

## MEDICINE AND THE LAW

# What's in and what's out? Recommendations for developing a legally sound health technology assessment process for South Africa's National Health Insurance

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On 15 May 2024, the National Health Insurance Act No. 20 of 2023 (the Act) was signed into law, and South Africa (SA) officially adopted a national health insurance (NHI) system as part of its efforts to achieve universal healthcare across the country. While NHI has been controversial and much talked about, plenty of how the scheme will operate remains an unknown, and has not been defined within the Act. However, it is evident that, with SA's limited healthcare budget, the NHI scheme is not going to cover everything for everyone. Some decisions will need to be made about what kinds of healthcare and other benefits South Africans can expect to have covered by the scheme – in other words, decisions about what will be included under NHI and what will be excluded. This paper does not aim to discuss the constitutionality or legality of the NHI Act, but focuses only on the issue of how government ought to consider making decisions about what services the NHI covers.

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The National Health Insurance Act No. 20 of 2023<sup>[1]</sup> proposes to make decisions about what services to cover using a mechanism called health technology assessment (HTA). This article will explain what HTA is and what HTA system the NHI Act envisages. It will then analyse the HTA system in the Act to outline some of the shortcomings in the HTA process from a legal perspective, and present recommendations of how to create a legally robust HTA scheme for NHI in South Africa (SA).

## What is HTA?

HTA is often relied upon to make a range of decisions about healthcare. This is not unique or specific to national health insurance (NHI) schemes and, in SA, is currently used to determine, for example, what the prescribed minimum benefits under medical aid schemes should be or which medicines should be included on the essential medicines list.<sup>[2]</sup> When employed, HTA systems have a significant impact of the kind and type of healthcare people receive.<sup>[3]</sup> However, the current system of fragmented and *ad hoc* HTA would not be fit for purpose in use for the NHI scheme.

Consequently, the Act proposes the creation of a dedicated HTA agency for NHI services. This is in line with the approach adopted in a number of other countries that have, in the process of implementing universal health coverage, created semi or completely independent bodies to conduct HTA to determine which healthcare interventions ought to be provided to patients.<sup>[3]</sup> Under NHI, this HTA agency will 'review the range of health interventions and technology by using the best available evidence on cost-effectiveness, allocative, productive and technical efficiency and health technology assessment.'<sup>[4]</sup> In layman's terms, the NHI HTA agency will determine, among other things, whether specific health technologies should be included or excluded from the NHI benefits package. The kinds of criteria

the proposed NHI advisory council and agency will use to make decisions represent a significant departure from the *status quo* of *ad hoc* HTA used elsewhere in SA. The anticipated powers of this HTA agency will have more far-reaching impact than simply allowing a technology or service to be provided – it will determine what kinds of healthcare South Africans have access to. This article now turns to discuss the HTA process outlined in the Act.

## What do we know about HTA for the NHI scheme?

The criteria and process for HTA bodies are variable, and not much is known about the proposed NHI HTA system.<sup>[3,5]</sup> Internationally, the considerations in HTA may be limited to the safety and efficacy of the intervention and burden of diseases, or include more expansive criteria such as cost-effectiveness, socioeconomic impact and ethical implications.<sup>[5]</sup> A typical HTA process consists of four phases: (i) topic selection, which is the process of determining which technologies and services will go through an HTA process for inclusion or removal from the scheme; (ii) analysis, which would involve gathering data on the technology, including its effectiveness, cost, budget impact and cost-effectiveness; (iii) appraisal, which is the process of evaluating the technology against a set of criteria to assess how it performs; and (iv) decision-making, where a final decision is made on whether the technology or service should be provided or removed from the healthcare system.<sup>[2]</sup> It should be noted that the Act does not provide detail of what the NHI's HTA process would look like. This article seeks to provide a suggested model adapted from a traditional HTA process.

Details on the role of HTA in the NHI scheme and, more importantly, the specific criteria to be used to evaluate interventions, are outlined to a limited degree in the NHI Act. The Act envisages the establishment of an HTA committee that will advise the Minister

of Health, but this committee will be a precursor to a formal HTA agency. The white paper on NHI provides slightly more background to the intended purpose and role of an HTA body. Specifically, the white paper contemplates a multidisciplinary team that will review health interventions for cost-effectiveness, a range of efficiencies as well as HTA.<sup>[6]</sup> The white paper defined HTA ‘as a systematic evaluation of properties, effects, and/or impacts of health technology’ that evaluates the ‘social, economic, organisational and ethical issues of a health intervention or health technology.’<sup>[6]</sup> The role of HTA is highlighted as being critical to mitigating corruption and ensuring that healthcare services are affordable, cost-effective and supported by scientific evidence, as well as ensuring the sustainability of the NHI by ensuring efficient use of resources.

In both the white paper and Act, the HTA process considers traditional criteria of efficacy and safety of interventions, as well as cost-effectiveness. Although these criteria are the cornerstone of an HTA process, they are insufficient on their own. Specifically, the current conceptualisation of HTA fails to account for some the legal, and specifically human rights, implications of an HTA decision, and the potential consequences of decision-making. This poses a significant risk to both the robustness of the HTA system and, more importantly, to the sustainability and feasibility of the NHI scheme. This article now turns to discuss the legal issues that should be considered in developing an HTA process.

