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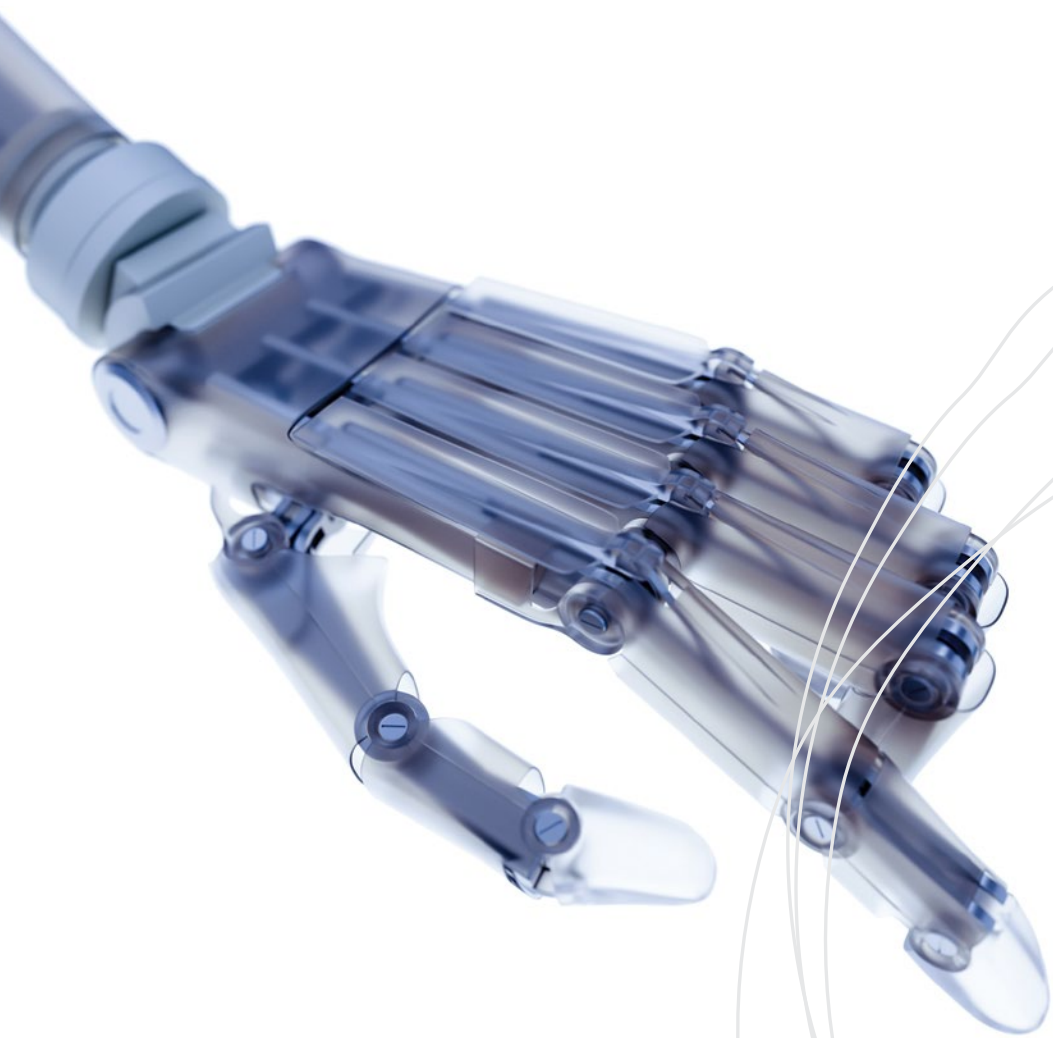
INNOVATION PROCUREMENT FOR MEDICAL DEVICES

Driving Health System Improvement.



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Innovation Procurement for Medical Devices: Driving Health System Improvement

Gabriela Prada and David Verbeeten

Preface

This report emerged out of the 2013 International Roundtable on Reframing the Role of Innovation Procurement for Medical Devices as a Key Enabler of Health System Improvement. The purpose of this conference was to explore best practices and contemporary trends in public procurement in health care, with an appreciation of the potential of this policy tool to advance innovation in the field. When done strategically and through evidence, procurement of innovative medical devices can improve health outcomes without driving system costs. This report describes the different methods that can be and are being used to achieve these goals and provides concrete detail of each step of the procurement process through case studies from around the world. Most of the case studies are based on the experience of organizations represented at the International Roundtable.

An executive summary, in both English and French, is included in this report.

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The findings and conclusions of this report are entirely those of The Conference Board of Canada and do not necessarily reflect the views of AdvaMed or Medtronic. Any errors or omissions in fact or interpretation remain the sole responsibility of The Conference Board of Canada.

EXECUTIVE SUMMARY

Innovation Procurement for Medical Devices: Driving Health System Improvement

At a Glance

- Total expenditure on health and long-term care is rising globally and budgets are coming under strain.
- Strategic, evidence-based procurement of new health technologies can improve outcomes and quality without driving up costs.
- This report captures the experience of a wide range of experts from Canada, the United States, and Europe on best practices for the innovation procurement of medical devices.
- Seven case studies of organizations that engage in innovation procurement are documented in this report.

As total expenditure on health and long-term care continues to rise globally, the resources devoted to this sector are straining budgets and challenging governments. Whereas the introduction of new products and processes into health systems has traditionally been perceived as a cost driver, the manner in which innovation is procured can prove decisive in turning a burden into a substantial boon. Studies confirm that public procurement, as a demand-side instrument, triggers more innovation than state subsidies for research and development. Innovation, in turn, is increasingly viewed as key to the sustainability of health care systems, both in the developed and developing worlds.

This report captures the essential conversation of the International Roundtable on Reframing the Role of Innovation Procurement for Medical Devices as a Key Enabler of Health System Improvement. This event was hosted by The Conference Board of Canada on December 2 and 3, 2013, and brought together delegates from Canada, the United States, and Europe, from hospitals, academic centres, supply chains, trade bodies, and industry.

Delegates to the International Roundtable shared their knowledge of and experience in the procurement of innovative medical devices and other health technologies. Best practices were recorded for each stage in the procurement process. Notable examples include the engagement of area experts or key opinion leaders in drafting technical specifications on behalf of purchasing staff and the use of multidisciplinary committees to assess the value of products and services. The concept of value was an important topic throughout the conference, and this report reflects the emphasis devoted there to understanding value in terms of outcomes,

balance, sustainability, and cost-effectiveness, rather than just price. Other themes explored include the relevance of guidelines, procuring for solutions, and forms of collaboration and risk management.

Throughout this report, case studies from around the world are presented in text boxes. They provide concrete detail to the more theoretical narrative of innovation procurement that guides the reader through the procurement process. With the exception of the Toronto-based program Excellence in Clinical Innovation and Technology Evaluation (EXCITE), all the case studies in this report are based on organizations that had representation at the International Roundtable. Those organizations are the Capital Region of Denmark (Hovedstaden); the Italian federation of hospital purchasers (FARE); the United States Trade and Development Agency (USTDA); the University of Toronto procurement services; Health Shared Services BC (HSSBC); and the EndoCAS research and education centre in Pisa, Italy.

