

HEALTH TECHNOLOGY ASSESSMENT
DISCUSSION DOCUMENT ON A STRATEGY FOR THE FUTURE

**PREPARED BY MEMBERS OF THE INTERIM STEERING COMMITTEE ON
HT ASSESSMENT**

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1 INTRODUCTION

Health Technology Assessment (HTA) is a multidisciplinary activity that systematically examines the technical performance; safety; clinical efficacy and effectiveness; cost effectiveness; organizational implications; Social consequences; Legal; Ethical considerations of the application of technology. Examples of HTA could include:

- ## Technical assessment of a medical device by the regulatory bodies
- ## An ethical analysis of a technology like Xenotransplantation
- ## Assessment of usefulness of routine X-Ray or some before administering general anaesthesia
- ## Whether or not there should be a public offer of flu vaccination to the elderly population

In this age where there are multiple solutions and generally a wide spectrum of possibilities and strategies for most health care problems, the need for the evaluation of the technology and of the relevant alternative technologies available has never been greater. Secondly, in this age where the health sector generally has to do more with less resources, HTA becomes one of the most important tools performed to contain increasing cost of health care, without compromising safety. In addition to these issues, there are a number of realities that face the healthcare industry and hence pose substantial challenges in the finding of an optimal solution. These include:

- ## The economically affluent regions wishing to promote innovation.
- ## The technology manufacturing industry wanting to, and having to make profits in order to create shareholder value and attract further investments.
- ## Patients becoming increasingly exposed to health care literature and other sources of information, as a result of which becoming more educated and, in a sense, more demanding of “newer and more effective treatments”.

HTA thus provides general guidelines that would assist the health sector to adopt evidence-based approach in decision-making at all levels.

It should be accepted that Health Technology Assessment (HTA), should form the basis for Health Technology Policies. Hence we recommend that cognisance should be taken of internationally accepted processes for HTA. Appendix 1 gives a brief account of this process.

1.1 South African Perspective

The need for the assessment of Health Technology has to be considered against the background of the general reform process that is currently underway in the South African health care sector. This reform process is at the uppermost level guided by the Constitution of South Africa, together with the Bill of Rights.

Based on the basic premises encompassed in the Constitution, a National Health Plan has been developed and published as far back as 1994. This National Health Plan is the road map of the reform process that is being followed within the health care sector and a number

of legislative changes have been effected over the last four years. These legislative changes include the following:

- ≠# Medical Schemes Amendment Act
- ≠# Pharmacy Amendment Act
- ≠# Medicines and Related Substances Amendment Act
- ≠# Amendments to the Health Professions Act

In addition to the legislative changes, a National health Bill has been published and accepted via the parliamentary processes. It is not yet an Act, but it could be reasonably expected that the State President will be signing this Bill into an Act in the near future.

Section 90 (1) (q) of the National Health Bill makes provision for the assessment and regulation of Health Technology.

The National Health Technology Policy Framework published by the National Department of Health in year 2000, will form the basis for these health technology regulations envisaged in the National Health Bill.

Finally, it should be noted that the focus on the regulation and management of Health Technology is not a South African trend alone. It is in fact a process that is in line with principles and processes that have been adopted by the World Health Organisation (WHO). According to Goal 31 of the WHO's "Health For All" strategy, member states should have established "structures and processes to ensure continued improvement of the quality of health services and an appropriate development and utilization of technology" Linked to this, the necessity of the necessity of establishing effective procedures for assessment of the advantages and relevance of health technology both in developmental as well as routine use.

1.2 Health Technology Policy Framework

1.2.1 Mission and Vision

The mission of this framework is:

"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."

It is also important to take cognisance of the expected outcome of the framework:

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

1.2.2 Definition of Health Technology

The HT Policy Framework defines health technology in the following manner:

"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 this definition therefore 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.

Consequently, the definition of Health Technology encompasses the whole of health care infrastructure and the associated delivery systems and processes. ***It should however be noted that although the definition of health technology is all encompassing, the focus for this work will be on the medical equipment aspects of it.***

1.2.3 HT System and HT Regulatory Framework

The thrust on the HT Policy Framework is on the development of the National HT System, which has the following four component/subsystems to it:

- ⌘ HT Planning
- ⌘ ***HT Assessment***
- ⌘ HT Acquisition
- ⌘ HT Management

The focus for this document is on the HT Assessment subsystem

Health Technology Assessment is intricately linked with the other three subsystems that form the national HT systems described in section 1.2.3. There is also a close link between the Assessment of technologies and the management and regulation of technologies. The framework that is being proposed is thus fundamentally based on the notion that there are a number of stages to the management and regulation) of HT. Figure 1 outlines these stages at a high level and shows how Health Technology Assessment fits within this framework.

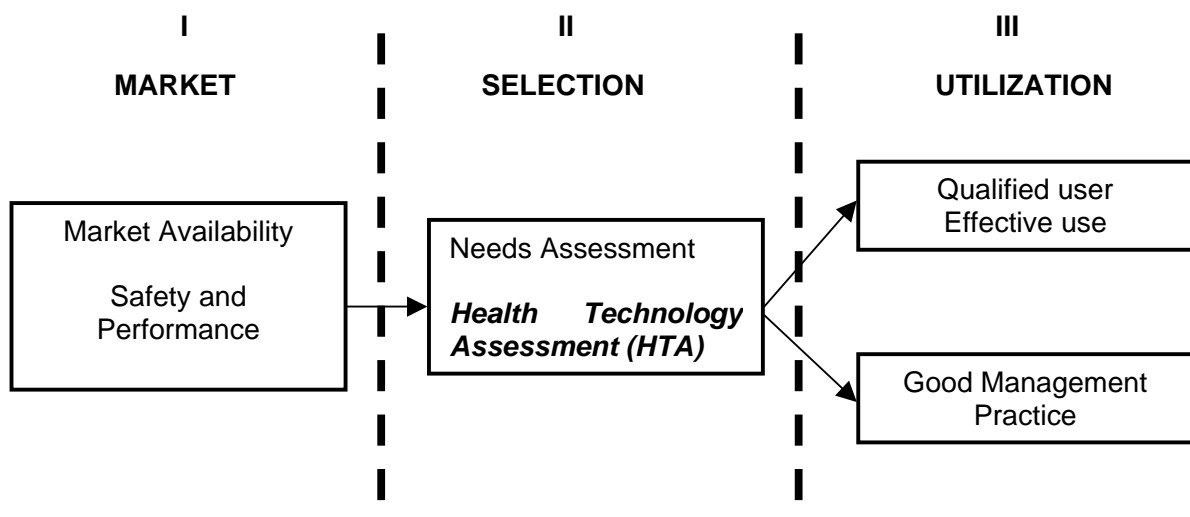


Figure 1: HT Regulation Stages

Briefly, this figure highlight the fact that there are essentially three levels of regulation of health technology, namely:

