Health Technology for Equitable Access to Quality Health Services

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Health technology (HT) is an important part of health systems, the acquisition, assessment, management and costs of which have brought about increasing challenges in delivery of healthcare services. In order to address the high levels and wasteful use of HT, the National Department of Health published a Framework for Health Technology Policies in 2001, following this with a draft National Health Technology Strategy document in 2005. The key outcomes envisaged in these documents are discussed against the backdrop of South Africa's high burden of disease and resource constraints in the public healthcare sector. The imminent piloting and implementation of National Health Insurance and Government's renewed drive for improved access to quality health care for all have placed HT firmly in the spotlight.

This chapter looks at some of the HT challenges and what improvements can be made in the key areas of prioritisation of public HT needs, HT management, HT regulation, HT innovation and public-private partnerships. It is notable that the long-awaited national audit of assets in public health facilities has commenced and is scheduled for completion in 2012. The inventory arising from this audit will provide the basis for effective asset management, including facilitating scheduling of preventative maintenance and providing financial information to support budget proposals and procurement requests. A further development has been the establishment of a Medical Devices Innovation Platform to harness and integrate skills and expertise from a number of universities and research institutions in the country. Promotion and pursuit of HT innovations present South Africa with an opportunity to build capacity to solve health challenges, and thus to have a positive impact on health and development.

In order to address the inappropriate use of and in some places lack of required HT, the National Department of Health published a Framework for Health Technology Policies in 2001, following this with a draft National Health Technology Strategy document in 2005. The key outcomes envisaged in these documents are discussed against the backdrop of South Africa's high burden of disease and resource constraints in the public healthcare sector.

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Introduction

According to the Framework for Health Technology Policies, the universally accepted definition of health technology (HT) includes devices, drugs, medical and surgical procedures and the knowledge associated with these, used 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.[1] This includes physical infrastructure such as buildings, utilities and healthcare equipment as well as supportive logistical systems which include supply, information and communication systems and transport.

For the purposes of this chapter HT refers to medical devices and medical equipment only and excludes drugs and pharmaceuticals.

The World Health Organization (WHO) defines medical devices and medical equipment as follows:[2]

> A medical device is an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means;

while

> Medical equipment are medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

HT forms an integral component of health systems, being used for the prevention, diagnosis and treatment of disease and to alleviate disability and functional deficiency:[3]

> From a clinical perspective, health technology is utilized to reduce the risk of disease, reduce duration of illness, improve quality of care, increase access and restore or limit the loss of a person's quality of life. Health technologies are also expected to contain costs and improve the management of risks associated with health interventions through enhancement of service efficiency and productivity of health care professionals.[4]

Rapid developments and innovations in HT have contributed significantly to the quality of health care – but have also brought increasing challenges in the management of healthcare services for both developing and developed countries. Challenges include provision of the necessary infrastructure and human resources required to plan, deploy, manage and assess new technologies, and also the strategies required to manage cost-containment.[5]

From an HT point of view the Negotiated Service Delivery Agreement,[6] commitment to primary health care (PHC) re-engineering[7] and the 10 Point Plan[8] (which highlights development of an HT plan for the country as a key objective) all impact on the management and use of such technology and effective and equitable delivery of health services.

South African context

According to the WHO, most developing countries are characterised by poor management of healthcare equipment, which results in high levels of inefficient and wasteful use of HT.[9]

Similarly, studies in South Africa (SA) show that a significant percentage of equipment is not fully functional, that there are unacceptable levels of maintenance backlogs, and that equipment is under-utilised due to a scarcity or lack of trained users. A fragmented approach to planning and/or lack of a strategy, approved guidelines and a coherent approach to HT planning combined with haphazard procurement procedures and processes compound the problems.[4,10]

The findings of these studies resonate with problems that SA's draft National Health Technology Strategy (referred to below) aims to address. Specifically, the strategy notes that:

> the present lack of systematic planning in the acquisition of health technologies, specifically during the procurement and utilization phases, has resulted in high levels of inappropriate utilisation of HT, and in unnecessary expenditure. 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.[11]

