

Where from and where to for health technology assessment in South Africa? A legal and policy landscape analysis

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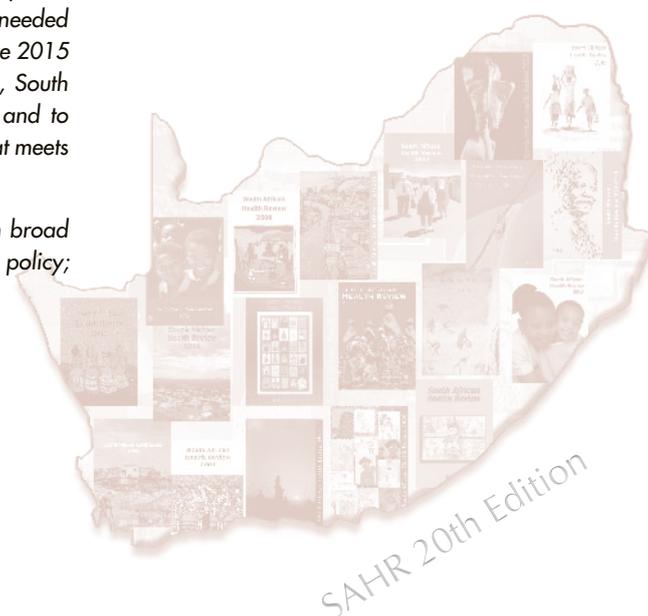
The aim of National Health Insurance (NHI) is to achieve universal health coverage by delivering a Health Service Package (HSP) of quality healthcare services to all South Africans. Health technology assessment (HTA) is an explicit, transparent and evidence-informed approach to healthcare prioritisation and HSP formulation. In this chapter, definitions of HTA are discussed, a legal and policy analysis of HTA development since 1994 is presented, and adoption of an HTA framework is recommended to guide future healthcare prioritisation, including HSP formulation.

The 2015 NHI White Paper includes a strong policy intent for the comprehensive adoption of HTA systems. However, limited attention has been given to financing these prioritisation mechanisms and structures. A comprehensive secondary data-gap analysis of relevant international and national resolutions and legislation revealed no specific provision in the National Health Act for HTA, which is narrowly and incompletely defined, and no legislative provision for evaluation of the broad range of interventions for which HTA could be used.

Much prior work has been done and much consideration has been given to HTA in South Africa, but implementation efforts have been fragmented. Further development and amendment of the relevant HTA policy and legislative frameworks are needed in order to inform appropriate universal health coverage, and to align with the 2015 NHI White Paper. With no national HTA mechanism or entity yet in place, South Africa is well positioned to learn from the experiences of other countries and to establish an HTA framework that delivers the components of HTA in a way that meets the needs of NHI and the National Development Plan.

A five-step implementation process is recommended to: define HTA through broad stakeholder engagement; align policies with NHI; harmonise legislation and policy; legislate amendments in Parliament; and implement a unified vision for HTA.

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Introduction

We live in a world of finite resources. Budgets are constrained within the health system, yet the demand for quality health care is seemingly infinite. In South Africa, healthcare policymakers face difficult choices on a daily basis as they balance optimal patient care against the best value for healthcare spending. Explicit, transparent and evidence-informed approaches to healthcare prioritisation can greatly enhance the quality and integrity of our policymakers' decisions.¹

South Africa has adopted a universal health coverage (UHC) approach to health care in its Constitution and recognises the health inequalities present in the country. This approach was implicit in the 1994 provision of free primary health care nationally and in the 1996 extended healthcare plan for pregnant women and children, but was made explicit in the National Health Insurance (NHI) White Paper in 2015.² The NHI mechanism aims to achieve UHC by 2025 with the delivery of a platform of comprehensive quality healthcare services to all South Africans (sometimes referred to as the benefits package). However, as noted in the 2016 *South African Health Review*, the 2015 NHI White Paper does not yet provide details of the package or the methods required to determine the contents of such a package,³ but proposes the establishment of an NHI Benefits Advisory Committee to do so.

Clearly, a fair, evidence-based and trusted approach to determining the criteria for inclusion of services and new technologies within the NHI healthcare platform will be required prior to implementation. International experience has shown that a health technology assessment (HTA) system can aid identification and inform decision-making about funding of health services and technologies. This might take into account clinical excellence and cost-effectiveness, practical issues such as affordability and human-resource constraints, and social values such as equity, fairness, and access to health services.¹ As a country moves towards UHC, one of the issues for consideration is governmental recognition of the need to drive, sustain and actively support the HTA process.⁴ This chapter documents the development of HTA legislation, regulation and policy in South Africa over the past 20 years. Existing gaps are identified and resultant opportunities are explored; thereafter, recommendations are made on the steps required prior to adoption of an HTA framework to guide future healthcare prioritisation, including health service package (HSP) formulation.

