MSAC Guidelines Review
Technical User Briefing

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17 September 2020

Webinar Objectives

Inform participants on:

- The review of the Guidelines for preparing assessment reports for the Medical Services Advisory Committee
- Proposed key changes to the Guidelines structure and guidance
- New approaches to preparing assessment reports
- *Key areas for feedback*
- How to participate in the public consultation

Respond to questions submitted prior to or during the webinar.

Review Process

Objectives

- Address the technical issues in the Guidelines raised by MSAC and stakeholders since the last substantial version
- Provide guidance for newer technologies
  - Genetic testing for heritable diseases
  - Screening tests (and other types of test purpose – prognostic, predictive, monitoring)
  - Exemplar / facilitated
  - Emerging technologies – AI / multifactorial algorithms
  - Alternative funding streams
  - Broader types of utility
- Ensure assessment processes are aligned with best practice in HTA

Steering and Technical committees

Public consultation

Current Guidelines

Current Guidelines (Therapeutic – 2016; Investigative – 2017)

Structure:

Section A – Details of the proposed technology (PICO + MBS listing)

Section B – Clinical evaluation + B(i) – indirect comparisons, B(ii) – non-randomised studies

Section C – Translation issue + C(i) – indirect comparisons

Section D – Economic evaluation + D(i) cost-minimisation

Section E – Utilisation and financial implications

Section F – Other relevant factors

Current Guidelines

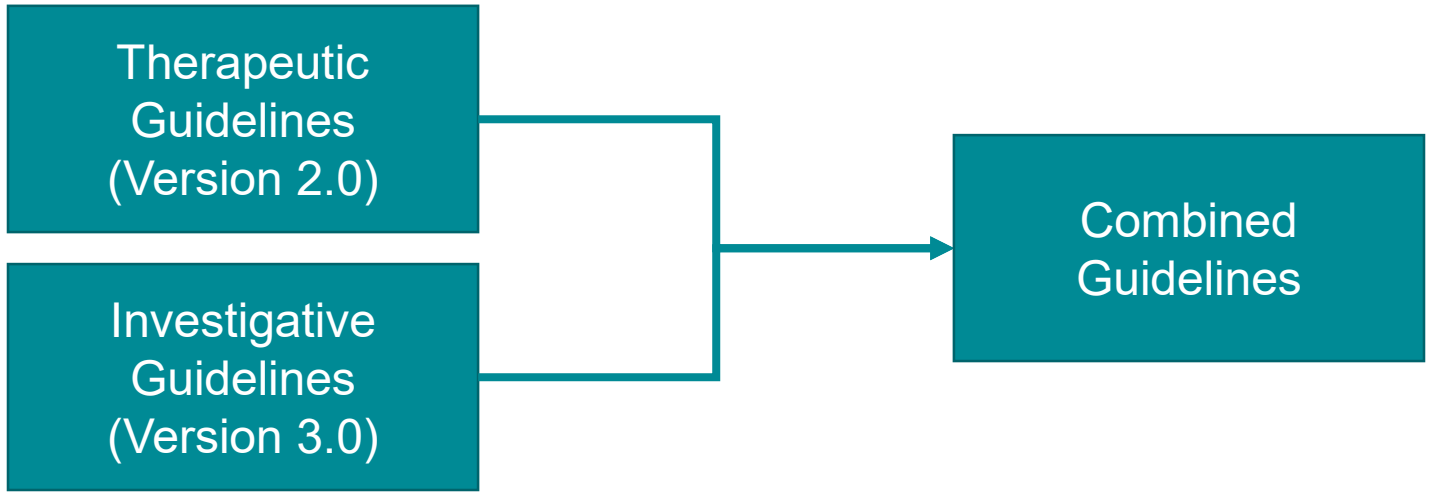
Therapeutic structure

- B1 – Search strategies
- B2 – Listing studies
- B3 – Bias
- B4 – Characteristics
- B5 – Outcomes
- B6 – Results
- B7 – Extended harms
- B8 – Interpretation / conclusion

Investigative structure

- 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

Combining the Guidelines



Version 1.0 of the Guidelines released in 2012.

By 2013, preparation to separate the Guidelines for therapeutic and investigative technologies. Separate Guidelines published in 2016.

Combined Guidelines for therapeutic and investigative technologies.

