Has the Pendulum Swung too far?
The Impact of Group Purchasing Organizations (GPOs) and Shared Services Organizations (SSOs) on Small and Medium Enterprises (SMEs) in the Medical Device Industry

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1. Executive Summary

Canadian hospitals and health authorities are increasingly purchasing medical devices through shared services organizations (SSOs) and group purchasing organizations (GPOs). By combining purchasing volume, this is thought to give increased market power to the purchaser, allowing them to achieve lower prices. A number of provinces have set up SSOs to coordinate tenders and two national GPOs (MedBuy and HealthPro) have emerged.

Theoretical and anecdotal evidence suggests that lower costs should be achieved in the short-run, particularly for standard or commodity type items. However, it is less clear that cost savings will be achieved in the high-tech segment, nor is it clear what the long-term implications of an increasingly concentrated medical device industry will be. Of particular concern is that by creating barriers to Canadian small and medium size enterprises (SMEs), a potentially important economic contributor and innovation driver will not reach its potential.

To examine these issues in more detail, we conducted a series of interviews with representatives from Canadian SMEs in the medical device industry as well as a number of other key stakeholders. A number of themes surrounding the tendering process emerged:

- It is not conducive for the uptake of disruptive technologies that have the potential to change the way patients interact with the health care system.
- It tends to favour larger, often multi-national firms that can supply hospitals across Canada. This procurement process is problematic for Canadian SMEs that are unable to compete on such a large scale.
- It is unnecessarily bureaucratic and cumbersome.
- Contracts tend to be too long in duration and often bundle together products, favouring firms with broader product lines.
- It restricts access to end-users, potentially stifling innovation.
- There is a lack of strategic purpose in purchasing and in particular, there is no advantage to being a Canadian firm.
- It may be advantageous to split the medical device sector into low and high technology segments. The GPO/SSO procurement model may be advantageous in the low-tech segment, but should be avoided in the high-tech segment.

Following these consultations and a review of the literature, we make the following recommendations:

1. Ring-fenced funding needs to be dedicated to the purchase of innovative medical technologies.

2. Firms and clinicians need to connect and form partnerships with hospitals and health authorities to develop and implement potentially disruptive technologies. A funding program should be provided to give grants to promising partnerships.

3. Tendering should be simplified as much as possible to encourage wider participation.

4. As much as existing trade agreements will allow, every possible advantage in the tendering processed should be conferred to Canadian firms.

This is an industry of potential strategic importance to the Canadian economy as well as one that that can improve the lives of people around the world through the development of new and innovative technologies. With financial support and some changes in the tendering process, this can be achieved.

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Introduction

In a recent report examining Ontario's public finances, (Ministry of Finance, 2012) Drummond, et al. shone a light on a fiscal crisis emerging in health care. An aging population and further advances in technology are driving health care costs higher than the rate of economic growth – a situation that is not sustainable. While the focus of this report was aimed at Ontario, every other Canadian province faces the same health care expenditure bubble.

While examining strategies to cope with an aging demographic (such as increasing fertility rates or encouraging more immigration) are beyond the scope of this paper, we can examine how we utilize health technology. Specifically, the focus herein is how this cost pressure has influenced medical device procurement and also how we can potentially make better use of technological advances through procurement to reduce the reliance on the health care system.

One of the strategies adopted by Ministries of Health and Regional Health Authorities (RHAs) to manage the cost of medical devices is to group together to collectively organize purchases of medical devices. Some provinces have formed Shared Service Organizations (SSOs) that - in addition to coordinating medical device purchases - seek to achieve economies of scale in other administrative functions. In addition, many RHAs have joined a Group Purchasing Organization (GPO), which seeks to lower costs by joining forces to tender for medical devices. Members of GPOs (and in Canada there are two dominant GPOs: MedBuy and HealthPRO) indicate that they are interested in participating in a particular Request for Proposals (RFP), and they then commit to the term negotiated with the vendor selected by the RFP.

Earlier research by Audas (2012) suggested that the movement towards concentrated and centralized purchasing of medical devices may be adversely affecting Canadian small and medium sized enterprises (SMEs) in this sector. The aim of this paper is to examine the impact of GPOs and SSOs on these firms and subsequently to explore the broader implications for developing and adopting innovative technologies.

This movement towards centralized purchasing raises a number of important issues. Do GPOs and SSOs act as a barrier to entry to SMEs in the medical device industry? In the attempt to professionalize and address accountability issues in the purchasing function, have the bureaucratic and administrative requirements made the purchase of medical devices unnecessarily rigid and constrained? By increasing the burden of tendering and making the prospect of getting innovative technologies into the market more difficult, is Canada lagging behind other countries in terms of fostering innovation? Is an industry that could be a larger contributor to exports and in the employment of highly skilled individuals failing to reach its full potential?

The focus of this paper is to examine procurement policies in Canada – specifically in Ontario and Quebec – to examine the extent to which the increased reliance on GPOs and SSOs has resulted in greater challenges for the SMEs to be active participants in markets, and to explore the extent to which this may be an impediment to innovation.

There are three broad themes that are addressed in this report:

The first theme is that the GPO/SSO procurement model – while perhaps delivering lower short-run costs to their members – disadvantages SMEs in the medical device sector.

The second is that innovative and potentially disruptive medical technology – for instance the trend towards personalized medicine – has the potential to change the way patients utilize and interface with the health care system and as such may result in much more efficient health care delivery. However the GPO/SSO procurement model is an impediment to the uptake of novel technology.

The third theme is that the medical device industry has the potential to play a much more prominent role in the Canadian economy. However, to achieve this potential, it will require support and more strategic direction. It will also require a greater openness towards innovation from Group Purchasing Organizations (GPOs) and Shared Service Organizations (SSOs).

The paper is organized as follows: Section 2 provides an overview of the medical device industry in Canada highlighting key trends. Section 3 examines procurement practices in Ontario and Quebec. Section 4 provides a summary of a series of interviews conducted with representatives from SMEs in the medical device sector. An important theme that emerged from this is that the GPO/SSO model of procurement makes innovation more difficult and hinders SMEs in this sector. This section also includes summaries of discussions with GPOs and SSOs that we have conducted as well as five organizations across Canada that seek to advance medical device firms with innovative medical technologies. Section 5 examines this in light of models of innovation and evaluates the impact that GPOs and SSOs have on innovation in the medical device sector. Section 6 provides a discussion of the key findings and indicates possible policy options. Section 7 concludes.

2. The Medical Device Industry in Canada

The medical device segment of the health care market is a multi-billion dollar industry in Canada, producing and selling everything from well-established disposable commodities to leading edge new technologies that have the potential to save lives and change how medicine is practiced. There is a focus on enhancing product lines and innovation. Firms that successfully innovate can find new markets anywhere in the globe.

According to Industry Canada, Small and Medium Enterprises (SMEs) can be defined as having annual revenue between $30,000 and $5,000,000 and having less than 100 employees. An enterprise can be defined as the organizational unit of a business that directs and controls the allocation of resources relating to its domestic operations, and for which consolidated financial and balance sheet accounts are maintained from which international transactions, an international investment position and a consolidated financial position for the unit can be derived (Industry Canada, 2012b).

A firm with a novel technology that offers substantial potential health gains can often extract a significant price for that product. Indeed, selling prices far above the marginal cost to produce are justified on the grounds that large margins are needed to fund future research and development (R&D) to develop even more new products or to further enhance existing products.

When firms hold patents on particular products this potentially conveys a great deal of market power to the supplier. As such, health authorities tend to be forced to pay up to their maximum willingness-to-pay for that particular device. Furthermore earlier research into price transparency in medical devices concluded that a lack of price transparency in this sector might not be driven by firms, but rather by GPOs. Further analysis suggested that GPOs survival depends non-disclosure of prices (Audas, 2012).

As of 2005, there were 1101 medical device facilities recorded with a total of 998 firms. Small facilities are defined as fewer than 49 employees, which comprised 94% of the medical device industry in 2005. Medium and large facilities each make up 6% of this industry. 90% of medical device industry is Canadian owned. Employment levels rose from 22,000 to 26,000 from 2000-2005. In 2008, the size of the Canadian medical devices market was valued at $6.4 billion. The United States is the primary market for Canadian medical devices exports, accounting for some 71% in 2009. (Industry Canada, 2012a)

3. Procurement Directives and Practices: Trends and Implications

In this section we examine the broad procurement trends in Canada, with a particular view to examining the move towards consolidating purchases through GPOs and SSOs. As noted earlier, increasing cost pressure has resulted in RHAs and Ministries of Health seeking ways to better manage procurement to extract lower prices from vendors. This has resulted in a proliferation of umbrella organizations to seek economies of scale in administrative functions and to gain more market power by concentrating purchasing. For RHAs, this allows them to get more competitively priced medical devices and reduces the administrative burden of managing numerous purchasing contracts simultaneously.

