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ORIGINAL RESEARCH ARTICLE

Perceptions and Attitudes Regarding Medical Device Development in Canada Among Canadian Innovators: A Qualitative Study

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Abstract

Objectives The Canadian medical device industry presents unique challenges to innovators. However, little attention has been paid to exploring the distinct experience of Canadian medical device innovators in the literature. The objective of this study is to explore the experience of Canadian innovators in navigating this industry, with a focus on their perceptions and attitudes towards the use of health economic evaluation.

Methods Semi-structured interviews were conducted using virtual conferencing technology. All participants were C-level employees of small- and medium-sized enterprises (SMEs) with adequate knowledge of their company's overall strategy. Qualitative data were analyzed to reveal emerging themes.

Results Interviews were performed with ten participants. Forty percent of participants rated themselves as having either minimal or basic knowledge of health economics. Thirty percent of participants had not pursued early economic evaluation of their device, while 90% rated health economics as being either "Quite important" or "Very important" to their company. The perception of increased barriers to successful device adoption in Canada relative to the USA was a prominent sentiment among participants, with 50% expressing discontentment with either the device approval process or health technology assessment process in Canada. Twenty percent stated that their primary target market involved the USA and/or other international jurisdictions.

Conclusion Canadian medical device innovators appear to understand the importance of health economic evaluation in the innovation process. However, they report difficulty with device approval and adoption, with some innovators focusing their efforts outside of Canada altogether. Further research should be directed toward understanding how to better support SMEs, given that they are a tremendous source of growth for the Canadian medical device industry.

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Key Points for Decision Makers

Canadian medical device innovators appreciate the importance of health economic evaluation in product development.

However, they encounter many other hurdles as they attempt to get their device to market.

Further research is required to better understand how to support Canadian medical device innovators as they navigate the Canadian medical device industry.

1 Introduction

There is an increasing trend toward the use of methods of health economics to answer complex questions around efficiency and value for money in healthcare [1]. As a result, experts are recognizing and promoting the benefits of using early economic evaluation (EEE) to support decision making during the early stages of clinical research [2]. Over the past two decades, it has been suggested that health economic evaluation in the early stages may benefit the development and diffusion of medical products [2]. While the iterative use of health economic evaluation along the product development pathway has been well established in the pharmaceutical field since the 1990s, the utilization of this approach in medical device development was not widely adopted until more than a decade later [2].

EEE of a medical technology is defined as an iterative economic evaluation process to assess its economic value and likely impact, and is typically conducted when a medical technology is experimental or emerging [3]. A key characteristic of early economic evaluation is the availability of limited data to draw conclusions about potential value before clinical efficacy has been rigorously established through clinical trials [3]. For example, EEE of medical devices often incorporates preclinical data as well as expert opinion, and as a result, there is considerable uncertainty associated with the conclusions drawn from such data [3, 4]. While EEE of medical devices can be performed using a variety of decision analytic models, they typically involve some form of headroom analysis, which is aimed at understanding the maximum cost at which a novel technology is cost effective at a given willingness-to-pay threshold [2, 3]. The results of a headroom analysis provide crucial information regarding the potential viability of an emerging medical device prior to significant research and development (R&D) investment [2, 3, 5, 6]. This is a critical distinction between EEE and economic evaluation performed at a later stage in the product lifecycle when data describing the effectiveness of the new technology is available.

EEE can contribute to efficient decision making earlier on the technology development pathway and may be used to inform predictions around potential reimbursement, decisions around pricing, managing research and development (R&D) portfolios, and early market assessments [2, 7, 8]. These potential benefits of EEE are of tremendous value to stakeholders, as they mitigate the risk of investing in technology that might never be cost effective [7, 9]. Grutters et al. highlight that, during the early stages of technology development, an innovative technology can be developed in multiple ways, such as targeting a range of pathologies, for specific populations, or at different points on a care pathway [7]. As such, the potential benefits of EEE allow for nuanced decision making with regard to subsequent directions in R&D [7]. While a critical element of medical device innovation involves determining whether to continue with the development of the novel technology, this nuanced approach transcends simple "go/no go" decisions [7]. The perspectives derived from EEE may allow for pivoting to a new clinical entity, reallocation of resources to focus research efforts on a specific component of the new technology, and secure investment as the EEE can be an attractive element of a company's value dossier [4, 7].

Policymakers may also benefit from the information provided by the EEE by identifying factors that may contribute to cost effectiveness in the future, such as the learning curve associated with the technology, dynamic pricing, quality variation, and organizational impact [10, 11]. Furthermore, if the conclusions drawn from the EEE are combined with other techniques such as scenario drafting, this may allow for the identification of factors that may influence the speed at which a novel technology may become cost effective [10]. Lastly, the use of multicriteria decision analysis (MCDA) as a tool in health technology assessment has become common in many Canadian provinces and has been identified as a facilitator of effective health technology assessment [12–15]. Elements of the EEE may potentially inform how MCDA can be applied to the technology as it becomes more mature, thereby providing critical information to both policymakers and medical device innovators. Additionally, some jurisdictions may allow for access with evidence generation, sometimes referred to as managed entry, which enables promising technologies to be adopted and assessed simultaneously with careful monitoring of the evolving data [12]. Conclusions drawn from the EEE may be used to determine which technologies are eligible for this approach, ultimately providing numerous benefits to both medical device innovators and policymakers.

Ferrusi et al. define a medical device as any health or medical instrument, apparatus, tool, machine, contrivance, or implant used in the diagnosis, prevention, treatment, or mitigation of a medical condition [16]. This definition aligns closely with previous definitions proposed by the US Food and Drug Administration (FDA) and Health Canada [17, 18]. Within the Canadian medical device landscape, some authors have suggested that medical device companies face significant challenges in meeting the evidentiary demands of the health technology assessment (HTA) process due to a number of factors [16]. Among these are the fact that the Canadian medical device market is small—representing less than 1% of the world market for medical devices—which places Canadian medical device innovators and manufacturers at a significant disadvantage [16]. Ferrusi

et al. emphasize that for many Canadian medical device manufacturers, the cost of conducting effectiveness studies far exceeds the value of the Canadian market [16]. Additionally, within the Canadian healthcare system, current healthcare budget cycles as well as budgetary constraints do not afford the flexibility required to easily absorb the significant upfront investment required to implement a technology that produces downstream benefits [16].

With regard to the HTA process itself, a recent scoping review by MacNeil and colleagues emphasizes a number of facilitators and barriers to the development of a responsive regulatory and policy environment that fosters robust health technology innovation in Canada [12]. Notable facilitators highlighted in this review include the utilization of HTA reports from other jurisdictions that may be of value in current assessments, the use of field evaluations and access with evidence generation where data on a novel technology is sparse, and the use of multicriteria decision analysis and other decision-making frameworks [12]. However, the extent to which these approaches are currently utilized is unclear.