1. Premarket and registration based on safety and performance as well as post market surveillance
2. Selection of technologies which includes *Health Technology Assessment* and the Certificate of Need (CON). These atke into consideration issues such as (cost effectiveness/benefit; socio, cultural and/or political considerations; alternative care and other considerations. Not all technologies will be subject to assessment, but generally restricted to those that have limited evidence, have high cost and have potentially high utilisation. All of these factors have a potentially high clinical and financial risk to patients and payers and would be assessed in the local context.
3. Utilization level, which regulates the essential elements of good management of medical equipment/devices including user training pertaining to technology and technology maintenance issues

1.2.4 Enabling Structures for the HT System

To enable the government to deliver on the HT system, the policy framework proposes the formation of a **National Health Technology Forum (NHTF)** that will become the custodian of the HT system. It is envisaged that the NHTF will will remain a sub-committee 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 orremains a PHRC Sub-committee.

An interim precursor to the NHTF, known as the Interim Health Technology Advisory Commission (IHTAC) has been established. The purpose for this committee is to advise the Director General on all aspects related to the implementation of HT policy, particularly on mechanisms and means on how to get the HT System (with all its subsystems) off the ground. This includes advising on matters related to HT Regulations.

Another structure envisaged in the HT Policy Framework is a national **permanent body/structure for HT Assessment**. Although the nature of this permanent body is not defined in the policy framework, its terms of reference are clearly defined 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 all stakeholders, 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, provide contributions to the preparation and

implementation of HTA projects as well as providing advice to the agreed upon HTA projects.

5. Establish co-operation for the development of HTA between all relevant stakeholders⁶. Promote the concept and use of HTA, particularly in management, clinical and other decision-making.
6. Ensure the establishment and development of an “early warning and monitoring system” (horizon scanning) for new and emerging health care technologies in the health service. This will also involve co-operation with relevant international organisations/HTA centers.
7. Monitor and evaluate international HTA activities and communicate the results, for utilisation in the SA National Health System.
8. Co-ordinate South African Health Technology Assessment activities.
9. Look at existing technologies and asses if there is a need for an assessment.
10. Assume responsibilities for dissemination/communication of HTA recommendations.

1.2.5 Interim HT Assessment Committe

Again as a precursor to the establishment of the permanent body, an Interim National Steering Committee on Health Technology Assessment (HTA), whose primary mandate is to devise the National Strategy for HTA, has been formed. The committee will operate no later than end of 2004 and is required to:

- ≠# Study the HTA systems of different countries, together with the enabling structures, with mapping of local HTA related activities.
- ≠# Suggest the relevant scope and most suitable system for the enabling structures for a South African HTA system after extensive local consultation.
- ≠# Make proposals relating to the legal status of the structure

Additional terms of reference for the Interim Steering Committee are:

- ≠# To make recommendations on funding
- ≠# Establish guidelines for prioritisation for HTA activities

Having regard for the direction that has been decided upon and the need to obtain the constructive engagement of all the stakeholders involved, a general stakeholder meeting was held during February 2004. At this meeting the Framework for Health Technology Policies was discussed with a specific emphasis on the Health Technology Assesment.

From the discussion, it was agreed that focus should be given to the enabling structure for the HT system, with specific attention given to the HTA system itself. Health Technology Management (HTM) has been receiving attention at a different forum for some time already,

and progress is already at an advanced stage – this also addresses GMtP. It was however recognised that suggestions that will be made would have an impact on the rest of the health technology scope.

In this vein, a representative working group was elected at the stakeholder meeting and was tasked with the functions of the interim Steering Committee, whose mandate has been described above.

The purpose of this discussion document is to provide a report back on the work that has thus far been performed by the interim National Steering Committee and to formulate certain suggestions on a way forward that have emanated from that work.

2 LOCAL AND INTERNATIONAL HTA ENVIRONMENTS

The assessment of health technology is an extensive and potentially costly process. The main challenge to the working group has therefore been to find a workable and affordable system, taking into account that some infrastructure and capacity already exists in South Africa. The HTA working group has had several meetings and has performed some research. Subsequently, a suggested way forward has been developed and the aim of this document is to outline that suggested process.

It should be noted that this should be accepted as a proposal, the principles encompassed in this document have to be accepted by the stakeholders that are represented by the members of the working group on the one hand, and the general stakeholders meeting on the other. Thereafter a formal proposal shall be made to the interim Health Technology Advisory Commission (IHTAC) once consultation is complete. The Interim HT Advisory Committee will, consider these recommendations and integrate them with other recommendations from the other three subsystems (viz, HT Planning, HT Acquisition and HT Management) and present a final proposal to the Director General.

2.1 SA HTA Context

Information on the current status of HTA in South Africa has been derived from inputs to HTA consultations and meetings. Further information was derived from presentations to the steering committee, by SAMA, SAMED, Discovery Health, and Medscheme, which are the organisations that have formal HTA processes in place. The table below summarises the available information.

Table 1

Healthcare Providers	SAMA has a comprehensive review process, based on inputs from the relevant specialists. Other professional groups have review processes related to their scope of practice, however detailed information was not obtained by the committee in relation to other professional groups.
Healthcare Funders	Several Funders have internal review processes to inform funding decisions. Managed care organizations develop guidelines and protocols. Discovery Health and Medscheme have developed extensive processes using input from established HTA organizations. SAMED members provide inputs to the review processes of providers and funder.
Medical devices manufacturers	A standardized reporting format has been devised based on international practice.
Private hospital	Major hospital groups have internal process to inform funding decisions
Research and education organizations	Limited HTA activities take place in support of innovation and/capacity development, or on contract from other organizations.
Standards organisations	StanSA is responsible for the development of national standards and provides a link between the local environment and international standardization processes

2.2 International HTA Systems and Lessons Learnt

There were three major activities in this regard.