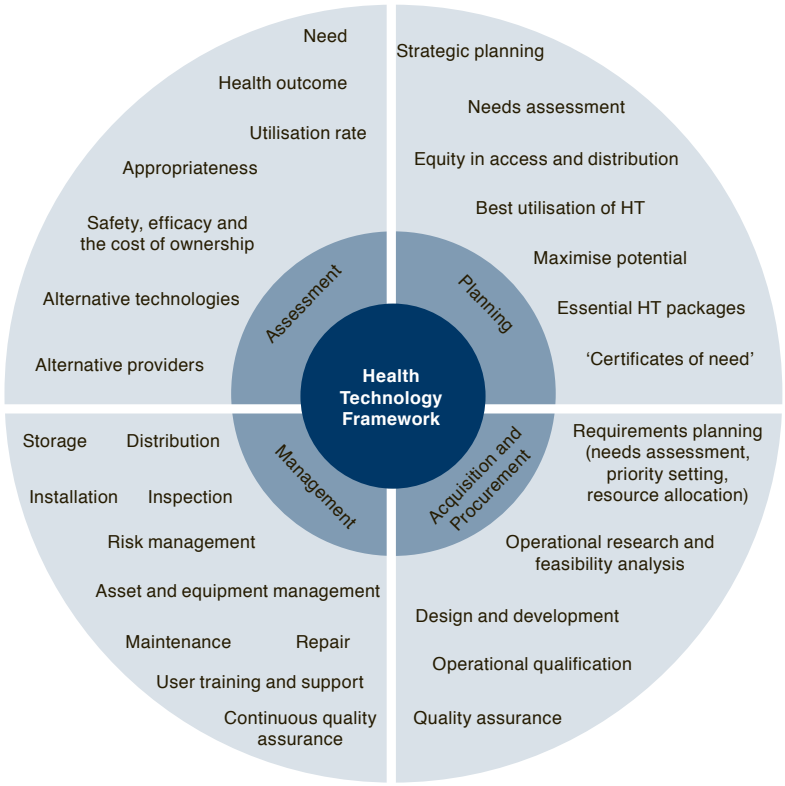
In 2001 the National Department of Health (NDoH) published its Framework for Health Technology Policies which set out to ensure that HT is harnessed to its fullest extent as one of the tools to improve delivery of health services.[1] The envisaged outcome was to create a unified and harmonious HT system that ensured optimal distribution of limited HT resources and to facilitate equity in access, the ultimate aim being to improve the quality of health services and enhance positive health outcomes.

The proposed framework model comprises four subsystems in the following domains: planning; assessment; acquisition and procurement; and utilisation. The key focus areas and elements of the HT policy framework are illustrated in Figure 1.

In 2005 the NDoH published a draft National Health Technology Strategy to ensure implementation of its policy framework.[11] The strategy is aimed at enabling HT to play a significant role in improving the quality of the health care of the people of SA, and to assist those involved and interested in delivery of quality health care. The vision espoused in this strategy is realisation of appropriate, safe and cost-effective HT available at the point of need.

Key challenges that the strategy aims to address are the lack of a scientific mechanism to decide on appropriate technologies in the face of increasing numbers and variety of medical devices, poor management of HT in general, and the fragmented approach to planning for acquiring new HT or replacing it. The key outcomes envisaged in the strategy are shown in Box 1.[11]

Figure 1: HT policy framework



Source: National Department of Health, 2001.[1]

Box 1: Key outcomes of the National Health Technology Strategy

- Development of Essential Equipment Lists as a planning tool. Essential HT Packages should be used as the basis of HT planning;
- establishment of multidisciplinary HT committees at each hospital, whose responsibilities will include determining HT needs at all levels of care and technology utilisation oversight;
- standardisation of medical equipment to reduce costs, ease the training burden and enhance implementation of national and sectoral strategies;
- a national tendering mechanism to centralise HT acquisition to reduce costs by bulk purchasing, streamlining processes and avoid duplication;
- adoption of Good Management Practice Standards;
- introduction of a National Healthcare Technology Management Information System;
- HT Asset Management Systems which would incorporate HT inventory lists and medical equipment management information such as maintenance, service, redundancy and replacement;
- a supporting clinical engineering infrastructure prioritised to address the current dearth of appropriate capacity;
- establishment of a Health Technology Assessment (HTA) Agency, with a governance model for the Agency and the process;
- regulation of medical devices with a focus on ensuring safety and equity and reducing the cost of health care;
- building of capacity in critical HT areas, especially clinical engineering and HT fields;
- establishment of a Ministerial Advisory Committee on HT, whose functions will include appointment of task teams to advise on HT, draw up guidelines concerning HT and make recommendations on HT acquisitions; and
- establishment of a National Health Technology Committee and Provincial Technology Management Committees, and an operational arm (the Equipment Committees) as well as District and Hospital Technology Management Committees.