There is a growing need to establish how the medical device industry incorporates economic evaluations of new products to articulate their value to purchasers and regulators, and the resulting impact of these analyses on decision making [1, 7, 9]. Furthermore, the experience of Canadian medical device innovators transcends health economics, and includes other factors such as stakeholder engagement, policy evolution at the regional or provincial level, and navigating complex elements of business management [16]. As the Canadian medical device landscape continues to evolve, a thorough understanding of how best to balance these factors would certainly prove valuable to medical device innovators and manufacturers operating within the Canadian context. However, little is known about the current level of knowledge and experience of applying economic evaluation techniques to novel technologies among early-stage medical device innovators in Canada.

This study aims to evaluate the knowledge, perspectives, and attitudes of Canadian medical device innovators and entrepreneurs regarding the use of health economics to inform product development and overall strategy, with emphasis on the role of EEE. To this end, we asked the question "What is the current level of knowledge of health economics among Canadian medical device innovators?" Additionally, the following research question was asked—"What has been the general experience of Canadian medical device innovators in achieving medical device adoption?" Lastly, a secondary objective is to characterize the experience of Canadian medical device innovators with regard to other elements of medical device adoption and strategic decision making, such as determining how best to demonstrate the value of their novel technology, the timing of entering markets outside of Canada, and the role of cost-effectiveness data in driving adoption, among others.

2 Methods

2.1 Ethics

This qualitative study was granted ethical approval by the University of British Columbia Behavioural Research Ethics Board (H21-03175).

2.2 Design

This qualitative study adopted an exploratory approach that utilizes interpretive qualitative inquiry rooted in grounded theory methodology [19–22]. This was evidenced by the careful balance of structured questions as well as open questions that allow for the identification of codes, themes, and theory inductively [21, 22]. A qualitative study design was implemented given that the experience of each Canadian medical device innovator and/or entrepreneur is likely to be complex and subjective. As a result, the study team concluded that a qualitative approach would be a more appropriate tool for extracting the complex nuances of the subjective experience and presenting it in a structured format. A quantitative approach was thought to be too restrictive and unlikely to allow for exploration of various themes in adequate detail. The use of semi-structured questions allows for capturing elements of the knowledge level and subjective experience of medical device innovators that lend themselves more to a quantitative format. This report was written in keeping with the principles set forth by the Standards for Reporting Qualitative Research [23, 24].

2.3 Participant Recruitment and Selection

The target population was a diverse range of Canadian medical device innovators from small- and medium-sized enterprises (SME), based on the definition put forward by Statistics Canada [25]. This decision was made because SMEs make up approximately 90% of the medical technology landscape in Europe, and it is likely that a similar trend exists in Canada [16, 21]. In addition, SMEs are likely to face unique challenges in the medical device industry relative to large enterprises, and elucidating these challenges was felt to be an important component of this qualitative study. Canadian medical device innovators were

defined as executive level employees of companies working to create new or improved medical devices with the aim of disseminating these devices for patient benefit [21]. The previously mentioned definition of a medical device proposed by Ferrusi et al. was used [16]. No limitations were placed on the type of device being developed. Additionally, recruitment was geared toward including devices in various developmental stages, from concept development to market access, in an effort to minimize stage-related bias [7, 21]. The detailed inclusion criteria are available in the appendix.

Participants were recruited between November 2021 and February 2022. Using purposive sampling, prospective participants were identified by searching websites of conferences on health technologies, reports on health technologies, accelerator-based websites and promotional material, LinkedIn, and via the networks of the authors. Representatives of companies that matched the selection criteria were invited to participate via email and LinkedIn messages where applicable. After no further responses for participation were received, recruitment was closed, and no new participants were invited. All participants provided consent to participate via email at least 24 h prior to their interviews. A professional relationship was established via email prior to all interviews, with participants gaining a clear understanding of the interviewer's research interests, clinical experience and research experience, as well as the rationale for pursuing this qualitative study.

2.4 Data Collection

Data were collected via semi-structured interviews conducted by I.B., a cisgender male physician with training in qualitative research methods obtained throughout both his clinical training and postgraduate/masters level education. The semi-structured interview format was deemed to be appropriate for open-ended, rich data generation given that less restrictive questions can be asked, and more detailed answers, opinions, and ideas can be prompted, particularly in a setting where participants feel comfortable [21]. A nonpiloted topic guide (Appendix) with a mix of open- and closed-ended questions was utilized. This guide was developed based on previous work by Craven et al., with relevant questions being identified and selected based on a thorough review of their study methodology and referenced works [1]. The guide was purposefully developed to allow for more in-depth conversation on the role of health economics in company development, in an effort to explore both the level of knowledge of health economics as well as the subjective experiences of medical device innovators in this regard. This topic guide was developed by the first author (IB) with input from all co-authors (AJS and WZ). Potential disagreements on the structure or content of the topic guide were resolved based on the expertise of one co-author (WZ).

In this study, the level of knowledge of health economics was quantified using a Likert scale [1, 21] (Appendix). Commonly used terms in the field of health economics were presented to participants in an attempt to objectively elucidate the level of familiarity with the field. These terms included cost-effectiveness analysis, headroom analysis, budget impact analysis, and decision analytic modeling. Participants were then allowed to provide a rating of their level of knowledge based on their subjective familiarity with these terms. There is no commonly agreed upon criteria for determining an individual's level of health economics knowledge, and as such, the values provided by participants reflect their perception of their level of knowledge based on interactions with other experts in the medical device industry. The participants' level of health economics knowledge, as well as the overall influence of health economics on company strategy is deemed to be relevant to participants' perception of their experiences in navigating the medical device landscape in Canada, and attempts were made to capture this thoroughly through semi-structured interviews. Structured questions on specific decision-making priorities that serve as motivating factors for developing novel health technology, as well as factors that are perceived to be of importance to purchasers were selected based on the work by Craven et al., and modified to meet the goals of our study [1].

At the end of each semi-structured question, participants were invited to expand on their responses. Other factors related to decision-making priorities and purchaser decisions during procurement were generated through further discussion. All interviews were conducted via virtual conferencing technology (Zoom under the University of British Columbia/Institutional Account) and were estimated to last between 30 and 60 min. No individuals were present during interviews apart from the participants and the interviewer. Pictorial representation of all questions that involved a Likert scale was provided during the interview allowing participants the opportunity to visualize their response. All interviews were recorded in audio format only, and this was transcribed verbatim. Notes were made during all interviews, which were used to inform subsequent interviews as well as data analysis. Complete transcription of each interview was performed using a routine transcription approach. The final anonymized manuscript was returned to all participants for feedback and correction. No corrections or adjustments were deemed necessary. Repeat interviews were not performed.

2.5 Data Analysis

Qualitative data analysis software Atlas.ti™ was used to support data analysis (version 9.1.3). Verbatim transcripts were read prior to commencing coding to ensure that the data were familiar to the authors. Data coding was

performed by one author (IB) and reviewed for consistency and accuracy by a second author (WZ). A coding tree was generated after empiric assessment of the data obtained (Appendix). Thematic analysis was conducted, and statistical analyses were performed using Microsoft Excel (version 16.58) where applicable. All figures were generated using Microsoft Excel (version 16.58). Direct quotes from participants are included to emphasize the authenticity of the themes highlighted. Participant identification is not included with direct quotes in an effort to maintain privacy in light of the sensitive nature of the topics discussed.