The link between innovation and procurement is a crucial one, although it is not well understood or appreciated by all stakeholders. Procurement lies at the intersection between new ideas and their successful implementation and diffusion throughout health care systems. When pursued strategically and through evidence, procurement can add holistic, long-term value to those systems and advance the agenda of innovation improvement. Doctors, patients, administrators, and state budgets are the beneficiaries of successful procurement.

RÉSUMÉ

L'approvisionnement en matériel médical novateur : Solutions pour améliorer le système de santé

Aperçu

- Partout dans le monde, les sommes allouées à la santé et aux soins de longue durée augmentent, et les budgets commencent à en souffrir.
- L'acquisition stratégique et fondée sur des données probantes des nouvelles technologies de la santé permet d'améliorer les services et la qualité sans faire augmenter les coûts.
- Ce rapport est une synthèse des expériences vécues par un large éventail de spécialistes canadiens, américains et européens au regard des meilleures pratiques concernant l'approvisionnement en matériel médical novateur.
- Ce rapport contient sept études de cas qui portent sur des organismes achetant du matériel médical novateur.

C'est connu, les dépenses liées à la santé et aux soins de longue durée sont en hausse constante partout dans le monde et les ressources allouées à ces secteurs pèsent sur les budgets et mettent les gouvernements en position difficile. Si l'arrivée de nouveaux produits et procédés dans le système de santé a toujours été associée à des hausses de coûts, la façon dont on acquiert ces nouveautés peut faire la différence entre le fardeau et la bonne affaire. Des études confirment que la demande engendrée que représente l'approvisionnement du secteur public donne lieu à davantage d'innovations que les subventions gouvernementales en recherche et développement. Les innovations, quant à elles, sont de plus en plus perçues comme essentielles à la viabilité des systèmes de santé, tant dans les pays industrialisés que dans les pays en développement.

Ce rapport contient les grandes lignes de l'*International Roundtable on Reframing the Role of Innovation Procurement for Medical Devices as a Key Enabler of Health System Improvement*. Cette rencontre organisée par le Conference Board du Canada a eu lieu les 2 et 3 décembre 2013, et ses participants étaient des représentants canadiens, américains et européens de milieux comme les hôpitaux, les centres universitaires, les chaînes d'approvisionnement, les organisations commerciales et l'industrie.

Les participants à cette table ronde internationale ont fait part de leurs connaissances et relaté leurs expériences en ce qui a trait à l'acquisition de matériel médical et d'autres technologies de la santé

novateurs. Pour chaque étape du processus d'acquisition, les meilleures pratiques ont été consignées. Dans certains exemples particulièrement intéressants, on note que des spécialistes du domaine ou d'importants leaders d'opinion ont aidé les responsables de l'approvisionnement à dresser la liste des exigences techniques et que l'on a recouru à des comités multidisciplinaires pour évaluer la valeur des produits et des services. La notion de valeur a été centrale lors des discussions de la conférence, et ce rapport reflète l'importance des efforts déployés pour la comprendre sous les angles de la production, de l'équilibre, de la viabilité et du rapport coût-efficacité plutôt que seulement du point de vue des coûts. Il a également été question de la pertinence des directives, de l'acquisition de solutions et des différentes formes de collaboration et de gestion du risque.

Tout au long du rapport, vous trouverez dans des encadrés des études de cas provenant de divers pays. Elles offrent des exemples concrets qui illustrent la procédure plutôt théorique d'acquisition de produits novateurs pour aider le lecteur à s'y retrouver. À l'exception du programme torontois Excellence in Clinical Innovation and Technology Evaluation (EXCITE), toutes les études de cas comprises dans le rapport concernent des organismes qui ont participé à la table ronde. Ces organismes sont la région de la Capitale du Danemark (Hovedstaden), la fédération italienne des acheteurs du milieu hospitalier (FARE), la Trade and Development Agency des États-Unis (USTDA), le service d'approvisionnement de l'University of Toronto, Health Shared Services BC (HSSBC) et le centre de recherche et d'éducation EndoCAS de Pise, en Italie.

La relation entre les innovations et l'approvisionnement est d'une importance capitale, mais certains intervenants la comprennent ou l'évaluent encore mal. L'approvisionnement se situe au carrefour des nouvelles idées et de la réussite obtenue dans leur diffusion et leur mise en œuvre dans les systèmes de santé. S'il est mené stratégiquement et à partir de données probantes, l'approvisionnement peut ajouter de la valeur à long terme à l'ensemble de ces systèmes et favoriser

l'amélioration des innovations. L'approvisionnement efficace profite en même temps aux médecins, aux patients, aux administrateurs et aux budgets gouvernementaux.

CHAPTER 1

Introduction

Chapter Summary

- Total expenditure on health and long-term care is rising throughout the world. This trend presents a major challenge to health system sustainability in both developed and developing countries.
- When pursued strategically and through evidence, public procurement of innovative medical devices can improve outcomes without driving costs.
- Public procurement has been shown to trigger more innovation than state subsidies for research and development.

Total expenditure on health and long-term care is rising and is predicted to continue to rise in both developed and developing countries well into the mid-century. The public resources that are devoted to this sector are straining budgets and represent a major concern for most governments. The severity of the problem is not necessarily greatest in Western countries. According to the Organisation for Economic Co-operation and Development, projected spending increases on health and long-term care, relative to existing outlays, are actually considerably steeper for some of the BRIICS countries (Brazil, Russia, India, Indonesia, China, and South Africa) than they are for its own developed member-states.[1]

The overall trend has put focus on the sustainability of health systems around the world. As populations prosper and age, the demand for more and better services grows. Recent research has suggested that innovation can play a crucial role in helping to "enhance the efficiency, safety, quality, and productivity of health and health care services."[2] Whereas the introduction of new products and processes into health systems has traditionally been perceived as a cost driver, the manner in which innovation is procured can prove decisive in turning a burden into a substantial boon.

The link between innovation and procurement is a crucial one. However, it is often not well understood or appreciated by policy-makers, administrators, or industry representatives. Innovation is defined not

1 Of course, health care spending as a percentage of GDP as a whole is lower in most BRIICS countries than in OECD economies. Maisonneuve and Martins, *Public Spending on Health*, 7.

2 Prada, *Innovation Procurement in Health Care,* 2.

simply as new ideas or items, but more specifically as their successful commercialization, implementation, and diffusion.[3] Procurement functions encompass "all actions for the acquisition, by purchase or lease, of property, including products and real property, and of services, including works," in line with applicable regulations.[4] By playing a key role in turning new ideas or items into widely used products, procurement lies precisely at the intersection between mere invention and beneficial, cost-effective clinical and social innovation. Various studies have confirmed that public procurement, as a demand-side instrument, triggers more innovation than state subsidies for research and development.[5]

As such, when pursued strategically and through evidence, and not just as an ad hoc transaction, procurement represents a "compelling opportunity" for health and other systems.[6] The right procurement methods and personnel can add holistic, long-term value to the functioning of hospitals, doctors' offices, nursing homes, and other venues, even as patient experience is improved, population well-being augmented, and sustainability ensured.

