ACCESSCR

Submission to the ‘Enhanced Consumer Engagement in HTA’ Consultation Paper April 2024

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About This Document

The document collates AccessCR's responses in the first week of April 2024 via the consultation survey and email to the Health Technology Assessment (HTA) Co-design Working Group consultation on their recommendations for an Enhanced Consumer Engagement Process in health technology assessment.

The Submission

As background and context for the submission, AccessCR is a social enterprise providing services to the research sector supporting clinical trials and consumer engagement and involvement in research. The goods and services we provide fund our advocacy and support activities for those we call CCReW - the Community and Consumer Research Workforce. We define CCReW as the individuals (and their carers/families) taking part in and contributing their lived experience to health and medical research, particularly clinical trials.

Q10. The consultation document proposes 'System-wide' recommendations that intend to embed consumer evidence and experience across the end-to-end health technology pathway as a whole. We are interested in the System-wide recommendations that are most important to you. To respond, please rank the recommendations listed below in order of importance.

AccessCR's ranking:

1	Consumer engagement framework
2	Centralised and expanded consumer support
3	Single digital consumer portal
4	Plain language communications
5	Stakeholder resources and training
6	Consumer identification and development
7	Consumer-informed horizon scanning
8	Facilitated collaboration with industry

Q11. Thinking now about your top three 'System-wide' recommendations, what difference do you think they will make for enhancing consumer engagement in health technology assessments?

The community cannot engage with health technology processes if

a) they are unaware of them;

b) they don't know where/when they can engage;

c) they don't know how to engage;

d) they do not have access to help and support to engage, for example, training or in-person mentoring/support; or

e) there is a culture or processes that siloes them, ie is not welcoming of their input and involvement.

An Engagement Framework would help address E. It is fundamental to enabling (and building expectations of) a cohesive approach to consumer engagement and involvement in therapeutic development, approval and reimbursement processes.

A well-resourced consumer unit that sits across all relevant functions of the Health Department (from research to TGA to HTA and post-market review) will help address points A-E. It is fundamental for providing that clear connection point with the community for information and support, building capacity and capability in the consumer workforce contributing to Department processes, as well operationalising (and accountability for) the Engagement Framework.

Further, a single digital platform provides a platform for increasing awareness, knowledge, and timeliness of engagement, providing the community are aware of its existence.

Q12. The consultation document proposes recommendations described as 'Pre-HTA enhancements', 'HTA Process Enhancements', and 'Post HTA Enhancements'. We are interested in which of these recommendations are most important to you. To respond, please rank the recommendations listed below in order of importance.

AccessCR's ranking:

1. Consumer evidence in Australian clinical research
2. Consumer evidence in TGA applications
3. Consumer evidence in PBAC submissions
4. Pre-listing status reports
5. Consumer notifications about TGA applications
6. Consumer notifications about PBAC submissions
7. Criteria for consumer hearings and stakeholder meetings
8. Consumer input feedback loop
9. Consumer-initiated submissions to PBAC
10. Consumer input on implementation considerations following PBAC recommendations
11. Consumer pathway to post-market reviews

Q13. Thinking now about your ranking for the top three recommendations above, what difference do you think they will make for enhancing consumer engagement in health technology assessments?

To contextualise our answer to this question, we feel the need to first describe what we think are the two different but complementary pathways for 'enhancing consumer engagement'. They are:

1. Requiring the system to engage and involve consumers;

2. Improving capacity of the consumer workforce to input, which in itself can be further subdivided into:

   a. Improved access to information;

   b. More opportunities to input.

In brief, our top 3 prioritised recommendations address point 1. Just the requirement to acquire/present consumer evidence throughout the research, regulatory and HTA phases will

by default help enhance consumer engagement. The mandate alone however will be ineffective if there is not a commitment from government, industry and the research sector (and its funders) to sustainably invest in the infrastructure, processes and consumer workforce needed for engagement.

