

Peer reviewed ORIGINAL ARTICLE

PHASE I: MAPPING PHASE HEALTH TECHNOLOGY IN SOUTH AFRICA: OPTIMISING *IN VITRO* DIAGNOSTIC DEVICE MANAGEMENT

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ABSTRACT

Objectives: In South Africa, the introduction of the *Medical and Related Substances Act R. 586* has focused more attention on the role of medical devices in health care. The objectives of this study were: a) to explore how the introduction of Health Technology Assessment (HTA) of *in vitro* diagnostic devices (IVD) can optimise the National Health Laboratory Service's (NHLS's) diagnostic test budget and b) increase test coverage to the public sector.

Methods: A literature search was conducted using multiple databases to understand how the assessment and management of Health Technology (HT) is conducted in established HTA organisations. In particular key searches were *in vitro* diagnostic medical devices. The study was limited to HTA organisations involved with Health Technology including all those who have adopted a Health Technology Management (HTM) system for medical devices. In particular, key searches included the annotation: *in vitro* diagnostic medical devices.

Results: The NHLS is the largest pathology service in the world. The decisions made in the diagnostic environment of NHLS can be compared to hospital based HTA. The literature review provided an overview of factors enabling the NHLS to determine whether new health technologies should be adopted. Those included, whether decision processes were appropriate, how to evaluate the methodology for IVD evaluations and how to assess factors likely to influence decisions and suggestions for current process improvement.

Conclusion: Improved decision making on the acquisition of new health technologies in pathology services through the use of the HTA framework can help reduce IVD acquisition expenditure. This will help in alleviating the ongoing cost of healthcare and allow present and future substantiality to be maintained.

KEYWORDS:

Medical and Related Substances Act R. 586, Health Technology Assessment, *in vitro* diagnostic medical devices, National Health Laboratory Services.

INTRODUCTION

Health technology is the application of organised knowledge and skills in the form of medical devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with healthcare technology.^[1]

Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technology. It may address the direct, intended consequence of technologies as well as their indirect unintended consequences. Its main purpose is to inform technology-related policy making in health care. HTA contributes to answering questions, in order to inform decision makers in areas and organisations related to health policy and/or practice.^[2]

Hospital-based health technology assessment (HB-HTA) is tailored in a hospital context and contributes towards managerial decisions on different types of health technologies available. It includes the processes and methods used to produce HTA reports regarding hospitals.^[3]

The WHO recognised the important role of health technologies and HTA. The World Health Assembly adopted resolution WHA60.29 in May 2007,^[4] which was recalled and replaced with resolution WHA67.23 on the 24th May 2014. The WHA67.23 resolution states: "*Health intervention and technology assessment in support of universal health coverage highlights issues arising from the inappropriate deployment and use of health technologies and emphasises the need to establish priorities in the selection and management of health technologies, specifically medical devices*".^[5]

The term medical device (MD) is defined as: "*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.^[4]

This article focuses on the role of HTA in optimising resource allocation for medical devices, in particular *in vitro* diagnostic devices (IVD) used in medical laboratory services.

Medical Laboratory Services

Medical laboratory services are an essential component of a well-functioning health system and are vital to the goal of delivering accessible, equitable and affordable quality healthcare to the population. Reliable and timely laboratory results are crucial to clinical and public health decision-making.

In South Africa the NHLS is the largest diagnostic pathology service and provides health laboratory services to the public sector which covers at least 80% of the 52 million South African population.^[6]

At present, the NHLS has a national network of 268 laboratories throughout South Africa utilising a common laboratory management system and transport network to facilitate the delivery of a diagnostic pathology service. It has a workforce of approximately 7500 employees including pathologists, public health and surveillance personnel, laboratory technologists and technicians, scientists and researchers and support staff.^[6] It has an operating budget of R3.8 billion and an annual expenditure on diagnostic reagents and consumables of R1.2 billion. Its annual expenditure on health technology amounts to R140 million and its current capital investments in health technology is around R177 million.^[6] There are unfortunately substantial maintenance backlogs pertaining to managing such an organisation. Multiple vendors and equipment lines necessitate the procurement of different reagents and the development of different multiple interfaces within the laboratory information system (LIS), all impacting on overall expenditure.