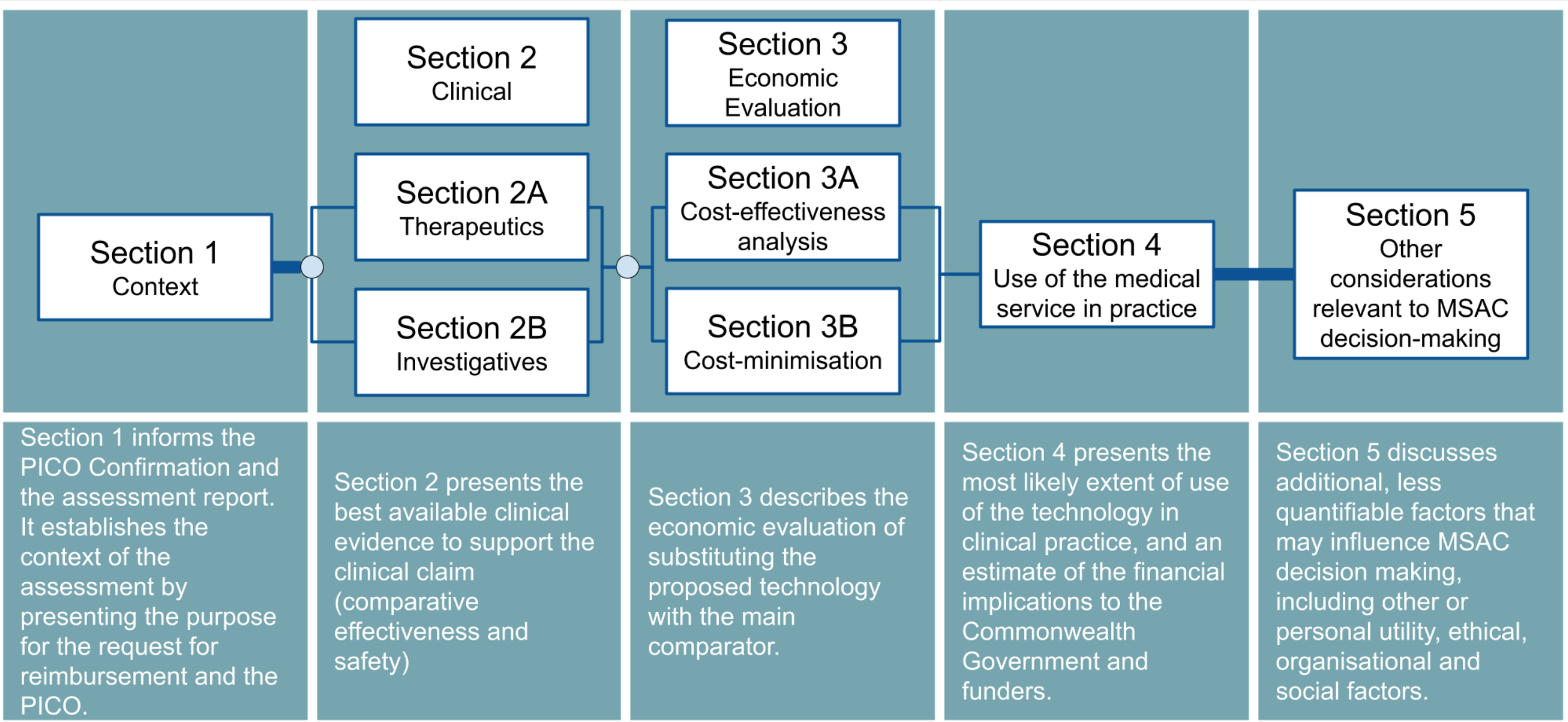
“Template” vs “Manual”

Current MSAC Guidelines (similar to PBAC Guidelines) are template-like.

- The sections in the Guidelines map across the sections in the MSAC templates.
- All of the sections are relevant – read start to finish

Proposed MSAC Guidelines structure – reference manual.

- Still maintain sections – Context, Clinical, Economics, Utilisation
- Within Sections are Technical Guidance “chapters” – abbreviated to TG1, TG2 etc.
- Not intended to be read from start to finish – but accessed for guidance on concepts relevant to the assessment.


Section 1
Context
Section 2
Clinical
Section 2A
Therapeutics
Section 2B
Investigatives
Section 3
Economic
Evaluation
Section 3A
Cost-effectiveness
analysis
Section 3B
Cost-minimisation
Section 4
Use of the medical
service in practice
Section 5
Other
considerations
relevant to MSAC
decision-making
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.

New Components

- Clinical claim
- Exemplar / facilitated approach
- Assessment framework
- Other utility
- Terminology: Clinical utility, clinical utility standard, direct from test to health outcomes evidence, test performance

