informed them of the consequences. This position is not meant to de-emphasize the effect of patient’s environment and socioeconomic status or the role of the government to provide better opportunities for TB treatment (Whittier 2007:6). This is meant to emphasise the government’s moral duty to act in the best interest its citizens to ensure they are educated and that opportunities are provided for them to both access and understand the health care system.

2.2.2.2 Case detection through quality-assured bacteriology

According to WHO (1994) bacteriology remains the preferred method that is used for TB case detection, first using sputum smear microscopy, then culture, and drug susceptibility testing. In addition, networks of well-equipped laboratories with properly trained personnel are required to ensure access to quality-assured sputum smear microscopy. It is important for South Africa to make certain that laboratory services are strengthened in order to cope with increased workload that is due to intensified TB case finding (Karim *et al.* 2009:930).

Therefore, the laboratory network ought to be based on the following principles (WHO 1994):

- Implementation of national standards in conformity with international guidelines,
- Decentralisation of diagnostic services, and maintaining a high proficiency levels,
- Interaction among members at different levels of the network, and
- Internal and external quality management functioning very well.

With the DOTS strategy high cure rates is a requirement for expanding case finding; this is the case with TB, where standard short-course regimens are able to cure more than 90% of new drug-susceptible cases of the disease (Dye 2007:364). Furthermore, “70% case detection, 85% cure and no co-infection with HIV, incidence should fall at around 5-10% per year, and prevalence more quickly.” However, factors such HIV co-infection, diabetes and over-population in urban slums (or areas marked by poverty and inferior living conditions) could reduce the rate of decline in many of the world’s high TB burdened countries.

The only reasonable and affordable way of identifying patients with TB is to diagnose and give treatment to those who present at healthcare facilities (Harries *et al.* 2008:0861). In addition, active case finding requires an enormous amount of human resources. So, simple diagnostic and treatment protocol are required for TB patients to make sure that the standard quality of care is maintained at all levels of the healthcare system.

2.2.2.3. Standardised treatment, with supervision and patient support

- *Treatment services*

The foundation of TB control in South Africa involves the ability to organise and administer standardised care for all adult and paediatric TB cases, that is, sputum smear positive, smear negative, and extra-pulmonary WHO (1994). So, it is important that WHO guidelines on patient categorisation and management be followed. These guidelines put more emphasis on the use of the most effective standardised, short-course regimens, and fixed-dose drug combinations to make easy patient adherence, and reduces the development of drug-resistance.

- *Supervision and patient support*

Treatment support and/or supervision are one of the essential elements of the DOTS strategy (Walley *et al.* 2001:3). “What gets supervised gets done” (Khatri & Frieden 2002:461). Additionally, supervision at all levels of the DOTS programme is critically important. The reason for this is because TB treatment takes longer than most other types of diseases, that is, for a period of six to eight months, and TB patients often need encouragement

to complete their drug medications. Encouragement is an important aspect of the DOTS strategy because it helps patients to adhere to their medications regularly and complete their treatment, consequently, achieving cure and preventing the development of drug-resistance (WHO 1994). Moreover, supervision should be carried out in “a context specific and patient-sensitive manner.”

Its purpose is to ensure adherence on the part of both the healthcare worker (in giving proper care and support) and of patients (in taking their medication daily). Patient supervision may be undertaken at a healthcare facility, the workplace, the community, or the patient’s home.

- *Improving access to treatment*

Barriers to accessing healthcare should be identified and addressed, and these include physical, financial, social, and cultural barriers (WHO 1994). All these barriers to access to healthcare are discussed chapter 3. So, particular attention to access to healthcare should be given to the vulnerable groups such as the poor, women, and children.

2.2.2.4. Disruption of drug supply

Interruption TB treatment is a perfect breeding ground for increased resistance to anti-TB drugs (Johansson *et al.* 1996:181. The consequences of unstable drug supply result in obvious non-adherence or patients defaulting from the DOTS programme (Oyugi *et al.* 2007:970). Regular, sustained drug supply is a vital element in the DOTS programme (Jaiswal *et al.* 2003:628 & Khatri & Frieden 2002:460). TB drugs must be available at all times to the DOTS supervisors in the TB clinics and healthcare facilities. Khatri *et al.* (2002:460) state that drug shortages are detrimental to public health programmes, and these programmes can also suffer from problems related to the quality or perceived quality of TB drugs provided by the government.

Additionally, drug shortages are not only related to interruption of TB treatment but also, more severely, it damages the reputation of government. Consequently, it undermines all the efforts linked to the TB programmes. Therefore, any shortage of TB medications at healthcare facilities should be treated as an emergency.

The success of the DOTS programme rests on the strength of diverse structural components, which includes reliable drug supply and distribution (Cheryl *et al.*

2003:1384). Alves-Filho (2008:447) is of the view that "inadequate drug treatment can be associated inadequate regimes, to inadequate supply/quality drugs, and/or inadequate drug intake." In many communities where TB is a common disease, inadequate therapy has enabled mutant *M. tuberculosis* organisms to develop and spread a reservoir of bacteria that resist first line TB drugs (Kim *et al.* 2005:848).

So, the availability of drugs at healthcare facilities positively influences adherence to the DOTS programme. With the assurance that TB drugs will be available at all healthcare facilities, and that each patient will have his/her own supply of drugs, TB patients will start to believe that they will be cured (Jaiswal *et al.* 2003:628). Further, some of the patients may even cite this as an incentive to adhere to their complete course of therapy, irrespective of any of the difficulties that they may face.

It very important also that issues such as poor communication, and insufficient support and attention from provider to patient be addressed (Jaiswal *et al.* 2003:628). This is because these factors tend to precipitate default from the DOTS programme. Steady and reliable access to TB drugs, in order to prevent non-adherence to DOTS programme, is vital to limiting the

development of MDR- and XDR-TB in resource limiting settings (Oyugi *et al.* 2007:970). Well-managed DOTS programmes should prevent disruptions of anti-TB drugs through reliable drug forecasting and six monthly procurement (Harries *et al.* 2008:860).

- *Anti-TB drugs*

This is the same problem that contributes to non-adherence to TB treatment; the lack of an effective drug supply and management system (Jaiswal *et al.* 2003:628). Access to TB drugs should be increased. It is crucial that medicines (TB-drugs) be accessible to the population, and by accessibility it is meant that they are physically available and financially affordable (Hassim *et al.* 2007:438). Furthermore, having access to essential medicines can only be certain if a sustainable supply of medicines can be guaranteed, that is, a regular, ongoing supply of affordable medicines.

Even when sustainability of supply can be guaranteed, new medicines are often unaffordable to the vulnerable population such as the poor (Hassim *et al.* 2007:438). The vulnerable groups are likely to experience barriers to accessing a regular supply of TB medication resulting in

the risk of non-adherence to treatment therapy. Therefore, potential shortages of drugs should be anticipated well in advance and alternate arrangements should be made (Khatri & Frieden 2002:460). Moreover, the introduction of computerised monitoring can improve the distribution of drugs.

2.2.2.5. Monitoring and evaluation system, and impact measurement

- *Recording and reporting system*

This involves establishment of a reliable monitoring and evaluation system with regular interaction between the central and peripheral levels of the healthcare system (WHO 1994). In furtherance, this will require a standardised recording of the individual patient data that includes patient information on treatment outcomes. Still, this information could be used to compile quarterly treatment outcomes in cohorts' patients.

Intensive monitoring and supervision of all aspects of the DOTS programme at every level is required and also vital, and this is required for the release of funds and drugs (Khatri & Frieden 2002:461). Moreover, there should be interaction between the national government

and district health services. And these interactions are aimed at commenting in detail on the important aspects of the DOTS quarterly reporting system. Analysis should be made of the quality of diagnosis and treatment, of consistency within reports and with reports from previous quarters, and of performance and epidemiological trends over time, and detailed suggestions should be made for further improvements (Khatri & Frieden 2002:461).

Others factors that are important to ensure adequate and accessible TB care.

2.2.2.6 Strengthening the established infrastructure

DOTS programmes require specialised healthcare personnel that can ensure accountability of the general health staff (Khatri & Frieden 2002:461). Furthermore, key healthcare personnel should include a full-time medical doctor for each district, one TB treatment supervisor and, one TB laboratory supervisor for each TB unit with an average population of 500 000 people (*district health service is discussed in 3.5.4*). The role of the medical doctor is to oversee the treatment and laboratory supervisors, and also undertake or arrange for

the observation of treatment, which can be done by either healthcare personnel or community volunteers.

2.2.2.7 Supporting the required infrastructure

An effective healthcare system, specialised services for TB, effectively integrated with the primary healthcare is essential (Khatri & Frieden 2002:461). Furthermore, adequate human resources are required in large areas that are implementing the DOTS strategy for smear microscopy and observation of treatment. And, adequate human resources are justified because more patients can be treated more effectively by them.

2.2.2.8 Systematically appraising each area before it starts service delivery

The purpose of the appraisal system is that it serves as the quality control mechanism for the programme (Khatri & Frieden 2002:459-460). Additionally, it ensures that each district meets a minimum standard before the DOTS strategy can be implemented. This is important because rapid, uncontrolled DOTS may lead to ineffective service provision, and the development and transmission of drug-resistant TB. In countries such as India, the DOTS

strategy cannot be implemented in any area until that area has met predefined criteria (Khatri & Frieden 2002:460). That area should complete a standard training of over 80% of doctors and laboratory technicians, and also 50% of allied healthcare staff, and should have volunteers to help with supervision of the TB patient. Appraisal also involves a review of quality of training of the medical staff (Khatri & Frieden 2002:460). Moreover, if DOTS is implemented without all the predefined criteria, it often leads to poor implementation of the programme.

2.2.2.9. Maintaining focus and priorities

Government programmes have a limited capacity for successful TB treatment and implementation (Khatri & Frieden 2002:460). A slight distraction from the fundamental goal of effective expansion of the DOTS programme with technical excellence can be detrimental. Therefore, the following points are important and should be considered when implementing the DOTS programme (ibid: 464):

- Operational research is an essential component of an uninterrupted programme improvement. However, the focus should be effective

implementation of the programme since operational research on a poorly implemented programme is of no value.

- Private sector involvement in the control of TB in South Africa is crucial. But no private sector policies can be successful unless the government takes a stand to monitor effectively the treatment of TB. The main aim, therefore, of the government should be establishment of a DOTS programme that will supply free, respectful, and convenient TB treatment with drugs of good quality. So, when this infrastructure is in place, involvement of the private sector should be successful.

- During DOTS expansion in South Africa, it is important that services in areas not yet covered by the strategy be improved.

2.3. Reasons why DOTS strategy is not effective

Although the DOTS strategy has been successful in improving worldwide cure rates, there are other circumstances that make the implementation of DOTS very difficult (Rodger *et al.* 2002:451). This is particularly

true amongst vulnerable groups such as the poor people, displaced populations, refugees, and people in areas of civil conflict.

According to Oze (2002:27), firstly the DOTS programme has not been implemented all over the world. This lacklustre implementation of an effective treatment strategy is a very unfortunate consequence of the countries that are able to help but, at best, decide to act in a very limited capacity. So, this failure of effective action by these countries has now come back to trouble the whole world. Irrespective of many countries' implementation of the DOTS programmes during the 1990s, the required global targets were not met by the year 2000, and as a result, the target was shifted to the year 2005 (Dye 2007:364). This is very unfortunate. The global TB burden has become worse over time (Oze 2002:27).

Secondly, the drug-resistant forms of TB are now spreading. So, where DOTS is not implemented there is no standard to guarantee TB patients are adhering to their full course of treatment. In resource poor countries where patients buy only TB drugs they can afford, acquired drug-resistance has increased dramatically. Additionally, the sad thing is that these TB strains of drug-

resistance will then be transmitted to others in close proximity with the infected individual. Again, these problems also arise in places with little DOTS implementation due to mismanagement, such as not having a constant drug supply, doctors prescribing incorrect drugs, and lastly, patients not being observed to ensure they take their TB drugs.

2.4. Challenges facing the South African DOTS programme

The current South African government policy specifies that individuals who are hospitalised at state expense lose their social welfare benefits for the duration of their hospitalisation (Singh *et al.* 2007:20). Furthermore, faced with the prospect of losing a state grant during hospitalisation, many TB patients choose not to be hospitalised. As a result, their treatment adherence and resistance profile must be closely monitored by a healthcare worker (Singh *et al.* 2007:20-21). So, this will present as a challenge to the DOTS programme in that if infectious TB patients fail to receive the necessary therapy and they default from the programme or interrupt the treatment the likelihood of drug resistance and TB spread increases. The other challenge to the DOTS

programme is what concerns the vulnerable groups. This is establishing patient-centred services, which is an integral part of successful DOTS implementation (Khatri & Frieden 2002:462). According to these authors, the DOTS programme's objective should be that no patient pays for transport or misses work in order to participate in treatment observation. Again, the vulnerable groups such as the poor, women, and children, those living in remote or rural areas, as well as migrants and refugees may still face barriers to health care.

In South Africa, about 15% of TB patients default on the first-line six month treatment, while almost a third of TB patients default on second-line treatment (HST 2000). So, this is a challenge for the DOTS programme which merits urgent remediation. DOTS programmes generally report consistently high treatment success rates, because they mostly follow recommended procedures for treating patients and evaluating outcomes (Dye *et al.* 2007:366). However, cure rates may be over-estimated in some areas (underestimation is less likely given that healthcare workers are responding to performance targets).