The purpose of this report is to explore the positive potential of public procurement of medical devices for innovation in health systems. It provides a description of common procurement tools and devotes space to each stage of the procurement process. Attention is paid to the writing-up of specifications and the complicated assessment of value; various possibilities, for and views on, the appropriateness of negotiations between public buyers and private sellers; and forward-looking practices, such as procuring for solutions, models of collaboration, and risk management. Case studies from around the world are used to provide concrete detail to each of these dimensions of procurement.

3 Bodewes and others, *Exploring Public Procurement,* 7.

4 United Nations, *United Nations Procurement Manual,* Section 1.3.

5 Edler and Georghiou, "Public Procurement and Innovation," 949–50.

6 Prada, *Innovation Procurement in Health Care,* 32.

Methodology

This report emerged from the International Roundtable on Reframing the Role of Innovation Procurement for Medical Devices as a Key Enabler of Health System Improvement. The event was held in Toronto, Canada, on December 2 and 3, 2013, and was hosted by The Conference Board of Canada. The Roundtable brought together leading experts in public procurement, both within and outside the health care field; from hospitals, industry, and government; and from Canada, the United States, and members of the European Union. The 28 attendees included three representatives from the Conference Board and two Italian-English translators. (See Appendix A.)

The presentations and discussions that were held at the International Roundtable form the foundation of this report. The diverse material was captured in minutes as well as audio recordings. Some participants also shared their knowledge about public procurement in writing, in response to a questionnaire that was sent to them by the Conference Board before convening.

In addition to the conference proceedings and the pre-conference surveys, other sources of information and evidence that have been used to produce this report include follow-up interviews or e-mail exchanges with delegates, peer-reviewed literature in academic journals and books, and government documents.

This report includes case studies that exemplify the main issues under consideration throughout the body of the text. With one exception, all of these cases are based on organizations that were represented at the International Roundtable. The exception is MaRS EXCITE. While this organization did not send a delegate to the International Roundtable, it was consulted by the Conference Board when the Roundtable was convened.

This report captures the discussion of the International Roundtable in relation to six key elements of the procurement of innovative medical devices:

- standard methods of procurement
- specifications
- value
- negotiations
- procuring for solutions
- collaboration and risk management

A chapter is devoted to an exploration of each of these elements. Each chapter is prefaced by a summary of key take-aways that are discussed at greater length in the main body of the text.

CHAPTER 2

Standard Methods of Procurement

Chapter Summary

- Requests for proposals (RFPs) are more flexible than bids and better able to address issues of quality. They typically leave part of the precise structure and format of the response to the discretion of the suppliers.
- RFPs are often considered a better tool for the procurement of innovative medical devices because the creativity and innovation aspects of the products that suppliers choose to highlight in their proposals may be used to distinguish one from another.

Two frequently used methods of public procurement are the invitation to bid (ITB) and the request for proposal (RFP). Both are tender documents used to solicit offers to supply a desired good or perform a certain service.[1] The terms "ITB" and "RFP" are employed by the United Nations.[2] Other jurisdictions may employ slightly different terminology for the same or slightly different methods of public procurement. Notably, the United States uses the term "invitation for bid" (IFB) instead of ITB, and Canada uses "invitation to tender" (ITT). In the European Union, a distinction between bids and proposals is not maintained; all procurement documents are known as tenders.

Neither a bid nor a proposal is in itself a contract, but both establish the basis for contract formation between buyers and sellers.[3] Both may be preceded by a request for information (RFI), which is a survey whose purpose is to collect information about a market or industry to ascertain potential sources of supply, to determine the likelihood and degree of competition, and to estimate costs. In the European Union, a prior information notice must be published, except in exceptional circumstances, at least 30 days before publication of a planned tender to provide a brief indication of its subject and content.[4]

1 Other methods of public procurement, notably the request for quotation (RFQ), also exist. RFQs are typically used for small items whose total purchase price is below a certain dollar threshold (often $25,000). RFQs do not need to involve formal disclosure and can be processed expeditiously. See United Nations Commission on International Trade Law, *Guide to Enactment*, 131.

2 United Nations, *United Nations Procurement Manual,* Rule 105.15.

3 Ngan and Smith, "RFPs—A Binding Process or Not?"

4 European Commission, "5.3.1.1. Publication of Prior Information Notices."

Proposals and bids are distinguished by the ways in which they are assessed and granted.

- In an ITB, the contract is awarded to "the qualified bidder whose bid substantially conforms to the requirements set forth in the solicitation documents and is evaluated to be the one with the lowest cost" to the seller. Bids are delivered sealed; cannot be changed or withdrawn; are almost never accepted late; and follow strict administrative rules for decision-making.
- In an RFP, the contract is awarded "to the qualified proposer, whose proposal, all factors considered, is the most responsive to the requirements set forth in the solicitation documents." RFPs are more flexible than bids.[5] In the United States and Canada, RFPs involve negotiations between buyers and sellers. In the European Union, negotiations are permitted but are strictly controlled.

As a "bid" approach tends to decide tenders on price, some consider ITBs to be a more strictly objective tool of procurement. In the area of complex and innovative medical devices, however, products are often quite differentiated, and price alone may not be deemed sufficient to judge the various competing characteristics. The "proposal" approach, which reserves more room for quality assessment of non-price factors, is often viewed as better suited for the procurement of complex and innovative medical devices, which are not simple commodities.[6] Of course, many systems still favour selection of tenders on low price, even when assessment of non-price factors is permitted. In the European Union, tenders tend to be distinguished by the extent to which they involve negotiations rather than non-price factors.

5 United Nations, *United Nations Procurement Manual*, Section 1.3. See also Public Works and Government Services Canada, *Bid on Opportunities*.

6 Canadian case law has distinguished bids from proposals as follows: "If there is a distinction between the two forms of soliciting offers, it may be this. When the government knows what it wants done and how it should be done (such as a construction project), it will already have its plans and specifications and is looking simply for the best price. On the other hand, when the government knows what it wants done, but not how to go about doing it, it seeks proposals on methods, ability, and price. Then it can negotiate on the best method to achieve the best value." *Socanav Inc. v. Northwest Territories (Commissioner)*, para. 21.

The delegates to the International Roundtable viewed non-price factors as important. In examining the basic approaches to designing and awarding tenders, they considered the methods and practices that would best support the goals of wisely managing the resources of their respective health care systems, as well as advancing innovation, in line with core tendering principles of transparency, equal treatment, objectivity, and fairness. (See Appendix B.)

