REVIEW OF CANADIAN VERSUS OTHER GUIDELINES FOR CONDUCTING BUDGET IMPACT ANALYSIS: DO CANADIAN GUIDELINES DIFFER AND WHY?

D. Tran[1], H. Cameron[1], C. Cameron[1]
[1]Cornerstone Research Group Inc., Burlington, ON, Canada

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.[1,2]

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.[3]

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.

METHODS

We performed a targeted literature review to identify full-text English-language guidelines for BIAs in Canada, from international health economics societies, and from existing and proposed countries used for reference-based pricing of patented drugs in Canada (ie, Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, the UK, and the US).

We extracted recommendations related to key elements from the available guidelines.

- Common BIA design elements were model structure, perspective, time horizon, discounting, population, comparators, off-label use, cost types to include, validation, and uncertainty assessment.[2]
- Other BIA elements were related to estimating market size and market share inputs and reporting of results.

We then compared similarities and differences between BIA guidelines in Canadian and other countries.

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.

Figure 1: Summary of Identified Guidelines and Their Alignment by BIA Element

Country	Agency	Model structure	Perspective	Time horizon	Discounting & inflation	Target population	Estimating market size	Comparators	Off-label use	Estimating market shares	Drug costs	Non-drug costs	Validation	Uncertainty	Results format
Canada	PMPRB[3]	✓	×	×	✓	✓	✓	×	✓	✓	✓	×	✓	✓	✓
	AB[4]	-	×	×	-	✓	✓	×	-	-	✓	×	-	✓	✓
	MB[5]	-	×	×	-	✓	✓	×	-	-	✓	×	-	✓	✓
	ON[6]	-	×	×	-	✓	✓	×	-	-	✓	×	-	✓	✓
US	AMCP[13]	✓	✓	✓	-	✓	-	-	✓	-	-	✓	-	✓	✓
UK	NICE[12]	✓	✓	✓	✓	✓	✓	✓	-	-	✓	✓	-	✓	✓
Australia	PBAC[7]	✓	✓	✓	✓	✓	✓	×	✓	✓	✓	✓	-	✓	✓
Germany	IQWiG[10]	✓	✓	✓	✓	✓	-	✓	✓	-	-	✓	-	✓	✓
France	HAS[9]	✓	✓	✓	✓	✓	-	✓	×	-	✓	✓	✓	✓	✓
Belgium	KCE[8]	×	✓	✓	✓	✓	✓	✓	×	-	-	✓	✓	✓	✓
Netherlands	ZIN[11]	✓	✓	✓	✓	-	-	✓	×	-	✓	✓	-	✓	✓
International	ISPOR[2]	✓	-	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	-

Legend: ✓ Guidelines with similar recommendations; × Guidelines with a different recommendation

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.

Table 1: Summary of Recommendations and Number of Guidelines in Agreement by BIA Element

BIA Element	Recommendations*	Canadian Guidelines in Agreement?
Model structure	The majority (n = 8/9; 89%) of the identified guidelines recommend a flexible, user modifiable, transparent, and simple calculator design in an accessible software.	Yes
Discounting	All (n = 8/8; 100%) of the identified guidelines recommend that costs should not be discounted or inflated in the model.	Yes
Time horizon	Two-thirds (n = 8/12; 67%) of the identified guidelines recommend a time horizon of 5 years or more to match the financial cycle of the budget holder.	The Canadian guidelines recommend a 3-year time horizon.
Perspective	Given that the perspective should be that of the budget holder, most countries (n = 7/11; 64%) consider a public national health system perspective.	The Canadian guidelines recommend that BIAs reflect a public provincial drug plan.
Population	All (n = 11/11; 100%) of the identified guidelines recommend that the analysis population should reflect all patients in the region/plan who will be eligible for and receive the new intervention over the time horizon.	Yes
Comparators	Slightly more than half (n = 6/11; 55%) of the identified guidelines recommend (or do not explicitly restrict) consideration of non-drug therapies.	The Canadian guidelines recommend "drug-based" treatment strategies for comparators.
Estimating market size	All (n = 8/8; 100%) of the identified guidelines recommend the use of region-specific epidemiology estimates for the disease under study (population approach) to calculate the number of treatment-eligible patients.	Yes
Estimating market shares	All (n = 3/3; 100%) of the identified guidelines recommend using data describing the degree of market growth and/or substitution between the intervention and comparators.	Yes
Drug costs	All (n = 9/9; 100%) of the identified guidelines recommend using the actual reimbursement price, per the drug plan.	Yes
Non-drug costs	For most of the identified guidelines (n = 8/12; 67%), the inclusion of non-drug costs was relevant to the perspective of the BIA.	The Canadian guidelines recommend excluding healthcare system or indirect costs.
Off-label use	Over half (n = 5/8; 63%) of the identified guidelines recommend including off-label use in a sensitivity analysis rather than in the main analysis.	Yes
Format of results	All (n = 11/11; 100%) of the identified guidelines recommend reporting disaggregated results, at a minimum by the difference in annual expenditures between the scenarios with and without the new intervention.	Yes
Assessment of uncertainty	All (n = 12/12; 100%) of the identified guidelines recommend conducting deterministic sensitivity analyses for exploring uncertainty surrounding the target population size, market shares, and drug price on the BIA results.	Yes
Model validation	All (n = 4/4; 100%) of the identified guidelines recommend performing internal validation (verification).	Yes

