



## Original Article

### Tuberculosis Treatment in The Human Genome Editing Era: Unbundling the Right of Access to Healthcare Services in South Africa

Tamanda Kamwendo 



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**Abstract:** Tuberculosis (TB) is both preventable and curable, yet it is the top killer disease in South Africa. In 2018, about 300,000 people in South Africa fell ill with TB and about 63,000 people died of TB. This demonstrates that the incidence of TB in South Africa is far greater than in other continents. This calls for a paradigm shift in the response to fighting the TB epidemic. Specifically, this necessitates promoting access to progressive treatment methods to fight the age-old disease that is still affecting a greater fraction of the South African population. Treating TB with monotherapy has, in most instances, proven to be ineffective. The burden of the TB epidemic as witnessed in South Africa is a compelling reason for alternative treatment options such as human genome editing. The main purpose of this paper is to examine to what extent the legal and policy framework in South Africa enables the government to provide TB treatment to patients using human genome editing. The paper concludes that the right approach to accessing this technology is important because it provides a solid ground to demand access.

**Keywords:** Tuberculosis, Human Genome Editing, Access to healthcare, health

**Introduction:** Tuberculosis (TB) remains a threat to global health. Although deaths due to TB seem to be decreasing, TB continues to be the leading cause of death in South Africa<sup>1</sup>. In 2019, TBFacts.org reported that 360,000 people in South Africa contracted TB and 58,000 of them died of TB<sup>2</sup>. Tracking national budgetary allocations is also critical in understanding the extent of the TB epidemic

on South Africa's healthcare system. Budget allocations to the Department of Health for HIV and TB have grown by seven percent annually, that is, from ZAR (South African Rand) 11.0 billion in 2013/2014 to ZAR 18.3 billion in 2017/2018. Astoundingly, in the 2022/2023 financial year, ZAR 55 billion which is 86 percent of the total allocation was allocated to health service activities related to HIV and TB<sup>3</sup>.

Lecturer, Department of Private Law, University of the Free State, South Africa

Email: [Kamwendot@ufs.ac.za](mailto:Kamwendot@ufs.ac.za) ORCID ID: <https://orcid.org/0000-0002-5434-113X>

Corresponding author: Tamanda Kamwendo <[Kamwendot@ufs.ac.za](mailto:Kamwendot@ufs.ac.za)>



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**Introduction:** Tuberculosis (TB) remains a threat to global health. Although deaths due to TB seem to be decreasing, TB continues to be the leading cause of death in South Africa<sup>1</sup>. In 2019, TB Facts.org reported that 360,000 people in South Africa contracted TB and 58,000 of them died of TB<sup>2</sup>. Tracking national budgetary allocations is also critical in understanding the extent of the TB epidemic on South Africa's healthcare system. Budget allocations to the Department of Health for HIV and TB have grown by seven percent annually, that is, from ZAR (South African Rand) 11.0 billion in 2013/2014 to ZAR 18.3 billion in 2017/2018. Astoundingly, in the 2022/2023 financial year, ZAR 55 billion which is 86 percent of the total allocation was allocated to health service activities related to HIV and TB<sup>3</sup>.

South Africa also has a very diverse population and an extraordinary variety of TB strains. Hence, the present inability of antibiotics to treat TB permanently indicates the need for an enhanced approach to combat the illness by taking heed to genetic variations among the different<sup>4</sup>. A genome-wide study was conducted on Zulus and Cape Coloureds population with the aim of identifying areas in the human genome containing TB-susceptibility genes. Results showed that TB susceptibility is not monogenic<sup>4</sup>. Moreover, evidence of TB susceptibility genes was found in more than two regions, chromosomes 15q and Xq which showed evidence of linkage to TB<sup>5</sup>. Owing to the genetic complexity of TB and the compounding financial implications current TB medication has on our health budget, there is a need to consider the possibility of human genome editing for the treatment of TB.

