Medical Services Advisory Committee (MSAC)

Review of the Guidelines for Preparing Assessment Reports: **Consumer Briefing**

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Webinar objectives

Inform participants on:

- The Review of MSAC's current Guidelines for seeking public funding via the Medicare Benefits Schedule (MBS) or other funding source - i.e. the
  - Therapeutic Guidelines for Preparing Assessment Reports
  - Investigative Guidelines for Preparing Assessment Reports
- Key changes to the Guidelines
- How to participate in the public consultation

Offer an opportunity to answer your questions about the review or public consultation process

Medical Services Advisory Committee (MSAC)

MSAC advises the Minister for Health on applications for public funding via the Medicare Benefits Schedule (MBS) and other funding sources

Medicare Benefits Schedule:

- Reimburses consumers (partially or fully) for medical services.
- Medical services can be **therapeutic**, **investigative** and/or **consultative**

Medical service applications are broad; from a GP consultation through to insertion of devices, imaging (e.g. MRI or X-rays) and genetically engineered cells (e.g. CAR-T cells)

MSAC also appraises health programs (e.g. community pharmacy programs) and other health technologies funded through other public funding sources (e.g. blood products and blood-related products through the National Blood Authority)

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How MSAC works

Health technology assessment (HTA) processes

Uses the best available evidence to consider and compare safety, clinical effectiveness, cost-effectiveness/financial impact and other considerations

Consultation process

MSAC asks:

- Does it work? (How well and in comparison to standard care)
- For whom?
- Are there risks/harms?
- How much does it cost?
- Is it value for money?
- Are there any other social, legal, professional, ethical impacts?

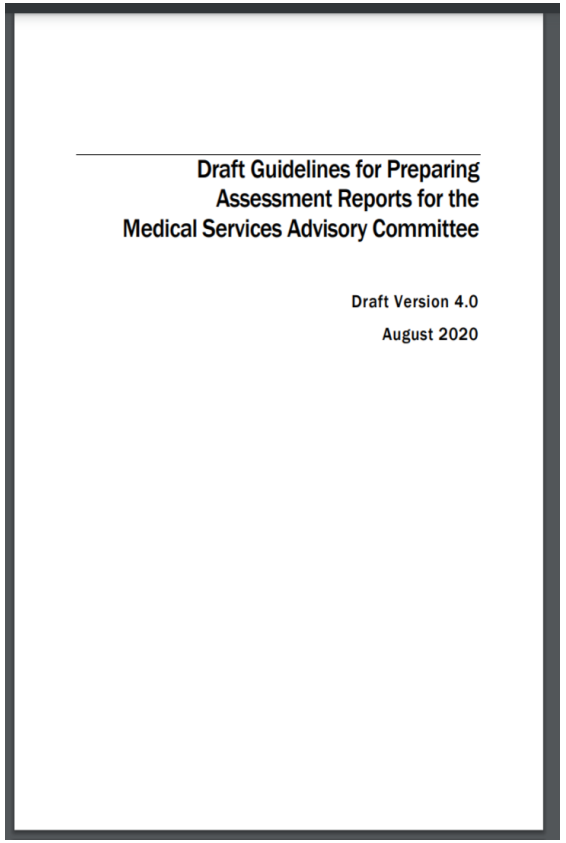
Review of MSAC Guidelines

The Guidelines provide practical information on how to present evidence to MSAC and its Sub-Committees

Used by applicants, health technology assessment groups, others *including interested consumers/organisations*

The Guidelines Review aims to help applicants :

- understand what MSAC needs to consider, including the level and types of evidence
- submit quality applications
- update information on the requirement for new technologies, such as genetic testing



How is the Review relevant for consumers

MSAC's advice affects consumers, so consumers are encouraged to be aware of (and involved in) the Review.

Principles underpinning Australian Government HTA processes

- Transparent and accountable
- Consultative and reflective of Australian community values
- Fit for purpose
- Informed by robust evidence

Understand opportunities for development of consumer-based evidence where there are identified gaps.