However, an argument can be made that GPOs and SSOs are symptomatic of a culture of cost containment and may adversely impact the drive towards continual improvement and the uptake of disruptive technologies. So even if the GPO/SSO procurement model were abandoned, it would not alleviate the need to keep prices low and short-run cost pressures would still make it difficult for purchasers to adopt novel technologies, even if they have the potential to be cost saving in the longer-term.

Role of Physician Preference Items

Historically, individual specialist physicians wielded considerable influence on the purchasing decisions made by hospitals and health authorities. In some cases physicians may have had a financial stake in a medical device firm and they would use their influence to get their preferred products purchased by their local health authority. If products were successfully implemented, then this would create opportunities for firms to expand to new markets with a strong body of evidence supporting their product's efficacy.

There seems to be a consensus view in the literature that these Physician Preference Items (PPIs) have caused significant problems for hospital administrators and health authorities (e.g. Lerner, et al. 2008). The over-arching concern was a conflict of interest between the individual physician who is promoting a particular product and the need for RHAs to ensure procurement decisions were made with value-for-money as the key decision criterion.

The GPO/SSO procurement model largely eliminates the influence of individual physicians on procurement decisions. Undoubtedly, this has increased the level of standardization, transparency and accountability in medical device procurement. However, it may have also led to eliminating a natural way through which SMEs with innovative products could gain entry into markets.

As such there is an apparent tension between the short-run cost pressures facing the health care system and the SMEs who are attempting to find markets for innovative and potentially disruptive technologies. Addressing short run cost pressures through the use of GPOs and SSOs may come at the cost of foregoing novel technologies that could be developed and improve health outcomes for Canadians and represent an important engine for economic growth for Canadian industry and the subsequent high quality jobs that would follow.

Historically governments have used the allocation of public dollars with a dual purpose. First, governments engaged in procurement to provide essential public services. Second, this procurement may be targeted to support industries that might have strategic value in terms of growing a market for export and identifying areas where domestic firms have the potential to be among world leaders. Allocation of public funds needs to balance the short-run cost pressures currently facing the

Canadian health care system, but must also recognize that the medical device industry is of strategic importance to Canada and that strategic purchasing decisions can provide necessary support to an important Canadian industry.

In the sections below we examine procurement practices in Ontario and Quebec in more detail.

Procurement Practices in Ontario

The Broader Public Sector (BPS) Accountability Act (2010), was introduced into Ontario in order to ensure goods and services are acquired through a fair, open and transparent process; to set stringent guidelines for BPS organizations to follow; and to ensure there is consistency among the way BPS organizations manage themselves. The directive follows five key principles: accountability, transparency, value-for-money, quality service delivery and process standardization. As per the BPS procurement directive, these five principles are highlighted below:

A. Accountability
- Organizations must be accountable for the results of their procurement decisions and the appropriateness of the processes.

B. Transparency
- Organizations must be transparent to all stakeholders. Wherever possible, stakeholders must have equal access to information on procurement opportunities, processes and results.

C. Value for Money
- Organizations must maximize the value they receive from the use of public funds. A value-for-money approach aims to deliver goods and services at the optimum total lifecycle cost.

D. Quality Service Delivery
- Front-line services provided by organizations, such as teaching and patient care, must receive the right product, at the right time, in the right place.

E. Process Standardization
- Standardized processes remove inefficiencies and create a level playing field.

The BPS regulates a supply chain code of ethics, which does not displace an organization's code of ethics, but merely becomes an addition to it. This ethics code surrounds three key ethical traits: personal integrity and professionalism,

accountability and transparency, and compliance and continual improvement. As per the Broader Public Sector procurement directive, these three ethical principles are highlighted below:

F. **Personal integrity and professionalism**
    - Individuals involved must uphold integrity by being honest, caring, due diligence and show respect for one another.
    - All conflicts of interested must be avoided in this process, i.e. accepting a gift, giving preferential treatment to a vendor, etc.

G. **Accountability and transparency**
    - Contract and purchasing must be fair, transparent and conducted with a view to obtaining the best value for public money.

H. **Compliance and continuous improvement**
    - The code of ethics mandated by the organization and the laws of Canada and Ontario must be abided by at all times.
    - Continuous improvement on supply chain policies and procedures is required.

The Canadian medical technology industry's national association is MEDEC. As per MEDEC's website, they are the primary source for advocacy, information, and education on the medical technology industry for members, the greater healthcare community, industry partners, and the general public. MEDEC ultimately wants to achieve advancement of health outcomes for patients in Canada using proven and safe technology developed by their members. MEDEC has outlined five key priorities in response to Ontario's BPS procurement directive:

1. **Adoption of new medical device technology**
    - Need a direct link between the needs of the health system and innovative technologies
    - Need to manage new technology appropriately

2. **Development of medical device technology**
    - Need a development process supported by the Ontario Health Technology Advisory Committee, industry, research and healthcare professionals

3. **Improvement of the procurement process and access to market**
    - Need to help clarify the new procurement process by:
        - Developing a handbook "how-to"
        - Bid process takes into consideration the value of innovative technology
        - Follow a collaborative approach in developing standardized competitive bid templates

4. **Engagement of the global medical device industry in the Ontario health technology strategy**
    - Use MEDEC to engage the global medical device industry
5. **Sustained advancement of medical device innovation and cost containment**
    - Government to develop a cross ministry "open for business" forum that includes MEDEC

(Ministry of Economic Development and Finance, 2010; MEDEC, 2012[2])

Procurement Practices in Quebec

In Quebec, Bill 100 (An Act to implement certain provisions of the Budget Speech of 30 March 2010, reduce the debt and return to a balanced budget in 2013-2014) was passed in June 2010 to reduce administrative costs within the health sector by 10%. The aim of this legislation was to try to achieve greater economies of scale through increased coordination of purchasing and administrative activities.

Procurement of medical devices in Quebec has been coordinated through 11 SSOs that serve regional amalgamations of health authorities (see www.cpaqsante.qc.ca). However they are currently in the process of being streamlined to three SSOs, with the view that with greater economies of scale, there will be increased participation in group purchasing that is expected to result in greater cost savings. AQESSS (the Quebec equivalent of the Ontario Hospitals Association) supports the need to reduce costs in the health care system, but believes that participation in group purchasing should be voluntary, rather than compulsory.

Bill 16 (An Act to amend various legislative provisions for health and social services in particular, in order to tighten the process of certification of residences for the elderly) was passed in Quebec in May 2011. This Bill contains legislation that dictates that SSOs will manage calls for tenders and contracts for the procurement of medical supplies and devices. They will also assist with helping agencies define their supply and device needs and will eventually take on the role of regional distribution of supplies and devices. The three SSOs will develop areas of expertise and will coordinate province-wide tenders in their respective areas of expertise.

There is a long history in Quebec of hospitals collaborating on purchasing, with the largest of the 11 existing SSOs (SigmaSante for the Greater Montreal area) having been formed in 1994 and with an umbrella organization called AQLASS

[2] A good example of this kind of practical collaboration between industry and government is the EXCITE initiative which is the result of a consultative process undertaken by Ontario. See: https://www.htx.ca/Announcement/call_for_innovative_medical_technologies.htm

(www.aqlass.org) providing support and training to Quebec health authorities since 1970.

No Health Authorities in Quebec are members of the national GPOs (MedBuy and Health Pro).

A list of GPOs and SSOs operating in Ontario and Quebec is provided in Appendix B

4. Interviews with SMEs

Following consultations with Industry Canada and MEDEC, a series of questions were developed and telephone interviews were conducted with representatives from nine firms that would be classified as SMEs in the medical device industry, five advocacy organizations, two SSOs and one GPO. To preserve anonymity quotes are not attributed to individual respondents (unless agreed).

The discussion largely revolved around four main themes.

The first was the view that that there was little support or advantage for being a Canadian firm, employing Canadians and paying Canadian taxes.

The second was that the process of responding to RFPs is very burdensome, complex and rigid and that there was little feedback provided when bids were not successful.

The third theme was that the RFP process was not conducive for the uptake of disruptive technologies.

The fourth theme was that access to end-users impeded product development and innovation. The RFP process does not provide entrepreneurs a satisfactory way to demonstrate their products.

To provide as much insight as possible, the comments of respondents to each of the questions are provided under key themes that emerged in each section.

Interviews were conducted by phone in February and March 2012. Both authors were present for all interviews and key points were transcribed. We detail responses provided to eight questions. In an attempt to maximize the useful data available, all relevant points raised are summarized or directly quoted. Within each question emergent themes are identified.

1) **Approximately what proportion of your firm's Canadian business (in terms of total sales volume) is conducted through tenders run by Group Purchasing Organizations (GPOs) such as HealthPro or MedBuy, or Shared Service Organizations (SSOs)?**

The proportion of association with GPOs amongst the interviewed suppliers ranged from 0%-90%. At the lower end of the spectrum, there is a split amongst those vendors engaging with GPOs, but having limited success and those vendors who believe that GPOs are significant obstacle to doing business. This difference can be observed due to the company's marketing strategy and their association with end users and manufacturers. The consensus was that GPOs and SSOs are capturing a growing proportion of the medical device procurement transactions in Canada.

