Role of the patient and citizen in health technology assessment and decision-making in South Africa

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Despite the implementation of multiple health interventions aimed at improving health and healthcare systems in sub-Saharan Africa, poor health outcomes remain a concern. This may be due to interventions failing to inadequately address the population's perceived needs and interests.[1,2] An increasing amount of evidence indicates that patients and citizens who participate more actively in their healthcare experience better health outcomes and lower expenditures, resulting in overall health system improvement.[1] Consequently, public and private healthcare organisations worldwide are implementing strategies to enhance patient involvement, such as educating patients about their ailments and involving them in care decisions. Patient activation refers to a patient's knowledge, skills, capacity and motivation to manage their health and care. In contrast, patient engagement is a broader concept that combines patient activation with interventions aimed at enhancing it and promoting positive health behaviours such as regular exercise or preventive care.[3] This approach aims to improve health outcomes, enhance patient care and lower overall costs.

Many countries utilise health technology assessment (HTA) to inform decisions regarding reimbursement, procurement or access to interventions. These assessments are based on multi-disciplinary processes that employ explicit methods to ascertain the value of health technology at various stages in its life cycle.[4] Health technologies encompass medicines, diagnostics, medical devices, surgical procedures, health educational programmes, and digital technologies. Key stakeholders affected by HTA and its decisions include patients and citizens. Therefore, the HTA appraisal process should consider their perspectives and ensure their voices are heard.[5] While clinical effectiveness, safety, affordability and cost-effectiveness are essential in HTA, patient-based evidence and input from patients or citizens provide valuable insights into their experiences, needs and attitudes. This includes perspectives from patients, families, caregivers, legal representatives, patient organisations and advocacy groups regarding the disease or health technology.[6] The principles of decision fairness, equity and patience relevance should be applicable to all countries despite the limited resources available. To facilitate the realisation of their healthcare objectives, patient and citizen involvement must be consistent with the sociocultural, ethical, regulatory, economic and political perspectives of the respective countries.[5]

Hence, this review examines how the role of patient and citizen has been conceptualised in legislation, regulations, and policies in South Africa (SA) and internationally to uncover different aspects of patient and citizen involvement related to the setting and HTA practice.

Background

SA's National Health Insurance (NHI) aims to achieve universal health coverage (UHC) by providing all South Africans with a Health Service Package of high-quality healthcare services. Section 27 of the SA Constitution mandates that the government 'take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation' of every South African's right to access healthcare services.[7] Innovative pharmaceuticals increasingly cater to the needs of vulnerable patient populations and small, specific groups. Nonetheless, there is growing consensus among SA stakeholders that new approaches are required to strike a delicate balance between stimulating true innovation, particularly regarding unmet health needs, and ensuring both financial sustainability for health funders and patients as well as their accessibility.

In accordance with the NHI White Papers[8] and NHI Bill,[9] enhancing HTA capabilities for pharmaceuticals and other health technologies will be a vital component of SA's NHI. HTA is a systematic, transparent, explicit, robust, unbiased scientific process to evaluate healthcare technologies to inform policies such as setting priorities and defining health benefit policies.[10] However, it is unclear how the HTA process will be executed and what its governance structure will be in SA.

Prior to the implementation of NHI, the Presidential Health Compact, signed in June 2019, intended to significantly improve the quality of healthcare. Pillar 2 of the Presidential Health Compact[11] requires all signatories to promote access to innovation, improve access to essential medicines and ensure treatment decisions are based on an in-depth assessment of the relative benefits of various therapeutic options at the population level, necessitating a budgeted HTA.

Specific action points under this pillar 2 include:

- Developing the HTA Strategy and a costed implementation plan by April 2020, detailing how evidence-based medicine and the value of innovation are addressed.
- Establishing an HTA Committee for medicines and medical products to oversee the HTA implementation from April 2021.
- Developing a stakeholder database of all relevant HTA stakeholders.
- Conducting stakeholder workshops to inform the HTA Strategy from March 2020.
- Develop a policy for innovative access models and re-establish compassion models.

However, the action points do not outline a strategy for multi-stakeholder engagement in HTA at any level. Despite the legal framework supporting public participation in South Africa, effective, accessible, and inclusive participation requires targeted efforts to promote awareness, address structural barriers, institutionalize inclusive processes and provide adequate resources.[12] Even though legal frameworks such as the Constitution and acts like the Promotion of Access to Information Act, 2000[13] and Promotion of Administrative Justice Act 2000,[14] support these efforts, ongoing commitment from both the civil society and government is necessary for democratic governance. In his paper, Taute[15] has made the case of the essential nature of collaboration for effective service delivery, however even though collaboration exists, collaborative governance has not permeated yet , among stakeholders, patient, patient advocacy groups and the public.