Table 1 Characteristics of the participants and companies

Variable	Category	*N* (%)
Age (in years)	25–35	3 (30%)
	36–45	4 (40%)
	45–55	1 (10%)
	> 55	2 (20%)
Gender	Women	3 (30%)
Financial stage of company	Pre-seed	1 (10%)
	Seed	8 (80%)
	Series A	1 (10%)
Participant role in company	Chief Executive Officer	5 (50%)
	Chief Operating Officer	3 (30%)
	Chief Technology Officer	1 (10%)
	Director of Strategy	1 (10%)
Province of the company headquarters	Alberta	5 (50%)
	New Brunswick	1 (10%)
	New Foundland and Labrador	1 (10%)
	Ontario	3 (30%)
Device category	Diagnostic	5 (50%)
	Therapeutic	5 (50%)
Clinical area addressed	Oncology	3 (30%)
	Cerebrovascular disease	1 (10%)
	Fracture fixation	1 (10%)
	Postoperative monitoring	1 (10%)
	Neurological diseases	1 (10%)
	Pulmonary disease/trauma	1 (10%)
	Critical care	1 (10%)
	Diagnostic services	1 (10%)
Product commercialized	Yes	1 (10%)
Company initiated from academic wok	Yes	6 (60%)
		Median (min–max)
Number of years of participant experience in health-care innovation		8.75 (2–25)
Number of years participant with current company		3 (1–8)
Number of years of incorporation of current company		3.75 (1–16)
Number of employees at current company		8.5 (4–25)

3 Results

3.1 Participants

Forty-four participants representing 21 Canadian medical device companies were invited to participate in this study. Of the 21 companies that were approached, 10 participants from 10 companies agreed to participate and completed the interviews. The remaining participants either did not respond to the invitations to participate in any way (29 participants) or were unable to coordinate an interview in the allotted time due to scheduling conflicts (5 participants). Due to the number of participants recruited, data saturation was not explored. The interviews generated 423.03 min (7.05 h) of audio data and the mean interview time was 42.30 min, with a median interview time of 41.61 min. During all interviews, the focus was on the development trajectory of one device per company. Three of the ten participants were female, and the age ranges of the participants are depicted in Table 1. A wide range of medical devices were represented with both diagnostic and therapeutic devices included. The development stages ranged from concept development (proof-of-concept) to devices already commercially available (market access stage). All companies had 25 employees or fewer, with three companies employing less than 5 employees. Most companies were at the seed stage. Five of the ten interviews were conducted with the chief executive officer of the relevant company. Four provinces were represented, with five companies headquartered in Alberta.

3.2 Health Economics Knowledge

Six participants (60%) reported having "adequate knowledge" of health economics with responses ranging from "minimal knowledge" to "adequate knowledge" (Fig. 1). Participants who rated themselves as having adequate knowledge demonstrated their exposure to health economics in a variety of ways as exemplified by the following quotes: "…we had a health economic study done for our technology…so I have enough knowledge…"; "…[we] worked with a health economics outcomes research organization…they're doing a health economics white paper [for our technology] for the US market…there are a couple other [analyses] there is cost minimization analysis…cost utilization analysis and then budget impact analysis"; "I have been through a couple different [economic] analyses with what we have done and I've learned from this [experience]…"; "I have intimate knowledge of the health technology assessment process…" Other direct quotes related to participants' level of health economics knowledge have been redacted for privacy related concerns; however, further details regarding participants' experiences with EEE are depicted in Table 2. Taken in totality, this information provides relative certainty with regard to the accuracy of participants' self-rating of their level of knowledge of health economics.

In terms of the importance of health economic evaluation to their company, six participants expressed that it was "very important" to their company, while three rated it as "quite important" (Fig. 2). Despite the fact that 90% of participants ascribed a high level of importance to health economic evaluation in terms of their company's development, three participants (30%) reported that their company had not pursued an EEE of their device, although these participants did indicate that an EEE would likely be pursued at a later date (Table 2).

Participants who reported that their companies pursued an EEE were then asked to expand on the reason for pursuing this evaluation, and to describe whether there was perceived benefit to having the EEE performed. Of the seven companies that pursued an EEE of their device, the most common reasons expressed for having this performed included a desire to understand the potential for cost effectiveness of the device, to provide these insights to potential investors, for market access and adoption conversations and to refine the company's value proposition (Table 2). The decision to pursue an EEE was made internally by six of the seven companies that pursued these insights, with one participant reporting that the EEE of their company's technology was coordinated by one of the company's funders, and that a decision to pursue this evaluation likely would not have been made outside of this funder's recommendation (Table 2).

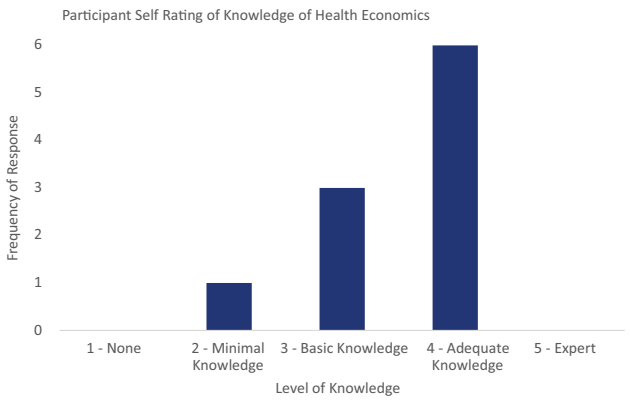


Fig. 1 Participant self-rating of knowledge of health economics

Table 2 Use of early economic evaluation and other formal decision-making tools among participant companies

Case	Formal early economic evaluation pursued	Reasons for pursuing formal early economic evaluation	Did your company derive benefit from the early economic evaluation (or do you envision this being beneficial in the future)?	Explanation—did your company derive benefit from the early economic evaluation (or do you envision this being beneficial in the future)	Formal decision-making tools utilized in product development	Approach to demonstrating value to purchasers
1	Yes	Internal decision based on desire to understand the potential for cost-effectiveness of the novel technology	No	Model results were less favorable than expected. This created uncertainty regarding how to use the results moving forward	User feedback on device features and willingness to pay	Utilizing key opinion leaders, effectiveness data from clinical trials, advocacy from patient interest groups
2	Yes	Internal decision based on desire to understand the potential for cost-effectiveness of the novel technology, and to generate robust data for further investment discussions and market access	Yes	Benefits included developing an understanding of potential areas for improvement of the novel technology, obtaining favorable data for use in a value dossier and valuable data for use in fundraising	Cost-effectiveness, cost minimization analysis, budget impact analysis	Clinical effectiveness data from controlled clinical trials, cost-effectiveness data derived from clinical trials, publishing case series, utilizing key opinion leaders
3	No	N/A	Yes	N/A	Detailed understanding of the unmet need, understanding the regulatory landscape, understanding the size of the market, understanding current costs and associated drivers	Preclinical data from cadaver models, effectiveness data from controlled clinical trials with a focus on procedure times, cost analysis
4	No	N/A	Yes	Health economics was not explored early enough in the company lifecycle and as a result the company needed to pivot	Detailed understanding of the scope of the clinical problem through literature reviews, secondary market analysis, stakeholder interviews	Effectiveness data from controlled clinical trials, cost effectiveness data derived from clinical trials, utilizing key opinion leaders
5	Yes	Internal decision based on need to understand requirements for market access and adoption by the provincial health authority	Yes	The early economic evaluation performed provided guidance on the type of data that would be required in the future to demonstrate value to purchasers	Lean methodology, assessment of customer experience and trends documented through robust customer relationship management systems, user surveys, cost associated with regulatory pathways in Canada versus USA, early economic evaluation	Effectiveness data from controlled clinical trials, cost-effectiveness data derived from clinical trials, patient testimonials, utilizing key opinion leaders
6	Yes	Commissioned by funding entity	Yes	The results of the headroom analysis were valuable as well as the range of potential price points for the novel technology	Headroom analysis, early economic evaluation, market analysis, user interviews, business model analysis	Preclinical data from animal models, effectiveness data from first-in-human trials followed by larger clinical trials, utilizing key opinion leaders, cost-effectiveness data derived from clinical trials, clinical presentations at conferences