Abbreviations: BIA, budget impact analysis.

* The percentage of guidelines in agreement is based on the number of identified guidelines that explicitly make a recommendation on each element. Some guidelines may offer additional recommendations beyond those presented in this table.

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

1. Mauskopf and Earnshaw. A methodological review of US budget-impact models for new drugs. Pharmacoeconomics 2016; 34(11): 1111-31. **2**. Sullivan, Mauskopf, Augustovski, et al. Budget impact analysis – principles of good practice: report of the ISPOR 2012 Budget Impact Analysis Good Practice II Task Force. Value Health 2014; 17(1): 5-14. **3**. Patented Medicine Prices Review Board (PMPRB). Budget impact analysis guidelines. Guidelines for conducting pharmaceutical budget impact analyses for submission to public drug plans in Canada. Ottawa, 2007. **4**. Alberta Health, Government of Alberta. Budget Impact Assessment for the Alberta Drug Benefit List. Version 9, 2018. **5**. Manitoba Health, Seniors and Active Living. Budget Impact Analysis For The Manitoba Health, Seniors and Active Living. 2017. **6**. Ontario Ministry of Health and Long-Term Care. Ontario Drug Benefits Program: Ontario Guidelines for Drug Submission and Evaluation. 2016. **7**. Pharmaceutical Benefits Advisory Committee (PBAC), Department of Health, Australian Government. Guidelines for preparing submissions to the pharmaceutical benefits advisory committee. Canberra (AU): Commonwealth of Australia, version 5.0, 2016. **8**. Cleemput, Neyt, Van de Sande, Thiry, Belgian Health Care Knowledge Centre (KCE). Belgium guidelines for economic evaluations and budget impact analyses: second edition. Brussels, 2012. **9**. Ghabri, Autin, Poullié, Josselin. The French national authority for health (HAS) guidelines for conducting budget impact analyses (BIA). Pharmacoeconomics 2018: 36(4): 407-17. **10**. Institute for Quality and Efficiency in Health Care (IQWiG). General Methods. Cologne, Version 4.2, 2015. **11**. Zorginstituut Nederland. Guideline for economic evaluations in healthcare. 2016. **12**. National Institute for Health and Care Excellence (NICE). Assessing resource impact process manual: technology appraisals and highly specialised technologies. 2017. **13**. Academy of Managed Care Pharmacy (AMCP). The AMCP Format for Formulary Submissions: A Format for Submission of Clinical and Economic Evidence in Support of Formulary Consideration. Version 4.0, 2016.

FUNDING

This research was supported by the PMPRB.

CONTACT INFORMATION

Diana Tran
Cornerstone Research Group Inc.
3228 South Service Rd., Suite 204, Burlington, ON, Canada L7N 3H8. Tel: 905.637.6231 ext. 248.
E-mail: dtran@cornerstone-research.com
www.cornerstone-research.com

ISPOR Annual Meeting; May 18-22, 2019; New Orleans, LA, USA