According to a framework by Carman ***et al***.,[16] patient engagement takes place at three main levels, the highest being policymaking, where consumers influence public health and healthcare policies, laws and regulations.

HTA has undergone a stepwise evolution, becoming more comprehensive and incorporating various stakeholders, with patients playing a significant role. Addressing patient-centred questions in HTA and involving patients more effectively throughout the process, enhancing patient empowerment can be easily increased, allowing patients to engage more actively in healthcare decision-making.[17]

In their article titled 'Why patients should be involved in health technology assessment',[18] the authors conclude that an HTA process that incorporates patient perspectives can be beneficial for patients, legislators and healthcare professionals. This conclusion is supported by four arguments. First, patients have both the right and obligation to have a role in the planning and delivery of their healthcare, individually and collectively. Second, treatment and service decisions should align with the patients' core beliefs and morals. Third, patients offer unique insights into living with a health condition and their needs for related services and treatments, which enriches the knowledge base and enhances the HTA process. Fourth, patient participation can promote the methodological development of HTA, particularly in early scientific advice and managed entry with evidence production.

The role and contributions of patient and citizen actors in HTA processes, policy development and eventually HTA institutionalisation are not considered in SA's journey toward HTA institutionalisation.[19] In addition, while these actors could contribute to HTA and reimbursement procedures, they lack country-specific tools and resources that would aid and enhance their capabilities.

Methods

To achieve this study's aim, relevant national and international documents and reports were identified and analysed to assess gaps and opportunities for patient and citizen involvement (PCI) in HTA in SA. Document selection was based on those retrieved for a previous study.[10] The review examined regulations, policies, guidelines and legislation introduced in the country since 1965.

Search terms included 'health technology assessment', 'decision-making processes', 'patient engagement', 'patient involvement', 'citizen engagement' and 'citizen involvement'. Peer-reviewed literature on NHI, HTA and decision-making processes in SA was sourced from Medline via PubMed and Google Scholar. Additional relevant materials were identified through purposeful searches of references cited in the initial literature set.

International documents will provide examples of patient and citizen roles at organizational and policy levels in countries with and without formal HTA agencies. All documents and reports are publicly available.

Data sources include resolutions, legislations, regulations, government policy and technical reports gleaned from the websites of relevant authorities such as the National Department of Health (NdoH), PubMed, International Journal of Technology Assessment in Health Care, and global and national HTA associations. Data analysis involved reviewing each document and extracting relevant information into a data extraction sheet. This sheet included the document title, type, date, purpose, key features and relevance to HTA.

The results were analysed using the stages of the engagement continuum—participation, involvement and engagement—with the ultimate goal of fostering partnerships and shared leadership.[3,16] This framework for patient and family engagement involves healthcare professionals at all levels, along with patients and families.

Results

Patient and citizen involvement (PCI) in HTA and/or evidence-based decision-making in SA

Table 1 presents excerpts from SA legislation, regulations and government policy reports[8-11,20-27] outlining various levels of patient and citizen involvement in health decision-making. Notably, not all retrieved documents explicitly reference patient or public engagement or involvement, despite emphasising evidence-based decision-making or the application of HTA. This table also showcases the relevant stages of the engagement continuum based on the content of these documents.

Additionally, some of the legislation also mandates community representation in advisory bodies and statutory Health Professional Councils.

PCI in HTA international

A study was conducted to pilot a questionnaire exploring context-specific aspects of PCI in low- and middle-income countries (LMICs), collecting experiences encountered with PCI and identifying opportunities for patient and citizen contributions to local decision- and policy-making processes related to health technologies.[5] The questionnaire was piloted in Brazil, Indonesia, Nigeria and SA. It

Table 1. Excerpts from relevant South African legislation, regulations and government policy reports

