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Item Type	Article
Authors	Rossouw, T.M.;Nienaber, A.G.;Boswell, M.T.;Moodley, K.
Citation	Rossouw TM, Nienaber AG, Boswell MT, Moodley K. Comorbidity in context: Part 2. Ethicolegal considerations around HIV and tuberculosis during the COVID-19 pandemic in South Africa. S Afr Med J. 2020 Jun 17;110(7):625-628.
DOI	10.7196/SAMJ.2020.v110i7.14857
Publisher	South African Medical Journal (SAMJ)
Journal	South African Medical Journal (SAMJ)
Rights	Attribution 3.0 United States
Download date	2024-12-02 18:01:13
Item License	http://creativecommons.org/licenses/by/3.0/us/
Link to Item	http://www.samj.org.za/index.php/samj/article/view/12990/9384

MEDICINE AND THE LAW

Comorbidity in context: Part 2. Ethicolegal considerations around HIV and tuberculosis during the COVID-19 pandemic in South Africa

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The COVID-19 pandemic has brought discussions around the appropriate and fair rationing of scarce resources to the forefront. This is of special importance in a country such as South Africa (SA), where scarce resources interface with high levels of need. A large proportion of the SA population has risk factors associated with worse COVID-19 outcomes. Many people are also potentially medically and socially vulnerable secondary to the high levels of infection with HIV and tuberculosis (TB) in the country. This is the second of two articles. The first examined the clinical evidence regarding the inclusion of HIV and TB as comorbidities relevant to intensive care unit (ICU) admission triage criteria. Given the fact that patients with HIV or TB may potentially be excluded from admission to an ICU on the basis of an assumption of lack of clinical suitability for critical care, in this article we explore the ethicolegal implications of limiting ICU access of persons living with HIV or TB. We argue that all allocation and rationing decisions must be in terms of SA law, which prohibits unfair discrimination. In addition, ethical decision-making demands accurate and evidence-based strategies for the fair distribution of limited resources. Rationing decisions and processes should be fair and based on visible and consistent criteria that can be subjected to objective scrutiny, with the ultimate aim of ensuring accountability, equity and fairness.

S Afr Med J 2020;110(7):625-628. <https://doi.org/10.7196/SAMJ.2020.v110i7.14857>

The advent of the COVID-19 pandemic has sparked widespread debate about the appropriate and fair rationing of scarce resources. Personal protective equipment is in short supply and access to intensive care units (ICUs) and ventilators is limited.^[1] This scenario has played out all over the world, with even the best-resourced countries unable to meet the demand for ICU admission and ventilation due to SARS-CoV-2 infection. Critical care triaging has become a reality. The World Health Organization has warned that Africa could be the next epicentre of the pandemic.^[2] Given the likelihood that the worst-off in society will be disproportionately affected by large COVID-19 outbreaks, it is important to pay attention to the ethical and human rights considerations, with particular reference to individuals who are vulnerable.

This is the second in a series of two articles focusing on individuals with HIV or tuberculosis (TB) infection. These groups are specifically discussed owing to their increased vulnerability, which stems not only from their possible susceptibility to SARS-CoV-2 infection, but also from their exposure to discrimination, marginalisation, and denial of their rights.^[3-6] Since patients with HIV or TB may potentially be excluded from admission to an ICU on the basis of an assumption of lack of clinical suitability for critical care, the first article argued that there is currently no evidence that uncomplicated HIV and TB *per se* should disqualify a person from admission to an ICU. This article outlines the ethicolegal implications of limiting ICU access of persons living with HIV and TB.

Estimating the size of the problem

Estimates for hospitalisation and ventilation due to COVID-19 vary across the world. A review of data from China reported that ~20% of patients with COVID-19 require inpatient care, with roughly 15% having severe symptoms and 5% needing mechanical ventilation.^[7] Reports from Italy and Spain put hospitalisation and ICU admission proportions at 40 - 55% and 7 - 12%, respectively.^[8] While the majority of patients require ~13 days of respiratory support,^[9] some may need ventilation for several weeks.^[10]

There is very little publicly available information regarding critical care resources in Africa. A systematic review found that >50% of included lower-income countries lacked any published data on ICU resources relative to their population.^[11] Based on limited data, most African countries are estimated to have 5 ICU beds per million people, compared with 4 000 beds per million people in Europe.^[12] While up-to-date and accurate numbers are difficult to find, SA appears to be slightly better off than other African countries and has been reported to have 7 195 ICU beds (2 238 in the public and 4 957 in the private sector) for its 59 million people.^[13] At a ratio of 122 beds per million people, this is still well below what will be needed if a large proportion (estimated to potentially be 60%)^[14] of the population becomes infected within a short period of time. In addition, the mere presence of ICU facilities does not necessarily imply adequate capacity for critical care. There is also a dire shortage of trained critical care specialists and nursing

staff, which will limit the capacity to treat critically ill patients even further.^[15]