What is health technology assessment?

Health technology assessment is variably defined. The classification of health technology is understood differently both between and within countries and institutions, often leading to confusion among healthcare decision-makers.

The World Health Organization (WHO) defines health technology broadly as: "the application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives".⁵

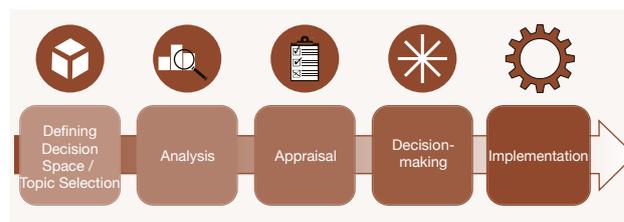
Health technology assessment is defined by the WHO as: "the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences".⁶

It is important to note that in accordance with these WHO definitions, HTA is not confined to pharmaceuticals and medical devices, but includes the broader organisation of the healthcare system.

For the purposes of this chapter, we use the working definition of health technology formulated at the first meeting of the International Decision Support Initiative in Africa held in March 2015 and hosted by PRICELESS SA:^a "A health technology is any intervention that may be used to promote health, to prevent, diagnose or treat acute or chronic disease, or for rehabilitation and palliative care."¹ This broad definition encompasses non-pharmacological interventions including behavioural and psychosocial interventions and public health programmes. It extends the range of health technologies to include a focus on prevention as well as diagnostic, treatment, rehabilitation, and palliative modalities.

Thus the mechanism and processes for assessment of the health technologies defined above constitutes HTA. Importantly, HTA goes beyond an analytical exercise and incorporates upstream processes such as policy decisions and selecting elements for assessment and downstream implementation in a multi-component process (Figure 1).⁷

Figure 1: The components of a health technology assessment process



Source: Adapted from Walker et al., 2007.⁷

How is HTA delivered?

There is no 'one-size-fits-all' for delivery of HTA. In a 2015 survey of 111 WHO Member States, most countries reported having a formal process for compiling, analysing and synthesising relevant information and scientific evidence systematically to support healthcare policy decision-making.⁸ In one-third of countries, this process was not termed 'HTA', and fewer than half of the countries legislated HTA. Health technology assessment was used for different purposes across countries, with planning and budgeting being the key driver of HTA.

Most countries reported having a national entity with more than six staff members doing HTA analysis for the ministry of health. As expected, organisations in high-income countries were better resourced than those in middle- or low-income countries.

^a PRICELESS SA (Priority Cost Effective Lessons for System Strengthening South Africa) was launched in 2009 to support the development of evidence-based information and tools to optimise the use of scarce resources so that better decisions can be made in prioritising public health (see <http://www.pricelessa.ac.za/Home.aspx>).

How is healthcare policy and legislation made in South Africa?

The National Department of Health (NDoH) is responsible for formulation of national health policy. Legislation and regulations that determine policy should be approved by Parliament following a period of public participation and comment.⁹ At provincial level, legislation can be passed that is specific to the provision and functioning of district health councils, and to establish and describe the functions of clinic and community health centre committees.¹⁰ Responsibility for development of legislation and policy related to HTA lies with the NDoH.

Methodology

Our aim was to identify and analyse relevant national and international documentation including resolutions, regulations, legislation, and policy reports to aid the identification of current gaps in, and opportunities for, HTA in South Africa. We recognise the existence of, but did not review, the decision-making structures in South Africa that use components of HTA methodology in decision-making. Some of these include the National Health Laboratory Services, the National Essential Medicines List, and provincial and hospital-based structures.

Our chosen method was secondary data analysis, which is the analysis of data or information gathered elsewhere, or for a purpose other than the current initiative, but that sheds light on the aim of the current initiative.¹¹ The following secondary data sources with a focus on HTA were included in our analysis: resolutions, legislation, regulations, government policy and technical reports.

The iterative search for documentation was conducted from March 2015 until June 2016 and included:

- websites of relevant agencies, e.g. the WHO, the NDoH, academic and research institutions, and international and national HTA associations;
- references on included documents; and
- contacts with experts in the field.