Reports and documents	Stages of engagement	Relevant excerpts
National Health Plan for South Africa 1994[12]	Community participation or involvement	All legislation, organisations and institutions related to health have to be reviewed ensuring that mechanisms are created for effective community participation, involvement and control. Accountability and Community Participation: The primary health care (PHC) approach emphasizes accountability to community structures at local, district, provincial, and national levels, ensuring effective community participation through democratically elected structures, sector representatives, and stakeholders, who have the power to decide on health issues. Mechanisms These policy principles will be translated into action by giving attention to cost-effective treatment and control methods of some infectious diseases (diarrhoea, acute respiratory infections), with strong involvement of families/communities.
Health Technology Policy 2001[14]	Patient perspective	Macro HTA – all levels of the health care delivery system from both public and private sectors, that can bring a patient perspective to bear on the decisions
National Health Act 2003[15]	Patient participation	Participation in decisions 8. (1) A user has the right to participate in any decision affecting his or her personal health and treatment.
Patients' Rights Charter 2008[21]	Public participation	2.2 Participation in decision-making Every citizen has the right to participate in the development of health policies, whereas everyone has the right to participate in decision-making on matters affecting one's own health.
Department of Health HRH Strategy for the Health Sector 2012/13–2016/17[17]	Patients complain mechanism. Patient-centred system	The Office of Health Standard Compliance (OHSC) was established under the National Health Amendment Act 2013 to improve care quality by conducting inspections and establishing an ombudsman for patient complaints, aligning with the Strategic Plan's emphasis on patient-centred care.
NHI White Paper 2015[5]	Public participation	….necessitate central hospitals becoming a competence of the national sphere of government requiring new governance structure entailing public participation. 6.5. Implementation of National Quality Standards for Health: The implementation of the Patients' Rights Charter will be strengthened to ensure a patient-centred approach where the principles of patient's rights, choice, empowerment, participation and access to safe, quality and appropriate services and information are recognized.
Health Market Inquiry 2019[20]	Patient's perspective Patient-centred care Patient engagement	Healthcare data, quality, and outcomes Critical success factors – 9.1. outcome measurement must be done from the patient's perspective, including patient-driven registration of symptoms, quality of life and functional status both pre- and post-intervention. Summary of recommendations 52. We recommend the creation of an Outcomes Monitoring and Reporting Organisation as a platform for providers, patients and all other stakeholders 62. Implementing a national system of outcome measurement requires the engagement of clinicians and patient representative groups as critical success factors in developing useful and effective outcome registries.
Presidential Compact 2019[8]	Community/ public engagement	Chapter 13. Community Engagement The population or the community including health service users must be actively engaged in the processes of unifying the health system. The quality dimensions and health services are people-/patient-centred.

Table 2. Examples of PCI in countries without HTA agencies[5,28]

Agency	How are individual patients and/or carers involved in the HTAs (e.g., submissions, participating on committees, etc)?	How are organisations representing the views of patients and/or carers involved in the HTAs?
Agency for Health Quality and Assessment of Catalonia (AQuAS) – Catalonia, Spain	AQuAS employs various strategies in Clinical Practice Guidelines (CPGs) to incorporate patient/carers perspectives, utilizing qualitative studies to identify major concerns and address them. • Incorporating patients/carers as members of the drafting team developing the guideline.	AQuAS collaborates with the Patient Advisory Council, which represents all Catalan patients' associations and with specific patients' associations. In PAGs, patient and carers (family and non-family members) associations can be used as the initial point of contact to properly select the most adequate participant profiles.
Agency for Health Technology Assessment – Poland (AOTM)	Individual patients may provide their opinions through patients' organisations	1. Providing written opinion to AOTM; 2. Providing oral opinion to Transparency Council; in the former case, the opinion is given on demand of AOTM analytical staff, in the latter – patient's organisations apply for a hearing.
Australian Department of Health and Ageing Prostheses List Committee and its Clinical Advisory Groups and Panel of Clinical Experts	Consumer representatives serve on Prostheses List Advisory Committees and Clinical Advisory Committees, providing clinical advice for balanced recommendations on products and associated benefits. Consumer representatives with technical knowledge are nominated through the Consumers Health Forum, a non-disease-based national peak consumer organization, and have a community network they interact with. Consumer representatives offer expert advice from a consumer/patient perspective, without requiring patient or patient organization submissions to be a formal part of the process.	Consumers are witnesses to the process and thinking, particularly during committee meetings, and: • Observe how decisions are made and the effectiveness of communications. • Determine if a fair process is followed, without conflicts of interest being evident. • Check that the developed recommendations are considered and clear, the rationale and reasoning can be followed (and is recorded) • 'Check' the consistency of decisions and reuse of evidence; influence poor decisions • Provide 'corporate memory'. • Witnesses participate in the process, contributing to discussions on evidence sufficiency for prostheses recommendations and managing uncertainties.
Canadian	• Two public members are appointed to the 13-member Canadian Drug Expert Committee (CDEC) to represent the public interest and present the patient group input at CDEC meetings. • Patient groups contribute patient perspectives via the CADTH Patient Input Process. • Online submissions are used to gather input during the drug submission review process, aiding in the review protocol and being included in the summary and where applicable. • Issues and outcomes of importance • Benefits and adverse effects • Unmet needs • Patient input is presented by public members, used in deliberations, and reflected in the CDR Recommendations, which are publicly available online.	
Centre for Drug Evaluation (HTA) - Taiwan	It is focused on the patient representative chosen from the patient groups, at the current proposed model, opinions from other patients or the public via the website, as other countries do, are not included.	The Expert Meeting and the PBRS Joint Meeting are two pluralistic appraisal committees that review and make final decisions on listing and pricing. If an appeal is submitted, experts or a patient representative may present their viewpoints in the PBRS Joint Meeting.
Federal Joint Committee (GBA) - Germany	Patients can propose topics for consultation, they are involved at all levels of decision-making, i.e. in all available committees. They cannot vote but they may agree or disagree.	

