Real-World Evidence in Action: A Review of Australia's Health Technology Assessment of Non-Drug Health Technologies

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Introduction

Compared to drugs, clinical evidence to support non-drug health technologies—such as medical devices, diagnostic tools, and digital health interventions—tends to be limited due to challenges in implementing a double-blind procedure and lack of infrastructure to conduct randomized controlled trials (RCTs).[1] As such, there is a growing interest in leveraging real-world evidence (RWE) to demonstrate the value of non-drug health technologies in health technology assessment (HTA).

Objectives

This study explores how RWE has been used to support clinical claims in applications assessed by Australia's Medical Services Advisory Committee (MSAC), and their influence on reimbursement outcomes.

Methods

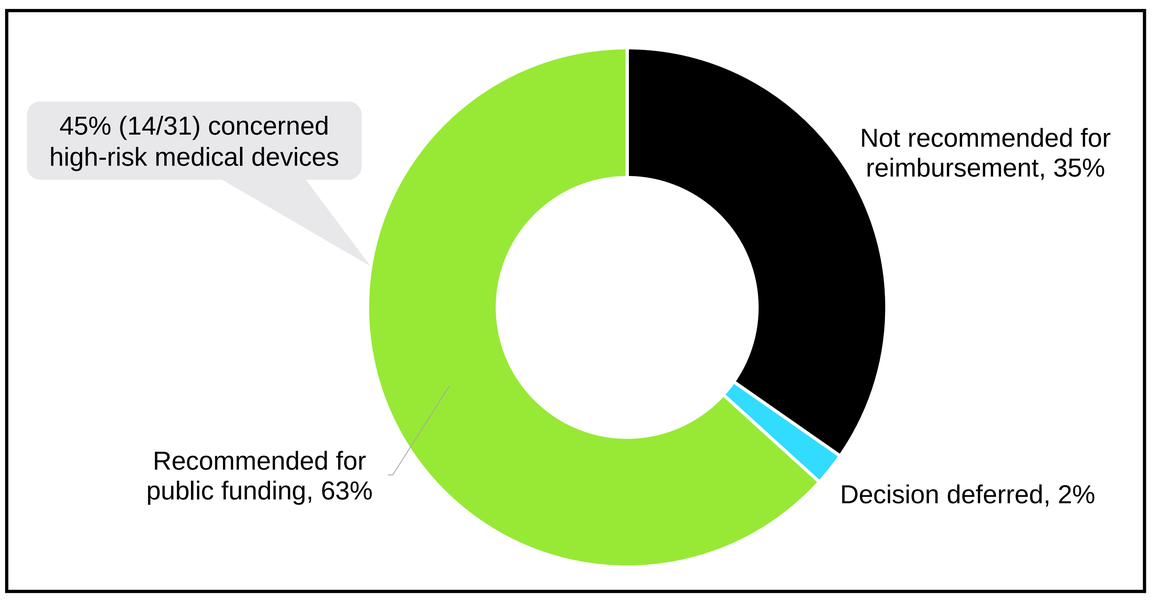
MSAC applications published between March 2019 and April 2024 were identified, from which RWE submitted by manufacturers and MSAC assessment outcomes were extracted and analyzed.

Results

74% (49/66) of the identified applications used RWE to support clinical claims.

- Applications using RWE included an almost equal mix of investigative (49%) and therapeutic technologies (51%).
- RWE was used in applications across various therapeutic areas, with the top 3 being oncology (18%), cardiology (16%), and reproductive diseases (10%).
- 29 (59%) of the applications using RWE pertained to high-risk medical devices, usually classified by the Therapeutics Goods Administration as devices that are life-sustaining, and/or are implanted permanently in the body (e.g., class III or active implantable medical devices).
- 31 (63%) of the applications received a recommendation for public funding (Figure 1).

Figure 1: Reimbursement outcomes for applications using RWE



Similar to drug assessments, RWE informed a range of safety and effectiveness outcomes (Table 1).