CHAPTER 3

Specifications

Chapter Summary

- Technical specifications should be drafted by key opinion leaders (KOLs), who have the technical and practical expertise in dealing with a given medical device.
- A diverse, multidisciplinary committee should review, and possibly modify, the technical specifications from the KOLs.
- Diversity, as well as rotation of experts, can help ensure transparency, objectivity, and fairness.
- A case study from Copenhagen indicates a productive way to distinguish clinically similar products and to determine value. The Capital Region procurement office structures tenders to include “mandatory” features, while allowing competition on “voluntary” (value-added) features. Approximately equal weight is given to price and non-price factors.
- Current guidelines for medical devices suggest that non-evaluation factors should be weighted as much as or more than price itself.

Specifications are a centrepiece of any tender. They identify the critical desired features that a purchaser seeks. Their design is crucial for procurement success and their drafting can be very complex, involving considerable market research. Many procurement challenges can be traced back to lack of clarity at this stage in the procurement process.[1]

An ITB requires firm specifications. Precise specifications help to ensure that competitors, who deal in essentially identical products, are placed on an equal footing, since bids win on low price. One example of this approach can be found on the website of the World Bank, which lists sample technical specifications for condoms. In this example, a manufacturer, in order to prevail against its rivals, must put forward the least-cost offer while conforming on the basic features of condoms (bursting volume and pressure, width and length, thickness, lubricant quality, and viscosity), as well as on labelling, packaging, case identification, lot traceability, and quality control.[2]

An RFP is awarded not just on best price, but also on the basis of non-price factors. These non-price factors may be weighted, so long as the respective weights are stated clearly in the tender document. Non-price factors typically include basic technical features, quality standards, and performance standards. On its website, the World Health Organization (WHO) provides a template of its technical scoring and weighting matrix for RFPs, which is replicated below. (See Exhibit 1.)[3]

Cutting-edge goods and services are not readily interchangeable between one manufacturer and the next, and their various characteristics may be so specialized that they cannot be precisely determined in

1 Office of Government Commerce, *An Introduction to Public Procurement,* 9.

2 The World Bank, "Notes for Preparing the Technical Specifications."

3 An instructive, very detailed example of RFP specifications may also be found in Phelps and Kleinke, "Choosing a Pump," 13–22.

Exhibit 1
WHO Technical Scoring and Weighting Matrix

	4 Excellent	3 Good	2 Satisfactory	1 Poor
The extent to which WHO's requirements and expectations have been satisfactorily addressed				
The number of products covered				
The quality of the overall proposal (X2)				
The appropriateness of the proposed approach				
The quality of the technical solution proposed				
The management strategy/plan detailed in the document				
The experience of the firm in carrying out related projects				
The qualifications and competence of the personnel proposed for the assignment				
The proposed timeframe for the project				

Total

Source: World Health Organization, ***Request for Proposals,*** 29.

advance. Some kind of communication between buyers and sellers, in compliance with principles of transparency and equal treatment, may be necessary in order to draft with accuracy the specifications for new medical devices and other innovative products. Both ITBs and RFPs allow for government contact with industry before tenders are issued, although RFPs alone can involve such contact afterward (as discussed in the section on negotiations). (See Case 1.)

Case 1: Region Hovedstaden

The Region Hovedstaden, or Capital Region of Denmark (Copenhagen), was established on January 1, 2007, as part of a national reform of the Danish public sector. It is one of five regions in the country, that are together governed by a council of 41 politicians and led by a chairman. The Capital Region's

administration is led by three directors and a CEO. Its main responsibility is health care, both somatic and psychiatric, with some responsibility for pollution and specialized disability services.[4]

The Capital Region includes a centralized procurement office. The employees who are responsible for strategic purchases are divided into four teams: consumables, services, medical devices and technology, and laboratory equipment and utensils. Procurement procedures for all these items are similar.[5]

The Capital Region's procurement office tends to award contracts based on both price and quality, rather than on price alone. A diverse committee of around 10 people, many of them end-users, is usually convened to draft specifications, evaluate quality, and determine value. Rules of financial disclosure ensure that there is no conflict of interest among the end-users or the purchasing staff.

The specifications are divided into "mandatory" and "voluntary" requirements. Mandatory requirements must be met by all vendors. If a vendor fails to meet these basic requirements, its proposal is rejected. Voluntary requirements are put forward by vendors in order to distinguish their goods or services, including medical devices, from those of others. They are subject to quality evaluation.

Vendors are awarded points to determine the winner of a tender procedure. Procurement officers typically use a scale from 1 to 5 or from 1 to 10. Points are assigned in relation to compliance with specifications, and are then multiplied by an assigned weight. Weighting might break down as follows: price, 45–55 per cent; quality and functionality, 30–40 per cent; delivery, service, and training, 10–20 per cent.

Government contracting agents under many legal systems are allowed to communicate and even meet with representatives from industry for market research before specifications are drafted, whether for bids

4 The Region has an English-language website with some information at Capital Region of Denmark, *About the Capital Region*.

5 European Commission, "Directive 2004/18/EC."

or proposals.[6] Some officials may hesitate to do so for fear that such interactions may appear to undermine their adherence to principles of transparency and equal treatment.[7] However, participants in the conference were of the view that proper communication with industry for market research, in accordance with tendering law, was important for developing effective tenders for innovative medical technology.

Drafting specifications involves a fine and challenging balance:

- Specifications can be made so narrow that only one company can submit a compliant proposal. The intention may be to filter in innovation and filter out pedestrian alternatives, but too few responses to an RFP can moot the tender and raise concerns about whether the tender was properly and fairly designed.[8] A "single source" purchase is avoided whenever possible in public procurement, not least because a "range of imperfect market substitutes" almost always exists even for patented inventions.[9]
- Broad specifications can ensure that enough competitors qualify for a tender, and the field is open enough to include innovative possibilities. However, broad specifications may raise concerns that too much individual judgment lies in the hands of officials deciding the award, with risks to their independence, transparency, and objectivity.

Treading the line between too narrow and too vague is not easy. Participants at the International Roundtable agreed that transparency can be bolstered by establishing complaint and recourse mechanisms, which should themselves be subject to independent oversight. Transparency can also be enhanced by a clear delineation of the precise role of the procurement office at the specifications stage.

6 Gordon, "Reflections on the Federal Procurement Landscape," 3. In the EU, government-industry contact is referred to as *technical dialogue* in the 2004 public procurement directive, and as *preliminary market consultations* in the 2014 public procurement directive. See European Commission, "Directive 2014/24/EU," article 40.