### Legal considerations in HTA decision-making

A handful of studies have included consideration of the legal dimensions of an HTA, and these recognise that the legal issues that arise in HTA are both significant and context-specific.<sup>[7-9]</sup> When an HTA body makes a decision, it is susceptible to being reviewed and even set aside by a court. This has meant that, in some countries, priority-setting and allocation decisions taken by HTA bodies and governments have been challenged and set aside through legal action. This poses significant risks to the feasibility and budget allocation process as, in some cases, governments have been forced to budget the funding of expensive drugs and technologies, resulting in less funding available for other essential services.<sup>[10,11]</sup> For this reason, the standard HTA process should be adapted to include three legal dimensions: the consideration of constitutional rights; the principles of good decision-making; and the procedural requirements of the Promotion of Administrative Justice Act<sup>[12]</sup> (PAJA), which are added to the standard HTA process in Fig. 1. Each of these additions will be discussed in further detail.

### Constitutional considerations

Since the HTA process will decide what healthcare services are made available or removed, the process will have a significant impact

on the right to health.<sup>[11]</sup> Under SA’s constitutional dispensation, the Constitution<sup>[13]</sup> is the supreme law of the land. This means that decisions will have to align with the government’s obligations under the right to health, and the Constitution more broadly. For example, under section 27 of the Constitution, the government has an obligation to progressively realise the right to access healthcare – this requires that the government work towards increasing access to healthcare, and cannot take away existing access people may have. In addition, there is a particular mention of reproductive healthcare. When healthcare technologies, treatments or interventions are excluded from the NHI benefits packages, it means that they will not be provided at state expense. This has the effect of making these interventions inaccessible, either physically or economically, to a large portion of the SA population. Exclusion decisions, particularly as a result of a review by the HTA committee, could undo existing access to healthcare and so infringe on an individual’s rights. In particular, the government will need to justify why the removal of services people already have access to is not regressive, or those decisions may be found to be unconstitutional and invalidated by the courts.<sup>[14]</sup>

Conversely, rights can be equally important in guiding inclusion decisions. Looking at whether a decision that supports the positive obligations imposed by section 27 could be used to ensure that healthcare decisions lead to progressive realisation of a right. The effect of this is that, from the outset of the HTA process, topic selection of the technologies must ensure that the technologies being selected for evaluation progress rather than regress the right to health. For this reason, how the decision impacts people’s rights should be considered as a component of the appraisal process.

In addition, a constitutionally compliant HTA system will also need to ensure that decisions are rational and reasonable – which requires that decisions be evidence-based and not discriminatory.<sup>[14,15]</sup> This impacts the kinds of considerations that may be factored in when appraising the technology. In particular, it may not be sufficient to consider only the cost of a product: the government may also need to consider whether the kinds of technologies being considered favour particular groups, and whether the distribution and type of healthcare services being offered as a whole are equitable. For example, where an intervention is not as cost-effective but leads to a more equitable distribution of healthcare services and lessens inequality, including it can assist the state in meeting its right to equality obligations.<sup>[15]</sup> In addition, explicitly including consideration of the rights implications of an exclusion or inclusion decision can assist in justifying the decision if it is later challenged.

Consequently, there is a strong case for including the constitutional rights implications as part of the topic selection and appraisal criteria to not only support the realisation of constitutional rights, but also to improve the robustness of the HTA process.

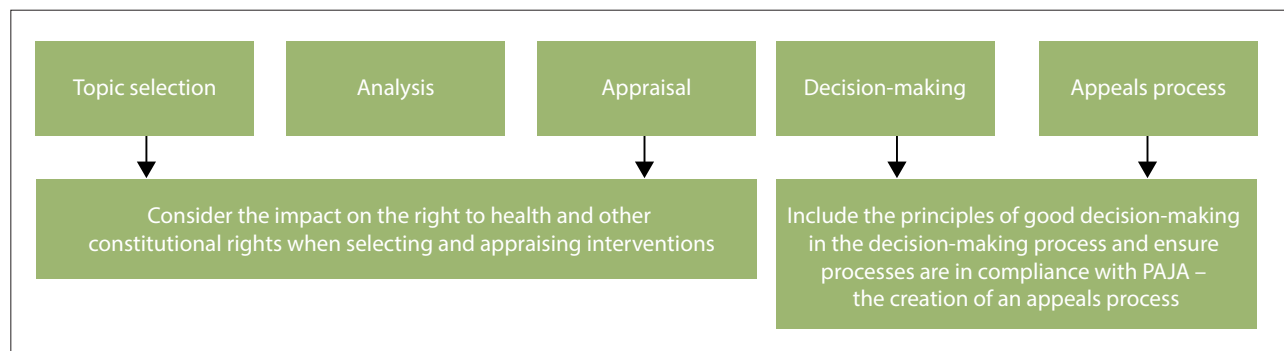


Fig. 1. A proposed process for a legally compliant health technology assessment process. (PAJA = Promotion of Administrative Justice Act No. 3 of 2000.)