Key references to HTA in the documentation were extracted and summarised. Focus was placed on the legislative and policy changes that would be required to establish an HTA entity in South Africa and the optimal structure and support platforms for such an entity. Data were interpreted by the authors to aid determination of the overall key gaps and opportunities within current law and policy.

Two analyses were conducted: a comprehensive review of relevant international and national legislation and regulation, and a historical review of HTA policy development in South Africa from 1994 to date. A separate synthesis of the gaps and resultant opportunities was done for each analysis.

Review of relevant international and national legislation and regulation

Regulations were scrutinised to identify the legislative changes that would be required to incorporate and apply an HTA framework in South Africa.^b

International

World Health Assembly Resolution 67.23

In May 2014, the World Health Assembly (WHA) passed Resolution WHA 67.23 “Health intervention and technology assessment in support of universal health coverage.”¹² The Resolution acknowledges the importance of evidence-based policy development and decision-making in health systems and recognises the need for regional and international networking, and collaboration on health intervention and technology assessment to promote evidence-based health policy. The Resolution urges Member States to consider establishing national health systems that include health intervention and technology assessment. As a WHO member, South Africa is obliged to incorporate the principles contained in WHA 67.23 in a national HTA policy and legislative framework.

National

The Constitution, Act 108 of 1996

The right of all South Africans to have access to healthcare services is enshrined in the Bill of Rights of the Constitution (Section 27(1)(a)).¹³ Provision is made for the State to take reasonable legislative and other measures, within its available resources, to achieve the “progressive realization” (Section 27(2)) of this right. Therefore, the Constitution requires that when making difficult and unavoidable decisions that necessarily impact on access to healthcare services, the State must demonstrate a degree of ‘reasonableness’. International experience in this area has shown that the establishment of an HTA framework may provide this reasonableness,¹⁴ as it facilitates consideration of a range of social values in the context of the health-system objectives and available resources.

National Health Act of 2003

The 2003 National Health Act (NHA) makes no specific provision for the establishment of an HTA framework.¹⁵ The Act includes a definition of HTA, but it is a narrow definition with a focus on machinery and equipment and excludes medicines, medical devices and intravenous devices. This definition will have to be amended as a first step towards establishing an HTA legislative framework.

The NHA (as amended in 2015) makes provision for the creation of the Office of Health Standards Compliance (OHSC), which interprets the National Core Standards relating to the assessment of healthcare provider quality.¹⁶ The creation of an independent HTA body would require similar legislation to that of the OHSC through amendment of the NHA, along with details surrounding the appointment of a Board, independent committees and the powers and functions associated with an HTA body.

Currently, the Minister may utilise Section 90(1) of the NHA, which provides authority to make regulations (standards and guidelines) for use of a health technology. As an interim step to legislative development, an HTA process could inform the Minister’s use of Section 90(1).

The Medical Schemes Act of 1998

Under the Medical Schemes Act,¹⁷ provision of prescribed minimum benefit (PMB)^c conditions is mandatory for all medical schemes providing health services in the private sector. Prescribed minimum

^b A summary of the main legal imperatives and the implications for HTA in South Africa can be found at www.pricelessa.org.za

^c Prescribed minimum benefits are a legislative requirement for those conducting the business of a medical scheme as defined in the Medical Schemes Act of 1998.

benefits consist of 25 defined chronic conditions, 270 defined diagnosis and treatment pairs, and any emergency medical condition. Medical schemes may develop reimbursement formularies and treatment protocols to manage the benefit of PMB treatment. The principles of evidence-based medicine and cost-effectiveness are applied when developing these formularies and protocols, implying that medical schemes in fact conduct a form of private or 'in-house' HTA. However, the Act does not specify a particular technical or procedural HTA standard to be applied by medical schemes when determining formularies or treatment protocols.

The Act applies only to medicines and not to devices. The Act would have to be amended in order for the governance of medical devices in use in the private sector to be included under the same conditions as medicines.

The Medicines and Related Substances Act of 1965

The Medicines and Related Substances Act provides for the registration, control and marketing of medicines under the Medicines Control Council (MCC).¹⁸ The Act was amended in 2015 to enable the establishment of the South African Health Products Regulatory Agency (SAHPRA), proposed for 2017.¹⁸ The Agency will have a broader mandate than the MCC, including the registration and control of medical devices, in vitro diagnostics, and complementary medicines.

