An update on the MSAC Guidelines review

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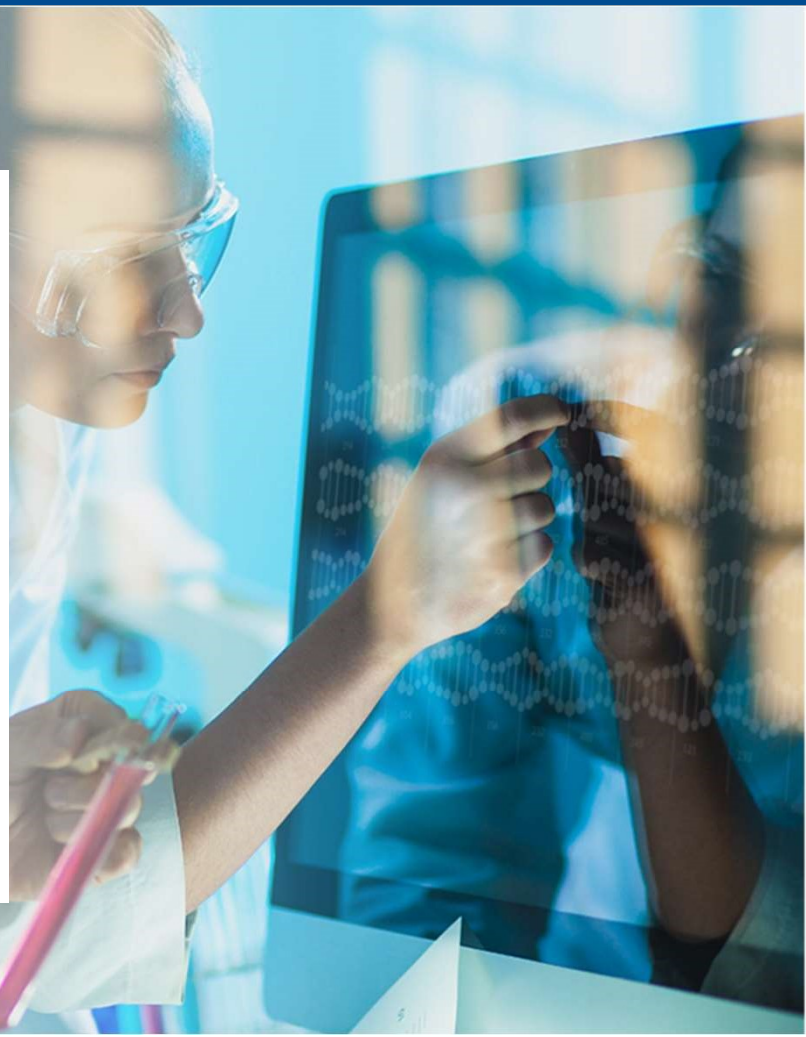
Chair
MSAC Guidelines Review Technical Reference Group



Revised MSAC Guidelines

What will be covered in this webinar

- Background – MSAC and it's remit
- MSAC methods vs MSAC processes
- Rationale for reviewing the MSAC Guidelines
- Approach to the review
- Key changes to the MSAC Guidelines
- Further information

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Medical Services Advisory Committee

- Members have expertise in different clinical areas, health economics, and consumer issues
- Meets 3 times per year and provides advice to the federal Minister for Health on whether a medical service should be publicly funded via the MBS, and the conditions of that listing
- Also appraises health technologies and programs funded through alternative public funding sources (e.g. national screening programs; blood and blood-related products via the National Product List)

Basis of advice from MSAC

Based on established principles of health technology assessment (HTA):

- Is the service/health technology effective?
- Who is it for? Which patients would be eligible for public funding?
- Is it safe – what are the risks or harms associated with it's use?
- How much does it cost – to patients and to the health system?
- Is it cost-effective – does it represent value for money?
- Are there any other social, legal, ethical impacts?

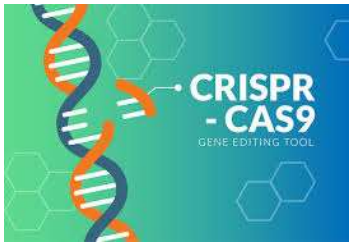
MSAC's remit

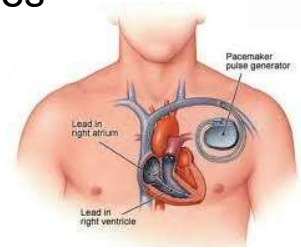
- To provide advice on the **comparative** safety, effectiveness, and cost-effectiveness of a range of health technologies and services

Prostheses

Recombinant clotting factors

Gene editing



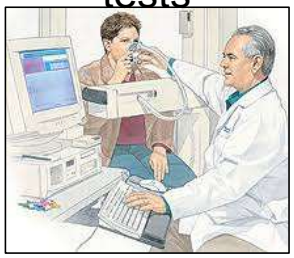


Within-hospital mobile resuscitation team

Therapeutic

Imaging

Genetic tests



Functional tests

Investigative

MSAC methods

How and **why** relevant information is selected and presented to MSAC:

