Health Technology Assessment Policy and Methods Review Reference Committee

Communique – 7 September 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 7 September 2023.

Representatives from the Centre for Health Economics Research and Evaluation (CHERE) and Adelaide Health Technology Assessment (AHTA) provided presentations on the progress of their papers. Ms Rosemary Huxtable AO PSM was invited to speak with the Committee regarding updates on the mid-term Review of the National Health Reform Agreement (NHRA) Addendum 2020-2025. Support staff from the Review Secretariat in the Department of Health and Aged Care (Department) attended.

What did the Committee discuss?

Presentation of Paper - Funding and Purchasing Decisions and Managing Uncertainty by CHERE

Research leads from CHERE provided a presentation update on the progress of their paper on funding and purchasing decisions and managing uncertainty.

The Committee heard CHERE's findings on the range of topics being addressed in terms of funding purchasing, uncertainty, rare diseases, and how uncertainty is being dealt with in terms of technological development. The Committee heard CHERE's findings on international approaches to equity in HTA and approaches to equity in HTA in Australia in particular, relating to First Nations people, disease severity, rare disease, and children. The Committee discussed that the description of equity outlined in the National Medicines Policy would be beneficial to include in the paper.

The Committee also discussed that it would be beneficial if there was clarity about the type of consumer engagement referred to in the paper, and provided guidance to CHERE on resources that may assist its research. The Committee spoke about the need for the paper to include consideration of the National Aboriginal Community Controlled Health Organisation views and recommendations and a broader consideration of access in terms of First Nations health issues, noting that some of these issues are broader than the HTA Review, however, is essential these issues are addressed.

The Committee noted significant variation in approaches, noted some areas where the Australian systems are leading, but also noted opportunities for improvement. The Committee considered challenges in co-dependent technologies (including companion diagnostic testing) that impose additional time in funding decisions. The Committee considered that a systematic process for horizon scanning may be required for early

identification of co-dependent and hybrid technologies as a way going forward for better preparedness.

The Committee heard CHERE's findings on international approaches to managing uncertainty, including in the areas of focus of clinical, economic, population, rapid technology development and in the broader landscape (e.g. development of new alternative treatments or combinations). The Committee and CHERE discussed a range of options to address some of the issues discussed and agreed that these options would require more detail and expansion in the paper.

Presentation of Paper - HTA Methods: Clinical Evaluation Methods by AHTA

Research leads from AHTA provided a presentation update on the progress of their paper on clinical evaluation methods in HTA. The update included an overview of clinical evaluation methodology, special considerations for particular technology or population types, recent reforms, results of their bibliographic database search, key differences between Australia and other jurisdictions, categories of methods (including non-traditional evidence, surrogate endpoints, value frameworks/multiple-criteria decision analysis (MCDA), equity considerations, consumer and stakeholder evidence, methods for specific technologies or populations) and methods for evaluating non-traditional evidence (including indirect comparisons and real world evidence (RWE)).

The Committee heard AHTA's findings on how various jurisdictions established/defined guidance for evaluation of clinical evidence, noting that this was consistent with the broad Australian guidance.

The Committee spoke about the challenges that arise with more complex methodology. The paper, therefore, needs to include discuss under what circumstances more complex methodology is justified, the appropriateness of using multiple methods, and how to reduce uncertainty associated with complex methodology.

The Committee heard that the literature suggests that RWE: is poorly defined, may be useful for reducing gaps in evidence and for reducing uncertainty following reimbursement, that jurisdictions are not accepting RWE as the primary source of effectiveness estimates, and RWE may be most relevant for the assessment of rare or ultra rare diseases.

The Committee discussed that a summary table for quality indicators for RWE/data may be useful to include in the paper and particularly where it is important for rare and ultra diseases. The Committee discussed that RWE has multiple definitions and being clear about RWE in the paper to avoid confusion would be beneficial.

The Committee spoke about the need for the paper to discuss in more depth the purpose of consumer engagement, noting there is more than one purpose (i.e data gathering, patient involvement in decision making etc). The Committee also discussed that it would be useful to outline in the consumer evidence section of the paper the current activities of the Consumer Evidence and Engagement Unit (CEEU) and to refer to the HTA international (HTAi) Patient And Citizen Involvement in HTA Interest Group's values and standards framework along with the HTAi/Professional Society for Health Economics and Outcomes Research criteria for deliberation.

The Committee heard about the overview of findings to do with surrogate endpoints, including that there is an increase in the use of surrogate endpoints in regulation. The Committee heard that the benefits of using surrogate endpoints include fast access to

treatments, and the ability to consider drugs with regulatory approval based on surrogate endpoints. The Committee heard that the risks of using surrogate endpoints include far greater uncertainty compared with patient relevant endpoints.

The Committee heard about qualitative, quantitative, and explicit value frameworks and MCDA.

The Committee heard that there are few methods to incorporate equity into decision making or evaluation, there are few jurisdictions that have clear approaches for considering equity, and key approaches tend to be deliberative.

A range of options were presented to the Committee by AHTA for orphan drugs, rare diseases, and advanced therapeutic medicinal products. The Committee heard AHTA's findings related to histology independent treatments and anti-microbials and vaccines.

Discussion on Mid-term Review of the National Health Reform Agreement (NHRA) Addendum 2020-2025

The Committee received a high-level briefing from Ms Rosemary Huxtable AO PSM on the Mid-term Review of the NHRA Addendum. The Committee discussed areas of potential alignment between the two processes and shared insights from inputs received so far including through draft HTA Expert papers and stakeholder consultations.

Consultation and Schedule Update

The Committee discussed challenges and options for timeframes for the remainder of the Review, including the timing and approach to Consultation 2.

Meeting close and next meeting

The Committee noted the next meeting will be held on 14 September 2023.

Who is the Reference Committee?

- Independent Chair: Adjunct Professor Debora Picone AO
- Patient Representatives: Ms Ann Single and Dr Dawn Casey PSM
- Chair of the Pharmaceutical Benefits Advisory Committee (PBAC): Professor Andrew Wilson
- Clinical/Scientific Representative: Professor Andrew Roberts AM
- Member Nominated by Medicines Australia: Ms Elizabeth De Somer
- Government Nominee: Ms Adriana Platona PSM

Where can I find out more about the HTA Review?

Health Technology Assessment Policy and Methods Review | Australian Government Department of Health and Aged Care