Some companies distribute only to original equipment manufacturers to avoid the administrative costs resulting from completing RFPs, while other companies are actively trying to engage GPOs in the integration process although to date been unsuccessful (as will be elaborated upon later in this paper). Those who would like to have greater involvement with GPOs are having a difficult time becoming associated with the GPOs. Those who are heavily involved with GPOs state this relationship is increasing due to the increasing share of total medical device purchases that are being coordinated through GPOs. It appears that the companies interviewed have a wide range of experience with GPOs and have a variety of reasons for their particular level of affiliation.

2) **Do you see any particular advantages or disadvantages in responding to RFPs through GPOs or SSOs?**

This question dominated the discussion with all respondents engaging in a lengthy conversation on this topic. The primary advantage of the GPO/SSO model was identified as potentially being able to offer lower costs to health authorities for commodity-type medical devices. These are areas where there are limited technological advancements and even substantial improvements would be unlikely to significantly appreciate value-for-money. Some respondents believed that once firms became established with GPOs and SSOs, it could result in a secure and predictable revenue stream for multiple years. However this must be tempered with the complement of this point. Firms on the outside of GPOs and SSOs struggle to survive.

The discussion on disadvantages with the GPO/SSO approach was considerably longer, and it was clear that none of the respondents – even those that conducted a considerable amount of business with GPOs and SSOs – considered this to be a positive trend for their business. A significant concern was that this process eliminated their capacity to effectively market and showcase their products and

demonstrate their innovative capabilities. A number of themes emerged in the discussion of the disadvantages of the GPO/SSO procurement model.

A. Win big, lose big and insider/outsider problem

A few vendors expressed a problem gaining a relationship with GPOs, and they have focused their main priorities on creating awareness and a rapport with GPOs in order to better sell their products. One vendor stated that when they went to sell their products to direct end users, they got responses such as, "We are a MedBuy Hospital" or "We are a Healthpro Hospital and we cannot see other vendors".

The vendors expressed frustration in trying to integrate themselves into hospitals because even though they provided sound, logical, money-saving opportunities, the end users are still unable to remove their association with these GPOs.

One vendor stated, "GPOs and SSOs feel that their role is a gatekeeper". This issue was raised by many of the vendors that were interviewed. Vendors currently associated with GPOs suggested that if they were on a GPO list and have completed an RFP, it is easier to integrate the company's product into hospitals. One vendor stated, "Once you're known, there is a high probability of getting repeat business revenue that you can count on."

A successful bidder is contracted for multiple years, typically between three to five years, and this also contributes to the barrier of entering into the marketplace. Vendors suggested shortening the contract lengths in order to accommodate the rapid turnover of innovative technology and to enable other SME to participate in the bidding process.

Vendors appear to be significantly disadvantaged if they are considered "outsiders" to this procurement process, and many SMEs have been forced to close their business as a result of not being able to integrate themselves with GPOs and then, in turn effectively not being able to integrate themselves into the marketplace.

B. Administrative burden

A vendor stated, "If you want to play, you've got to pay". By this he meant that the RFP process requires a considerable amount of effort and resource allocation.

Virtually all vendors discussed the issue around the administrative burden resulting from the RFP process. Effectively, the RFP process becomes a barrier to accessing the marketplace. SMEs may not have the human resources to allocate towards the RFP process, and consequently, this will lead to decreased revenue and possible failure of their business.

One vendor suggested that to respond to an RFP required dedicating two people for 10 days to complete the necessary documentation. To a small organization, this is a sizeable allocation of resources for what might be a low chance of success.
A few vendors discussed the need to consider the risk/reward ratio when competing in a business while approaching a new market place, sometimes opting to not respond to RFPs if they perceived the effort to submit a bid as extensive, and the probability of success to be low.

An interesting point that was raised is that while the RFP process is extremely burdensome and is meant to maintain a fair, transparent process in order to achieve the best vendor, organizations may not in fact obtain the best vendor because of the criteria they have set out and the weighting that they have allotted to it. "Purchasers of innovative technology may not be fully equipped to prepare the RFP to cater to them appropriately", a GPO stated. It was clear from all of the vendors interviewed that the ability to cope with the administrative burden determines how successful a vendor's bid will be.

One vendor summed this up by saying: "They may have a great piece of technology, but they don't have the horsepower to get it in."

C. No conferred advantage for Canadian companies

A few vendors had mentioned that there are no advantages for innovative Canadian companies. According to a vendor, in the past, the province of Ontario would provide a 10%[3] reduction in their tenders if the company was Canadian; however, that incentive has been removed. Another concern was that organizations were accepting bids from outside of Canada, and while they may be initially cheaper, the organization is not contributing to the Canadian economy and building new jobs for Canadians.

D. Government communication issues

Vendors expressed concern regarding the BPS process, GPOs, and SSOs, and that these vendors were unable to maintain communication with governments. The vendors wanted to provide feedback to the government on the process, however they felt that they were chasing government representatives. If they were successful in communicating with these people, their rate of turnover made it impossible to maintain on-going dialogue regarding improving the procurement process in Ontario.

[3] We interpreted this as meaning that a foreign bid of $10 would be treated as being the same price as a Canadian bid of $11.

E. Lack of innovation / Rigid RFP Process

The rigid RFP process was discussed among vendors and a consensus was formed that it does not have the flexibility to capture the benefit of innovative technologies.

A consistent view emerged that RFPs are appropriate for commodity-based items; however, the RFP is unable to cater to innovative technology as the purchasers may be unaware of its existence and subsequently cannot have appropriately weighted criteria.

"A blanket procurement process should not be applied to innovative technologies, especially when the medical device industry is driven by innovation", a vendor stated.

One vendor spoke about a contract they were secured in for three years and had full support from their purchaser (scoring 100% on the key performance index), but when the time came to reapply for the contract, they were unable to secure the position due to the RFP process.

Another vendor thought it was clear that the RFP has no allocation for past performance, and while this may be a way to attempt to eliminate bias amongst purchasers, it does not take into account the rapport that the vendor has established and their product rating.

Overall, the RFP process can deter the incentive for companies to become innovative, and this could lead to serious consequences in the future for the medical device industry.

F. End User Disconnect

The lack of communication between vendors and end users was another theme that emerged from the organizations that were interviewed. Vendors felt that the competitive advantage to drive innovation comes from communication with end users. However, GPOs and SSOs were inhibiting the relationship.

One vendor stated, "We would love to have clinicians tell us 'this is the tool I need, can you create this?'" However, because of the guidelines surrounding vendors and end-users interaction, these simple yet crucial questions cannot be addressed. This lack of communication can lead vendors to becoming less innovative, or of greater concern, going out of business.

Another vendor addressed this issue with the question, "Why develop a new product if you know you are not going to be able to get its approval within the medical community?" It was widely perceived that the lack of end-user and vendor communication hinders the ability to produce new technology. Though it is

acknowledged that this was eliminated in order to make a more fair and transparent tendering process, it also eliminates innovation in the medical device industry.

3) Has centralized tendering affected your business in terms of developing and enhancing products?

The next interview question also generated a lot of discussion, with the consensus being that the GPO/SSO tendering model created an impediment to developing and enhancing products. The comments generally were clustered around access to GPOs and end users, the complexity and bureaucracy of the RFP process, and the rigidity of the RFP process.

A. Access

One vendor indicated that if a market can be penetrated and a relationship established with the GPOs, then feedback can be acquired from end-users. That expedites the product maturation cycle and assists with product evolution. If the vendor is not part of the GPO, then they not going to get feedback, which is necessary to refine the product.

Another vendor stated that the rise of GPOs and SSOs has done nothing to help them. Generally the small companies are at the bottom of their list in terms of asking suppliers to bid and having a chance to get the business.

Another vendor stated that they have no dealings with GPOs. He said he cannot get them to return calls, and cannot make any in-roads with them.

B. Complexity

A second theme that was raised was that the RFP process was now highly complex and laden with bureaucratic requirements.

One vendor stated: "We (as an SME) do not have any advantages in terms of the tendering process from GPOs. They seem to be germinating in somebody's office all across Canada… every couple of months you see a new GPO coming out. They all claim to be saving all kinds of money for their region (which is false), what is the public going to do because they don't know anything about it."

Others complained that the tendering documents were too long and that the requirements to complete the proposal were unduly onerous.

C. Rigidity

A common issue raised was that the RFP requirements offered little flexibility to adapt to reviewing truly innovative technology.

One vendor indicated that there were some differences between Ontario and Quebec in this regard: He stated:

"If I'm in Quebec, if you take a innovative technology and they are in a position where they can adopt new technology and do not need the RFP, if you are the manufacturer of one of those technologies, you can work the key stakeholders, and they are in a position to accept it without having to go through the formal process, in Ontario, they are so concerned about following the implied directives and they lose sight of this."

Another vendor suggested that this was now a 'process' and that they generally make the decision not to go through that process. He argued that the rigidity of the process does not truly allow firms to market new technology.