Table 1: Outcomes informed by RWE

Outcomes	Examples
Safety	• Adverse events from testing • Adverse events from change in management
Effectiveness	• Test accuracy and analytical sensitivity • Concordance tests (especially for genetic tests) • Outcomes from change in patient management • Change in medication requirements • Change in clinical endpoints • Percentage of patients achieving minimum clinically significant difference • Prognostic value (longitudinal accuracy) • Change in quality of life • Percentage of patients returning to work

RWE supported clinical claims in multiple ways (Table 2).

Table 2: Ways in which applications used RWE to support clinical claims

Use of RWE in supporting clinical claims	IDs of example applications
Confirming RCT evidence in the form of cohort studies with similar comparative efficacy outcomes to clinical trials	1727, 1740, 1764
Providing a control arm for single-arm treatment comparisons	1651, 1657, 1668
Addressing evidence gaps such as lack of clinical trial evidence for interventions and comparators	1680, 1684, 1703
Understanding patient experience through patient-reported outcomes and quality of life changes from using intervention vs comparator	1673, 1701, 1711
Establishing standard of care	1707, 1713, 1749

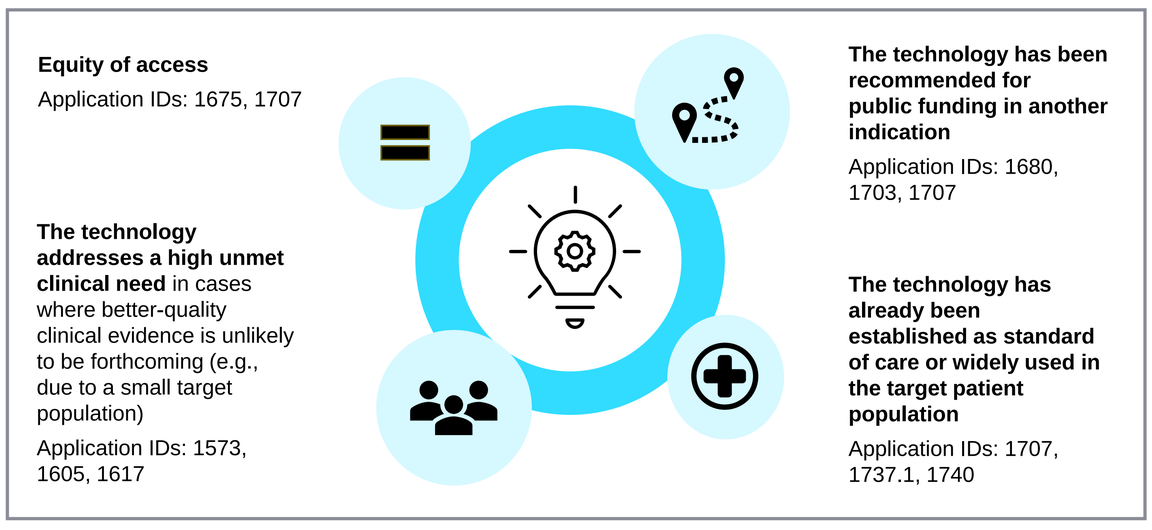
Despite the frequent use of RWE in supporting non-drug health technology applications, concerns surrounding the reliability of the evidence base remain (Table 3).

Table 3: Reasons for MSAC rejection of applications using RWE

Reasons for MSAC application rejection	IDs of example applications
Risk of bias (e.g., due to small sample size in case series studies)	1523, 1628, 1629
Poor internal validity (e.g., small sample size due to the rarity of the condition, lack of long-term data)	1523, 1555, 1656
Insufficient evidence on efficacy outcomes to establish comparative clinical benefit	1569, 1595, 1626
Lack of comparator	1691

However, concerns around the reliability of RWE may be superseded by other factors. MSAC has recommended public funding of non-drug technologies based on additional considerations (Figure 2).

Figure 2: Additional factors considered by MSAC for reimbursement recommendation



Conclusions

RWE is used in diverse ways to support clinical claims in the HTA of non-drug health technologies in Australia. Consistent with current MSAC guideline recommendations, RWE is often acknowledged as a valid source of evidence in MSAC applications, particularly when high quality RCTs or comparative non-RCTs are limited. The relative impact of RWE compared with other factors warrants further exploration.

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