- MSAC Technical Guidelines – Therapeutic services (2016)
- MSAC Technical Guidelines – Investigative services (2017)
- Clinical Utility Card Proforma
- Guidelines for Codependent Technologies (*with PBAC*)

Focus of Guidelines review

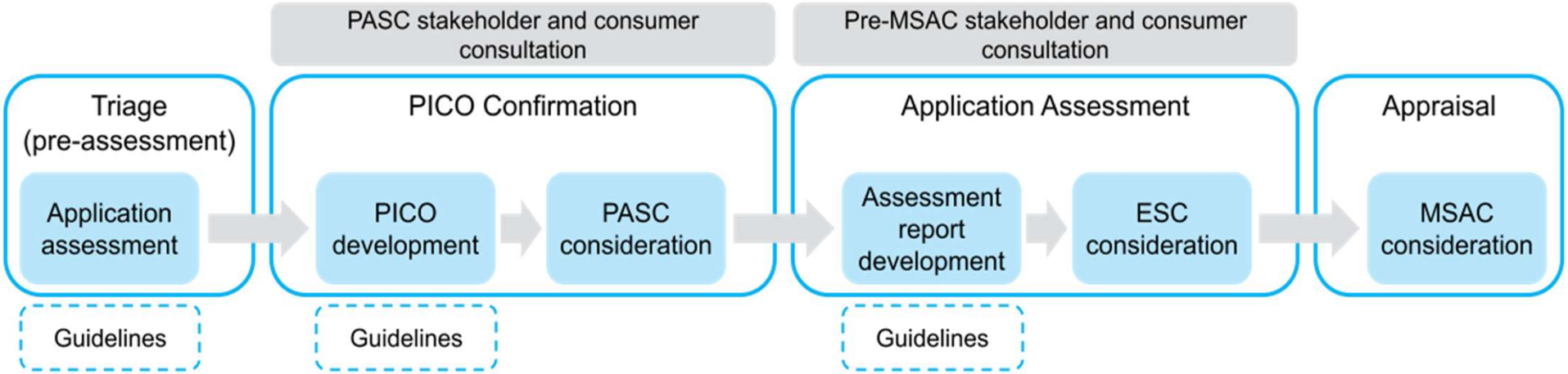
MSAC processes

Who does what and **when** to select and present relevant information to MSAC:

- Role of MSAC subcommittees – PASC and ESC
- Role of Consumer Consultative Committee
- Opportunities for engagement by applicants, consumers, and other stakeholders

↔ **Process improvements**

Relationship between methods and processes



For information on recently announced improvements to the consultation process please go to the **MSAC Consultation Process page**

http://msac.gov.au/internet/msac/publishing.nsf/Content/MSAC-Consultation-Process

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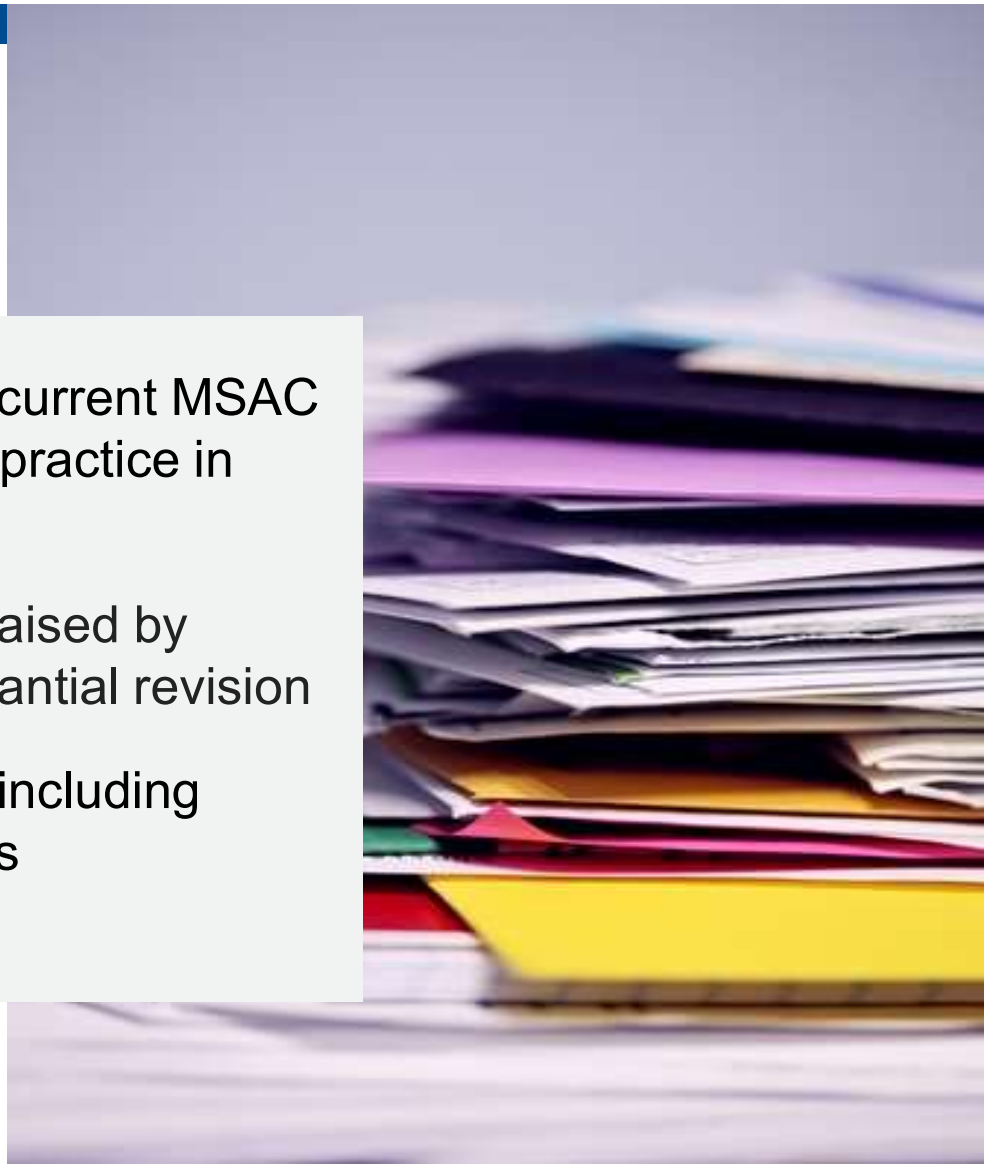
The MSAC Guidelines