4) What are the most significant challenges in terms of managing the tendering process for the sale of medical devices in Canada?

Again this was a very wide-ranging discussion that generated a great deal of material. And again, the main themes in terms of the challenges of managing the tendering process were around access, complexity and rigidity.

A. Access

Without having direct contacts with those who are involved from the purchasing side, many found getting up-to-date information on RFPs was challenging. It should be noted that all RFPs are posted on websites, but a significant monitoring effort from SMEs is required to remain abreast of upcoming opportunities.

One respondent indicated that GPOs and SSOs needed to be aware of one's company to compete in RFPs.

Another firm had taken to contracting out monitoring of RFPs to have relevant competitions forwarded to them.

One vendor indicated that the biggest challenge is getting a foot in the door. He said that they have missed opportunities because they were not aware that a pertinent RFP was on-going.

Another vendor suggested that there was no coordination between the vendor and the actual user (the surgeon), with the implication being that the GPO/SSO was impeding the vendor's access to users.

Another vendor complained that to enter into the RFP process it is necessary to have $1million of liability insurance, which costs $30-35K per year for insurance coverage. This is a barrier to enter the bidding process

Another vendor complained that the GPO/SSO process was almost like it was done deliberately to eliminate the small players. The physicians, nurses and technicians can no longer see sales representatives because the hospital has a contract with a GPO.

One vendor stated:

"In my view, the GPOs and the province of Ontario would like to cut down the number of purchase orders they make. We will send out a broad tender that a multinational will carry, and the little guy is shut out because he can't provide everything."

Another vendor suggested that the GPO/SSO model was driving them to increasingly move their focus abroad. If they are going to develop something new, they go outside Canada.

One vendor opined:

"From my experience, if I go back 10 years ago, when you would get a request from a physician, nurse or technician to look at possibly making a widget, your ears would automatically get attention and you would definitely talk to them to figure out their needs and how they can develop that in their own structure. You would go back to your engineers and within two months, you would have a widget to show, which would then make it to the market. Nowadays that is gone. We do not get those opportunities anymore. First of all you cannot enter the hospital anymore, your sales rep have to fight to get into the hospital ("we are Medbuy/HealthPro hospital"). Major barriers to get to the users like you used to. They just locked the whole industry from gaining some more opportunities for manufacturing in Canada."

B. Complexity

There was a consensus that the centralized tendering model is unnecessarily complex and that SMEs find this complexity a challenge to manage.

One vendor complained that each GPO uses a different template and they do not resemble each other. Each province has different mandate and different questions.

GPOs and SSOs make it very difficult for the SMEs to participate, suggesting that this model works best for firms that have significant resources to dedicate to managing these RFPs.

Another vendor stated: "Instead of having the way it used to be and we can compare from what we used to fill out in terms of forms and now with the GPOs you are looking at 50 plus pages to fill out, which is the standard form."

This vendor went on to say that if the form is not entirely completed, the GPO/SSO will use a rating/percentage for each line, which makes the bid less competitive. This firm has gone as far as hiring an individual dedicated to responding to RFPs. This has been advantageous because once they have responded to a few RFPs they can see commonalities in their requirements.

On vendor argued that the level of complexity forced firms out of the market. He stated:

"We raised that at the provincial level when we met with them and I raised it with the federal government. We had several meetings with them (provincial and federal governments), but nothing changed, it is still the same. It leaves out many companies that can just not afford to participate [in RFPs]."

Another vendor argued that GPOs/SSOs increase the costs of doing business. And those costs are driven up with the use of the tendering process. The cost burden increases.

C. Rigidity

One vendor complained that in addition to managing the RFP process, there were other bureaucratic burdens. For instance, Health Canada must also be contacted (takes 90 days) if you are adjusting your product.

One vendor stated:

"There aren't many clauses that allow you to open the door, you must push your way in. There needs to be more appropriate and new technology clauses to invite a company in, which could be a huge benefit later on."

And he went on to say:

"A lot of these processes are procedurally directed and this process does not allow for new dialogue. If you break the process, then you are not being fair to everybody."

This respondent argued that there needed to be a new technology clause in RFPs that would make the uptake of novel technologies compulsory among health device purchasers and that this would need to be externally funded with new monies.

5) **Do you think the tendering/procurement policies or practices have affected your ability to enter into new markets? Please elaborate.**

The main theme introduced here was access. In response to earlier questions, many firms indicated that breaking into new markets was a challenge and that there was a perception that cracking the GPO/SSOs is difficult. So much so, that some firms ceased to pursue this business.

In response to the question, one respondent said:

"Definitely - in the sense that we make a conscious decision not to enter certain markets. We are an established organization that deals with every hospital in Canada, they already have some contact information with their members and it's not a black and white barrier. We can only go to so many places and to try and sell our technology."

Another vendor opined that most of the small companies in this sector are run by entrepreneurs who saw a business opportunity several years ago and pursued it. Today that is just not happening because of the mentality, "why should I do that if I can't sell it?"

Another respondent indicated that this is a different approach to doing business, and that the GPO/SSO approach tends to concentrate risk. Firms that are successful in the RFP process get large contracts, while others get little or nothing. Unsuccessful bidders often struggle to maintain a presence in these markets until the next round of RFPs. This reinforces the 'win-big, lose-big' characterization of the market described earlier.

Other respondents described the challenges of remaining abreast of tendering opportunities and lamented the instances when viable RFP opportunities were missed. They noted that if an important opportunity were missed it was difficult to subsequently get into this market, since the duration of the awarded contract tended to be at least three years.

6) **Are there differences in tendering and procurement policies and practices in Ontario and Quebec? Can you describe these differences? Is it easier to conduct business in Ontario or Quebec? Please elaborate?**

Most respondents did not identify one province or the other as being a particularly different from one another in terms of ease of doing business.

One respondent indicated that both Ontario and Quebec are difficult to penetrate - if you are not on the participating list, it is very difficult to get in.

One respondent stated:

"Quebec is RFP dependent. Quebec is really tough."

One respondent suggested there was a language barrier with Quebec not issuing RFPs in English. To respond to an RFP, the firm has to hire a translator. Despite making numerous requests to the Quebec government, this firm has been unable to get translated RFP documents provided to them. As such, they no longer pursue business in Quebec.

Another vendor noted that the RFP process was more transparent in Quebec, with all RFP respondents being able to see the winning bid, and as such, losing bidders get an opportunity to gain valuable feedback on how their proposal fell short.

Another vendor indicated the Quebec RFPs tended to be less 'bundled' meaning that firms could bid on a relatively small (or even a single) item. RFPs from Ontario tended to group together related devices, which made it more challenging for a firm that did not manufacture or distribute the entire product line. This makes it challenging for SMEs who may produce a very narrow product line.

Another respondent indicated that in Quebec, there seemed to be a greater willingness to 'do a deal'. This individual reported that rather than go by a rigid RFP process that senior managers within the health sector were eager to negotiate and to try to get the best products in use.

7) **Do you have any additional thoughts on the tendering/RFP process for medical devices in Canada?**

Most respondents chose to reinforce the points they made earlier in the interview. These again, can be highlighted under the themes 'Complexity', 'Access', 'Rigidity', and 'Buy Canadian'.

A. Complexity

Reiterating a common theme, one vendor complained:

"Why do they have to send out 100 page documents? The basic outline for the RFP is the same in any deal. Just tell us what you want and it would make it a lot easier. We spend a lot of time doing a MedBuy or HealthPRO response."

Another thought there was a lack of coordination between purchasers:

"The problem is the SSOs. Their thought patterns are not consistent"

B. Access

One vendor returned to the issue of contract length. He stated:

"… Many of the contracts that are signed with multinational companies are for multiple years. Once the contract is signed, the door is locked. So you cannot sell any of your products to these hospitals. If it is going to be run by GPOs, it should be a shorter contract so other SMEs can compete. To not sell your product for five years, you get to a point where you go outside of Canada or shut down your company. Contracts should be a shorter duration."

C. Rigidity

Multiple vendors pointed out that the GPO/SSO model tended to treat its members as having equivalent needs. There was some concern that if members had different needs, these unique requirements may not be met by the device ultimately selected from the RFP responses.

One vendor suggested:

Government could give some of the mandate back to the organizations (meaning RHAs). In Ontario, for example, there are limitations of various products. Better guidance for the materials management people on how to interpret these limitations and greater flexibility to opt out would be desirable. He stated: "The government can't have a cookie cutter approach. There needs to be flexibility in the process to account for real differences in products/technology."

Another vendor offered a similar view:

"There is the ability for those decisions to be skewed based on representation at the GPO/SSO. How do (individual hospitals) prevent their needs from being hijacked?"

D. 'Buy Canadian'

There was a consensus that there needs to be a greater weighting assigned to being Canadian. If Canadian firms are unable to match the technical specifications of international bidders, then this is reasonable, but if a Canadian product is as effective, a preference weighting should be given to the domestic firm.

One vendor stated:

"There has to be some sort of preference weighting that is given to the Canadian companies to compete or to be inclusive in GPO initiatives."