7 See, for example, the case of the Netherlands, in Tazelaar, *The Prisoners Dilemma.*

8 See, for example, Weiss and Thurbon, "The Business of Buying American," 717.

9 Cotter, *Comparative Patent Remedies,* 45–46.

The procurement office's role is not to write up technical specifications. Specialized area experts should carry out this function. In many countries, it is common for respected key opinion leaders (KOLs) to draft the technical specification for a medical device. These specifications are then distributed to a multidisciplinary committee for peer review and revision. For a new surgical device, for example, the committee might include the relevant surgeons, but also nurses, anaesthesiologists, patient safety personnel, and dedicated cleaning (sterilization) staff. A diverse committee can help to mitigate against possible conflicts of interest, even as it will likely go on to play a role in economic or value analysis. Some contracting authorities further protect against possible corruption by rotating the KOLs with whom they work on a regular basis.[10]

The proper role of the procurement office is to ensure competition and due administrative compliance. In particular, purchasing staff are responsible for rendering generic specifications. An end-user may think there is only one version of a medical device that he or she wants, but purchasing staff must conduct market research to determine whether appropriate alternatives actually exist. Almost all jurisdictions prohibit simple brand-name designation in tenders.[11] A procurement office may avoid an RFP entirely if sole-sourcing is deemed the only viable option in a given case. Legal exemptions must be invoked and approved in order to pursue this course. Such rules are often set out in professional guidelines. (See Case 2.) Guidelines can also serve as a resource for fairness commissioners or monitors, in the event that such an independent agent is hired to ensure that established procedures are followed transparently and equitably, especially for major purchases.

10 On the topic of ethics within public procurement, see Organisation for Economic Co-operation and Development, *OECD Principles for Integrity*.

11 United Nations Commission on International Trade Law, *Guide to Enactment*, Article 10 (5) a.

Case 2: FARE

The Federazione delle Associazioni Regionali degli Economi e Provveditori della Sanità (FARE) was founded in the Lombardy region of Italy in 1960 to promote the study of problems related to supply management in private and public health facilities. This national federation of hospital purchasers encompasses 13 regional federations and covers the 20 administrative regions of Italy. It includes a president, a board of directors, a board of auditors, and an assembly. FARE seeks to hold a national congress every three years. Since 1962, it has published *Teme*, a journal that is distributed by subscription to institutional bodies.[12]

FARE does not itself engage in purchasing. Its main purpose is to train personnel in the field of procurement through courses, conventions, conferences, and publications. One of its most important contributions in this regard is its publication of a series of guidelines on different aspects of procurement in health systems. The first guidelines for medical devices were published in October 2008.[13] The first guidelines for consignment accounts were published in March 2010.[14]

Guidelines establish criteria for tenders. They help maintain transparency through open disclosure and provide coherence to the activities of purchasers across a fragmented administrative geography. They set out best practices, including on competition and compliance, as well as on the use of penalties for non- or partial performance and the means for monitoring contracts. FARE's guidelines encourage the engagement of multidisciplinary stakeholders for writing specifications and analyzing value, with an emphasis on cost-effectiveness.

FARE's medical devices guidelines support technical dialogue with suppliers, yet suggest selective use of this method by the contracting authority for cases of public supply contracts and public service contracts with one or more of the following characteristics:

- They involve innovative specifications or terms of execution.
- They are particularly complex and complicated in terms of their scope.

12 For information on FARE (in Italian only), see FARE, *Home Page*.

13 FARE, "Linee Guida nell'ambito."

14 FARE, "Linee Guida per la formulazione."

- The contracting authority has limited experience in the preparation of the required tender documents, and use of an outside consultant is not possible for correcting and completing the tender documents.

  FARE maintains that suppliers should be engaged in dialogue separately from one another in order to maintain confidentiality and to glean as much information as possible from each. Any notification-invitation for dialogue is published on the website of the contracting authority in order to reinforce transparency and guarantee the common treatment of all suppliers.

  FARE recommends that new technology be assessed on quality and price factors. Points for price are typically weighted at 40 per cent. Non-price factors, including quality (45 per cent) and service (15 per cent) are typically weighted at 60 per cent. As such, non-price factors are considered more definitive by FARE than price alone. The association emphasizes four non-price criteria: the ability of vendors to provide technical assistance, educational services, clinical consultancy, and health economics advice.

A KOL contributing to technical specifications is likely to be a practicing physician, who has to take time away from regular work in order to cooperate with the procurement office. To lighten the load that the KOL bears, a local or regional procurement office can search to find whether another procurement office elsewhere has produced specifications for a similar medical device. If so, these specifications can be given over to the KOL as a template.

CHAPTER 4

Value

- The United Nations upholds “best value for money.” This principle recommends that value be determined by consideration of price and non-price factors, including life-cycle costs. The USTDA also supports this position.
- *Best value for money* (BVM) means that new medical devices should not be rejected as solutions simply due to increased ticket price. Impact on outcomes and cost-effectiveness should be as important as price in awarding contracts.
- As with drafting specifications, the responsibility for assessing value should lie with a diverse, multidisciplinary committee of end-users. Diversity will provide crucial insights from multiple stakeholders, leading to broader professional acceptance and helping to ensure transparency, objectivity, and fairness.
- Various methods for evaluating technologies, including independent health technology assessments, while not always available or timely, can provide useful evidence to determine value.

Almost all proponents agree that proposals should be selected on the basis of best value for money (BVM), which in the parlance of the European Union signifies the most economically advantageous tender (MEAT).[1] The principle of BVM is meant to facilitate the introduction of new medical devices into health systems by taking a more holistic and flexible approach to the assessment of tenders. BVM does, however, present its own challenges, ambiguities, and best practices. What is value, if not the ticket price? Who determines and calculates this value?

The United Nations' procurement division defines BVM as "optimization of whole life costs and quality needed to meet user requirements, while taking into consideration potential risk factors and resources available." It emphasizes that "price alone is not necessarily determinative" of BVM.[2]

- **Cost-related factors,** above and beyond ticket price, should consider life-cycle costs or total cost of ownership: maintenance and cleaning, ongoing operating costs, upgrade and storage costs, staff training, and disposal.[3]
- **Non-cost-related factors** might include timeliness of delivery, general technical merits, overall compliance, and a vendor's track record of competence, reliability, and financial capacity.
- **Other factors** might look at risks to the sustainable use of a product due to geopolitical circumstances, legal exposure or liability, market environment concerns, or patient preferences.

1 European Commission. "Directive 2004/18/EC," Article 53.

2 United Nations, *United Nations Procurement Manual,* Section 1.2.

3 The United Nations provides guidelines on how to conduct life-cycle costing. See United Nations Environment Programme, *Guidelines for Social Life Cycle*.

The United Nations regards BVM "as one of the general principles" of procurement. However, its benefits are not always appreciated, especially in developing countries, where concerns about due process and corruption are often paramount. (See Case 3.)[4]

Case 3: USTDA

The United States Trade and Development Agency (USTDA) was established in 1961 to advance economic development in emerging markets in conjunction with the promotion of American commercial interests. The agency's mission is to link American "businesses to export opportunities by funding project planning activities, pilot projects, and reverse trade missions while creating sustainable infrastructure and economic growth in partner countries."[5]

Through its work in emerging markets, the USTDA has learned first-hand of the limitations that least-cost methods place on the procurement of innovation. Emerging markets tend to prefer process-driven bids, due to concerns about local corruption. However, the USTDA has noted that inflexible bidding methods often preclude "the benefits that can be gained from high-quality products and services that include warranties, maintenance agreements, and reliable customer service." The USTDA provides assistance to emerging markets to teach them about BVM and the best practices that can be used to procure innovative products without compromising on transparency, fairness, and objectivity.