An active TB patient's non-adherence to the treatment regimen is very harmful, to not only themselves, but also the greater populace (Whittier 2007:4). Therefore, it is

essential to understand those factors that cause patients to default from the DOTS programme. Again, it is also essential in subpopulations in order to develop more effective strategies for treatment and eradication of the disease (Greene 2004:402). Deaths resulting from the TB epidemic compromise 25% of all the deaths that should have been avoided in many developing countries (Mishra *et al.* 2005:1134).

Other challenges facing the South African DOTS programme which are discussed later are the high treatment interruption of drug-sensitive TB and consequent low cure rates, together with HIV co-infection which contributes to the emergence of drug-resistant TB and needs urgent government intervention (Singh *et al.* 2007:21). Furthermore, the emergence of drug-resistant TB may be due to inappropriate treatment regimes (such as choice of drugs, dosage, duration of treatment), programme factors (such as lack of human resources), and patient factors such as poor adherence to the treatment regimen and mal-absorption. On the same view, a lack of a coordinated and managed TB control in South Africa (until the introduction of DOTS in 1997) has contributed to the emergence of drug-resistant TB (HST 2000).

2.5 Conclusion

In this chapter, I focused on the DOTS strategy. The reason for DOTS to be recommended was to target, among other things, treatment adherence to TB medication in an attempt to control the global problem of TB. Political commitment with increased and sustained financing, case detection through quality-assured bacteriology, standardised treatment, with supervision and patient support, and disruption of drug-supply is important in ensuring adequate and accessible TB care. Interruption of drug-supply, for example, will result in non-adherence to the DOTS programme.

In the following chapter I will focus on the problem of non-adherence and the problem of drug-resistance.

Chapter 3

Problems with non-adherence and the emergence of drug-resistance

3.1. Introduction

In this chapter I will first discuss the problem of non-adherence to the DOTS programme, and the emergence of drug-resistant TB. Secondly, I will discuss factors that contribute to non-adherence. Contributing factors that play a part in South Africa's low cure rate include, but are not limited to; unequal national drug distribution, lack of skilled healthcare personel, counterfeit medication, access to healthcare, high rates of poverty and illiteracy, and lack of education concerning healthcare matters.

Of these factors, in this chapter I will discuss lack of skilled healthcare personel, counterfeit medication, and access to healthcare. These factors can affect negatively a community's ability in implementing the programme that is effective. These factors are external to the patient which requires an in-depth analysis of the socioeconomic factors and also government's responsibilities related to public health.

3.2. The problem of non-adherence

Non-adherence to TB treatment is a product of programme (DOTS) problems or failures. Viewing non-adherence as the patient problem alone is not only inaccurate, but it is also unhelpful (Jaiswal 2003:631). Further, placing the burden on the patient will not empower programmes or programme implementers trying to identify and solve these problems.

Many patients with TB, particularly those in the developing countries never receive treatment, and of those who do, many of them never complete the treatment regimen (Greene 2004:402). So, the DOTS strategy which has emerged as the main control strategy was in partial response to the problem of treatment adherence. Nonetheless, problems with the delivery and maintenance of anti-tuberculosis treatment remain, allowing TB to remain the number two killer next to HIV/AIDS.

TB's public health impact has been even greater than HIV/AIDS as a result of its airborne transmission (Fanning 2008:229). This is because TB is a highly infectious disease which is spread through emitted aerosol droplets of individuals infected with active TB (Whittier 2007:1). Many of the aggravating issues related

to the transmission and treatment of TB are because the TB patient can act as the vector of the disease by simply breathing and coughing in his everyday surroundings, a concern that is not relevant to HIV/AIDS. So, the manner in which TB is transmitted contributes to its high prevalence and rate of transmission, particularly in those areas characterised by overcrowding, poor ventilation and populated by immune-compromised individuals.

WHO (1998) has frequently named non-adherence to the treatment regimen as the essential barrier to the global management of TB (Greene 2004:402). It has become clear that many TB patients are consistently unable to report to the healthcare facilities for treatment presenting the issue of non-adherence (Whittier 2007:4). Regardless of the effective and free available anti-TB drugs in many national TB programmes (NTPs), non-adherence to the DOTS treatment has shown to be a major barrier to the global control of this disease (Mishra *et al.* 2005:1134). So, the low cure rates for TB cases is the result of poor adherence to the treatment programmes by individuals affected by this infectious disease (Naidoo *et al.* 2004:2).

Additionally, many individuals with TB who do not cooperate during the first episode of being diagnosed as having TB underestimate the seriousness of a

communicable disease such as TB, and “the reasons for having a regimented treatment programme.” Still, the reasons for non-cooperation with the treatment regimen are that the more extensive and complex the treatment is the more likely patients will see the treatment selection as a threat to their personal freedom. Again, non-adherence may be seen by the TB patient as a means of resisting medical dominance. Non-adherence to a treatment regimen may be a threat to the community in which the patient lives. So, non-adherence to the treatment regimen poses a threat to the populace in two ways (Whittier 2007:4):

Firstly, non-adherent individuals with active TB continue to be transmitters of the disease, and as a result are thus readily able to spread the harmful bacilli.

Secondly, and even more problematic, non-adherence to the treatment regimen promotes the development of drug-resistance TB which can be transmitted to the community, and “for which treatment is not as readily available.” It also causes persistent infectiousness and higher rates of treatment failure and relapse. So, this will require a lengthy and more expensive treatment that is less likely to be successful than treatment for drug-susceptible TB (Mishra *et al.* 2005:1134). The emergence

of multi-drug resistant strains makes more complex the treatment regimes, and also posing a serious threat to public health (Whittier 2007:4).

The Science Daily (2008:1) reported that patients with drug resistance (XDR-TB) are four times more likely not to respond to the treatment, and also three times more likely to die as compared to other forms of multi-drug resistant TB (MDR-TB). Drug resistant TB is a serious threat to public health and the global control of TB (WHO, 2007). Moreover, it raises more fears of TB epidemics with serious confinement of treatment choices that could pose a threat to the gains already made in global TB control.

The emergence of drug resistant TB poses specific challenges to the fight against HIV/AIDS worldwide, and it also compromise the advancement already made in many countries globally towards universal access to HIV treatment and prevention (WHO 2007). So, this view also holds true for South Africa. In addition, however, the outbreak in Kwazulu-Natal serves as a serious warning that developments already made in the management of HIV might be lost if drug-resistant TB is not efficiently and swiftly addressed (Wayer 2007:391).

The reports of XDR-TB in patients with HIV in the province of Kwazulu-Natal, South Africa, have renewed global awareness of drug-resistant TB, that is, the threat it poses to both individual TB patients and public health system, challenges that are faced by TB control programmes, and HIV/AIDS treatment in those countries with a high burden of HIV co-infection (NIAID 2007).

In one of the government district hospitals in Tugela Ferry, Kwazulu-Natal 554 cases of TB were identified (NIAID 2007). So, of those 554 cases, 221 (41%) were MDR-TB, 53 (24%) were resistant to the second-line drugs kanamycin and ciprofloxacin which the definition of XDR-TB. Furthermore, of the 53 cases with XDR-TB, 44 were tested for HIV, all patients were found to be co-infected, and 15 of those patients were receiving anti-retroviral therapy (ART), about 52 (98%) of those patients died within a median of 16 days following sputum collection for culture and drug susceptibility testing. Further still, several healthcare providers who were in contact with these patients were also casualties related with XDR-TB in Tugela Ferry.

Araujo-Filho *et al.* (2008:447) say, “XDR-TB is a man-made problem.” In addition, the emergence of drug-resistance, for example, XDR-TB cases, is a reflection of

weaknesses, or how poorly TB is managed by the government. This affects the government negatively as more funds will be channelled towards fighting multi-drug resistant TB. A moral response therefore, must be effective to the fight or control of the disease (Booker 1996:93). In addition, it is certainly worth noting of the history of successful control of these disease which precedes the discovery of the first effective anti-TB drug (*streptomycin*) in 1943.

3.3. Lack of skilled healthcare personnel

In South Africa there has been a drain of healthcare professionals to developed countries such as the United Kingdom and Saudi Arabia. Low staff morale, and the inability of the government to train and retain staff can be a factor in TB control programmes. The way healthcare professionals are remunerated and their poor working conditions can also be a factor. So, lack of skilled healthcare personnel such as doctors, nurses or community healthcare workers to increase TB control and treatment is a problem.

Quality is a very important aspect in healthcare services. This quality “for the meaningful enjoyment of the right to

the highest attainable standard of health" (Pieterse 2007:166) should include having skilled health professionals to be able to manage TB control programmes and treatment. This lack of human resources is a major problem because patients needs to be followed up as soon as he or she interrupts treatments (Kandel *et al.* 2008:47c). Furthermore, home visits to TB patients who default from the DOTS programme is crucial.

The problem of shortage of staff is further compunded by the HIV epidemic in the fact that many healthcare personnel are HIV infected (Steward *et al.* 2004:32). In South Africa it is estimated that approximately 16% of healthcare personnel are HIV positive.

3.4. Counterfeit TB drugs

Kelesidis *et al.* (2007:1) wrote about a growing concern globally regarding counterfeit medications. WHO (2006) reports that trade in counterfeit medication is predominant in countries with weak drug regulation and enforcement, scarcity of provision of basic medication, unregulated markets, and also in instances where drugs are unaffordable. Due to inadequate drug regulation and

enforcement, the quality, safety and efficacy of both imported and locally manufactured drugs in the developing world cannot be guaranteed (WHO 2006). Further, as counterfeiting becomes more sophisticated, these types of medication are now available even in better controlled markets. Counterfeit drugs are not only made available in countries with ineffective drug regulation but they are also exported or re-imported (WHO 2006).

3.4.1. What is counterfeit medication?

According to WHO (2006) “counterfeit medicines are part of the broader phenomenon of substandard pharmaceuticals”. Whilst (Sherma 2007:6) says they are mislabelled medicines manufactured with unsatisfactory safety, quality and effectiveness.

These medicines are manufactured below par the required standards of quality, and consequently they may be a hazard to the TB patient’s health and lack the ability (or strength) to cure TB. What happens with counterfeit drugs is that they are deliberately and deceitfully misbranded with respect to identity or source (WHO 2006). So, counterfeinting occurs both with branded and

generic products, they may contain products with the "correct ingredients but fake packaging, while other drugs contain wrong ingredients, without active ingredients or with insufficient active ingredients".

Many countries across the globe come across medicines seemingly packaged in the correct way as tablets or capsules that look right but do not contain active ingredients, and these medicines may be filled with highly harmful substances (WHO 2006). Lack of knowledge regarding counterfeit medication and the necessary preventive measures, and how the information is disseminated among health workers and the TB patients, makes their detection very difficult (Newton *et al.* 2006:207). Moreover, there is usually no or there is less awareness regarding the problem of counterfeit drugs. So, in some instances drug sellers (or pharmacies) and consumers are not aware of the existence of poor quality drugs.

Counterfeit medications have shown to be a threat to public health with serious consequences for patients; increased mortality and morbidity and also the development of drug resistance and toxicity, and as a result of this the patient lose confidence in the healthcare system and also in the drug regulatory authories if action

is inadequate (Newton *et al.* 2006:207). Furthermore, loss of confidence in correct medication is unavoidable particularly in areas where drug quality is seen as been poor. Further still, healthcare practitioners can also lose faith in the medications they normally depend on.

According to Newton *et al.* (2006:602), there is even less objective information on the potential health and economic consequences of poor drug quality and how to put a stop to this harmful trade. Furthermore, much of the information on counterfeit drugs is only found in the grey literature and newspapers, which suggests a significant under-reporting of the problem.

If medication (in this case TB drugs) contains less or absence of active ingredients, whether counterfeit or substandard, are used for the treatment of common diseases known to have untreated high mortality such as TB, then mortality and morbidity must increase Newton *et al.* (2006:602). Counterfeit TB drugs may discourage TB patients from continuing with the DOTS therapy because the medication they are taking may be ineffective but cause lots of side effects, contribute to drug resistance, and even death.

Anti-infective medication that contains subtherapeutic quantities of the active ingredient, whether counterfeit or

substandard, adds to the risk of spread of drug resistance (Newton *et al.* 2006:602). This is particularly worrisome for diseases such as TB that are treated with combination therapy. Poor quality *rifampicin and pyrazinamide* have shown to stimulate the spread of multidrug-resistant *Mycobacterium tuberculosis* (Newton *et al.* 2006:602).

"Substandard TB drugs are particularly worth highlighting" notes Senior (2008:666). On this view, there is no reason to decide the best possible treatment regimens for TB when medicines that patients actually use will not produce any cure, and at the same time they encourage the spread of multidrug resistance. Counterfeit TB drugs may cause adverse side effects as a result of patients taking excessive doses, because they contain potentially toxic active ingredients or pathogenic contaminants (Newton *et al.* 2006:607).

3.5. Access to Healthcare

The term Access to Healthcare includes not only physical access to healthcare facilities but it also refers to any barriers that may hinder patients form the using health services (Katz & Green 1997:90-91). In furtherance, these barriers may be either financial which includes the

(TB) patient's ability to pay for healthcare services and non-financial such as discriminatory attitudes of staff.

