

Reception of RWE: Trends in CADTH Reimbursement Reviews

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BACKGROUND

- The Canadian Agency for Drugs and Technologies in Health (CADTH) is Canada’s health technology assessment (HTA) agency, responsible for providing public reimbursement recommendations for drugs entering the Canadian market.
- The agency has had a recent focus on real-world evidence (RWE), with publications and working groups providing guidance on RWE use.¹⁻³

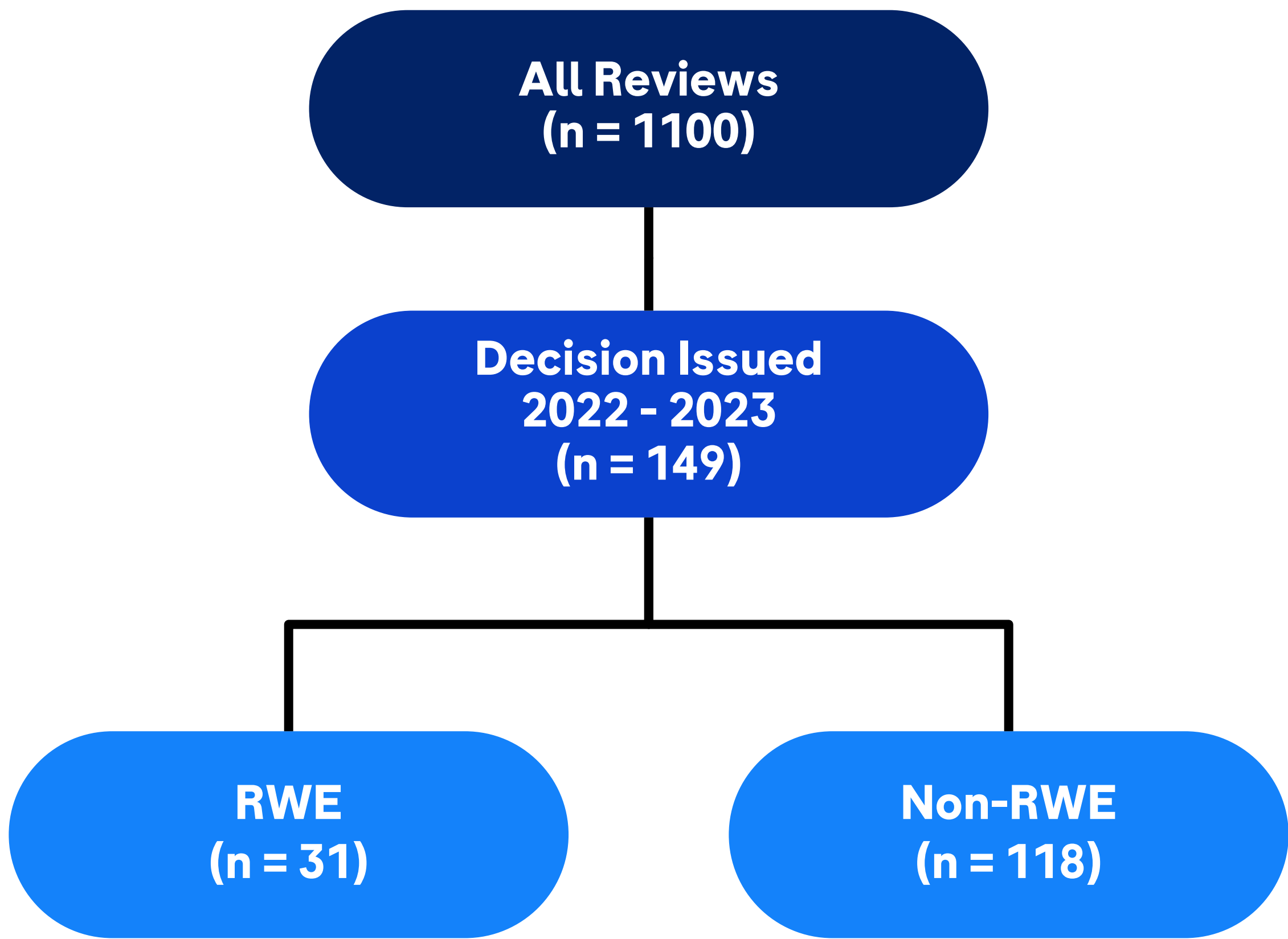
OBJECTIVES

This research aims to explore trends among RWE usage and appraisal in reimbursement reviews.

METHODS

- All CADTH reimbursement reviews with recommendations issued from 2022-2023 were gathered.⁴
- Reviews were assessed for the evaluation of RWE in the clinical and/or economic evidence sections.
- RWE was classified by evidence category (effectiveness/safety/economic), data source (patient registry/medical records/claims), and therapeutic area.
- Data analysis examined positive recommendation rates and review duration.
- Qualitative data on comments from CADTH regarding critical appraisal of RWE were gathered and analyzed.