Many South Africans have risk factors associated with worse COVID-19 outcomes: ~13% of female and 9.7% of male adults have diabetes, and 8.1% of females and 33% of males smoke.^[16] A nationally representative survey of people aged ≥50 years found that 77.9% (95% confidence interval (CI) 76.4 - 79.4) had hypertension. Only 38% (95% CI 36.2 - 39.8) were aware of their condition, and only 7.8% (95% CI 6.8 - 8.8) achieved optimal blood pressure targets.^[17] Apart from these known risk factors, it is speculated that infection with HIV and TB may increase the risk of SARS-CoV-2 infection and poor outcome of COVID-19. In this context, it is sobering to consider that SA has one of the largest burdens of disease in the world, with an HIV prevalence of 19% (among 15 - 49-year-olds) and a TB incidence of 301/100 000 (uncertainty interval 215 - 400).^[16] This high level of vulnerability is concerning as we enter the annual influenza season, which traditionally places increased demands on ICU admissions and disproportionately affects immunocompromised people, especially those with HIV^[18] and TB.^[19] Rationing of ICU admission and care will be inevitable.

Legal considerations

The allocation and rationing of scarce healthcare resources must be done in terms of SA law. The Constitution of South Africa^[20] and specifically the Bill of Rights guarantee the right of 'access to health care services' in section 27(1)(a). Of course, this guarantee is not absolute: it is impossible in a developing country such as SA to provide for everyone's needs, and therefore limitations are placed on the right in terms of section 27(2) of the Constitution and in accordance with the general limitations clause in section 36. It should be remembered that the right of access to healthcare services should not be seen in isolation, as many rights in the Bill of Rights bear on the rationing of scarce resources. Examples are the right to equality (section 9), dignity (section 10), life (section 11) and physical integrity (section 12).

Section 27(2) of the Constitution enjoins the state to 'take reasonable legislative and other measures, *within its available resources*, to achieve the *progressive realisation* of each of these rights' (our italics). The right of access to healthcare services, therefore, is realisable only over time and in accordance with the state's resources. However, the right to emergency healthcare services is not subject to limitation – it appears to be immediately enforceable. According to section 27(3), no one 'may be refused emergency medical treatment', which is not defined either in legislation or in case law. Such a definition is urgently needed, and more conceptual work needs to be undertaken on what exactly constitutes 'emergency' healthcare services. Nevertheless, despite this lack of conceptual clarity, it is doubtful that continuous and sustained ICU care for COVID-19 patients will be interpreted by the courts as constituting 'emergency medical treatment'.

Because of their abstract nature, constitutional or human rights have meaning only when interpreted by the courts in concrete situations. The South African Constitutional Court has decided a number of cases dealing with access to resources, and a case that is pertinent to the present discussion is *Government of the Republic of South Africa & Others v Grootboom & Others*.^[21] *Grootboom* dealt with vulnerable persons' access to housing, which is realisable progressively, as is the right of access to healthcare services. In order to assess whether the measures to ensure the progressive realisation of the right were adequate in this instance, the Constitutional Court formulated a 'reasonableness' standard which ensures access to

be 'comprehensive', 'coherent', 'balanced' and 'flexible', and 'non-discriminatory'^[22] as a 'programme that excludes a significant segment of society cannot be said to be reasonable'.^[23] Evidently, policy decisions on which COVID-19 patients' access to ICUs are based must adhere to the standard of reasonableness. Significantly, the Constitutional Court stated that those 'whose needs are most urgent and whose ability to enjoy all rights is therefore most in peril, must not be ignored by the measures aimed at achieving realisation of the right'.^[24] We argue that the need of COVID-19 patients to access ICU services is 'most urgent' as contemplated by the Court; it is literally a life-and-death matter.

The requirement that a 'programme that excludes a significant segment of society cannot be said to be reasonable' in relation to access to ICU facilities is in keeping with the wording of section 27(1)(a), which guarantees the right of access to healthcare services to 'everyone'. The use of 'everyone' in this context may be interpreted to mean that decisions on which patients access ICU services may not be discriminatory on the basis of their HIV or TB status. Furthermore, the rights in the Bill of Rights are considered to be interrelated, so the right to life as guaranteed in section 11 of the Constitution could be used to argue that as a limitation on TB and HIV patients' access threatens their survival, their right to life is unconstitutionally limited.