The USTDA signed a memorandum of understanding in 2013 with the law school at George Washington University (GWU). The two institutions agreed to collaborate in the USTDA's Global Procurement Initiative, which aims to foster training on BVM. They expressed hope that a "more sophisticated analysis of the total cost of ownership can lead to smarter, longer-term investments with overall savings to our partners overseas."[6]

4 See, for example, Jin and Chunzi, "The Legislation of Public Procurement," 99, 101.

5 United States Trade and Development Agency, *Mission Statement*.

6 United States Trade and Development Agency, "U.S. Trade and Development Agency and George Washington University Announce."

Participants at the International Roundtable in Toronto understood well that the concept of "value" is multi-faceted. During the proceedings, they were asked to note the word or term that came to mind when they contemplated the meaning of "value" in relation to the procurement of new medical devices in contemporary health systems. The results are plotted in a word cloud. (See Exhibit 2.) As indicated by relative font size, the most common response was "outcomes," followed by "balance," "sustainability," "efficiency," and "cost-effectiveness." "Price" by itself was not an especially strong association that delegates made with "value."

Exhibit 2

Word Cloud of "Value" in Relation to the Procurement of Medical Devices

Source: The Conference Board of Canada. Produced at wordle.net.

As with the drafting of specifications, it is best to designate a diverse committee to carry out economic or value analysis. Delegates to the International Roundtable all stressed that the engagement of

various end-users and subject experts in value analysis needs to be encouraged. There are strong reasons to support this approach, including the following:

- Assessment of medical devices often requires multidisciplinary and complementary knowledge, experience, qualifications, and skills. There "isn't a single person with the complete skill set for device evaluation."[7]
- Diversity affords genuinely different perspectives, which should be heeded by the contracting authorities. An orthopaedic surgeon, for example, may prefer a certain hip prosthesis due to personal experience of use or due to personal relationships with manufacturers. His preference may not, however, take into account cost, cost-effectiveness, or overall context. Purchasing staff will need to ensure that other physicians, nurses, and even physiotherapists are consulted to determine whether they share the surgeon's preference and to explain why.[8]
- Diversity of personnel lends credibility to the procurement process and reduces the potential for corruption to enter into the procurement process. Participation of physicians is key, given that these professionals are known to resist top-down dictates in relation to their medical practice. It is easier for physicians to accept the advice of peers than of non-peers.[9] What is more, physicians who are KOLs can help manage changes in clinical practice that might result from the procurement of innovative medical devices.

Demonstrating the value of a new medical device can do much to ensure cooperation and compliance among and between different stakeholders. That being said, it is important for purchasing staff, as well as end-users, to recognize that medical devices provide different long-term evidence, compared with pharmaceuticals, because they present different learning cycles, user experiences, organizational impact, and risk

7 Ventola, "Challenges in Evaluating and Standardizing," 349.

8 See, for example, Pennington and others, "Cemented, Cementless, and Hybrid Prostheses." Compare National Institute for Clinical Excellence, *Guidance on the Selection of Prostheses.*

9 Montgomery and Schneller, "Hospitals' Strategies for Orchestrating Selection," 308.

profiles; and they operate on different business cycles. In comparison with pharmaceuticals, medical devices tend to involve less risk and to proceed through rapid cycles of incremental improvement and model change, albeit punctuated by breakthrough innovation.[10]

As some participants of the International Roundtable observed, manufacturers face increasing pressure to generate more and more data to help health care officials, providers, and payers evaluate the economic characteristics of medical devices. They are expected to submit proposals that present better business cases for their products. Nonetheless, the laboratory, animal, or clinical data that may be required for regulatory approval of a new medical device may not answer all questions about "value" as held by tendering officials. What is more, additional data from observational studies, before or after regulatory approval, may not exist at the time of the initial availability of products to allow for comparisons across all products.

The challenge in generating all the data that each stakeholder might want—for each model in each health care system in each country—could present a significant burden to the pace of innovation, delaying introduction of new therapies and undermining the development of innovative small and medium-sized enterprises. For this reason, contracting authorities will likely need to continue to rely on a combination of balanced judgment from clinicians and other stakeholders along with the best clinical and economic data available.

A few countries started with health technology assessment (HTA) units in hospitals to assess if new technologies should be offered. Others have HTA agencies that evaluate clinical and economic data of medical devices as well as pharmaceuticals. The United Kingdom's National Institute for Clinical Excellence (NICE) is well recognized as a leader in this type of evaluation and has put several programs in place to assess cost-effectiveness from the perspective of the National Health Service (NHS). There is also a discernible movement toward the use of independent agencies to produce HTA reports on behalf of

10 Ventola, "Challenges in Evaluating and Standardizing," 349–50.

industry for use by contracting authorities. (See Case 4.)[11] HTA can support determination of value, but certain limits exist with regard to consideration of full societal or patient benefits in the short, medium, or long term.

HTA reports often express their findings in terms of incremental cost-effectiveness ratios (ICERs), whereby the cost of changing an existing treatment is measured against the positive (or negative) health effects. Costs are usually described in monetary units, while effects can be measured in quality-adjusted life years (QALYs) or another metric. Evaluations from such organizations can add objective data helpful in some tendering decisions, although differing regional or national cost structures within health care systems may limit whether economic conclusions will transfer. All delegates to the International Roundtable agreed that better clinical and economic data, as resulting from different evaluation methods, including HTA, is a positive trend, helping purchasing staff make value-based decisions. (See Case 4.)

Case 4: MaRS EXCITE

The MaRS Discovery District is a not-for-profit corporation that was founded in Toronto, Canada, in 2000. MaRS works with partners to catalyze, accelerate, and amplify innovation and supports entrepreneurs who are building Canada's next generation of growth companies. MaRS "provides resources—people, programs, physical facilities and networks—to ensure that critical innovation happens."[12]

The MaRS Excellence in Clinical Innovation and Technology Evaluation (EXCITE) program was launched as a strategic initiative in the fall of 2011. EXCITE "helps companies increase the likelihood of success for their breakthrough technology-based health innovations through a more effective approach to navigating the required approvals, adoption and uptake." EXCITE harmonizes the HTA of new technology into a "single, pre-market,

11 Feldman and others, "Who Is Responsible for Evaluating," 59–60.

12 MaRS, *Our Mission. Our Vision.*

evidence-based process," whereby inventors, investors, hospitals or clinics, and health care providers can prepare for implementation of new technologies and make better use of them once they are adopted.[13]

Manufacturers pay methodological centres that are partnered with EXCITE to produce a Core Evidentiary Bundle on their respective new medical technologies. Since 2011, fees for this service have averaged around $1.3 million, with a range between $900,000 and $2 million. EXCITE predicts a future range of costs from $800,000 to $5 million, depending on the complexity and maturity of the device in question and the scope of the review. Duration is estimated at between 12 and 30 months.

