MEDICATION NONADHERENCE IN TB PATIENTS: INNOVATIVE TECHNOLOGY USE AND RELATED LEGAL FRAMEWORK

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Abstract— Tuberculosis is a deadly disease that has been at the forefront of many deaths around the world, but patient nonadherence to medication has been a foremost contributor to this result. Nonetheless, there could be innovative, technological intervention to aid patients' adherence to medication and prevent the many deaths. However, some of the medication nonadherence causes as well as technological interventions could have legal consequences, but the impact of this has not been investigated, especially with regards to the impact on the human rights of the patients and on the society. The article is written to add to the body of expertise on the topic and will be useful for policymakers and all stakeholders in the related area of using technology to improve patient health in the bid to attain the Sustainable Development Goals of bringing an end to the tuberculosis epidemic by 2030 (SDGs).

Keywords— Medication nonadherence, Tuberculosis, technological innovation, Legal framework, data protection, right to privacy, South Africa

Introduction

The World Health Organization (WHO) designated tuberculosis (TB) as an international health problem decade back, and global efforts to contain the illness have expanded since then [1-3]. Notwithstanding the ongoing efforts to stop the TB epidemic, ultimately culminated in the estimated 53 million lives saved between 2000 and 2016, this old disease remains a significant burden [1-3]. In most developing countries, including South Africa, TB is a widespread infectious disease, with over five million people living with TB and HIV/AIDS in a population of around 50 million. KwaZulu-Natal (KZN) is a South African province with the highest population density.

In 2018, the population was about 11 million people [4], In addition, the province experienced a 41% decrease in employment in 2018 [5], in conjunction with a non-tertiary education level of over 70% in 2016 [6]. Tuberculosis (TB), which killed 380 people per 1000 in 2016, is one of the foremost causes of loss of life in South Africa [7] and is relegated due to social norms and health problems. Many people living with tuberculosis are stigmatized by family and friends [8], are expelled from their homes by their families, and lose their jobs. The stigma associated with tuberculosis makes it difficult to seek medical care [9, 10], starting medication/dosage [11, 12], resulting in nonadherence to care [12, 13], with the risk of vastly resistant variants to the distinct antimicrobial isoniazid/rifampicin therapies [11, 12]. Many cases of tuberculosis and multidrug-resistant tuberculosis (MDR-TB) exceed 567, with TB and HIV each accounting for 25 in every 100,000 people [1, 2]. The disease accounts for the highest proportion of the overall mortality rate of over 6% in South Africa in 2016 [4]. Consequently, based on the Global Burden of Disease Report of 2017, tuberculosis is the fifth leading cause of death and ill-health-associated life-years in the world [14, 15]. MDR-TB is essentially lethal and fatal, according to an estimation of 31 percent cases in death rate [16, 17], which aggravates the downward spiral of TB stigma and decreased attention to treatment. MDR-TB was detected in 3% of KZN residents from 2012 to 2014 [18], and it appears to be a big concern for the health system. Contacting MDR-TB will be profoundly distressing and transformative in life encounters with insufficient sustenance approaches [19], resulting in long-term danger to critical human protection, environmental degradation, and economic loss due to loss of lives [20].

However, maintaining drug adherence remains a major obstacle for health initiatives [12]. According to Haynes, McDonald [21], medication adherence is defined as patients following the prescription instructions issued by a health expert. Treatment

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adherence is frequently thought to be influenced by one's beliefs and place of origin. Patient characteristics, the relationship between healthcare staff and patients, the treatment regimen, and the health care environment have all been related to TB medication adherence [22]. The legal environment is also important as this relates to the use of technology particularly as it affects the rights of the patients, impacts the doctor patient relationship and the society at large. As a result, the emphasis of this article is to explore the impact the legal system has on medication nonadherence, as well as what legal changes can be made to improve medication adherence over time. The paper will provide some perspectives and hints on what privilege patients have when it comes to TB treatment, as well as practical recommendations for successful technological advancement on medication adherence.