- Technically-focused
- Provide detailed guidance on presenting clinical, economic and financial information to PASC, ESC, and MSAC
- Used by applicants, HTA groups, and others (including interested consumer organisations) to develop the documents that underpin the MSAC assessment process
- Accompanied by **templates** for completing these documents: Application form, PICO Confirmation, Assessment Reports, Commentaries

MSAC Guidelines Review
Rationale for the review

- Aim of the Guidelines Review was to ensure current MSAC assessment processes are aligned with best practice in HTA
- To address technical methodological issues raised by MSAC and stakeholders, since the last substantial revision
- To provide guidance for newer technologies, including genetic/genomic testing for heritable diseases



Previous MSAC Guidelines
Overall structure

- Guideline structure mirrored Assessment Report Structure
  - Section A – Details of proposed technology and its place in practice
  - Section B – Clinical evaluation
  - Section C – Translation issues
  - Section D – Economic evaluation
  - Section E – Utilisation and financial implications
  - Section F – Other relevant factors
- Across Investigative/Therapeutic Guidelines, Sections A and C-F similar, but Section B quite different

Previous MSAC Guidelines
Structure of Section B

Therapeutic services

B1 – Search strategies

B2 – Listing studies

B3 – Bias

B4 – Characteristics

B5 – Outcomes

B6 – Results

B7 – Extended harms

B8 – Interpretation / conclusion

Investigative services

B1 – Direct evidence
- B1.1 – Search strategies
- B1.2 – Results

B2 – Linked approach
- B2.1 – Basis for linked evidence
- B2.2 – Steps for linked analysis

B3 – Diagnostic performance
- B3.1 – Reference standard
- B3.2 – Search strategies
- B3.3 – Listing of studies
  - B3.3a – Listing of direct studies
  - B3.3b – Listing of indirect studies
- B3.4 – Bias
- B3.5 – Characteristics
- B3.6 – Results
- B3.7 – Extended reliability
- B3.8 – Concordance
- B3.9 – Interpretation / conclusion

B4 – Clinical validity
- B4.1 – Measures
- B4.2 – Supplementary data for prognosis

B5 – Clinical utility
- B5.1 – Impact on management
- B5.2 – Therapeutic effectiveness

B6 – Impact of repeat testing

B7 – Extended harms

B8 – Overall interpretation / conclusions

Approach to the Review

Governance

- Steering Committee (SC)
- Technical Reference Group (TRG)

Process

- Regular meetings to define scope (SC) and workplan and changes in response to consultation (TRG) [July 2019 – May 2021]
- Public consultation [6 weeks from Aug to Oct 2020]
- Targeted consultation [6 weeks from Dec 2020 to Jan 2021]

Resourcing

- Dedicated unit within Department & Contracted assessment group

Responses to consultation

- **Public consultation**: Forty-five (45) submissions received from:
  - Patient advocacy groups
  - Pharmaceutical companies
  - Medical technology companies
  - Clinical groups
  - HTA groups/consultancies
  - Individuals
- **Targeted consultation**: submissions were also received from:
  - MSAC/PASC/ESC members
  - TGA and Departmental experts
  - the HTA Consumer Consultative Committee