And another vendor offered a similar view:

"It if is developed and supported within the country and then go to outside markets by export, and on taxes alone, everyone benefits. It is a matter of will and policy supporting Canadian business."

8) How do you think procurement practices affect the development of innovative technologies? How could this be improved?

A number of key themes emerged in the discussion around how innovation among Canadian firms could be better supported.

A recurrent theme was, again, that the lack of access to clinicians and end-users was a significant impediment to innovation. The second theme that was raised again was that more support needed to be offered to Canadian firms trying to do business in Canada.

A. Access

One vendor stated:

"We would love to have clinicians say: 'This is the tool I need. This would help me. Build me this tool. If I could convince my hospital administrator one or two or ten and all of my colleagues would then want to buy them.' "

Another voiced a similar viewpoint:

"In this past week, I sat down with my new manager and R & D staff. I told him we are blocked from hospitals from going in and talking to clinicians. We have to figure out what technology clinicians need. The manager is going to contact the director of community services, and see if they can meet, and go over some of the challenges they have at the home level. The communities they reached out to both responded

well to the manager. They wanted the help from them, and in turn the company gets to develop more novel products. "

And yet another offered a similar view:

"[We need to] have a more concise gateway to the user. There needs to be a better way of access to encourage product development. [This lack of access] puts up another barrier that the small companies are not well enough equipped to review the documents. "

Another vendor suggested that it was necessary to increase the interface between clinicians and vendors. "The way that a hospital does procurement is a little bit empathically, they are procuring physical products by going through a catalogue of the kinds of items on the market, but wouldn't it be great if they could say, "I want to solve this particular medical imaging problem", "I have a big backup with x-rays in ER, so instead of buying a bunch of x-rays, maybe a company has a solution to that problem with a high technology medical device. We need to buy solutions, rather than off the shelf products".

Another simply stated:

"It boils down to one word: 'access'".

B. Increased Emphasis on 'Buying Canadian'

There was a general sense of frustration that the rigidity of the tendering process allowed little or no room for purchasers to deliberately 'buy Canadian'.

A respondent summarized his views by saying:

"We have no advantage being a Canadian company, and in some cases, we are disadvantaged."

One respondent suggested more strategic sourcing and developing a better inventory of what Canadian firms are doing, might help to keep more business in Canada.

Another respondent suggested:

"Let's at least have a process to see whether something made in Canada does exist and set up an infrastructure to see whether it can be made in Canada. Make it part of government's thought process. What are we buying from abroad? And if we are buying products from abroad, do we have a Canadian manufacturer that produces these products? If not do we have the infrastructure to support this?"

Another respondent said:

"We are buying a lot of stuff that is not made in Canada, and there is no reason why we can't make it here, and in some cases, we are making it here and its not making its way to end users."

And another respondent suggested:

"Government has to play a role, you may be saving a little more by buying outside of Canada, but spending 5-10% more on a Canadian product, then we are investing in the Canadian economy and creating jobs."

Finally one respondent indicated that more grant money for research and development would be useful. He stated:

"If you're a SME and coming up with innovation means you spread the cost to your entire company. Anything we have done, we have had to spread the cost over the business, you get a tax break from the feds, but it would nice to get some grant money"

So a number of key themes emerged and respondents tended to be remarkably similar in their views that GPO/SSO purchasing model was not a good trend for their business primarily because this approach was unnecessarily bureaucratic and rigid, and because it reduced access to firms. In terms of fostering innovation, most firms believed that the process was not conducive for the uptake of new and novel technologies and that lack of access to clinical end-users was a significant impediment to the innovation process.

The GPOs, SSOs and an Advocacy Group's Perspective

"All industry needs is a clear commercial pathway, and that a customer is at the end of it", Gail Garland, President and CEO of OBIO stated.

OBIO (Ontario Bioscience Industry Organization) is a private sector, membership based organization that is an advocate for Ontario's life science sector. Its overall goal is to deliver more innovative products and services to a global market (OBIO, 2012).

In the medical device industry, the current climate of cost-saving reductions leaves little incentive for organizations to invest in innovative technology. OBIO argues that legislation needs to be established that supports and mandates the implementation of innovative technology. OBIO is involved with developing a strategy in attempt to drive the industry forward, with one of their initiatives relating directly to innovation adoption and procurement. According to Garland, there are a number of jurisdictions that implement policy at the systems level, for example: Sweden's policy requires that 2% of hospital budgets must be allowed to procurement of new

devices that have not been implemented last year, and the Netherlands' policy requires that the new technologies entering the hospital must supersede the use of the old ones. These are the type of policies OBIO feels would help make a clear commercial pathway.

A few SSOs and MedBuy (GPO) provided a different perspective on the procurement process in Ontario. The SSOs supported the notion that the new procurement directives, as well as their companies were not inhibiting innovation but that it was the purchasers' inability to make an effective internal business case, and the vendors' inability to sell their technology on paper. MedBuy supports the view surrounding how organizations are unable to properly acquire innovative technology due to a lack of understanding of the RFP process. They have sponsored many conferences to bring together end-users and vendors, and to bring awareness relating to the process of initiating an RFP. An SSO stated, "It will take a few years for organizations to flush out the process", meaning that health care organizations need to become more familiar determining appropriate scoring questions and weightings of the RFP in order to obtain the innovation that their association requires.

An SSO identified a process they used called "Vision Sessions" in order to bring together end-users and vendors. The conversation is regulated in the meetings; however, vendors are able to ask questions pertaining to what products clinicians need, and what products would help make them more effective. They are not allowed to gather insider information, and certain information discussed in these sessions may disqualify vendors from the RFP bidding process. This session is an initial step from an SSO to try and collaborate end-users with vendors.

Another challenge of implementing innovative technology into hospital sectors is that one department will have to allocate budget to the innovative product, while another department may benefit from it. Because departments' budgets are separate (or 'siloed'), it becomes less advantageous to purchase new technology. This comment was echoed by another advocate, who argued that silo budgets were detrimental to the uptake of novel technologies. Silo budgets mean the department paying for the device that will not benefit from future savings, ergo they will not be inclined to pay for it, even though it may save the organization money and result in a better patient outcome. Procurement needs to take a system view, rather than focus on specific departmental budgets.

Another theme was that the RFP process typically did not include health technology assessments (HTA) on medical devices. This means that a superior, but perhaps marginally more expensive device that would offer good value for money may be overlooked because the review process (and the criteria for device selection) may not adequately assess this device.

5. Innovation in Medical Devices – an Opportunity Lost for Canada?

Technological innovation implies the creation, development, use and diffusion of a new product, process or service and the significant technological changes of the product. (Technalia, 2012)

A recent report by the Conference Board of Canada examined the role of procurement in fostering innovation. The author demonstrated that Canada lags behind other OECD countries in terms of strategically utilizing procurement to fund innovation. Given the climate of rising costs, RHAs have increasingly utilized GPOs or have organized into Shared Service Organizations (SSOs) to coordinate purchase of medical devices. The Conference Board paper argues that the coordination of purchases may have driven the costs of purchasing medical devices lower, however, this may have come with a significant trade-off: a loss in innovation.

When purchasing was more fragmented and widely distributed this gave opportunities for SMEs in the medical device industry to gain a market presence – often through partnerships with clinicians. While there was undoubtedly some abuse in this system – there is a well-documented literature on the influence of physician preference items on purchase decisions of RHAs – it may be that creating a barrier between the end-user and the entrepreneur impedes the development of novel technologies that would address the needs of clinicians.

As the market is now increasingly concentrated, individuals or groups of physicians have very little impact on purchasing decisions. This has also made it more difficult for SMEs to actively pursue RFPs if they are unable to service RFPs that may include RHAs from across Canada. As such, these SMEs are finding it increasingly difficult to access markets.

SMEs have been shown to be important sources of product innovation and increasing concentration of the medical device market among large firms may be limiting Canada's potential to develop disruptive technologies.

Despite the concentration of purchasing power through GPOs and more efforts to coordinate drug review, with an increasing reliance on cost-effectiveness and value for money, health expenditure continues to rise at an unsustainable rate. At the very time when we need game changing technology – devices and products that will change how citizens interface and interact with the health care system – we are seeing the firms with the potential to develop these technologies being squeezed from the market.

