NACCHO
National Aboriginal Community Controlled Health Organisation

HTA Review Options Paper

NACCHO Response Feb 2024

NACCHO welcomes the efforts by the Committee to address the concerns raised by NACCHO. NACCHO's first submission outlined challenges and priorities brought to us directly from Aboriginal and Torres Strait Islander people and communities, our member services, our jurisdictional affiliates, subject matter experts and industry. We acknowledge that the Paper's Options go some way to addressing these priorities and needs, both in the explicit First Nations Options and in several interacting Options throughout the Paper. However, there are several areas where we will provide further feedback and wish to highlight the importance of building "implementable and sustainable" HTA policy, as is referenced by the Review's own Terms of Reference.

Fundamental to any Options for Aboriginal and Torres Strait Islander people is
1) meaningfully incorporating the foundational health priorities and voices of Aboriginal and Torres Strait Islander people and communities throughout HTA (i.e. a core aim of Option 1.3); and
2) improving the appropriateness of the whole HTA system to respond to these priorities (captured throughout other Options).

We would like to reiterate that Australian HTA can be time-consuming and costly, especially for small organisations. For example, in the case of the IPAC Trial, the sponsor surmised that the cost of the HTA through MSAC may have exceeded the cost of the Commonwealth-funded IPAC Trial evaluation itself. We support HTA generally being more flexible, and expansion of the range of evidence (especially real-life studies) being assessed. We support State and Territory collaborations in addition to national approaches, to enhance the visibility of decision-making and utilise expertise from the jurisdictions, transparent consultation, implementation planning - these issues don't just pertain to hospitals but also impact on our broader health system (e.g. the ACCHO sector).

We acknowledge that the current section of the PBS that outlines PBS medicines for Aboriginal and Torres Strait Islander people. We support such a list conceptually and acknowledge the impact it has had in improving access to medicines for First Nations people for a couple of decades, including areas where there is high unmet clinical need. However, the current list has no real custodianship. It exists through implicit mechanisms and vague incentivisation. While we realise that sponsors may receive additional support (i.e. those currently outlined in PBAC guidelines and procedures) in applying for a listing such items, priority medicines for our sector are not manifestly being listed and several critical medicines have recently been delisted. We provide several reasons for this in our previous submission, which may be considered as cases to adjudge the potential effectiveness of the Options in this current paper. For example, whether nicotine replacement therapy for Aboriginal and Torres Strait Islander people would be listed through these Options. We feel the most effective way to manage such a list is outlined broadly within section 1.3.

We would like to reemphasise the importance of price negotiations at multiple points in the HTA system. Funding and purchasing is possibly the most acute issue for NACCHO within HTA currently (we can cite specific cases on request). The medicines that our sector would like listed are commonly low-cost items for a relatively small population. Even with medicines and technologies with a high degree of uncertainty, the low cost and small population creates a very low financial risk for government. We

therefore propose price policy should be more much explicitly addressed in the Options Paper in relation to listing for Aboriginal and Torres Strait Islander health technologies on MBS and PBS. Specifically, the payer should have structured means to pay a higher price for an item that will disproportionately benefit Aboriginal and Torres Strait Islander people. Such an approach is a practical way in meeting equity needs expressed in the National Medicines Policy.

We accept the current very low involvement of consumers and Aboriginal and Torres Strait Islander people throughout HTA. We feel that this was in part related to the apparent intense scrutiny and duplication undertaken in the HTA on the IPAC Trial submission. For example, the external analysis commissioned with the HTA process to investigate if the IPAC Trial was a community-based participatory study (CBPR) was unnecessary for the purpose of the MSAC assessment. Within the existing submission the sponsor had already provided evidence and reports on CBPR design and methods, and this was published in the trial protocol citing and documenting WHO standards. We consider that this cost to government was unnecessary and suggests an intrinsic lack of knowledge and guidance on this type of study design.

The Options paper identifies: “Health technologies may not perform as well in the real-world as they did in trials for a range of reasons. It was identified that Australia does not have sufficient systems to evaluate whether subsidised health technologies work as well as expected after the original subsidy assessment…” From another perspective, HTA policies and processes have found it challenging to understand and evaluate ‘real world’ studies when submitted for HTA. For example, the HTA has capacity to assess RCT or other large-scale experimental studies but did not readily assess a pragmatic, interventional, pre-post study (not an experimental study), that offers strengths with external validity. The IPAC Trial explored the performance of an intervention in the real world. This study design made it ‘fit for purpose’ to inform policy making decisions based on a range of population health outcomes and not just one clinical endpoint. We propose that if HTA templates were better designed to accommodate such examples identified above, the assessment process would be less foreboding for new sponsors.

We highlight comments in the Options paper that many stakeholders more flexibility in the evidence base used in HTA, including greater acceptance of non-randomised evidence. We support Options relating to updated guidance on the use of non-randomised and observational evidence (including indirect comparisons, Real-World Data (RWD) and Real-World Evidence (RWE), other non-traditional evidence.