Access to healthcare also refers to the extent to which individual TB patients are able to obtain appropriate healthcare from the "medical system in a timely fashion" (Morales *et al.* 2002:6). Moreover, TB patients may lack access to healthcare for a number of reasons, such as financial, structural and personal barriers. Morales *et al.* (2002:6) refers to 1) financial barriers as insufficient or the absence of health insurance and low personal income whereas 2) structural barriers are refered to as organisational barriers to care for the TB patient, poor geographical access to providers, the absence or lack of transportation to and from the clinic (DOTS clinic), 3) personal barriers are "cultural and linguistic factors" and 4) the TB patient's perception with regard to the quality of care offered.

3.5.1. Physical accessibility

Adherence to tuberculosis treatment regimen requires that healthcare facilities be accessible to the patient, and also that the patient be given appropriate healthcare (Volmink & Garner 2009:2). This involves people being

diagnosed correctly, given the right information about their disease, and also the importance of completing treatment, and lastly, to be supplied with the necessary outpatient drugs (ibid). Long distance to TB services is associated with diagnostic delay (Gele *et al.* 2010:7). So, the structure of the DOTS programme needs to be addressed from the equity perspective to ensure that all people living in unique and difficult settings, especially the vulnerable have access to TB care.

Travelling long distances to the clinic or hospital can be challenging for very sick TB patients, and also the poor people who cannot afford transport money. Although TB medication may be obtained freely at healthcare facilities, patients often incur the costs of transport, meals, and tests as well as the costs of income foregone due to long travel and long waiting periods at these facilities, which give rise to problems of economic inaccessibility (Perera, Gunatilleke & Bird 2007:385-386).

3.5.2. Economic inaccessibility

Economic inaccessibility is one of the factors that affects adherence to the DOTS programme. If patients cannot afford the costs of travelling long distances, it gives rise to

high patient default. Referring to article 14th of the International Committee on Economic, Social and Cultural Rights' (ICESCR) recommendations, the government should make available public health care facilities (for example, clinics and hospitals), goods (e.g. medicines) and services (e.g. behavioural care, medical or emergency services) in sufficient quantity, and they make sure that these facilities are functioning well (Ngwena & Cook 2005:116).

The DOTS programme requires TB patients to come to the hospital or clinic each day to be observed by the healthcare professional taking their medication for the first phase of the treatment (Greene 2004:422). Additionally, while this is very important in addressing the problem of non-adherence, mandatory hospital visits bring upon poor patients increased time and transport costs, and this can also lead to increased default rates from the TB control programme.

Again, in a community that is well-educated, that knows about the importance of adherence, such a centralised programme may lead to increased non-adherence than it can prevent. If patients have to walk about 5km to the healthcare facility, then this shows a problem that needs

to be addressed by the government as this contributes to the TB patient's defaulting.

3.5.3. Quality of care

Lengthy and inconvenient procedures in healthcare facilities may deter patients from adhering to the treatment regimen (Perera *et al.* 2007:387). Private care is perceived to be of a higher quality than is public care, the reason being that private care over public care is considered to be of convenience, shorter waiting times, and better staff attitudes.

Gilson & McIntyre (2007:687) are of the same view, when they say that the critical factor that influences perceived quality of care in health facilities is staff attitudes. Irrespective of the government's introduction of policies like Batho Pele and the Patients' Rights Charter, the problem of staff rudeness in government facilities is widely reported (ibid). Unprofessional behaviour a problem to very sick TB patients waiting for hours to receive their medications is unprofessional as it does not respect the dignity and worth of humans and remains a deterrent to public service usage.

Adherence to TB medication is a complex issue influenced not only by socio-cultural and economic factors but also the attitudes of healthcare workers and the overall quality of TB care at DOTS centres (Johansson *et al.* 1996:179).

Discrimination by healthcare professionals on the basis of disease at healthcare facilities worsens the problem of non-adherence to the DOTS programme (Kaona *et al.* 2004:2). This is particularly true when there is no privacy during drug collection schedules and as a result of this TB patients may decide not go and collect their medication at the healthcare facilities. So the type of language used both at the healthcare facility and the home has strong implications on the reactions patients may have and the adherence to their drug medications.

3.5.4. Access to good quality care services is still inequitable in rural areas

People in rural areas normally have difficulty in accessing healthcare services unless healthcare services are highly decentralised (WHO 2006). Weyer (2007:391) writes that despite the control of TB in South Africa being fully integrated into the primary healthcare services and

decentralised to district level, delivery is hindered by competing health priorities, slow district reform and deficient management capacity, particularly at the level of implementation. Therefore, providing poor people with quality healthcare is not only a challenge for those in remote rural areas but also for the urban poor such as those living in informal settlements.

Minnaar (2003:330) reports on the development and the importance of having the district healthcare system in South Africa. So, the district health system should ensure effective leadership, and must consist of a decentralised leadership team for the delivery of comprehensive and integrated healthcare to the population. The term decentralisation refers to transferring of authority from the central government to such bodies as local government, to make policies and decisions, carry out management functions, and use of resources (Katz & Green 1997:68).

The advantages of decentralising resources, functions and authority to lower levels is that the district health system has shown to be an appropriate form around which to organise and manage health services (Katz & Green 1997:210). And again, it has shown to be closer to communities and therefore an appropriate level for facilitating community participation in addition to an

understanding of, and identification with community needs. It also ensures access to healthcare services. In terms of size, Katz & Green (1997:210) further say that it is seen as convenient for the organisation of a package of health services which effectively ensures access to the majority of the healthcare needs of all the citizens. Additionally, it should be large enough to be able to operate a district hospital, and management of support for all healthcare workers operating from health centres, units, and post.

The vulnerable TB patients living in the poorest communities often find it difficult to approach the district hospitals for TB treatment (Bates *et al.* 2004:370). So, this inability to access healthcare is the main obstacle for commencement with early TB therapy, and also "prevention of severe diseases and death". Furthermore, passive case finding identifies approximately half of active tuberculosis cases, and the DOTS programme can only be implemented for cases that are found.

3.6. Progressive realisation of rights

Section 27 (2) of the Constitution of the Republic of South Africa requires the government to take positive measures

to assist the general population in realising the right to access to health care services (Ngwena & Cook 2005:127-129). In addition, the state may be obliged to adopt legislation and policies in realising the right to health, make provision of healthcare services, which includes DOTS programmes for TB patients, and to ensure access to the underlying determinants of health such as nutritiously safe food, potable drinking water, basic sanitation and adequate housing and living standards.

So, in many countries, resource and other constraints can make it difficult to fulfil all rights immediately and completely (WHO 2001). Additionally, this principle of progressive realisation allows the government to proceed "progressively" with special attention to the "maximum of its available resources." On the same matter, inadequate resources cannot be used as an excuse not to implement human rights (WHO 2001). It is the government's responsibility (or obligation) in supporting the fulfilment of basic human rights and services in resource poor areas.

It is their responsibility, again, to take all the necessarily measures which includes but not limited to legislative, administrative, budgetary, and judicial, towards the fulfilment of human rights. Furthermore, this includes the

government's responsibility in providing some kind of remedy that people know about and can access if they feel that their health-related rights have been impinged upon.

3.7. Conclusion

In this chapter, I looked at the problem of non-adherence, factors that contribute to non-adherence and the emergence of drug-resistance. Non-adherence to the treatment regimen is the barrier to the management of TB globally. It is clear that many individuals infected with TB are consistently unable to present to healthcare facilities for treatment presenting the issue of non-adherence.

One of the important factors that can contribute to non-adherence to TB medication is the issue of counterfeit medication. Counterfeit medications were referred to as mislabelled medicines manufactured with substandard safety, quality, and efficiency. Therefore, these medicines may be a hazard to the TB patient's health because they lack the required strength to cure TB. TB patients can experience severe side-effects and default from the DOTS programme. Access to healthcare is also vital, particularly for the vulnerable groups. The state must ensure that healthcare facilities is accessible for all population groups.

Chapter 4

Is there a moral duty for patients to adhere to TB treatment? Factors contributing to non-adherence

4.1. Introduction

Non-adherence to treatment is a major problem despite different interventions that are directed at improving treatment completion, and also a major barrier to finding effective solutions (Munro *et al.* 2007:1231). Moreover, this may be due to deficiency of comprehensive and holistic understanding of barriers of adherence to TB medication or completion of treatment. In the same context, adherence to the DOTS programme may be influenced by the interaction of a number of factors.

Non-adherence is also a complex, dynamic phenomenon with a number of interacting factors that influence the patient's treatment taking behaviour (Cramm *et al.* 2010:2). Furthermore, it poses a substantial threat to both the individual and public health, and it is linked with a higher transmission rates, the relative incidence of TB, and the costs of TB programmes.

4.2. Adherence: Culture and Myths

Deficiencies in National TB control programmes are deepened with widespread misconceptions and false beliefs among individuals infected with TB (Khan *et al.* 2006:211). Moreover, "these myths have turned TB into a social stigma." This stigmatisation is an important factor that contributes to the patients' reluctance in seeking treatment, or affecting adherence to the DOTS programme.

In some cultures, being diagnosed with diseases like TB is seen as a social-disgrace. This cultural myth is a problem and it affects management of TB. The consequences of these myths are that the TB patient may be discriminated against by members of the family and/or the community. When patients attend the DOTS clinic, for example, it will be obvious that they have TB. In this way, the patient may fail to adhere to the treatment with the fear of being stigmatised.

For example, *"I was coughing a lot, and I lost weight and became ashamed and embarrassed to be together with my friends. I didn't know what they were thinking about me honestly. I then withdrew myself from them. Sometimes I was irritable and didn't feel like talking to anyone even at home"* (Naidoo *et al.* 2008:6). According

to Johansson *et al.* (1996:182), “TB creates fear of the disease and of the patient, fear of death and of social isolation.”

Inaccurate ideas about TB may lead to stigmatisation of TB patients, so, they may decide to default from the treatment therapy they are currently receiving. Patients may think that it is a shameful thing to be diagnosed or to live with a disease like ‘TB’ (Bate 2002:5). In this context, “In African traditional culture sickness has both social etiology and social consequences” (Magesa 1997:172-179). Moreover, people who are very ill, and there is no hope that they may get better, become a source of pollution to society, and so, they are hidden by the family.

Example of this; *“I arrive early in the morning so that people could not see me. I used to conceal my illness from people...people think that we are the filthiest people...it was really difficult that I have TB” (male patient,* South Africa*)* (Munro *et al.* 2007:1240)*.*

This practice is often seen in the community with AIDS sufferers whereby the family will hide the patient, and in some cases the patient is discriminated against or “even expelled from the community” (Magesa 1997:172-179).

So, a positive attitude from the TB patient and moral support from family members and friends is the key to early diagnosis and sustaining drug intake for TB which otherwise is often stopped once symptoms disappear after initiating drug therapy for a short period (Yadav *et al.* 2006:194).

"Everybody in my birth-home knows about my disease. Everybody knows about my suffering and so I am taking drugs. They didn't feel anything wrong. All of them love and don't hate me – rather they take care [of me] more" (Baral *et al.* 2007:5).

Family instability and unsupportive family members is associated with the disruption of TB therapy (Naidoo *et al.* 2008:15). Moreover, when very sick individuals are faced with disharmony in their families, or are experiencing family instability or social isolation, the chances are very high that they will be non-adherent to the treatment regimen.

According to Magesa (1997:179), this myth communicates a number of behaviour patterns because this deters people from testing. In the case of TB patients, if they are confirmed to have TB, "the myth appears again in the person's desire to avoid the information getting out."

"*None of friends know that I'm suffering from TB. I didn't let them know. I don't have faith in my friends so I don't say [this] with friends. They do back biting and if they get a small issue they will make it larger and so I didn't share this suffering with them"* (Baral *et al.* 2007:4).

In some African cultures, removing people with incurable diseases from the society was often seen as a traditional way of dealing with the evil associated with the sick (Bate 2002:6). Similarly, Selgelid *et al.* (2008:241) say that in the past, patients with infectious TB were isolated in a hospital for recuperation for prolonged periods, and sometimes even for the rest of their lives. Moreover, the reason this was done was to protect others from being infected with TB. And, this is still been done even today, in many countries, it is common to isolate people infected with TB until it is proven that they are no longer infectious.

In this culture, sickness is understood as a communal affair (Bate 2002:6). Still, the sickness of one person will affect the entire community which in turn will be sick. Therefore, isolation in this way is used as a way to prevent further sickness from affecting the whole community "by cutting off the human relationship which makes it up."

Social factors play a crucial role in the diagnosis and treatment of the TB patient (Yadav *et al.* 2006:194). Ibid notes that the stigma associated with the disease is the cause of delayed treatment and poor adherence to the DOTS programme. Stigmatisation, Perry & Donini-Lenhoff (2010:225) wrote that it predominates in global health ethics because it prevents patients from seeking care from health care facilities or professionals, engenders fear of those who are diagnosed with certain diseases, affected groups or communities may be discriminated against, and also, in some cases, the stigmatised group have also vehemently been attacked. Further, the society we are living in, often expresses negative feelings about individuals with diseases such as HIV/AIDS and TB.

In Baral *et al.* (2007:6) a community member said

> *As the disease can transmit to other people, there is risk of getting disease in the community. So, we need to take care of ourselves. How? – we should not meet with the people who have TB; we should not visit the homes of those who do have any of the members with TB.*

Similarly, misconceptions and stigma which is related to the dreaded nature of the disease are cultural barriers

leading to unwanted behaviour towards TB patients (Yadav *et al.* 2006:194). Moreover, these factors tend to stop TB patients from attending social functions and isolate themselves from their loved ones.