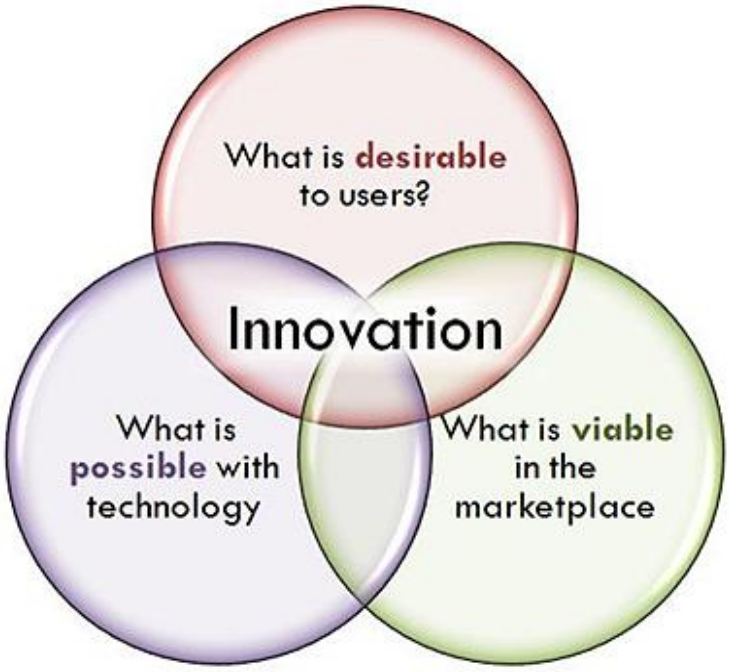
Most standard models of firm organic growth involve the SME breaking into their local or regional market and using this as an opportunity to expand and achieve economies of scale and gradually grow into national and international players in their chosen market. However, by restricting responses to competitive tenders to

firms that can supply on a large, multi-institutional scale as represented by a GPO's members, this may effectively eliminate small and medium sized firms from getting into this market. This may further result in firms that could have developed innovative new products (and potentially been significant players in the international market) being unable to reach their potential.

Models of Innovation

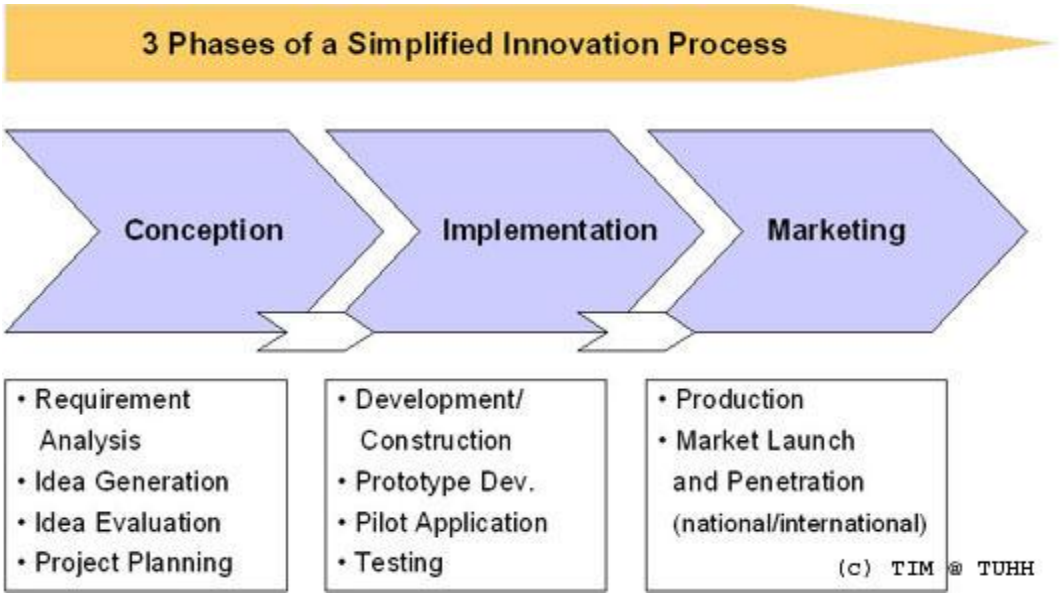
To further examine the role of innovation we conducted a brief review of models or templates of product innovation. Below are three schematic diagrams of how product innovation occurs.

Model 1



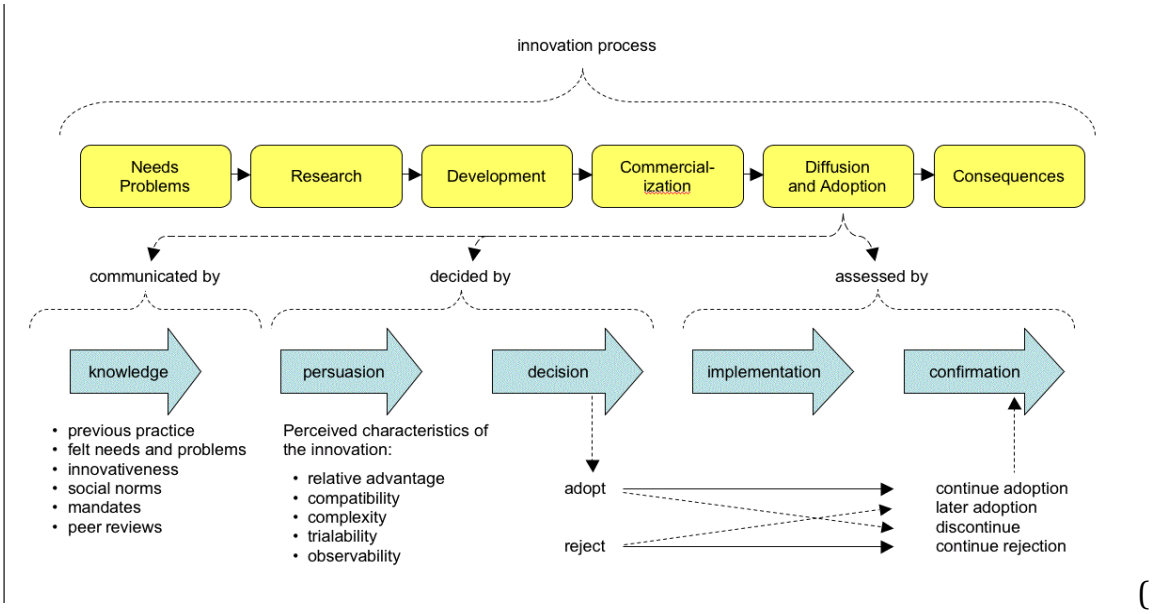
(TROeMAR, 2012)

Model 2



(TUHH, 2008)

Model 3



(Smart Code, 2012)

A consistent element in the development of innovative products is identifying demand and integrating external ideas and feedback throughout the development process. This involves examining user need and identifying possible opportunities to leverage existing technologies. End users may be given opportunities to trial prototypes and to suggest modifications to improve functionality. Furthermore end-users can act as product champions and encourage uptake and utilization.

However the GPO/SSO model of procurement has largely resulted in reducing the role of local end users in procurement decisions. The result is that one of the key channels of innovation remains untapped and under-utilized.

A common message that emerged from the interviews with SMEs is that access to end-users (i.e. clinicians) is difficult and the opportunities for true collaboration are minimal.

Warren and Susman (2004) identify the cultural attributes of successful innovative enterprises. Of relevance here, they argue that engagement with customers and the willingness to take risks are key drivers of becoming an innovative firm. However, the current emphasis towards larger national tenders and separation of firms and purchasers greatly reduces the ability of firms to engage with customers (or potential customers). Furthermore, the trend towards a relatively small number of vendors winning large national or provincial RFPs reduces the willingness of firms to take risk in new product developments.

6. Discussion

In this section we highlight a number of themes that have emerged in this research and explore possible policy directions for procurement of medical devices in Canada.

GPOs/SSOs are potentially constraining growth of SMEs in the Medical Device Industry in Canada

The overwhelming view of the respondents was that GPOs and SSOs are an impediment to growth of Canadian firms. The bureaucratic and rigid nature of the process results in a number of SMEs choosing to limit or selectively engage with the RFPs. In addition, SMEs find new product development difficult because they do not have a dynamic dialogue with end-users. As a result, new technologies may not be developed.

GPOs and SSOs are a Barrier to Entry

Discussions with representatives from smaller firms in the medical device industry indicated that GPOs might be restricting their opportunities to get a toe-hold in the Canadian market. Typically, GPO tenders are broad in scope meaning they need to serve a large and geographically dispersed market (which may be critical when products are complex and require intensive training and support). Vendors that cannot guarantee this level of support may not be invited to participate in the tender, or if they are able to respond to tenders, will be eliminated because they lack the scale to service the dispersed GPO members.

The RFP Process is too Rigid and Bureaucratic

A point that was raised by all the vendors interviewed as well as from the advocacy organizations and the GPOs/SSOs was that the rigidity of the RFP process could result in developing RFP scoring frameworks that would not effectively accommodate novel technologies. It is important that the framework be flexible and sufficiently reactive that when emergent technologies are tendered, special consideration be given. Increased fairness, transparency and accountability are important, but these features should not come at the expense of foregoing cost effective technologies that could significantly improve patient outcomes.

At least some discretion needs to be given to health authorities to adapt and experiment with new technologies. Preferably, the ideas being promoted in Ontario that will legislate the mandatory adoption of novel health technologies by RHAs will be successfully implemented.

There may be merit in looking at different RFP approaches when there is potentially disruptive technology available. Mature technologies, where there is limited capacity for technology to enhance health outcomes could be managed through a more straightforward tendering process. Products that are potentially innovated would be classified as high technology.