A well-functioning SAHPRA will be critical to the success of HTA in South Africa. Regulation is primarily concerned with public safety and demonstration of efficacy, whereas HTA is applied to reimbursement decisions, which involves consideration of value for money, effectiveness and wider health-system objectives.⁷ An HTA system that is co-ordinated but independent of a regulatory function enables decisions about public-resource allocation to be separated from decisions about safety, thus facilitating accountable and clear decision-making systems.

Regulations relating to a transparent pricing system under the Act (last amended in February 2016)¹⁹ include provision for the Director-General to request detail from stakeholders as to the comparative efficacy, safety and cost-effectiveness of a medicine relative to other medicines in a therapeutic class when setting the price at which medicines are available in the private market (the single exit price (SEP)). Guidance on the methods required to evaluate the information received (the Guidelines for Pharmacoeconomic Submissions) were gazetted pursuant to the Regulations in February 2013. Although decisions regarding the SEP are different in nature from decisions about public subsidy of different types of technologies, these Regulations provide a potential mechanism to request evidence inputs in HTA processes.

The following gaps were identified in South African legislation and Regulations with regard to HTA:

- There is currently no specific provision in the NHA for the establishment of a dedicated HTA body and associated structures.
- Health technology is narrowly and incompletely defined within current legislation.
- While assessment of the efficacy and safety of medicines is covered under the Medicines and Related Substances Act, and under the Medical Schemes Act in the private sector, no

provision is made for the assessment of medical devices in either sector (although a Bill is currently before Parliament to include devices within the Medicines Act).

The following opportunities were identified arising from the gap analysis:

- A precedent exists for amendment of the NHA to include an HTA body, namely the example of the legislation governing the Office of Health Standards Compliance.
- Stakeholders will be required to formulate a coherent and encompassing definition of health technology and health technology assessment, acceptable to all, prior to drafting HTA legislation.
- The limited legislative framework for HTA currently provides the opportunity for the required legislation (such as the establishment of an HTA Agency and legislated interactions with other regulatory bodies) to be tailored towards the specific requirements of NHI.

Historical review of HTA policy development in South Africa, 1994–2017

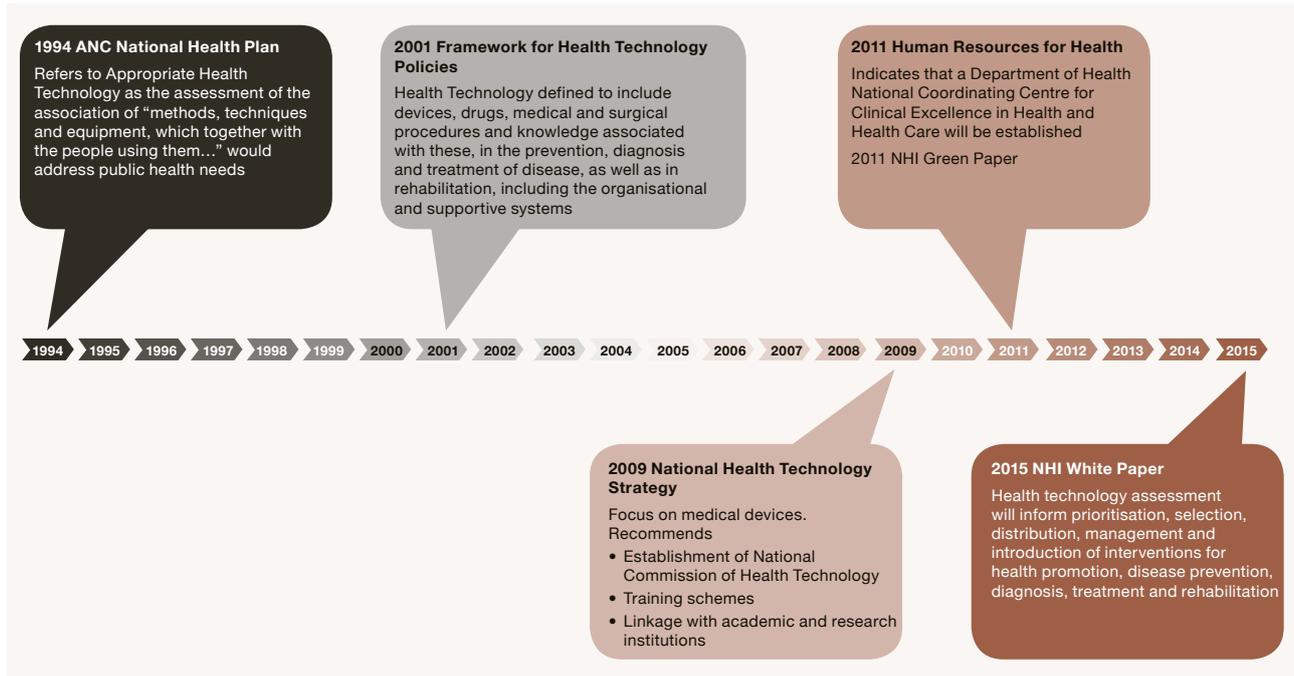
Five key HTA or HTA-related policy documents^d have been published since 1994:

