HTA50

A Review of Real-world Evidence in Non-Oncology Submissions made to four Health Technology Assessment Agencies

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OBJECTIVES

- To discover how real-world evidence (RWE) was appraised by the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS), the National Institute for Health and Care Excellence (NICE), and Pharmaceutical Benefits Advisory Committee (PBAC) in the reimbursement of non-oncology treatments.

CONCLUSIONS

This review showed that inclusion of RWE in support of reimbursement submissions is low overall, except for rare disease submissions.

Overall, NICE had a higher proportion of RWE studies included in their received submissions, followed by INESSS, CADTH, and then PBAC.

Critiques for RWE were similar across the four HTA agencies, and focused on non-comparative design, limited follow-up, low sample sizes, and selection bias.

When RWE was included in a submission, the majority received a positive recommendation.

ACKNOWLEDGEMENT

The authors thank Elaine Shang for her contributions to the review of the Poster.

DISCLOSURES

AbbVie Canada funded this study and participated in the design, analysis, data collection, study conduct, interpretation of data, and the review and approval of the publication. All authors had access to relevant data and participated in the drafting, review, and approval of this publication. No honoraria or payments were made for authorship.

Chakrapani Balijepalli and Lakshmi Gullapalli are shareholders of Pharmalytics Group which has been contracted by AbbVie Canada to complete this work and both declare no conflicts of interest outside of this work. Joyce Li is a former employee of Pharmalytics Group and declares no conflicts of interest. Emily Mathers and Amnah Awan are employees of AbbVie Canada. Simon Ferrazzi is a consultant to AbbVie Canada and declares no conflict of interest.

Presented at ISPOR 2024 International Conference, 5 – 8 May 2024

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INTRODUCTION

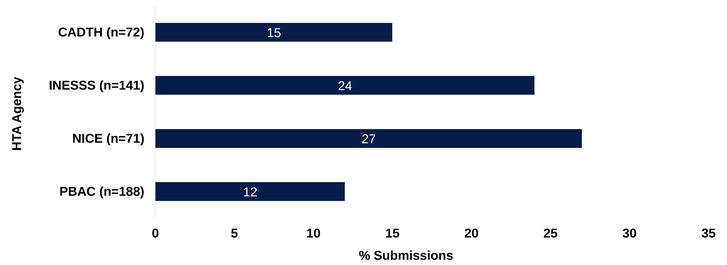
- Health technology assessment (HTA) agencies have been showing an increased interest in real-world evidence (RWE) to supplement pivotal clinical trial data.
- CADTH considers the inclusion of RWE in reimbursement reviews in three scenarios: (1) during the initial submission to CADTH; (2) with time-limited recommendations; and (3) for resubmissions and reassessments of previously reviewed products [1].
- Although various associations (ISPOR, ISPE) have published their positions on the inclusion of RWE in the HTA process, guidance is not clear on the types of RWE accepted and the level of importance given to RWE in the HTA decision-making process [2].

METHODS

- We reviewed reimbursement recommendation reports for non-oncology drugs assessed by CADTH, INESSS, NICE, and PBAC from January 2021 to December 2022.
- Data were extracted for all submissions that included RWE, with a focus on RWE parameters including:
  - the sources of RWE, study period, study design, outcomes assessed, limitations / critiques of the submitted RWE, and any clinical benefit identified by including RWE
  - proportion of submissions with RWE receiving a positive recommendation
  - number of rare disease submissions containing RWE

RESULTS

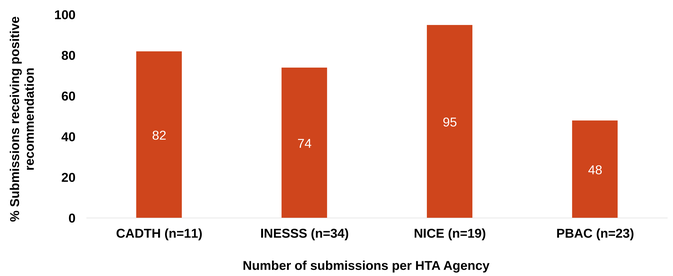
Figure 1. Submissions with RWE from four HTA agencies



Overall submissions

- Between 2021 and 2022, CADTH, INESSS, NICE and PBAC assessed 72, 141, 71 and 188 unique submissions, respectively, for non-oncology products.
- Of these submissions, 15% (11/72) of CADTH, 24% (34/141) of INESSS, 27% (19/71) of NICE, and 12% (23/188) of PBAC submissions included RWE as a part of their submission (Figure 1).
- Data from RWE was critiqued inconsistently across the HTA agencies, with 82% (9/11) of CADTH submissions, 3% (1/34) of INESSS, 42% (8/19) of NICE, and 48% (11/23) of PBAC submissions receiving a critique of the RWE submitted.
- The main critiques regarding RWE were similar across the agencies reviewed and included: non-comparative study design, limited follow-up, low sample sizes, and selection bias of the participants.
- CADTH particularly acknowledged the lack of Canadian participants in the RWE studies as a limitation.

Figure 2. Submissions with RWE receiving positive recommendation



Submissions with RWE

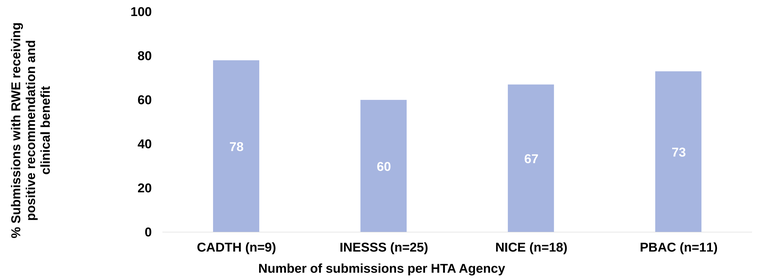
Positive recommendations

- Of the submissions that included RWE, NICE had the highest proportion of submissions receiving a positive recommendation (18/19; 95%) followed by CADTH (9/11; 82%), and INESSS (25/34; 74%), while PBAC had the lowest proportion (11/23; 48%) (Figure 2).

Rare disease indications

- Of the submissions that included RWE, CADTH had the highest proportion of submissions for rare disease indications (82%), followed by PBAC (78%) and NICE (53%), while INESSS had the lowest proportion (32%).

Figure 3. Submissions including RWE receiving a positive recommendation and having a clinical benefit



Submissions with RWE and receiving a positive recommendation

- Among positively recommended submissions with RWE, 78% of submissions from CADTH (7/9), 73% (8/11) from PBAC, 67% (12/18) from NICE and 60% (15/25) from INESSS had an acknowledged clinical benefit from RWE according to the evidence review group (Figure 3).

DISCUSSION

- This review showed that RWE inclusion for HTA decision making remains relatively low, between 12%-27%.
- Reimbursement submissions for rare diseases included RWE in a higher proportion than non-rare diseases.
- RWE for HTA purposes was heavily critiqued for its limitations, however agencies were inconsistent in providing feedback across RWE containing submissions.
- Prior studies have shown that there are still substantial barriers to the inclusion and acceptance of RWE in HTA [3].
- HTA agencies are encouraged to provide greater clarity on when/how RWE is incorporated into HTA decision-making and the level of importance ascribed to it.

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