Health Economics Methods Advisory (HEMA) Working Group Guiding Principles

Summary

- The Working Group's (WG) primary focus is the suitability of a given method to support decision-making and/or recommendation-setting by Health Technology Assessment (HTA) bodies (with a focus on Canada's Drug Agency (CDA), Institute for Clinical and Economic Review (ICER) and National Institute for Health and Care Excellence (NICE)).
- To reflect variation between HTA bodies, the WG may need to condition its comments and recommendations by HTA body or by the alternative policy or value positions.
- In situations where the methods under discussion support policy or value positions deemed to be outside the purview of all the sponsoring HTA bodies, the methods would also be deemed outside the scope of WG activities.
- Given the primary focus of HEMA on the methods of economic evaluation or those used in such studies (e.g. evidence synthesis), the WG could helpfully define the key elements of such a study to make it fit for the intended purpose (i.e., informing HTA recommendations and/or decisions).
- Key policy and value positions are those which define how HTA bodies have chosen to make decisions about the adoption, pricing, and reimbursement of health technologies.
- In general, the WG will take the policy and value positions defined by HTA bodies as given and not the focus of its deliberations.
- The aim would be for white papers to be based on WG consensus. When this is not
 possible, there should be an attempt to describe the alternative views expressed, the
 key considerations that those views depend on and the implications of the
 alternative views for HTA bodies.

1. Introduction

The purpose of this note is to outline a set of suggested principles for the HEMA Working Group (WG). What is often described as "methods" research or comment may in fact consider several factors which extend outside of methods, including the political, operational, and contextual. The hope is that, by setting forth principles on what the WG should focus on and the activities it intends to inform, this might help work planning in terms of what considerations are within and outside of the group's appropriate scope.

2. Methods for what purpose?

Critically reviewing existing or novel methods for HTA could be approached from several directions. For example, the group could seek to establish which methods are more consistent with specific economic theories (positive or normative). Given the purpose of HEMA, it's reasonable to have a primary focus on the suitability of a given method to support decision-making and/or recommendation-setting by HTA bodies. Of course, assessing "suitability" will need the group to consider alternative theoretical underpinnings (which themselves may be contested). However, it will also need the WG to reflect on considerations such as practicality of implementation, expected effects of "novel" analytical results compared to "standard" methods, and their overall coherence given the stated objectives of the HTA bodies funding HEMA.

It is recognised that these considerations may be challenged by the fact that the HTA bodies in HEMA (even more so, those outside) vary in terms of their audiences, stakeholders, standard methods, and stated objectives. To reflect such variations, the WG may need to condition its comments and recommendations by HTA body or by the alternative policy or value positions on which those bodies may not yet have been explicit. In addition, there may be situations in which the methods under discussion support policy or value positions deemed to be outside the purview of all the sponsoring HTA bodies, in which case the methods would also be deemed outside the scope of WG activities.

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3. What is included in economic evaluation methods?

HEMA is principally focussed on analytical methods used in economic evaluations, although some of these may be used in other types of evaluation. For example, methods to synthesize estimates of clinical effectiveness could be a topic for the group and, although these can be used in economic evaluation, they might stand on their own outside economics in evaluations of relative effectiveness. However, given the expected primary focus, it would seem reasonable for the WG to define the key elements of such a study to make it fit for the intended purpose (i.e., informing HTA recommendations and/or decisions). A starting point for discussion is that these constituent parts are:

- A defined population of patients or other individuals for which interventions are relevant (alternatively defined as an indication)
- A complete set of feasible interventions for that population (which could be characterised as a new technology plus a full set of alternative comparators)
- A stated set of benefits relevant to the chosen study perspective, and explicit means for their valuation and aggregation to facilitate suitable comparison given the study perspective
- A consideration of all costs relevant to the chosen study perspective
- A consideration of opportunity cost(s) appropriate to the chosen study perspective, ideally empirically based and consistent with the measure of benefit
- A suitably justified evidence base relating to all empirical parameters in the analysis

4. Policy and value positions

Distinguishing methods from policy and value positions will be an important task for the WG, although this may not always be straightforward. The policy and value positions of most interest are those which define how HTA bodies have chosen to make decisions about the adoption, pricing, and reimbursement of health technologies. These include (but are not limited to) which benefits are considered relevant (e.g. mortality, quality of life, caregivers' health, impact on the wider economy, alternative distributions of benefits); the weights that are used to value and aggregate relevant benefits; the costs falling on the individuals, sectors and organisations that will be considered; and other means by which policy priorities are reflected in decision making (e.g., through cost-effectiveness thresholds).

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In general, the WG will take these policy and value positions as given and not the focus of its deliberations. In doing so, however, the WG may face challenges in some of these areas. One example relates to the fact that there are research methods which can be used to inform HTA bodies' decisions about policy and value positions. For example, there are alternative methods to elicit the preferences of the public or selected population groups on how it would weight different benefits and distributional considerations. More generally, the WG's experience is suitable for setting out the strengths, weaknesses and implications of different policy and value positions about this is not methods research as such and should not be confused with recommendations about what those positions should be—this would be considered outside the WG's purview.

5. A way of working

The WG is made up of individuals working in different countries, and with different types of experience and skillsets. As such, it will not be surprising if there is some variation between WG members in their knowledge about and assessment of different methods on a given topic. Whilst the aim would be for white papers to be based on WG consensus, this may not always be possible, not least because achieving consensus may take time the group does not have. In such situations, there should be an attempt to describe and document the alternative views expressed, the key considerations that those views depend on and the implications of the alternative views for HTA bodies.

An important aspect of most white papers is likely to be its recommendations about methods and their practical implementation which, as discussed, may need to vary by HTA body, policy or value positions which have not yet been stated by HTA bodies or reflect different viewpoints in the WG. The WG is also very likely to consider recommendations regarding further research to inform decisions about appropriateness of alternative methods as the research base for novel methods may need further development.

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