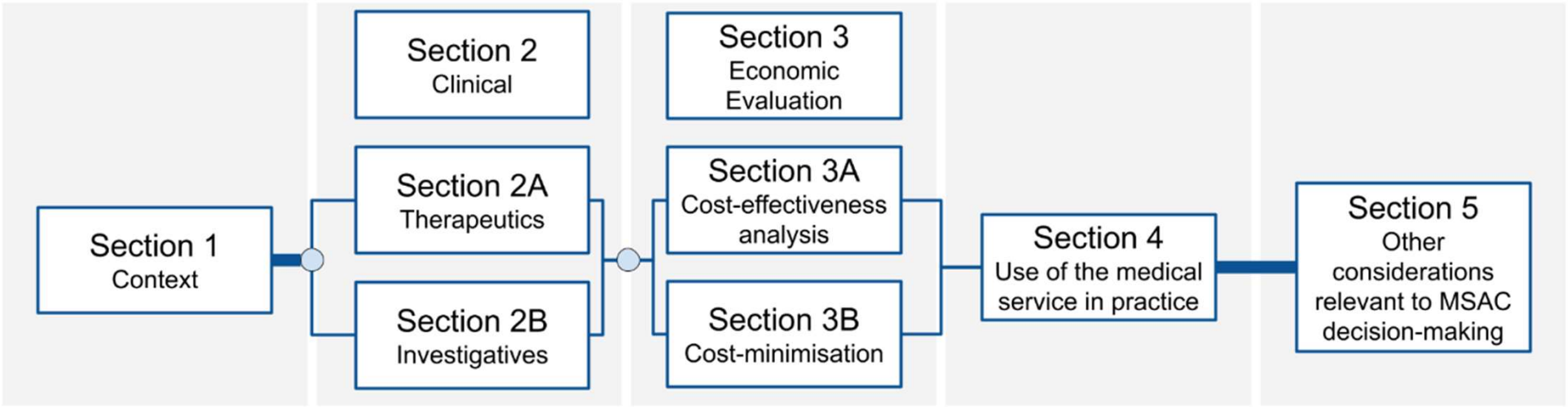
Addressing feedback from consultation

- All feedback related to **process** matters was collated and provided to the Department for consideration. Process matters were not considered by the TRG or SC.
- All feedback related to **methodological matters** was documented and analysed by theme and sub-theme
- Each theme was discussed by the TRG and an approach to addressing the issue(s) was proposed and subsequently endorsed or revised by the SC
- All responses to feedback were documented – including decisions not to revise the draft Guidelines in response to feedback

Key themes from consultation feedback

1. Concern that the MSAC Guidelines are written in an overly technical way
2. Mixed reactions to new structure of Guidelines
3. Concern that the new ‘diagnostics’ information was overly complicated
4. Perception that too much emphasis is placed on RCT evidence
5. Support for the concept of ‘exemplar’ and ‘facilitated’ genes in gene panels
6. Strong support for the inclusion of the concept of ‘personal utility’

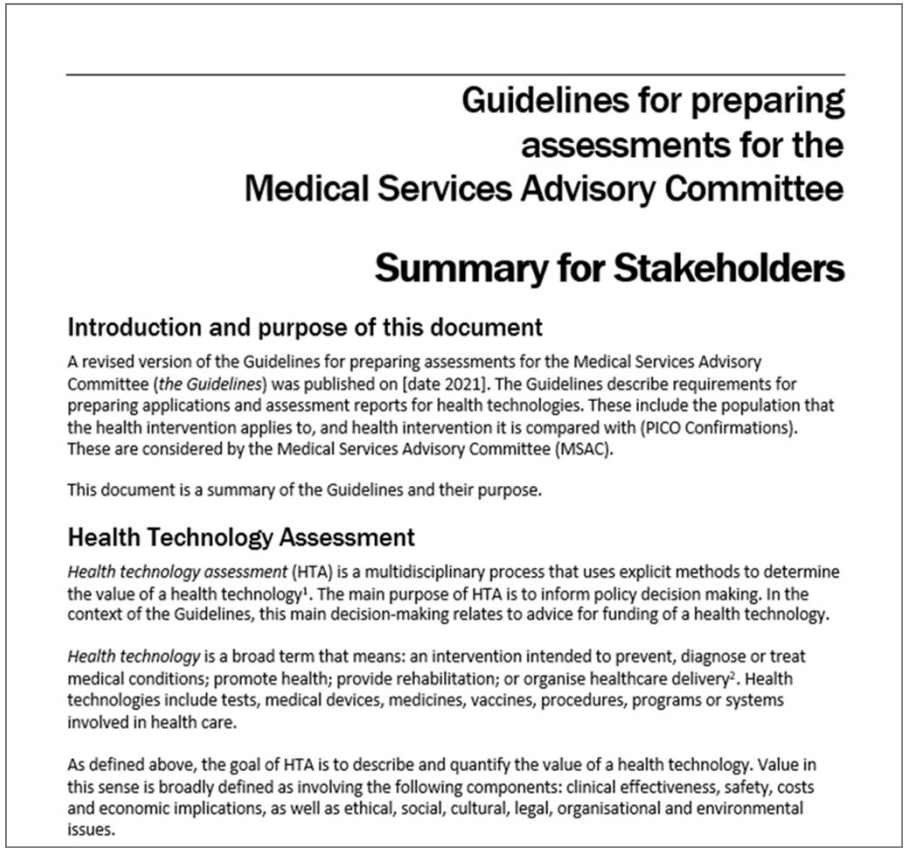
Changes to Assessment Report structure



Section 1 informs the PICO Confirmation and the assessment report. It establishes the context of the assessment by presenting the purpose for the request for reimbursement and the PICO.	Section 2 presents the best available clinical evidence to support the clinical claim (comparative effectiveness and safety)	Section 3 describes the economic evaluation of substituting the proposed technology with the main comparator.	Section 4 presents the most likely extent of use of the technology in clinical practice, and an estimate of the financial implications to the Commonwealth Government and funders.	Section 5 discusses additional, less quantifiable factors that may influence MSAC decision making, including other or personal utility, ethical, organisational and social factors.

