High unmet clinical need (HUCN) and high added therapeutic value (HATV) – Delphi Study

Participant Information Sheet: Version 3.0
29 April 2026

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PROJECT TITLE: High unmet clinical need (HUCN) and high added therapeutic value (HATV) definitions in Australia – Delphi Study

HUMAN RESEARCH ETHICS COMMITTEE APPROVAL: Iris Ethics, Reference Number AU5471

LEAD INVESTIGATOR: Professor Tracy Merlin

RESEARCH TEAM: Adelaide Health Technology Assessment, Adelaide University

Dear Participant,

You are invited to participate in the research project described below.

What is the project about?

The Department of Health, Disability and Ageing has contracted Adelaide Health Technology Assessment (AHTA) to undertake a research project to provide insights into the current understanding of high unmet clinical need (HUCN) and high added therapeutic value (HATV) in the HTA environment and how these terms have been defined and used nationally and internationally when referring to HTA.

The project has two main phases:

1. AHTA will undertake a desktop (scoping) review to identify common uses of the terms HUCN and HATV used in Australia and Internationally.
2. Characteristics of HUCN and HATV identified in the first phase will be presented to a panel of stakeholders in a study using an iterative Delphi survey method with the aim of reaching a consensus definition of these terms.

The goal of the project is to identify a working definition for HUCN and HATV, which may then influence prioritisation of health technologies in the Australian HTA framework. The exact use of HUCN and HATV definitions will be considered at a later date but may include eligibility for evaluation pathways and incentivising health technologies that address HUCN or that provide HATV.

Who is running the project?

The project is being run by Adelaide Health Technology Assessment, Adelaide University. The primary research team comprises of:

- Professor Tracy Merlin
- Rebecca Trowman
- Dr Mahlaka Hassan
- Dr Drew Carter
- Skye Newton

- David Tamblyn

Why am I being invited to participate?

This participant information sheet relates to the Delphi study component of the research. Potential participants have been identified through a stakeholder mapping process, including by identifying those stakeholders that provided a public submission in response to the Australian Government's HTA Policy and Methods review in 2023.

What am I invited to do?

You are being invited to participate in up to 3 rounds of online surveys (maximum number of rounds may vary based on convergence of responses). In each round, you will be provided with several questions relating to the concepts of HUCN and HATV, and your response will be analysed to gauge the importance of specific concepts to the definition of these terms.

After round 1, propositions will be modified based on responses from the first round and each participant will be provided with an aggregated anonymised summary of responses from other participants. You will then be asked to consider your previous responses and update your responses in the next round if they have changed based on the feedback from the other participants. You do not need to change your response if your position has not altered.

How much time will my involvement in the project take?

The Delphi study is expected to be run over a maximum of 3 rounds. Each round of questions is expected to take 20 to 30 minutes to complete and can be completed at any time during the survey response window (approximately 1-2 weeks for each round).

The first Delphi window will start on 30 April 2026. Subsequent windows will be scheduled after a brief period of data analysis. You will receive one notification when subsequent Delphi surveys are available, and one reminder email.

The Delphi survey will be entirely asynchronous (i.e., the survey can be answered at your convenience within the response timeframe for that round). There will be no face-to-face component of this study.

Are there any risks associated with participating in this project?

There are no foreseeable risks associated with this project related to your physical or psychological health.

There may be potential for professional or reputation risk in the adverse case of disclosure of information about your opinion or experience. However, the identities of participants in the study will not be shared with other participants. Although the storage of a contact email address is necessary to enable a link between the rounds of the Delphi surveys, the project will otherwise be anonymous. Email addresses will not be included with the analysis dataset and the likelihood of individuals being identified is very low.

Participants are encouraged to provide free-text explanations or context in response to survey questions. Participants will be reminded that identifying information should not be included in the free-text responses and will be removed by investigators if they are inadvertently included. Prior to

subsequent rounds, free-text responses will be summarised so that specific quotes will not indicate the identity of a respondent.

All study data used for analysis will be stored securely and confidentially where access is restricted to investigators within AHTA.

What are the potential benefits of the research project?

The project is not associated with any direct personal benefits. Your participation will help ensure broad and comprehensive involvement of stakeholders likely to be affected by changes to HTA pathways or prioritisation activities in the Australian setting as a consequence of defining HUCN and HATV. The project is intended to deliver improvements to the healthcare system, benefits to the Australian public, and to stakeholder groups.

What will happen to my information?

Participation in this project is completely voluntary. If you agree to participate, you can withdraw from the study at any time before the completion of this study.

The information you provide during the study will contribute important information for the outcomes of the study. If you withdraw from the study after your information has been aggregated and shared in a subsequent Delphi round, it is not possible to remove your responses. If you withdraw prior to a round and wish for your information to be removed from the study, any information that has not been aggregated into a Delphi round can be removed.

Digital copies and consent forms and transcripts will be stored within a secure area in the School of Public Health at Adelaide University. These data will be only accessible to the research team linked to this research project. Any storage drives and hard copies of the data will be kept securely in locked cabinets in a secure area in the School of Public Health. In accordance with ethics committee requirements, your information will be securely retained for five years from the data of last publication, then it will be permanently deleted.

The final results of this study will not contain any identifying information and will be summarised and provided to the Department of Health, Disability and Ageing. We expect the results will be published either in a stand-alone publication, or as part of broader research into HTA reform in Australia. The raw survey data from the Delphi study will not be re-used or shared. We will email you a summary of findings after completing analysis of all Delphi results. If you would prefer not to participate, but would still like a summary of findings when they are ready, please email us to let us know.

Your information will only be used as described in the participant information sheet, and it will only be disclosed according to the consent provided, except as required by law.

None of the researchers have a conflict of interest.

Who do I contact if I have questions about the project?

If you have any further questions regarding the project you can contact any of the listed research team members via the AHTA email address:

- Professor Tracy Merlin

- Rebecca Trowman
- Dr Mahlaka Hassan
- Dr Drew Carter
- Skye Newton
- David Tamblyn

AHTA email address: ahta@adelaide.edu.au

What if I have a complaint or any concerns?

The study has been approved by a Human Research Ethics Committee at Iris Ethics (reference number AU5471). This research project will be conducted according to the 2025 Edition of the National Statement on Ethical Conduct in Human Research. If you have questions or problems associated with the practical aspects of your participation in the project or wish to raise a concern or complaint about the project, then you should consult the Lead Investigator (Prof Tracy Merlin). If you wish to speak with an independent person regarding concerns, a complaint, or your rights as a participant, please contact the Iris Ethics Human Research Ethics Committee:

Phone: +61 8 8313 6028

Email: complaints@irisethics.com.au (note the reference number AU5471)

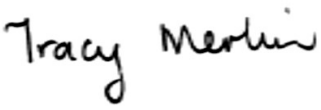
Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.

If I want to participate, what do I do?

If you would like to participate in the research project, a link to the Delphi study is included in the introductory email to which this information sheet has been attached. The first page of the Delphi survey will ask you to provide consent, request your email address for subsequent rounds, and provide you with a unique ID (which will be used to link the rounds of your Delphi responses).

You are expected to answer the Delphi survey questions as yourself, but you will be asked what organisation or sector you feel you best represent.

Yours sincerely,



Professor Tracy Merlin