- 1994 African National Congress National Health Plan²⁰
- 2001 Framework for Health Technology Policies^e
- 2009 National Health Technology Strategy^e
- 2011 Human Resources for Health South Africa: HRH Strategy for the Health Sector 2012/13–2016/17²¹
- 2015 National Health Insurance White Paper (which superseded the 2011 NHI Green Paper).²

d A tabulated summary of the HTA-relevant sections of each document can be accessed at www.pricelessa.org.za

e This document is not available on the governmental sites. A scanned copy can be accessed at www.pricelessa.org.za

Figure 2: Timeline of key events in the development of health technology in South Africa from 1994 to present



The synthesised findings and the implications for HTA in South Africa are outlined below.

2001 Framework for Health Technology Policies and 2009 National Technology Strategy

Two NDoH policy documents focus specifically on the establishment and administration requirements for a National Health Assessment mechanism. However, similar to the findings in the legislation review, different definitions and understandings of what constitutes health technology and HTA exist across these documents. The 2001 Framework provides overarching guidance on the components of policy, and proposes the establishment of several committees, including a National Health Technology Forum to be chaired by the Director-General of Health. The 2009 National Health Technology Strategy acknowledges the broad definition of HTA but focuses exclusively on medical devices. Despite detailed guidance in the annexes on the mechanisms and activities required to establish a functional national HTA system, there has been relatively little progress in the application of such a national HTA system since then. A universally understood definition of HTA and its application within the healthcare system is required to harmonise current South African policy.

2011 Human Resources for Health South Africa HRH Strategy for the Health Sector 2012/13–2016/17

The HRH Strategy published in 2011 recommends that a National Coordinating Centre for Clinical Excellence in Health and Health Care be established with functions reflective of HTA. However, the recommendation is not explicit.

2015 NHI White Paper

South Africa is progressing towards adopting UHC through provision of a comprehensive platform of health care as outlined in the 2015 NHI White Paper.² The White Paper definitively states the intended direction regarding the use of HTA to support decision-making under

NHI. The principles of evidence-based health care clearly underpin NHI, providing an ideal platform to support the establishment of a national HTA structure. Although not explicitly stated, the implication is that creation of an HTA entity is critical to ensure the efficient use of resources in an NHI environment. However, limited attention is given to the detail of how affordable health technologies will be selected for a comprehensive set of services. The HTA components of the NHI will require alignment with previous or revised HTA policy and frameworks and with future HTA legislation, and this must be made explicit.

The following gaps were identified in South African policy and the development process with regard to HTA:

- The NDoH 2001 Framework for Health Technology Policies and the National Health Technology Strategy (2009) are not aligned with the NHI White Paper in terms of definitions and application of HTA.
- The National Coordinating Centre for Clinical Excellence in Health and Health Care outlined in the HRH Strategy is tasked with HTA activities but is not aligned with, nor referenced in the NHI White Paper. It currently does not exist.
- Limited detail is provided in the NHI White Paper regarding the mechanisms and structures required to apply HTA to determine the components of the essential healthcare services or other healthcare interventions more broadly.

The following opportunities arise from the identified gaps:

- The current policy documents provide a broad understanding of utilisation and practice of HTA, and as such, an opportunity to develop a comprehensive HTA strategy based on an existing foundation.
- NHI is built on the same principles as those underpinning the objectives of HTA. The establishment of a functioning NHI system will create a policy demand for HTA outputs, providing

an opportune moment for stakeholders to develop a South African-appropriate HTA framework and associated policy mechanisms to support the selection of the HSP specifically, and all healthcare interventions more generally.

Conclusions

Over the past 20 years, much work has been done and much consideration has been given to HTA in South Africa. Unfortunately, several proposals to establish mechanisms and structures to develop and implement a functional and robust national HTA system have not come to fruition. By linking HTA outputs with the explicit decision-making needs of UHC policies, the 2015 White Paper on NHI provides the best opportunity to realise a functioning and sustainable HTA system in South Africa. However, a central finding of our gap analysis is that the relevant policy and legislative frameworks require updating; further development and amendment is needed in order to meet the imperative to deliver UHC to all South Africans.