Introduction of the Medical and Related Substances Act

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 sector.^[7] The reform includes the introduction of the South African Health Products Regulatory Authority (SAPHRA). The introduction of the *Medical and Related Substances Act R. 586*^[8] (gazetted in 2011), in South Africa allows for the implementation of comprehensive Medical Devices (MD) and in vitro diagnostic devices (IVD) regulations. Currently only devices that emit radiation and electro-medical devices need to be registered with the Medicines Control Council (MCC) as per the Hazardous Substances Act, Act 15 of 1973. Presently there are thousands of medical devices and IVDs that are not regulated. This situation may compromise the safety of patients/users and the overall quality of health care provided in South Africa.^[9]

It was against this background that the National Health Council resolved to regulate medical devices.^[7] Lack of regulations posed challenges relating to possible dumping, recalls, safety issues, post market surveillance, quality issues, maintenance and servicing issues, sterilisation and disinfection of equipment, to name but a few. This has resulted in an influx of medical devices into the South African market.

In vitro diagnostic medical devices

The introduction of the regulation for in vitro diagnostic devices (IVDs) is new for South Africa. IVDs are defined in the Principles of Conformity Assessment for Medical Devices (GHTF/SG1/N17:2012) in particular "*In vitro diagnostic (IVD) medical*

devices are defined as: a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status".^[10]

The need to adopt scientific methodologies for the IVD management at the NHLS

The pathology diagnostic services are constantly bombarded by requests from suppliers to purchase these new technologies. These new technologies are intended to replace current technologies and promise effective clinical outcomes and cost efficiencies with increased diagnostic turn around time.

The NHLS has seen a need to implement a HT programme in IVD management in synergy with the National Department of Health (NDoH). And to adopt a health technology strategy for scientific methodologies to determine the mechanisms on the appropriate technologies available for the pathology services of the NHLS.

METHODS

Review of Literature

The study was limited to all organisations involved with health technology using HTA, including those who have adopted a health technology management (HTM) for medical devices.

A literature search was conducted using multiple databases for HTA organisational websites including the Cochrane Library for articles related to the HTM of IVD. The following search engines were used: Pubmed, Scopus, Cinahl, and Clinical-Key. The MESH terms used in these searches included: Technology Assessment, Biomedical, Reagents, Kits, Diagnostics, Equipment and Supplies, WHO and Health Policy. Other key word searches included *in vitro* diagnostics; HB-HTA, HTM Regulations. Searches were conducted over the periods July 2012 to December 2016. The review was limited to those publications written in English from 2005 to 2016.

RESULTS

The initial literature search included HTA organisations categorised and classified by the World Bank into high, middle and low income countries. The review focused on HB-HTA, Health Technology Regulation (HTR) and HTM, as these areas were relevant to in vitro diagnostic medical devices.

An Overview of Institutionalised Health Technology Assessment

In the developed world, HTA is largely driven by well resourced academic centres experienced in research that scrutinise all technologies and subsequently generate guidelines through a fairly comprehensive appraisals process.

The International Network of Agencies for Health Technology Assessment (INAHTA) is a non-profit organisation that was

formed in 1993 and has grown to include 54 member agencies from 33 countries across North and Latin America, Europe, Africa, Asia, Australia, and New Zealand. All members are linked to regional or national governments.^[10]

The formation of INAHTA was an important step in the evolution of HTA as it became associated with increased international cooperation. Although its resources are modest, INAHTA has been effective in improving communication between agencies and in the developing a source of expertise in HTA.^[11]

Health Technology Assessment International (HTAi)^[11] is another global scientific and professional society for all those who produce, use, or encounter HTA. HTAi embraces all stakeholders, including researchers, agencies, policy makers, industry, academia, health service providers and patient/consumers, and acts as a neutral forum for collaboration and in the sharing of information and expertise. Members are from 59 countries and six continents. HTAi is actively committed to international collaboration, and has signed a formal “memoranda of understanding” with the INAHTA.