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Review Scope

The Review is looking at the Guidelines ***on the technical methods for undertaking a health technology assessment of a medical service***

Includes guidance on :

- establishing the context of an assessment (population, intervention, comparator, outcomes)
- how to conduct a literature search and what studies to include
- analysing and assessing the studies to be included
- conducting an economic analysis and budget impact analysis

The Review is not considering processes (for example: how and when consultation occurs). This is covered in the ***MSAC Process Framework,*** which will be reviewed in the future.

Key Guideline changes

New and refocussed advice on:

- **Evidence** (clinical claims and health outcomes at the forefront)
- **Investigative technologies** (e.g. tests and how best to provide evidence when no there's no direct evidence)
- **Personal utility** (e.g. definition of what this means)
- **Economic modelling**

New and refocussed advice

Technical Guidance (TG) on issues that may be of interest to consumers:

- Recognition of patient-relevant outcomes [TG1 and TG2]
- Inclusion of qualitative information [TG28]
- Incorporation of ethical issues [TG1, TG2, TG8, TG9, TG16, TG29]
- Assessment of new disruptive technologies [TG5 and TG15]
- Acknowledgement of benefits and harms outside of health outcomes [TG28 and TG29]

Evidence

Focus on studies (evidence) that address:

- health outcomes
- patient-relevant outcomes

Guidance on providing evidence for other relevant considerations, including:

- ethical issues
- organisational aspects
- patients and social aspects
- legal aspects
- environmental aspects
- rule of rescue

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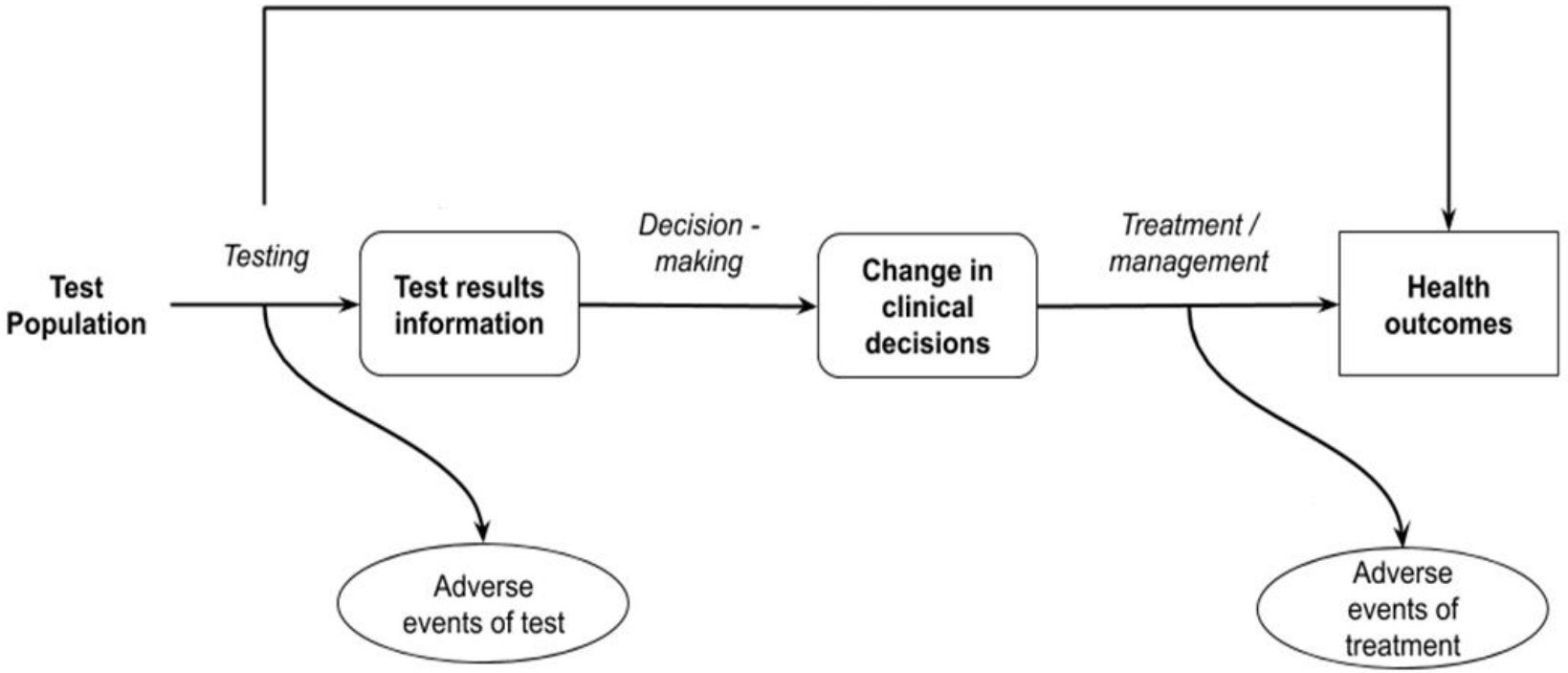
Investigative technologies