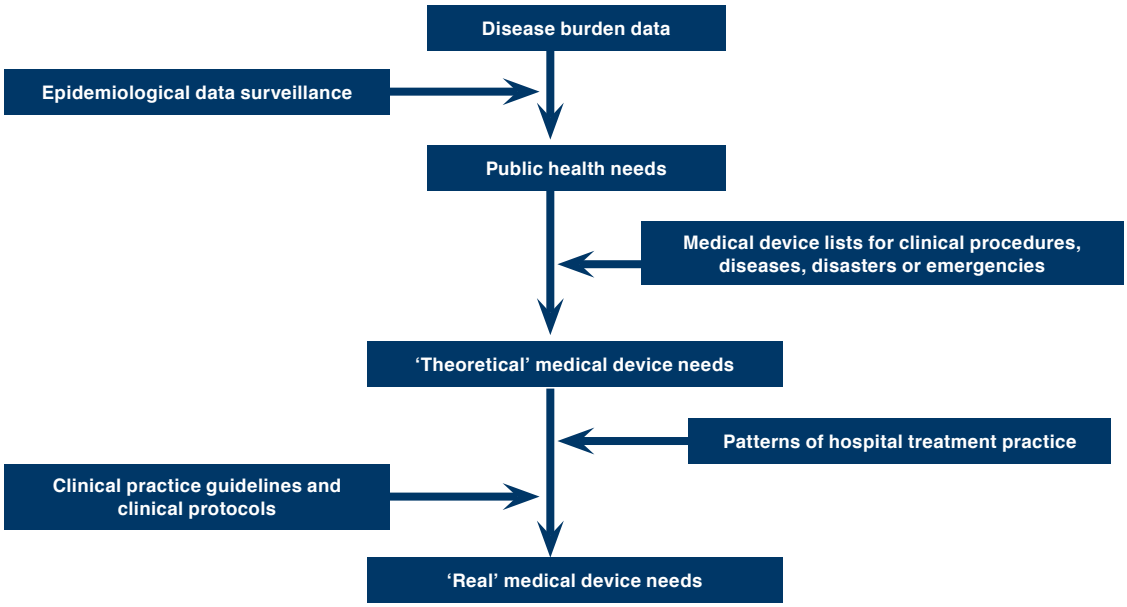
Source: National Department of Health, 2005.[11]

The NDoH has prioritised delivery of appropriate HT in their 2010/11 - 2012/13 strategic plan.[8] There is no specific budget allocation for HT, which falls under the Hospital Services sub-programme; according to the NDoH Annual Report 2010/11 they have underperformed in meeting the HT targets set for the reporting period.[12]

Prioritising public HT needs

Burden of disease (BoD) information is an important component of health information required for health planning as well as planning for and provision of appropriate HT. Public health needs, also based on SA's BoD profile, should guide determination of HT needs to prevent a mismatch between needs and available HT. It is essential to link the disease priorities as identified by BoD data with specific medical devices that can be used for prevention, diagnosis, treatment and rehabilitation. The WHO has proposed a sequence of steps to determine medical device needs based on priority public health needs, as shown in Figure 2.[13] First a theoretical medical device list for clinical procedures, diseases, disasters or emergencies is compiled; this is then used to determine the real need by selecting HT from the list, based on the BoD of the specific health facility and clinical protocols for managing the specific disease conditions.

Figure 2: Setting medical device priorities based on public health needs



Source: World Health Organization, 2011.[13]

The "real need" then becomes the desired standard. The desired standard can be determined at national, provincial, district and health facility level. A comparison between the real need and the existing situation concerning HT at a specific level will determine what needs to be procured and managed. The cost of the real need should be determined per level so that an adequate budget is established.[14]

HT management

HT management covers a wide range of activities, some of which are listed in Box 2.[9]

Box 2: Activities associated with HT management

- Providing technical advice
- Planning and costing work
- Selection and procurement
- Installation and commissioning
- Training users and maintenance personnel
- Operating equipment
- Maintenance and repair work
- Monitoring contracts
- Decommissioning and disposal
- Managing workshop facilities
- Managing staff
- Record-keeping
- Managing the inventory
- Stock control of parts, consumables, etc.
- Managing waste
- Implementing safety protocols

Source: Lenel, 2005.[9]

A broad spectrum of skills is required to cover the HT management needs for the whole range of equipment at various levels of healthcare facilities. Where feasible these skills should be shared across facilities in a particular health district or region.