The EUnetHTA project was established in 2006 as EU member states saw the need to establish a sustainable network for HTA in Europe. It established an effective European network to connect public HTA agencies, research institutions and health ministries, enabling the effective exchange of information. It also helps in supporting policy decisions on the use of health technologies in member states at national or regional levels. A total of 63 HTA institutions and organisations have become members of the EUnetHTA project.^[12] The EUnetHTA project namely: “*Methods for Health Technology Assessment of Medical Devices: a European perspective*” focused on medical device assessment for Europe.^[3]

WHO collaborating centres as designated by the WHO Director-General, are responsible in assisting member states to carry out activities that support the WHO programme. In 2009 at the annual HTAi meeting in Singapore, the Global Network for WHO Collaborating Centres for HTA was launched. “*The aim of the network was to connect the various collaborating centres across the world involved directly or indirectly in HTA to promote international dialogue and collaboration and to strengthen existing projects. This networking will lead to increased capacity for using HTA as a key tool in decision-making and policy-making processes, especially in developing and emerging countries.*”^[4] There are 14 WHO collaborating centres whose work is directly linked to institutionalised HTA organisations. In continued recognition of the role of health technologies the World Health Assembly adopted resolution WHA67.23: “*Health intervention and technology assessment in support of universal health coverage*” in May 2014.^[5]

An overview of HTA in middle and low income countries

In the developing world, because of economic resource allocation, equity and access issues, HTA is mainly driven from a policy perspective through regulation. The implementation of the results of HTA i.e. recommendations or guidelines, as well as perceived lack of transparency, remains problematic.^[10]

The mapping exercise of selected middle-income countries by Oortwijn et al.,^[14] in 2010 and later in 2013 compared the level of HTA activities. The 2010 exercise included the following

selected middle-income countries where HTA activities were evident: Argentina, Brazil, China, Colombia, Israel, Mexico, Philippines, Korea, Taiwan, Thailand, and Turkey. The findings indicated evidence of the development of HTA in decision-making in middle-income countries; increased health care spending and the resulting access to modern technology. All providing a strong impetus to adopt HTA. However, HTA is developing at different rates in middle-income countries and many countries are building on the organisational and methodological experience from established HTA agencies.^[14]

To highlight this a subsequent study, by Oortwijn et al.^[15] in 2013, compared selected middle-income countries Argentina, Brazil, India, Indonesia, Malaysia, Mexico and Russia with the levels of HTA development in Australia, Canada and the United Kingdom. The outcome of this mapping exercise was to establish a baseline measurement for future monitoring and influence key stakeholders in informing strategies and justifying HTA expenditure.^[15]

According to Rao et al.,^[16] the health reforms in Brazil, the Russian Federation, India, China and South Africa (countries known as BRICS) represent some of the world’s fastest growing economies.^[16] These five countries health challenges are common and over the past 20 years they have undertaken numerous health reforms to address these challenges. Although the health reforms of BRICS are diverse they share a central and common aim i.e. the strengthening of the government’s role in health and, particularly, in financing health care. These health reforms represent an important attempt to translate the growing wealth of BRICS into better healthcare for all.^[16]

The Lithuanian case study by Danguole^[17] highlighted how HTA can be incorporated in health policy decision making. The results of this study demonstrated that the incorporation of HTA is new and there is a growing need to increase awareness and support from key stakeholders.^[17]

Demirdjian’s study^[18] described the first hospital-based health technology assessment programme in a public hospital in Argentina. The article reiterated that the HTA programme was feasible and useful in a public hospital of a developing country in promoting hospital-based HTA and justifying hospital expenditure.^[18]

According to the study by Hass et al.,^[19] demonstrated how HTA interventions from Canada on atrial fibrillation (although more expensive than the current standard of care) improved clinical outcomes and represented a cost-effective use of public health resources.