Where possible, GPOs and SSOs should seek to develop common tender templates and there should be a concerted effort to reduce the administrative burden of completing RFP documents. Current practice tends to result in increased burden on many firms, to the point where some firms choose to not engage in tendering.

Being Canadian Should Matter

A theme raised by all SMEs and by most individuals who have a role in supporting the medical device industry is that there is no advantage to being Canadian when responding to Canadian RFPs. This was a source of some frustration, as many respondents believed their businesses contributed to the Canadian economy by employing people in good (high-skilled, well-paying) jobs and they paid Canadian corporate tax. They believed that there should be some incentive for GPOs and SSOs to 'Buy Canadian', however, this seemed to be superseded by a mandate to minimize short run costs.

Track Record Should Matter

Firms that have successfully provided medical devices in the past should be rewarded for their past successes. Transitioning from one technology to another may not be seamless, and as a result, bonus points should be awarded in new tenders to vendors that have successfully delivered goods and services to a particular RHA in the past. A theme that emerged from some vendors was that a track-record of providing high-performing devices and exemplary service was not rewarded in subsequent RFP processes.

Need to Separate Medical 'Commodities' from 'High-Technology' Medical Devices

The movement towards centralized purchasing will undoubtedly bring benefits and cost savings for mature items where there is limited technology or where there is limited capacity for innovation to bring substantial improvements in patient outcomes and improve the efficiency of health care delivery. However, in the high-technology segment of the market – where product innovation can be substantial and there is potential for significant improvement in patient outcomes (or where patient outcomes can be preserved at a significant reduction in cost) a different tendering process is required. In the high technology segment the process needs to be much more flexible.

Contract Duration Should be as Short as Possible

While recognizing that a longer duration may have some advantages for the purchaser and the firm if they are required to make a substantial strategic commitment to meet the terms of the contract, contract durations should be limited to their shortest possible duration. This serves numerous purposes. First, it allows for the more rapid uptake of new technology as it becomes available. Second, if there are innovations in production that lower manufacturing costs, the purchaser can take advantage of these and finally, it may provide more opportunities for firms who have been previously unsuccessful in the bidding process.

In the Longer Term the GPO/SSP Procurement Model May Result in Higher Prices

In the effort to reduce costs and achieve greater efficiencies in the short run (which may favour centralized purchasing through GPOs) we may be trading off longer-term efficiencies that could be gained if smaller firms were given more opportunities to grab a niche of the market. It may also be that having a relatively small number of firms be successful in RFPs results in oligopolies emerging. This may have the longer- term effect of increasing prices for medical devices due to a lack of competition. Many SME respondents suggested that the GPO/SSO

procurement model made staying in business difficult. Since there were relatively fewer channels through which products could be sold and contract durations tend to be long, there can be long periods where there are very few market opportunities. Many individuals from advocacy groups indicated that this inhibits a vibrant and competitive market and may lead to longer-term cost increases.

Transparency Matters

One theme that emerged from several vendors was that the lack of transparency in RFP outcomes was detrimental. For firms to become more competitive they need to know what aspects of their proposals were weak and how they could be improved in the future. While issues around price transparency limit full disclosure of RFP outcomes, Canadian firms would benefit from knowing where they lack competitiveness.

Recommendations Towards a Program of Innovation

McKinsey & Company (2008) ranked developed countries in terms of innovation, placing Canada 13th out of 17. Similarly the Conference Board of Canada places Canada 14th out of 17. However, as a nation, we dedicate a great deal of resources to basic R&D and have leading universities that are at the forefront in the creation of new knowledge. Where we lag is in commercializing research – going from the lab to the market. The medical device industry is a segment where we could potentially improve on this poor showing. However to do so, will require policies that encourage (or make compulsory) the uptake of innovative technologies in the health sector.

The Conference Board (2011) report highlights the successes that have occurred in the UK as a result using procurement to play a more strategic role in innovation. 'What gets rewarded gets done' is their mantra this is undoubtedly true.

While there are undoubtedly benefits in increasing monopsony power in purchasing, some effort and coordination needs to be taken to encourage Canadian firms to develop innovative new technologies that have the potential to change the way Canadians interface and utilize the health care system. In addition to promoting greater preventative measures, these are our best hopes of maintaining a single-payer universal health care system.

To do this, SMEs must be incentivized to develop new technologies in partnership with local RHAs. Echoing the call of the Conference Board, coordination should come from the Government of Canada (perhaps through Industry Canada).

A common complaint from vendors during the interviews was that there was no channel through which innovative products could be brought to market. If there is

no way to bring a product to market, then it is difficult for firms to invest in and develop new products. We would argue that a market structure that discourages innovation – particularly when new products could save money and improve patient well-being – is misguided.

We observe an inconsistent direction from governments on this issue. Medical device firms are encouraged to be innovative and to invest in R&D and to seek breakthrough disruptive technologies. This encouragement comes from Ministries of Industry and Economic Development. However, the directive from Ministries of Finance and Health is to contain costs, and this usually means forgoing innovative and more expensive technologies in favour of cheaper and more mature products. There is no point in developing an innovative product if there is no market for it.

Shared Risks - Shared Rewards

Developing and purchasing innovative technology is risky for both vendors and firms. RHAs are not encouraged to take risks in procurement and as a result there is limited incentive for firms to develop novel technologies as the potential for uptake is uncertain. An area that has not been explored carefully is to try align the risk-and reward incentives through Public-Private Partnerships between SMEs and RHAs with matched funding from the federal government.

Firms Need to Re-engage with Clinicians and Practitioners

Business models need to be developed in which firms can re-engage with practitioners and clinicians. Technological innovation needs to be more directly tied to anticipated health care needs. While the dialogue sessions that are sponsored by GPOs and SSOs are undoubtedly useful, the process of innovation requires more dynamic interplay between entrepreneurs and end-users. As highlighted earlier, virtually every model of product innovation points to the generation of ideas and the direct interaction with end-users as playing a key role in moving innovation from the lab to generate a commercialization opportunity.

Snowdon, et al. (2010) argue that physicians need to be re-engaged in the procurement process. One of the outcomes of increased centralization of purchasing has been to marginalize the role of practicing physicians in procurement decisions. Physicians and other practitioners need to collaborate more closely with entrepreneurs to conceive and develop the game changing technology the health system needs.

What gets rewarded gets done – building on the work of the Conference Board of Canada, if Canada is serious about increasing the uptake of innovative technologies, then new funding will needed to be earmarked to encourage this. Current levels of health funding are insufficient to encourage the uptake of new technologies that

may be more expensive in the short-run, but which could be considerably more cost effective in the longer term. OBIO, among others, is leading an effort to get legislation in place that would require health authorities to purchase novel technologies. However, it remains vital that RHAs purchase the *right* technologies. So the emphasis should be on buying products that have the greatest long term potential to fundamentally change how (and how often) patients interact with the health care system. It should also give some preference (to the extent that trade agreements will allow) to Canadian firms and Industry Canada should seek to identify firms and technologies that could be disruptive.

Snowdon et al. (2010) make two important conclusions that we wholeheartedly endorse. First, they argue that health practitioners need to be engaged with product developers much earlier in the innovation cycle. The second key point is that purchasers need to be engaged in early proof-of-concept testing. Vendors need a natural outlet to test the viability of their innovative products. This must occur through hospitals and health authorities. Snowdon et al. describe this as a 'fail early, fail cheap' strategy, which will allow vendors to get a critical early view of the viability of new technologies. This will provide a crucial filter in the innovation process that will separate products with true market potential from those that will not be successful at a much earlier stage in the innovation cycle, thus allowing vendors a better chance to develop marketable innovation.

This is consistent with the models of innovation described earlier, each of which indicated that an end-user's perspective was critical throughout the product development process and is particularly vital in the idea generation and product development phase. In discussions with one GPO, the respondent indicated that vendors often struggled to make a good business case with their technology. While it may be superior, they need to demonstrate that it offers superior value either in terms of better patient outcomes or by reducing costs elsewhere in the health system. Engaged practitioners can facilitate this. Furthermore, this speaks to an expanded role for independent HTA analysis to evaluate new technologies for their potential to improve patient outcomes and improve efficiency in health care delivery.

Robinson (2008) also concludes that physicians are central to the uptake of new technologies. Furthermore Pauly and Burns (2008) calculate that research surrounding physician generated devices are far more cited than devices generated by others, suggesting that they generate more interest and have a greater chance of being widely accepted and having a significant impact.

Increased Local Discretion and Greater Partnerships Between Industry and RHAs

To develop truly innovative technologies that meet key health care needs, local health authorities need discretion and empowerment to forge partnerships with firms. Similar to the role that health authorities play in educating health

professionals, health authorities need to be more engaged with firms in the medical device industry to develop relevant technologies that will have market potential.

The Conference Board of Canada (2011) made four recommendations for improving the uptake of innovative technologies in Canada. They recommended:

1. Federal leadership is needed and suggested a National Health Innovation Office could be created to identify promising new technologies and encourage (or subsidize) their uptake.