The range of skill levels required includes persons who are semi-skilled, such as in-house artisans or equipment users; skilled people such as in-house technicians or people who have a basic certificate or diploma; skilled people such as technologists and engineers with higher national diplomas/technical degrees; and people with specialised skills, such as equipment manufacturers or their in-country representatives or independent private sector maintenance companies.[9]

Evidence indicates that there is a grave shortage of highly skilled personnel in the public health sector, which means work would have to be outsourced to the private sector in the short to medium-term and expertise imported from other countries.[1,11]

Asset management

Public healthcare facilities are subject to South African Treasury guidelines for asset management, according to which asset management is "the process of guiding the acquisition, use, safeguarding and disposal of assets to make the most of their service delivery potential and manage the related risks and costs over their entire life."[15] Although Treasury has published guidelines, evidence suggests that asset management does not have the strategic profile it requires.[11] Asset management should be seen as a key part of business planning which connects strategic-level decisions about an organisation's business needs, deployment of assets and future investment needs.[16]

In respect of HT asset management across all healthcare facilities, development and implementation of national, standardised guidelines on classification, categorisation and definition of medical equipment assets in both the public and private sectors is critical.[9,16,17] It is also important to align investment and asset

management at a strategic level to ensure a national framework which balances planning for future investment with full utilisation and maintenance of existing assets. There is also a need to deploy asset management expertise more effectively, particularly where such expertise is limited and in high demand. This would also entail coordination of existing skills within the public sector and reinforcement with expertise from the private sector to address weaknesses in capacity of government agencies to work creatively on optimising disposal values and engaging productively with the private sector. Here public-private sector partnerships should be considered, and automation of HT asset management should be a top strategic priority. Finally, development and/or adoption of data standards that uniquely identify products and locations through automatic capture and transmission of information via barcode scanning will improve operational inefficiency, eliminate errors in the HT supply chain and drive down overall healthcare costs.[18]

Regulation of HT

Safety, quality and efficacy of medical devices and equipment are critical. It is estimated that about 95% of all medical devices and equipment is imported into SA.[19] In 2004 the South African market for medical devices was estimated at US$435 million, which translated into 3% of SA's national expenditure and 0.3% of the global medical device market.[20]

At present a comprehensive system of medical device regulation is not in place. However, electromedical devices are currently regulated in terms of the Hazardous Substances Act (Act 15 of 1973) and Regulation No. R1302, 14 June 1991.[21] In terms of the Act and Regulation, prior to a listed device being sold in SA a licence for each model of electromedical device shall be obtained from the Directorate: Radiation Control, NDoH. Devices with a CE[a] marking are normally approved by the Directorate.

Draft Regulations have recently been published for comment, in terms of which provision has been made for eight categories of devices, ranging from non-invasive devices which do not penetrate the body (category C1) to category C8: in vitro diagnostic medical devices which are intended for in vitro examination of specimens derived from the human body to provide information for diagnostic, monitoring or compatibility purposes.[22]

Medical devices will also be classified into low-risk, low-moderate risk, moderate-high risk and high-risk categories, and in terms of draft regulations a licence holder shall have in place a post-marketing surveillance system and systems for recall and disposal of devices.

The NDoH is planning to establish a new authority, the South African Health Product Regulatory Authority (SAHPRA), to oversee registration of both medicines and medical devices. It will operate as an independent and autonomous body and function under the mandate of the Minister of Health, replacing the Medicines Control Council and starting operations in 2012.

In September 2011 the NDoH convened a Medical Devices Regulatory Summit in Johannesburg in order to raise awareness and understanding of the regulatory framework, share information with key stakeholders on practical considerations for regulations, and prepare for implementation of regulations.[23]

HT innovation

In 2011 the WHO published a compendium of new and emerging technologies suitable for use in low-resource settings, which "specifically focuses on innovative technologies that are not yet widely available in developing countries, and product concepts under way."[24]

Given the huge BoD in SA and the vast inequities in health services, the challenge is to accelerate HT innovations that address inequity, accessibility, affordability and availability in a cost-effective way, at the same time targeting the health priorities of the country.