Tantivess et al.,^[20] shared the experiences of Thailand, with the emphasis on the creation of the Health Intervention and Technology Assessment Program (HITAP). Lessons learnt from this study maybe helpful for resource constrained countries when considering how best to strengthen their capacity to conduct economic appraisals of health technologies and interventions.^[20]

The lessons learnt from the developing world, is that HTA is viewed as a valuable framework for health care decision making. However, the buy-in into processes and principles around HTA by the users of the technology, namely the healthcare professionals requires capacity, as well as strong interventions from all stakeholders.

Insight into HTA in sub-Saharan Africa

In Africa, HTA is limited to health ministries, universities, research organisations, third party payers, medical devices and the pharmaceutical industry. There are no formalised institutionalised organisations. However, the multi-faceted health systems utilise where possible, HTA interventions for evidence based decision making. The WHO collaborating centres provide an integral support to ministries within these countries.

Early studies by Ogembo-Kachiengain from 1998^[21] and 2004^[21] highlighted the urgent need to apply health technology to the management of medical devices in public health facilities in South Africa and Kenya.^[21] Govender et al.,^[9] outlined the growing need to utilise an effective tool (i.e. the mini HTA tool) to aid decisions in health technology management in South African public hospitals. This tool addresses current challenges, such as the influx of rapidly developing diagnostic technologies for example, point-of-care testing (POCT) devices for National Health Insurance.^[9] The mini HTA tool described by Govender et al.^[9] has been adopted from the EUNetHTA core model as a HB-HTA design in order to guide the end user in their selection of medical devices.

A systematic review by Kriza et al.,^[22] provided an overview of proposed HTA tools for “resource-poor” settings with a specific focus on sub-Saharan Africa (SSA).^[22] The review discussed the reasons for the lack of HTA in SSA explaining that this could be attributed to the lack of capacity to undertake HTA; a weak health system capacity to implement interventions, limitation on high quality data availability and the lack of research evidence. The aim of this review was to provide a tool to resource limited health systems in SSA. In summary the systematic review by Kriza et al.,^[22] highlighted that SSA had no structured HTA organisation however, the continent had pockets of expertise capable of developing a HTA organisation for healthcare, that would be supported by health technology regulations and health technology management.

Regulation and Management of HT

The focus on the regulation and management of health technology is not a South African trend alone. The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonisation. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonisation Task Force on Medical Devices (GHTF), and to accelerate international medical device regulatory harmonisation and convergence.^[23]

A review of the regulatory environment for medical devices indicated that well resourced countries with strong regulators were able to provide policy makers with evidence based decisions. However, in low to middle income countries where resources are limited the regulatory forums are in development. Lamph et al., described the regulatory forums outside Europe.^[24] The article referred GHTF founder members Australia, USA, the European Union (EU), Japan and Canada, supporting developing countries in promoting medical device harmonisation and convergence. This was established through regulatory forums such as Asian-Pacific Economic Cooperation (APEC), Asian

Harmonisation Working Party (AHWP), Pan American Health Organisation (PAHO) and South America Mercado Comùn del Sur (MERCOSUR).