Development of a framework to look at investigative technologies



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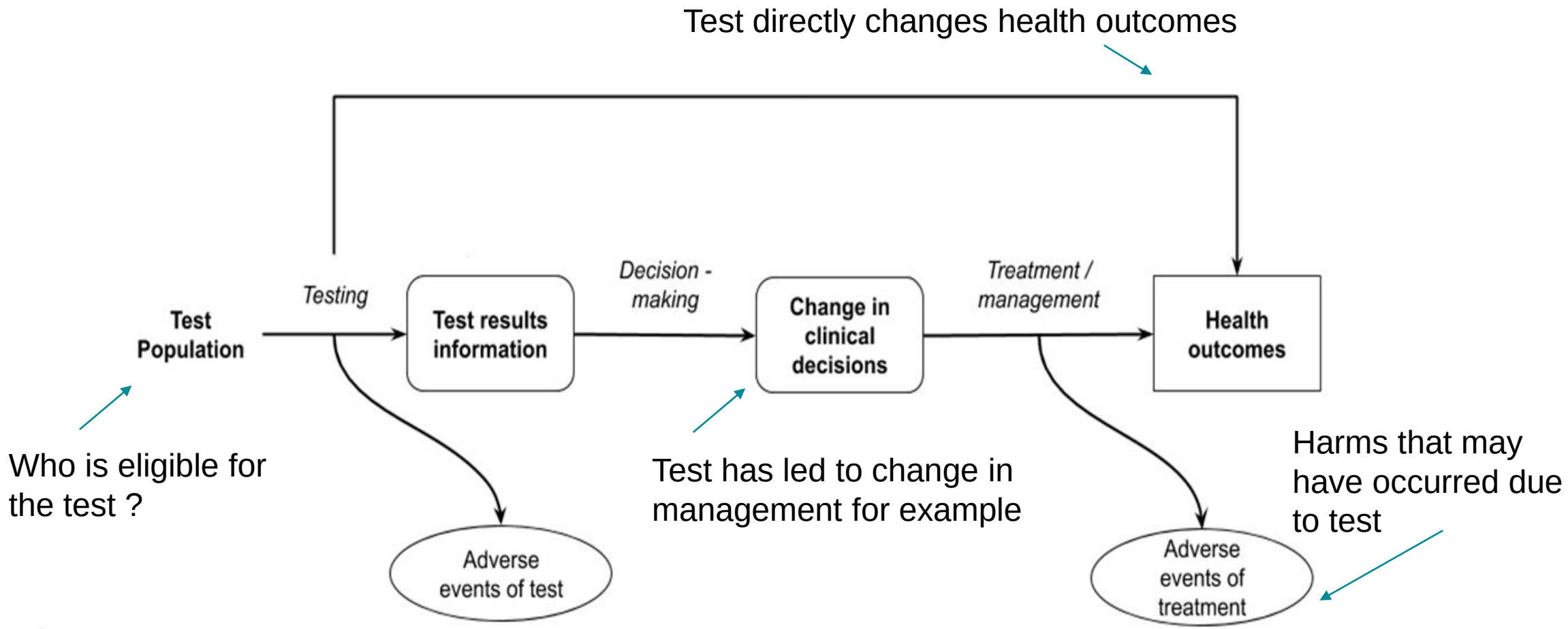
Investigative technologies