How feedback has shaped the final Guidelines
Theme 1

- MSAC Guidelines are necessarily technical
- Remain written for their primary audience of HTA professionals
- Companion document has been written for a broader audience, to explain what MSAC considers and why:
  - **Summary for Stakeholders**
  - http://www.msac.gov.au/internet/msac/publishing.nsf/Content/MSAC-Guidelines



Guidelines for preparing assessments for the Medical Services Advisory Committee

Summary for Stakeholders

Introduction and purpose of this document

A revised version of the Guidelines for preparing assessments for the Medical Services Advisory Committee (*the Guidelines*) was published on [date 2021]. The Guidelines describe requirements for preparing applications and assessment reports for health technologies. These include the population that the health intervention applies to, and health intervention it is compared with (PICO Confirmations). These are considered by the Medical Services Advisory Committee (MSAC).

This document is a summary of the Guidelines and their purpose.

Health Technology Assessment

Health technology assessment (HTA) is a multidisciplinary process that uses explicit methods to determine the value of a health technology[1]. The main purpose of HTA is to inform policy decision making. In the context of the Guidelines, this main decision-making relates to advice for funding of a health technology.

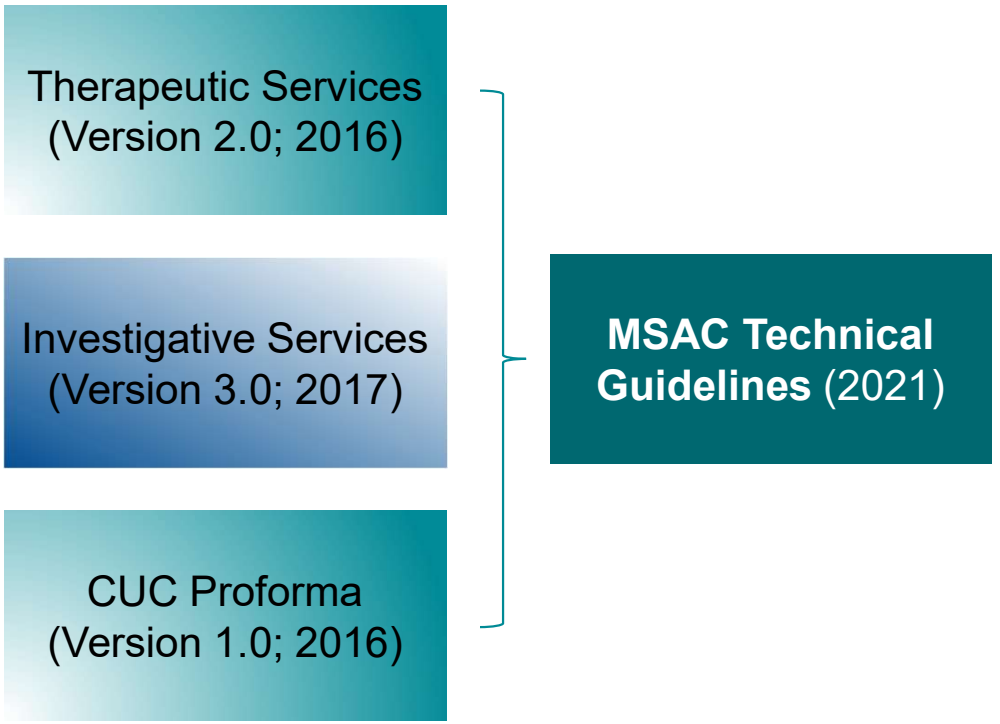
Health technology is a broad term that means: an intervention intended to prevent, diagnose or treat medical conditions; promote health; provide rehabilitation; or organise healthcare delivery[2]. Health technologies include tests, medical devices, medicines, vaccines, procedures, programs or systems involved in health care.

As defined above, the goal of HTA is to describe and quantify the value of a health technology. Value in this sense is broadly defined as involving the following components: clinical effectiveness, safety, costs and economic implications, as well as ethical, social, cultural, legal, organisational and environmental issues.