Section 9 of the Constitution guarantees the right to equality. The section enumerates the grounds upon which people may not be discriminated against unfairly. The test for determining whether law or conduct amounts to unfair discrimination was developed in *Harksen v Lane NO and Others*.^[25] First, it must be determined whether the law or conduct at issue differentiates between persons. If there is differentiation (such as not allowing access of certain groups of people to ICU facilities), it must be determined whether the differentiation bears a rational connection to a legitimate government purpose. Second, it must be considered whether the differentiation amounts to discrimination, and whether the discrimination is fair. If the differentiation is on a ground listed in section 9(3) of the Constitution, then it amounts to discrimination and is *presumed* to be unfair. The word 'presumed' indicates that, in the case of a ground listed in subsection 9(3), the onus shifts to the person who defends a case of discrimination to show that the discrimination indeed was fair. If it is not on a ground listed in subsection 9(3), whether or not the differentiation is regarded as discrimination depends on the potential of the differentiation to impair the human dignity of persons.

Neither TB nor HIV status is a listed ground in section 9(3). However, the Constitutional Court in *Hoffmann v South African Airways*^[26] held that HIV status amounts to an analogous ground, as discrimination on the basis of a person's HIV status impacts negatively on a person's dignity based on an 'ill-informed prejudice'. Although no case concerning TB status has reached the Constitutional Court, the outcome of such an enquiry would probably be similar.

So far, triage guidelines developed in SA, such as those of the Critical Care Society of Southern Africa (CCSSA),^[27] appear to conform to the Constitutional Court's 'reasonableness' standard as outlined above. Nevertheless, some literature suggests that, in practice, these guidelines are not always adhered to when decisions are made regarding who to admit to ICU facilities. A recent study found – even in the absence of a health emergency such as COVID-19 – in a tertiary public hospital in KwaZulu-Natal Province that malignancies and HIV positivity *increased the chances of ICU refusal more than two-fold*.^[28] This evidence of exclusion of certain classes of persons indicates that stigma associated with certain diseases may in some instances influence decisions to limit access. In the light of

evidence that suggests that well-managed HIV or TB infection on their own do not predispose to an increased risk of worse outcomes for COVID-19,^[29] potential decisions that result in a blanket non-admission of people living with HIV or TB to ICU facilities will clearly amount to unfair discrimination.

The right to equality and the right of access to healthcare services in section 27(1)(a) of the Constitution are subject to the general limitations clause; section 36 of the Constitution determines that any law of general application that attempts to limit a constitutional right must be 'reasonable and justifiable in an open and democratic society based on dignity, equality and freedom'. Furthermore, it dictates that an inquiry into whether a limitation is justifiable includes a proportionality assessment, referencing factors such as the nature of the right, the purpose of the limitation, the extent to which it limits the right in question, and whether it is possible to achieve the purpose of the limitation in a less restrictive manner. Applying the proportionality assessment to criteria for ICU admission, these criteria would pass constitutional muster only if they are proportional to the aims supporting the restriction and therefore do not unfairly limit any of the constitutional rights outlined above.

Clinical facts and associated medical criteria alone are relevant in determining whether or not a particular person qualifies for access to ICU in specific circumstances, such as the COVID-19 pandemic. In this context, Pieterse^[30] states: 'most societies increasingly contend that rationing decisions and processes should be based on visible and consistent criteria, should be capable of rational justification and should be subjected to objective scrutiny, so as to ensure that they resonate with values of accountability, equity and fairness.'

Ethical considerations

Apart from the legal considerations, selection of patients for critical care in the context of resource limitations is fraught with ethical complexity. As such, it must be guided by sound principles. It is well accepted that considerations of individual autonomy, reflected here by the individual's wish to be given potentially life-saving treatment, may be limited in times of pandemic outbreaks of disease. Nevertheless, while individual rights may become subservient to the greater good, any limitation has to be aligned with human rights considerations and be judged to be necessary, reasonable, proportional, equitable and non-discriminatory.^[31] Triage during disaster situations is therefore based on the principle of distributive justice. Accordingly, scarce resources are reserved for patients with life-threatening conditions, with priority given to those who are predicted to have the best chance of survival as a result of treatment.^[32]

In particular, distributive justice requires that fairness is integral to prioritisation strategies. Should the pandemic escalate in SA, decision-making regarding the allocation of scarce critical care resources will occur at two main points: firstly, access to ICU care or ventilation, and subsequently if withdrawal of ventilation becomes necessary based on clinical deterioration or futility.^[33] Access to ICU care itself may be decided at the primary care level in referral hospitals or clinics (when a patient deemed suitable for ICU care is intubated) or in a tertiary hospital COVID-19 ward when a stable patient suddenly deteriorates and must be considered for transfer to the ICU. Different sets of criteria may be necessary – one that guides quick decision-making prior to intubation by a primary care/emergency care doctor, and another that allows a slower decision-making process using detailed criteria (such as those proposed by the CCSSA^[27]) in a patient being monitored in a tertiary hospital. At all three points, decisions will be made around patients with HIV infection or TB.

