

A Framework

for Health Technology Policies

Department of Health
Republic of South Africa

Mission

To ensure that Health Technology is harnessed to its fullest extent as one of the tools to improve the delivery of health services. A strategy that facilitates the appropriate utilisation of health technology for the South African health system shall be devised.

Outcome

To create a unified and harmonious HT system that ensures optimal distribution of the limited HT resources and to facilitate equity in access, with the ultimate aim of improving the quality of health services and enhancing positive health outcomes.

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Executive Summary

The framework proposes various strategies that form the nucleus of the HT policy, and will be used to accomplish the stated objectives. It is divided into two parts.

PART I

Chapters 1 and 2

In these chapters, the broad scope of the policy, as defined and accepted by the World Health Organisation (WHO), is presented. The strategy to manage and integrate all these areas in the South African context, given the present fragmentation that exists, is outlined. The process that will be followed in the development of comprehensive HT policies is also suggested. Other critical concepts like the proposed Health Technology System are outlined.

Chapters 3 and 4

In these chapters, the situation analysis and major goals to be achieved through the HT policy are presented. The situation analysis includes a problem statement indicating **lack of systematic planning**, resulting in **high levels of inappropriate utilisation** of HT as well as **unnecessary expenditure**. It also shows the lack of a **coherent system of regulation and assessment of HT**, within both the public and private sectors. The rationale behind the HT policy is presented, motivating the shift from focusing on expensive and high technologies. It proposes as an alternative, the need for proper planning and systematisation of HT. In essence, the creation of a Unified National Health Technology System is proposed.

A brief analysis of the legislative and regulatory framework, as well as the national policy framework is also presented. The shortfalls in the present legislation and regulation, as well as the association with other national policies, are briefly addressed. Chapter 4 outlines the fundamental goals guiding the HT Policy formulation.

PART II

Chapters 5 -10

Chapters 5 to 8 present the essence of the document, introducing the various systems, which together form a Health Technology System. The HT system is the focus for health technology in the Department's Strategic

Framework document, and thus forms the basis for health technology policy strategic delivery. Chapter 9 presents the three proposed structures that should be put in place as enablers for policy implementation of the HT system, whilst chapter 10 lists ways of dealing with the relevant human resources.

Chapter 5 - HT Assessment (HTA) System

The system is devised to ensure the appropriate introduction, adoption and continued use of suitable health technologies into the country. The concept of HTA is outlined and the importance of the incorporation of HTA into all levels of planning (strategic and routine operational planning) is emphasised. This includes all levels of health care, be they in the private or public sector, including the health technology industry, where all research and development of technologies is conducted. It is proposed that HTA should be given due consideration in budget approval of public institutions.

Chapter 5 should be read in conjunction with Ch 9.3, which proposes the establishment of the National Steering Committee on HTA, whose mandate will be to devise a strategy for HTA establishment in the country.

Chapter 6 - HT Planning System

This system is aimed at ensuring rational and optimal distribution of HT and at improving equity in access. It is proposed that Essential Health Technology Packages will give guidelines for the levels of HT required per region and per health care facility. It is proposed that these technology packages be on national health plans, health needs, regional disease profiles and existing levels of technology sophistication, including logistical support infrastructure.

Chapter 7 - HT Acquisition System

This system is introduced to reduce the unnecessarily high cost of HT that results from unsystematic and unplanned acquisition and inappropriate use of technologies. The central themes relate to (i) the need to base all acquisition programmes on clearly defined, identified, documented and validated needs and (ii) the need for strategic requirements planning, in order to ensure that needs are met. These are followed by procurement decisions and strategies to ensure that Health Department needs are

taken care of, over and above the procurement rules set by the Department of State Expenditure. The most critical of these is the need to consider the total cost of ownership in procurement decisions, over and above the purchase cost.

Chapter 8 - HT Management System

The purpose of this system is to ensure safety, efficiency and effectiveness of HT, which in turn enhances delivery of health care services. The central themes are (i) the need for proper budgeting of health technology maintenance and (ii) the need to properly plan the Clinical Engineering Services in the country, linking these to the establishment of an appropriate equipment management system. Legislation in certain areas is also proposed in order to ensure patient safety. Certain aspects of this policy will be binding to both the public and the private sectors.

This chapter should be read in conjunction with Chapter 9.2, which proposes the establishment of the HT Management Committee, as the enabling structure for this system.

Chapter 9 - Summary of Important Structures

Two of the proposed structures are presented [National Steering Committee on HT Assessment (Ch 9.3) and HT Management Committee (Ch 9.2)]. Their terms of reference are outlined. Another major structure is the National Health Technology Forum (NHTF), an umbrella body for all HT related Committees. It is recommended that this be a subcommittee of PHRC, convened by the DG or his/her nominee. The rationale is outlined. Once all the major policies have been developed, it will be decided whether the NHTF remains a PHRC subcommittee or becomes a statutory body.

Chapter 10 - Capacity Building and HT Human Resource Strategies

The importance of building capacity, and the need for proper HR development strategies within HT, are stressed in this chapter. Another important aspect is that of linking the distribution of technologies with a reasonable distribution of persons with appropriate skills. It is also suggested that the degree to which each province succeeds in attracting appropriate personnel away from metro areas is monitored. Finally it is suggested that competency profiles, training levels and types • and frequency of training must be determined, and will need to be finalised by the National Health Technology Forum.

Chapter 11 - Regulation and Incentive Mechanism

The ideas put forth in this chapter relate to the

consolidation and strengthening of the existing regulatory framework. The important aspect is that HT needs to be regulated with respect to (i) the need and distribution, (ii) safety and efficacy, as well as (iii) continuous quality assessment. These should include all aspects of HT regulation, rather than just radiation and electrical safety, where the emphasis lies at present.