Like leprosy and HIV, TB is an extremely stigmatised social disease (WHO 2001). Furthermore, widely held, and sometimes mistaken, beliefs about what leads to TB, how it spreads, and whether it can be cured are associated with stigmatisation and discrimination against TB patients. So, these people infected with TB, may do anything to escape stigma and discrimination. They may also go to a great length to prolong both their suffering and the time they remain infectious by rejecting a diagnosis of TB and "shop around" for another, a more 'acceptable'. In this way they can hide their diagnosis from their employers, family and/or the community they are living in; or simply ignore or delay their diagnosis altogether (WHO 2001).

An example in Munro *et al.* (2007:1240)'s study explains this,

> *We are two sisters and marriage arrangements have been made with men from our family. If my (future) family in laws knows that I have TB they will be sure then to break the engagement...I'm worried*

for my sister. Her engagement also could break off because of my sickness".

On the same issue, TB patients also may do their best to avoid healthcare facilities which are associated with TB diagnosis for fear of exposure, instead seeking diagnosis treatment in a different setting (Munro *et al.* (2007:1240). While this may give them more privacy, it can also make travel, thus completion of the treatment regimen very difficult.

Delayed diagnosis, in particular of smear–positive pulmonary TB (PTB) cases leads to prolonged spread of TB (Karim *et al.* 2007:330). Furthermore, delayed diagnosis and treatment has been a serious problem for most DOTS programmes. This is because many people who are afraid of the stigma attached to TB are unlikely to discuss it and also to learn about TB or even go for early treatment (Gibson *et al.* 2005:940). This highlights the importance of the education programme that could help in the reduction of persistent stigma surrounding the disease, and/or also that could help TB patients to adhere to their medical treatment.

So, due to these cultural myths, patients have the view that once their diagnosis becomes known, their families will respond by turning away from them (Yadav *et al.*

2006:194 & Johansson *et al.* 1996:180). Close family members and friends might fear that they will contract the disease, and as a result of this TB patients will feel guilty and unable to share their problem (Edginton *et al.* 2002:1078). Such non-disclosure by the TB patient can cause harm to the health of the family members, the patient themselves and the community at large by spreading the disease because of avoidable delays in the treatment (Edginton *et al.* 2002:1078).

The DOTS programme is not only the solution in addressing the burden of TB (Edginton *et al.* 2002:1079). A large number of patients continue to suffer from TB due to insufficient awareness, social stigma, myths, and discriminatory attitudes towards them hindering their treatment seeking behaviour. These socio-cultural factors and belief systems are more disturbing for the TB patient, and they have a greater impact on their social lives, especially women's marital relations and help seeking behaviour (Karim *et al.* 2007:331). As a result of this, "most TB patients, considering their symptoms normal, often seek help from inappropriate sources, delaying timely consultation with appropriate ones". Gibson *et al.* (2005:939) wrote that TB is a treatable disease, although practically this only makes more sense in the developed

nations where TB control programmes are well supported by the government. In the same vein, it remains, then, that “TB is a disease best understood through the lens of social consequence”.

Much needs to be done, therefore, in educating the communities for attitudinal change, active measures for early identification, sustaining treatment, minimising defaulters through community participation (Yadav *et al.* 2006:194). By so doing, it will help to curb or control the TB problem in high risk group population in the community.

Secondly, the myth of margins also affects adherence or patients defaulting from the DOTS programme. In most developing world cultures, some diseases such as TB are seen as something that only happens to people who are living on the margins of society, and are seen not as ordinary people (Bate 2002:2). Moreover, these is because ordinary people are viewed as living normal lifestyles, which follow social conventions, are educated, employed and are also settled. Ibid says this is referred to as the myth of the ‘European civilisation’.

So, TB is often seen as the disease that affects the poor people in the developing world. These are the vulnerable population. The vulnerable and marginalised population

often bear an unjustified amount of health problems (WHO 2001). They live in poverty, in under-developed areas, and they often travel longer distances to healthcare facilities to receive their TB treatment. Johansson *et al.* (1996:180) wrote that TB is often seen as a hereditary, infectious, 'dirty', social disease, which affects only the poor. Again, hard work or overwork and bad hygiene are the factors believed to cause TB.

Poor people may also be stigmatised by the diagnosis of TB. Stigmatisation and thereby social isolation seem to be the result of the fear of contracting the disease from others, but also rejecting "dirty" TB patients who are seen as practising poor hygiene and are living in poverty (Johansson *et al.* 1996:181). This will affect their adherence to the TB treatment regimen. The reason for this is that low socioeconomic status is often associated with unhealthy behaviours or lifestyles among other cultures (Morales *et al.* 2002:3). This is perpetuation of the stereotype that poor people are the only ones who are infected with TB in the developing world, and this is unethical. So, this may have an effect (or affect patient's adherence to treatment) on treatment adherence to TB medication among poor people. Poverty, inequality, and social conditions are often associated with poor people

(Gibson *et al.* 2005:939). So, the reason for this is that poor people are economically and politically disadvantaged, dwell in overcrowded conditions with insufficient nutrition, and are also often isolated from medical facilities.

The health seeking behaviour of poor people who become infected with TB is much different to that of wealthy people (Bates *et al.* 2004:373). This is because poor people often experience problems in mobilising resources rapidly, consequently delaying seeking treatment.

Moreover, in an attempt to save money they first consult traditional healers or herbalists for help. The reason for poor people preferring these courses of action or whether high costs and poor quality of formal health care forces their decision to consult traditional healers is not clear[4] (Bates *et al.* 2004:374). On this view, some TB patients even if they seek and to a certain extent trust biomedical treatment they still believe that it must be complimented by other practices (Gele *et al.* 2010:5).

[4] These may be the reasons: poor quality of services which includes staff attitudes, worn-out buildings, long delays or waiting periods, and inaccurate tests (Bates *et al.* 2004:374). So, this may be reasons why people, particularly the poor with limited resources, prefer to self-treat or consult traditional healers and the herbalists.

Cultural differences in health beliefs and practices are seen as barriers to the effective distribution of healthcare (Greene 2004:404). These may not be helpful for TB sufferers because they may end up using counterfeit drugs or medicine that is not approved by the medicine control council (MCC) of South Africa.

Vulnerable TB patients may die from the use of counterfeit medication or drugs because some of these medicines are not scientifically tested, and therefore not approved. The manner in which these drugs are dispersed or prepared by some of the traditional healers or herbalists is unsafe, and also unethical. So, it is important to note that a delay in the treatment of TB is associated with worst morbidity and mortality (Greene 2004:404).

TB should not be linked to poor people only, as this may harm health promotion messages. Moreover, poverty and discrimination can have an effect on literacy and education, and can also alter prioritization of needs and the ability to maintain a steady schedule (Greene 2004:404). So, these factors can affect the TB patient's ability to adhere to the treatment therapy. The association between TB and poverty is linked to overcrowding, poorly ventilated housing, malnutrition, smoking, stress, social

deprivation, and poor social capital (Figueroa-Munoz & Ramon-Pardo 2008:733). Greene (2004:404) says that the knowledge about how TB is contracted is an essential part of effective prevention. Furthermore, if healthcare professionals and patients agree on how TB can be contracted, professional advice is likely to be well received. Consequently, default from the DOTS programmes will be limited.

Another myth that contributes towards TB patients from defaulting from the DOTS programme is the myth of incurability. Bate (2002:7) says this myth is based on "western scientism". This myth can be explained by the fact that TB is now the major cause of illness and death worldwide, particularly in the developing countries where it is fuelled by HIV/AIDS (Cramm *et al.* 2010:1). Again, the co-infection rate of HIV is approximately 73% in all TB cases. So, in this myth there is no cure for HIV/AIDS (Bate 2002:7). This simply means that experiments that were conducted in the form of scientific methods have shown that once the HI virus is inside the human body it cannot be eradicated (Cramm *et al.* 2010:1).

When TB patients are also HIV positive, this myth can inform a number of behaviour patterns among patients, if they find truth in it (Cramm *et al.* 2010:2). So, one of the

things that can affect the behaviour patterns is that being HIV positive is a death sentence. This can be depressing for the TB patients who are HIV positive because they know that they may not be cured. As a result they may default from taking TB medication because they have lost all hope of being cured.

Writing in the *Nursing Update,* Anon (2010:27) says, “HIV and TB are the twin epidemics”. There is a cure for TB, including those who are diagnosed with HIV (ibid). Therefore, the fact that TB is curable, it makes understanding of TB very important for people living with HIV, and their families.

4.3. Adherence: Influence of Culture

In a study conducted in one of the provinces in South Africa Cramm *et al.* (2010:2), reveals some misunderstandings about the diagnosis of TB and its relationship with HIV. Non-adherence to drug therapy can occur when patients discover that they are co-infected with HIV (Naidoo *et al.* 2008:14). Furthermore, the emotional reaction of the dual diagnosis may be probably of shock, psychological numbness, and disbelief. Still, this feeling of being overwhelmed may hamper the TB

patient in psychologically integrating and accepting that he/she is infected with TB, and also HIV positive. Consequently, the patient will need time to process the fact that he/she is infected with the HIV virus, an incurable disease.

Some people believe that TB patients will develop HIV, and this perceived link could be explained by the fact TB is now main cause of morbidity or mortality among an estimated 5.5 million people in South Africa who are living with HIV/AIDS (Cramm *et al.* 2010:2). Whereas some people believe that TB is a typical African disease and also thinks that only people living in poverty will become infected with TB.

Many wrong beliefs about the diagnosis of TB may have an effect in the patient's non-adherence to the DOTS programme. As Ibid have found out that some people have the belief that irresponsible individuals who do not adhere to their treatment are mainly to blame for spreading TB (90%). Furthermore, besides, they also accuse these individuals of hiding their TB status for fear that the community might react negatively (95%). Still, they also believe that people who are infected with TB through smoking and drinking are getting what they

deserve (74%), and also TB patients have no respect from the community.

In Baral *et al.* (2007:7), community members said:

> *In the community TB can easily be guessed to those people who do have a habit of drinking alcohol and smoking cigarettes. People seem thin and usually not interested in food ... we have seen and heard that TB usually got to those who drinks, who smokes, who [goes to many] prostitutes, who drives trucks, who do not care about food*

It is also because in some communities being diagnosed with TB is perceived as having infringed cultural rules and TB is known locally as a disease of "bad" people (Edginton *et al.* 2002:1079). Further, the reason why it is perceived that way is because TB is associated with heavy drinking and poverty. This finding by ibid suggests that people who are diagnosed with TB are subjected to a high level of stigmatisation. In the family, if one of the partners is diagnosed with TB, this can cause family and social disharmony, as there is a belief that they should abstain from making love (Edginton *et al.* 2002:1079). In addition, a myth exists that red urine which is due to the

TB drug rifampicin will adversely affect the other sexual partner, and as a result the other partner will look elsewhere for sexual gratification.

Other beliefs which can affect adherence to the DOTS programme are the belief that TB can only be treated by traditional healers. Some TB patients may believe that "no doctor is able to cure this" (Edginton *et al.* 2002:1080). Beliefs about the causes of TB appear to vary in different communities and to specific cultural groups.

An example of this is of a 45 year old HIV negative female woman who was diagnosed with TB (Naidoo *et al.* 2008:9),

> *I did feel better after the treatment but then in the middle of 2000 I started becoming sick again. Since then I was on an off. I drank some herbal medication from different herbalists. Then in 2003 my mother heard about the witchdoctor who said he will be [able] to help me. My family then had to give a sheep plus fifty rand to him. He also gave herbal medication to drink. It didn't help but I continued to use it with the hope that was going to get better. But what I noticed since I have been using the medication from the clinic my health has improved a*

lot ...I use them in the same amount because to me both treatments are strong and they can help me. The only extra thing with the water I get from the spiritual healer is that it also helps in keeping away evil spirits

In addition, reports from some African countries have described the importance of treating TB by traditional healers which is thought to originate from sexual "misbehaviours" or from witchcraft. Again, some traditional healers who were consulted by TB patients attribute the disease to bewitchment or food poisoning (ibid: 10). So, some patients visiting traditional healers consider them a valuable alternative.

TB patients often visit traditional healers before they go to the hospital. This is the source of the problem because patients often come to healthcare facilities too late, and when the disease has already advanced. The traditional healers may prescribe[5] something different to what the doctors will prescribe in the hospital.

It is believed in some African cultures that failure to consult a traditional healer within a certain time (for example, six weeks) of the onset of the illness will result

[5] It is believed that injections given to patients by traditional healers are fatal (ibid).

in death. The use of an African indigenous healer plays a role or is associated with periods of non-adherence to the DOTS programme (ibid: 14). This is because consulting a traditional healer when an individual is very sick is "deeply embedded in the psyche of African people, and forms part of the African cultural identity" (Naidoo *et al.* 2008:9). As a result patients feel that the going to the medical doctor or the hospital will delay their real recovery (Edginton 2002:1078). Furthermore, it is reported that traditional healers keep patients for a period of four weeks, after which they say if the patient does not improve, they are referred to medical doctors for consultation.

Other problems which may be associated with non-adherence to the DOTS programme is that patients in some communities prefer receiving TB treatment from someone they can trust, not a stranger (ibid:1079). The reason for this is that some people believe that if they receive treatment from strangers they may be bewitched.

In Edginton's study, it was found out that respondents felt strongly that nurses should give patients the right to select healthcare givers whom they know and trust. In the same study, other patients said that they preferred self-treatment.

