Introduction

This submission to the consultation on the Medical Services Advisory Committee (MSAC) Revised Draft Guidelines represents a joint response prepared by a group of Health Technology Assessment consultancies: HTAccess Consulting, Shoten Consulting, Lucid Health Consulting and THEMA Consulting. Each organisation has extensive experience in the preparation of Assessment Reports for consideration by MSAC and will be users of the updated MSAC Guidelines. None of our organisations were sought out for comment in the preparation of the Draft Guidelines.

The comments and feedback on the Draft Guidelines provided herein represent a consensus position from all parties. It does not necessarily reflect the views of any of our clients. It is hoped that the feedback provided is valuable to the MSAC Guidelines Review team in shaping the final version of the updated MSAC Guidelines.

Feedback point: Process

In our opinion, opportunities for the MSAC Guidelines to reflect the expansion in the knowledge base relating to Health Technology Assessment techniques that can be, and are, applied in the discipline appear to have been missed.

The process for revising the MSAC Guidelines appears to have presumed that the contracted group (along with the steering committee and technical reference group) have knowledge of all of the developments and practical challenges in the field of HTA and are in a position to revise the MSAC Guidelines without broader consultation.

Due to the limited opportunity for consultation (only 6 weeks to provide feedback), the process of revision of the MSAC Guidelines does not allow for any meaningful correspondence with a broad range of stakeholders and technical experts.

The investment made by the Department of Health in commissioning the MSAC Guidelines review could have been better leveraged in the process of revising the MSAC Guidelines. There was a significant opportunity for the assessment group to engage with a broader range of methodological experts and/or users of MSAC Guidelines within academia, industry, consulting firms and consumer organisations.

Although consulting with stakeholders prior to presenting a revised set of guidelines may have been a more time-consuming process, such a process would have resulted in the revised guidelines being more inclusive and addressing the identified needs of all users and stakeholders.

Feedback point: Content and layout

Each party considered that the Draft Guidelines did not provide clear and consistent guidance on how to prepare an Assessment Report for consideration by MSAC. The following observations are made which are considered to contribute to this issue:

- The Draft Guidelines discuss the same (or highly overlapping) information requests and concepts at multiple locations resulting in unnecessary duplication.
    - As an example, concepts around measures of investigative test performance of sensitivity and specificity are discussed in the following sections: Technical Guidance 9, Technical Guidance 10, Technical Guidance 11 and Appendix 7. Discussing these concepts in single location would be sufficient.
- The Draft Guidelines tend to describe general principles of Health Technology Assessment and clinical evidence analysis. The final MSAC Guidelines would benefit from a greater focus on the application of these principles in the preparation of an MSAC Assessment report.
    - The description of principles of Health Technology Assessment and clinical evidence analysis provided in the draft Guidelines is very high-level. It is considered that the information provided is of limited value to the intended users of the MSAC Guidelines that would have training and experience in these areas.
- The Draft Guidelines lack consistency in providing advice on the preparation of an MSAC Assessment report where a PICO Confirmation has been ratified by PASC.
    - The pre-submission phase represents a significant investment of time and resources for applicants, Department of Health staff, evaluation groups and PASC.
    - Clear and consistent guidance on the application of the PICO Confirmation when preparing an Assessment Report would enhance the return on investment made in the development of PICO Confirmations.

Suggested improvements

Overall, we agree with the 'modular' rather than 'template' style of the Draft Guidelines as it promotes an understanding that various components may not be relevant to a particular MSAC Assessment. However, it is not the case that the template approach of the current MSAC Guidelines and the technical guidance approach of the Draft Guidelines are mutually exclusive concepts. Therefore, it is suggested that there should be clear separation of advice on the information needs of MSAC and general layout of MSAC Assessment Reports (MSAC Guidelines) from technical guidance (Methodological Guidelines). Separation of MSAC Guidelines and Methodological Guidelines into separate, but complementary, documents is suggested. The principle behind this suggestion is that:

- MSAC Guidelines should assist applicants and evaluation groups prepare MSAC Assessment Reports with a consistent 'look and feel' regardless of the nature of

the intervention being assessed or the submission being an Application Developed Assessment Report or Contract Assessment Report.
    - In its current format the Draft Guidelines could lead to substantial variation in the interpretation of what is required to inform MSAC decision-making and how to present evidence to MSAC in an Assessment Report.
    - Improving the guidance on the structural elements and presentation of evidence within an MSAC Assessment Report would support more consistent preparation of MSAC Assessment Reports and MSAC decision-making.
- Having Methodological Guidelines as a separate, but complementary, document to MSAC Guidelines would allow for the addition and refinement of methodological issues as developments in this area evolve in a flexible fashion.
    - The focus on methodological considerations in the Draft Guidelines exposes them to risk of becoming out-of-date quite quickly given the rapidly evolving nature of health care technologies considered by MSAC.
    - This risk could be mitigated with the development of separate methodological guidance which is able to be updated as needs arise without the substantial investment required for a complete MSAC Guidelines review.