Chapter 13 - Self Sufficiency in Identified HT Areas

It is observed that South Africa relies heavily on imports, even in those areas where the country has a certain level of capability. It is noted that this pushes up the cost of health care. Strategies to promote self-sufficiency in identified areas are suggested. The need for the department to properly organise acquisition and procurement activities to allow for maximum Counter Trade activities, is addressed in order to benefit the country's economy. In addition, the need to leverage Industrial Participation Activities from the Department of Trade and Industry to benefit the Health Sector specifically, is identified. To this end, a Health Industrial Participation strategy is proposed.

Chapter 12,14 and 15

These chapters deal with the required collaboration between all sectors involved. Possible areas of collaboration and co-operation between the public and the private sector are listed. Government departments with whom the Department of Health will need to co-operate are listed and finally, possible areas of co-operation with SADC and WHO member states are highlighted.

Introduction

1.1 Health Technology (HT) Defined

The universally accepted definition of Health Technology (HT) includes devices, drugs, medical and surgical procedures and the knowledge associated with these, in the prevention, diagnosis and treatment of disease, as well as in rehabilitation, including the organisational and supportive systems within which health care is provided.

Incorporated in the definition are:

- Organisational/physical infrastructure composed of buildings, utilities, services and health care equipment
- Supportive/logistical systems, whose components are supply systems, information systems, communication systems and transport.

The South African HT situation has evolved in a manner that divided all the components that make up HT. The policy environment relating to these various aspects of HT has developed at various uncoordinated paces and is therefore at different stages of development owing to this fragmentation. This factor is taken into account in the development and implementation of health technology policies. Nevertheless, a comprehensive definition of HT is upheld in this document, in order to ensure the consolidation of HT in South Africa. This applies especially at the strategic planning and macro policy making levels.

1.2 Scope of Health Technology

According to the World Health Organization's (WHO) Health for all Policy in the 21st Century, released in January 1998, the scope of technologies for health, extends from those technologies that provide a direct benefit to health (such as molecular genetics, biological, Pharmaceuticals, and medical devices), to those that support health system functions (like telecommunications, information technologies, devices for environmental protection and food technologies).

This statement lays the basic foundation for, and is the fundamental concept behind this document. Because its enormity is recognised, this document will provide a framework and basis for the different HT policies that will

arise out of the needs determined by the Minister of Health. The entire scope of HT related issues cannot be adequately covered in one policy document. A good example is the issue of drugs, where the processes are already under way, and provide comprehensive coverage of all issues relating to drugs. Processes have also been established to address the area of Information Technologies and other HT sub-systems in general, however, the issues surrounding devices and medical equipment have not been addressed adequately.

Currently, policy surrounding HT is fragmented. The many components that constitute Health Technology have been broken down into independent sub-components that do not form a holistic approach. A critical study of the aims and objectives of these sub-components indicates that there is in fact great commonality across components. The implications are clear; a concerted effort is critical to the realisation of goals. Synergy must be created between all stakeholders so that health resources are optimised.

In a nutshell, the fundamental theme running through this policy is the need for a unified HT system, which is crucial to the realisation of the stated HT mission.

1.3 Health Technology System

This refers to the proper integration of health technology resources and processes, including the supportive and organisational infrastructure within which health technology is applied, to address the interrelationship of quality, quantity, and economics, in support of the stated health care objectives.

The resources that must be included in the HT system include supportive technologies such as environmental, food, information and other related technologies. In a systems context, technology covers the whole spectrum of health technologies, and in all their manifestations. These include emerging and established technologies, high, conventional, intermediate and basic health technologies. In this context, cognisance is taken of the technology lifecycle in all areas of policy making, implementation and monitoring.

Against this background, the activities within technology systems at a macro level are generally divided into three phases:

Phase 1: Health Technology Audits and Foresight, which inform on health technology status and indicate or forecast future health technology needs, which in turn, provides a scientific basis for HT policies.

Phase 2: Feasibility Studies, which include cost assessment, suggestions on alternative technologies and/or development of new technologies.

Phase 3: Implementation Decisions, which consider issues such as cost effectiveness, appropriateness, quality and modifications, availability and development of support infrastructure.

This is an iterative process, which is applied throughout the HT lifecycle. It involves health technology acquisition, management and assessment processes as outlined in this document. The HT system seeks to address the entire country's problems in terms of HT application, in a holistic manner.

Purpose and Processes of the Framework Policy

This is a macro-policy, whose purpose is to provide a framework for health technology policies, set strategic guidelines for operational and technical policies, and systematise health technology.

2.1 Developmental Phases

The development of this framework policy into strategic, operational, and specific policies will be carried out in the following phases:

Phase 1: Development of strategic policies

This will largely be the responsibility of the National Department of Health (NDoH), in consultation with the provinces and stakeholders. Stakeholders are defined in the broadest sense, and include both the public and private sectors. At this level, long-term strategies, the details of which shall be finalised in operational strategies, will be suggested.

Phase 2: Development of operational strategies.

These will be medium term strategies, determined in line with policy guidelines. They will be reviewed every five years or as required. Provincial Health Departments and the stakeholders in both public and private sectors that are directly linked to the specific areas in question should be involved. The National Department of Health will play a co-ordinating role.

Phase 3: Development of protocols.

These will be narrowly focused in specific technical areas. As such, relevant technical expertise that will be drawn from both public and private providers will be required in their development. They will be developed on a consultative basis and might be specific to particular types of institutions

2.2 The Systematisation Of Health Technology

In an effort to ensure equity and standardisation in the country, and in order to fully address health needs and accomplish the stated health care objectives, HT must be systematised. A multi-disciplinary and all-inclusive approach must be adopted in deciding on all HT policy related matters. In this regard the HT policy should cover the whole spectrum of health technologies, in all their manifestations.

The proposed Health Technology System will comprise four sub-systems:

- *Health Technology Acquisition and Procurement*
 - *Health Technology Assessment*
 - *Health Technology Planning, and*
 - *Health Technology Management*
- These are systems in their own right, but are closely interdependent.*

Operational policies that will provide the basis for the development of these systems will be developed with a strong input from provincial and district health care planners, including local health care authorities. The private sector shall also be involved in policy development and in the design and development of these systems.