Experience has shown that innovation can only thrive if there is a pool of critical skills to engage in research, a considerable cash injection into a medical device and equipment research and development (R&D) infrastructure, strong ties between the public and private sector, and support of key Government departments including the Department of Science and Technology (DST), DoH and Department of Trade and Industry. This calls for a major national effort to bring together the three most important elements which are still disconnected – scientific research, industry partners and funding.[25]

HT innovations are most likely to take place if there is good, long-term, sustainable collaboration between academia, clinicians, users, industry and patients: "A multidisciplinary approach is required given that technology must have clinical utility, should integrate seamlessly with the relevant operational activities with the healthcare system and be readily embraced by health professionals."[26]

National Facilities Audit

The need for an audit of assets in public healthcare facilities was expressed more than a decade ago, and further attention was drawn to it in the HT strategy document as well as the Green Paper on National Health Insurance (NHI) which calls for an assessment of existing health infrastructure (including facilities, technology and management capacity) and a plan to improve its capacity and effectiveness to support health services delivery and provision (especially within the context of NHI).[1,11,27]

In response to this need, the NDoH released a tender in 2010 which sought to appoint a service provider to conduct a national PHC facilities audit, including district hospitals.[28] As described in the tender document, the aim of the audit was "to conduct a national audit of public health facilities, including all clinics, community health centres, maternity and obstetric units, district hospitals as well as regional, specialized and tertiary hospitals".[28] Briefing documents required that the audit be conducted in all provinces using standardised existing measurement tools, with the data being deposited into a database established by the NDoH.

Among the specific objectives of the audit as it relates to HT are provision of input that will assist with developing certain norms and standards where these are deficient, in particular (but not limited to) those related to HT and infrastructure, and to conduct an audit regarding availability and basic functionality of medical equipment and back-ups, including an age analysis of replacements required,

a The letters "CE" stand for "Conformité Européenne". With the CE marking on a product the manufacturer ensures that the product conforms with the essential requirements of the applicable European Community medical device directives.

status of HT and replacement requirements for critical equipment.

Some of the deliverables include an estimate of costs required to close identified gaps in human resources, missing equipment and infrastructure (space and repairs).

The tender was awarded to the Health Systems Trust, a not-for-profit organisation specialising in health systems strengthening support, and the audit commenced in February 2011. At last count (in November 2011) approximately 2 800 of the 4 200 facilities had been audited, with the entire exercise scheduled to be completed in 2012.[29]

Several questionnaires and checklists have been developed for the audit. In respect of the HT component the domains and number of types of medical equipment being assessed are shown in Table 1.

Table 1: HT audit domains and numbers of equipment per domain

Domain	No. of equipment types
Trauma and emergency	30
Maternity room	38
General wards	16
Diagnostic radiology	35
Theatres and recovery room	117
Outpatients department	54
Intensive care – adult dept	27
Intensive care – neonatal dept	37
Emergency trolleys	26
Critical equipment – maintenance records	5

Source: Health Systems Trust, 2011.[b]

In the audit exercise the following information is recorded: number of units available, number of units functional, and number of units required for each piece of equipment.

The inventory arising from the audit and ongoing updating of the inventory should provide a technical assessment of the assets on hand, giving details of the type and quantity of equipment and the current operating status, as well as provide the basis for effective asset management, including facilitating scheduling of preventive maintenance and tracking of maintenance, repairs, alerts and recalls.[2] In addition, such an initiative is likely to provide financial information to support economic and budget assessments and serve as the foundation needed to organise an effective asset management department. Items such as equipment logbooks, operating and service manuals, testing and quality assurance procedures and indicators can be created, managed and maintained under the umbrella of the equipment inventory. Accessories, consumables and spare parts inventories can be directly correlated with the main medical equipment inventory.

Ideally, an economic analysis should complement the audit. The economic dimensions may include a cost-benefit analysis, cost-utility analysis, cost-effectiveness analysis and cost-minimisation analysis, and also budget-impact analysis and other forms of economic assessments. Quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs), as used in cost-utility analyses, are often seen as the hallmarks of HTA, but in many situations budget is much more important and useful for decision-makers.

Overall, the use of HTA to inform national coverage policies leads to a more explicit and transparent resource-allocation process, improving not only technical or allocative efficiency but also health equity.[14]

b Personal Communication Jeanette Hunter: 16 October 2011.

eHealth

With the advent of the digital age several innovations in the delivery of health services have been made possible. eHealth is a recently coined term for healthcare practice that is supported by electronic communication and encompasses a range of services or systems; it includes telemedicine and mobile health (the latter commonly referred to as mHealth). However, in the South African context there are a number of hurdles to overcome – including the high cost of mobile communications, compliance with health legislation and ethical rules that cover privacy and doctor/patient confidentiality.