4.4. Adherence: Adverse side-effects of drugs

Adverse side effects may contribute to the patient's non-adherence to the DOTS programme. A patient might complain of a funny taste in his/her mouth,

> *...Unpleasant metallic taste in his mouth...asked if a non-vegetarian diet would improve this problem. He was laughed at by the (provider) along with a number of others in the clinic and some personal remarks were made...he finally left treatment* (Munro *et al.* 2007:1239).

TB drugs, even though they have been improved slightly over time, are very difficult to consume because of severe side effects (Oze 2002:26). Moreover, short-course chemotherapy was developed as an alternative to the current TB medications but it still has unpleasant side effects.

Anti-TB medications cause a lot of side-effects which can range from nausea and rashes to kidney failure and liver damage (Booker 1996:92). Consequently, TB patients stop taking their medications long before they are advised to do so. These end-up causing an easily communicable, deadly, and potentially incurable disease in the form of multi-drug resistant TB. The problem related to TB

medications is that patients may not know or be informed what to do once they have side effects (Wares *et al.* 2003:333). So, a number of patients give the reason of side effects for defaulting from the DOTS programme. For example,

> *I said no wonder they defaulted, many of them defaulted, you know, because it is (side effects) just too much, it is just too much ...* (Munro *et al.* 2007:1239).

Non-adherence to the DOTS programme is also associated with patients stopping treatment when they feel better (Naidoo *et al.* 2008:8).

> *I think that I feel healthy, my lungs are good, but I have a bit of fear that the sickness will return....but as I told you, I don't want to take this pills, they make me sick, they hurt me ...* (Munro *et al.* 2007:1237).

So, the TB patient in order to avoid the side-effects will sometimes continue with the TB medications until their health *seems* to improve, and then decide to stop the treatment (Oze 2002:26). In this case the patient fails to uphold his/her ethical duties in the physician-patient relationship (Resnik 2005:171, 178). Furthermore,

patients diagnosed with diseases such as TB that pose a threat to public health have an obligation to follow the prescribed treatment or a moral duty "to cooperate with the treatment plan". This pattern of non-adherence to the treatment regimen has been established in other conditions as well, for example, a patient who is taking medication to lower cholesterol may default because the symptoms have disappeared (Naidoo *et al.* 2008:13-14).

This may indicate that either the information regarding the DOTS therapy is not accurately being given or the information given to the patient is not absorbed (Bam *et al.* 2006:274). It also calls attention to the fact that each person may react differently to TB drugs. Thus health care professionals should be sensitive and aware of other medications which may relieve adverse drug side effects.

Adherence to drug-therapy appears to be better during the initial, acute phase of the illness when the individual patient is more symptomatic (ibid). In addition, normally patients experience symptom relief by continuing with the recommended drug therapy for TB.

TB is an ancient disease with which communities have lived for many decades (Jaiswal *et al.* 2003:632). Curing people of TB is a great challenge which requires the TB patient to adhere to treatment therapy (DOTS

programme). Achieving cure will require that all the individuals involved in the DOTS programme do their part (Jaiswal *et al.* 2003:632). Furthermore, taking steps to change the way people think about TB is very important. Still, this may mean taking a new look at the way one uses the language that stigmatises the TB patient, and places undue burden on one responsible set of patients over another (for example, “misleadingly labelling TB patients as defaulters”).

On the same matter, blaming of the TB patient, that is, the degree to which the term “noncompliance” (noncompliance a more authoritarian term) became a means of positioning the responsibility for treatment failure on the patient instead on the provider (Greene 2004:402).

4.5. Adherence: An ethical analysis

In this section I will argue that TB patients have a moral duty to adhere to the treatment regimen once they have accepted TB treatment. Although the TB patient have the right to decline medical treatment, their duty to adhere to the DOTS programme is a *prima facie* duty, which can be

overriden by their other ethical duties if they outweigh them (Resnik 2005:167-168).

However, TB patients do not have the right to refuse to adhere to the treatment regimen if their non-adherence to TB medications will pose a substantial threat to the general populace. Moreover, the patient's duties in this case not to place others at risk of harm implies that the patient adhere to the prescriptions that are required to prevent harm to other people. Still, a TB patient who is not taking medications as directed places himself or herself as well as the community that he/she lives in at risk because the disease can spread and harm others.

Consider these examples from Naidoo *et al.* (2008:6):

> *I got infected from my father. During that time I was staying with my parents at the Eastern Cape. My father had been suffering from TB and refused to eat his treatment properly. Even when the TB workers came to visit him at home and tried to encourage him to take his treatment, he refused ...*
>
> *I got infected from my uncle whom I was staying with at my maternal grandmother's house at the Eastern Cape, in the homelands. My uncle was refusing to eat his treatment and tried getting the*

assistance from the clinic to come and give him his treatment at home. He only ate his treatment for one week and thereafter he stopped again. So, when i started getting sick and my mother heard about it she said that i must rather come and stay with her here in Cape Town. I then had to organise with the clinic to give a referral letter that states that I am a TB patient so that I could get treatment here.

A TB patient who does not adhere to his/her medications places other people at risk because he or she could spread the disease. This also implies that the patient can develop a drug resistant form of TB which is costly to treat, or may not respond to medications. People with diseases that pose a threat to the populance have an obligation to adhere to their treatment (Resnik 2005:178).

Additionally, public health officials can take the necessarily measures such as isolation or quarantine in order to protect the community from harm (The Harm Principle and isolation / quarantine measures are discussed in chapter 5 under the Stewardship model).

Eventhough the medical treatments are physically ingested under direct supervision (at least in the initial

phases), it is mainly the responsibility of the TB patient to adhere to the treatment regimen. Defaulting from the DOTS programme has serious consequences for both the individual patient and the community.

4.6. Conclusion

Attempts must be made to improve treatment outcomes and understanding of particular barriers that affect adherence to TB treatment. Again, understanding of the facilitators of non-adherence to the treatment regimen, and of patience's experience with regard to the treatment is very important. These will also help in understanding why problems of treatment adherence are much more severe in certain cultural groups, and also develop effective strategies and eradication.

So, there are cultural barriers and myths, beliefs, and adverse side effects of the treatment that may affect adherence to the DOTS programme. The recognition of cultural barriers and linguistic barriers to TB control is very important to developing effective interventions (Greene 2004:403).

Chapter 5

The government's obligations to public health

5.1. Introduction

In this chapter I will discuss the role of the government in public health under the stewardship model. According to the Nuffield Council on Bioethics (NCB 2007), the concept of the stewardship implies that a liberal state has obligations to look after the essential needs of its people, individually or in general. Consequently, they act as stewards to individual people, for example, taking care of different needs that arise from factors such as age, gender, ethnic background, or socio-economic status. The concept of Stewardship places responsibilities on governments to provide necessary conditions that will able its people to lead healthy lives, particularly decreasing health inequalities (NCB 2007).

5.2. Essential principles for evaluation of public health interventions

As a disease with a known causal agent, pathogenesis, mode of transmission and predisposing factors, and

having an effective cure, the goal to eradicate this disease in communities in South Africa should be possible (Verma *et al.* 2004:1). The Nuffield Council of Bioethics identifies three principles which they claim are crucial to the ethical evaluation of public health interventions, that is, the harm principle, caring for the vulnerable, and autonomy and consent (Dawson & Verweij 2008:194). All these three principles give central place to autonomy.

5.2.1. Principle 1: The harm principle

The public health risk posed by TB requires that programmes be developed that will secure the cooperation of those who have TB and eradication of the social, medical, and psychological barriers to adherence with drug-therapy (Bayer 1993:651). In addition, it also allows for the ethical, constitutional, and legal justification for individuals to undergo such treatment.

The harm principle provides the ethical and legal foundation for enforced isolation of individuals with TB during the acute infectious stage of their illness (Bayer 1993:651). Moreover, legal orders to isolate individuals with active disease are uncommon, and a lot of those

patients were very ill and desired treatment. The harm principle also conditions which constraints of personal freedom can be acceptable in a manner that is fully consistent with the supreme value of the principle of autonomy (Dawson & Verweij 2008:194).

As conceived by JS Mill the harm principle holds that the only end for which mankind are necessary, individually and collectively, in interfering with the liberty of action of any of their number, is self-protection (Van Bogaert 2008:63). According to Anomaly (n.d), any endeavour in interpreting the harm principle often brings up two fundamental difficulties, that is, what is harm, and how can it be measured? Moreover, in applying the harm principle, a clear conception of the kinds of harm that is to be prevented is needed. Hence, by virtue of analysis it is true that for 'A' to be harmed by 'B', 'B' must act in a manner that decreases 'A's welfare.

Mill's harm principle allows for the restriction of an individual's autonomy and self-determination for the purposes of preventing harm to others, and benefit liberty overall (Coker *et al.* 2007:612). Furthermore, this is one of the reasons taken by the state for advocating the detention of individuals with TB since they are considered to pose a threat to the public health. According to ibid

(2007), in recognising this principle, a lot of human rights documents (such as the Siracusa principles[6]) recognize that the public's health might justify some qualifications of rights. Health authorities have a duty to prevent the transmission of TB to other individuals who are not yet infected with the disease, which can be life threatening if other people are infected. If there is no intervention, the welfare of these people will be damaged for no good reason. Therefore, an individual with tuberculosis who does not adhere or refuses to take his or her medications as directed places himself or herself as well as other individuals at danger because that individual could spread the disease (Resnik 2005:178). Consequently, that individual will be reducing other people's welfare interests. Health authorities should act in the interests of the population as a whole.

Besides the principle of autonomy and self-determination introduced above, the principle of beneficence is also of great importance. Van Bogaert (2008:96) defines beneficence as a "means for doing good for others".

[6] Coker *et al.* (2007:613) say that the Siracusa principles provide a useful framework by which to examine whether coercive public health interventions to curb the spread of infections such as XDR-TB are justified. Furthermore, "The first of the principles is the notion of whether any proposed restriction of (individual) liberty is a legitimate objective of general concern". Therefore, the objective of preventing the transmittance of tuberculosis and reducing drug resistance is undeniably both legitimate and also in the public interest.

Additionally, from a utilitarian point of view, it is referred to as a moral obligation because the aim is to maximise the amount of global happiness, pleasure, or utility. Nowadays, government officials do not blow the ram's horn to warn of contagious diseases in the community, but health promotions about appropriate individual behaviour are given in ways that trigger the ethical, if not legal, responsibilities of citizens to do no harm to others (Ibid 2007:624).

It is therefore important to note that individuals infected with TB have an ethical duty not to harm other uninfected individuals (Harris & Holm 1995; Selgelid *et al.* 2008:239). Selgelid *et al.* (2008) do note that it is also unreasonable to expect infected individuals to take *all* possible measures to avoid infecting others. Therefore, appropriate limitations to this duty must be taken into consideration. Again, though in this case where a contagious individual fails to take appropriate precautions to avoid infecting others, and fails to warn close contacts that he/she is infected with TB, the main question is whether the health worker should take the decision to inform identifiable third parties at risk (Ibid 2008).

From the utilitarian perspective, the health worker should inform the third parties at risk. This is the duty to avoid

harm to other individuals who are uninfected. Transmitting TB to other people who have not consented to run the risk of this disease should be considered harm to others. As Selgelid *et al.* (2008) puts it, “failure to warn could (in the context of TB) conflict with the innocent third party’s right to life, which many would say is more important than the incautious patient’s right to confidentiality”.

In the case of TB, compromised confidentiality and restrictions in the TB patient’s movement have been viewed as an acceptable social price to pay for effective disease control (Liechty & Bangsberg 2003:1385).

5.2.2. Principle 2: Caring for the vulnerable

Vulnerable groups are ones without the capacity to make informed judgements on their own (NCB 2007). The vulnerable groups often are the ones with higher rates of TB infection and diseases are likely to have the worse prognosis than the general population (Figueroa-Munoz & Ramon-Pardo 2008:734). Furthermore, their complex needs are often ignored and they are faced with barriers to access to healthcare.

The vulnerable may experience barriers to accessing healthcare such as stigmatisation, poor cultural awareness, and psychological distress, disruption of families and social networks, and economic difficulties (Figueroa-Munoz & Ramon-Pardo 2008:734). So, the vulnerable population may be targeted unfairly, for example, they may be isolated unfairly in the event of an outbreak of an infectious disease such as TB.

TB is often stigmatised affecting the patient from taking or continuing with the medications. So, the impact of disease reporting is often felt by the patient to the benefit of those without TB. If vulnerable populations such as the poor, women, and children are the ones who are targeted when reporting of disease, these groups may be harmed. This is invasion of privacy, and these groups need to be protected by all means because they can be harmed by "virtue of the violation of their privacy".

Vulnerable groups may be harmed when their rights to privacy and confidentiality are not observed, and this will make adherence to the DOTS programme problematic. When notifying the state about disease, the TB patient should be told that it is imperative that their condition be reported and that by law it is also important that this will be done confidentially. So, programmes such as the

DOTS should pose fewer risks to other moral claims, such as liberty, confidentiality, and justice.

According to Immanuel Kant (1724-1804) on the force of morality,

> *...All living natural bodies having needs, sensations/desires, and intelligence are thus human, and as natural bodies they (humans) have an absolute worth that makes it necessary that all humans treat each other as one wishes to be treated ...* (Papadimos 2007:2).

Therefore, those who are vulnerable like the poor with infectious diseases such as TB should be treated with respect and in a benevolent way. Kant also says that "human beings have an intrinsic worth, that is, dignity which makes them valuable above all price" (van Bogaert 2008:191).

The government then has an obligation to care for the vulnerable and protect them from any form of harm that may occur when taking measures to control the spread of TB. The state has an obligation to reducing inequalities in health and also protecting the health of the vulnerable populations.