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Evidence – Other relevant considerations

- **Ethical issues**
- **Organisational aspects**
- **Patients and social aspects**
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- **Legal aspects**
- **Environmental aspects**
- **Rule of rescue**

New definitions

Clinical utility – The health benefit/harm derived from a health technology

Other utility - The umbrella term for types of utilities (or things people value), which have not been quantified in the clinical utility evidence. This could be for the patient, or their family members/carers. If the benefit is for the patient, this can be termed ‘personal utility’

Personal utility - This includes concepts such as the benefits and harms of knowing, the benefits and harms of naming, and the impact on patient well-being through being able to plan non-health resources such as accommodation, education, insurance.

Personal utility

- In some cases, an investigative technology is used to detect a condition (often a diagnosis or prognosis) for **which there is no effective treatment, or that will not result in a change in treatment**.
- The value of the technology is then in terms of the benefits and harms that arise (for the patient or the family) from the knowledge of the results
- The review of the MSAC Guidelines acknowledges these issues under the new concept of personal utility.

Personal utility

Examples of personal / other utility are provided, including:

- Ending the patient's diagnostic odyssey
- Reproductive planning
- Long-term planning (education, career, housing, finances etc)
- Increased / decreased sense of control
- Psychological (positive or negative) impact on index patient
- Stigmatisation or discrimination
- Access to National Disability Insurance Scheme
- Greater understanding of future health care needs
- The ability to connect with others in the same situation

An example: Genetic testing for childhood syndromes

First considered by MSAC in July 2018
MSAC did not support the application, but acknowledged the high clinical need for whole exome analysis (WEA) for childhood syndromes.

MSAC was concerned about several issues, including:

- who would be eligible for the test
- what was the best type of technology to perform the test
- the limited data provided for effects of changes in clinical management and improvement in health outcomes
- implementation issues, such as equity of access, ethics of consent and specialised workforce availability

An example: Genetic testing for childhood syndromes

MSAC held a stakeholder meeting in October 2018.

In addressing health outcomes, MSAC heard how a genetic confirmation helped families in accessing support or enabling avoidance of unnecessary interventions.

Following the stakeholder meeting, MSAC considered the application again

Review of MSAC Guidelines gives new advice for applicants on what information to include.

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How to participate in the consultation

- Open process
- Can focus on one particular point or question
- For example, in commenting, you may advise:
  - What should be included in the definition of personal utility?
  - What should be included in other relevant considerations ?
  - What are the key pieces of consumer evidence or perspectives that should be included ?

How to participate in the consultation

- Consultation Hub
https://consultations.health.gov.au/technology-assessment-access-division/msac-guidelines-review-consultation/

- Feedback to be provided by **12th October 2020**

- Consumers and consumer groups can contact the Consumer Evidence and Engagement Unit email: HTAconsumerengagement@health.gov.au
or the MSAC Guidelines Team: MSAC.Guidelines@health.gov.au

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Useful links

Overview of how to apply for public funding
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/how-to-apply-for-public-funding

Overview of the MSAC process
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/guidelines-review-webinars

Principles of the Australian Government HTA framework
https://www1.health.gov.au/internet/hta/publishing.nsf/Content/policy-1#principles

MSAC Process Framework
http://www.msac.gov.au/internet/msac/publishing.nsf/Content/msac-process-framework

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Questions

Email: MSAC.Guidelines@health.gov.au