How feedback has shaped the final Guidelines
Theme 2

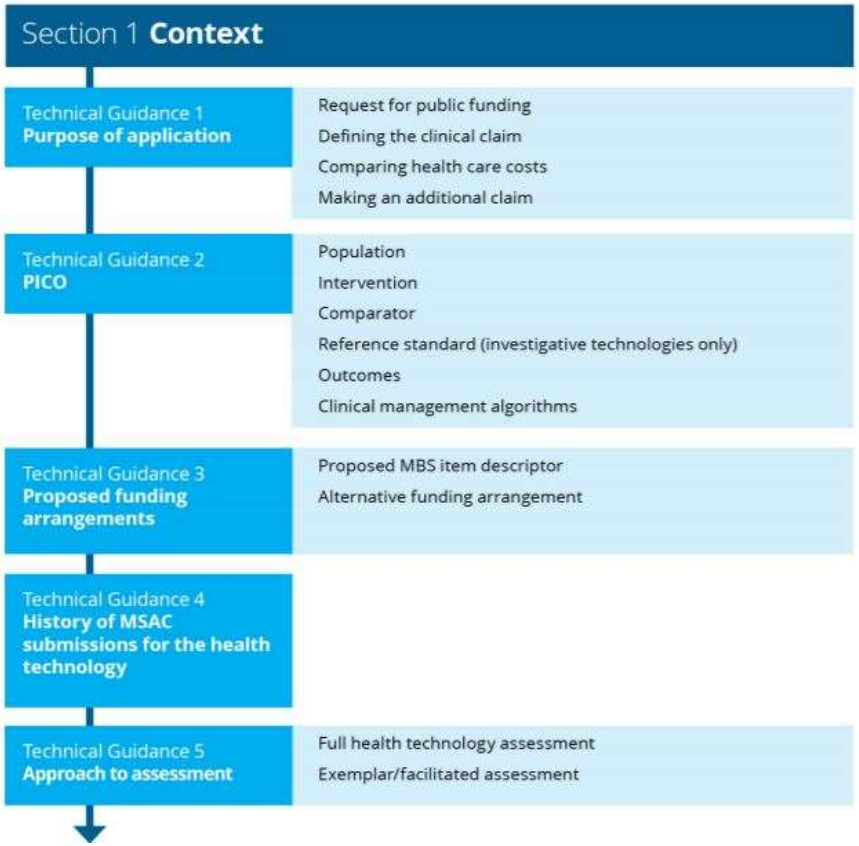
Guidelines and Templates restructured simultaneously:

- All previous Guidelines now combined in one resource
- Guideline organised by Chapters **not** by Assessment Report Sections – is now more like a 'manual'
- Templates cross-reference relevant Chapters in the Guidelines



How feedback has shaped the final Guidelines

Theme 2



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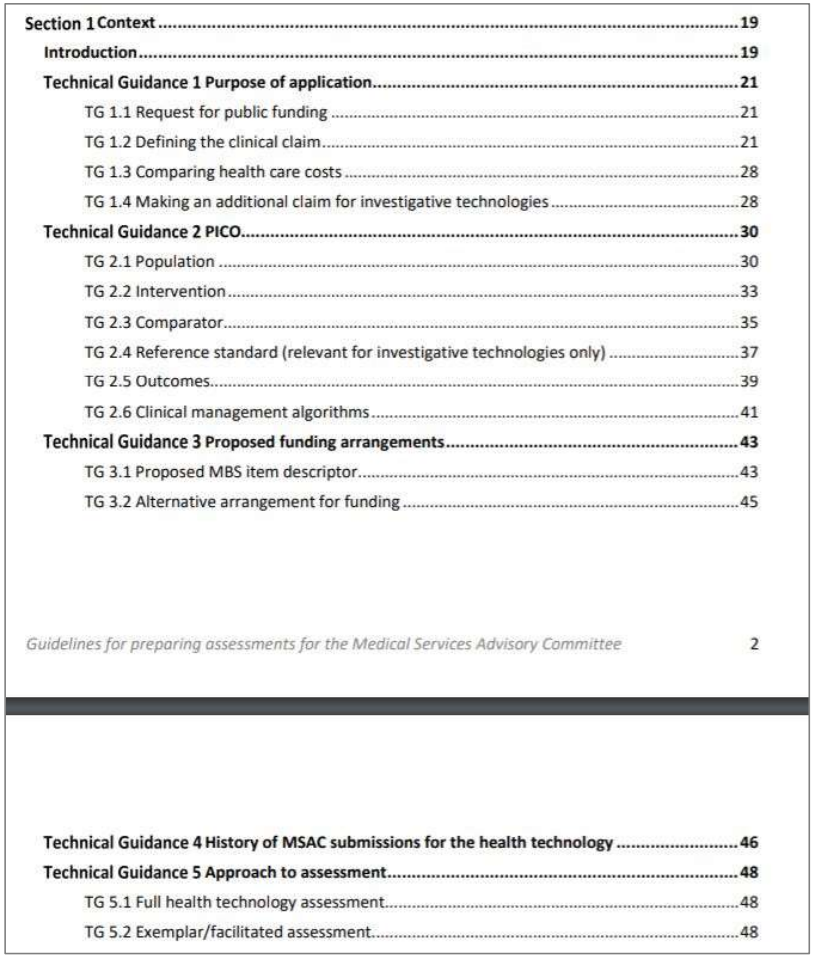
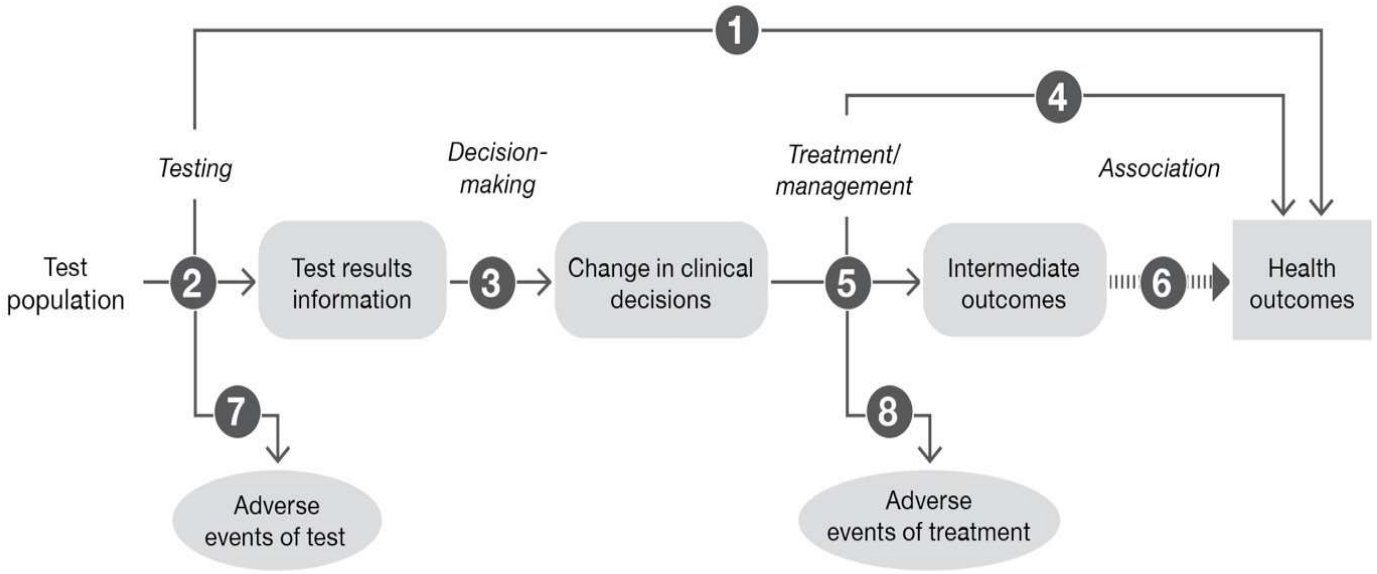