Situation Analysis

3.1 Problem Statement

The present lack of systematic planning in the acquisition of health technologies, specifically during the procurement and utilisation phases, has resulted in high levels of inappropriate utilisation of Health Technology (HT), and in unnecessary expenditure. This is a phenomenon in both public and private sectors although the causes differ between the sectors. Further waste is incurred due to the absence of sharing of technology between the two sectors. The lack of proper and uniform acquisition strategies also contributes to high health technology costs, and results in a lack of equity with respect to patient access and distribution of technology. More importantly, there is no coherent system of regulation and assessment of these technologies. The fragmented, inefficient and ineffective manner in which some HT resources are managed and distributed, is thus cause for concern. This observation is of equal concern in the public and private sectors and applies both inter and intra-provincially, at both local and provincial levels and between academic institutions.

3.2 Rationale For Health Technology Policy

Technology is central to the functioning of contemporary society. The health sector, within which HT occupies a critical role, is no exception. This is borne out by the ever-increasing slice of health technology within the health expenditure of all nations. Decisions on HT often have *long-term* impacts. These decisions are frequently accompanied by long- and short-term implications, in terms of maintenance, supplies, and conversions. Further considerations include safety, efficacy and efficiency. These factors necessitate a decisive Health Technology Policy (HTP), which includes systematisation and a Health Technology Assessment (HTA) mechanism. Without these factors, key aspects of national health policy, such as promotion of equity in access and distribution, will be compromised.

The WHO has emphasized that *"Health technology is the core of what health care has to offer."* It is therefore clear that if health care is to influence and restore health, *"...it must have efficacious and beneficial technology, and this technology must be affordable, available, accessible and*

appropriately used." HT is therefore central and indispensable to contemporary medicine. To fulfill their mandates, health institutions are obliged to acquire HT. These HTs must not only be assessed in terms of opportunity cost but also, in terms of the cost of not having the particular technology. Whilst certain technologies may require high initial capital investments, they may offer far-reaching gains. Alternate technologies, on the other hand, may be perceived to be less expensive, but have inherently high running and/or recurrent costs.

By implication therefore, there is a need to distinguish clearly between the relatively high costs of HT and exorbitance. The often-quoted exorbitance of HT is based primarily on the failure to recognise the reliance of contemporary medicine on HT, and reflects a lack of clarity with regard to the difference between the two. More specifically, however, given the indispensability of HT, the unplanned and unsystematic acquisition of HT inevitably results in exorbitant costs.

Another critical factor of note is that HT policy is not only needed to control exorbitance, but also needed to provide a framework within which any institution/health facility, whether in the public or private sector, can acquire and use HT. It is needed to provide efficient and effective health care and to promote equity and the optimal use of resources.

A unified, uniform, planned and forward looking HT system, applied across the health services, in both public and private sectors equally, and underpinned by a Health Technology Assessment (HTA) mechanism, will ensure the optimal use of limited health resources (both from the direct paying public's pockets and from the government's budget). Most importantly, the fragmented nature of current operations, both in terms of legislative control and inconsistencies from province to province, dictates that a unified national HT system is both critical and urgent.

3.3 Present Regulatory Framework

The current regulatory mechanisms with regard to HT are fragmented and do not constitute a comprehensive system which, as has already been established, is critical for

optimal functioning of the health care system as a whole. The emphasis in the current institutional mechanisms is on licensing and regulation in terms of safety, and whether the particular HT performs the function as stated by the manufacturer.

Although some groups address certain of the following important issues, they are not addressed systematically:

1. There are no regulations requiring that acquisition and distribution of HT be based on need, supported by a robust HTA mechanism. The systems to monitor these are also not in place.
2. No regulations are in place to ensure that the following best management principles are given high consideration in the acquisition and procurement process, or in HTA (once the need has been established):
 - Maintenance and the life cycle cost of the particular HT
 - A cost-benefit analysis in terms of comparable and alternative HTs
 - The organisations within which these HTs are to operate - specifically, availability of personnel for optimal utilisation, maintenance personnel and the availability of line process resources and supporting technologies, at the product system level
 - The availability of funds
 - The financial implications for the health system of the nation due to limited or widespread use of the HT.
3. There are no regulations stipulating the minimum required technologies for the optimal functioning of health institutions

The above observation applies equally to the collective regulatory instruments impacting on HT including:

- The amended Medical Research Council (MRC) Act
- The proposed SAMMDRA Bill
- The Draft Health Bill
- The Medicine and Related Substances Control Act (Act 101 of 1965), and
- The Hazardous Substances Act of 1973.

Whilst some of these, notably the proposed Health-Bill, the MRC Act, and SAMMDRA Act, include some provision for assessment, the key operational focus of these mechanisms remains licensing and regulation, rather than assessment, planning and evaluation. Further more, they do not focus specifically on HT or deal with it in detail.

3.4 National Policy Framework

Health Technology Policy (HTP) operates within a broader national policy environment, and as such must be congruent with national strategies. Regulations or legislation regarding HT should therefore not produce barriers that will negate national strategies. The national policies that impact most on HT include:

- The Constitution of the Republic of South Africa
- White Paper for the Transformation of the Health System in South Africa
- The Medical Research Council (MRC) Act
- The Health Act, 63 of 1977
- The Hazardous Substances Act
- South African Medicines and Medical Device Regulatory Authority (SAMMDRA) Bill
- Medical and Dental and Supplementary Health Professions Act
- White Paper on Science and Technology
- Industrial and the Macro Economic Policy
- National Procurement Policy
- Public Finance Management Act
- Technology Foresight Results

The mission statement of the Department of Health reads: *To provide leadership and guidance to the National Health System in its efforts to promote and monitor the health of all people in South Africa, and to provide caring and effective services through a primary health care approach."*

This accords with the right of access to health care as reflected in the Bill of Rights in the Constitution. Key elements of the mission statement that are of immediate impact to a Health Technology Policy are (i) Leadership and guidance; (ii) National Health System; (iii) promote and monitor; (iv) all people; (v) caring and effective; and (vi) primary health care approach.