The first one was a national HTA Symposium held with the Swedish Council for HTA. The symposium took place on 9-10 March 2004 at the JHB Airport Holiday Inn. The main topic was on *Starting And Empowering A South African HTA Unit*. Key lessons learned from the symposium are attached as Appendix 2

The second activity was the attendance of the Health Technology Assessment International (HTAi) conference in Krakow Poland, by three of the members of the working group. Valuable lessons were learned from this event, as it was an international conference where various topics were discussed. This formed the basis of the lessons listed in the following section.

The last one was the International Survey of 54 international HTA organisations. Responses were received from 13 out of 54 international HTA organisations that had been identified for survey. The survey investigated the following issues.

- ⌘ HTA Entity Legal Status
- ⌘ HTA Entity Unit Funding
- ⌘ Entity Assessment Work Funding
- ⌘ Entity Assessment Work
- ⌘ Entity Methodology
- ⌘ Stakeholder Involvement in Assessment
- ⌘ Stakeholder Involvement in Final Decision Making
- ⌘ Entity Project Outcomes Content
- ⌘ Entity Project Outcomes Dissemination
- ⌘ Entity Project Outcomes Usage
- ⌘ Budget Per Annum in US\$ (Millions)
- ⌘ Number of Projects Completed Annually
- ⌘ Entity Permanent Staff Numbers
- ⌘ Average Number of Consultants in Employment

An extract of the report prepared based on the returns, is attached as Appendix 3. A more comprehensive document can be obtained through the HTA website at the following address www.sahealthinfo.org/hta

2.2.1 International Lessons on Implementation of HTA

In the consideration of a workable structure for the assessment of health technology it would be prudent to take cognisance of issues that have been experienced in an international context so that the same mistakes are not repeated. In the South African context, it is believed that there is an opportunity to learn from the international experience and implement a process that is not only workable but also applicable to a developing country.

The following list of lessons learnt from international experience emanates from a number of papers that were delivered at the International Health Technology Assessment conference in Krakow, Poland, that was attended by three members of the working group.

1. There is a perception that the review panels for the assessment of the literature pertaining to health technology are too academically oriented with a resultant insufficient focus on certain practical issues.
2. The HTA structures are often perceived to have a lack of independence, as they are in many instances centrally or government controlled.
3. The emphasis of HTA structures is generally on the assessment of the available literature, as opposed to the actual appraisal of the findings in relation to the practical implementation thereof and the context in which it is to be used.
4. The application of cost-effectiveness thresholds are often applied too rigorously, with the result that cost precedes equity, effectiveness and access
5. The assessment processes are often too long (up to 24 months) and at times lack transparency.
6. There is often insufficient collaboration between the different stakeholders.
7. There are often insufficient criteria for the prioritisation of the technologies that are to be assessed.
8. The processes that are historically based on the review processes that are followed for drugs.
9. HTA is often used to inhibit the diffusion of health technology, rather than to promote access thereto.

Whilst some may perceive these lessons as biased, they are important to take note of in the development of a workable system for South Africa. The following issues therefore require close consideration:

1. The closer involvement of the providers of health care at the “coal face”, meaning that the practical perspectives of HTA also require consideration. This is particularly important in the conducting of head-to-head studies, as opposed to double blind studies, and the ‘marketing’ of the HTA concept amongst the actual providers of health care.
2. The closing of the proverbial “loop” in that academic research needs to be guided to be performed in order to find solutions to the particular health care issues that face a country and that research grants are awarded accordingly.
3. HTA should, where possible, be performed on a pro-active, rather than a reactive basis. In other words, technology should be assessed before it has diffused into the

market and not after the fact, simply because it will always be difficult to remove technology from the market once it has established itself in the market, even if it does prove to be inappropriate. The body should consider using existing groups for assessment, and use its wisdom to identify any “gaps” which would need to be considered to complete the appraisal.

4. The HTA process and governing body should, in order to obtain maximal support from all the stakeholders, aim to be collaborative, rather than prescriptive, have some legal authority, be autonomous, authoritative, representative and have statutory power.
5. The main objective of HTA should be to provide an advocate for patients by demonstrating value, rather than focus on issues such as cost etc. This does however not imply that the latter should be ignored.
6. HTA should and cannot be a substitute for clinical judgement and sufficient latitude should be allowed for such clinical judgement. Failing this certain medico-legal ramifications may become apparent. Where a device affects a professional relationship between provider and patient, then professional expert sub-committees should be consulted for recommendations.
7. Cognisance should be taken of the ever-increasing sophistication of health care and the impact that such sophistication has on clinical outcomes. Therefore, the aim should be to find the balance between the management of health technology and the stemming of improvements in clinical outcomes and efficiencies.

2.3 Challenges Facing HTA

In the wake of the above, there are a number of particular challenges that face an HTA process and strategy. These challenges may differ, depending on whether HTA is being performed or the results thereof is being used.

2.3.1 Performing of HTA

In the performing of HTA, the following challenges need to be met:

1. Technology cannot be assessed in isolation and cognisance should also be taken of the numerous other related and semi-related factors that may or may not play a role in the final analysis. Such factors would range from socio-economic factors through patient expectations to medico-legal considerations.
2. Substantial attention should therefore be paid to the wider impact of health technology, including general economic impacts.
3. Patients *per se* should therefore have the opportunity to provide input into the process and the ultimate appraisal of the technology in question and the recommendations made.

4. By the same token, the actual providers of health care should, as has been stated before, have the opportunity to participate in the process.

That is why we should recommend that the HTA body will not DO the systematic review part of the assessment but will sub-contract this out to expert bodies; the HTA group will co-ordinate the appraisal component, considering these other factors.

2.3.2 Using of HTA

Similarly there are challenges that are associated with the use of the results of HTA, namely:

1. The giving effect to the earlier, rather than the later, use of HTA by the industry.
2. The entrenching of the notions of consistency yet flexibility in the application of the results of HTA.
3. The establishment of partnerships between various stakeholders, in order to be in a position to share at least some of the risk in cases on uncertainty.