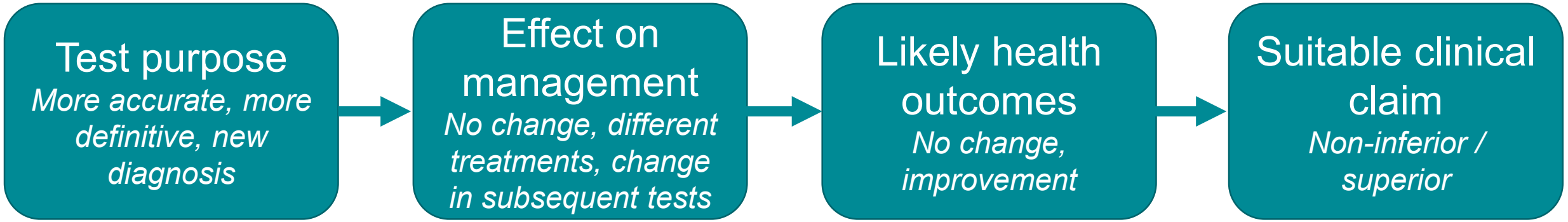
Clinical Claim

TG1 – Purpose of application

Clinical claim

- Straightforward for a therapeutic technology – better, same, worse health than an appropriate comparator
- Complicated for an investigative technology
  - Test benefits / purposes described using different terms / metrics
  - Often surrogates or earlier endpoints than health
  - Information derived from tests may have impacts outside of health
  - Tests impact more than one population (simply – the impact is on both +ve and –ve)

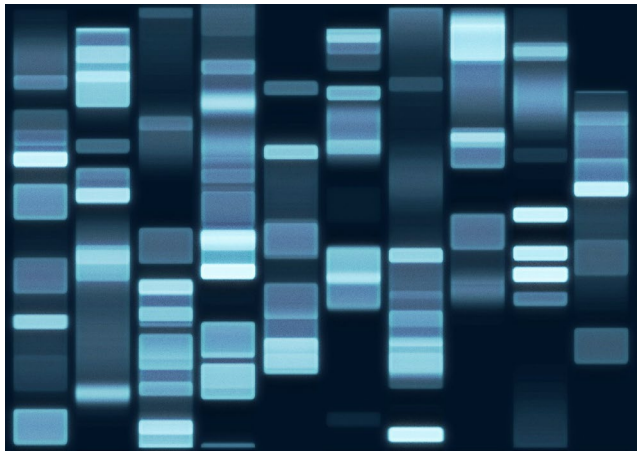
Clinical Claim

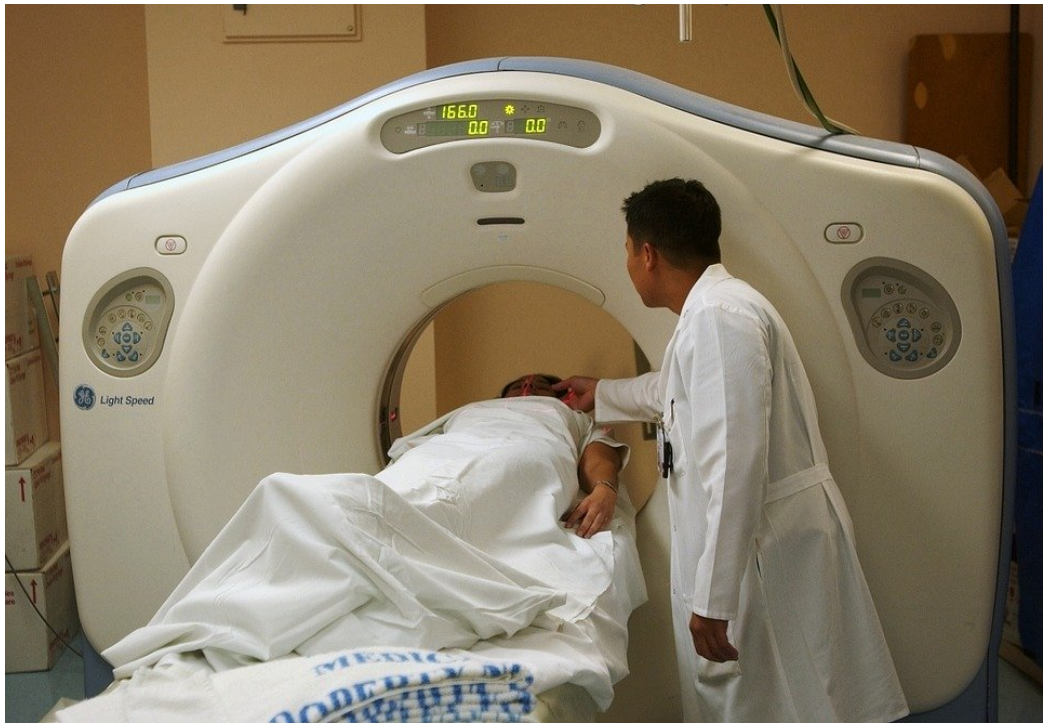


Exemplar / Facilitated

TG5 – Methods of assessment

Simplify the assessment of *related* technologies.





