CATAG
Council of Australian
Therapeutic Advisory Groups

Health Technology Assessment Policy and Methods Review - Consultation 2

February 2024

Introduction

The Council of Australian Therapeutic Advisory Groups (CATAG, www.catag.org.au) is an authoritative, expert, consensus-based collaboration of representatives from all Australian State and Territory Therapeutic Advisory Groups or their jurisdictional committee equivalents.

CATAG contributes to the equitable, safe, cost-effective and quality use of medicines primarily (but not exclusively) in the hospital sector across Australia. CATAG aims to improve medicines management and use within the framework of the National Medicines Policy as it applies to clinical practice in Australian hospitals, at transitions of care, within the public sector and wider community. It promotes the equitable, safe, cost-effective and quality use of medicines, with the objective of realising the best possible health outcomes for all Australians.

CATAG supports Medicines and Therapeutics Advisory Committees (including Medicines governance committees such as Medicines Advisory Committees, Drug and Therapeutics Committees) to be well functioning which leads to a strong QUM framework within the individual health service.

CATAG is independent and cognizant of QUM issues and the cost pressures faced by governments, policy decision makers, individual healthcare organisations and clinicians.

In responding to the consultation, CATAG has grouped responses according to the areas of interest.

CATAG provides the following feedback on the principles and recommendations resulting from the initial HTA consult.

1. Transparency, communication and stakeholder involvement in HTA

CATAG supports activities to improve transparency, visibility and communications, including:

- The proposed approaches to publish plain language summaries of HTA reviews.
- Improvements to the HTA websites to improve visibility and transparency of process.
- Developing a framework for consumer engagement.
- Ensuring there is a clear and consistent process for partnering with first nations people.

CATAG supports collaborative horizon scanning activities, with the aim of empowering jurisdictions to prepare and plan for new technologies.

However the KPI approach to applying timeframes to implementation of new HTAs is concerning. Whilst access to emerging treatments is important, this needs to be delivered in a safe, effective and quality manner. There may be several reasons why health services choose not to implement, or delay the implementation of, a new technology. KPIs appear to be a blunt mechanism for implementation and do not account for the variety of services which may be captured, nor the readiness and suitability of delivering that HTA in the proposed setting.

CATAG also has concerns regarding the proposal to accept lower grades of evidence to demonstrate effectiveness and cost-effectiveness. Should lower grades of evidence be used in these reviews and assessments, the inherent bias and uncertainty surrounding this evidence needs to be clearly acknowledged and addressed.

CATAG holds concerns regarding the perceived administrative burden that may be created by jurisdictions seeking individual agreements with sponsors and suppliers. Legislative requirements and government policy exist at a state level to protect state and public interests. Whilst sponsors may have concerns regarding administrative workloads, this needs to be effectively balanced with ensuring good value for money and protecting the interest of the Australian community.

2. Health technology funding and assessment pathways

One of CATAG's primary interests is to support the equitable access to and funding of hospital medicines. Outlined in the consultation document, there appears to be an assumption that access to HTA is funded for public hospital inpatients through the National Health Reform Agreement (NHRA) and activity-based funding (ABF) arrangements. However, in the setting of HTA's specifically, there are barriers to this funding approach. It is known that there is a significant delay between the actual cost and the calculation and implementation of the nationally efficient price (NEP). Practically, in a setting such as oncology, new treatments are entering the market at such a speed that the NEP never keeps up with current practice.

Availability of medicines for public hospital inpatients is predominantly determined by medicines formularies. Medicines formularies are managed by Medicines and Therapeutics Advisory Committees and will consider the most cost-effective processes for their local health service. These committees exist, at local, district (network) and statewide levels. CATAG is supportive of measures to improve equitable access to medicines and minimise postcode lotteries. However, any such measures need to be mindful of local variability in service availability due to access to specialist health workforce and infrastructure. In a setting where NHRA arrangements do not sufficiently cover the cost of new health technology in real time, and where smaller services and jurisdictions may struggle to achieve service delivery at the nationally efficient price, there needs to be a mechanism to recognise the need for equitable service delivery that is safe and sustainable.

Currently, medicines that have a PBS listing make up only a small proportion of medicines routinely used in the hospital setting. It should be noted that the current Pharmaceutical Benefit Advisory Committee (PBAC) approach will not sufficiently cover the broad reach requirements for hospital medicines, which frequently require access to medicines which are not TGA registered, or medicines that are used for non-registered indications. As per CATAG's Rethinking medicines decision-making in Australian Hospitals. Guiding principles for the quality use of off-label medicines, there are processes in place to provide effective governance for medicines used for non-registered inidcations. It is not currently clear how these items would be accommodated under the new proposed assessment and funding pathways.

CATAG supports improvement in communication between the Commonwealth and jurisdictions in relation to HTA matters, this needs to be undertaken in a manner that encourages meaningful two-way engagement.

CATAG notes proposals to streamline some submissions, which may be based on cost-minimisation. Whilst CATAG supports processes that minimise and streamline administrative processes, there is a need to ensure any new process does not create a perverse incentive for sponsors to seek higher levels of evidence and clearly establish the superiority of their treatments.

3. Methods for HTA for Australian Government Subsidy (technical methods)

CATAG does have concerns with proposals to support the use of lower quality evidence. CATAG acknowledges there are populations where the completion of randomised controlled trials (RCTs) are challenging, and this can lead to health inequity. However, there needs to be caution applied to accepting lower quality data sets, such as non-randomised, or observational studies, as this may discourage investment in high quality RCTs in the future.

The PBS is often used as a surrogate indicator for clinicians in understanding the evidence available to support the use of a product in a particular indication. Currently, if an item is PBS listed, then the clinician can be confident that there is a high level of evidence to warrant the safety and effectiveness of the medicine for the specific indication. However, where there is a transition towards accepting lower quality evidence to support a PBS listing, this needs to be accompanied by appropriate education and disclaimers, to ensure clinicians are aware of the new limitations of PBS listings and to facilitate appropriate patient consent.

The issue of using and interpreting surrogate endpoint assessments is well known to CATAG members. CATAG welcomes a framework which seeks to address this challenge and provides a clear and consistent mechanism to manage this type of evidence. However, noting the recent work by the PBAC looking at the consistency and reliability of surrogate markers this will likely be challenging to achieve and there is need to apply caution.

Thank you for the opportunity to provide feedback into the second stage of consultation for the Health Technology Assessment review.

Kind Regards

Anita Shutt BPharm(Hons), GradDipPubHealth, FANZCAP (Lead&Mgmt, MedsMgmt)
Chairperson
Council of Australian Therapeutic Advisory Groups.

[redacted]