The result of these challenges is that the HTA methods need to be developed in such a way that it meets the needs of all the decision-makers and a balance between the effective use of resources in health care and effective innovation needs to be found.

2.4 The Balancing Act

In the development of a workable model for the assessment and management of health care technology, consideration needs to be given to the various and varying needs of the different stakeholders in the health technology arena. The success and sustainability of the eventual model will in fact be dependent on the accommodation of the various needs within such a model.

Figure 2 attempts to describe the disparate needs of the main groups of stakeholders as well as the conflicting nature of those needs. Hence, the need to involve the various stakeholders in the development and maintenance of the eventual model should be apparent.

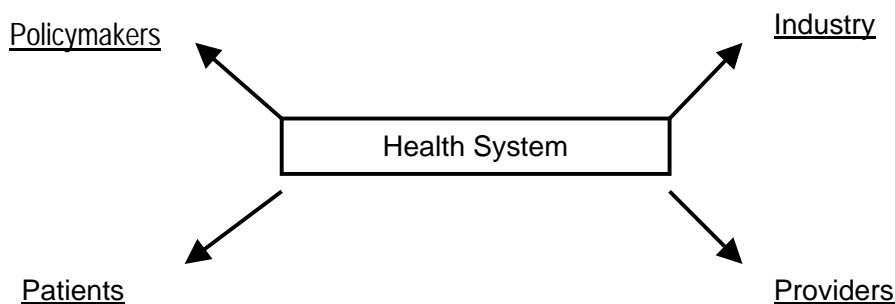


Figure 2: The Balancing Act

The balance that therefore needs to be struck is between:

1. The politicians or the makers of the relevant policies that would want to ensure that the needs of the population at large are accounted for and met, and that the policies that are introduced are not unnecessarily unpopular.
2. The patients typically, and especially in light of the increasing level of education of patients on the advances that are made in the field of health technology, would want access to the best possible technology at the lowest possible price.
3. The providers would want to provide the best technology and would expect the funders of health care to pay for such technology, regardless of whether the services are provided in the private or the public sector.
4. The industry, regardless of whether the manufacturers of the technology or the funding of health care services represents it, will and should have a profit and a creation of investor value motive. On the one hand, the manufacturers would want to maximise the diffusion and proliferation of technology in the market, whilst the funding industry, on the other would want to achieve the exact opposite in order to limit their financial exposure.

The only way in which this balance can be struck would be through the assessment of the health care technology on a formal transparent quantitative and qualitative basis. Failing this the system will be permanently fraught with conflict and controversy.

In this vein, issues that need to be taken into account would be the following:

1. The process of the assessment of technology, rather than the outcomes of the process per se, needs to be acceptable to all the relevant stakeholders.
2. All the stakeholders need to buy into the process and perceive it as fair.
3. The process needs to be practical enough so that it can actually be implemented in such a way that the stakeholders will support it.
4. By the same token care needs to be taken that the desired results and undertakings are actually delivered upon, failing which the credibility of the process will be at stake.
5. Finally, it has to be accepted that a process of this nature will be a costly process and an acceptable return on investment will only be achievable if it is accepted and supported by all the stakeholders.

3 PROPOSED NATIONAL HEALTH TECHNOLOGY ASSESMENT MECHANISM

From the preceding discussion it is evident that the performing of HTA and its link to the development of a HT management policy framework will not be a straightforward process. In fact, it needs to take into account the needs and requirements of the various stakeholders and at the same time, be as cost effective as possible. By the same token much can be learnt from the experiences that have been gained in the rest of the world on this particular topic. It might also be added that to date no perfect model has been designed.

The interim National Steering Committee has, in the short time available to it, attempted to examine the experiences from the rest of the world, taking into account the needs of the South African market and the infrastructure and abilities that are available locally. From this a proposed framework for the assessment of health care technology has emerged. It should however from the outset be noted that at this stage it is merely a framework that is being proposed and that a substantial amount of further work will be required before a final model and process can be designed.

3.1 Proposed Organisational Structure

Figure 3 below, illustrates the organisational structure proposed for HTA in South Africa. The proposal suggests that an independent Health Technology Assessment (HTA) Agency is established and that all the stakeholders in Health Technology become part of that agency. This will allow the HTA processes that are currently functioning to continue to do so, but feed the results of their work into a central, but independent body, whilst maintaining economies of scale. The HTA Agency will then, in turn, act as an advisory body to the Health Technology Regulatory Authority, which should be the ultimate regulatory authority.