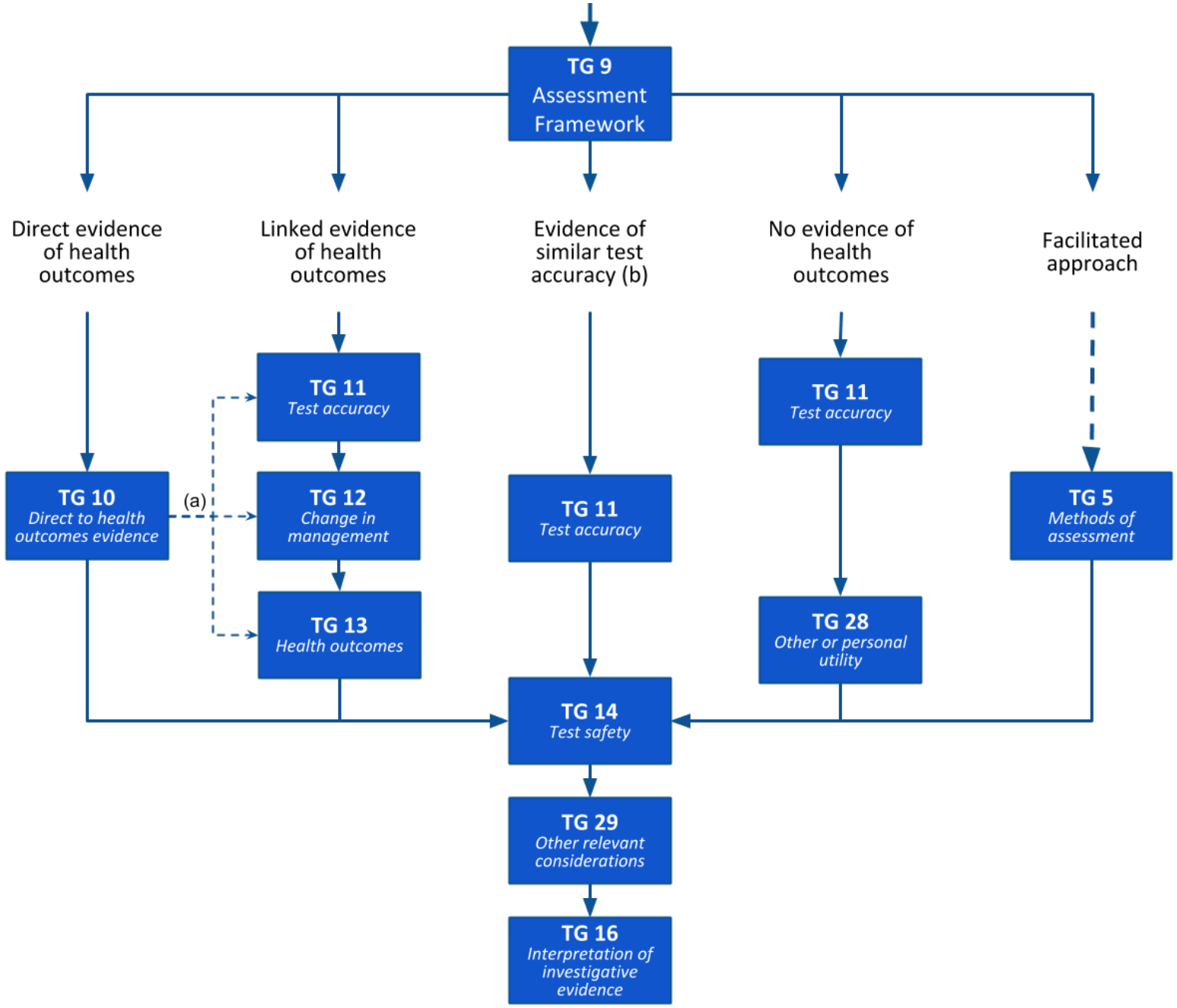
Exemplar / Facilitated

Type of approach	Exemplar	Facilitated
Same population, different intervention e.g. gene panel	e.g. One or several genes on a panel that have evidence to support clinical utility	e.g. Additional genes in the same panel, used in the same population, but do not have strong evidence, due to rarity of gene variant
Different population, same modality e.g. imaging for multiple tumour types	e.g. One or several tumours that have the evidence to support clinical utility	e.g. Additional tumours that might be detected with the same imaging, but do not have strong evidence, due to rarity of the disease
Substantially equivalent devices	One or several technologies that have evidence to support effectiveness, safety and cost-effectiveness	An alternative device that is substantially equivalent, plus has evidence of non-inferiority on a surrogate