Table 2 (continued)

Case	Formal early economic evaluation pursued	Reasons for pursuing formal early economic evaluation	Did your company derive benefit from the early economic evaluation (or do you envision this being beneficial in the future)?	Explanation—did your company derive benefit from the early economic evaluation (or do you envision this being beneficial in the future)	Formal decision-making tools utilized in product development	Approach to demonstrating value to purchasers
7	Yes	Internal decision based on desire to understand potential price points, as well as the fact that the technology may not be eligible for a CPT code in the USA. Thus, it became important to establish a clear ROI	Yes	Previously stated goals for performing an economic evaluation were met	Early economic evaluation, analysis of marketing specification requirements, end user feedback, thorough stakeholder analysis	Cost-effectiveness data from controlled clinical trials, utilizing key opinion leaders, patient experience data, patient advocacy groups, workflow data derived from user feedback and clinical trials
8	No	N/A	Yes	Establishing economic feasibility is critical and economic modeling of the novel technology and the range of potential use cases along with the potential overall healthcare cost savings is important to have	Market research, financial valuation of project ideas	Research on feasibility (assessment of technical requirements of technology), cost-effectiveness data from controlled clinical trials, effectiveness data from clinical trials, utilizing key opinion leaders, presenting at relevant conferences
9	Yes	Internal decision based on desire to understand the potential for cost effectiveness of the novel technology	Yes	Previously stated goals for performing an economic evaluation were met	Strategic milestone setting, early economic evaluation, market analysis, and assessment of competition and/or device landscape, thorough evaluation of clinical need including incidence and prevalence estimates, geographic analysis of both clinical parameters and innovative landscape (by state in the USA), thorough understanding of payer dynamics (private payers/patients versus institutional payers/large health insurers)	Effectiveness data from controlled clinical trials, cost-effectiveness data derived from clinical trials, cost comparisons to the current gold standard, data from workflow studies, data focused on the user experience, utilizing key opinion leaders

Table 2 (continued)

Case	Formal early economic evaluation pursued	Reasons for pursuing formal early economic evaluation	Did your company derive benefit from the early economic evaluation (or do you envision this being beneficial in the future)?	Explanation—did your company derive benefit from the early economic evaluation (or do you envision this being beneficial in the future)	Formal decision-making tools utilized in product development	Approach to demonstrating value to purchasers
10	Yes	Internal decision based on desire to refine value proposition and develop robust data for investment conversations	Yes	The results of the early economic evaluation provided guidance on which clinical indication to focus on with the novel technology, as well as how best to refine the value proposition	Early economic evaluation, thorough understanding of the unmet clinical need, thorough understanding of the competitive landscape, refinement of the value proposition using the results of the early economic evaluation	Effectiveness data from controlled clinical trials, cost-effectiveness data derived from clinical trials, utilizing key opinion leaders, presenting at relevant international conferences, inclusion of technology in relevant clinical guidelines

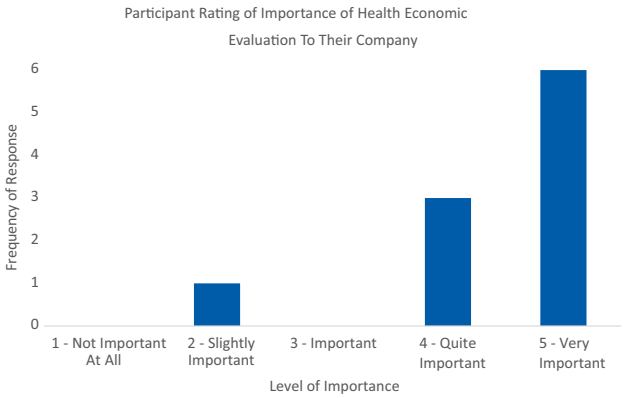


Fig. 2 Participant rating of the importance of health economic evaluation to their company

3.3 Benefits of Early Economic Evaluation

One participant (of the seven companies that pursued EEE) reported that they did not deem the evaluation beneficial to their company (Table 2). The reason for this perceived lack of benefit was the fact that the model results did not suggest a favorable cost-effectiveness profile, and as a result, the participant felt that it created significant uncertainty with regard to how the company should proceed. This is exemplified in the following quote: "Our evaluation showed that [our technology] provides [cost] savings, but not massive savings to the point that it is hard to really make a company [based on this result]…One person…[developed] some kind of a model that [they] ran that was very obscure to me. I think [economic analyses] should be done by two or three different entities." Conversely, one of the three participants that had not pursued an EEE expressed the sentiment that the benefit of such an evaluation was clear in hindsight, as their company was forced to pivot as a result of not exploring economic evaluation early enough in the company's life cycle (Table 2; "We did not explore health economics early enough and we had to pivot because of this.")

3.4 Decision-Making Tools

Participants were asked to identify any formal decision-making tools used within their company. Common tools reported included cost-effectiveness analysis, EEE, headroom analysis, market research, and user feedback (Table 2). Of note, lean methodology, strategic milestone setting, and financial valuation were also referenced.