In Africa, regulation is in its infancy. A study by Rugera et al., described the current regulatory environment in Africa, providing insight into the regulation of medical devices and in particular in vitro diagnostics tests that have been neglected in the East African Community (EAC) and its partner states.^[25]

The Pan African Harmonisation Working Party (PAHWP) was conceived in 2012 following a stakeholders meeting in East Africa. The formation of PAHWP was announced in a satellite symposium at the African Society for Laboratory Medicine Conference on 3rd December 2012 in Cape Town and the 1st African Regulatory Forum on Medical Diagnostics was held in July 2013.^[26]

Information from clinically appropriate testing contributes to early detection, diagnosis, choice of treatment, therapeutic monitoring, reducing adverse events, improved health outcomes and quality of life. The clinical benefits and appropriate use of laboratory screening and diagnostic tests are essential in achieving the goals of health system reform in South Africa. The absence of regulations has aggravated the situation with thousands of health technologies (drugs, devices, surgical and medical procedures or ways of delivering health services) appearing in the South African market. To date, only a fraction of the existing technologies have been evaluated, while additional new technologies continue to be adopted without evaluation.

The challenge of new technology adoption and management is not unique to South African diagnostic services. A pilot study in Brazil for the Xpert MTB/RIF (Xpert), an automated polymerase-chain-reaction-based assay, for the rapid diagnosis of tuberculosis, showed that the use of a new technology called for detailed preparation and adaptation.^[27]

According to Phillip Weinfurt,^[28] evaluating biomedical technology poses a significant challenge in light of the complexity and rate of its introduction in today’s healthcare delivery system. Successful evaluation requires an integration of clinical medicine, science, finance, and market analysis. Little guidance is available however, for those who must conduct comprehensive technology evaluations.

Research by Ruffano et al.,^[29] illustrated that ideally, new tests should only be introduced into clinical practice if the evidence indicated that they have a better chance of improving patient’s health than the existing available tests.^[29] It is therefore vital for health care purchasers and providers to assess the importance and role of new diagnostic technologies in the diagnostic environment. It is essential to have a process that can identify which of those technologies require detailed formal assessment, such as technology assessments or evidence-based summary reports.^[30] The Cochrane Review by Leeflang et al, illustrated that finding good evidence regarding the performance of diagnostic tests and interpreting their value for practice is more challenging and less straightforward than for intervention. Furthermore, a highly accurate test does not necessarily improve patient outcome.^[31] The introduction of point-of-care testing (POCT) technology, highlights the urgent need for efficient evaluation methodologies and robust regulatory frameworks so that these tests address the health care needs of the population in low resource settings.^[32]

Peeling and McNerney advocated “*faster policy development for adoption of new technologies and novel financing mechanisms to enable countries to scale up implementation.*”⁽³³⁾

Hospital Based HTA

HTA that is performed in a the hospital context for managerial decisions is called hospital-based Health Technology Assessment (HB-HTA). This form of HTA uses a systematic and evidence based approach. Usually the assessment is conducted internally by a team of hospital professionals, which leads to decision making on health technologies. The reason for the adoption of HB-HTA, is that hospitals require information on emerging technologies. Presently there is little good quality evidence available to produce a reliable HTA report according to the requirements of HTA organisations. Furthermore, hospitals need information on medical devices where no assessments have been performed by HTA agencies.^[3]

DISCUSSION

The literature review explored HTA frameworks in the developed as well developing world. Key concepts such as HTA, HB-HTA, regulations and HTM are integral for medical devices in particular IVD's in aiding and guiding healthcare in the decision making processes. Therefore, HTA is dependent on the specific context of the decision making, based on the decision maker's requirements. The literature on health technology explained the different concepts i.e. HTA, HB-HTA, HTR and HTM in supporting medical device selection. It also highlighted the significance each area plays towards the adoption and implementation of medical devices. Over the years the model of institutionalised HTA has evolved into hospital based HTA, regional and provincial health care authorities supporting health care systems.

Reviews of institutionalised organisations that are members of INAHTA and HTAi are well resourced, with adequate funding and staff; driven by good governance that have established good collaboration with partners for the successful implementation of HTA projects at a country level. These HTA institutions not only inform the country but provide a global input into other HTA frameworks such as WHO collaborating centres, in the European EUnetHTA and other international organisations.