The central policy theme running through all policy aspects relating to development and delivery of all services, inclusive of health, is that of universal (equitable) access. This is critical because health policy in general, and the Health Technology Policy (HTP) in particular, do not occur in a vacuum, but within the framework of all other sectoral policies. All of these, to a greater or lesser extent, impact upon the attainment of the stated objectives.

The interrelationship derives primarily from the basic requirement for improvement of the quality of life, critically placed in focus by the levels of poverty witnessed in South Africa. In this regard, the recognition of, and focus on upliftment, development and poverty alleviation, in the economic policy framework of South Africa, is worth not-

Objectives

The areas listed below constitute the main objectives for a health technology policy. They form the focus for key strategies, addressed in Part II.

1. Integration of Health Technology into the overall strategic objectives of the DoH and those of the country. This includes planning and implementation of health care programmes that ensure optimal and sustainable use of HT resources.
2. Ensuring equity in distribution of and access to health technologies for patients.
3. Planning for the introduction of new HTs, hospitals and other health care facilities, taking into consideration their long-term management.
4. Promotion of good clinical practices.
5. Promoting the appropriate use of HTs.
6. Improvement of technical capability and capacity in health technology acquisition, with consideration for issues related to health technology transfer that will lead to sustainable health care systems and services.
16. Management of issues surrounding obsolete and redundant technologies, and their phasing out and/or redeployment.
17. Creation of systems for assessment and evaluation of technologies.
18. Extension of the lifetime of technologies, including maintenance strategies.
19. Strengthening of bargaining power via bulk purchasing, to ensure that the country acquires technologies that are most suited to South African conditions, rather than subject to technology push.
20. The introduction of HT project management, such as management of large, complex and interdisciplinary technology projects or systems and exploring options for integration and/or rationalisation within South Africa and within the SADC region.
12. Ensuring standardisation and compatibility within HT systems
13. Regulating and monitoring of HT suppliers/products.
14. Capacity building linked with strategies to strengthen the existing South African HT industry, including promotion of innovation in health care technology.
15. Strengthening areas of collaboration between the Department of Health, private health care providers, other government departments, related institutions and other countries in the SADC region in all technology areas.

Health Technology Assessment System

Health Technology Assessment (HTA)

This refers to a comprehensive, systematic evaluation of the assumptions for, and consequences of the application (initial and continued) of health technology. It is applied at all levels of the health service as an in-depth scientific analysis forming the basis of policy, as a systematic process in planning and operational policy, and as an underlying process for the operation of health institutions and routine clinical decisions of health professionals.

HTA also informs research, analysis and evaluation aimed at examining health technology impacts on individuals, the organisation, economy and society at large. It requires a comprehensive and systematic evaluation of the assumption for and the consequences of the initial and continued application of a technology, before any decision is made regarding the adoption and the continued use of any HT

A distinction is drawn between **Macro HTA** and **Micro HTA**.

Macro HTA assesses the impact of HT on the patient, the organisation, the economy, the society, and on the health technology environment as a whole. It will be a multidisciplinary exercise that will involve experts from the following groups, depending on the technology under consideration:

- Health economists,
- Health professionals,
- Health administrators,
- Technical experts,
- Legal and Ethics Specialists
- Relevant NGOs
- 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

Micro HTA on the other hand assesses the scientific soundness of a technology on the basis of safety, cost and efficacy, ease of use, upgrade, and performance. At this level, the related specialists and professionals shall be

charged with the assessment task.

Key factors to be considered in the HTA exercise include:

- The need for the technology
- Benefits of application and health outcome
- The status of existing equipment
- The volume of the work and utilisation rates
- Future plans within that technology
- Compliance with occupational health guidelines
- Appropriateness for the level of care
- Desirability of the technology
- Safety, efficacy and the cost of ownership (i.e. capital and recurrent cost), as well as all factors that are considered for a macro HTA
- Potential savings
- Equity in access
- Availability of alternative technologies for the same procedure or outcome
- Availability of alternative providers of the same technology

HTA will be incorporated into strategic and operational planning at all levels, both in the public and private health sector, centrally, provincially, at district and institutional levels and at political, administrative, professional and research levels.

HTA must be adopted as a systematic method to be applied during routine planning and operational decision making in the health sector, in both public and private services, including industries where the research and development of technologies is conducted. It must be applied in day-to-day planning of the health services, so that the preconditions for adopting a technology and the effects of that technology are assessed. In line with this, HTA must be used as a tool in setting up norms, standards, and guidelines in the appropriate use of HT. To this end, it must be ensured that all health institutions and services in both public and private sectors integrate HTA into their systems and their routine operational planning, with provision for enforcement. Strategies will be devised to ensure that the HTA exercise is given due consideration in

the budget approval of all institutions, from the smallest clinic to the most advanced specialist institution.

The HTA of some existing deployed technologies will be performed as part of the Health Technology Audit. The output of this exercise will inform the development of redistribution strategies, as well as the acquisition system.

HTA is expected to produce the following positive effects:

- Improved health outcomes
- Enhanced patient acceptability
- Optimal, appropriate and effective utilisation of resources
- An improved and objective basis for decision-making
- Enhanced scientific planning.

Health Technology Planning System

Planning forms an integral part of the HT system. In this regard, systematic planning shall be undertaken to ensure optimal distribution of HTs, in order to promote equity in access and distribution, ensure best utilisation of HT and maximise its potential.

Planning will be operationalised through the HT acquisition system that will in turn be informed by HTA. The extension of this strategy will be the establishment of essential health technology packages and a process for the determination of "Certificates of Need" per region and per health care facility. As this exercise is premised on a fully functional HTA mechanism, provision will be made for the utilisation of existing international health technology assessments in some instances, while the South African HTA system is under development.

6.1 Essential Health Technology Packages (EHTPs)

In order to facilitate proper planning, guidelines will be developed for the levels of health technologies required per region and per health care facility. These will be based on national plans, health needs, disease profiles of each region and the existing level of technology sophistication, taking into account the extent of logistical support infrastructure.