Despite that human genome editing may yield valuable results as far as the prevention and treatment of TB is concerned, in a country that is already heavily burdened with diseases such as HIV, the cost of the treatment is too steep and so the South African healthcare system is expected to be confronted with the burden of absorbing high upfront costs. Human genome editing treatments currently cost between \$373,000 and \$2.1 million<sup>6</sup> which locally translates to ZAR5 439 190.44

and ZAR 30, 622 788.00 respectively<sup>6</sup>. The use of gene editing technology to treat TB is therefore dependent on the interpretation of the right of access to healthcare in order to determine the quality of healthcare services South Africans are entitled to. The key question is whether the legal and policy framework on the right of access to health care services in South Africa enables the government to provide TB treatment to patients using this technology.

**Methodology:** In this paper, I implore a doctrinal legal research methodology as it is central to the juridical interpretation of concepts. Furthermore, in discussing health rights and corresponding obligations, social, economic, and political factors form part of the foundation of legal arguments thus, making an interdisciplinary approach necessary. This makes it possible to evaluate the government's efforts in fulfilling its healthcare obligations in light of shifting values as well as other economic factors.

In order to achieve the above objective, the subsequent content of this article has been organized into 3 parts: the first part looks at the Constitutional rights-based position in South Africa; the second part explores the court's jurisprudence and their interpretation of the right of access to healthcare services; the last part focuses on the progressive realisation of health rights.

### **The Constitutional framework of health rights:**

The Constitution and the National Health Act constitute the fundamental legislations of South Africa's health rights. Socioeconomic rights were encoded in the Constitution to make it applicable to most South Africans, particularly the historically disadvantaged. Access to healthcare services in South Africa has historically been inequitable due to gender, colour, disability, and a variety of other factors<sup>7</sup>. Structures built to provide healthcare facilities continue to harbor a disproportionate prejudice against specific communities and diseases. Section 27 of the Constitution is the primary source of

healthcare obligations as it guarantees the right of access to healthcare services for everyone<sup>8</sup>.

The World Health Organization (WHO) has defined 'access' as the equitable availability and affordability of essential medicines<sup>9</sup>. As such, the right of access to healthcare services imposes on government tripartite obligations to protect, respect, and fulfil<sup>10</sup>. These healthcare obligations originate from international healthcare commitments that the South African government, similar to other governments in the world, has promised to undertake as well as the Court's interpretation of socio-economic rights<sup>7</sup>.

The obligation to respect is a negative obligation that enjoins the government not to unnecessarily interfere in the enjoyment of the right (directly or indirectly)<sup>10</sup>. This bestows a duty not to unnecessarily restrict biomedical research and not to unnecessarily interfere in society's efforts to access gene editing technology<sup>10</sup>. Whereas the obligation to protect encourages the government to ensure that third parties do not unnecessarily restrict people's access to certain forms of treatment. The state is further implored, inter alia: to control the pricing of pharmaceuticals and thus ensure that vulnerable populations are given special attention<sup>10</sup>. Lastly, the obligation to fulfill relates to the Government's constructive measures or actions taken to ensure that the right of access to healthcare is realised. This obligation calls for steps that 'create, maintain and restore' the health and well-being of the people<sup>10</sup>. Accordingly, it enjoins the government to take steps to ensure the protection of the rights by imploring legislative, budgetary, and administrative measures. Essentially, this duty ensures that the government takes positive measures to assist certain classes of people or the society at large in enjoying their rights. Implicit in these obligations and in exploring whether South African citizens can reap benefits from this gene editing technology within the ambit of the right of access to healthcare services is the need to analyse the court's jurisprudence in interpreting this right.

### **Court's interpretation of the right of access to healthcare:**

Notwithstanding the right of access to healthcare, it is trite to say that section 27 must be construed in its context. The relatable question to this paper is what quality of healthcare services the Constitution seeks to guarantee to the people of South Africa since the manner in which the right is couched has made it difficult to enforce. The ability to define the essence of this right is thus critical, as it is difficult to assess the government's efforts in meeting its commitments and to dispute it where necessary. According to Kotzé, a right entails entitlement, not what they wish to have, but what must be had and can be claimed when necessary<sup>11</sup>.