Assessment framework is the first step

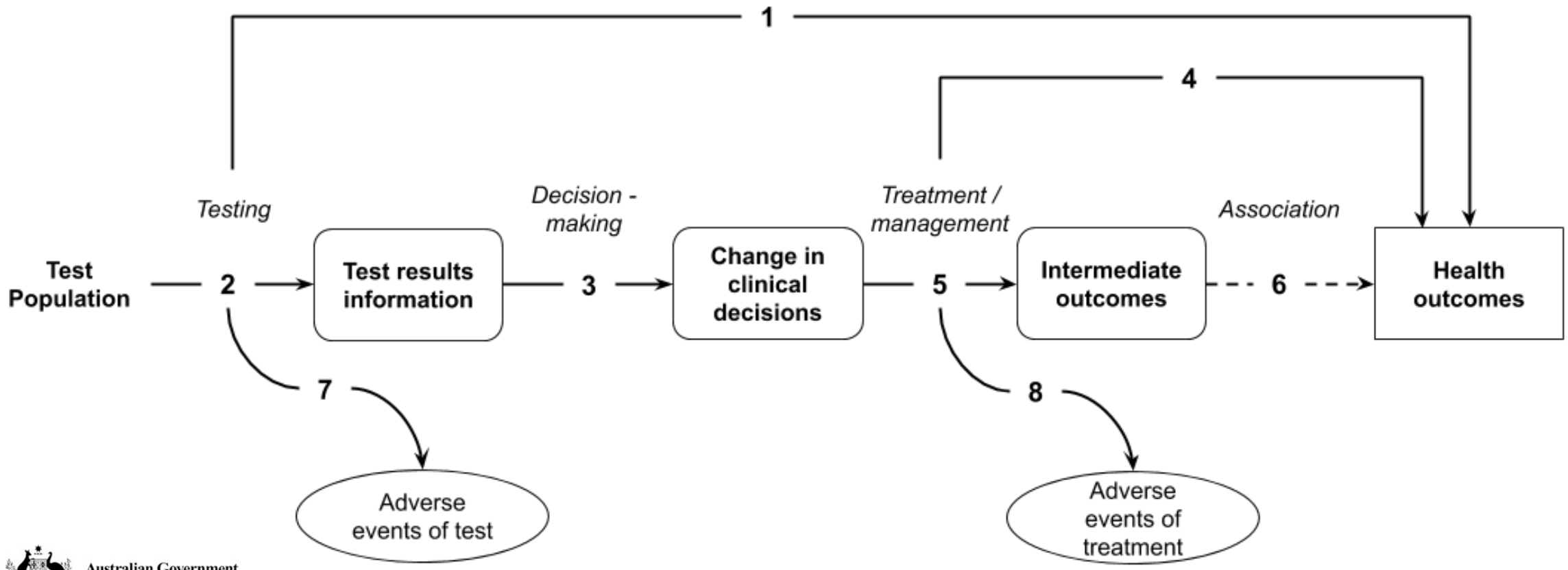
Begins with development of an assessment framework.

The subsequent TG rely upon the approach taken.



Australian Government
Department of Health

Assessment Framework



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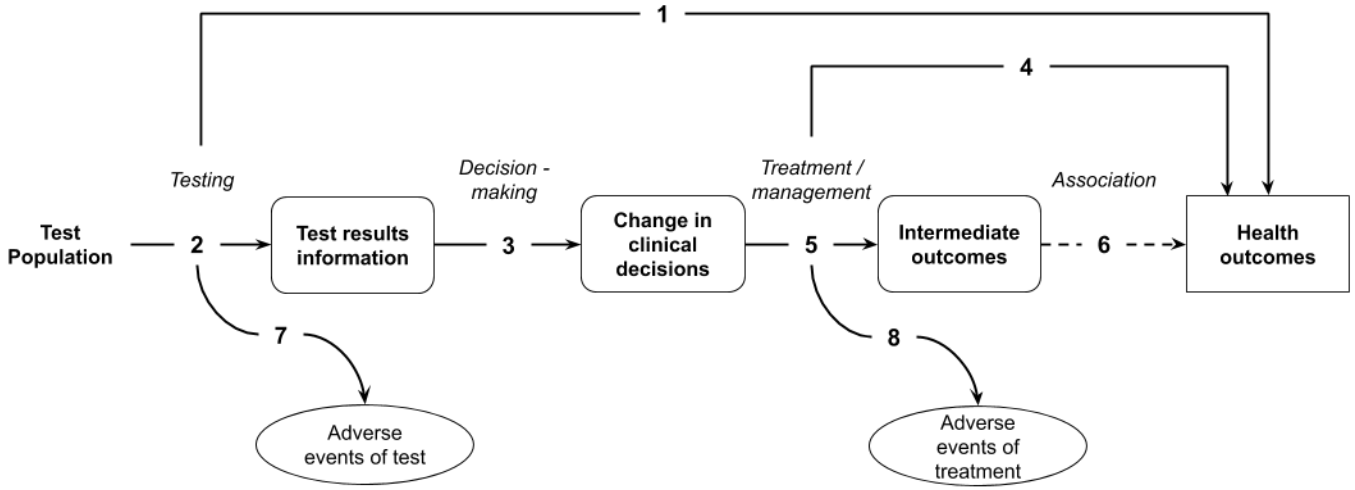
Assessment Framework

Generate research questions relating to each of the connections

The shortest distance between testing and health outcomes is #1 – which would reflect direct from test to health outcomes evidence.