The distribution details will be drawn up and forwarded to the country's National Health Technology Forum (NHTF) (outlined in section 9.1) for ratification, with strong user input as advised through the HTA System, particularly from epidemiological studies and the socio-economic profile of the region. The HT planning function shall be a responsibility of government, vested in this proposed body. The HT Plan for the country, as recommended by the NHTC shall be submitted to the Minister for consideration and approval.

6.2 Essential Health Technology List

Arising out of the guidelines for EHTP will be the list of recommended HTs per health facility. These will differ according to the different types of health facilities. Special approval will have to be sought from the National Health Technology Forum where HT levels exceed or fall short of the recommended HT levels set for the facility in question. Approval of such special motivations shall be based on a single HTA mechanism that applies equally to the public and to the private sectors. The Essential Health Technology List will include an essential equipment list, linked to an essential drug list and coupled to the Human Resource development and deployment strategies, as devised by the relevant bodies.

Institutions will therefore be required to establish and maintain an updated inventory lists, after conducting comprehensive technology audits.

HT Acquisition and Procurement System

Acquisition programmes must be based on clearly defined needs, which are identified, documented and validated. These may be initiated by the desire to acquire new technological capabilities, to improve on existing capabilities, to reduce costs, and/or to enhance performance. Acquisition and procurement will be premised on the HTA mechanism, and the desired distribution pattern of HT, as determined through the national HT planning system, or applicable Acts.

Strategic requirements planning, evaluation and selection should be conducted prior to the development and/or procurement and delivery of any HT, to ensure that HT needs will indeed be met. Studies will include the evaluation of the given options, based on applicable costing models, like RAM analysis (Reliability, Availability and Maintainability) of HTs and at the least, thorough optimisation assessments. These may, for instance, result in the decision to perform a major upgrade of existing technologies rather than introduce a new HT.

Procurement and delivery strategies will form part of the selection decision. In the case of public sector procurement, the procurement strategies should take into account the needs of the Department of Health, particularly as dictated in terms of HT System planning. This consideration should be given in addition to the rules set by the Department of State Expenditure. Of special consideration shall be the needs relating to HT management and logistics issues. Health technology management considerations will form a major part of the acquisition decision. In the case of a request for permission to proceed with an acquisition in the private sector, the needs of the public in general will be considered, based on the HT system.

Discussions will also take place between the DoH (national and provincial) and the State Tender Board, to refine procurement strategies relating to HT. The intention is to introduce the concept of "Cost of Ownership" (CO), which includes running cost, over and above the purchase price. It must be ensured that the CO concept is applied as a

decision-making tool, when there are competing options for investment in terms of new equipment.

Acquisition, Procurement and Provisioning

Acquisition, procurement and provisioning have distinct, although inter-related meanings.

1. Acquisition refers to all those actions that have to be taken to satisfy specific user requirements, throughout the operation life cycle.

Acquisition is divided into three phases, involving, sequentially:

Phase 1

- i. Requirements planning, which entails
 - Needs assessment
 - Priority setting
 - Resource allocation
- ii. Operational research and feasibility analysis
- iii. Design and development
- iv. Operational qualification
 - Operational test and evaluation
 - Clinical trials
- v. Quality assurance
- vi. Industrialisation

Phase 2 (This is the initial procurement phase)

- i. Planning
- ii. Technology assessment
- iii. Selection

Phases

- i. Utilisation
- ii. Decommissioning

Health authorities and healthcare providers are responsible for Phases 2 and 3. Policy will thus focus largely on these phases. Phase 1 is mainly within the purview of industry and academic institutions, however health authorities and health care providers shall adopt a proactive role and work closely with industry in the

determination of and planning for HT requirements. This is necessary to avoid the introduction of HT through technology push. Government shall introduce certain regulations relating to operational qualifications, specifically, clinical trials and quality assurance.

2. **Procurement** involves contracting for a requirement on the basis of an existing specification, by purchasing off-the-shelf, manufacturing, leasing or hiring where the production process has been previously qualified during the acquisition phase.
3. **Provisioning** entails making provision for the supply of spares and supportive equipment or materials, for a particular system that has been identified for procurement.

Health Technology Management System

Health Technology Management

This largely refers to the activities carried out during the utilisation phase of health care technology, namely, storage, distribution, installation, inspection, asset and equipment management, risk management, maintenance, user training and support, continuous quality assurance, repair and decommissioning.

In the realisation that HT demands a high investment, with substantial recurring operational expenses, the maintenance of any HT must be provided for, and itemised on the health technology budget. **As a general rule, the maintenance budget shall be given as a percentage of the initial procurement cost and will cater for scheduled as well as unscheduled maintenance.**

Users of specified technology will be required to demonstrate in their motivation that adequate consideration has been given to (and provision made for) proper ongoing management of the HT in question.

Of great importance and urgency will be the proper planning of clinical engineering departments in the public sector and/or clinical engineering companies in the private sector. This strategy will also address issues related to:

- training and support,
- an asset/equipment management system,
- establishment of asset registers and inventory control mechanisms,
- risk management,
- the promotion of proper maintenance and repair.

The strategy will also look at promoting the practice of upgrading HT or functional enhancement, as well as addressing "Life-Cycle costing" and monitoring.

Implementation and monitoring strategies in respect of these shall be devised in collaboration with the private sector and tertiary institutions.

In an effort to ensure public safety and to deliver professional Health Technology management services, some areas will require legislation. A committee, whose brief will be to look into these areas, will be established.

The HT Management function will be supported by the HT Department Committee as outlined in section 9.2.

Enabling Structure for the HT System

To enable government to deliver on the HT system, the **National Health Technology Forum (NHTF)** will be established and will become the custodian of the HT system. This Committee will remain a subcommittee of the Provincial Health Restructuring Committee (PHRC), until such time as all the technology policies are developed, at which time it shall be determined whether the NHTF becomes a statutory body or remains a PHRC Subcommittee.