If point 1 is not addressed, the organic shift to involve consumers across the lifecycle that has been occurring over the past two decades will continue slowly, ad hoc and disconnected. There will be a continued lack of investment in the training, infrastructure and support necessary for consumers to be involved, as well as the likelihood that consumer engagement and involvement will be the first activity cut in the face of time and/or financial pressures.

Though there was no requirement to explain how we prioritised remaining recommendations, for completeness, priorities 4-8 contribute to improving point 2a, with the final 3 helping deliver point 2b.

Consumers cannot be expected to engage effectively if there is an absence of information about what products are in the system and at what stage, when input is required, and how to input effectively. Equally, there is a missed opportunity to reduce uncertainty when they don't have clear opportunities to proactively bring forward their lived experience of health conditions and real world use of therapeutics.

Q14. How can we improve any of the proposed recommendations? Please describe your response below.

Recommendation 1 - the Framework:

There is a need to integrate policy, guidance and activities across many areas of Health where consumer engagement is being considered, include NHMRC/MRFF activities, the One Stop Shop for clinical trials, TGA and HTA. For example, how will the NHMRC Statement on Consumer Involvement in Health and Medical Research currently being revised complement or integrate into an overarching framework for consumer engagement in therapeutics development and beyond?

We would also encourage consideration for who would be accountable for delivering on the expectations of the Engagement Framework.

Rec 2 - Single Digital Portal

While this will be critical infrastructure, its design and support will be key. People must know about it, be able to find it, navigate and search it successfully, and then get support from a human if it is to be inclusive of the diverse language, literacy and technology access of different Australians.

Recommendation 3 - plain language - touchpoints

We agree there is a need for plain language protocol summaries, that could be made available as part of the 'new' clinical trials registry, as well as lay results summaries post-trial. We would like to see both made mandatory, with significant penalties for those that do not comply in a timely manner.

A touch point we would like considered is what plain language information could be made available publicly about the protocol and/or product and indication at the time a CTN is approved?

Recommendation 5 - Horizon scanning

The concept and intent of horizon scanning requires further exploration. Should it be about identifying any technology in development that may get applied cross-therapeutically or is it about understanding a health condition and identifying and prioritising which technology may be useful for it. We think there is a difference in how consumers will inform, depending on the focus of the horizon scanning.

Recommendations 10 + 11 - Consumer evidence in, and notifications of, TGA applications

We are supportive of both requirements and offer a suggestion to expand them.

We would encourage consideration of what information about consumer engagement could be required in a CTA or CTN to the TGA, and what information about those applications/notifications could be made available in a public summary, to assist with transparency about the status of therapeutics in development.

At the CTA/CTN stage, in addition to what consumer engagement has been undertaken, the department could collect information about the consumer groups that have been engaged with locally, which could enhance the Department's intelligence on the consumer stakeholders it could engage with and inform of future consultations relating to the approval or reimbursement of those therapeutics, or others addressing their therapeutic interests.

Q15. Are there any recommendations that you think we should add? If so, please describe your proposed recommendation and its purpose.

As previously mentioned, there needs to be an additional systemic recommendation to embed long-term funding for the development, support and infrastructure needed to build a sustainable consumer workforce. Concentrating effort on "professional" activities (ie government, industry, research sector activities) to enhance consumer engagement will fall short if consumers are not supported to contribute. The time and effort contributed by the consumer workforce cannot be a wholly volunteer endeavour, else there will be burnout, bias and a lack of diversity in who is engaging, and further inequity in the health outcomes across our very diverse Australian population.

Q16. Are there any recommendations that you do not support or require further explanation? Please describe your response below.

Recommendation 6 – consumer identification and development

We support a process whereby consumers can pre-register their interest in specific therapeutic areas or topics, such that they can be made aware of potential consultations, that training is made available that anyone can avail themselves of.