A strong lead by the NDoH is necessary to build on this prior body of work and to engage again with critical thinkers around the best fit for HTA in South Africa. All internal and external stakeholders should come to an agreement and work together to develop and implement a unified vision for HTA in the country. A robust and functional HTA system will best inform the provision of the NHI-recommended platform of healthcare services. Health technology assessment can be viewed as one of several tools needed to implement the NHI more broadly in order to achieve the aim of evidence-based and affordable health care for all South Africans, ultimately contributing to the improvement of the health of the nation.

Recommendations

Consideration was given to the findings of the gap analysis, the opportunities identified, and the implications thereof for South Africa, and steps are proposed to develop legislation and policy to support a functional HTA system in South Africa (Figure 3). Specific recommendations are categorised as short-, medium- and long-term in duration.

Short-term recommendations (6–12 months)

In the short-term, the NDoH might consider hosting an HTA summit that would include relevant government, non-government, academic, private-sector, and civil-society stakeholders. The aims of the summit would be to gain consensus on an acceptable and useful definition of HTA appropriate to the South African context, and to discuss the policy and legislative requirements for a national HTA agency or alternative mechanism in South Africa.

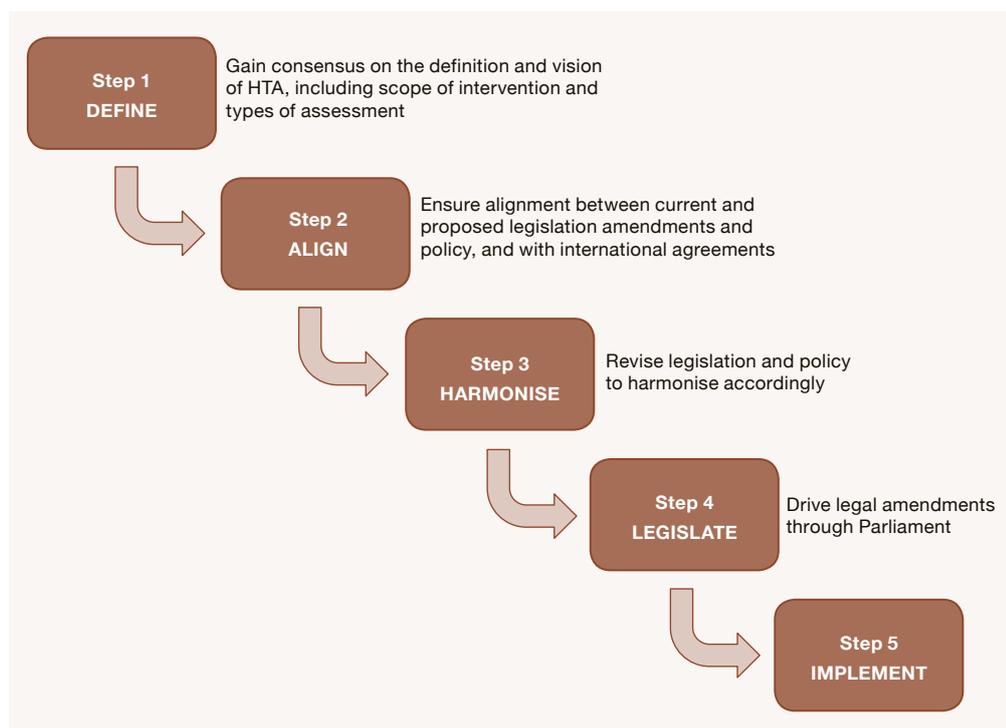
Medium-term recommendations (12–24 months)

In the medium term, consideration should be given to revision of relevant national legislation and policy in order to align with the NHI agenda and the international WHA resolution.

Long-term recommendations (24–48 months)

We propose that development and promulgation of legislation is key for HTA to become an effective component of NHI. Legislation and revised policy is necessary to support the selection of optimal methods to inform some of the components of the NHI health services. Ongoing public engagement at all stages is critical to this deliberative process. Development of the necessary human-resource capacity to perform HTA, and identification of related training needs, will be required to support these processes.

Figure 3: Step-by-step approach to the development of legislation and policy for a functional HTA system in South Africa



Acknowledgements:

This chapter prepared by PRICELESS SA was funded by the International Decision Support Initiative (www.idsihealth.org<<http://www.idsihealth.org>>/>) through a grant from the Bill and Melinda Gates Foundation and the United Kingdom's Department for International Development.

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