TB NONADHERENCE EFFECTS AND CHALLENGES

The WHO developed the End TB Strategy with the objective of decreasing TB incidence by 90% and TB deaths by 95% by 2035, with a focus on low-prevalence nations [23]. In 2015, the United Nations Millennium Development Goals settled on plans for countries to work on refining the goals and strategies of health issues. Although communicable and non-communicable health complications presented numerous challenges, this approach provided the most significant growth potential. However, the method of eradicating tuberculosis in rural and urban areas with a temporary disease burden is still uncertain [24]. To end the TB pandemic before 2030, a worldwide government-led effort is needed [25]. Despite considerable progress in previous years, the SDG target on TB may not be reached by the deadline set as reported by [25], due to the current pace of growth. Furthermore, with an increase in multidrug-resistant tuberculosis (MDR-TB), an increased number of cases were seen in 2017, and international immigrants pose a substantial economic and political challenge to disease prevention [1, 26].

Impact of Nonadherence on the Patients and Society

Kanabus [27] detailed certain control programmes for TB as built by WHO, the disease remains uncontrollable, but it is also facing an enormous challenge of adherence resulting in a growing number of drug-resistant cases [3, 28]. Further research studies described by Wolever and Dreusicke [29] explained that adhering to medication necessitates personalized behaviour change based on motivation that are not linked with educational status and reminders. In the meantime, nonadherence is connected with bad clinical results and greater danger factors [12], amplified hospitalization and utilization of healthcare service [30] and raised healthcare prices [31]. Nonadherence to medication for TB has critical human, social and economic effects. Interruption to medication might cause drug resistance and negatively affect treatment efficacy which result to high mortality, morbidity, and further infections. Researchers discovered that without assistance, long-term treatment adherence rates in high-income countries are about 50% [3, 13], although it may be even lower in middle-income and low-income countries [31].

Patient behaviour and nonadherence to medication have been significant roadblocks in the battle to eliminate tuberculosis [32]. Nonadherence is multifaceted, has complex definition that involves a variety of interconnected problems that impact medication enforcement [13, 31]. It presents a major risk to both public health and individual patients, it also contributes to higher transmission rates, illnesses, and TB control program costs [32]. Furthermore, it leads to the persistence and revival of tuberculosis and is the primary cause of drug resistance and degradation [33]. According to new studies, daily observations may help understand why people do not stick to their treatment plans [31]. This article recognizes that recognizing the perceptions that lead to medication nonadherence requires a legal and social rights perspective.

Treatment Perceptions in Tuberculosis Patients

Some epidemiological studies have revealed linkages to adherence, frequently investigating the issue from a biological standpoint [12, 31, 33]. The framework of TB patients have occasionally been characterized as patients receiving treatment being required to heed health experts' directives. Nonadherence happens when patients do not follow medication guidelines [12]. The approach shows that behavioural components are dynamic and are influenced by varieties of factors including patient health values, sociocultural settings, healthcare facilities, personal disease experiences, condition-related factors, and therapy. [3, 12]. The following section explain people's attitudes toward TB treatment and care.

TB Patients must stay on treatment for more than three months to show that TB is curable. Patients look forward to being cured and return to their normal lifestyle. When Patients have concerned with DOTs helper, who help them stay on treatment, also support from friends and family is very important [33]. Many do not pay attention to gossip about them, and they stayed focused and strong [3, 34]. People who are seeking treatment for tuberculosis (TB) avoid taking their pills until they are fully cured. They stop taking their drugs once they feel better. When they fear what others think when they go to their clinics to collect

medications and standing in line for ARV medications makes them feel embarrassed [32].

Individual patient behavioural factors connected with TB treatment nonadherence are: loss to follow up due to lack of knowledge about the disease, the impacts of treatment on TB patients, the duration of treatment, lack of self-efficacy or motivation to complete treatment, fear of stigma, loss to follow up when TB patients feel better after few weeks of treatment, attitudes toward treatment, and poor communication with health care workers [32, 35]. Furthermore, alcohol use and cigarette smoking are two specific behaviour factors that have been linked with TB treatment nonadherence and loss to follow-up. Nonadherence to medication potential consequences have grown, including treatment failure and relapse, which leads to comorbidities, deaths, extended transmission of bacilli, and the development of medication-resistant tuberculosis types [32, 35]. When friends, relatives and colleagues are uncaring, they believe they are being irresponsible, and should not be bothered using medications [35, 36].

Another reason for delay in attending clinics is being afraid of testing positive to HIV [12]. Fearing that people are talking about their regular visit to the hospital. Also, patients do not want TB treatment to hinder their lifestyle socially [3]. Afraid of lengthy queues at the clinic, scared of losing their jobs due to disclosing their status. Moreover, patients do feel TB treatment will be tough and unfriendly, so they wish to consult a traditional expert [37, 38].