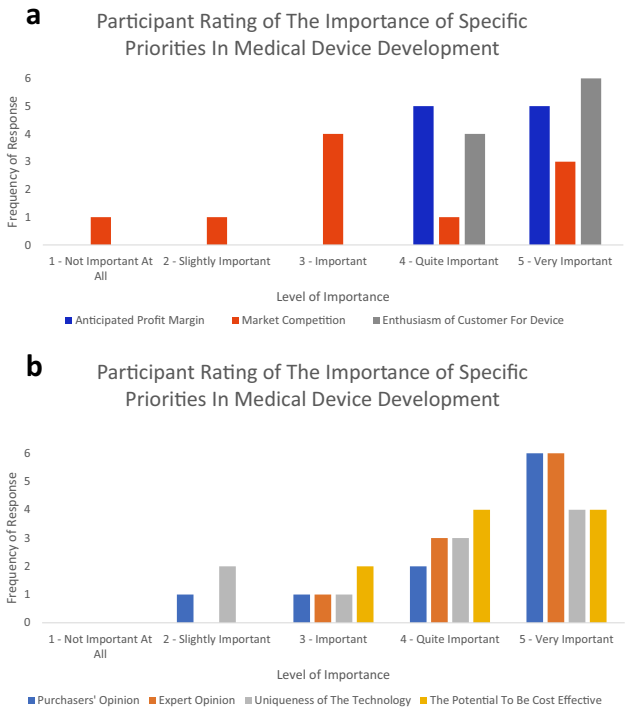


Fig. 3 **a** Participant rating of the importance of specific priorities in medical device development. **b** Participant rating of the importance of specific priorities in medical device development

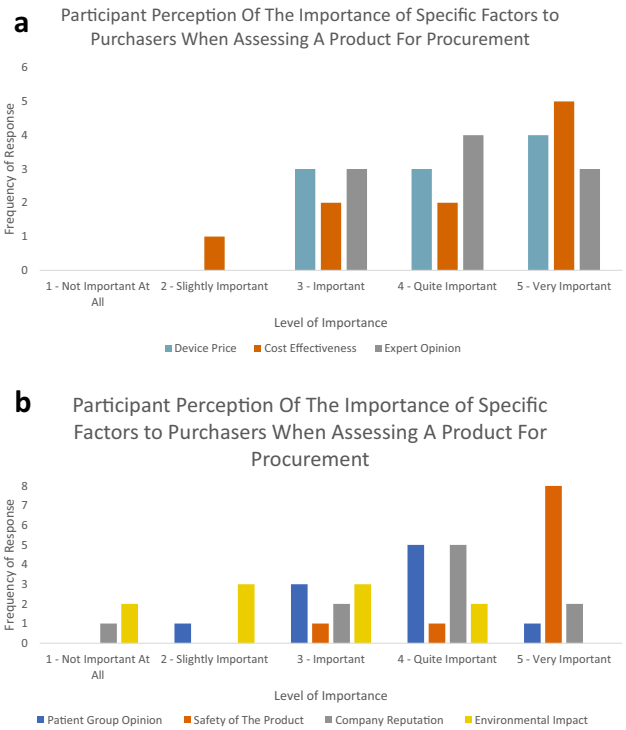


Fig. 4 **a** Participant perception of the importance of specific factors to purchasers when assessing a product for procurement. **b** Participant perception of the importance of specific factors to purchasers when assessing a product for procurement

3.5 Decision-Making Priorities

The importance of seven specific decision-making priorities in medical device development as rated by participants is illustrated in Fig. 3a, b. The priorities that were consistently rated to be either "Quite important" or "Very important" were anticipated profit margin and enthusiasm of the customer for a device. Expert opinion and the potential to be cost effective were consistently rated at "Important," "Quite important," or "Very important," while the priorities that demonstrated the widest spread in terms of responses were market competition, purchasers' opinion, and uniqueness of the technology (Fig. 3a, b). Some participants expressed a positive attitude toward market competition. with one participant stating "We actually would like there to be a lot of competition in the market…[because] the more likely that you can find a distributor that wants a differentiated product…and we don't have to worry about building a supply chain. We like competition because it'll make our exit strategy and our distribution and commercialization strategy much easier." Conversely, other participants suggested that high levels of market competition could be detrimental to their company, with one participant suggesting that their company made the decision to pivot due to significant competition in the space they were originally planning to enter*:* "We did a significant pivot in terms of product development after realizing kind of our first concept had a huge amount of market competition, and we have pivoted to a space where there is no competition. Basically, we're creating an entirely new market. There are less barriers to entry, there is the opportunity for faster market adoption and we're creating a new business so that kind of makes our business more viable and provides us with a larger opportunity."

3.6 Factors Perceived to be of Importance to Purchasers

The factors that demonstrated the widest spread in terms of responses were cost effectiveness, patient group opinion, company reputation, and environmental impact, with environmental impact having the lowest median rating of 2.5

(Fig. 4a, b). With regard to cost effectiveness in particular, some participants expressed the sentiment that the ability to provide convincing cost-effectiveness data is of significant importance to purchasers and other decision makers. This is exemplified by the following quotes: "For the US white paper they gave a lot of importance to cost effectiveness analysis…"; "This is more and more proving to be very, very important because if you don't have a cost-effective device you probably will get into the best hospitals let's say 10–15 hospitals in the US, and then you are saturated"; "within the value-based system now cost effectiveness is a really big part of being accepted into that value-based healthcare system."; "In the United States I think this is very important…they are finding that the cost of care is increasing and I think that… the hospital value committees are now…that's how they evaluate new technology to be adopted is cost effectiveness so whether that's workflow improvements or direct hospital costs or improvements in the patient experience. I think maybe less in terms of QALYs…and those types of things but certainly more in terms of direct hospital costs…" Conversely, some participants felt that cost effectiveness might not be an important criterion for decision makers.

3.7 Approach to Demonstrating Value to Purchasers

Participants were asked to describe their company's approach to demonstrating value to purchasers through the use of an open-ended question. Common responses include utilizing the results of clinical trials, cost-effectiveness data from pragmatic trials, utilizing key opinion leaders, presenting at conferences, and utilizing patient advocacy groups (Table 2).

3.8 Innovation in Canada as Compared with the USA

Positive elements of the Canadian medical device ecosystem were identified by some participants. Two participants referenced the support their company received from the Ontario Bioscience Innovation Organization (OBIO), specifically the Early Adopter Health Network (EAHN^{TM}) program. One participant gave this response when asked if they were aware of any programs or institutions that offer assistance with real world economic evaluation of novel technology: "…the one program that I'm thinking of is OBIO's EAHN program… I think it's generally intended for more adoption data." Another participant had this to say about their company's experience: "We're starting to see some signs of the government's support in terms of being able to provide companies with some early-stage funding in order to pilot those technologies over here. For example, there's an organization called OBIO…they're running the EAHN program…you've probably heard of CANHEALTH as well… Mohawk MedBuy…they've tried to support companies [in terms of] value-based procurement."

Two participants referenced the Coordinated Accessible National Health Network (CANHEALTH), while four participants referenced the National Research Council of Canada and its Industrial Research Assistance Program (IRAP), highlighting the program as a valuable resource for medical device innovators both in terms of mentorship and financial support. Lastly, one participant referenced the Atlantic Canada Opportunities Agency (ACOA) and its Regional Economic Growth through Innovation (REGI) program, outlining the agency as a source of engaging and incredibly experienced mentors, and the REGI program as a great source of funding for early stage medical device companies.

With regard to the experience of interacting with decision makers and stakeholders at all levels, one participant had this to say: "I will say this on a positive note… Canada has been an extremely friendly place…the clinicians and the hospitals that we've engaged with have been extremely excited [and] willing to engage with us, very fast to communicate with us…it's easy to interact with clinicians here… it's a good starting place I'll definitely say that."