The moral legitimacy that priority-setting enjoys in the context of a public health crisis has as much to do with the criteria selected as the process that is followed. Since the COVID-19 outbreak, several resource allocation frameworks have been proposed globally.^[10,34-39] To date, various frameworks have taken different approaches to ICU admission criteria, ranging from broad principles excluding those least likely to survive based on evidence and clinician experience^[40] to detailed scoring systems that aim for objectivity at the cost of time inefficiency.^[27] In both scenarios, a detailed clinic history and examination will be needed to screen for comorbidity and possible poor prognostic indicators. Given the large number of people with undiagnosed hypertension and underlying infections, accurate assessment of risk will be challenging.

Regarding the process followed in fair allocation guidance, Norman Daniels^[41] described an approach to rationing several years ago, referred to as the 'Accountability for Reasonableness' (A4R) approach. While this approach has been widely used in dialysis programmes and other limited-resource prioritisation, it has relevance to resource rationing necessitated by the COVID-19 pandemic. Central to this approach is that decision-making for a priority-setting process be based on evidence, principles and values. Given the fact that there may be differing conceptions about which principles should inform the process, Daniels proposes three key elements of a fair process: the basis for decisions should be transparent; decisions should be based on motivations that are deemed relevant to meeting health needs fairly; and procedures should be in place to revise decisions when they are challenged.^[41]

Where HIV and TB are concerned, clinical evidence for inclusion or exclusion from ventilation must guide rationing frameworks.^[29] Similar to other patients, criteria around comorbidities and prognosis will apply. The CCSSA framework, while silent on exclusion or inclusion criteria for TB, is specific that HIV-infected patients will be considered for admission to an ICU unless there is the presence of an AIDS-defining illness, a CD4+ count <50 cells/ μ L in untreated patients, or an HIV viral load >10 000 copies/mL in treated patients. It is essential that guidelines be evidence based and not unfairly exclude patients who may benefit from treatment. Public health measures that involve significant costs and/or burdens, such as limiting ICU access, should be backed up by sound evidence.^[42] In this regard, it should be noted that while the two former criteria proposed by the CCSSA framework have been associated with an increased risk of ICU mortality,^[43] HIV viral load has not.^[44] A high viral load could be a sign of an inadequate treatment regimen, drug interactions, treatment interruption due to non-adherence or drug toxicity, or the presence of drug resistance. Since all of these scenarios are manageable, and since a single viral load measurement is not associated with mortality, we argue that this criterion should not be considered when assessing ICU eligibility.

Given the paucity of evidence on prognosis in patients with HIV and TB in the context of COVID-19 in the SA setting, guidelines could warrant revision and adjustment in subsequent weeks. In addition, the scientific evidence is constantly evolving, and at the time of writing, concerns were being raised that invasive ventilation may not always be associated with good outcomes,^[45] as had also been reported previously in studies evaluating the management of acute respiratory distress syndrome.^[46] As such, decisions have to be revisited in light of emerging evidence. Transparency around the grounds for decision-making, strongly supported by the A4R approach, would be imperative. Transparency is important to afford civil society the opportunity to engage with guidelines, and to challenge and revise decisions under normal circumstances.

However, in the context of a pandemic surge, an appeals mechanism may be logistically challenging.^[33]

Conclusions

Rationing of ICU admission and care will be inevitable if the COVID-19 pandemic expands as predicted. In the context of limited resources, coupled with high levels of vulnerability in the SA population, ICU admission criteria need to be carefully scrutinised for their ethical and legal robustness. All allocation and rationing decisions must be in terms of SA law, which prohibits unfair discrimination. In addition, ethical decision-making demands accurate and evidence-based strategies for the fair distribution of limited resources. There is no evidence at this early stage of the epidemic suggesting that HIV or TB infection on their own will predispose people to an increased risk of infection with SARS-CoV-2 or worse outcomes for COVID-19. It will therefore be unconstitutional and unethical to deny people ICU access based purely on the presence of these infections. We recommend that protocols for determining eligibility for intensive care focus on validated disease-specific scoring systems, with the caveat that these may change as the epidemic unfolds in SA. Rationing decisions and processes should be fair and based on visible and consistent criteria that can be subjected to objective scrutiny, with the ultimate aim of ensuring accountability, equity and fairness.

Declaration. None.

Acknowledgements. None.

Author contributions. TMR conceived the article. TMR, AGN and KM wrote the first draft. TMR and MTB made substantial contributions with regard to content and editing of the manuscript. All authors read and approved the final version.

Funding. None.

Conflicts of interest. None.

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Accepted 18 May 2020.