## Principles of decision-making

Beyond drawing on our legal framework to ensure that the substantive decisions align with government's constitutional obligations, our legal system also imposes certain procedural and process requirements on decision-making. Irrespective of whether the NHI HTA body is an independent decision-maker or provides recommendations for the Minister of Health to act upon, HTA decisions will be subject to the principles for good administrative decision-making contained in section 195 of the Constitution,<sup>[13]</sup> which states:

'Public administration must be governed by the democratic values and principles enshrined in the Constitution, including the following principles:

- (a) A high standard of professional ethics must be promoted and maintained.
- (b) Efficient, economic and effective use of resources must be promoted.
- (c) Public administration must be development oriented.
- (d) Services must be provided impartially, fairly, equitably and without bias.
- (e) People's needs must be responded to, and the public must be encouraged to participate in policymaking.
- (f) Public administration must be accountable.
- (g) Transparency must be fostered by providing the public with timely, accessible and accurate information.
- (h) Good human-resource management and career-development practices, to maximise human potential, must be cultivated. Public administration must be broadly representative of the SA people, with employment and personnel management practices based on ability, objectivity, fairness, and the need to redress the imbalances of the past to achieve broad representation.'

There is some overlap between these principles and the criteria that the NHI has already outlined for the HTA body. In particular, the obligation to ensure efficient and effective use of resources aligns neatly with the overall objectives of an HTA body in evaluating the effectiveness and cost-effectiveness of interventions. However, the current process leaves little room for public participation in decision-making.

This can be rectified by including public comments in the appraisal process or allowing community representatives to participate in decision-making. An additional shortfall of the current NHI Bill is that there are no mechanisms for dissemination of determinations and reasons for decisions that could improve transparency. A number of HTA bodies, including those in Germany and Sweden, make the appraisal documentation or their determinations, with reasons, publicly available.<sup>[5]</sup> Following a similar process would improve compliance with legal obligations. However, these principles are not limited to the appraisal process, but could also be fulfilled post appraisal before a decision is taken.

These requirements of good decision-making and efficient use of resources apply equally to both topic selection and implementation. It is possible to challenge the use of specific service providers or even why certain health technologies are being prioritised for consideration. As a consequence, the HTA body must not only ensure good administrative decision-making through the appraisal process, but also include features to ensure that proper processes are followed both when choosing what interventions to review and determining who will be tasked with implementing them.

## Procedurally robust decision-making

Section 33 of the Constitution,<sup>[13]</sup> coupled with PAJA, entitles everyone to lawful, reasonable and procedurally fair decision-

making. This means that the HTA decision-making process will need to comply with PAJA, which imposes certain process requirements on any decision-making process, including procedural fairness and reasonable decision-making. This carries with it a host of obligations for decision-makers to not only take lawful and fair decisions but also to provide mechanisms for these decisions to be reviewed. This means that decision-makers in the context of HTA must ensure that their decisions are reasonable and within the bounds of what the law allows. In addition, where a person's right is affected, a decision-maker may be required to provide reasons for taking a particular decision. As discussed above, this will likely always be the case for decisions related to healthcare. In addition to the above, there must be mechanisms to review the decision internally – using either the National Department of Health or HTA body's infrastructure – and through the court system.

Most significantly, the requirements of fair administrative decisions require a level of standardisation in decision-making to ensure that the same sorts of criteria are applied consistently through evaluations. If an HTA body is the decision-maker, this is limited to ensuring that the correct criteria are assessed in a consistent manner. However, if the HTA body makes recommendations that a decision-maker, such as the Minister of Health, may choose to follow, the process is more complicated, as the Minister may opt to go against the recommendations of the HTA body, provided he has valid reasons to do so.

## Conclusion

In conclusion, the introduction of the NHI Act in SA marks a significant step towards achieving universal healthcare in the country. The Act proposes the use of HTA to make decisions about the inclusion or exclusion of healthcare interventions in the NHI benefits package. However, as this article highlights, there is a need for legal considerations to be integrated into any HTA process adopted to ensure the robustness of decisions on what services are included or excluded from the NHI, and compliance with legal requirements.

The HTA process, as outlined in the NHI Act, lacks clarity on the specific criteria and processes that will be used to make critical decisions about what the NHI will cover. This poses a significant risk to any decisions made about what to cover, leaving the scheme's coverage susceptible to legal challenges. The present article underscores the importance of incorporating three crucial legal dimensions into the HTA decision-making process. Firstly, constitutional rights, especially the right to health, must be considered to avoid decisions that may infringe on individuals' access to healthcare. Secondly, principles of good decision-making, including transparency, accountability and public participation, should be integral to the HTA process. Lastly, procedural fairness, as mandated by the Constitution and PAJA, is essential for lawful and reasonable decision-making to improve the rigour of decisions on what the NHI will cover.

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