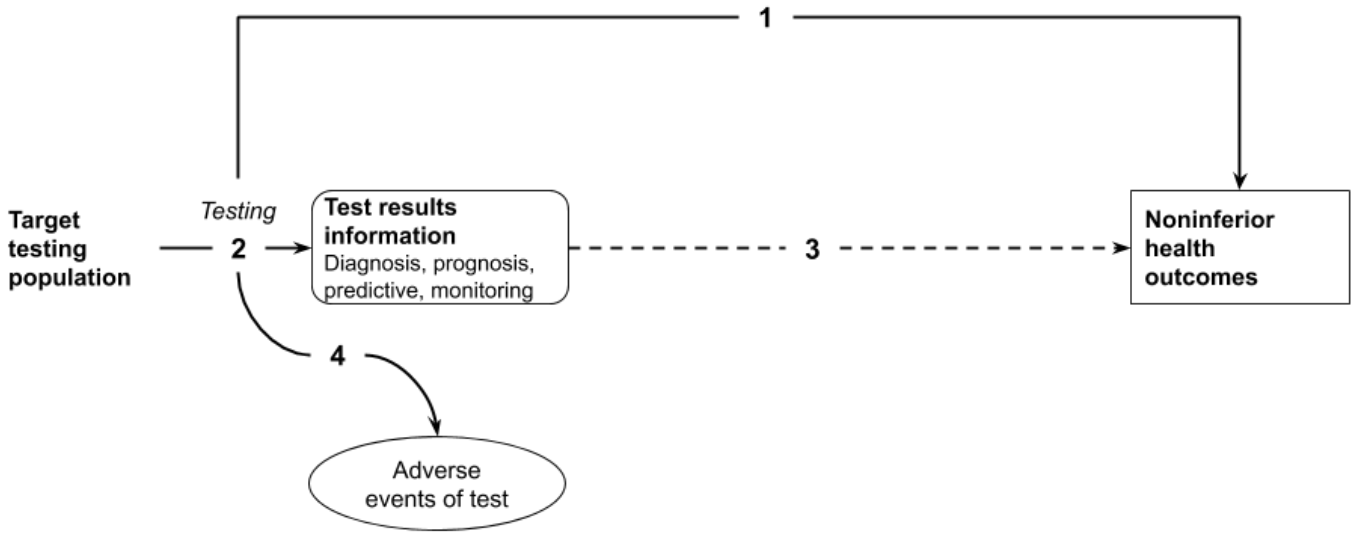
Taking the alternative path – through #2, #3, #4 (or #5+#6) represents the linked evidence approach, which attempts to describe test performance, change in management and health outcomes.



Assessment Framework

Option to truncate the assessment framework in some circumstances

Example of a framework for supporting a claim of non-inferiority, based on equivalent test performance.



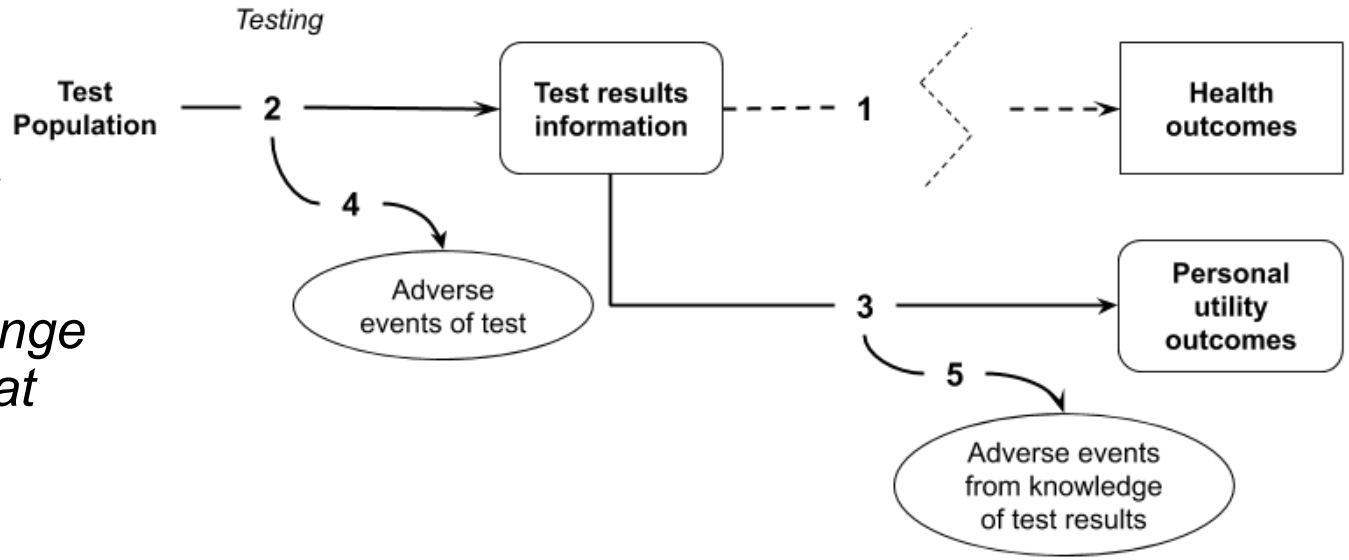
Assessment Framework

Frameworks can incorporate other utility outcomes

Example of a partial framework that incorporates steps for measuring other utility outcomes.