TB patients want regular access to supporting treatment facilities, such as hospitals and clinics where they can be cared for by nurses [39]. At home and at different locations where DOT volunteers pay them visits and prescribe their medicine on a regular basis [38]. A family member may also collect for them, whether it is at work or at home [3, 39].

Patients dislike faraway clinics and are more likely to miss appointments if their medical facility is too far away [36, 38]. Patients often could not afford TB treatment due to poverty level [32]. Complex regimen is also part of the problem where patients do not understand the implication of nonadherence [36]. If the perceptions are regarded as a general norm among TB patients, stigma causes individuals to reject the diagnosis this now leads to infecting more people and drug resistance potentially sets in [12, 33, 39].

Novel AI and ML solutions in promoting medication adherence may well be considered with the perspectives at heart when planning for interventions for currently identified problems [33, 38]. Human and social rights of the community members as well as family support mechanisms are fundamental in digital solutions. Most are concerned with how to overcome health-care hurdles and the stress that TB patients experience during clinic visits [11, 38].

Previous research has shown that TB patients are likely to get treatment and medication under difficult conditions and face significant hurdles, many of which are directly beyond their control [32]. Administering a long-term course of medication is stressful and regularly comprises of uneasy decisions, occasionally at an important social and personal cost to the health-seeker [38]. Adherence is a dynamic and self-motivated strategy; several interconnected variables affect drug adherence and patient behaviour, which continues to evolve over time. In order to improve medication adherence and reduce the global disease burden attributed to tuberculosis, more patient-centred approaches are required, with a greater emphasis on organizational barriers [13, 35].

TECHNOLOGICAL INNOVATIONS TO SUPPORT TB ADHERENCE

Innovative ICT processes are designed to deliver the treatment adherence and prevention required to meet the National End TB Strategy targets together with sustainable development goals (SDGs). The End TB Strategy's methods require that national TB initiatives and other participants re-plan how the mentioned targets would proceed in order to sustain the post-2015 path [40]. E-health is intended to perform a vital function of the major events in accomplishing a set of sustainable development goals and ending the worldwide TB pandemic, whether through the new- or old-fashioned approach that is focused on patient care, observation, programme sponsorship, staff training or the appointment of community volunteers [41, 42].

In the previous years, caregivers and patients have profited unpredictably from (e-health) digital technologies in combating tuberculosis [35, 38]. Unique investment in ICT solutions have been experienced, for keeping disaggregated information on TB investigation, for linking diagnostic equipment, also to help patients in TB care. These are magnificently advanced China and India with high population coupled with a huge burden of TB [32, 43]. Healthcare procedure seems to have risen to the top of a dynamic change. Disruptive technological development altered medical practice, and the integration of machine learning (ML) and artificial intelligence (AI) into medical tools are all possibilities now [44, 45]. Continuous advances in software development and the availability of phones/computers with unrestricted internet are expected to help more people around the world. Many organized innovations would increase the accessibility of digital solutions through mobile electronic devices in all dimensions imagined by the digital “agenda for action” for tuberculosis [40, 45].

Furthermore, innovation using mobile phones have greatly increased across the globe, this has led to various development in our nations [45]. The

technology advancement has contributed immensely to a healthier lifestyle and healthcare system. Improve procedures are available to manage the successes and failures of the intervention systems. Interventions like mobile text messaging (SMS) as a reminder to TB patients for medication adherence was done, Video-supported treatment (VOT), and Medication Event Monitoring System (MEMS) under RCT conditions have all been carried out and its effect and challenges have been identified [45]. The limitations from the above interventions opened for further research to find a lasting and best-suited solution to medication adherence in TB patients [1, 22].

According to the WHO, successful implementation of an emerging method includes consideration of the effect on the patient population as well as the impact on the health system. When implementing a digital advancement, it is important to take a holistic look at the whole patient. Any proposed solution for high-quality support and treatment should be focused on TB patients' willingness to make decisions in partnership with health practitioners and other stakeholders [12]. Self-monitoring services, psychological counselling, patient education, family therapy, telephone follow-up, and other supportive interventions, however, would demonstrate viability in reducing medication nonadherence for TB patients [11, 12, 42]. Despite many technological innovations and regulation programmes that are already in existence for monitoring, assessing and alerts made available as a reminder for taking medications, there are still human right factors that impacts on medication adherence which is scarce in literature. Therefore, this paper considers some of the issues surrounding legal rights in medication nonadherence.