The case of *Soobramoney v Minister of Health (KwaZulu-Natal)*<sup>12</sup> was the Constitutional Court's first opportunity since the adoption of the new South African Constitution to explore the nature of socioeconomic rights and their normative content. The Constitutional Court ruled that the right to healthcare services cannot be interpreted apart from the availability of health services in general<sup>12</sup>. Furthermore, the Constitutional Court stated that 'it would be significantly difficult for the State to fulfill its primary responsibility under section 27(1) and (2) to provide healthcare services to 'everyone'<sup>12</sup>. The Constitutional Court was in this case not convinced that it was reasonable to require the state to allocate additional resources to the renal dialysis program for all patients. This demonstrates notwithstanding the interpretation of access, 'the right does not lead to automatic 'access' because access is dependent on the availability of resources'<sup>13</sup>. Similarly, one can therefore assert that the right of access to healthcare services is an empty promise if there is no practical access to such services.

The case of *Government of South Africa v Grootboom*<sup>14</sup> also becomes useful in the analysis of the context of the right of access to healthcare services. In *Grootboom*, the court distinguished between the right to access housing under Section 26 and the right to

housing under Article 11(1) of the International Covenant on Economic, Social, and Cultural Rights (ICESCR). The Constitutional Court emphasized that, while international law is important in interpreting our Constitution, the distinction between the relevant provisions of the ICESCR and our Constitution is significant in determining the extent to which the provisions of the ICESCR can be of assistance in interpreting section 26<sup>14</sup>. Yacoob J in projecting the broader sense of a right of access in relation to adequate housing stated that a right of access simply enjoins the state to empower individuals and other stakeholders with the legal and other measures to provide housing for the people. As such, the needs of societies may vary depending on each society's specific needs and circumstances. For instance, some persons may require water<sup>14</sup>.

Based on the *Grootboom* decision, section 27 of the Constitution must be viewed through the prism of section 26. Thus, the right to obtain healthcare services encompasses the principles encapsulated by ideas such as the right to healthcare and the right to health. Accordingly, the court in *Grootboom* further demonstrated that in satisfying the duty to fulfill, the state should refrain from providing an umbrella form of access to healthcare services, alternatively put, the state should consider the needs of different categories of people<sup>14</sup>. In this situation, individuals suffering from TB and those with a genetic susceptibility to TB require some form of special attention and to neglect these people whose rights are in peril is a violation of the right.

Accordingly, the Constitutional Court developed a framework for assessing the obligations imposed by socioeconomic rights. The Constitutional Court's main inquiry is whether the approaches used are fairly capable of assisting in the fulfillment of the socioeconomic rights in dispute<sup>15</sup>. Hence, the Court in *Grootboom* embarked on an effort to define the bounds of 'reasonable measures'. That is, the Constitutional Court established criteria for determining whether a government program has been reasonably implemented to realize the socioeconomic right. It was held that

a legitimate program or policy must be thorough, organized, and transparent, and have its contents appropriately communicated to the public. Furthermore, in *Minister of Health v Treatment Action Campaign*,<sup>16</sup> the court noted that in assessing reasonable measures 'such determinations may in fact have budgetary implications but are not in themselves directed at rearranging budgets<sup>16</sup>.

It must, however, be noted that in assessing the government's duty to fulfill its constitutional obligations, the concept of reasonableness entails more than a simple assessment of progress made; rather, there has to be evidence demonstrating that the specific need has received sufficient consideration<sup>14</sup>. Pillay also suggests that reasonable implementation must be understood as reflecting on the results and to what degree the interventions achieve the goals proposed<sup>7</sup>. This suggests that the level of scrutiny used by the Constitutional Court goes beyond just determining whether the policy was logically thought out and implemented in good faith.

Unlike the CESCR, the Constitutional Court has been reluctant to recognize minimal core obligations as a self-standing right conferred on everyone due to the diversity of people's needs and their varying contexts. Accordingly, the Constitutional Court in *Grootboom* was hesitant to define a minimum threshold for the gradual fulfillment of the right without first determining what is required for the enjoyment of such a right<sup>14</sup>. The Constitutional Court emphasized that this problem is made more difficult due to the fact that different groups have distinct societal expectations.