5.2.3. Principle 3: Autonomy and Consent

The central ethical dilemma in public health is balancing respect for individual autonomy and liberty with the obligations of governments to provide their citizens with some form of protection in relation to health (NCB 2007). Thus, liberal governments have obligations in terms of provision of healthcare to the population as a whole.

Concerning John Stuart Mill's argument *On Liberty,* van Bogaert (2008:70) explains that in order to maximise the overall human welfare, respect for the autonomy of other individuals is required provided that this respect does not harm others as long as those individuals respected possess competency and maturity. Again, "given that human happiness is constituted to a large extent in the exercise of autonomy, it follows that respect for autonomy is a major obligation to maximise welfare".

Respect for autonomy translate into the right of self-determination and is often extended to embrace a right to privacy (Brazier 2006:399).

According to the stewardship model the state should not force people or even put restrictions on people's movements unnecessarily (NCB 2007). Furthermore, this includes the responsibility of the state to provide the right

conditions under which people can be able to live healthy lives. When TB patients are under the DOTS programme, or having supervised therapy in their homes, every attempt must be taken in ensuring that such treatment poses minimal intrusion with the patient's daily routine and does not compromise confidentiality (Bayer 1993:653). Additionally, failure to do so would impose additional burdens on the patients and compromise their adherence to drug-therapy.

The stewardship guided government recognises the health of its people as its primary asset. What this means is that higher levels of health is related to a greater overall well-being and productivity (NCB 2007). Below is a summary of the stewardship model (Calman 2009:e7):

Concerning goals, public health programmes should:

- Aim to reduce the harm caused by ill health that people might impose on one other;
- Aim to reduce causes of diseases by governmental rules that will ensure environmental conditions that maintain good health, such as provision of clean air and water, safe food and appropriate housing;
- Give special attention to the health of children and other most vulnerable groups;

- Promote health not only through the provision of information and advice, but also by programmes that assist people defeat addictions and other unhealthy behaviours;
- Aim to ensure that people lead healthy lifestyles easily, for example by provision of convenient and safe opportunities for exercise;
- Ensures that society accesses healthcare facilities; and

  aims to minimise health inequalities

In terms of contraints, such programmes should:

- Not attempt to force people to lead healthy lifestyles;
- Minimise interventions that are introduced without consulting the affected individual or without procedural justice
- Attempt to reduce interventions that are perceived as intruding personal privacy and in conflict with important individual values**.**

5.3. The Intervention Ladder

NCB (2007) wrote that one of ways in which this philosophical model can be converted into policy is

applying the “intervention ladder”. The intervention ladder is a tool that is used to demonstrate how “interventionist a public health policy is” (Purkayastha 2008:1). This intervention ladder is also a view that holds that policy choices must be framed in such a way as to ensure that restriction to individual freedom is minimised (Dawson & Verweij 2008:194).

The higher up the ladder a particular intervention is ranked the stronger the need for validation and proof for carrying out that intervention (NCB 2007). Therefore, compulsory quarantine or isolation is an example of a measure at the top of the ladder that is undertaken when there is an outbreak of an infectious disease such as TB.

5.3.1. Compulsory quarantine or isolation

The desired health outcome should be accomplished through measures that are less intrusive (Radoilska 2009:137). Hence, from both an ethical and legal view, these are measures that rely on voluntarily cooperation and are less intrusive in terms of human rights are concerned (Singh *et al.* 2007:0021). Nevertheless, failure of the measure that are less intrusive often leads to public health authorities carrying out measures that are more

restrictive, provided that the expected health benefits still offset the interference with people's lives and financial cost (Radoilska 2009:137).

Measures that are intrusive must be taken with due consideration for the possibility that they may "increase disincentives to seek care" (Singh *et al.* 2007:0021). Nevertheless, if due care is taken to provide for the rights and needs of individuals who are detained and therapeutic goals are kept paramount, such measures may play a significant role in containing drug-resistant TB before it is transmitted more generally in the population globally.

Although, the constitution of the republic of South Africa bestow a wide range of human rights on individuals, these rights can be restricted if doing so is reasonable and justifiable (Singh *et al.* 2007:0021). Furthermore, the judiciary also has the right to issue orders forcing involuntary confinement or hospitalisation and treatment against the wishes of individuals, if doing so is to the benefit of the public. Further still, this is the last resort where non-coercive measures have been ineffective.

When the TB patient leaves the healthcare facility or hospital against medical advice and having a history of noncompliance to treatment is a strong indication for

involuntarily confinement (Verma *et al.* 2004:4). So, measures such as involuntary confinement have been endorsed by the European Court on Human Rights (ECHR). The ECHR case involved the applicant who was HIV-positive who had infected another party and disobeyed the instructions of healthcare authorities to refrain from irresponsible and harmful behaviour (Singh *et al.* 2007:0021).

Thus, compulsory quarantine or isolation has significant infringement of liberty and can only be ethically justified when the harm to others is minimised (NCB 2007). Moreover, the ethical validation of applying these two measures involves weighing the traditional harm principle on the one hand, and individual consent and the importance of avoiding invasive interventions on the other. So, where risk of harm to other individuals can be radically reduced, these considerations can be outweighed (NCB 2007).

Generally patients who are diagnosed with TB receive their treatments from healthcare facilities such as the local clinic or TB hospital as outpatients, and are encouraged to complete their six month course treatment (Hlongwane 2009:29). So, with the emergence of the extra drug resistant TB (XDR-TB) strain, the government

has to introduce a policy which forces XDR-TB patients, who in all probability pose a danger to public health, to be admitted at the TB hospital, and be isolated from their families. Isolation implies separating XDR-TB patients for a period of communicability that is, known infected persons from the community for the purposes of preventing further transmission of the infectious agent (Fidler, *et al.* 2007:620).

Isolation also implies treatment which includes DOTS programme, which the detaining authority offers or imposes on individuals subject to isolation orders. Fiddler *et al.* (2009:29) also writes that the purpose of this policy is to monitor patients who do not take the full course of their prescribed medication. So, isolation of TB individuals typically, if not globally, is due to failure of the patients to heed instructions concerning treatment regimen (Fidler *et al.* 2007:624).

And, quarantine refers "to the restrictions on the activities of a healthy person or group of people suspected of having been exposed to an infectious disease and who might go on to develop it" (Gainotti *et al.* 2008:469). Similarly, implementing quarantine powers which includes authority for both isolation and quarantine actions is essential, not only for dealing with certain cases but also

utilisation of such authority allows for a window on broader issues of public health, the legal rules, ethical principles, and the governance systems that support it (Fidler *et al.* 2007:616).

Both isolation & quarantine's purposes is the prevention or limiting the transmission of diseases. Drug-resistance TB such as XDR-TB is difficult to manage as compared to multidrug-resistant TB (MDR-TB) which is easier to manage (Su 2008:827). Furthermore, XDR-TB is regarded as being virtually untreatable, and is also defined as being simultaneously resistant to at least isoniazid and rifampicin. Again, this includes the two most powerful classes of second line anti-tuberculosis agents, that is, the injectable agents and the fluoroquinolones. Hlongwane (2009:29) says that the drug resistant TB strain is made worse by those patients not completing their prescribed dose, that is, their full six to nine month drug regimen.

5.4. Conclusion

The government is obligated to take cognizance of the essential needs of its people, individually or in general. Consequently, they act as stewards to individual people, for example, taking care of diverse needs. Therefore, the function of the government in public health is unique due to their responsibilities, and their main focus is taking care of the health of the whole population, rather than the health of an individual. Taking care of the vulnerable groups is important.

They should seek to provide conditions that allow people to be healthy, and decreasing health inequalities. It is also important that they undertake interventions that reduce harm to the population, also respecting the autonomy of others provided that autonomy does not cause harm to others. In protecting the population from harm it requires that TB patients who fail to comply with treatment be isolated to protect others. Non-adherence to treatment therapy can lead to drug-resistant.

Chapter 6

An ethics framework for public health

6.1. Introduction

In this chapter I will look at ethical issues involved in the problem of patient adherence as it concerns the fair communal distribution of burdens and benefits. Effectiveness in the ethical application of public health programmes relates to the published scientific evidence indicating that any proposed intervention will do more good than harm.

Nancy Kass (2001) formulated a six step framework for public health: 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 minimised? Are the alternative approaches, 5) Is the program implemented fairly, and 6) How can the benefits and burdens of a program be fairly balanced”. This framework is recommended in this study for analysing the effectiveness of the DOTS programme. Furthermore, it is also an analytic tool designed to help public health practioners consider the ethics implications of proposed

interventions, policy proposals, research interventions, and programmes.

6.2. An ethics framework for public health

6.2.1. What are the public health goals of the DOTS programme in South Africa?

The DOTS programme was introduced as a public health measure for the treatment and management of TB. The foundation of TB control remains the detection and cure of new infectious TB cases under the DOTS programme (Karim *et al.* 2009:929). The South African DOTS programme should aim to reduce the incidences of mortality and morbidity due to TB. The incidences of TB cases and patients defaulting from the DOTS programme should decrease dramatically.

Non-adherence to the DOTS programme leads to increased mortality and morbidity. Moreover, a reduction in the incidences of mortality and morbidity will be the basis on which the DOTS programme will be assessed. So, the DOTS programme must be designed as a means to increase TB patients' adherence to drug therapy.

A high cure rate is very important if this country is to interrupt the transmission of TB (Karim *et al.* 2009:929).

Furthermore, South Africa's treatment success (cure or treatment completion) rate for TB cases is about 58% whilst the WHO's ultimate goals is to cure more than 85% of new drug-susceptible cases of the disease. Still, if a target of 85% is reached, this will reduce a number of TB incidences and mortality.

- *The late detection of TB cases*

Late detection of TB cases doesn't help either. So, a high detection rate of new infectious under a DOTS programme is vital to reduce the period that that TB cases remain infectious and undiagnosed in the population (Karim *et al.* 2009:929). If there can be 70% case detection, 85% cure and the patient is not co-infected with HIV, incidence should fall around 5-10% per annum and prevalence more quickly (Dye *et al.* 2007:364). South Africa's case detection rate needs to improve from the current 62% to the WHO's ultimate goal of 70% cases (Karim *et al.* 2009:929). As mentioned before in this study (in 1.3.1), 50% of the detected never receive treatment, reflecting a classic mistake of identifying TB cases but not treating them adequately (Weyer 2007:391).

The following must be implemented to improve case detection (Karim *et al.* 2009:929): ensure that the presence or absence of TB cases is recognized in each symptomatic individual presenting to healthcare facilities, active screening of domestic contacts of communicable TB cases, identify communities with a high TB prevalence in order to target programmes that promote increased identification with respiratory symptoms for TB investigation, and provider-initiated and intensified TB case finding in individuals with HIV co-infection attending healthcare services.

6.2.2. Is the DOTS programme effective?

Currently, the following challenges affect or reduce the effectiveness of the DOTS programme in South Africa (NTBCP 2003):

- *The late presentation of patients*

Late presentation of patients to the DOTS programme can be associated with the stigma surrounding the diseases. The stigma that occurs as a result of TB and HIV causes the infected individuals to hide their illnesses and seek help very late when the disease has already

advanced (NTBCP 2003). Consequently, the patient may harm or spread the disease to others, while this could easily be prevented. Again, cultural factors can be a hindrance to adherence to the DOTS programme, and associated with stigma that affects the patient from continuing with treatment regimen. These factors can render the programme to be ineffective because they can affect the patient in seeking much needed help.

In cases where there is considerable stigma about diseases such as TB, systems such as home visits or door-step delivery should be developed (Buse *et al.* 2005:11).

- *The failure for TB patients to complete their treatment.*

The failure of TB patients to complete their treatment under the DOTS programme is also a problem. These affect or reduce the effectiveness of the DOTS programme, and the aspect of the problem will be the development of drug-resistant TB which may be complex and difficult to cure (NTBCP 2003). Furthermore, MDR-TB is associated with failed or interrupted treatment.

Failure to complete treatment can be related to disruption in drug-supply.

Striking healthcare workers, for example, can disrupt drug supply to TB patients. These can affect the effectiveness of the DOTS programme especially when the strike takes longer. When patients present at healthcare facilities for treatment and there is no staff, and TB drugs also not available they will default from the DOTS programme. Striking health workers can cause more harm to the patient that good. When health workers are on strike systems must be in place to ensure that TB patients receive their drugs.

The government must ensure that there is an uninterrupted drug-supply of high quality, affordable, first-line TB drugs (WHO 2006). According to WHO's (2006) global plan, "the target for 2015 is the clinical trial of a rational combination therapy that can reduce the required time of treatment to 1-2 months or less". These can help also in reducing interruptions of treatment since the current TB treatment is about six (6) months or more. Therefore, a longer treatment duration can be associated with treatment interruptions.

Experiences in other countries show that the proper management of supplies of appropriate ARV's drugs is

essential to the sustainability of the HIV programmes, and is a requirement for increasing community confidence in the public health system as a regular and reliable source of HIV/AIDS treatment (Steward *et al.* 2004:35). This information can be extrapolated to TB programmes.

Systems for drug procurement, as well as storage and distribution systems which ensure the required level of security and accountability for TB drugs across the entire supply chain must be in place (Steward *et al.* 2004:35). Well-run DOTS programmes should be able to prevent interruptions of anti-TB drugs through relable drug forecasting and six-monthly procurement (Harries *et al.* 2008:0860). Again, TB (and ARV's) drugs are "valuable commodities, and corruption and leakages can occur during storage and distribution of drugs" (Steward *et al.* 2004:35).