LEGAL FRAMEWORKS ON TECHNOLOGY INTERVENTION ON PATIENTS' MEDICAL NONADHERENCE

Nonadherence to medication is a significant concern in the medical community. Nonadherence can lead to a variety of preventable health problems; as a result, many countries are considering laws to help boost medication adherence [46]. Many advanced countries have established legislation requiring insurance companies to provide a process that enables patients to schedule their medication refilling so that all medications are ready on the same day [46].

The Legal aspect of medicine and health may focus on medication use, the doctor and patient relationship as well as the extent of assistance to be provided and such related issues of treatment. There have recently been global and regional measures at standard practices to figure out the crucial things to include when writing a prescription for medication, so there may be a legal framework or rules on medication use as well as adherence to medication [47].

With the development of technology, where many innovative measures can be applied and easily too, it is possible that patients be assisted to adhere to medication. If this be the case, then it is also expected that there are procedures for these, with legal implications and challenges too.

Legal Perspective of the Use of Medical or Health Technology and Innovation

Generally, the discourse under this head could be linked to human rights and regulations on the use of technology. Hence provisions on human rights and that relating to the application of technology will be relevant. The first aspect of the right that comes to mind would be the right to life and health. The right to information and education too may be relevant. Again, the right to privacy or its protection may come close as needful, alongside its attending issues.

Simply put a right is something to which one has a claim [48]. Human rights are the rights someone acquires by being human or by being alive [49]. Patients are citizens and the issue of health relates to the right to life and right to health is linked to this which may mean access to medical assistance, health facility or medication. Most times, human right provisions are connected or interlinked. The issue of human right to make a choice may be connected to education or enlightenment, and these may lead to the right to information/education or even access to technology or access to assistance through technology. Right to life, right to healthcare are important rights that may be considered when it comes to the right of patients. Right to privacy or data protection are also issues of right that may come to view.

Doctor/Patient Rights and Obligations on Nonadherence to Medication

Medical personnel have the obligation to make medication and information accessible which may terminate or assist in adherence to medication [50]. After accepting therapy, patients have a moral obligation to take the drug as prescribed. Patients may be required to comply with therapy for their own safety and the protection of others [50]. Within doctor/patient rights and obligations, doctors have the duty to prescribe which makes the right to accept treatment the right of the patient while patients have the duty to adhere to prescription. Although the patient also has the right to refuse treatment, make medical decisions, receive information, and so on [50]. Nonadherence appears to entail the patient failing to keep his/her ethical responsibilities in the physician-patient relationship while assisting in ensuring medication adherence refers to medical professional's obligations [50].

The rules on doctor/patient relationship are quite advanced in developed countries while some developing countries are trying to come up with implementing their existing framework. It is even becoming more necessary now with the advent of advanced technology to apply in the health sector. The American Medical Association (AMA) Code of Ethics adopted in 1847 contains a discussion of the patient's duties to doctors and one of the assertions is that the patient has a duty to obey the physician's instructions [50].

The Legal Implication of the Use of Technology in Assisting Patients to Adhere to Medication

In developed countries the non-liability of a medical practitioner in the involvement of patients' nonadherence is not an easy sorted issue [51]. The implication of nonadherence to medication by a patient could mean his choice to die, or the non-performance of his duty to adhere which could also reflect ignorance of his knowledge about medication nonadherence. To this end it could have legal connotations. Is a patient entitled to choose to die? [52]. What is the doctor's duty or responsibility to this, and since it has a cost on society, what is society's response to this nonadherence?

Within the performance of their duties, medical practitioners can use measures and effective strategies to assist their patience to adhere to medication. They can use relatives, care givers, etc. and where technology is available, then it should be employed or accessed [51, 53].

The use of technology in many ways to enforce medication adherence is not new [54], including the case of tuberculosis patients [55]. Technological software could be utilized as a medical device. Adaptive artificial intelligence and machine learning technologies referred to as SaMD or AI are applied in healthcare interventions [56]. AI has been useful for medical adherence although it comes with some legal considerations [57]. This is because it has to do with data collection and tracing. This relates to the right of the patient, bordering on issues of data privacy and protection, consent as well as some other legal considerations [57]. Patient privacy issues is one major legal consideration in the use of technology for medical assistance [58]. The issue of bias and fairness may also come to play [59].

