INTRODUCTION

The budget impact analysis (BIA) is one key component of a comprehensive economic assessment of a new healthcare intervention for a listing or reimbursement submission. All public (provincial, territorial, and federal) and private drug payers in Canada require BIAs to demonstrate the intervention’s affordability and as part of the reimbursement submission to make funding decisions. Standard methods for conducting and presenting the results of BIAs for health technology assessment (HTA) submissions have been developed in Canada, as well as from international and national agencies. The alignment of Canadian guidelines with recommendations from other BIA guidelines is unknown.

OBJECTIVES

To review available guidelines for conducting BIAs for HTAs and identify similarities and differences from the viewpoint of Canadian payers.

RESULTS

Literature Review

The literature review identified from Canada one national (Patented Medicine Prices Review Board [PMPRB]) and three provincial guidelines (Alberta, Manitoba, and Ontario), seven other national guidelines (Australia, Belgium, France, Germany, the Netherlands, UK, and US), and one recommendation for good practices from ISPOR.2-13

Comparison of Guidelines

The Canadian guidelines were largely consistent with recommendations from other guidelines in terms of model structure, discounting, population, estimating market shares, drug costs, off-label use, presentation of results, uncertainty assessment, and model validation (Figure 1).

Differences between the recommendations from Canadian and other guidelines were observed for the key elements of perspective, time horizon, comparators, and the inclusion of non-drug costs (Table 1). Among the Canadian guidelines, there was some variability in terms of recommendations for determining province-specific target population and drug cost for inclusion in the BIA.

DISCUSSION

This research is the first known study to focus on the comparison of Canadian BIA guidelines with existing methodological guidelines from other countries and health economic societies. Although the literature review did not include guidelines from all countries used for Canadian reference-based pricing of patented drugs, BIA best practices from major HTA regions and an international health economic society were included in the comparison. This research suggests that differences identified in the comparison are consistent with how drug budgets are managed in Canada.

- Budget holder (perspective) in Canada is the drug plan in each province (rather than one national health care payer), which pays for drug costs only, so no other comparators or costing beyond drug plan are considered in Canadian BIAs.

CONCLUSIONS

- Most of the Canadian BIA recommendations are in line with those of national guidelines and international health economic societies.
- Notably, Canada has unique requirements for BIAs related to its payer landscape, where public drug plans and private insurers are responsible for drug costs but not other healthcare expenditures.
- The specific requirement for multiple payer-specific BIAs is likely due to the unique Canadian drug reimbursement landscape where drugs are funded by siloed drug payers in each province rather than a national healthcare payer.

REFERENCES


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