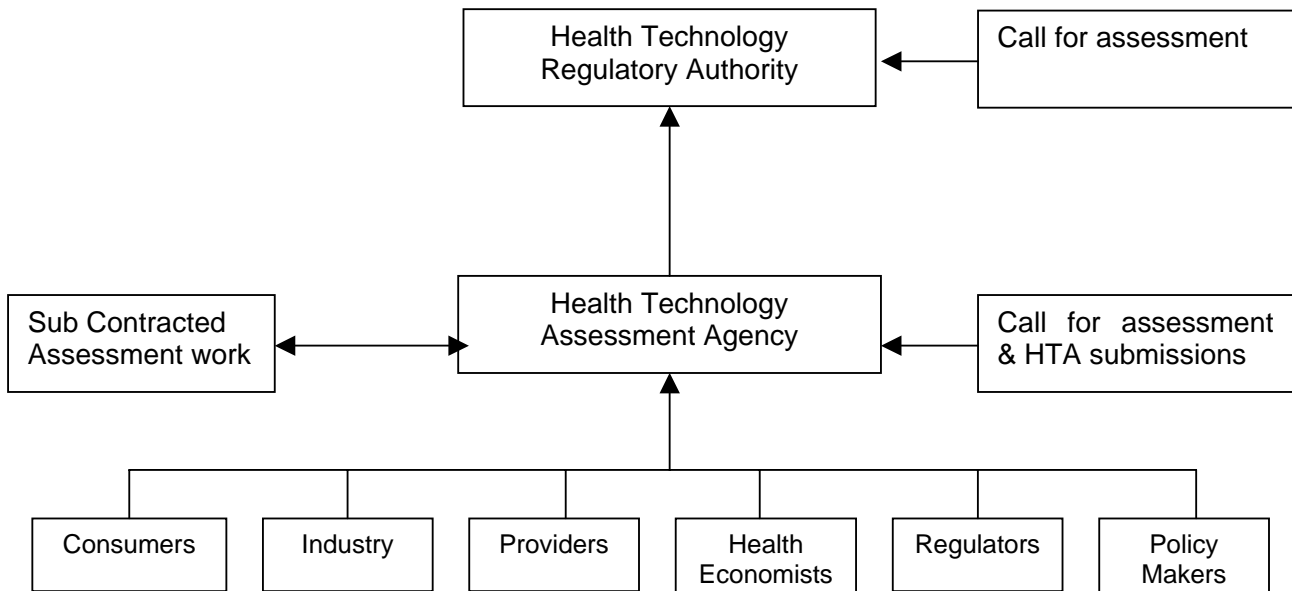


Figure 3: Proposed Organisational Structure

Figure 4 below illustrates a process through which specific projects can be outsourced to panels of contracted experts and reviewers. The result of this approach would be that the number of permanent staff in the HTA Agency per se could be kept to a bear minimum. At the same time the expertise of the various academic institutions in the country can be utilised.

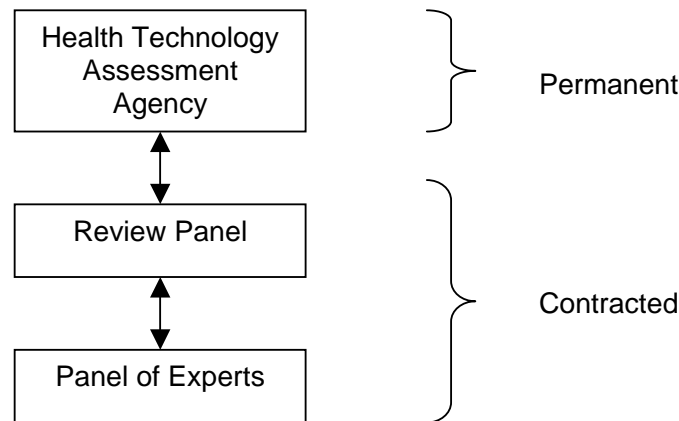


Figure 4: Proposed process for outsourcing HTA work

There is however an additional issue that relates to HT environmental scanning and the assessment of technology before significant diffusion of that technology takes place in the market. This will require a system of continuous environmental scanning and an ability to assess emerging technology efficiently and with short turnaround times. By the same token even the existing capacity may be insufficient to deal with the volume of assessments that may be required.

Rationale for the Proposed organisational Structure

This proposed structure is similar to the Australian model via the Medical Services Advisory Commission (MSAC), which has been functioning well for a number of years and acts in an advisory capacity to the Australian ministry of health. Canada also has a similar model and the major advantage of these models is that they allow for stakeholder involvement and participation and therefore transparency, whilst leveraging off existing capacity.

Furthermore, members of the working group acknowledged that the key issues that have to be taken into account in the design of a process that is both workable and sustainable relate to the cost of the process, the optimal utilisation of available resources and the efficiency of the process. These are based on the fact that international experience on HTA has proven that it is extremely expensive, with the annual budgets of HTA agencies literally running into millions of dollars, and that the turnaround times on research projects are quite long, ranging from twelve to eighteen months per project.

Clearly there are opportunities to leverage off work that has been done elsewhere in the world, but it still has to be borne in mind that the results of such work have to be brought into context in the South African environment. Hence the key to success within a limited

budget environment will be to make optimal use of the existing capacity and resources.

Broadly such resources are currently in existence in the following areas: -

1. The funding industry and more notably by Discovery Health and Medscheme. There are however also some HTA activities taking place within the Board of Healthcare Funders (BHF) as a representative body of the majority of the medical schemes in South Africa.
2. The private hospital industry is involved in some HTA activities.
3. The CSIR and the MRC are also involved in HTA activities, although arguably on a less formalised basis.
4. Some academic institutions, such as UCT and the Nelson Mandela School of Medicine are involved in some HTA activities.
5. The South African Medical Association (SAMA) has an established process based on intra- and inter-disciplinary peer review and encompassing doctors in both the private and public sectors as well as leading academics.

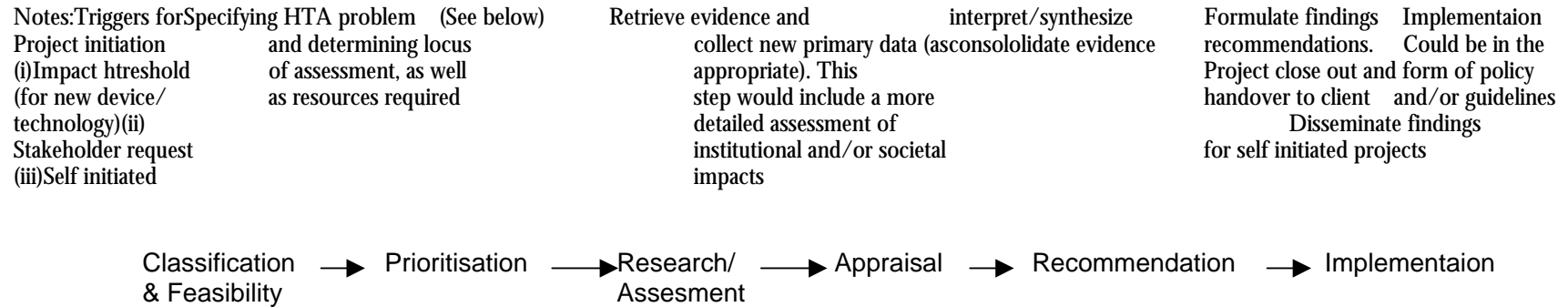
It is acknowledged that there will always be at least an element of bias in the appraisal of the available information and that this bias will be dependent upon the point of departure of the organisation performing the HTA. Hence it is believed that, in order to make optimal use of the available resources, yet as far as is possible eliminate the inevitable bias, a collaborative approach should be adopted and an appropriate vehicle to accommodate such a collaborative approach be created. The proposed organisational structure shown in figure 3 above, attempts to illustrate the composition of such a vehicle and the relationship between that vehicle and the national Health Technology Regulatory Authority being proposed.