9.1 National Health Technology Forum

Convenor

In an effort to consolidate and streamline activities related to the HT system, the NHTF shall be convened and chaired by the Director General of Health or his/her nominee. Special precaution shall be taken to ensure that this body does not represent narrow sectoral interests, as far as HT elements are concerned.

Functions

This body shall have the following functions:

1. Appoint subcommittees or task teams to advise on all areas of HT. The first subcommittee to be immediately constituted is the HT Management Subcommittee.
2. HT Planning: Draw distribution details and endorse EHTPs, mandated to approve and/or disapprove HT requests above the predetermined levels.
3. Strategic coordination of all HT areas and draw up national guidelines concerning HT.
4. Make recommendations for control of specific HTs (HTs to be determined by this body, for approval by the relevant authority).
5. HT Acquisition: Approve HT Acquisition strategic requirement plans. This body, for approval by the relevant authority, shall endorse decisions on acquisition issues.
6. Establish relevant task teams to work on HT operational policies.
7. Endorse HT operational policies.
8. Act as a filtering body for all work related to HT, before any submission to relevant decision making bodies.

Composition

There shall be a National DoH Health Technology Planning Committee (NHTPC), with Provincial Health Technology Planning Committees (PHTPC) in every province. These PHTPCs shall be constituted in such a way as to have district and institutional representation. Considering that Health Technology is a broad area that cuts across several functions within health, these committees shall be composed of officials who, between them, cover all areas of HT. A **National Health Technology Forum (NHTF)** shall then be composed, comprising members of the NHTPC, PHTPCs, the private sector, the health care funders, and others, as determined by the Minister.

The NHTF may itself need to appoint subcommittees or task teams to advise it on particular issues. These subcommittees will be represented in the NHTF, and task team representation will occur on an ad hoc basis.

9.2 Health Technology Management Committee

As Health Technology Management (HTM) is an ongoing activity that affects both the public and the private sector, it will have representation from all sectors and levels of the health delivery system. The HTM committee will be specifically geared towards all medical-engineering practitioners, viz. clinical, biomedical and hospital engineers, medical physicists and other technology practitioners, whose work entails the handling of HT equipment and resources. The HTM committee shall be a sub-committee of the NHTF.

Major Functions

1. Promote and oversee safety related issues in all areas of HT (this shall include both public and private sector institutions)
2. Advise on all areas of HTM that require legislation (initially, this subcommittee will be asked to consider the recommendations of the National Steering Committee on Clinical Engineering)
3. Promote collaboration and networking in the area of HT

These functions shall be finalised by the HTM directorate after the first meeting that will be held with the provincial HTM representatives. These could include issues like ensuring standardisation in the area of HTM as far as is practically possible, and the setting of national standards and norms in the area of HTM.

9.3 National Steering Committee on HTA

An **interim** National Steering Committee on HTA, whose primary mandate is to devise the National Strategy for HTA, will be formed. The committee will be required to:

1. Study the HTA systems of different countries, together with the enabling structures.
2. Suggest the most suitable system and the enabling structures for a South African HTA system.
3. Make proposals relating to the legal status of the structure. There are three possible options which could include:

Proposal 1

The body becomes a legal persona, with all the legal and financial powers.

Proposal 2

The structure is formed as a collaborative body, comprising members from councils, authorities and institutions whose functions impact on HT, and which have been mandated to function within one or more of the areas listed below. This should be seen in the context of a broad HT definition.

- Medical Devices
- Equipment
- Maintenance
- Drugs
- Clinical and surgical procedures

Proposal 3

Expand the mandate on an existing body. For example SAMMDRA could be expanded to incorporate a HTA Working Group as one of its committees.

The Minister shall approve the formulation and the composition of the National Steering Committee on HTA, together with its mandate.

9.3.1 Terms Of Reference For The HTA Enabling Structure

The terms of reference for the permanent body/structure that will be suggested by the interim National Steering Committee on HTA are as follows:

1. Build HTA capacity, to ensure that it is able to provide independent and objective scientific advice that will inform on HT policy decisions.
2. Identify areas for HTA after proper consultation with medical colleges, universities, medical associations, research institutions, and all the councils whose mandates have bearing on HT.
3. Prepare and assist with the implementation of the national strategy for HTA in the National Health System.
4. Initiate and commission HTA projects.
5. Provide contributions to the preparation and implementation of HTA projects.
6. Provide advice to the agreed upon HTA projects.
7. Establish co-operation for the development of HTA between Public and Private Health Organisations, the health authorities across the three tiers of government, medical professions and councils and all the relevant research institutions.
8. Promote the concept of HTA, particularly in management, clinical, and political decision-making.
9. Ensure the establishment and development of an 'early-warning system'¹ for new and emerging health care technologies in the health service. This will also involve co-operation with international bodies such as the International Society of Technology Assessment in Health Care (ISTAHC) and co-operation with other international HTA centres.
10. Monitor the international HTA activities and communicate the results, for utilisation in the SA National Health System.
11. Co-ordinate South African HTA activities.

Capacity Building and HT Human Resource Strategies

Technology resides in the minds of people and does not exist free from the human resources who operate and maintain it; nor is it independent of the professionals upon whose judgement the decision to apply and/or use it is made, and the results interpreted. Due to this factor, capacity building and HR development will be of crucial importance. Strategies to address these issues will form a critical component of the implementation and success of the HT system.

Reasonable distribution of, and access to technology, shall be linked with a reasonable distribution of persons with appropriate skills to work with HT. To this end, an environment conducive to the development and maintenance of the necessary human resource capacity must be fostered.

The operational strategy shall address capacity building issues related to HT professions including the previously disadvantaged groups, and HT human resource distribution. The degree to which each province succeeds in attracting appropriate personnel away from metro areas, whether into the public or the private sector, will also be monitored.

Competency profiles for HT workers, training levels, types of training required, practical training and frequency, location of training courses and other issues related to HT HR capacity building shall be discussed and finalised by the NHTF. A special task team composed of relevant stakeholders including the private sector under the auspices of the NDcH, shall be formed and mandated to determine these strategies, which will then be submitted to the relevant decision-making bodies.

