Australian Government
Department of Health and Aged Care

Health Technology Assessment Policy and Methods Review Reference Committee

Communique – 17 October 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 17 October 2023.

Representatives from multiple clinical registries, key experts on outcome data collection, and the Australian Digital Health Agency (ADHA) were invited to speak to the Committee. Support staff from the Review Secretariat in the Department of Health and Aged Care (Department) and the probity advisor also attended, along with Departmental staff.

A representative from the Environmental Health and Climate Change Branch discussed the potential role of HTA processes in reducing the carbon footprint of the healthcare system.

What did the Committee discuss?

Deep dive discussion on the use of registries and outcome data collection to inform HTA lifecycle management

The Committee heard from multiple key experts on outcome data collection and representatives from clinical registries on the topic of registries, their current and future uses, and examples of current challenges to the timely and cost-effective data collection.

These presenters included Department representatives from: The Technology Assessment and Access Division; the Drug Utilisation Sub Committee (DUSC) secretariat; the Medical Services Advisory Committee (MSAC) secretariat; the Health and Medical Research Office; The Medical Research Future Fund.

Representatives of DUSC and MSAC secretariats outlined examples in which departmental reviews accessed registry and observational data to support the findings of clinical trials, and to reassess the efficacy, safety, and cost-effectiveness of products on the market.

The Committee noted the benefits of Registry Trials as a cost-effective supplement to existing clinical trials in assessing the efficacy of a treatment. Data is collected directly into an existing registry, alleviating the usual cost of creating a new database for every clinical trial. In conjunction with clinical trial evidence, registry trials may allow for the collection of real-world evidence for timely review of provisional listings, and registry data may allow for a more nuanced perspective in head-to-head comparisons, as comparisons between drugs that have been released at different times could be made. For patients that switch treatment options (as successively more effective options are released), registry data analysis could capture real world- examples of treatment popularity and interactions in usage that cannot be simulated in pre-market clinical trials.

The Committee noted that accurate collection of primary care clinical data has historically been challenged by patient concerns about privacy frameworks and a need for transparency in data use. Another challenge raised was the administrative support in hospitals to facilitate data entry of clinician reports.

The Committee noted that large datasets and national frameworks are already in existence and in development, namely ADHA. One of ADHA's purposes is to improve access to clinical registry data to optimise the reuse of data in an effort to better inform clinical decisions and to make data available for research and public health purposes.

Overall, the Committee noted several common challenges faced by HTA committees, clinical registries, and clinicians regarding efficient and cost-effective data generation: variability in administrative support for registries, obtaining consistent and usable data from clinicians, patient concerns about data collection, the disparity in precision of Patient-Reported Experience Measures (PREMS) between hospital data and private institution data, the relative difficulty of compiling data from multiple private institutions (with varying policies in data sharing) compared to hospital-generated data.

The Committee noted proposed solutions raised by multiple parties: the call for a national data framework that more efficiently facilitates data linkage, increased transparency in data use and clinician engagement to address patient concerns about ongoing data collection, and a financial incentive by government or private sponsors for registries to participate in data-linkage.

The Committee sought additional feedback from the presenters in the form of a survey, to be completed after the conclusion of the meeting.

Proposed Options for the Life Saving Drugs Program (LSDP)

In a previous meeting, the Committee discussed with members of the LSDP Expert Panel (EP) how the LSDP operates, the role of HTA in the LSDP and the challenges in assessing and subsidising medicines for ultra-rare diseases.

The Committee heard from Prof Andrew Roberts on issues and potential options for reform in the assessment of ultra-rare diseases, to be considered further as part of the options paper for Consultation 2.

The Committee identified potential issues with the LSDP in the context of HTA: that some of the existing HTA processes may be duplicative and impact on timely decision-making and time t-o access for patients and carers; and an opportunity may exist to increase transparency of decision-making, as the LSDP does not require the consideration of value -for money.

The Committee heard three interrelated suggestions to address identified issues: PBAC to become the sole HTA committee for drugs for ultra-rare diseases, subject to satisfactory price and deed negotiation; that a statement of rationale for the LSDP be developed and published, ensuring that it outlines the principles underpinning the program and the criteria for eligibility for a drug to be listed on the LSDP, including cost considerations; and that the process for a product's inclusion in the LSDP could include an assessment of cost-effectiveness.

The Committee noted two potential risks to manage with the proposed options: that the LSDP could be misperceived as a default route to subsidy for products related to ultra-rare

diseases, and that in circumstances where eligibility for LSDP no longer apply, that a streamlined mechanism to transfer products to the PBS may be required.

Alignment with the Australian National Health and Climate Strategy plan

The Committee welcomed a representative from the Environmental Health and Climate Change Branch to discuss the potential role of HTA processes in reducing the carbon footprint of the healthcare system.

The Committee heard that the majority (60%) of healthcare greenhouse gas emissions were associated with providing clinical care, and therefore driven by clinical decision-making-.

The Committee noted some proposed options for potential review: reporting of embodied greenhouse gas emissions in the assessment of cost-effectiveness by HTA bodies; potential for use of these data in approval and reimbursement decisions; potential for public reporting of these data, to inform clinical decision-making; alignment with international best practice in comparable jurisdictions; the role of international standards for carbon footprinting of health technology products.

Other Business

The Committee discussed several administrative matters regarding the operation of the Committee.

Meeting close and next meeting

The Committee noted the next meeting will be held on 27 October 2023.