3.2 HTA Process

The HTA process proposed for South Africa is summarized in figure 5 overleaf. Other factors not captured include the following:

- Ø HTA will be triggered by devices that fall within the following category:
 - (i) New developments OR
 - (ii) Reevaluation of existing devices with high impact. OR
 - (iii) Redesign, significant improvement or modification of an existing device.
- Ø HTA needs to look at society and institutional impact.
- Ø The entry point for HTA will be an assessment on the basis of safety and anything that does not pass safety standards will not be considered for HTA.
- Ø Triggers for HTA will come from Stakeholders. The HTA body in consultation with stakeholders, will then put the request through the classification and prioritization process
- Ø Provision for stakeholder participation and Transparency will be made

Figure: Suggested HTA



Setting Assessment Priorities (Source: Goodman CS (1998) Introduction to Health Care Technology Assessment)

Some assessment programs have explicit procedures for setting priorities, others set priorities only in an as hoc or vague way. Given limited resources for assessment and increasing accountability of assessment programs to their respective stakeholders, it is important to articulate how assessment topics are chosen.

Examples of selection criteria that might be used in setting assessment priorities are:

- # High burden of morbidity and/ or mortality
- # Large number of patients affected
- # High unit or aggregate cost of a technology or health problem
- # Substantial variation in practise
- # Potential to improve health benefit/ patient outcomes
- # Potential to reduce health risks
- # Sufficient research findings available upon which to base assessment
- # Scientific controversy or great interest among health professionals
- # Public or political demand
- # Need to make regulatory decision
- # Need to make payment decision

⌘ Available findings not well disseminated or adopted by practitioners

A 1992 report by the institute of Medicine provided recommendations for priority setting to the office Healthcare Technology Assessment of the Agency for Health Care Policy and Research. Seven criteria were identified.

⌘ Prevalence of health condition

⌘ Burden of illness

⌘ Cost

⌘ Variations in rates of use

⌘ Potential of results to change health outcomes

⌘ Potential of results to change costs

⌘ Potential or results to inform ethical, legal or social issues

3.3 Critical Success Factors

There are a number of factors that will be critical to the success of a Health Technology Management policy and once again the following list of factors has been developed out of encounters with international experts in the field of Health Technology Assessment.

1. An HTA Agency ideally has to be independent and unbiased.
2. By the same token it has to be independent, both in terms of its funding and its assessments.
3. It has to be objective and base its findings on factual available evidence.
4. The processes that are followed have to be fully transparent.
5. It has to build and maintain credibility.
6. It has to be effective and efficient.
7. It has to be able to facilitate the implementation of its findings and recommendations.

In the absence of these factors, the risk of the HTA agency becoming hamstrung by political issues from various stakeholders, will become real, resulting to poor implementation of HTA.

4 CONCLUSION

In terms of the Health Technology Policy Framework of the South African department of Health and interim National Steering Committee was formed. The mandate for this committee was to devise the National Strategy based on a study of HTA systems in different countries and with mapping of local HTA related activities. The strategy had to focus on the relevant scope and most suitable system for the enabling structures for a South African HTA system. This had to include a proposal relating to the legal status of the structure and recommendations on funding and guidelines for prioritisation for HTA activities.

The committee has within its mandate and available time and resources investigated some of the HTA systems that are operational elsewhere in the world and attempted to document the learning points that have emanated from that investigation. It has further mapped local HTA activities, and based on that, proposed a workable HTA organisational structure.

As far as the legal status of the agency is concerned, the committee felt it would be appropriate to propose that the body should be established by an act of parliament. The committee members also felt it prudent that the broad principles upon which this body must function should be:

1. The independence of the agency must be safeguarded, and for this reason, a Section 21 organisation would not be recommended.
2. Transparency is essential.
3. Stakeholders Representation is crucial
4. Time limits for its work have to be set and be adhered to
5. There must be an appeal process
6. There must be provision for review
7. Possible HTA outcome will be
 - a YES, unrestricted acceptance
 - b. NO,
 - c. CONDITIONAL APPROVAL (Experimental requiring mandatory reporting as determined by the HTA Agency)

Based on these principles and on the preceding discussion that has been presented in this document it is hereby proposed that the stakeholders be the ones who propose a legal status for the body. This will be the last stakeholder consultation, before the proposal/document is presented to the Interim HT Advisory Committee, in the National Department of Health.

The funding of the proposed HTA agency remains unresolved, but it is believed that, given the fact that its existence will be as a result of a legislative imperative, it would require a substantial government subsidy. It is felt that other beneficiaries of the output of SAHTA should contribute in some form.

Lastly, the Steering Committee members would like to thank everyone for their interest and valuable contributions, without which this work would not have been a success.

APPENDIX 1: INTERNATIONALLY ACCEPTED PROCESS OF HEALTH TECHNOLOGY ASSESSMENT

HTA is fundamentally based on the assessment of the available clinical evidence pertaining to the health technology in question. Therefore the following basic steps should be followed in the assessment of health technology:

1. A systematic review of the available literature
2. A synthesis of the findings from the review of the literature
3. An analysis of the cost-effectiveness of the health technology in question
4. An assessment of the social and ethical implications of the technology in question and the findings of the preceding analyses
5. An assessment of the potential policy considerations pertaining to the health technology in question

Figure 1 below illustrates the HTA process that is internationally accepted. This is in line with the terms of reference of the envisaged permanent body/structure.

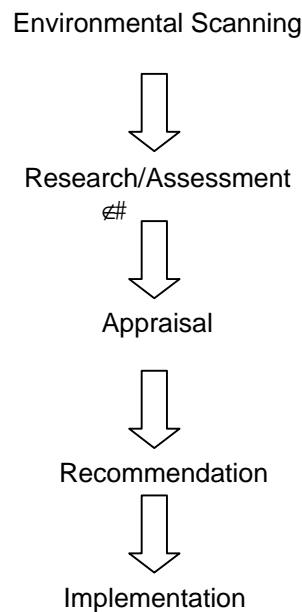


Figure 1: HTA Process

There is however a difference in the point of departure between the developing versus the developed world. In the developed world HTA is largely driven by well resourced academic centres experienced in research who scrutinise technologies and subsequently generate guidelines through a fairly comprehensive appraisals process, which is including more and more input from a broader group of stakeholders. In the developing world, however, because of economic, resource allocation, equity and access issues, HTA is driven from a policy perspective through regulation. The implementation of the results of HTA, ie recommendations/guidelines, as well as perceived lack of transparency, however remains problematic regardless of the point of departure. The reasons for this relate to the buy-in into the processes and the principles around HTA by the users of the technology, namely, the healthcare professionals, and by extension, the patient. This aspect will however be discussed in more detail later in this document.