However, we stop short of supporting that the department should be picking and choosing whom it develops as experts in an area. The department should maintain its independence from picking and choosing the voices it hears from.

If the department requires consumer representatives, an open call for expressions of interest and transparent section criteria and process should be outlined.

Once recruited, there is a role for the department to support and mentor the consumers they have recruited according to the roles they have been placed in.

Recommendation 7 – Facilitated collaboration

It seems hard to imagine how the department will be able to maintain independence and avoid conflicts of interest if it is involved in facilitating industry-consumer collaboration.

Rather, we would support a review of the legislative framework that currently prevents industry-consumer collaboration. It would be enabling for a definition and role for expert individual consumer representatives and health consumer organisations to be described in the legislation. This could alleviate a range of unanticipated consequences that lead to suboptimal capacity for consumers to engage with clinicians, research, and industry across the lifecycle (for example, inability to participate in conferences and networking events where industry partners might sponsor or exhibit).

Recommendation 8 – Facilitated support

We strongly support an adequately funded and resources consumer engagement unit that sits across all functions in the Department of Health, supporting, overseeing, and with accountability for enhancing consumer engagement from research to reimbursement and beyond.

We would like to advocate for a consumer unit that spans the MRFF, NHMRC, TGA and HTA processes and committees, ensuring a diversity of voices (and transparent consumer recruitment opportunities, expectations, and processes), the peer support and sharing of ideas between consumers across these various functions, and mentoring/capacity building of these consumers. This would also provide an opportunity for improved transparency about the work and outputs of these various consumer activities (e.g. meeting agendas and minutes) and any training developed publicly and transparently. Such a unit would provide a front door for engagement and involvement across all Health functions, and accountability for delivering on the Consumer Engagement Framework.

Recommendation 9 – Consumer evidence in Australian clinical research

We strongly support the need for consumer involvement in the design, prioritisation, conduct and dissemination of clinical research conducted in Australia. For research initiated overseas, an account of how the relevant populations have been consulted and involved in that work should be mandated. Within the current frameworks, requiring Human Research Ethics Committees (HRECs) to evaluate the appropriateness of the level of engagement, and holding researchers accountable to that involvement through reporting mechanisms and audit, is likely to be the most effective lever for changing the culture of research. HRECs however will need guidance however to be able to make judgement over what is appropriate consumer involvement for a specific project/population/therapeutic area, from the nature of involvement (eg. the IAP2 spectrum of involvement), to the quantum and diversity of consumers involved,

to the tasks in which they are involved, and how that is reported. There is no one-sized fits all process that will suit all projects.

As an implementation consideration, we assume that development of this recommendation with involve the Inter-Governmental Policy Reform Group (IGPRG - https://www.australianclinicaltrials.gov.au/about/igprg) and they will have some accountability for helping drive consumer engagement and public availability of information about the research phases of therapeutic development, through their One Stop Shop and Clinical Trials Front Door activities.

As an aside on a practical level, mandating consumer involvement does not in itself lead to meaningful involvement, nor does it recognise the nuances of different types of research, the barriers, and enablers for specific populations to be involved and the resourcing that is required to do it well. Much of Australia's research ecosystem is bound by guidelines and codes, rather than formalised legislation and so mandates in these frameworks are still optional. Requiring demonstration of consumer engagement in grant funding applications, while providing a carrot, can lead to tokenistic box-ticking. There is a need for accountability to the engagement proposed in grant applications, through reporting of activities and impact subsequent to the award of grant funding and significant consequences for not following through.

Current legislation (preventing advertising to the public) does not recognise a place for "expert consumers/consumer representatives or health consumer organisations", and therefore dismisses their ability to engage with confidential and sensitive information, in a responsible way. It can also systematically exclude consumers from spaces like scientific conferences (with industry sponsorship or trade halls) and having the relationship building conversations with industry or researchers which can inform and influence research. Given the age of empowerment, we think it is time to address the legislation to remove these unintended consequences, while still protecting the general public from advertising.