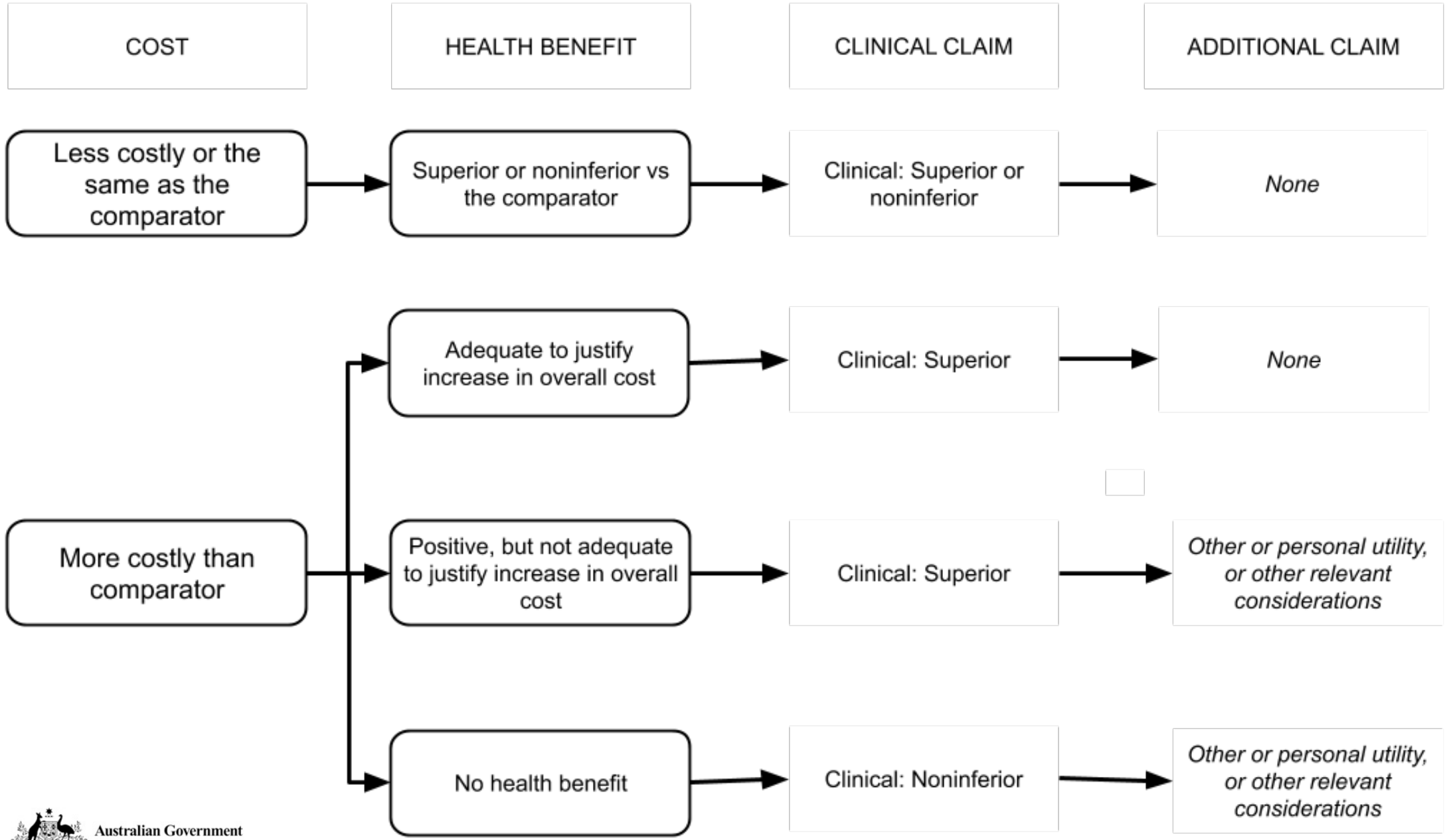
If this assessment was to claim no change in management, it would be truncated at the step towards health outcomes.

If a change in health outcomes is expected or required, it would resemble a full framework, with a personal utility arm.