It is evident from the literature that HTA informs regulation. Drugs are well regulated and established however, medical devices regulation is at different stages of development in certain middle and low income countries. The IMDRF is a non-profit organisation (previously known as GHFT) to promote harmonised and standardised regulation of medical devices. The 5 founding countries for the GHFT are: Japan, USA, EU, Canada and Australia. All have established strong regulatory frameworks that support other international medical devices regulatory forums such as the PAHWP. South Africa, is a member of the of the PAHWP therefore, under the IMDRF regulatory forum the NHLS can adopt GHFT member states regulatory frameworks (namely the FDA, CE, Canada, Japan and Australia,) until the “new” South African regulatory body for medical devices is ready. The NHLS would need to understand and adopt the classification of medical devices based on the *Medical and Related Substances Act R. 586*^[8] to determine the type of technology assessment required for the different classes of IVDs. And where

relevant define criteria for review, i.e. laboratory based evaluations based on the HB-HTA framework. This approach would focus on local SA infrastructure, prevailing treatment options, patient populations and NDoH priority settings. The initial assessments conducted would focus on in vitro diagnostic medical devices used currently at the NHLS such as, reagents, reagent products, calibrator materials or instruments; as well as specimen receptacles intended by the manufacture for the in vitro analysis of specimens obtained from the human body. This exercise would enable the organisation to establish guidelines that are appropriate for the selection of IVDs in a diagnostic environment. This would also facilitate the optimising of procurement budgets, thereby improving diagnostic test coverage to address the health care programme of the proposed NHI scheme in South Africa.

Medical devices are an integral part of any health system. The cycle of medical devices can be reviewed into four areas namely (i) research and development; once these devices are ready for market use (ii) regulatory approval in sort; once approved (iii) evidence evaluations of the product deeming the product “fit for use” and (iv) the final cycle is the management of the medical device until retirement. Therefore, in order to address the call for universal health coverage, under the proposed NHI scheme, pathology services are under increasing pressure to provide reliable diagnostic tests, safely, cost effectively and efficiently.

This review provides an overview to key stakeholders within the organisation, as well as to healthcare services, on how new health technologies should be adopted within the NHLS, i.e. the technology assessment and decision processes; the methodology for IVD assessment; factors likely to influence decisions and suggestions for current process improvement.

STUDY LIMITATIONS

The literature review has paved the way for the NHLS to utilise the current experiences and resources available, to develop a programme that suits the organisation. There is currently no clearly defined HT programme for diagnostic pathology services, but lessons from HTA organisations, academic facilities and NGO's can aid in ensuring aspects in key areas of health technology assessment, management and regulation are incorporated in the near future.

CONCLUSION

The aim of this study was to conduct a literature review on health technology focusing on medical devices to support IVD management in a diagnostic pathology laboratory services setting. The medical device cycle can be streamlined with the support of evidence based decisions from HTA. In the case of diagnostic tests there maybe limitations to data availability therefore requiring a strong regulatory support and health technology management processes, to support decision making. The review demonstrated harmonisation and standardisation efforts that are intended to inform overall health technology strategies through evidence based decision making processes, by utilising HTA, HB-HTA, HTR and HTM. This will ultimately establish the HT unit as a single port of entry at the NHLS for all IVD management. The NHLS can decrease instrument diversity, as

well as develop appropriate instrument placement strategies in laboratory networks by optimising the procurement budget. All this will contribute in providing greater diagnostic test coverage in order to address the proposed scheme of NHI in South Africa. Further studies should be undertaken to assess the use of HB-HTA methodologies that can be adapted or adopted for IVD management. The HTA framework will ultimately support assessment, decision making, procurement and the introduction IVD's.

CONFLICT OF INTERESTS

The author has no conflict of interest to report.