Recommendation 12 – Consumer-initiated PBAC submissions

While supportive of this possibility and think a process similar to the DCAR used by MSAC is a good idea, there is the practical issue already identified of how consumers will be able to access the proprietary information necessary to support their applications. Additionally though, even if there is a consumer application, what requirement will a company have to support access to the product for the stated population, indication, etc in Australia?

Recommendation 17 – Consumer input on implementation considerations following PBAC recommendations

We support consumer engagement in all stages leading to public access to a therapeutic. If the consumer engagement proposed in other recommendations is already in place, the consumer evidence should be passed from one stage of the process to the next ie automatically passed to the pre-listing/post HTA committee review. We would hope that the evidence considered during this phase should already have been collected through other stages and another phase of input should not be required. However, we will defer to the experts if this is not the case.

Recommendation 18 - Pre-listing status reports

Having a transparent picture of the stage of development of a therapeutic can be critical for patients needing to make decisions about their healthcare. We therefore support all efforts to increase transparency about therapeutics in development, their anticipated indication and target population, and anticipated timelines to approval and reimbursement (or any updates on reasons for delay, should they occur). We understand the risk/commercial concerns in product development and fluidity of information and timelines will need careful consideration for how such information is presented and when.

Recommendation 19 – Consumer pathway to post-market reviews

There should be clear public mechanisms for submitting feedback on real world use of therapeutics at any time, as well as regular review by TGA/HTA bodies of submitted information on products and criteria that could trigger post-market reviews. There should also be some kind of visibility to the nature of feedback received that could inform a patient about real world experiences with a product and whether their own experience is different, as well as information if a review is triggered (and for what reason).

Relying on consumers to trigger a review puts a lot of onus on consumer to be connected, sharing their experiences, identifying issues that need addressing and coordinating that feedback. However, in the event a health consumer organisation becomes aware of significant issues they may wish to request of review of, we support there being a transparent mechanism for initiating and being involved in that review.

Q17. The consultation document describes implementation considerations for the proposed recommendations. We are interested in the implementation considerations that are most important to you. To respond, please rank the implementation considerations listed below in order of importance.

AccessCR's ranking:

1	Invest in systemic change
2	Partnership work for positive flow-on-effects
3	Strengthen the use of consumer evidence and experience
4	Facilitate beneficial communication between the medicines industry and consumers
5	Commit to timely consumer-focused reform
6	Leverage existing and emerging strengths for consumer engagement
7	Address health equity and access needs

Q18 Please describe why you selected your #1 most important implementation consideration.

Systemic change is the most important implementation consideration, if we are to reduce current barriers and leverage most benefit from the possibilities consumer engagement could add to improving certainty in the therapeutics industry. It will force the reform, culture change, and investment that is needed to embrace the patient perspective. It will help prioritise research, development and reimbursement for those products and services that are most likely to serve the needs and interests of the targetted populations.

Q19. Are there any implementation considerations that you would like to change or add?

Leveraging existing and emerging strengths:

It is important we don't reinvent the wheel, but equally we currently have a fragmented system of advice, guidance, and responsibilities with respect to consumer engagement and involvement across the therapeutic lifecycle. Further development of disconnected guidelines by different agencies and organisations will continue to create a burden to those attempting to 'join the dots'. The development of an overarching Engagement Framework should seek to streamline the guidance and requirements, to reduce the barriers to implementation.

Commit to timeline consumer-focussed reform:

We support the intent of this consideration, and would encourage regular transparent communication about meeting outcomes, decisions on priorities and directions (and why), and the opportunity for broader public consultation when appropriate.