How feedback has shaped the final Guidelines
Theme 3

Assessment frameworks for investigative services have been simplified, and accompanying text edited for clarity



1: direct from test to health outcomes evidence

2: test accuracy

3: change in diagnosis/treatment/management

4: influence of the change in management on health outcomes

5: influence of the change in management on intermediate outcomes

6: association of intermediate outcomes with health outcomes

7: adverse events due to testing

8: adverse events due to treatment

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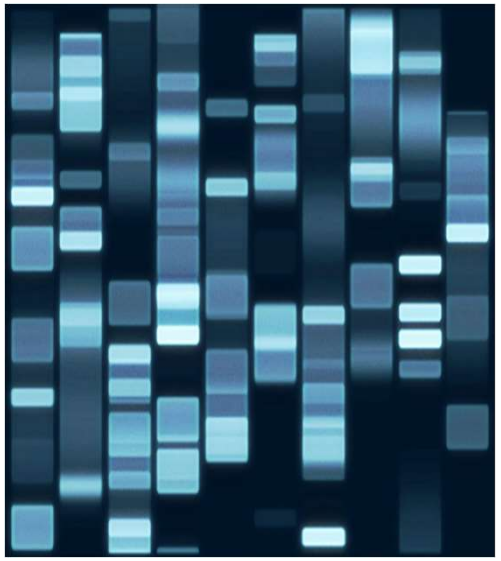
How feedback has shaped the final Guidelines
Theme 4

- Emphasis on **RCT evidence** remains
- MSAC's remit is to consider **comparative** safety, effectiveness, and cost-effectiveness
- Most reliable way to do that is with comparative evidence, and most reliable comparative evidence is from RCTs
- BUT relevant evidence from other study designs will be considered and 'real world' evidence has always been allowed
- The higher the quality of that 'real world' evidence the more likely it is to influence MSAC advice (e.g. longitudinal data from a well-conducted, prospective clinical registry study)

How feedback has shaped the final Guidelines
Theme 5

Exemplar/Facilitated approach

- When full HTA of a technology is not likely to be feasible
- Simplifies the assessment of related technologies
- Currently restricted to investigative (genetic) tests
- Unlikely to apply to therapeutic interventions



Exemplar / Facilitated Approach
Example

Type of technology	Exemplar aspect	Facilitated aspect
Gene panel for a testing for a specific condition in a specific population	One or several genes on a panel that have evidence to support claim of clinical utility of testing	Additional genes in the same panel do not have strong evidence for clinical utility on their own (e.g. due to rarity), but including them enhances diagnostic yield with no additional testing cost
Testing for heritable breast cancer in individuals with breast cancer	BRCA1, BRCA2	STK11, PTEN, CDH1, PALB2, TP53

How feedback has shaped the final Guidelines
Theme 6

- Concept of **Personal utility** was introduced in the draft revised Guidelines
- It is now clarified as the **Value of knowing**
- Applies to investigative services only
- Captures non-health impacts of testing
  - ‘Peace of mind’ - Confirming a diagnosis or prognosis without any change in treatment options/clinical management or health outcomes
- Non-health impacts may also be negative
  - e.g. Detection of non-paternity, loss of hope