To give an example to illustrate our general suggestion: one of MSAC's information needs (i.e., 'what' is needed), regardless of what type of intervention is being assessed, is that a systematic search of the literature be conducted. MSAC expects that, at a minimum, MEDLINE, EMBASE and Cochrane Library databases should be searched. MSAC also expect that the Assessment Report provides the search strategy used to identify potentially relevant studies and an explanation of the approach taken to narrow down results from the search to the studies selected for presentation in the Assessment Report. The purpose of this section of an Assessment Report (i.e., the 'why') is to permit an independent confirmation that no critical studies have been missed and there is no bias in the selection of studies for presentation in the Assessment Report.

Under our suggestion, details of 'what' and 'why' information on the systematic search of the literature needs to be presented in an Assessment Report would be discussed in the MSAC Guidelines. Complementing this, guidance on 'how' to present the search strategy, the results of applying the search strategy, and the approach to selection of studies (e.g. in the form of a PRISMA flow chart) would be presented in the separate Methodological Guidelines document as these preferences are more subject to change over time than the principle that an appropriate search of the literature is required and details presented with the Assessment Report.

As another example of the need for this separation is the fact that the various Technical Guidances in the Draft Guidelines do not appear to have a consistent perspective with some referring to concepts but others referring to content. For example, TG 10.1 'Purpose of Guidance' is conceptual whereas, TG 26.2 'Results' is material. We are concerned this

mixture of content and concepts will make the MSAC Guidelines quite difficult to use in the preparation of an Assessment Report.

Overall, the Draft Guidelines would benefit from substantial consolidation of contents and information requests to remove duplication, enhance readability and focus on the most important factors for MSAC decision-making. A reduction in overall page count by 50% would seem achievable without compromising usefulness.

Feedback point: Applicability of Draft Guidelines to the breadth of interventions assessed by MSAC and types of evidence

Overall, the content of the Draft Guidelines does not seem to reflect the breadth of health care technologies actually assessed by MSAC, nor the evidence base available to support MSAC consideration of these technologies.

The guidance for clinical evaluation (Section 2) in the Draft Guidelines is heavily weighted towards investigative technologies. A substantial component of this guidance discusses hypothetical clinical trial designs which may be used to assess investigative technologies. This information is of limited assistance for users of MSAC Guidelines that are required to identify and present the available evidence for investigative technologies, especially as the overwhelming majority of MSAC submissions for investigative technologies will not be based on the results of clinical trials designed as described.

The Draft Guidelines present comparatively little information relating to the clinical assessment of therapeutic interventions compared with investigative interventions. Further, the guidance offered has a focus on the presentation of head-to-head clinical trial evidence. The identification and presentation of head-to-head clinical trial evidence is acknowledged as the most rigorous way to assess any health care intervention. However, the development of non-pharmaceutical therapeutic interventions is often iterative in nature with series of incremental changes and refinements being made as the technology develops or clinicians become more experienced with performing a procedure. The evidence required to obtain regulatory approval for the use of non-pharmaceutical therapeutic interventions is also not as dependent on the results of head-to-head clinical trials compared with pharmaceutical interventions. Together, this means that conducting head-to-head trials of non-pharmaceutical therapeutic interventions, while ideal, is not widespread. Inspection of recent MSAC agendas suggests that therapeutic interventions represent a significant proportion of technologies assessed by MSAC, and that many of these assessments require the consideration of evidence that is not from head-to-head clinical trials.

The other consideration with regards investigative interventions is that a case can be made that, from a HTA point of view, they are actually not necessarily that dissimilar to therapeutic interventions. An improvement in a diagnostic or investigative endpoint could be thought of as a step in a link towards a final health outcome in the same way a therapeutic intervention improving cholesterol or blood pressure is a step in a link towards

a final health outcome. If the guidelines were to focus on these conceptual similarities, rather than the practical differences, then the need to completely re-structure the MSAC Guidelines to accommodate a specific type of intervention might be reduced or even eliminated.