Figure 1 - Process for CADTH Reimbursement Review Analysis



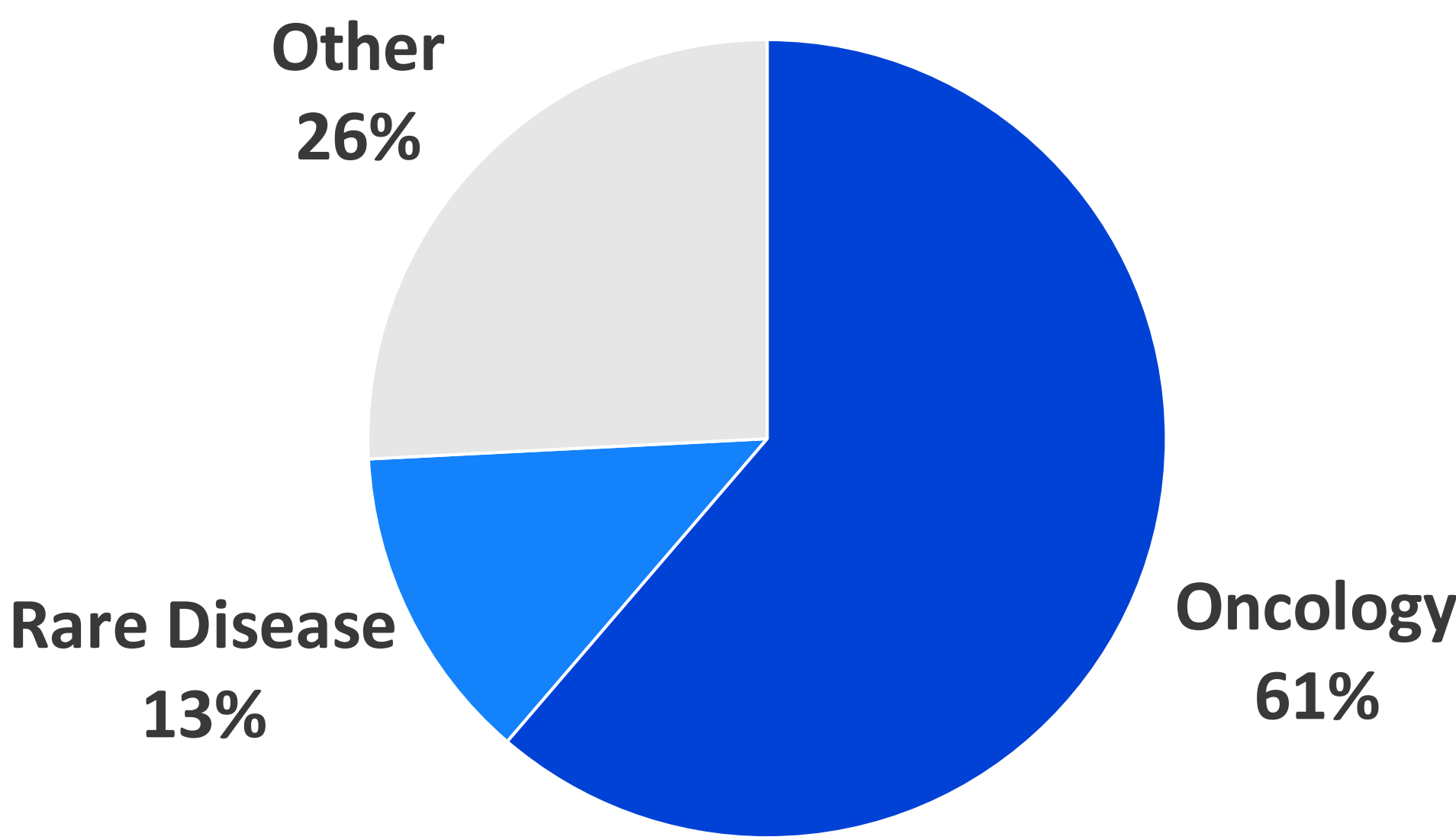
RESULTS

- 31/149 reviews (21%) included RWE evaluated by CADTH in their clinical and/or pharmacoeconomic review reports.
- RWE categorization was mostly effectiveness (24/31) [77%], followed by safety (12/31) [39%], and economic (11/31) [35%].
- Patient registries and medical records were the data source for RWE in 29/31 (94%) reviews.
- 19/31 RWE reviews (61%) were for oncology drugs.
- A positive recommendation was issued in 123/149 (83%) reviews, and in reviews with RWE 23/31 (74%) recommendations were positive (p=0.1683).
- Reviews containing RWE had an average review time of 266 days, compared to 254 days for reviews not containing RWE.
- CADTH discussed limitations of RWE in 26/31 (84%) reviews.

Figure 2 - Reimbursement Reviews with RWE



Figure 3 - Therapeutic Areas of Reviews with RWE



DISCUSSION

- RWE was evaluated by CADTH in approximately 1 in 5 reviews.
- RWE was most frequently in support of effectiveness evidence and was typically used in oncology reviews.
- The association between reviews with evaluated RWE and a positive recommendation was not statistically significant. A possible explanation is the inclination of sponsors to use RWE to show additional value in more complex files.
- Files which used RWE as pivotal evidence had a notably lower positive recommendation rate compared to files where RWE was supplementary to other pivotal evidence.
- Although CADTH has had a recent focus on working to guide how sponsors use RWE in reimbursement submissions, they typically discussed its limitations in their critical analyses.
- Limitations of this research include the 2 year scope of the review and the methodological reliance on reports only for data. Data may have been limited by variability in what CADTH publicizes and by subjective interpretation of the influence of RWE on these reviews.

CONCLUSIONS

- RWE continues to be prevalent in CADTH reimbursement reviews, typically in support of effectiveness and for oncology.
- Despite CADTH’s recent focus on RWE for decision making, the agency consistently discussed its limitations in their reviews.
- Although file complexity and sponsor strategy may play a role in the average positive recommendation rate and review times, it is uncertain exactly how RWE contributed to these outcomes.
- As RWE use in HTA submissions grows, uncertainty remains regarding its use in decision-making, suggesting further guidance and research on the evaluation of RWE in reimbursement reviews is needed.

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