ACKNOWLEDGEMENTS

The author will like to acknowledge: M. Sekano, A. Ribisi, T. Moletsane, P. Dabula and Dr J van Heerden from the NHLS. Dr I Edoke from PRICELESS SA Research Unit / School of Public Health /University of Witwatersrand.

REFERENCES

- World Health Organisation(WHO), 2011. Health Technology Assessment of Medical Devices, Geneva.
- The International Network of Agencies for Health Technology Assessment (INAHTA). HTA glossary June 8, 2009. Available from: http://www.inahta.org/HTA/Glossary/#_Health_technology. (Accessed 02 March 2014) .
- AdHopHTA (Adopting hospital-based Health Technology Assessment in EU) research project,funded by the European Commission under the 7th Framework Programme (Grant Agreement305018). www.adhophta.eu. (Accessed 12 Dec 2015).
- World Health Organisation(WHO), 2011. Medical Device Technical series: Development of medical device policies. Geneva
- World Health Organization, 2014. Health intervention and technology assessment in support of universal health coverage. The Sixty-seventh World Health Assembly, 24 May, Geneva. Epub 24/05/2014.
- National Health Laboratory Services (NHLS), 2013. Annual Report. Available from : [www.nhls](http://www.nhls.org.za). (Accessed 02 March 2013).
- National Department of Health(NDoH), 2001. Health Technology Policy Framework. Pretoria,Republic of South Africa.
- Gazette. Medicines and Related Substances Act (101/1965): Regulations: Medical Devices. In: Africa RoS, editor. Regulation Gazette no 34463 of 22 July 2011. Republic of South Africa.
- Govender M, Mueller DB, Basu D. Purchasing of medical equipment in public hospitals: the mini-HTA tool. *South African Medical Journal* 2011; 101(11):807-8. Available from: <<http://samj.org.za/index.php/samj/article/view/5044/3671>>
- The International Network of Agencies for Health Technology Assessment (INAHTA). HTA resources May 15, 2009. Available from: <http://inahta.episerverhotell.net/HTA/>. (Accessed 02 March 2013).
- Hailey D. Development of the International Network of Agencies for Health Technology Assessment. *Int J Technol Assess Health Care*. 2009 Jul; 25 Suppl 1:24-7. PubMed PMID: 19500434.
- Garrido MV, Kristensen FB, Nielsen CP, Busse R. Health Technology Assessment and Health Policy-Making in Europe Current status, challenges and potential. Denmark: WHO Regional 2008. p.1-181
- Govender M, Letshokgohla ME, Basu D. Health technology assessment - a new initiative in South Africa : correspondence 2010; 100(6):334. Available from: http://reference.sabinet.co.za/webx/access/electronic_journals/m_samj/m_samj_v100_n6_a4.pdf. (Accessed 01 March 2014).
- Oortwijn W, Mathijssen J, Banta D. The role of health technology assessment on pharmaceutical reimbursement in selected middle-income countries. *Health Policy*. 2010; 95(2-3):174-84. PubMed PMID: 2010618774.
- Oortwijn W, Broos P, Vondeling H, Banta D, Todorova L. Mapping of Health Technology Assessment in Selected Countries. *International Journal of Technology Assessment in Health Care*. 2013;29(04):424-34.
- Rao KD, Petrosyan V, Araujo EC, McIntyre D. Progress towards universal health coverage in BRICS: translating economic growth into better health. *Bulletin of the World Health Organization*. 2014; 92(6):429-35. PubMed PMID: 2012600178.
- Danguole J. Development of health technology assessment in Lithuania. *International Journal of Technology Assessment in Health Care*. 2009;25(SupplementS1):140-2.
- Demirdjian G. A 10-Year Hospital-Based Health Technology Assessment Program in a Public Hospital in Argentina. *International Journal of Technology Assessment in Health Care*. 2015; First View: 1-8.