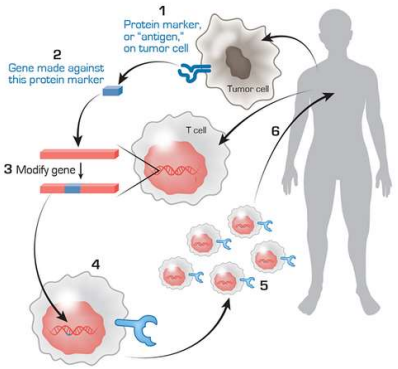
Other key changes in final Guidelines
Cascade testing for family members

- Key concept from CUC Proforma
- Genetic testing for heritable conditions impacts on:
  - ❑ clinically affected individuals
  - ❑ and their biological relatives (cascade testing)
- Cascade testing allows estimation of each family member's predisposition for future risk of developing the clinical disease
- Clinical utility may accrue to the affected individual and/or to their family members,
  - ❑ 'co-production of utility' captured in the economic modelling

Other key changes in final Guidelines
Highly Specialised Therapies

- Under the National Health Reform Agreement (NHRA; 2020-2025), Highly Specialised Therapies (HST) are assessed by MSAC, and co-funded by the Commonwealth and State/Territory governments
- From an HTA perspective, the approach to the clinical and economic evaluations for HSTs are no different to other therapeutic technologies
- EXCEPT that the setting of service delivery is different (public not private hospitals), and the different payers must be accounted for when developing budget impact analyses

CAR-T therapy



Other key changes in final Guidelines

Other relevant considerations

- Provides guidance on how to identify other factors that may influence MSAC decision making, and applies to investigative and therapeutic technologies.

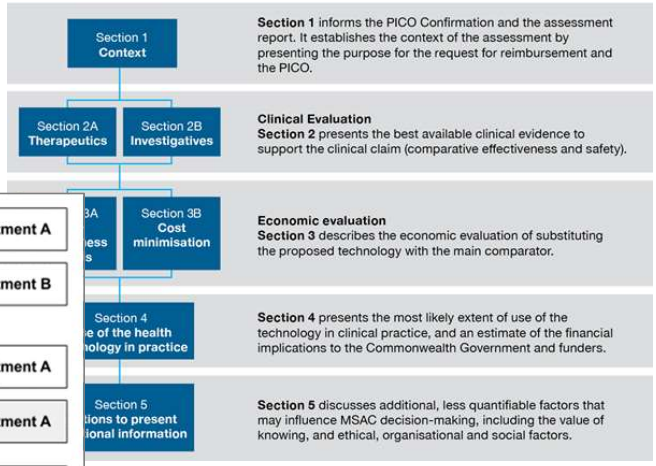
- Identify issues most likely to affect MSAC decision making, rather than provide an exhaustive review of possible issues.

The issues of most relevance are:

- ❑ unique to the proposed technology, which MSAC is unlikely to have considered previously
- ❑ have an impact on the way that clinical or economic evidence is interpreted
- ❑ those that were included in the Ratified PICO Confirmation, for further assessment

Other key changes in final Guidelines
Sign-posts and visual summaries

- Cross-referencing between Guidelines and Templates
- Visualisation of key concepts
- Call-out boxes for each TG



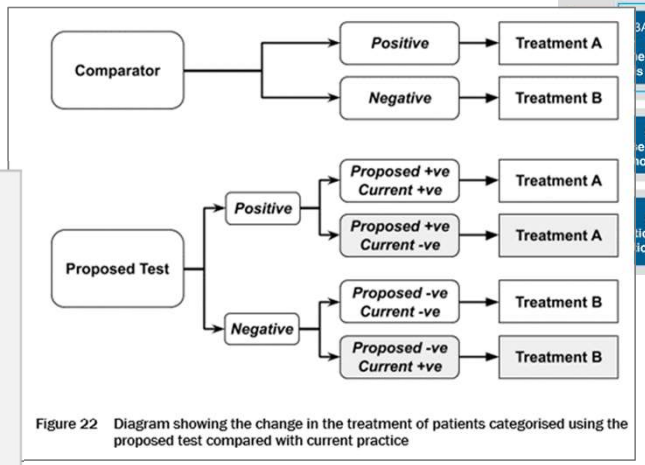


Figure 22 Diagram showing the change in the treatment of patients categorised using the proposed test compared with current practice

KEY CONSIDERATIONS

- Summarise the request for public funding (TG 1.1)
- Provide a claim, based on safety and effectiveness of the proposed health technology, compared with the main comparator (TG 1.2)

For investigative technologies

- If the proposed technology is unlikely to be considered cost-effective on the basis of health gains, provide a claim based on the 'value of knowing', that is derived from the proposed investigative technology, compared with the main comparator (TG 1.4)

Revised MSAC Guidelines
Further information

- Guidelines for preparing assessments for the Medical Services Advisory Committee (MSAC Guidelines)

- The new MSAC Guidelines and associated Templates were published on 16 June

- Targeted education sessions will be made available to assessment groups, consultants and applicants. The Department will make announcements about these sessions in future

Questions

Email: MSAC.Guidelines@health.gov.au