Experiences in Botswana show that the following actions might be useful (Steward *et al.* 2004:35):

- Purchasing covered, lockable trucks with air conditioning for transportation of TB and ARV drugs,

- Using and reinforcing existing 'habit-forming drug' protocols for drugs,
- Ensure that a limited number of people access these drugs in pharmacies
- Ensure that storage sites are well secured, and
- Ensure that TB patients adhere to their treatment as prescribed.

In India, all drugs for each TB patient are packaged in pouches. One pouch is for the initial phase of treatment, and one for the continuation phase of the treatment (Khatri *et al.* 2002:460). Additionally, these pouches are placed in a box that contains the entire treatment for a single patient. So, the use of boxes makes the logistics simpler, and reduces any chance that some medicines may disappear from the supply chain and, therefore, greatly increasing the patient's confidence in the DOTS programme. Moreover, when patient's treatment commences, the patient's name is written on the box, to ensure a sufficient supply of drugs. Khatri *et al.* (2002:460) also say that drug quality should be systematically and independently monitored, to ensure that the treatment is effective and to prevent loss of confidence in the DOTS programme.

Health workers who are involved in DOTS programmes need to be trained and, they need to have appropriate knowledge, understanding and information about new treatments, side effects of TB drugs, mode of transmission of TB, nutrition and drug storage (Steward *et al.* 2004:33-34). Additionally, the widespread lack of experience with TB medication across the entire supply chain, combined with the lack of pre-existing curricula for rapid training of health providing TB (ARV's) in Southern African healthcare personnel, is a significant challenge for public health sectors in developing countries.

So, every healthcare facility should be able to establish its current cure rate and develop a locally appropriate plan to reach the target within a specified period (Karim *et al.* 2009:929). Moreover, policies to support such a plan can be considered, such as giving once-off incentives to individuals who completed their TB treatment successfully. Non-governmental organisations (NGO's) and family members can be enlisted to provide on-going support to TB patients (Steward *et al.* 2004:34). In addition, employment of lay counsellors can ease the burden of healthcare workers (or nurses).

6.2.3. In South Africa what is known about the problems facing its implementation?

Although the DOTS programme has been implemented in at least three quarters of the country, implementation of the programme is faced with serious challenges, that is, the threat posed by TB/HIV co-infection (NTBCP 2003). On this matter, between 1995-2005, the South African government made significant progress in the control of TB by implementing the WHO strategy, that is, DOTS strategy and standardised recording system, and by strengthening central coordination of TB control programme and disease control management at all levels (Karim *et al.* 2009:923). So, despite the progress that was made, TB cases continued to increase, fuelled by the HIV-infections.

Other problems that affected its implementation was that in the last decade the South African government's response to TB and HIV/AIDS diseases was marked by denialism, and poor implementation of policies and programmes (Karim *et al.* 2009:921). Moreover, their response to the epidemics was marked by incompetence, ignorance, and deliberate efforts to undermine scientific evidence. This was evident when the then Minister of Health's attempted to undermine the HIV/AIDS treatment

programme, promoted untested and unlicensed traditional remedies and vitamins as alternatives to medical treatment of HIV/AIDS (Karim *et al.* 2009:924). Furthermore, the Minister's insensitivity towards the fight against HIV/AIDS and TB was evident at the XVI International Aids Conference in Toronto, Canada, where the South African government's stand at the exhibition hall displayed food such as garlic, beetroot, and lemons for HIV/AIDS treatment instead of Anti-retroviral therapy (ART).

Therefore, the South African government needed to take decisive action for the implementation of evidence-based, priorities for the control of HIV and TB epidemics (Karim *et al.* 2009:921,926). Moreover, the South African government formulated the comprehensive document, the TB strategic Plan for South Africa, 2007-2011. Furthermore, despite South Africa's formulation and broadly accepted Strategic Plans for HIV/AIDS and TB it lacks political will. And, also inadequate financial and human resource capacity to deliver on many of the urgently needed health care intervention are major deficiencies in the country's response to these two epidemics. "Similarly, South Africa has not been able to

stimulate effective implementation of the TB Strategic Plan, 2007-2011" (Karim *et al.* 2009:928).

6.2.4. Can burdens be minimised? Are there alternative approaches?

This will require that the South African government or health care authorities reduce burdens as soon as they are recognised (Kass 2001:1780). The threat of HIV/AIDS/TB co-infection has been recognised as a burden that affects the progress in the implementation of the DOTS programme.

Creation of the Stop TB partnerships which builds on the South African DOTS programme and comprehensive HIV/AIDS prevention and care can be initiated for the prevention and care of HIV-related TB (WHO 2006). Furthermore, the goals of this partnership must be:

- Promotion and support of research for the establishment of a comprehensive evidenced-based policy on collaborative TB/HIV activities.
- To build effective partnership between TB and HIV programmes and communities, and therefore,

engaging all healthcare workers in implementing TB/HIV activities in areas and/or provinces such as Kwazulu-Natal with a high burden of HIV-related TB.

TB/HIV activities are not a replacement for DOTS programmes and comprehensive HIV/AIDS prevention and care programmes (WHO 2006). Instead, their main purpose is to build on the current programmes, thereby exploiting the synergies and commonalities between them to deliver comprehensive, high quality, accessible, patient-centred prevention and care, and support services to individuals who are co-infected with HIV and TB. Again, this will help in reducing the impact of HIV-related TB.

6.2.5. Is the DOTS programme implemented fairly?

This emphasizes the ethics principle of distributive justice which requires the fair distribution of benefits and burdens. Faced with the number of avoidable deaths due to TB which occurs every year in South Africa, one might be tempted to think that they amount to a major infringement of the doctrine of justice famously laid out in

A Theory of Justice by John Rawls (1971) (Tolchin 2001:152). Furthermore, a country that allows its people to die of TB when it has the resources to prevent such deaths is not fulfilling Rawls' second principle of justice. So, this requires that unequal resources be distributed to the greatest accepted benefit of the vulnerable population within that community. Again, when resources are available that could prevent TB deaths and are not used, it is obvious that the unnecessarily dying people are worst off, and "that the resources are not being distributed to the greatest advantage".

- *Prioritise the needs of the poor and vulnerable population*

According to WHO (2006), access to quality TB services should not be based on the type of TB, financial capacity, or the social status of the patient in the community. Furthermore, given the low socioeconomic status of majority of people with TB in South Africa, "a pro-poor and equity-based approach requires that healthcare services pay special attention to the needs of the most disadvantaged groups". This means identification of the barriers that impede access to healthcare services, and also implementing measures intended for the early

diagnosis and effective treatment of TB to reduce the social and financial burden of the disease for patients (WHO 2006).

TB control should be strengthened to allow everybody to gain access to treatment medication. The DOTS programme should not be seen as benefiting certain individuals, for example, benefiting rich people over poor people. Poor people are often vulnerable and marginalised which makes access to TB treatment impossible. The vulnerable population show signs of the worst health status (Papadimos 2007:1). Rich people should not only be the ones who are accessing DOTS programmes, in most cases they are the ones who have access to resources. Quoting John Rawls' second principle, "there must be equality of opportunity provided by social structures so all citizens may have the same chance of gaining income, wealth, position, and social advantages" (Papadimos 2007:1).

The aspect of social vulnerability with regard to TB treatment needs to be addressed. TB patients may be refused or denied TB treatment because they are classified as among the poorest and most socially marginalised in society (Singh *et al.* 2002:699). Moreover, these people are denied the opportunity for TB treatment

because they are deemed unable to comply with the DOTS programme, since they are poor, with no stable employment, with less social networks in the community to fall back on for support, or considered very sick. Still, the government should be responsible to all patients not to those who are relatively better off and/or living in less socially and economically stable conditions.

The most important aspect in the control of TB in South Africa is that the government should make TB medications and healthcare facilities more accessible to every TB patient. This will improve adherence to the DOTS programme, and consequently improve the cure rate. Inaccessibility to the DOTS programmes should be a thing of the past. Everybody infected with TB should benefit from these programmes or resources. These resources may include financial, physical and human resources. If for example, healthcare facilities are not adequately staffed adherence to the DOTS programme may be a major problem. They may be a problem in dispatching TB drugs, and no follow up if the patient is non-adherent to TB drug, etc.

Therefore, equity is crucial when it comes to public health programmes and it is important to ensure that human rights are not sacrificed because of the nationally and

internationally approved target cure rates (Singh *et al.* 2002:700).

6.2.6. How can the benefits and burdens of a programme be fairly balanced?

In this section I look at the benefits that arise when the DOTS programme is being implemented, then the burdens of the programme. Lastly I will discuss how this benefits and benefits can be fairly balanced.

- *The benefits of the DOTS programme*

1). This benefit of the DOTS programme is based on the theory that holds that protecting or promoting public health always has precedence over the *TB patient's privacy* (Childress *et al.* 2002:171). It is the utilitarian theory which aims to maximise utility by focusing on achievement of the greatest possible collective benefit (Calman 2008:8). Moreover, what this means is that actions are generally measured by the degree to which they reduce pain and suffering, and also promote overall happiness and wellbeing. As a matter of principle, it also allows the welfare of some individuals to be sacrificed if

this were to lead to an increase in overall welfare (Calman 2008:8).

TB programmes such as the DOTS are known to control the spread of TB, and also reduce the development of drug-resistance TB, which is the benefit. Drug-resistant TB makes it difficult to control TB and it poses a serious threat to public health. In this case, the risk of infection is reduced to society in general.

Effective TB control is a public good because TB is a highly infectious disease, curing an individual of the disease makes the population healthier (Peabody *et al.* 2005:352). Moreover, TB treatment and control should be the responsibilities of the government and public policy. Therefore, maintaining the health of the population, for example, the health of the workforce and adult men or women, who normally are the bread winners, is a 2) *societal benefit*, and since the burden of TB remains high and 3) *the economic benefits* of TB control outweigh the costs, there is a strong incentive for the government to develop policies to reduce the spread of disease.

- *The burdens of the DOTS programme*

Appropriate measures when reporting of TB should be followed because burdens such as 1) *social stigma* ensue from unnecessary disease disclosure (Kass 2001:1781). Furthermore, TB patients may find it difficult getting employment, or they can be discriminated against in the workplace. Moreover, TB patients are often stigmatised by the community they are living in and they may have their bodily integrity compromised because of the treatment they are undergoing (Fidler *et al.* 2007:624).

If individuals infected with TB are harmed or stigmatised in any way, default rate from the DOTS programme may increase. The DOTS programmes may also be a burden in certain situations particularly when it targets the vulnerable and marginalised groups. In other societies TB is seen as a disease that affects a particular group of people.

2) There is a theory that holds that *individual liberty* should take precedence over protecting or promoting public health (Childress *et al.* 2002:171). It is the Kantian theory which differs from utilitarian in than its interest is not to "impose a moral obligation to maximise human happiness, but only to take it very seriously and seek to promote it" (van Bogaert 2008:51). Its interest also, "is not

motivated by others' interests but by their intrinsic worth or dignity".

Then, a burden can arise from the DOTS programme when there is infringement of the TB patient's right to privacy. When the TB patient's privacy is sacrificed for the sake of public health, harm to the individual patient may occur. The right to free movement by the patient, and the relationship with family and friends may be affected. The right to work so that they can provide for their families can be violated if TB patients lose their jobs, and also access to a social security grant (this can be referred to as 3) *socio-economic burdens*).

TB patients may be seen as a danger to society by healthcare authorities. The reason for these burdens is because some public health interventions to control the spread of disease to society are fear driven (Morgan & Mir 2008:16). Moreover, these public health measures tend to provoke fear and panic in the communities. Again, this fear can lead to emotionally driven decision-making that violates 4) ethical principles like *autonomy and social justice*. According to Kass (2001:1780), threats to autonomy are the most obvious burdens posed by public health interventions, such interventions can, in some

instances, be associated with physical risks, or risks to individual health as well.

The DOTS programme can also be a burden to the vulnerable groups. Morgan & Mir (2008:16) wrote that it is important to give consideration to individual rights where possible, as the blame, stigma, and isolation associated with public health measures to control diseases are especially real for diseases linked to the poor or the disenfranchised.

Some public health policies to prevent the transmission of an infectious disease are formulated without carefully considering the goals of those policies (Gostin & Mann 1999:56), that is, whether the measure adopted for the prevention of disease will accomplish those goals, and/or whether the specified benefits will outweigh the financial and human rights burdens. Hence, Verma *et al.* (2004:3) writes, “self-management assures the most autonomy and dignity and least intrusion in a person’s life, whereas detention is decidedly autonomy denying”.

- *How can the benefits and burdens of the DOTS programme be fairly balanced?*

This step of the framework simply means that if public health programme such as DOTS, is likely to accomplish its stated goals, the possible burdens with the programme are known and reduced, and it is anticipated that it will be implemented in a non-discriminatory manner, then a decision should be taken as to whether the anticipated benefits validate the recognised burdens (Kass 2001:1781).

Respect for human rights is crucial when implementing the DOTS programme. So, it is very important to uphold human rights for maintaining both public trust and public co-operation in fighting against the transmission of TB (Gainotti *et al.* 2008:468). Empower the community with knowledge about infectious diseases such as TB, and the danger they pose to society and the importance of the DOTS programme.