Other / Personal Utility

- Section 5
- Utility derived by the subject, family or carers
- Claims include:
  - Avoiding the diagnostic odyssey
  - Planning for end of life
  - Access to support groups / insurance
- Claims must be supported with evidence
- Both the benefits and harms of testing are included



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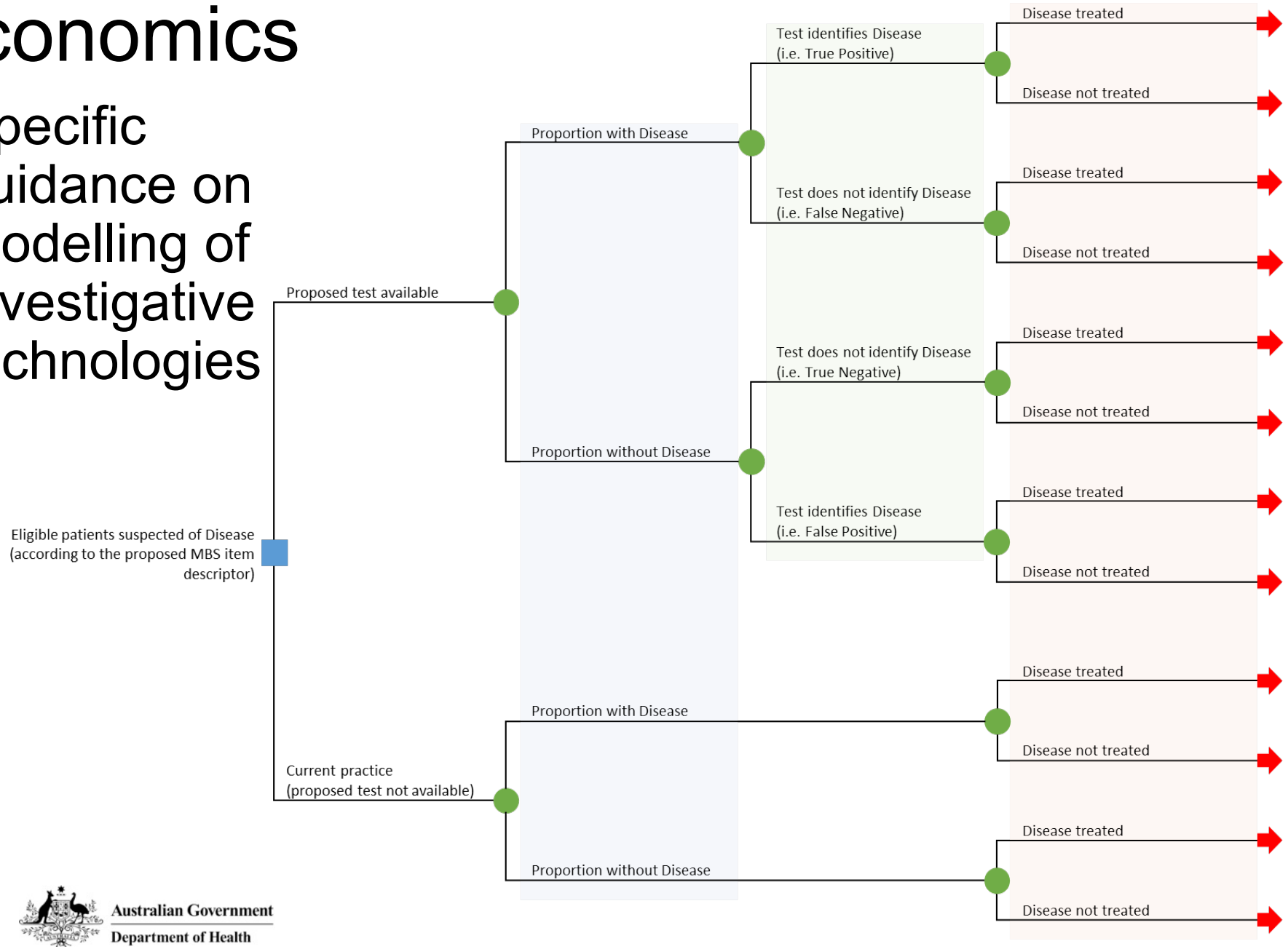
Economics

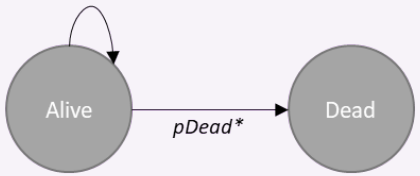
- Align with the PBAC Guidelines
- Removal of a section dedicated to translation (Section C)
- Formal guidance on model validation
- Separate sub-sections for guidance on model inputs
  - Population / setting
  - Transition probabilities
  - Utilities
  - Costs
- Minor changes to align with best practice (e.g. structuring process, use of published utilities)

Economics

- Specific guidance on modelling of investigative technologies



Costs and outcomes may vary according to whether: 1) Disease is present; and 2) whether or what treatment is received. For example:



** Probability of dying depends on:*
1) whether Disease is present;
and, if Disease is present,
2) whether treatment is recieved

Depending on the disease process, different Markov model structures may be appropriate for patients who enter the model with and without the underlying disease

Australian Government
Department of Health

How to submit your views

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

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

OR

- MSAC.Guidelines@health.gov.au

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Questions

Email: MSAC.Guidelines@health.gov.au