The Core Evidentiary Bundle includes a clinical trial or field evaluation of safety and utility; a systematic review of relevant existing research and data; and an economic analysis of quality, outcomes, cost-effectiveness, and potential downstream savings for the health system related to the use of the device.

These elements generate the minimum amount of data needed both to inform a regulatory submission for licensing (Health Canada) and to provide proof of value for the purpose of reimbursement reviews (Ontario Health Technology Advisory Committee for Health Quality Ontario).

EXCITE has reviewed 27 applications to date, and is currently working on 9 projects. It only accepts technologies that have the potential to improve patients' outcomes significantly or to lower costs substantially relative to existing treatments. Manufacturers benefit from the comprehensiveness of reviews, which are designed to answer all relevant regulatory, reimbursement, and adoption questions at once. They can also make adjustments to their technologies without undue expense or time spent on re-licensing, given that the reviews happen in the pre-market space.[14]

13 EXCITE, *What Is EXCITE?*

14 Information gathered by The Conference Board of Canada from MaRS EXCITE on January 28–29, 2014. See also Langille, "The Game Changers," 24–26.

CHAPTER 5

Negotiations

Chapter Summary

- Negotiations are useful for the acquisition of innovation, for they expand the extent to which non-price factors are given due consideration by purchasing staff.
- Negotiations are restricted in their use in Europe and other jurisdictions due to concerns about transparency. Nonetheless, the University of Toronto has successfully used negotiated requests for proposals (NRFPs) to improve quality, save money, and speed up procurement without compromising on objectivity or fairness.
- By tying negotiations to a competitive framework, the likelihood of obtaining the most economically advantageous tender (MEAT) is enhanced.

The degree to which a tender can be negotiated after it has been issued depends upon its type. By definition, an ITB is never negotiated. In the event of a tie, tie-breaking mechanisms exist, such as random assignment or further rounds of bids between those tied. An ITB is submitted sealed, cannot be changed or withdrawn, and is awarded on low price. Bidders compete on price. An RFP, by contrast, can be negotiated to varying degrees in certain jurisdictions.

Many jurisdictions may be unsure of the proper use of negotiations as a part of the procurement process, whether for health-related goods and services or otherwise. It may be difficult to envision how to follow core tendering principles of transparency and equal treatment when undertaking negotiations with different parties. For instance, negotiations may lead to pertinent information being shared with one supplier to the exclusion and disadvantage of others.

The European Union's 2004 public procurement directive is very careful to delineate the "cases justifying use of the negotiated procedure." Negotiations are allowed "in the event of irregular tenders" and in "exceptional cases." Examples of "irregular" and "exceptional cases" include "public works contracts … when no tenders or no suitable tenders or no applications have been submitted in response" to an advertisement; situations of monopoly due to intellectual property protections; instances of "extreme urgency"; and contracts "purely for the purpose of research, experimentation, study, or development."[1]

Negotiations can be simultaneous or sequential. In simultaneous negotiations, such as competitive dialogue, the procurement office engages with several vendors at the same time to learn about market capabilities, refine specifications, bargain on price, and assess value.

1 European Commission, "Directive 2004/18/EC," articles 30 and 31.

As contracting authorities must "ensure equality of treatment among all tenderers," simultaneous negotiations can be time-consuming.[2] Information given to one vendor must be shared with all. Further, every supplier must be notified of any iterative changes in the specifications and given sufficient time to respond accordingly.

By contrast, sequential negotiations can be more time-efficient, although somewhat less transparent and possibly less effective at eliciting price concessions from vendors.[3] In this procedure, proposals are first assessed and ranked from most to least attractive. The vendor with the highest-ranked proposal is invited to negotiate, and "as long as its representatives can come to terms with the state, it will obtain the contract. Lower-ranked proposals are considered only if negotiations with higher-ranked proposers fail."[4]

Proposals can be clarified and fine-tuned through negotiations. The basic features of the RFP, however, cannot be substantially changed after a proposal document has been distributed, for this would likely distort competition or have a discriminatory effect. In the event that negotiations lead to major reconsideration of purchasing needs, a new RFP is required.

While negotiations amount to extraordinary measures in many systems, they are considered by some experts, including various delegates to the International Roundtable, to be particularly useful for the acquisition of innovation. Negotiations expand the extent to which non-price quality factors are given due consideration, and the extent to which their characteristics can be fully appreciated by purchasing staff. (See Case 5.) By tying negotiations to a competitive framework, the likelihood of obtaining best value for money is enhanced. Despite restrictions on use, the latest European Union public procurement directive recognizes

2 European Commission, "Directive 2004/18/EC," Article 29.

3 For evidence on price concessions in relation to negotiation strategy, albeit in a slightly different context from procurement, see Perreault, Kida, and Piercey, *The Relative Effectiveness of Simultaneous,* 3.

4 University of Pennsylvania, "Requests for Proposals," 197.

that negotiations with competitive dialogue have "increased in terms of contract values over the past years" and represent an opportunity for flexibility in cases where other procedures "are not likely to lead to satisfactory procurement outcomes."[5]

Case 5: U of T

The University of Toronto (U of T) is spread out over three campuses and employs about 20,000 people. Its procurement services are decentralized and spend, salaries included, around $2.4 billion annually to help the university's more than 400 departments buy what they need. For purchases below $100,000, departments procure directly. For purchases over $100,000, departments procure through the central procurement office, which oversees between $400 million and $600 million annually.

Edward Jin was director of central procurement services from 2008 until late 2013. Upon arrival, he discovered that most professors viewed his office as an obstacle rather than a helpful service in getting what they wanted. They avoided rather than sought out its services. Jin decided to overcome the "red-tape fatigue" that he observed among faculty, by redesigning the university's procurement processes with end-users in mind. The result was the negotiable request for proposal (NRFP), which was produced with careful attention to Canadian procurement law.

The NRFP is similar to the RFP, albeit with a greater emphasis on flexibility. This emphasis was required in the Canadian context due to certain features of Canadian contract law, notably the "Contract A" concept, which stipulates very strict fairness and equality of treatment standards when public buyers procure from private sellers. The problem with the Contract A model is that these standards can be so rigid that they hinder the procurement of state-of-the-art products across any field or industry.