(continued)

Table 2. (continued) Examples of PCI in countries without HTA agencies[5,28]

Agency	How are individual patients and/or carers involved in the HTAs (e.g., submissions, participating on committees, etc)?	How are organisations representing the views of patients and/or carers involved in the HTAs?
NICE, UK	Scoping, development, consultation, publication, implementation support Levels of involvement • Consultation with the patient and voluntary organisations/charities • Patient/carer evidence and views (submission*) • Patient/carer experts (personal testimony) • Lay members (part of decision making – minimum 2, often 3, sometimes 6 – patient experiences!) of committees/ developmental groups • Patient/public versions of NICE guidance • Citizens Council (societal values) Patient evidence is presented as a summary.	

was determined that patient organisations exert their influence mostly through lobbying and awareness initiatives or through legal channels to gain access to medicines (litigation).

Patient engagement remains limited to disease-specific sectors and depends on the prominence of various patient organisations or advocacy groups. While Brazil has a legal structure for involvement, religious groups and other advocacy organisations play a significant role across all levels of the healthcare system and attempt to impose their perceived rights (e.g., access to a specific therapy). The involvement of religious communities and consumer associations and communities or the participation of civil society has emerged in all countries analysed in accordance with the cultural, religious and societal context of patients and the general public in these countries.

This study aligns with a scoping review[1] conducted on patient and public engagement strategies for health system improvement in sub-Saharan Africa. The research mainly focused on engagement in 'service design' or health research, particularly before implementing new health interventions. The findings identified five key engagement strategies: (1) traditional leadership support, (2) community advisory boards, (3) community education and sensitisation, (4) community health volunteers/workers and (5) embedding engagement within existing community structures. Patient and citizen engagement initiatives were generally located at either the 'involvement' or 'consultation' stages of the engagement continuum, rather than higher-level engagement.

Another study[29] on public engagement in Health Priority Setting in LMICs suggests that countries should reconsider their engagement policies owing to the substantial resources required, the lack of evidence on effective public engagement in health planning and the risks associated with these processes. The authors argue that the resources currently spent by development partners on promoting public engagement may be better used to strengthen evidence through small-scale, community-driven trials in LMICs. National authorities should strive to create an environment conducive to citizen participation by implementing practical measures such as publicising resource allocation decisions and establishing an appeals process.

Discussion

This review highlights the current gaps and opportunities for patient and citizen engagement in SA. By examining how the role of patients and citizens is conceptualised in legislative, regulatory and policy frameworks, this review aimed to identify gaps and opportunities for PCI in HTA within this setting.

A key limitation was the number of legislative, regulatory and policy documents retrieved; a more extensive search might have identified additional relevant materials. This limitation can be addressed by engaging with patient advocacy groups, healthcare professionals, and policymakers to better understand their challenges in accessing treatment and participating in the HTA process.

The legislation and policy documents indicate that engagement initiatives are located at either the 'involvement' or 'consultation' stages of the engagement continuum, rather than at higher levels. Patient advocacy groups typically focus on raising awareness of the disease burden, advocating for access to specific technology or using legal channels to compel coverage arrangements for specific therapies. More formal and active stakeholder participation could boost acceptance and agreement with HTA or HTA-like recommendations and final choices.[5]

In countries with formal HTA institutions, patient and public engagement are embedded at different levels into the HTA processes (Table 2). However, several barriers hinder individual-level engagement including:

- Lack of appropriate skills, training and education
- Insufficient information regarding roles and responsibilities
- Lack of logistical and/or financial support for work.
- Lack of integrated strategy

These examples demonstrate that PCI in HTA and decision-making processes can be a dynamic, step-by-step process that begins with understanding of HTA followed by participation in the HTA process and leads to involvement during various phases of the assessment and membership in the HTA appraisal committee. The key is to select appropriate starting points that build on HTA research partners' strengths, meet some of the immediate needs of the policy- and decision-makers and contribute to longer-term goals.[30] However, involvement in HTA entails continuous skills development and educational and training of patient and citizen actors as well as those conducting the assessment. In addition to comprehensive training, sensitization prior to engagement, implementation to boost people's knowledge and confidence to willingly get involved is recommended.[31] Hence, with the current level of collaborative governance and engagement of patients, patient advocacy groups and citizens, there is an opportunity for their involvement in the HTA and subsequent decision-making process, provided that all actors make a concerted effort.

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