Regulation and Incentives Mechanisms

All of the existing regulatory mechanisms shall be consolidated to constitute a comprehensive system, which is critical for the optimisation of HT. To this end, all regulatory policies that impact on HT shall be amended or augmented to ensure that HT is regulated with respect to:

- Need and distribution
- Safety and efficacy
- Continuous quality assessment

11.1 Need and distribution

A "Certificate of Need" will be instituted for certain categories of HTs as determined by the Minister. Regulation of distribution shall take into consideration a 'Certificate of Need process'¹ that recognises different needs according to criteria determined by the Minister. This applies equally to the public and to the private sectors.

11.2 Safety and efficacy

Requirements for safety and efficacy shall include all aspects, inclusive of, but not restricted to radiation and electrical safety (where the current emphasis lies). In order to cater for medical devices and equipment regulation properly, the implementation and monitoring of these activities, shall be governed by applicable Acts.

11.3 Continuous quality assessment

Continuous quality assessments shall ensure best management practices, which shall include:

- Maintenance and life cycle costing
- Accreditation of HT practitioners
- Strategies to utilise and integrate all existing institutions that seek to ensure quality assurance.

Interface with the Private Sector (Public Private Partnerships)

Strategies shall be devised to ensure that the country's total health technology resources are utilised to their fullest capacity. Public-private partnerships (PPP) shall be encouraged in facets of the HT policy development and implementation. However, in the realisation that a partnership is a two-way commitment, the public sector must be recognised as a potential service and HT provider to the private sector just as the private sector can be a provider to the public sector. As its basic premise in the partnership, the public health sector shall strive to equalise its capacity to serve the population that is dependent on the State for care. In some instances, the State will enter into partnerships with the private sector, with a view to building capacity within the public sector.

The forms of PPP that shall be considered in respect of the actual provision of HT (other than the partnership in policy and monitoring mechanisms) may include, among others:

- Training related to equipment management
- Cross utilisation and sharing of knowledge
- Acquisition strategies
- Out-sourcing of services, acquisition and management of specified technologies
- Pay as per use
- Quality assurance programmes
- Alternate financing methods and mechanisms
- Government provision of health services to private patients and vice versa

Promoting Self Sufficiency in Identified Areas

In an attempt to curb the cost related to importation and discourage total reliance of health technologies on other countries, South Africa will attempt to promote self-sufficiency in identified areas. The focus will be on areas of HT where the country's capability and/or potential has been established, and in all the areas identified as "critical".

Strategies for this shall include:

- Technology Conversion and Creation plus enhancement of the concept of "knowledgeable buyer", within centres of expertise.
- Counter Trade/Health Industrial Participation
- Promotion and support of the Local HT Industry

Relevant clinicians, research workers, professional groups, and trade and industry will be invited to participate in dialogue regarding the promotion of self sufficiency.

13.1 Technology Conversion

South Africa has a good technology base, especially within the defence industry. Strategies should therefore be devised to harness this capability and to convert appropriate technologies to the benefit of the health technology industry.

Defence technologies that were mainly developed for operational purposes in areas where there are no facilities, should receive attention in the first instance. These technologies can be "civilianised" at costs relatively cheaper than the initial developmental costs. These technologies shall be used to enhance our human resource capacity and be applied towards solving the country's rural problems, in line with the Government's health priorities. To this end, formal co-operation with the South African National Defence Force (SANDF) and other government departments, organisations and institutions that impact on HT shall be established. The capacity at universities and technikons shall be monitored regularly to determine our level of expertise and to determine the country's capacity in this regard.

13.1.1 Centres Of HT Expertise

Centres of HT expertise shall be established and/or strengthened in order to maximise the capacity for HT development and conversion in the country. Research and conversion areas shall be identified by the DoH, and informed by HTA outputs.

These centres shall also be used to groom and develop capacity, based on agreed norms and priorities, and will also be used to develop enough capacity to entrench the concept of "knowledge buyer".

The private sector will be actively encouraged to contribute to a national programme (besides its own R&D) in pursuance of national priorities.

13.2 Counter Trade/Health Industrial Participation Principles for the DoH

Procurement strategies shall be devised and designed in order to support the health sector in leveraging the power of bulk purchasing. The DoH will motivate to the Department of Trade and Industry (DTI) that counter trade activities must be identified for all imports above a predetermined threshold. The function of determining this threshold level shall be left to the NHIF or a task team established by it.

The above concept shall be embodied in the Health Industrial Participation (HIP) programme, which will be premised on National Industrial Participation (NIP) guidelines as administered by the Department of Trade and Industry.

The institutionalisation of a dedicated HIP programme shall address the differences between the limits imposed by the DTI and those suggested by the DoH, stemming from the specific requirements of the DoH. This will enable the DoH to manage and administer aspects resulting from purchases by the DoH, in consultation with DTI.

The DTI shall be engaged in discussions around the following issues:

13.2.1 Health Industrial Participation (HIP) Strategies

The detail of this strategy shall be finalised after the HTA exercise and after proper consultation with the role-players in the HT industry. These shall include:

- Production and/or manufacturing under licence.
- Collaboration research and/or development, to position SA for technology transfer matters
- Requirements for the inclusion of varying percentages of local technologies as sub-systems of the overall system. The percentages will differ from one system to the other
- Adapting technology systems to suit our local conditions.
- Programmes that will promote capacity building in identified critical areas and programmes that will provide incentives for local engineers and people in technical fields
- HR training specifically related to HT utilisation.

13.2.2 Intellectual Property Rights

Legal issues surrounding Intellectual Property Rights (IPR) shall be considered. Thorough research shall be conducted in order to establish how IPR affect these guidelines. It is also necessary to determine South Africa's capacity and potential for the successful discharge of this policy.