Although the Constitutional Court did not expressly reject the minimum core in *Minister of Health v Treatment Action Campaign*, it did rule that the socio-economic rights outlined in the Constitution should not be interpreted to give everyone the right to demand that the minimum core be provided to them without taking into account progressive realization and resource availability<sup>16</sup>. It further held that it

is difficult to provide everyone with immediate access to even basic services, and that the state should only be held accountable for acting appropriately to provide access to socioeconomic rights progressively<sup>16</sup>.

Based on the judgments discussed, the right to healthcare services is vulnerable to cultural, political, economic, linguistic, and legal issues. While the economic and legal issues can be resolved in time, I believe that the language in which the right is couched remains a major issue. Language is crucial in explaining the scope of government obligations. According to Sprumont, 'as long as the content of the right to healthcare cannot be defined substantively, the obligations imposed on the state remain more political than legal'<sup>17</sup>. The availability of resources ought to be the pinnacle of the quality of healthcare services that the government can deliver. One could argue that delivering healthcare services in South Africa has taken on the role of 'charitable labour,' with the government merely making available what it can afford rather instead of what the people are actually entitled to.

Although not specific to CRISPR, the emergence of CRISPR therapies then raises concerns and controversies about fairness and distributive justice across the different layers of society as CRISPR therapies are likely to be costly at the initial stages of clinical applications and therefore available in limited quantities. Owing to the existing health care inequalities, I am of the view that it is paramount to explore the meaning of the term 'progressive realisation' as stated in section 27.

**Progressive realisation of health rights:** In Section 27 government is obligated to take reasonable legislative and other measures to 'progressively realize' this right. This is quite similar to Article 12 of the ICESCR which requires State parties to take steps to ensure the realization of the right to health. The term progressive realisation has been defined by the ICESCR. The ICESCR provides that the concept of progressive realization involves an understanding of the fact that full realization of

all economic, social, and cultural rights will typically not be achievable in a short period of time. The covenant however imposes a duty on the government to attain that objective as swiftly and efficiently as can possibly be done<sup>18</sup>.

The requirement under the ICESCR to gradually realize the right to health over time implies that States are subject to particular, ongoing duties that require immediate action and evaluation of the most efficient approach to achieving their health objectives. The term 'progressive' realisation by its very nature indicates that the steps taken by the government to achieve its health goals must be proactive and not a retrogression of progress already made. Paragraph 32 of General Comment 14 makes it apparent that retrogressive measures in relation to the right to health are not permissible<sup>19</sup>. If any intentionally regressive actions are taken, it is the State party's responsibility to demonstrate that they were implemented after thoroughly considering all available options and that they are appropriately justified in light of all the rights guaranteed by the Covenant. According to Liebenberg, retrogression is permissible when it is aimed at achieving equity and correcting structural imbalances and that the steps taken are not particularly averse to the disadvantaged and marginalized<sup>20</sup>. In the *Grootboom* case, it was held that, in accordance with the CESC, the term 'progressive realisation' meant that the right to access does not have to be realized immediately, but that the government must take action to fulfill the Constitution's mandate that the basic needs of all people in our society be met efficiently<sup>14</sup>. Even if people already have socioeconomic rights, progressive realization places a responsibility on the state to improve the nature and quality of the services to which they have access. Hence, if current TB policies or treatment methods are not sufficiently efficient in emolliating TB, the government is duty-bound to incorporate other policies that seek alternative forms of treatment such as heritable human genome editing. This must also be coupled with deliberate and quantifiable government

action that is subject to structures of accountability. There is little value in a treatment that is inaccessible to people who need it the most. In eradicating the TB epidemic in South Africa, the benefit of human genome editing can only be understood once the masses have access to its transformative and lifetime effects.

**Conclusion:** The promise of human genome editing to remedy the TB disease burden is profound. The main purpose of this paper was to explore the extent to which the legal and policy framework in South Africa enables the government to provide TB treatment to patients using CRISPR. As such, the arguments given in this paper have demonstrated how the right of access to healthcare services is germane to the sustainable accessibility and enjoyment of CRISPR therapies. This rights approach to the issue of accessing gene editing technology is important because it provides a solid ground to demand access to this technology as well as guiding the standard for rationing these therapies in order to achieve the goal of fulfilling, protecting, respecting the right of access to healthcare services.

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