When the DOTS programme is implemented, procedural justice should prevail. Furthermore, there must be fairness and transparency in the procedures by which decisions are made (Kass 2001:1781). Still, society should be able to engage the government in a democratic manner to determine the benefits of the DOTS

programme and also being aware that this might cause infringement to personal liberty and make other burdens unavoidable. So, an open discussion in this regard is necessary of what the society will benefit from good public health and why such benefits cannot be obtained without infringements to personal liberty.

Kass (2001:1781) writes “in balancing values and interests, therefore, the greater the burden imposed by a programme, the greater must be expected public health benefit, and the more uneven the benefits and burdens (that is, burdens are imposed on one group to protect the health of another), the greater must be the expected benefit”.

6.3. Conclusion

The number of TB cases in South Africa is still very high. This can be associated with late detection of TB cases. The DOTS programme should be able to achieve a high detection rate of new infections to reduce the period that TB cases remain infectious and undiagnosed in a community, and those cases must be treated. The programme must be implemented fairly, paying particular attention to the needs of the vulnerable. Their needs should be prioritised based on a pro-poor and equity-based approach that requires that healthcare services pay special attention to the needs of the most disadvantaged groups. When implementing the DOTS programme, again, it is important that burdens that arise as a result of the programme and benefits are balanced. Infringement to liberty can occur, and also there are public health benefits that arise as a result of implementing the programme.

Chapter 7

Concluding Remarks

TB is indeed a major problem particularly in developing countries such as South Africa. The morbidity and mortality rate due to TB is very high. The sad thing is that TB is a curable disease which can be treated with inexpensive drugs as compared to e.g. HIV treatment (ARV's) which is expensive. What makes matters worse is the problem of TB and HIV co-infection. The relationship between TB and HIV is devastating, and therefore presents a greater challenge to the control of TB.

Strengthening the implementation of the DOTS programme

In this section I would suggest ways on how Implementation of the DOTS programme should be strengthened in order to reduce the number of patient who default from the programme. I will first discuss why political commitment is important or necessary in the implementation of the DOTS programme.

Political commitment

It is vital that the government of South Africa review its current DOTS programme placing greater attention on the problem of adherence faced by its citizens, particularly the most vulnerable people in our country. TB prevention and treatment should be the government's number one priority. Khatri *et al.* (2002:459) maintain, "Government commitment is the engine that drives any health programme".

So, the government with the help of society should do what it can to fight the spread of TB, and reduce the impact of this disease on human development and the economy. This is important because regular interaction at all levels of society can lead to the creation of a large body of highly skilled, motivated and responsible TB workers (ibid: 459). Moreover, TB control societies must comprise of members from civil society, and each to be chaired by the relevant district. Again, the government and district members can make decisions on budget formulation, hire contractual staff, purchase the necessary items needed for the DOTS programme, oversee the programme planning, implement, and monitor the programme.

Political commitment is needed in acknowledging publicly the extent of past successes and failures in the fight against TB and HIV, and to show a firm commitment to these two epidemics (Karim *et al.* 2009:928). Furthermore, new high level political commitment should show enthusiasm and be determined in the fight against these diseases.

1) Commitment at all levels of healthcare service

Commitment to the DOTS programme is crucial at all levels to make sure that essential resources, such as staff, drugs and laboratory supplies are allocated (Walley *et al.* 2001:5). In addition, it is important to form partnerships, that is, public and private healthcare services, non-governmental organisations, medical aid companies, private practitioners, and the local community.

Encouraging the community to participate, working in partnership will result in positive health outcomes (Meikle 2007:2). Moreover, with the community actively participating in decision making, identifying concerns about TB and suggesting solutions will result in better cooperation with medical treatment.

2) Address the HIV burden

In addressing the problem of adherence to the DOTS programme, an effort must be made to manage the HIV epidemic. The reason for this is that HIV patients are more likely to be infected with TB, and these affect patient adherence to the DOTS programme. According to WHO (2006), "to effectively address the TB/HIV co-infection, national TB and HIV/AIDS control will need to work very closely, in order to jointly develop policy and operational guidelines to accelerate efforts towards addressing the needs of the increasing numbers of dually-affected patients".

South Africa is currently not doing well in its efforts to fight the HIV epidemic (Karim *et al.* 2009:928). Furthermore, what is more surprising is that the country has the financial resources, and the potential to rise above these challenges. So, the problem is that it is unable to dedicate resources comparable to the magnitude of the problem. It also lacks the leadership to tackle this problem.

According to Karim *et al.* (2009:928), "active surveillance for drug-susceptible and drug-resistant TB is a crucial component of TB control activities and will help to guide rational deployment of resources". And, a large amount of

data are available for HIV, but not for TB. However, in the past South African scientists had few, if any, opportunities to provide and interpret the available data to policy makers and planners for either epidemic. Furthermore, due to the hostility between government and scientists, the available data were not used. Further still, the current leadership should develop a partnership with researchers based on mutual respect to develop information base that can be utilised to guide action and monitor performance.

3) Addressing poverty in TB control

The relationship between TB and poverty are well established (WHO 2006). The vulnerable groups such as the poor, homeless, displaced populations, women, and children are the ones who are affected more by TB. So, in most instances TB is spread more readily in the environmental conditions of poverty such as overcrowding, inadequate ventilation, and malnutrition (WHO 2006). On the same matter, improving the socioeconomic conditions will reduce the number of TB cases, access to care, its rational use, and quality of care.

Assess the barriers to accessing TB services faced by the poor and vulnerable groups (WHO 2006):

- Economic barriers

In addressing these barriers, TB services should be integrated within “primary care provision, encourage pro-poor public-private mix (PPM) DOTS, promote TB control in workplaces, improve the coverage of smear microscopy networks, avoid user-fees, provide free smear microscopy and other diagnostic services”.

- Geographic barriers

The usual health seeking behaviour in times of illness is to travel a shorter distance to the public facility or government hospital (Perera, Gunatilleke & Bird 2007:385). So, geographic barriers may be addressed by extending diagnostic and treatment services to remote regions, providing free transport to TB patients from such regions, and promoting community-based TB care (WHO 2006).

- Social and cultural barriers

TB patients may choose to consult traditional healers for their treatment instead of seeking professional help or hospital care. When the medication prescribed by traditional healers is not helping, they will come to healthcare facilities and the disease is already advanced. Consulting traditional healers may also be influenced by individual culture, myths and beliefs and/or side effects of the drugs.

Cultural differences in health care and practices were seen as barriers to the effective distribution of healthcare. These become worse when society likened TB or HIV to bad behaviour. Some may even go to the extreme of associating TB with drinking and smoking and/or prostitution. Consequently, TB patients hide their diagnosis from family, co-workers and friends and, the patient will end up using medications that are not approved. This does not benefit TB patients because they end up using counterfeit drugs detrimental to their health.

The use of counterfeit medication is a challenge in the fight against TB due to its severe side-effects because the quality of these medications is generally poor. Social stigma as a result of being diagnosed with TB is a problem because it hinders patients from seeking help

instead they hide their diagnosis and put the lives of other people at risk.

Social and cultural barriers can be addressed by identifying areas and population groups where TB services are underutilised (WHO 2006). Moreover, involve former TB patients who have completed treatment and TB support groups to campaign for services and encourage community mobilisation.

- Health systems barriers

It is vital to assess staff attitudes towards poor patients or the vulnerable groups, and also investigate as whether decentralisation leads to strengthening of TB services at primary care level (WHO 2006). Furthermore, address health system barriers by "engaging in health service decentralisation to ensure capacity strengthening in less well-served areas and by establishing TB control as district level priority".

4) Addressing the health workforce crisis

Human resources are the backbone of the healthcare system, without them, individual or public health

interventions cannot be carried-out (WHO 2006). Additionally, a shortage of and less motivated human resource is a barrier in achieving TB control. During healthcare worker's strikes the quality of the health services are affected. The quality of care that patients with TB receive from healthcare facilities is very important, and can affect adherence to the DOTS programme.

Proper remuneration of healthcare professionals can change staff attitudes. As Peabody *et al.* (2005:352) put it "we are now learning how to precisely measure how much government regulation and incentives change provider behaviour and therefore quality of care". However, this is an area that needs further research.

The South African government needs to commit itself to "support the overall structural and financial changes needed to improve the availability, distribution and motivation of competent healthcare workers" (WHO 2001). Furthermore, they should plan strategically to ensure the availability of adequate and competent human resources for healthcare in general, but what is more important they should ensure that there is enough human resources for TB programmes.

5) Community education

Education is important, and the community must be made aware about TB programmes that are used in controlling or curbing the transmission of TB. The role of the community should involve encouraging the TB patient to seek treatment, educate them about the disease, its symptoms (Walley *et al.* 2001:2). Having knowledge about the disease, how it is diagnosed and treated is very important, and this may help the patient to overcome the stigma. Moreover, community education plays a vital role in the treatment of TB because it will encourage patients with TB symptoms to seek treatment, and this will encourage them to adhere to TB drugs for the complete six to eight month course (ibid).

Health education is very important since "it is the ideal public health intervention", it is completely voluntarily, and will seek to empower TB patients to make the right decisions once they are equipped with the necessary information about their treatment (Kass 2001:1779). TB education is the area where the government needs to be more responsible and make an investment. "What is invested by a country/government, education for example, benefits the health of the nation" (Papadimos 2007:6).

So, investments in education regarding the importance of adhering to treatment medication can yield positive results such as TB patients completing their treatments, and as a result cure will improve, the number of drug resistance cases will drop. Society should be equipped with education and given the necessary information regarding adherence to TB medication, possible side-effects of the drugs, the effects of non-adherence to treatment medication, such as possible physical complications, treatment failure, multidrug-resistant TB and extensively drug resistant TB (Kandel *et al.* 2008:47b).

However, education programmes should not be aimed only at the vulnerable and marginalised groups such as the poor of a certain community. The problem is that people might see TB as a disease that affects only the poor people. These people lives in poverty, and they find it difficult to access healthcare. Social stigma in these cases often if only the poor, women and children are seen as the only ones who are carriers of TB. Stigmatisation looms large in global health ethics because it hinders those with TB from seeking care, brings forth fear in those who have the disease, causes discrimination against the whole group, or communities,

"and has, in some cases, led to violence against the stigmatised group" (Perry & Donini-Lenhoff 2010:225). As Perry & Donini-Lenhopff note (ibid)

> *…the opportunity for public health intervention will be missed entirely if we all come to believe, through well-intentioned media campaigns, that only certain groups are at risk.*

Instead of stigmatising the TB patient, support can play a crucial role in helping the patient to adhere to the treatment (Walley *et al.* 2001:3). And, it is one of the features of the DOTS strategy.

6) Identify TB patients who default from treatment.

According to WHO (1994), services for TB should identify and address factors that are a hindrance to adherence to the DOTS programme. It is essential to identify patients who stop treatment before they are cured (Walley *et al.* 2001:3). So, how do you identify defaulters? These can be done by issuing of treatment cards or taking photos (kept at the treatment facility) for record purposes and, this can help in identification of patients who have defaulted from the DOTS programme (ibid). Furthermore, these treatment cards can be updated at supervisory

visits by healthcare workers and/or during monthly visits with the TB patient. Again these must be filled by the healthcare worker as they observe each dose of treatment.

People who interrupt should be encouraged re-*start* treatment, but this will depend on (ibid: 3):

- The type of person, that is, first TB treatment, multi-drug resistant, or repeat treatment,
- Length of time the patient was on treatment,
- Length of time the patient defaulted from treatment,
- Whether they are sputum smear negative or positive when they come back for treatment, and
- Whether they had been assessed by a trained TB nurse or doctor who will then prescribe the necessary treatment.

6) TB register

A record of every TB patient on treatment should be kept (ibid 2001:7). And this is done to ensure that all patients with positive sputum smear results, that is, those diagnosed with active TB are receiving treatment.

7) Case detection

Screening people who come to healthcare facilities who had experienced a cough for more than three weeks may help in detecting TB (ibid: 2). Moreover, when TB is suspected by the healthcare worker, and had discussed this with the concerned individual, that individual needs to provide samples of his/her cough to be taken to the laboratory for testing. This will help in the detection of TB earlier, therefore, reducing the threat of TB transmission to the community.

8) Smear conversion reports

Patients receiving TB treatment should have smear examinations at two months (new treatments) or at three months (retreatment) (ibid: 8). Moreover, the two month smear conversion report is for those patients who were smear positive at the beginning of treatment. Therefore, follow-up sputum examinations are important to decrease the danger of treatment failure or relapse and to be able to evaluate the cure rate.

Smear conversion reports are the measure of the TB patient's response to drug medication, and also give an early indication of effectiveness of the healthcare facility

in providing DOTS (ibid). Additionally, they are crucial in that a change in smear conversion rates can help to identify problems quickly and address them urgently.

9) Treatment outcome reports

Treatment outcome reports are important because they 1) include information about how many TB patients have successfully completed treatment and how many have not. Successful treatment includes data of how many TB patients were cured and those who completed treatment. Unsuccessful treatment is the data about those who defaulted from the treatment, treatment failures, and those who died. 2) The treatment outcome reports identify whether the treatment schedule is effective or not, and 3) they can be used to assess whether the DOTS programme is providing high quality of care, or whether the quality of care for TB patients needs to be improved.

In conclusion, I have tried to show that TB as a *disease* is possible to cure. However, to stop the increasing rate of TB infection requires a firm commitment from both the government and society. It is the duty of governments to protect their citizens from harm; likewise, citizens too have a responsibility to keep their families and

communities safe. Only by political and social commitment can TB be eradicated.

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