Facilitate beneficial communication between the medicines industry and consumers:

This is the consideration we are most challenged with. It would seem impractical and resource intensive for the Department to negotiate/facilitate all consumer-industry interactions. This approach would also potentially inhibit the development of a long-term "bench to bedside" partnership between industry and consumers in product development, which is ultimately where we should be heading. We would encourage further consideration to whether there can be a definition of patient experts and health consumer organisations added to the Therapeutic Goods Act/Legislation to allow for the exchange of information that is useful in the development (but not promotion) of therapeutic goods. This would alleviate some of the tension that currently stands in the way of enhanced consumer engagement throughout the lifecycle in Australia.

Address health equity and access needs:

This is important. We would encourage expansion of the key point to reference designing, implementing and evaluating enhancements with these diverse groups, not for them.

Q20. Do you have any further comments you would like to make about the consultation document?

A general comment regarding terminology

Terminology in this area can be confusing. Internationally, the terms 'participation', 'engagement' and 'involvement' can vary in meaning depending on your jurisdiction. To avoid confusion over intent in Australia, we would encourage a defined, intentional, and consistent use of these terms in any future framework and/or guidance documents that pertain to the nature/purpose of interactions with consumers in research and health technology assessment.

Key terms - Consumer

We would like to acknowledge the challenge that this word presents to many, and also the broad definition that has been applied to the word for the purpose of this document. In future guidance/legislation we would like to encourage a consistent definition and use of "consumer" and a recognition that in practice, individuals may prefer alternative labels such as patient, carer, caregiver, liver experience expert, citizen scientists, people with lived experience, advocate, representative, patient expert, etc depending on their circumstances, preferences and the nature of the input/involvement they are providing.

Design Principle 2 - Recommendations to enhance consumer engagement must not delay access to medicines.

As a comment, there is nuance to meeting this principle, that we would encourage consideration of. Meaningful consumer engagement can take time. In the clinical trials phase, there are pressures to start trials as quickly as possible. This need for speed can be used as an excuse why patient input has not been sought. Speed can result in issues with the protocol and operational planning that results in delays to recruitment, the additional cost of amendments and in some cases failure of protocols [1]. Some of this may have been avoided by taking a little extra time in the start-up phase to get these parameters right. So while it might look like getting patient input could slow the start up phase (and hence access), in the longer term, it can potentially also reduce operational delays that mean access will be faster.

The same could be said of patient input at the regulatory and HTA phases – having patient input and evidence up front, may actually reduce uncertainty and lead to faster access. We also think the earlier consumer input is required, the less likely consumer engagement is likely to impact later phases, as it will already be incorporated into the process. So we would ask for a considered approach as to why there are delays in access to medicines, and whether allowing more time for consumer engagement and evidence actually helps or hinders.

Figure 2 – Map of proposed recommendations

The Clinical Trial Application (CTA) or Clinical Trial Notification (CTN) schemes are not specifically mentioned as a touchpoint in recommendations 10 and 11. Further to our comments on recommendations 10 and 11 [in Q14], these could be added to Figure 2.

References:

1: Levitan B, Getz K, Eisenstein EL, Goldberg M, Harker M, Hesterlee S, et al. Assessing the financial value of patient engagement: a quantitative approach from CTTI's Patient Groups

and Clinical Trials Project. Ther Innov Regul Sci. 2018;52(2):220–229. doi: 10.1177/2168479017716715.

On the whole, AccessCR supports the majority of recommendations as important, interrelated activities necessary to enhance consumer engagement throughout the therapeutics lifecycle. There is however plenty of potential 'devil in the detail' for how they could be implemented that we appreciate are yet to be discussed. There is also additional recommendation needed with respect to properly resourcing and supporting the consumer workforce itself. How these missing elements are addressed is ultimately what will lead to success or failure in enhancing consumer engagement.

We look forward to the ongoing, transparent, public conversation about these recommendations and opportunities to contribute to enhancing consumer engagement, particularly in clinical trials, to help minimise uncertainty in the regulatory and health technology phases.

Janelle Bowden, PhD Managing Director | AccessCR Pty Ltd