- Hass B, Pooley J, Feuring M, Suvarna V, Harrington AE. Health technology assessment and its role in the future development of the Indian healthcare sector. *Perspectives in Clinical Research*. 2012 Apr-Jun; 3(2):66-72. PubMed PMID: PMC3371551.
- Tantivess S, Teerawattananon Y, Mills A. Strengthening Cost-Effectiveness Analysis in Thailand through the Establishment of the Health Intervention and Technology Assessment Program. *Pharmaco Economics*. 2009; 27(11):931-45. PubMed PMID: 2010463247
- Ogembo-Kachieng'a M, Ogara WO. Strategic management of technology in public health sector in Kenya and South Africa. *East African medical journal*. 2004 Jun; 81(6):279-86. PubMed PMID: 16167674. Epub 2005/09/20. eng.
- Kriza C, Hanass-Hancock J, Odame EA, Deghaye N, Aman R, Wahlster P, et al. A systematic review of Health Technology Assessment tools in sub-Saharan Africa: methodological issues and implications. *Health Research Policy & Systems*. 2014; 12(1):66. PubMed PMID: 2012842807.
- The International Medical Device Regulators Forum(IMDRF), 2015. Available from: www.imdrf.org. (Accessed 27 May 2015).
- Lamph S. Regulation of medical devices outside the European Union. *Journal of the Royal Society of Medicine*. 2012; 105(Suppl 1):S12-S21. PubMed PMID: PMC3326589.
- Rugera SP, McNerney R, Poon AK, Akimana G, Mariki RF, Kajumbula H, et al. Regulation of medical diagnostics and medical devices in the East African community partner states. *BMC health services research*; 14:524. PubMed PMID: PMC4221680.
- The Pan African Harmonisation Working Party(PAHWP), 2015. Available from: www.pahwp.org.6.html. (Accessed 27 May 2015).
- Durovni B, Saraceni V, Cordeiro-Santos M, Cavalcante S, Soares E, Lourenço C, et al. Operational lessons drawn from pilot implementation of Xpert MTB/Rif in Brazil. *Bulletin of the World Health Organization*. 2014; 92(8):613-7. PubMed PMID: 2012672934.
- Weinfurt P. Biomedical Technology Assessment: The 3Q Method: Morgan & Claypool Publishers; 2010. Available from: <http://dx.doi.org/10.2200/S00256ED1V01Y201002BME033>. (Accessed 02 March 2014).
- Ruffano LFD, Hyde CJ, McCaffery KJ, Bossuyt PMM, Deeks JJ. Assessing the value of diagnostic tests: a framework for designing and evaluating trials. *BMJ*. 2012 (February) 12:06:23;344.
- Pluddemann A, Heneghan C, Thompson M, Roberts N, Summer-ton N, Linden-Phillips L, et al. Prioritisation criteria for the selection of new diagnostic technologies for evaluation. *BMC health services research*. 2010; 10:109. PubMed PMID: 20444274. Pubmed Central PMCID: PMC2881057. Epub 2010/05/07. Eng.
- Leeflang MM, Deeks JJ, Takwoingi Y, Macaskill P. Cochrane diagnostic test accuracy reviews. *Systematic reviews*. 2013; 2:82. PubMed PMID: 24099098. Pubmed Central PMCID: PMC3851548. Epub 2013/10/09. eng.

32. Garcia PJ, You P, Fridley G, Mabey D, Peeling R. Point-of-care diagnostic tests for low-resource settings. *The Lancet Global Health*. 2015 5//;3(5):e257-e8.
33. Peeling RW, McNerney R. Emerging technologies in point-of-care molecular diagnostics for resource-limited settings. *Expert Review of Molecular Diagnostics*. Jun 2014; 14(5):525-34. PubMed PMID: 1526139211; 24784765. Eng.
34. World Health Assembly Resolution 67.23: Health Intervention and Technology Assessment in Support of Universal Health Coverage. Geneva: World Health Organisation, 2014. http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R23-en.pdf (accessed 7 August 2015).

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