



Health Technology Assessment Policy and Methods Review Reference Committee

Communique – 19 September 2023 meeting

The Health Technology Assessment (HTA) Policy and Methods Review (Review) Reference Committee (Committee) met by video conference on 19 September 2023.

Representatives from the Antimicrobial Resistance Branch of the Department of Health and Aged Care (Department) and the Australian Antimicrobial Resistance Network (AAMRNet) participated in a deep-dive discussion on antimicrobial resistance (AMR) with the Committee. Representatives of the Department, the National Aboriginal Community Controlled Health Organisation (NACCHO), Deakin University, Flinders University and the Kirby Institute participated in a deep-dive discussion on addressing health inequities for Aboriginal and Torres Strait Islander peoples with the Committee. Support staff from the Review Secretariat in the Department and the probity advisor attended.

What did the Committee discuss?

Deep Dive into Antimicrobial Resistance

Representatives from AMR Branch, in the Department of Health and Aged Care, and AAMRNet gave their respective presentations on the state of AMR in Australia.

Representatives from AMR Branch described the context, scope, and focus of the Australian Government's strategy related to AMR. The Committee learned about the contributing factors to AMR, both domestically and abroad, including the lack of development of new innovative antibiotics by pharmaceutical companies globally and some of the underlying economic and policy drivers of this. Examples of international initiatives relating to AMR were discussed, including the concept of a "subscription model" of payment and Australia's participation in the Global AMR Hub Pull Incentives working group and Pricing and Reimbursing Scoping Study. The approach and outcomes of an initial Pricing and Reimbursement Scoping Study related to AMR were presented, including details of antimicrobial medicines accessible globally that are not currently available in Australia.

The Committee noted the paradox of the need to have access to antimicrobials while also needing to avoid their uptake until required which reduces the economic viability of new antimicrobials, further contributing to the multifaceted landscape of issues for AMR. The Committee noted the National Health Service England and the UK's National Institute for Health and Care Excellence has been piloting a "subscription model" program for antimicrobials and this was described as an effective initiative that could be applied in Australia (noting the model has some challenges that will need consideration). Other approaches including different pathways to antimicrobial funding and different legislative or funded approaches to promote bringing new antimicrobials to market were discussed however it was noted that other jurisdictions found some of these approaches to be

unsuccessful. The Committee noted that tight control over use and continuous surveillance of antimicrobials, as is the case for antibiotics in Australia, would be essential and that access to relevant diagnostics may need to be a part of antimicrobial stewardship. Global cooperation was noted to be increasingly important to respond adequately to AMR.

The Committee briefly discussed the applicability of points raised in the presentation to inform the future Consultation 2 Options Paper and considered further discussion would be required.

Presentation of Paper on HTA and Funding Pathway for Special Populations by the Department of Health and Aged Care

The Committee heard a presentation from the Department on the initial draft paper on populations and indications that may warrant a special approach to funding and assessment of health technologies. The Committee noted the purpose of the paper was to facilitate Committee consideration of circumstances where there may be a need for special approaches to the HTA or funding of health technologies (or both) for specific populations and indications, including:

- populations experiencing disadvantage, inequity in health outcomes, or circumstances or life stages that give rise to vulnerability
- small eligible patient populations, for which there may be challenges associated with evidence availability and market-size
- other populations with high unmet clinical need and limited evidence availability
- other populations or indications where there is a significant population health need or public health threat that may warrant a specialised approach such as antimicrobial resistance, vaccines, and treatments for pandemics or declared public health emergencies.

The Committee considered material in respect of the importance of equity considerations in the assessment and provision of health technologies to patients and had a broad discussion around how equity should be considered under the HTA Review.

The Committee heard the background regarding the varied and extensive determinants and causes of inequities for special populations and their need for, and access to, relevant treatments. The Committee noted a range of potential approaches to this including prioritisation of resource allocation, provisions to ensure special populations are specifically considered in HTA processes and methods, responding to social or structural determinants to inequity and optimising use of medicines through quality use of medicines and other structures. The Committee noted the complexity of the meaning of health equity and the varying aspects to health equity, including the important intersection with ethics in resourcing decisions. The Committee was reminded that the *National Health Act 1953* specifies that the Pharmaceutical Benefits Advisory Committee (PBAC) can only recommend a therapy more costly than an alternative if it is satisfied that it provides for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy (which is not necessarily the same as improving access). The Committee also noted the challenges in obtaining the relevant evidence to consider all aspects of equity in an HTA context.

The Committee discussed the concepts of unmet clinical need and public health threat, and considered how they may feature in future HTA policies and methods. The Committee considered the concept of special funding and HTA pathways for special populations,

including a potential framework which demonstrates where such under-representation may exist in the evidence considered by HTA.

It was agreed that further refinement was required to the paper and further consideration required by the Committee.

Deep Dive into Addressing Health Inequities for Aboriginal and Torres Strait Islander peoples

The Department provided a presentation of the current state of considerations and challenges in HTA related to First Nations Australians, including the Medical Services Advisory Committee and PBAC guidelines and processes, as well as specific PBS listings and restrictions related to Aboriginal and Torres Strait Islander people. Despite previous examples of engagement to support access for Aboriginal and Torres Strait Islander people, there are challenges to replicate these efforts due to Therapeutic Goods Administration registration status, evidence base, sponsor support and resourcing. Subsidised off-label use of old medicines (as opposed to re-purposing) was noted as being part of a solution for some access issues (noting that this would require some form of evidence to support the HTA).

The Committee received a presentation from Deakin and Flinders University researchers on distributional cost-effectiveness analysis (DCEA) as a method to incorporate equity impacts (equity weights) into cost-effectiveness assessment. This included a walk-through of a Health Equity Impact Calculator.

The Committee received a presentation from NACCHO, which emphasised the need for an Aboriginal and Torres Strait Islander voice throughout the HTA cycle and a range of structured policy supports including repurposing and delisting medicines, incentives for sponsors of medicines that meet the needs of Aboriginal and Torres Strait Islander people, and the design and application of an equity framework. Involvement of Aboriginal and Torres Strait Islander people in horizon scanning and engagement with the pharmaceutical sector was also discussed as activities which may facilitate equity. NACCHO noted a key change needed is strategic oversight and input for Aboriginal and Torres Strait Islander people to the HTA process. The Committee noted NACCHO has previously prepared PBAC submissions, but this is highly resource intensive, and requires support from academic institutions.

The Committee received a presentation about point of care (POC) testing for infectious diseases in rural and remote communities. The Committee heard that POC testing is important in providing equity of access to pathology services in remote and rural communities and in turn facilitating access to needed treatment. The Committee heard possible solutions to providing POC testing includes multi-stakeholder support access pathway (such as the RADx model in the USA), a low complexity test registration pathway and/or a reimbursement model for POC testing. The Committee noted this may be less of an HTA issue, and more of a funding model issue.

The Committee reaffirmed it would develop options in relation to equity of access for Aboriginal and Torres Strait Islander people, including guidance and communications as to what considerations should be accounted for within HTA. The Committee noted that the application of “equity weights” could have some very positive benefits but would need to be supported by data (which may be difficult) and may be an imprecise tool.

Meeting close and next meeting

The Committee noted the next meeting will be held on 22 September 2023.