TWO SOUTH AFRICAN HEALTH TECHNOLOGY ASSESSMENT METHODS GUIDES: WHICH ONE IS MORE SUITABLE FOR THE ASSESSMENT AND APPRAISAL OF MEDICINES?

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INTRODUCTION

- The imminent roll-out of National Health Insurance (NHI) in South African will lead to the use of health technology assessment (HTA) and economic evaluations to determine the cost-effectiveness of technologies provided as part of the NHI Fund.[1]
- To date, there are no formal processes or guidelines for national HTA as part of the NHI, but in 2012 the National Department of Health published the South African Guideline for Pharmacoeconomic Submissions (SAGPS).[2]
- The SAGPS, which came into effect in April 2013, outlines the requirements for assessing the cost-effectiveness of a medicine relative to that of other medicines in the same therapeutic class. It is, however, a voluntary process and is only aimed at medicines in the private health sector. [2]
- More recently, in 2021, the National Department of Health issued the draft South African Health Technology Assessment Methods Guide (SAHTAMG) for public comment.[3]
- The SAHTAMG aims to clarify, strengthen and standardize the practice of HTA for medicines provided in the South African public health sector by establishing formal budget impact and cost-effectiveness estimation methods, and for incorporating equity and other social values into the appraisal. [4]
- The technology assessment process using the SAHTAMG will consist of two stage, namely a technical review and additional analysis. Figure 1, taken from the draft methods guide, illustrates steps taken to determine the type of analysis required.[6]

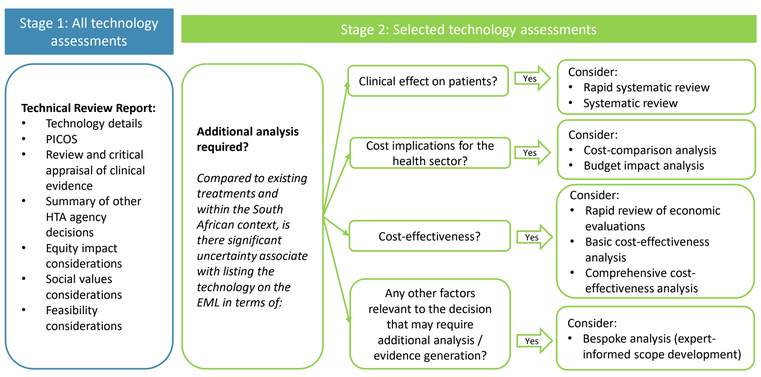

Figure 1. Determining the analysis required for a technology assessment

- Whilst these two guidance documents have different objectives, the need for two separate documents that both aim to support access and reimbursement decisions for medicines, should be questioned.

OBJECTIVE

- To determine which between the 2013 SAGPS and the 2021 draft SAHTAMG are more useful for evaluation of medicines and decisions on selecting medicines for coverage and reimbursement in South Africa.

METHODS

- The evidence and information requirements for the SAGPS was previously evaluated using the European Network for Health Technology Assessment Core Model, version 3.0 (the Model®).[5]
- The exercise was repeated for the more recent draft SAHTAMG:
  - The guideline content was deconstructed in Excel® according to the nine domains in the Model®, their respective topics and questions related to the topic (also called 'issues').
  - One issues, namely 'Willingness-To-Pay' was added.
  - Three rating criteria were used for each issue: "Yes - guideline completely requires the same / similar information as the Model®, "No - guideline does not the require the same / similar information as the Model® and "Partly - guideline only requires some of the information as the Model®.
  - For those issues that were made up of several requirements, all the requirements had to be met to be considered as completely requiring the same or similar information; otherwise, it was classified as 'Partly'.
- The rating results for the SAHTAMG were compared against the results previously obtained for the SAGPS.[5]

RESULTS

- Overall, the draft SAHTAMG performed better on the EUnetHTA frawework than the SAGPS, with a total of 44.7% of the issues rated 'Yes' compared to 28.1% in the SAGPS (Table 1).
- The SAHTAMG also outperformed the SAGPS in 7 out of 9 domains.
- Notably, the SAHTAMG required much more thorough consideration of the ethical, organisational and patient aspects of a technology.
- However, the SAGPS performed better in the cost-effectiveness and safety domains.
- Neither guideline performed well in the safety, legal, patient and societal domains.