2. Targeted funding is necessary to encourage RHAs to adopt new and potentially risky technologies.

3. Regional innovation hubs should be supported – these would encourage entrepreneurs and end-users to collaborate on product development.

4. A change in culture and attitudes is needed – innovative technologies need to be embraced and end-users need to interact with entrepreneurs.

We believe these are all important ideas and would encourage the federal government to give these recommendations thorough consideration.

The Role of the Federal Government

One of the recurrent themes – particularly among those who support the medical device industry – is that there is a role for the federal government to play in this industry. A number of ideas emerged:

- Make the purchase of innovative (and potentially disruptive) technologies a requirement for all RHAs.

- Play a greater coordinating role in identifying areas where Canadian firms could compete with international firms in supplying medical devices to RHAs.

- Provide more funding to RHAs to purchase innovative medical technologies.

- Provide more funding through grants and tax concessions to SMEs developing innovative and potentially disruptive technologies. Grants should

be conditional on firms having committed partnerships from clinicians and RHAs

- Provide analytical expertise (perhaps through the Canadian Agency for Drugs and Technologies in Health) to help identify potentially disruptive technologies.

- Ensure that there is a market for innovative technologies.

Although the main objective of this line of questioning was to examine what role the Canadian Government can play in fostering the medical device industry, the comments did suggest a misunderstanding of the roles of various levels of government in the provision of healthcare to Canadians. Devices are approved and regulated by Health Canada but their purchase is a provincial issue that goes right down to individual health authorities. While many of the ideas are worthwhile, implementation will require coordination between Federal and Provincial governments and regional health authorities.

7. Conclusion

Coordinating Canadian health policy is particularly challenging, given the separate and distinct roles of the federal and provincial governments. Health care is co-financed by the federal and provincial governments, with pharmaceuticals and medical devices regulated and approved by the federal government. However, health care is delivered by provincial governments (or Regional Health Authorities who are accountable to provincial Ministries of Health). As such coordinating any policy mechanisms directed toward encouraging more flexibility in procurement, increased emphasis on innovation and trying to support Canadian firms has to be conducted within the broader federal framework.

The Drummond report recommended that Health Quality Ontario expand their mandate to become a regulatory body to establish and govern evidence-based directives to guide treatment decisions and OHIP coverage. Health Quality Ontario directly impacts the medical device industry by making recommendations for the industry based on scientific evidence. It is further emphasized in this document that particular focus needs to be placed on ensuring that innovation is not diminished by directives that are unreasonably rigid. To achieve this goal, it is recommended that effective input be acquired from key stakeholders including physicians and effective liaisons be established with quality/research organizations in other provinces and the federal government. (Ministry of Finance, 2012)

Different provinces have different capacities to pay for innovation and to experiment with the use of novel technologies and leading edge firms (or potentially

leading edge firms) tend to be clustered around major research nodes in the country. And the flexibility to favour Canadian firms in procurement must not violate existing trade agreements, which may classify these actions as anti-competitive.

Canada has invested heavily in basic research, yet the track record of commercializing this research into successful business ventures is poor. What is required is a more strategic view of research and its importance. In order to maximize our return on investment, these technologies must find their way to market. There is no doubt that this will require more strategic thinking and behavior from all levels of government with particular leadership from the Federal Government to generate a vision of an innovation driven health care system. This will also require local autonomy to allow organic partnerships between practitioners and entrepreneurs to flourish.

If this can be achieved, the enormous potential of the medical device industry to both deliver better health care for Canadians and the advancement of world leading industry can be reached.

APPENDIX A

25 Mandatory BPS Requirements *Copied* from Broader Public Sector Procurement Directive Document

1) Segregation of duties

- Must have 5 roles (requisition, budgeting, commitment,
- receipt, and payment)
- Responsibility must lie with different individuals
- External auditor must be in place for small organisations

2) Approval authority

- Goods and non-consulting services
    - Approval authority schedule (AAS) must be established for procurement of goods and non-consulting services
    - AAS must be approved by board of directors of organization
    - All procurement must be approved by AAS

3) Competitive procurement thresholds

- Procurement process must be in place for goods and services over $100,000 dollars. Procurement of goods must be as follows:

Goods, Non-Consulting Services and Construction		
Total Procurement Value	**Means of Procurement**	**Recommended/Required**
$0 up to but not including $100	Petty cash	Recommended
$100 up to but not including $3,000	Procurement card (P-card)	Recommended
$3,000 up to but not including $10,000	Purchase order	Recommended
$10,000 up to but not including $100,000	Invitational competitive procurement (minimum of three suppliers are invited to submit a bid)	Recommended
$100,000 or more	Open competitive process	Required

- Organizations are not allowed to decrease the value of procurement by separating one procurement into multiple in order to avoid means of procurement.

4) Information gathering

- Request for Information (RFI) and Request for Expression of Interest (RFEI) may be requested at the discretion of the organization obtaining procurement; however, this information may not be used to bias the vendors in any way.

5) Supplier pre-qualification

- Request for Supplier Qualification (RFQS) allows organizations to pre-qualify suppliers based on their capabilities and qualifications

6) Posting competitive procurement documents

- Open competitive procurements must be made available through electronic tendering system available to all Canadian suppliers

7) Timelines for posting competitive procurement documents

- 15 calendar days is the minimum response time that organizations must provide suppliers for open competitive procurements (over $100, 000)

8) Bid receipt

- Competitive procurement documents must contain a bid submission date and closing time, any bids submitted afterwards must be returned unopened.

9) Evaluation criteria

- All evaluation criteria must be finalized prior to commencement of the competitive procurement process
- Must outline mandatory, rated, and other criteria that will be used to evaluate submissions, including weight of each criterion
- Can only be altered by means of an addendum to the competitive procurement documents

10) Evaluation process disclosure

- Organizations must full disclose the evaluation methodology and process to be used in assessing submissions
- Must state criteria that will disqualify a supplier from the bid

11) Evaluation team

- Must have an evaluation team in place that has signed a conflict-of-interest declaration and non-disclosure information agreement

12) Evaluation matrix

- Each team member is required to complete an evaluation matrix rating the submissions

13) Winning bid

- Highest score received is the winning bid

14) Non-discrimination

- Organizations cannot discriminate or give preferential treatment to a supplier in a competitive process

15) Executing the contract

- Agreement between organization and successful supplier must be formally defined in a signed written contract before the provision of supplying goods or services commences

16) Establishing the contract

- Contract must be finalized in terms of the agreement that was released with the procurement documents

17) Termination clauses

- All contracts must include appropriate termination clauses

18) Terms of agreement modifications

- The term of agreement modifications must be set out in the competitive procurement document
- Extending the agreement beyond that set out in the competitive procurement document amounts to non-competitive procurement

19) Contract award notification

- Contract award notification must be posed for procurement of over $100, 000

20) Supplier debriefing

- Within 60 days are receiving an unsuccessful bid, suppliers are allowed to request a debriefing with the organization

21) Non-competitive procurement

- It is recommended that organizations employ a competitive process to achieve optimum value for money
- Non-competitive procurement may be used as outlined above

22) Contract management

- Payments must be made in accordance with contract
- Assignments must be properly documented
- Dispute resolution processes should be included in the competitive procurement document

23) Procurement records retention

- All procurement documentation must be kept for 7 years

24) Conflict of interest

- Any conflict of interested must be evaluated and then mitigated appropriately

25) Bid dispute resolution

- Bid dispute resolution must be outlined in competitive procurement documents

APPENDIX B

SSOs and GPOs Operating in Ontario and Quebec

ONTARIO:

GPOs

Medbuy
Health pro

SSOs

Plexxus – serves the 12 largest hospitals in the GTA
HMMS-London ON
Champlain – Ottawa
3SO- Kingston and surrounding area hospitals
Northwest supply chain- 13 hospitals in northwestern Ontario
Procure- Windsor
COHPA- Central Ontario healthcare procurement alliance

QUEBEC:

Le Groupe d'approvisionnement en commun de l'Est du Québec - Section Bas-Saint-Laurent, Gaspésie, Îles-de-la-Madeleine,
Le **Groupe d'approvisionnement en commun de l'Est du Québec Section Saguenay - Lac-St-Jean / Nord-du-Québec**
Le Groupe d'approvisionnement en commun de l'Est du Québec - section Québec / Chaudière-Appalaches
Le Groupe d'approvisionnement en commun de l'Est du Québec - Section Mauricie/ Centre-du-Quebec
Le Groupe d'approvisionnement en commun de l'Est-du-Québec - section Estrie
Le Groupe D'approvisionnement en commun de l'Est du Québec section Côte-Nord
La **Corporation du réseau de la santé et des services sociaux de l'Outaouais (CARSSSO)**
Le Groupe d'approvisionnement en commun du Nord-Ouest du Québec - secteur Abitibi-Témiscamingue
Le Groupe d'approvisionnement en commun du Nord-Ouest du Québec - secteur Laurentides-Lanaudière
SigmaSante

Le Groupe d'approvisionnement du Monteregie

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