13.2.3 Promotion and Support of the Local HT Industry

During acquisition and procurement, preference shall be given to domestic products that conform to local and international quality and safety standards, particularly in cases where the HT is economically viable. Where technology requirements are satisfied by imported HT only, then local or general rules that apply to HIP shall be encouraged. Foreign companies may be requested to enter into partnerships with local companies, especially in critical areas where the availability of spares or a local maintenance capacity base is crucial. Conversely, the HT industry must be committed to the development of skills among all employees, especially amongst previously disadvantaged individuals. The DoH shall seek ways to support the HT industry. This may involve support through

obtaining science and technology funds where the budget authority rests with other government departments.

Other means to promote the local HT industry shall take the form of government-to-government agreements. In such cases the SA government shall enter into agreements with other governments to enable industrial co-operation in areas of research, with each government that is party to the agreement financially supporting and maintaining its own industry. The research and development priorities shall be based on previously agreed upon needs. The respective governments will inevitably be bound to acquiring the technology developed through co-operation. This shall be included in the memorandum of understanding.

Protocols on issues in this area shall be devised in consultation with the local HT industry, through the proposed National Health Technology Commission.

Interdepartmental and Intersectoral Collaboration

All technology systems are interdependent, therefore planning for health technology will not happen in a vacuum. National technology development strategies will be considered. To this end the government will advocate that a proper strategy for national co-operation be devised. Entire national plans in the areas of health, technology, economics and trade, need to be considered and a proper interface between all government departments and other organisations whose policies impact on the nation's health (and, by extension, health technology) must be considered.

Organisations and institutions involved will include the Medical Research Council (MRC), the Centre for Scientific and Industrial Research (CSIR), ARMSCOR, academic institutions, South African Bureau of Standards (SABS) and other organisations or institutions that impact on health technology. Other government departments to be involved will include the Department of Trade and Industry (DTI), addressing counter-trade issues and related programmes; the Department of Defence (DoD), particularly on issues of collateral utility in technologies and technology conversion programmes; the Department of Foreign Affairs (DFA), on international collaboration issues, technology transfer, etc; and the Department of Arts, Culture, Science and Technology (DACST) which is already driving technology audit issues and the "Foresight Programme", whose results shall contribute to the design of acquisition strategies. The Department of Education (DE) and the Department of Labour will be involved particularly with human resource and capacity building issues. The objective is to be as inclusive as is practical.

Collaboration With SADC and WHO Member States

Areas of collaboration between South Africa and SADC countries, plus WHO member states shall be explored, particularly in the fields of technology management, capacity building (in terms of HT Human Resources and HT industry logistics support), HT Assessment, distribution guidelines, setting up of proper information systems and acquisition including procurement. To this end, South African participation in regional organisations like the African Federation for Technologies in Health care (AFTH) shall be strengthened and supported from a national level. All guiding resolutions and declarations, adopted at various regional summits where HT is being discussed, if applicable, shall be considered by the National Department of Health.

In the short to medium term, strategies to address the following issues shall be devised:

- The exchange of HT assessment information
- Collaboration in HT Assessment research
- Collaboration in the research-and development of technology
- Collaboration in training of technology managers
- Collaboration in standardisation of certain selected equipment
- Collaboration in exploring common bulk purchasing of certain technologies.

Glossary of Terms

Cost-benefit exercise	A comparison of alternative interventions in which costs and outcomes are quantified in common monetary units
Efficacy	The benefit of using a technology for a particular problem under ideal conditions, for example, in a laboratory setting, within the protocol of a carefully managed randomised control trial, or at a "centre of excellence"
Essential Health Technology Package	A planning tool used to determine health care provision requirements based on need and evidence
Essential Health Technology List	An output of the Essential Health Technology Package consisting of the required amounts or numbers and types of drugs, medical equipment, human resources, and facilities
Health Technology Assessment (HTA)	The systematic evaluation of properties, effects, and/or impacts of health technology. It may address the direct, intended consequences of technologies as well as their direct, unintended consequences. Its main purpose is to inform technology-related policymaking in health care. It is conducted by interdisciplinary groups, using explicit analytical frameworks, drawing from a variety of methods.
Health Technology Management (HTM)	Proper management of health technologies during the utilisation phase. This phase covers the procurement, installation, maintenance, replacement, and phasing out of technologies
Health Technology Planning (HTP)	Refers to the strategic planning for acquisition, distribution, and utilisation of technologies, based on the outcomes of HTA
Life-cycle cost	Integrated costs of an item which includes procurement costs, operational and maintenance costs, and all costs up to the costs required to dispose of the item when it is obsolete
Maintenance Medical	Care-taking of medical equipment to ensure its availability.
Devices Outsourcing	Technology instruments or tools used in the diagnosis, therapy, and rehabilitation of patients
Quality Assurance	Separating non-core activities of an institution in order for these to be carried out by contractors. Activities intended to ensure that the best available knowledge concerning the use of health care to improve health outcomes is properly implemented. This involves the implementation of health care standards, including quality assessment and activities to correct, reduce variations in, or otherwise improve health care practices relative to these standards.
Scheduled maintenance	Periodic maintenance and care-taking of medical equipment
Technology Conversion	Refers to the conversion of the application of a technology from one industry to another, with or without modifications, for example, converting a technology used in the defence industry for use in health care.
Unscheduled maintenance	Refers to the repair and replacement of spare parts of medical equipment

List of Acronyms

AFTH	African Federation of Technologies in Health Care
CO	Cost of Ownership
EHTP	Essential Health Technology Package
HIP	Health Industrial Participation
HT	HEALTH TECHNOLOGY
HTA	Health Technology Assessment
HTM	Health Technology Management
HTP	Health Technology Policy
IPR	Intellectual Property Rights
ISTAHC	International Society of Technology Assessment in Health Care
N-HTPC	National Health Technology Planning Committee
NHRD:CG	National HR Development Core Group
NHTF	National Health Technology Forum
NIP	National Industrial Participation
PHRC	Provincial Health Restructuring Committee
PHTPC	Provincial Health Technology Planning Committee
PPP	Public-Private Partnership
SAMMDRA	South African Medicines and Medical Device Regulatory Authority
WHO	World Health Organisation