Conversely, a number of negative elements of the experience were highlighted by some participants, with a few repeatedly expressing the sentiment that achieving adoption in Canada as a Canadian medical device start-up is fraught with difficulty. One participant stated "…trying to get a technology adopted over here is sort of impossible in the early stages of a startup…" Another quote emphasizes this perception "…The research opportunities and the research support that we get over here in Canada is absolutely phenomenal, but it gets to a point where we are trying to commercialize our own technology in our own backyards, and we just don't get the support to do that. It practically gets to the point where it's about to get past the goal line and everything stops…" This sentiment was shared explicitly by five participants (50%), with one participant sharing that for their company, very little resources have been directed toward exploring market entry in Canada.

Further elaboration by participants revealed potential subthemes that may explain the reason for the perception of an easier path to adoption in the USA, with one participant

referencing the size of the US medical device market relative to the size of the Canadian market: "…the size of the medical device…industry [in Canada] is like a splash in the bucket when you consider the size of the United States [market]…" A second participant expressed a similar sentiment with the idea that "we just don't have enough health technology innovation going on [in Canada] to have a robust system [for health technology assessment]." A third participant referenced the difference in medical device approval between the USA and Canada as another barrier to pursuing market entry in Canada, particularly citing the strenuous quality system requirements in Canada for noninvasive devices. Furthermore, the lack of clarity regarding how algorithms are evaluated by Health Canada in the context of medical device innovation was also highlighted by one participant.

Reference was also made to the general trend of procurement practices in Canada through group purchasing organizations (GPOs), with the specific sentiment that start-ups that are operating on smaller budgets - and that do not have an established reputation - cannot compete with larger entities in this process. Lastly, one participant cited poor communication between innovators and clinicians as a contributor to the difficulty encountered with moving innovation forward in Canada. "…I feel like another barrier [to] adoption and [to] medical device innovation is that we're not all sitting [at] the same table. So, innovators are not sitting [at] the same table with clinicians, [and] they're not sitting [at] the same table with policymakers. And the lack of communication across these three different stakeholders… there's one of the reasons why we don't see innovation come to life, and it really stops in the research phase…"

3.9 Cost-Effectiveness in the USA Compared with Canada

An interesting subtheme that was unearthed through discussion was the relative importance of cost-effectiveness analyses for market entry in the USA as compared with Canada. One participant suggested that demonstrating cost effectiveness was arguably more important in the US due to an increasing culture of bundled payments associated with diagnosis-related groups, and an increase in value-based procurement committees at large healthcare institutions. A particular quote supports this notion: "…because I think that we evaluate medical technologies in Canada very differently than [they] do in the United States. Even though…[some] hospitals in the United States are meant to be not for profit, I think they are very much more run as per a business model than Canadian healthcare institutions…" The idea here is that this business focus creates greater impetus for establishing a favorable return on investment prior to procurement, hence the need for robust cost-effectiveness analyses. Other quotes highlighted in Sect. 3.6 above also emphasize this sentiment.

However, another participant suggested that based on their company's experience, multiple drivers of adoption were identified within the US medical device landscape, and cost-effectiveness was not as strong a driver there as it is in the Canadian landscape. This participant went on to state: "…the generality is that interestingly health economics was not that important [in the USA], it was…a two [on the previously established five-point Likert scale] … and the most important driver for them was that it was going to help the clinician to make important decisions, so it had to have a very good clinical value proposition…"

4 Discussion

This study explored the experiences of Canadian medical device innovators in navigating the Canadian medical device landscape, with a focus on the use of health economics as it relates to the process of medical device innovation. The level of detail shared by each participant was robust, and a range of themes, ideas, and perspectives were elucidated.

In our study, 10% of participants reported "none" or "minimal" knowledge of health economics principles. This is in stark contrast to the data presented by Craven et al., in which 60% of respondents reported low or no knowledge of health economics [1]. There are two important distinctions to be made with regard to this finding. The first is that our sample size is much smaller than that of Craven and colleagues. As a result, it is difficult to draw robust conclusions based on a comparison of these numbers. The second is that the definitions used to construct the Likert scale in our study were slightly different than the ones used by Craven et al. At the extreme ends of the scale, "None" and "Expert knowledge" were the same. However, "Low knowledge" was replaced by "Minimal knowledge" in our study, while "Medium" and "High" were replaced by "Basic knowledge" and "Adequate knowledge," respectively. These modifications were made based on the idea that the words minimal, basic, and adequate would provide more meaningful categorization in this specific context.

While we recognize that this modification makes it impossible to compare the results of our sample with that of Craven and colleagues in this regard, the fact that the categories at the ends of the scale were unchanged potentially allows for some conclusions to be drawn about the distribution of responses between this range. In our sample, 90% of participants rated themselves as having either basic or adequate knowledge of health economics. By contrast, 23% of the participants in the study by Craven et al. rated themselves as having no knowledge of health economics.

This perhaps can be explained by greater general awareness of health economics among Canadian innovators as a result of various educational initiatives and the increasing demand of relevant evidence from decision makers. As highlighted in our data, funding institutions have promoted EEE as part of their required activities even when innovators may not have been inclined to pursue such evaluations. It is likely that these practices have increased the general awareness of health economics within the Canadian medical device ecosystem.

An interesting finding was the relationship noted between participants' rating of the importance of health economics to their company, and the number of companies that had pursued an EEE at the time of the interview. Ninety percent of participants rated health economics as being either quite important or very important to their company; however, only 60% of companies made an internal decision to pursue an EEE of their technology. One company pursued an EEE only as a requirement of one of its funders, and the remaining companies suggested that they would be pursuing economic evaluation in the future; however, no clear timelines were indicated. While the decision to pursue an EEE is multifactorial, this finding does raise an important question—why are EEEs not being pursued by all medical device companies? Some innovators have expressed the idea that such evaluations can be costly, and it is possible that this may have influenced the decision; however, in our sample, there was no clear evidence that cost was a factor.

One innovator expressed discontentment with the results of the EEE performed, due to the fact that their technology was found to have an unfavorable cost-effectiveness profile. This finding underscores the importance of pursuing EEE at an early stage where the results can be used to guide strategic decision making and product development prior to irreversible decisions being made. The experience of another innovator in our sample, whose company was forced to pivot as a result of not pursuing an EEE early enough in the company's life cycle, provides further evidence of this. Innovators should be wary of avoiding EEEs for fear of receiving unfavorable insights, as this is more likely to result in investments in technology that have a low probability of adoption, ultimately resulting in wasted resources.

In terms of decision-making priorities in medical device development, the spread noted in the responses to market competition, purchasers' opinion, and uniqueness of the technology was somewhat surprising. Even more noteworthy was the fact that some participants saw market competition as a favorable factor, while others saw it as harmful to their company. It is likely that this reflects the nuances of specific markets that are device and patient dependent. While some may argue that the existence of multiple companies in a specific market, with none exerting a monopoly, may suggest that there is room for new entrants, this argument ignores the nuances of intellectual property arrangements, which often play a significant role in the medical device landscape.