As for the legal framework, the fact is just as is the case for most emerging technologies, the law is still trying to catch up with the issue of legislation and other related issues. This, however, does not mean that there are no areas of law that they can fit in, or that there are no regulations on it.

For developed countries where technology is more advanced and AI has been applied in the medical field, the laws obviously cater for the regulation of its application. There are federal and state requirement in the US for the application of technology to assist patients in many ways [60]. The European General Data Protection Regulation (GDPR), which went into effect in May 2018, is important in the UK. [61]. Although, at present, there is no specific proposal for a change to civil Law regulations as many matters relating to AI, and mostly with robotics based on AI, inclusive of the validity of contracts, and such related issues have still not been clarified. Even though, a resolution with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)) on 16 February 2017 was adopted by the European Parliament [61].

Despite the fact that many African countries lack a national digital health policy or plan to guide the adoption and evaluation of digital health policies, AI is being employed in Africa, including the health sector [62]. There are no rules in Africa or around the world that govern who is responsible for negative effects that may result from the use of AI in healthcare. Naturally, negative results are likely given how and where AI may be used in healthcare. The most likely answers involve the application of the existing rules; yet some situations and conditions are not foreseeable or covered by existing laws. As a result, users and patients in these African countries could suffer legal consequences [62]. The common areas where regulations may exist presently are data and privacy issues. For South Africa, although health technology is in use, which presupposes the inclusion of technology related assistance in medical adherence, no particular policy or regulatory standard regarding ethical AI was found despite the fact that, it was suggested that It is the responsibility of developers and innovators to act ethically and self-regulate. [63].

However, S14 Constitution of South Africa deals with the right of citizens to their privacy. To give effect to protection of privacy in communication, the POPI Protection of Personal Information Act 2013 was promulgated. This stipulates the regulation for data collection and use. The S26 of the POPI requires the consent of the patient for data to be processed. However, S32 provides for circumstances where health data can be processed free of the conditions in Section 26. For example, medical practitioners, healthcare systems, and social services should protect healthcare information when it is being processed. This is essential for the care and treatment of personal data, management of the establishment's information using the standard practice. The goal must be clear, specified, and legal. Other laws and or regulations relating to Doctor- Patient ethics are also in place, all of which can form the basis for the right to remedies or enforcement whichever way it falls.

It would help if medical personnel ensured that there are written agreements between physicians and

patients as a basis for promoting patient adherence [50]. These agreements could also be technology based. They should also guarantee that the contents of the agreement are understood and implemented to the letter by patients in order to avoid difficulties and unneeded legal disputes. The legal aspect remains open for more research.

SUGGESTIONS AND CONCLUSION

One of the assumption of data privacy is the mistaken belief that data protection legislation can provide individuals' with control over their data, which it cannot. Another myth is that the reform simplifies the law, when actually it makes fulfilment much more difficult. The third premise is that the data protection law should be thorough, this could push data protection to the breaking point and render it only law in the books [64]. Furthermore, unless data protection transformation changes their focus - returning to basic fundamentals, playing other regulatory tunes on different instruments in other legal fields, and reviving the spirit of data protection by encouraging best practices in medication adherence, if not, data protection reform will be a failure [64].

Noncompliance with TB medications have significant impact on medical and economic TB outcomes. Controlling the medication nonadherence and implementing worthwhile intervention programs should be given top attention to meet WHO TB elimination goals. Our findings point to the need to improve TB treatment delivery, particularly for individuals with limited access to healthcare, as well as to frequently provide education to patients to boost their knowledge of TB and TB treatment. Furthermore, more attention should be paid to younger patients and those with a family history of tuberculosis.

This article has revealed that, based on the concepts of factors influencing TB medication adherence of TB patients, physicians, policymakers, and patient advocacy organizations must agree that adherence to medication can be strengthened by creating a patient-centred approach that is consistent with community law and practice. Digital solutions that allow patients to be more self-sufficient should be encouraged. Furthermore, patients should be allowed to engage in drug adherence decision-making. Less fortunate citizens should be motivated to seek technological education. In South Africa, more emphasis should be put on the effects of medication nonadherence and the legal ramifications. Changes to current legislation in developed countries are welcomed to promote technological interventions in our health system using AI and machine learning. To increase drug adherence, regulations that protect patients' interests and the whole society must be enforced.

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