RESULTS (continued)

Table 1. Overall results according to the EUnetHTA Core model domains and issues

	2013 SAGPS			2021 SAHTAMG		
DOMAIN (% of row)	**YES**	**PARTLY**	**NO**	**YES**	**PARTLY**	**NO**
Health problem and current use	50.0%	22.2%	27.8%	77.8%	16.7%	5.6%
Description and technical specification	30.8%	23.1%	46.2%	53.8%	30.8%	15.4%
Safety	22.2%	0.0%	77.8%	11.1%	0.0%	88.9%
Clinical effectiveness	33.3%	16.7%	50.0%	41.7%	16.7%	41.7%
Costs & economic evaluation	75.0%	8.3%	16.7%	58.3%	23.3%	8.3%
Ethical analysis	10.5%	10.5%	78.9%	47.4%	5.3%	47.4%
Organizational aspects	9.1%	9.1%	81.8%	45.5%	9.1%	45.5%
Patients and social aspects	16.7%	16.7%	66.7%	33.3%	16.7%	50.0%
Legal aspects	0.0%	7.1%	92.9%	7.1%	7.1%	85.7%
TOTAL (100%)	**28.1%**	**13.2%**	**58.8%**	**44.7%**	**14.0%**	**41.2%**

Note that the row % for each guideline do not add up to 100% in some instances due to rounding

- Figures 2a and 2b show the weighting of the different domains and topic for each guideline, based on the issues marked as 'Yes' and 'Partly'.
- Both guidelines have as their strongest focus the health problem and current use domain, and the cost and economic evaluation domain, albeit that the topics are ranked differently, indicating that each guideline has a slightly different focus and evidence requirement.
- As mentioned, the ethical aspects of the technology features more prominently in the SAHTAMG than in the SAGPS. This is due to the inclusion of more topics and, notably, asking similar questions as those posed in the EUnetHTA Core Model®. The same observation was made regarding the organisational domain.

Figure 2a. SAGPS performance according to the EUnetHTA Core Model® - "Yes" and "Partly"

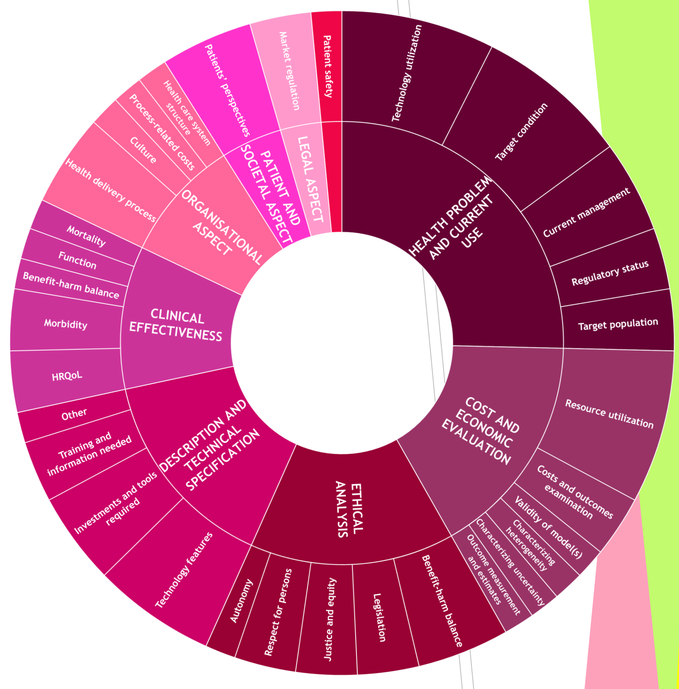

Figure 2b. Draft SAHTAMG performance according to the EUnetHTA Core Model® - "Yes" and "Partly"

DISCUSSION

- Differences between the guidelines may be explained by their different scopes and intended audiences. The SAHTAMG also encompasses more stages and analyses than the SAGPS, albeit this depends on the technology being assessed and the level of uncertainty in the clinical and economic evidence.
- Nonetheless, the draft SAHTAMG has the potential to provide more information and evidence for decision makers as it encompasses more aspects related to the patient and society, ethics, and health care organisation. This also suggests that it is less of a technical and analytical tool as it will incorporate value judgements related to the ethical and wider societal benefits. Explicitly incorporating ethical and societal value judgements into the assessment will make it more open, transparent and acceptable thereby promoting accountable and robust decision-making.[7]
- Areas where the draft SAHTAMG could be improved include incorporating safety aspects other than to the patient (namely, occupational safety and safety risk management) and legal aspects (such as patient autonomy and privacy, health care equality and safety regulations).
- And despite incorporating more aspects related to the patient and society than the SAGPS, evaluating the patient communication needs in relation to introducing the technology into the health care system would strengthen this domain.

CONCLUSION

- The SAHTAMG is generally indicative of the evidence requirements for a full HTA and due to its comprehensive nature, may be more suitable for HTA decision making for medicines coverage and reimbursement in South Africa than the SAGPS.
- Consequently, the need for a separate, less comprehensive guideline for the private health sector should be reconsidered.

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DISCLOSURE

The author provides consulting services to the pharmaceutical and medical devices industry but did not receive funding for this analysis and poster.

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