Somewhat less surprising was the fact that purchasers' opinion also demonstrated a wide range of responses. Throughout our study, the distinction between purchasers and end users was made clear, with all participants given the opportunity to expand on their interpretation of this difference. Some participants expressed the idea that many purchasers have no clinical expertise in the medical device area they oversee, and as a result depend on the expertise of the end user/customer to influence purchasing decisions. This was the most common reason cited for the low importance of purchasers' opinion as a decision-making priority. Conversely, other participants saw purchasers as the gatekeepers of the procurement process and expressed the idea that although they often have low levels of clinical expertise, their opinion of a company or a specific device can be the difference between adoption and nonadoption, making them very important players in the medical device landscape.

These findings perhaps suggest that most Canadian innovators do not fully understand the objective criteria used by purchasers when assessing products for procurement. This point is further supported by the rating of the specific factors that participants deemed to be important to purchasers, in which there was a significant range in the importance attributed to cost-effectiveness, patient group opinion, company reputation, and environmental impact. While it is possible that the range of responses seen regarding the importance of cost effectiveness may be related to a lack of understanding of the concept, taken as a whole, our data suggests that perhaps more clarity is needed in terms of the expectations and requirements of purchasers. MacNeil et al. highlight the fact that improvements in the HTA process, including more prompt disclosure of the results, minimizing technical jargon, and patient involvement in the HTA process may remove barriers to health technology innovation in Canada [12]. The findings from our study suggest that further improvements are needed in this regard.

The influence of GPOs on the ability of medical device companies to achieve widespread adoption in Canada was referenced in our sample and deserves special mention. One participant in our study expressed the idea that the use of GPOs is detrimental to small Canadian medical device companies as they cannot compete on volume and reputation. This practice, in which purchasers extend their buying power through procuring supplies in bulk quantities, can be a cost-saving method; however, other authors have highlighted the negative impact on Canadian medical device companies [12]. As MacNeil and colleagues point out, the Canadian healthcare landscape is one in which there are a few large

GPOs and many smaller payers, which creates a highly fragmented market [12]. The result is a complex landscape in which it is quite challenging for Canadian innovators to validate the effectiveness of new products, sell to early adopters, or spread and scale a technology widely [12]. Although several policies and proposals have been put forward to mitigate the impact of GPOs on Canadian innovators, this challenge persists and is ultimately proving difficult to solve [12].

Perhaps the most notable finding identified through open discussion is that a significant proportion of Canadian innovators make the strategic decision to focus their time and efforts on market adoption outside of Canada, specifically in the USA. Several possible reasons for this were identified including the small size of the Canadian medical device market relative to the US market, less stringent regulatory and device approval requirements in the USA for specific classes of devices, and arguably less rigid cost-effectiveness requirements depending on the type of technology being developed. These factors have been explored in previous publications, with some authors proposing a range of approaches to address them and combat the relative talent drain that occurs when Canadian innovators choose to develop their technology in the USA [12, 16]. While many initiatives have been developed to mitigate the effects of these factors, talent migration persists, and this phenomenon warrants further research if growth of the Canadian medical device industry is to be realized.

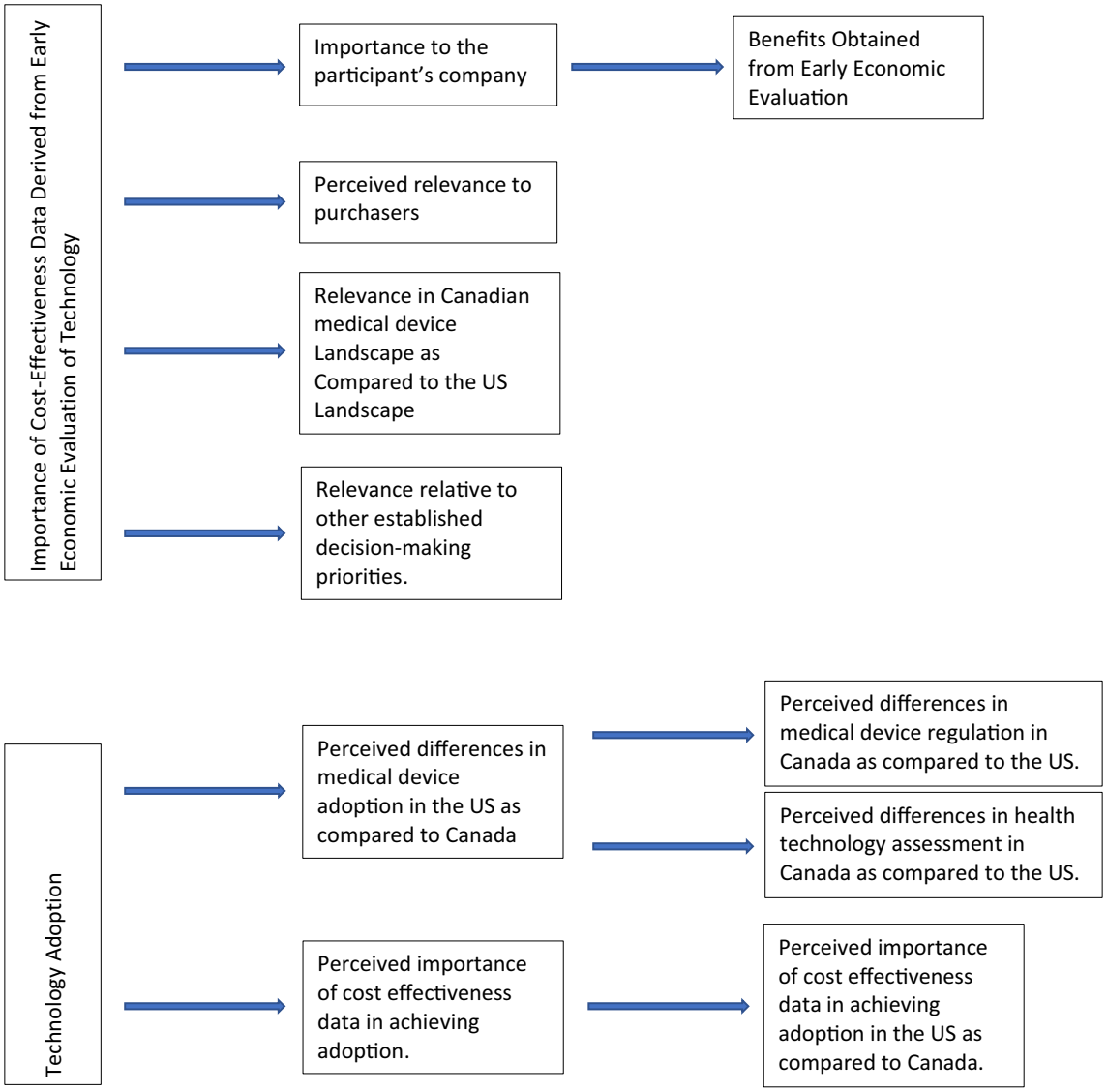
Despite the barriers to medical device innovation described by participants in our study, a number of positive elements were highlighted. There was generally a sense of appreciation for a number of national and provincial programs that have served as a source of both funding and mentorship. These included CANHEALTH, OBIO, and the ACOA REGI program. The development and mandate of these programs are in alignment with the recommendations proposed by MacNeil and colleagues, namely the provision of national seed funding to decrease the need for foreign investment and spur innovation activities within Canada [12]. In addition, the ability to easily access clinicians and engage with hospital administrators and other decision makers was highlighted as a positive attribute of the Canadian ecosystem.