Suggested improvements

MSAC Guidelines should be suitable to assist in the preparation of Assessment Reports for investigative technologies and therapeutic interventions on an equal basis. Streamlining the guidance on investigative technologies and removal of descriptions of hypothetical clinical trial designs is suggested. This would offer more space for enhanced guidance on the preparation of Assessment Reports for therapeutic interventions. Specific areas which could be addressed in more detail include: the appropriate use and presentation of evidence from single-arm trials when head-to-head clinical trial evidence is not identified; the role and presentation of real-world evidence for therapeutic interventions to MSAC; better guidance on the conduct and presentation of indirect treatment comparisons of a new therapeutic intervention versus comparator treatment(s) when no head-to-head clinical trial data is available.

Feedback point: Definition of comparator

The Draft Guidelines state that it is the expectation that the chosen comparator is a health technology with established cost-effectiveness. Where the cost-effectiveness of the comparator is unknown, then the cost-effectiveness of the comparator as well as the intervention will need to be established. This guidance is problematic in numerous ways:

- The overwhelming majority of items on the MBS were added before the MSAC was established. For applications where an MBS item(s) is the appropriate comparator, there is no way for applicants to know if the comparator MBS item(s) have been formally assessed for cost-effectiveness or have unknown cost-effectiveness. Thus, there is no way for applicants to know when such a 'dual cost-effectiveness assessment' would need to be undertaken.
- A major review of MBS items is being undertaken as part of the MBS Review Taskforce. Critical issues regarding cost-effectiveness of existing MBS items should be (or should have been) addressed in a systematic way through that process.
- If the cost-effectiveness of comparators that are not listed on the MBS but are already receiving government funding is unknown then reviews of comparator cost-effectiveness should be undertaken by Department-initiated reviews and/or a suitable sponsor of the comparator. It should not be responsibility for applicants seeking funding for a new intervention to perform cost-effectiveness reviews for existing interventions on behalf of Government or other sponsors.
- Whether current practice is cost-effective or not is largely redundant because it is a sunk cost. What if the new intervention was cost saving and dominant relative to the current 'cost-ineffective' comparator. Would MSAC be required to reject

this intervention despite the cost savings and health improvements an MBS listing would bring?

Suggested improvements

The proposed requirement of establishing the cost-effectiveness of the comparator as well as the intervention is not feasible and will not be possible in many circumstances. It is suggested that this requirement be removed from the MSAC Guidelines and that the review of cost-effectiveness for any treatments currently receiving government funding where cost-effectiveness is unknown is undertaken in a systematic way through existing post-implementation review pathways.

Feedback point: Guidance on appropriate setting of MBS fees

Having an MBS fee that reasonably reflects the true cost of the efficient delivery of a medical service is important. It is important for patients as having a MBS fee that is too low increases the likelihood of a patient incurring out-of-pocket expenses. Appropriate MBS fees are also important for tax payers and Government as having an MBS fee that is to high represents a poor use of health care funding and incurs an opportunity cost as the resources used to fund services above the efficient cost could be deployed elsewhere.

MSAC have a remit to consider the cost-effectiveness and financial cost of funding a health technology. Thus, having a clear and consistent method to establish MBS fees is central to its ability to performs its role. The current MSAC Guidelines and Draft Guidelines provide minimal information to applicants regarding the appropriate development of MBS fees. A general principle tends to be that MBS fees for new interventions are set in reference to 'similar' MBS items. This approach risks perpetuating inappropriate fees or establishing MBS fees for new interventions based on the cost of delivering a service that is no longer relevant to contemporary practice.

Suggested improvements

The MSAC Guidelines would benefit from providing applicants with clear advice on what cost components are/are not eligible to receive funding as part of an MBS fee, as well as relevant sources for cost inputs which can be used to 'work up' an MBS fee.

This guidance would facilitate MSAC being able to assess the 'true' cost-effectiveness of new interventions at an MBS fee reflective of the actual delivery of the service. It would also assist in assessing to what extent out-of-pocket costs may be incurred by patients if an item were listed on the MBS at a fee lower than the estimated cost of delivering the service, as well as the magnitude of potential out-of-pocket costs.

Concluding comments

The opportunity for stakeholders to provide feedback on the Draft Guidelines is welcomed. It is hoped that the feedback provided provides useful insights from parties experienced

in the preparation of MSAC submissions in the past and who will be users of the updated MSAC Guidelines in the future.

It is believed that further consultation with stakeholders would be valuable before the finalisation of the updated MSAC Guidelines. This will help ensure the time and resource investment made by the Department of Health in commissioning the MSAC Guidelines Review results in the publication of updated MSAC Guidelines supporting the preparation of consistent, robust, and informative Assessment Reports supporting MSAC decision-making. Each party involved in the preparation of this document would be pleased to offer further feedback assisting the MSAC Guidelines Review team in the finalisation of the MSAC Guidelines.

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