From the above it should be clear that the assessment of health technology is an extensive and potentially costly process.

Criteria for Consideration of HTA

The following diagram at a high level illustrates the various steps in the assessment of health technology which actually forms the criteria for consideration of HTA

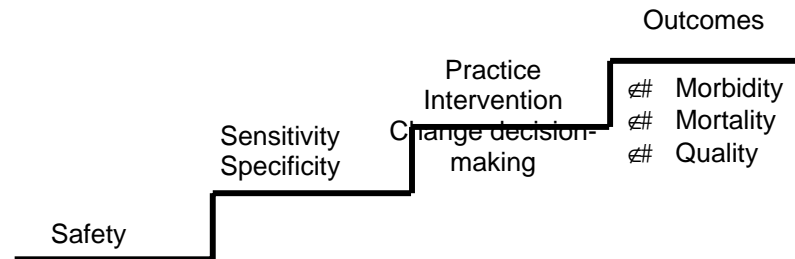


Figure 2: Criteria for Consideration of HTA

Figure 2 illustrates that the safety of health technology needs to be established before any other assessment would make sense. Thereafter, the clinical sensitivity and specificity of the technology in question has to be assessed, before an intervention at a practical level is suggested.

Once implemented, the clinical outcomes related to the use and application of the technology have to be monitored, in order to facilitate the reassessment of technology, based on actual clinical outcomes.

APPENDIX 2: KEY LESSONS LEARNED AT THE SOUTH AFRICA – SWEDISH NATIONAL SYMPOSIUM ON HTA

1. Successful model for agency based on:
 - a. Independence which is crucial for credibility purposes
 - b. No authoritative power
 - c. Should utilise contracted researchers
 - d. Assistance from research houses (i.e. Cochrane)
 - e. Should have strong dissemination and implementation capability
2. The unit must have a small staff component with contracted researchers. Staff composition could be as follows:
 - a. Director
 - b. Medical expertise
 - c. Well defined HTA- Methodology
 - d. Information Specialist
 - e. Health Economist
 - f. Administration
 - g. Communication marketing
3. The terms of reference for the unit should be as follows:
 - a. Should look after financial issues in the organisation
 - b. Organisation and prioritisation of projects
 - c. Decision around projects
 - d. Time frame
 - e. Who does/undertakes
 - f. Approve summary of reports
 - g. General strategic decision
 - h. Project planning and timing
 - i. Strategic decision making
 - j. Administration
 - k. Approval summaries of reports
4. Links with Cochrane INAHTA network need to be explored
5. Focus on dissemination & Implementation, which can be accomplished through:
 - a. Local conferences
 - b. Implement project
 - c. Health promotion
6. Special funding for traditionally neglected areas such as psychiatry and dentistry is required
7. A continuous self assessment of how HTA will be used vs. how to do the work itself is important
8. Avoid “battles” that cannot be won
9. Multi disciplinary, inclusivity

10. It is important to agree on procedures from the onset
 11. Acknowledge that there will be a conflict of interest, therefore transparency is crucial
 12. Checks & balancing mechanism needs to be put in place
 13. Various models such as NICE in UK must also be studied
 14. SBU has a budget of SK48m, 20% of which is the Running cost, 10% used for marketing and 18% for Research.
 15. It is important to strengthen the use of other HTA's
 16. SA can start-off with other reviews, but strengthen quality control and ensure SA customisation
 17. Try to narrow focus the scope/ Define the scope more sharply
 18. Early assessment for emerging techs
 - Strategies will include provisional (recommendation)
- Need to be careful with the definition, words (e.g. Review & HTA)

APPENDIX 3: EXTRACT FROM THE INTERNATIONAL SURVEY REPORT

The survey investigated the following issues.

- HTA Entity Legal Status
- HTA Entity Unit Funding
- Entity Assessment Work Funding
- Entity Assessment Work
- Entity Methodology
- Stakeholder Involvement in Assessment
- Stakeholder Involvement in Final Decision Making
- Entity Project Outcomes Content
- Entity Project Outcomes Dissemination
- Entity Project Outcomes Usage
- Budget Per Annum in US\$ (Millions)
- Number of Projects Completed Annually
- Entity Permanent Staff Numbers
- Average Number of Consultants in Employment

Responses were received from 13 out of 54 international HTA organisations that had been identified for survey.

1) Health Technology Assessment (HTA) Entity Legal Status

The purpose of this question was to ascertain the legal identity of each Health Technology assessment (HTA) entity.

From the limited data return so far, it seems that most entities in Europe and Canada are governmental or quasi-governmental entities. MSAC in Australia is notable in that it is a statutory body, however we know that there are others whom haven't responded yet. It makes sense for these entities to be further investigated by his committee. Poland is only due to start up their HTA activities in 2005.

2) Health Technology Assessment (HTA) Entity Unit Funding

The purpose of this question was to ascertain whom funds the entity only, as opposed to whom pays for the assessment work itself.

From the limited data returns so far, it seems that governments fund most entities in some way, either directly or through trusts. Some entirely private concerns fund themselves, some with governmental contribution. It is notable that the EU also funds about 10% of FINOHTA, the Finnish HTA agency. It thus seems likely that others in the European Union may be similarly subsidised.

3) Health Technology Assessment (HTA) Entity Assessment Work Funding

The purpose of this question was to ascertain who funds the assessment work itself.

From the limited data returns so far, it seems that governments fund most assessments either directly, via trust revenue or by way of paying for projects performed within private entities. Vice versa some government entities accept private projects revenue contribution.

4) Health Technology Assessment (HTA) Entity Assessment Work

The purpose of this question was to ascertain whom does the assessment work itself.