Telemedicine can be broadly defined "as the use of tele-communications technologies to provide medical information and services", and is increasingly being used as shorthand for 'remote electronic clinical consultation'.[30] It seeks to deliver the best medical advice and treatment options to patients irrespective of their location.

In 2009 the Botshabelo community in the Free State was one of the first beneficiaries of four PHC telemedicine workstations developed by the South African Medical Research Council (MRC) and Stellenbosch University under a DST/National Research Foundation Innovation Fund award. The DST is also supporting the Botshabelo telemedicine project together with the MTN SA Foundation, which is providing bandwidth. This partnership is an example of government, research institutions and the private sector working together to enhance healthcare delivery.

Telemedicine's major constraints include access to and cost of the higher bandwidth required for transmitting physiological data and complex medical images, the skills level and willingness of health workers to embrace and use this technology, and the rapid pace of changes in digital technology which result in an inability to continue to use the 'older' technologies.[30] Research is required to determine the feasibility and sustainability of the pilot telemedicine projects currently being undertaken in SA.

Medical Device Innovation Platform

In 2010 the MRC established the MRC-University Medical Device Innovation Platform (MDIP) to engage in research and development of innovative medical devices for the South African and international markets. MDIP is a collaborative research and development platform that integrates the medical device research expertise and competence found at various universities in SA. It is based on a hub-and-spoke model where all universities with HT R&D competence are encouraged to be part of the platform. The MRC is responsible for co-ordinating and managing the MDIP and provides funding for approved projects, including support for MSc and PhD graduates engaged in such projects. There are now 10 South African universities that have signed or are in the process of signing up to be part of the platform, and a number of collaborative projects are in progress. Science councils such as the Council for Scientific and Industrial Research and international universities

may also become collaborative partners in specific projects. In this regard the MRC has proposed that African universities involved in ANDI – the African Network for Drugs, Diagnostics and Medical Device Innovation – engage in the MDIP to meet the objectives of this pan-African initiative. The DST together with the MRC provides funding support for the MDIP initiative.

The focus of MDIP activities is to develop appropriate technologies to meet unmet health needs in underserved communities through:

- capacity development of students leading to Masters and Doctoral postgraduate qualifications, with emphasis on previously disadvantaged individuals;
- identification of clinical needs and proposed solutions by medical researchers and practising medical doctors, leading to market-focused projects;
- utilisation of specialised prototyping and manufacturing facilities and product development expertise found within certain universities;
- generation and protection of intellectual property, spin-out company creation and development of manufacturing and distribution activity in the field; and
- development of new academic courses (MSc/MTech and PhD/DTech) and entrepreneurial career paths in HT for mainly black engineers, scientists and managers who are often enticed prematurely into professions such as energy, mining and construction.

Public-private partnerships

The private health sector in SA is well developed and provides world-class care and patient services. Their skills and experience in a wide range of HT areas need to be brought to bear on the public health sector through public-private partnerships. These include:[1]

- knowledge transfer;
- procurement practices;
- HT acquisition, assessment and management;
- outsourcing of services;
- quality assurance programmes;
- alternate financing methods and mechanisms; and
- public sector provision of health services to private patients, and vice versa.

Conclusion

The need for improved HT regulation, assessment and management has long been recognised as essential to address patient safety, poor asset planning and management, inappropriate procurement practices, inadequate technical support services and skill shortages in critical areas of healthcare service delivery. In response to this need the DoH has published a visionary policy framework and draft strategy for HT. Furthermore, the long awaited audit of assets in public health facilities has commenced, National Core Standards for health establishments in SA have been published and the draft policy paper on NHI in SA has been gazetted for public comment.

Most of the critical building blocks are now in place to have a significant impact on the unacceptably high BoD in SA and promote optimal use of HT assets and skills in the public health sector. The piloting and phased implementation of the NHI is likely to fast-track the finalisation of the HT strategy, leading to development of implementation and action plans and identification of organisational structures and resources required to implement the plans at national, regional, district and local level. Monitoring and evaluation will be important to determine performance in achieving the objectives and targets of the implementation plan and to ensure accountability.

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