To our knowledge there has been little focus on evaluating the subjective experience of medical device innovators specifically with regard to the use of health economics in product development. While the study by Craven et al. attempts to gauge the level of knowledge of health economics demonstrated by the medical device innovators that completed their survey, there were no other published studies identified that had a similar goal. As a result, it is difficult to draw conclusions regarding the accuracy of this method of knowledge assessment. A number of similarities and differences were noted in our data when compared with the data presented by Craven et al. [1]. A notable difference in our study is the fact that Canadian medical device innovators routinely rated anticipated profit margin and enthusiasm of the customer for the device as the most important decision-making priorities when developing new technology. However, in the data presented by Craven et al., participants rated six of the seven decision-making priorities included in our study equally as highly [1]. We included the potential to be cost effective as a seventh decision-making priority in our study, and this was consistently felt to be either important, quite important, or very important among our study participants. Similarly to the data demonstrated by Craven et al., Canadian medical device innovators in our study were less likely to deem environmental impact, patient group opinion, and company reputation as important to purchasers, and safety of the product and expert opinion were consistently felt to be important, quite important, or very important to purchasers [1].

The results of our study emphasize the need for further research into the experience of Canadian medical device innovators specifically with regard to the use of early economic evaluation in product development. While our study took a global approach to assessing the use of health economics in this population, a more tailored focus on the nuances of EEE utilization would be of value. In addition, further research should be directed to understanding whether previously identified barriers to health technology innovation persist for Canadian medical device innovators, and how best to mitigate these.

5 Limitations

A number of limitations exist with regard to this study. The first is that participants were invited to be involved through a detailed recruitment letter outlining the study aims. As a result, selection bias may have had an impact on study findings in that only medical device innovators who were comfortable with health economics concepts agreed to participate, while those without much experience in this regard may have declined the invitation. This may explain the lower percentage of respondents reporting low or no knowledge of health economics. In addition, the study sample was relatively small, and as a result, extensive statistical analysis of quantitative responses was not possible. Consequently, it is difficult to draw conclusions regarding general perspectives among Canadian innovators on a large scale.



Coding tree identified through analysis of data obtained from semi-structured interviews with Canadian innovators

6 Areas of Further Research

Policymakers and other decision makers were not included in this study. Further research should be directed toward gaining the perspectives of these stakeholders, to allow for a balanced understanding of facilitators and barriers to medical device innovation in Canada. In addition, patients or public representatives were not involved in the design of this study. Given that patients are key stakeholders in medical device innovation in Canada, further research geared toward assessing patient perspectives on the approach to medical device innovation should also be explored. Lastly, obtaining a larger sample size in all future studies of this nature would be critical in ensuring that robust conclusions can be drawn.

7 Conclusions

Canadian medical device innovators appear to demonstrate awareness of health economics principles, including the benefits of EEE, and the role that such evaluations can play in strategic decision making. However, they have a difficult time navigating the Canadian medical device industry, particularly regarding device approval and market adoption. A number of innovators focus their efforts outside of Canada altogether, a trend that could have multiple downstream effects on the Canadian medical device landscape. Further research should be directed toward understanding how to better support small- and medium-sized enterprises given that they are a tremendous source of growth for the Canadian medical device industry.

Appendix

Inclusion Criteria

- Executive level employees of medical device companies
- Companies that are or have been previously affiliated with government entrepreneurship initiatives including but not limited to the Canadian Technology Accelerator.
- Companies that are or have been previously affiliated with an academic institution, municipally funded or provincially funded accelerator in Canada (e.g., Hunter Hub for Entrepreneurial Thinking, Haskayne School of Business)
- Companies involved with the development of either diagnostic or therapeutic devices
- Companies with less than 99 employees as informed by company data posted on LinkedIn.

Questions Included in the Topic Guide

1. What type of device does your company develop (diagnostic or therapeutic)?
2. What clinical entity is being addressed?
3. Demographic data: age range (20–24, 25–30, 31–35, 36–40, 41–45, 46–50, 51–55, > 55 years), gender, number of years of experience in the field of medical device innovation, number of years at current company, number of employees at current company, number of years your current company has been incorporated.
4. Describe your company (e.g., stage of development) and your position and role within it.
5. How would you rate your knowledge of health economic evaluation on a 5-point Likert scale from "none" (0) to "expert" (5)?
6. How important is health economic evaluation to your company (rated on a 5-point Likert scale from "not at all important" to "very important")?
7. What formal decision-making tools if any are used in your company to support product development (e.g., strategic and financial valuation of projects, weighting and scoring of products, established product criteria etc.)?
8. How would you rate the importance of the following seven decision-making priorities (using a 5-point Likert scale ranging from "not important at all" to "very important") when initiating medical device development?

   (a) Anticipated profit margin.
   (b) Market competition.
   (c) Enthusiasm of customer for a device.
   (d) Purchasers' opinion.
   (e) Expert opinion.
   (f) Uniqueness of the technology.
   (g) Potential to be cost effective.

9. Who are your major targeted purchasers?
10. How would you rate the importance of the following seven factors to purchasers (using a 5-point Likert scale ranging from "not important at all" to "very important") when assessing a product during procurement?

    (a) Device price.
    (b) Cost effectiveness.
    (c) Expert opinion.
    (d) Patient group opinion.
    (e) Safety of the product.
    (f) Company reputation.
    (g) Environmental impact.

11. How would you demonstrate the value of your medical product to purchasers (e.g., using clinical trials, key opinion leaders, cost-effectiveness data)?
12. Do you envision that an early economic evaluation of your company's product would be beneficial to your company? If so, how do you envision that this will be performed (Who will commission it? Who would perform it? How would the results be used?)
13. What is your understanding of the health technology assessment process in Canada?
14. What is your understanding of the health technology assessment process established by the funding decision makers in the province in which you operate?
15. Are you aware of any programs or institutions that may offer assistance with economic evaluation of your device?

Declarations

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Ethics approval This qualitative study was granted ethical approval by the University of British Columbia Behavioural Research Ethics Board (H21-03175).

Consent to participate Informed consent was obtained from each participant prior to commencing all interviews. Due to the sensitive nature of this topic, a consent template has been included with this submission.

Consent for publication N/A.

Availability of data and material Due to the sensitive nature of this topic and the proprietary implications of the information discussed, complete transcripts have not been made publicly available. Anonymized transcripts have been made available to the journal only.

Code availability N/A.

Author contributions ILB and WZ were responsible for conception and study design, data collection, data analysis, data interpretation and manuscript preparation. AJS was responsible for data analysis, data interpretation, and manuscript preparation.

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