With the exception of two entities, it appears so far that almost all entities utilise a combination of their own staff and outsourced professionals to perform the assessment work. It cannot be explained that AETS in Spain performs all work with in-house staff, cited as 14 members completing 10 projects annually, we need to look at the diversity of those projects to understand this, particularly that they also cite both systematic review and meta-analysis methodology. UHSC in the USA cites that they are performing in-house assessment, this response is easily explained by the fact that they are an association of >50 universities, thus this is entirely plausible. Overall, the usage of outsourced professionals is the clearest trend seen thus far; it makes sense that if a wide diversity of complex projects is to be assessed, that outsourced professionals will definitely become the required norm.

5) Health Technology Assessment (HTA) Entity Methodology

The purpose of this question was to ascertain what methodology the Health Technology Assessment (HTA) entity employs.

It is notable that no responses have yet cited meta-analysis only. Almost all responses cite both systematic review and meta-analysis. Expert panels, primary research (RCTs), development of methodologies to assign causality between intervention and outcomes, the usage of large clinical databases for trend analysis and consensus guidelines development, economic, organisational and patient related analyses are also entries under the survey provided free text field.

6) Health Technology Assessment (HTA) Stakeholder Involvement in Assessment

The purpose of this question was to ascertain whether stakeholders were involved in the assessment work itself.

The majority of respondents say that stakeholders are sometimes involved in assessment work, some say always (notably Canada), with only one so far saying that stakeholders are never involved in the assessment process (MTPPI – USA). No responses have advised us who the stakeholders actually are, despite requesting that. It seems most likely that stakeholders are simply involved as required, yet we still don't have a clear definition of the term 'stakeholders'.

7) Health Technology Assessment (HTA) Stakeholder Involvement in Final Decision Making

The purpose of this question was to ascertain whether stakeholders are involved in the final decision / outcomes of the assessments.

FINOHTA (Finland) views this question as not applicable, simply advising that it does not make decisions, instead referring information/evidence for decision makers. Two Canadian responses are that stakeholders are always involved in the final decision-making. The bulk of the returns so far are 50/50 split between 'sometimes' involved in the final decision and 'never' involved in the final decision.

8) Health Technology Assessment (HTA) Entity Project Outcomes Content

The purpose of this question was to ascertain what the assessment project outcomes are.

Marginally just over half of the responses so far refer to a full HTA report as an outcome. Many provide a full HTA report and Clinical Practice Guidelines. The ASERNIP-S (Australia) has a defined response being a full HTA report OR Clinical practice Guidelines. MSAC (Australia) is cited as providing reports consisting of a review of safety, efficacy and cost-effectiveness. MTTPI (USA) cites peer reviewed journal papers.

9) Health Technology Assessment (HTA) Entity Project Outcomes Dissemination

The purpose of this question was to ascertain how the assessment project outcomes were disseminated.

The majority of responses so far indicate both active and passive dissemination of reports on a free basis. Some entities seemingly only distribute their outcomes to registered entities on a free basis, but except in the case of UHSC (USA), no entity has yet referred to fees basis dissemination. Whilst not strictly a survey question, it is known that the Internet is used extensively for dissemination.

10) Health Technology Assessment (HTA) Entity Project Outcomes Usage

The purpose of this question was to ascertain how assessment project outcomes are used.

Marginally just over half of the responses so far refer to their outcomes reporting being used on a national/international basis. Two responses cite that outcomes are to be used on a national basis by legislation, namely MSAC (Australia) and the proposed new PHTTA (Poland), understood to become operational in 2005. OHTAC (Canada) is believed to have its reports used on a regional basis by legislation. ASERNIP-S (Australia) is cited as having its reports voluntarily used by professionals and/or institutions, however it is believed that they also do work for MSAC. Whilst we don't have any returns for NZHTA (New Zealand), it is believed that they too tie in with the Australian entities. It would recommend that this triangle be further investigated.

Additional Data Requested:

11) Health Technology Assessment (HTA) Budget Per Annum in US\$ (Millions)

Less than half of all responses so far have indicated a budget figure. Budgets cited range from 1 Million US\$ for 4 projects completed annually (MTPPI – USA) to 6 Million US\$ for >50 projects annually (CCOHTA – Canada). DACEHTA (Denmark) cites 5 Million US\$ for 20 projects, so it has so far been especially difficult to quantify or come up with a cost per project analysis, however it is suggested that this be a key ratio to be examined in future against methodology and outcomes, also taking into account numbers of permanent staff and consultants employed. Economy of scale could also become a factor to be considered if overheads prove to be relatively high. It is believed that there will still be returns that outstrip the 6 Million US\$ Mark reached so far.

12) Health Technology Assessment (HTA) Number of Projects Completed Annually

Projects per annum range from 4 to >50, however the bulk of returns so far seemingly range within the 10-20 mark. There is (as advised in the preamble) insufficient data to provide meaningful numeric averages etc.

13) Health Technology Assessment (HTA) Entity Permanent Staff Numbers

We have requested organograms and staffing resources profiles (if available) to examine what human resources a typical HTA entity would require or could use. Only one profile from FINOHTA has been received thus far – see last sheet addendum.

The smallest number of permanent staff reported employed thus far is 5 (OHTAC-Canada and MTPPI – USA). OHTAC cites 10 projects per annum and MTPPI 4 projects. On the face of it OHTAC requires further investigation, also given its reports being used on a statutory basis. The largest permanent staff complement so far is 35, being CCOHTA (Canada) with >50 projects per annum.

14) Health Technology Assessment (HTA) Average Number of Consultants in Employment

AETS (Spain) claims no consultants are employed. Thereafter, the least claimed is DACEHTA (Denmark) with 2 consultants and 20 projects annually. Perhaps health professionals in allied institutions are not being classed as consultants, on the other hand they spend 5 Million US\$ to achieve 20 projects per annum? More explanation would be required if they were to be seen as a possible model, however it doesn't seem so at this stage.

CCOHTA (Canada) with >50 projects per annum is so far the largest cited employer with 40 consultants. Unfortunately ASERNIP-S and MSAC (Australia) and OHTAC (Canada) cite "Variable" as their responses, these three entities seemingly worthy of investigation.