The NRFP offers a solution to the problems inherent in the Contract A RFP, in that it stresses and allows for quality evaluation, rectification, and negotiation. The template was designed with the aid of Canadian legal experts to ensure

5 European Commission, "Directive 2014/24/EC," Preamble 42.

compliance with existing codes. The main features of the NRFP include the following:

- **Evaluation:** Price is usually given a low weighting of 30 per cent (or less). Almost all purchases over $100,000 are strongly weighted toward quality, which is determined by the end-users. What is more, final contracts are tracked to measure financial and non-financial outcomes.
- **Rectification:** Late tenders can be accepted within a designated grace period. Minor non-conforming issues, like typos or small pieces of missing information, no longer invalidate an entire submission.
- **Negotiation:** Sequential arbitration is employed to ensure speed. If no progress is made with the most highly ranked proposer within the first 15 days of negotiation, the next best is engaged as an optional strategy. If a conclusion is not reached with the highest ranked proposer within the first 30 days, that vendor is moved off the short list of prospective suppliers.

NRFPs are now the de facto procurement method at U of T. Since 2010, U of T's central procurement staff have gone from being "policy police" to being "policy advisors." They have earned the respect and appreciation of professors, management, and suppliers. Since implementation, the procurement office has run over 400 NRFPs, covering $200 million in contracts. The program has resulted in over $3.5 million negotiated savings, and compliance and traction have improved dramatically.

CHAPTER 6

Procuring for Solutions

Chapter Summary

- Procuring for solutions targets a care outcome as the basis for tender award. It involves the procurement from one vendor of all the tools and services that are necessary to treat, cure, or manage a given disease, rather than just one tool or one service.
- Procuring for solutions involves customization to the needs of provider and patient populations to be served. Related to procuring for solutions is the concept of a construct. A construct is a grouping of products that all deal with the same medical condition, yet vary slightly according to the age or other characteristics of the intended patient.
- Procuring for solutions requires a great deal of sophistication on the part of buyers and sellers, and, in many instances, a change in business model and approach.
- Procuring for solutions has enormous potential to drive innovation in health systems, as suggested by the British Columbia case study.

Negotiations play an important role in procuring for solutions. To procure a solution in the health system is to procure from one vendor all the tools and services that are necessary to treat, cure, or manage all the various aspects of a given disease, rather than procuring for just one tool or one service to treat, cure, or manage one aspect of the disease. Ensuring objectivity when procuring for solutions is one of its greatest challenges.

When procuring for solutions, an RFP typically states a therapy or care outcome that is desired. The vendor is required to meet this therapy or care outcome within a certain budget and time frame. For example, purchasing staff who wish to procure a solution for diabetes might seek out companies that make insulin pumps along with continuous glucose monitors, glucose meters, and test strips. In addition, they might set out in the specifications that the insulin pumps provide superior glycemic control such that severe hypoglycemic events are reduced for each patient.[1] Finally, the procurement office might decide between RFPs on the ability of each vendor to provide various secular services—such as replacing old pumps when they break down and maintaining professionally staffed helplines for patients.[2]

Related to procuring for solutions is the concept of a construct. A construct is a grouping of products that all deal with the same medical condition, yet that vary according to the age or other characteristics of the intended patient. Thus, an orthopaedic surgeon specializing in hip replacements may prefer to use a certain prosthesis on a 40-year-old who is sporty and active or "high demand"; another on a 60-year-old who just underwent chemotherapy for cancer; and yet another on a 75-year-old who suffers from bad arthritis. This is a process called demand

1 Johnson and others, "Long-Term Outcomes."

2 See, for example, Medtronic, *We're a Partner for Life*.

matching. A company that could provide the entire variety of prostheses, tailored to each persona, would meet the requirements of the care construct and, as such, would be providing a comprehensive solution to the challenge of patient variation.

Procuring for solutions requires a great deal of sophistication on the part of buyers and sellers and, in many instances, a change in business model and approach. Notably, procuring for solutions takes the theory and practice of total cost of ownership, or life-cycle costing, to a higher level of complexity. RFPs need to draw up specifications and assess value with the entire solution to a given health problem in mind. The buyer and seller need to work together to create a care system, including the products as well as the services. Needs assessment, market research, and negotiations are vital to ensuring the success of such initiatives. Purchasing staff also need to be trained in the correct techniques and geared toward their innovative potential. (See Case 6.)

Case 6: HSSBC

Health Shared Services BC (HSSBC) is an organization that has enjoyed considerable success in procuring for solutions. HSSBC's Supply Chain group was established in February 2009 to centralize the purchasing power of the BC Health Authorities, which include five regional health authorities and one provincial health authority. At inception, it was estimated that $150 million in procurement savings could be achieved within five years. By 2013, with over 1,000 Supply Chain employees and oversight of $1.9 billion in total annual spending, that figure had risen to over $230 million in projected savings, exceeding original estimates.[3]

The use of advanced purchasing techniques helped produce these impressive figures. HSSBC Supply Chain has become a national leader in procuring for solutions by creating contracts that not only deliver products and services at

3 HSSBC Supply Chain's savings projection is based on using current and future pricing for a defined "historical" volume. Actual achievement of savings is reliant on the BC health care organizations using the contracts. See Health Shared Services BC, *Health Shared Services BC Supply Chain*.

the best possible price, but also meet desired outcomes. One such outcomes-based procurement process involves peritoneal dialysis supplies.

The Peritoneal Dialysis Program of the BC Provincial Renal Agency (BCPRA) currently assists over 850 patients with kidney failure to perform this less intrusive form of dialysis at home on their own.[4] In this model, which is seamless in terms of access, the vendor is part of the care cycle. Patients contact the vendor call centre to order supplies and arrange for delivery, and the vendor provides frontline patient support and liaison with care providers. When BCPRA's exclusive contract for products and services with a single vendor expired, HSSBC Supply Chain worked with BCPRA to design a request for proposal in a way that would not only meet the current needs of the program, but also reduce costs and significantly improve services for patients.

In order to get the best possible contract in place for peritoneal dialysis supplies, HSSBC Supply Chain partnered with two other provinces and two group purchasing organizations for a pan-Canadian RFP. Combining the purchasing power of these entities created greater negotiating power, and made the RFP more attractive to potential vendors, due to increased volumes from and the cost-saving opportunities of entering multiple markets with a single proposal. HSSBC Supply Chain led the initiative on behalf of the group.

To avoid certain limitations that had plagued earlier efforts to procure for peritoneal dialysis, specific clauses were written into the RFP to ensure that the final contract would meet the needs of service providers into the future:

- **Regional Flexibility:** Vendors could choose to submit proposals that were tailored to the regional needs of each participating organization or to submit proposals that identified the value of a multi-participant (pan-Canadian) award. This approach allowed participants to be involved in the way that best suited their region.
- **New Technology:** Purchasing organizations have the ability to evaluate new products or services from different vendors that were not available at the time of contract signing. If the new products are found to be superior over those provided under the contract, and the contracted vendor cannot produce a comparable new product within six months, the purchasing organizations can

4 The BCPRA provides access to this form of dialysis and all forms of dialysis at no cost to the patient.

buy the product of their choice without financial consequences. This clause makes room for clinical innovation and adoption over the course of the contract.

- **One-Stop Shop:** The primary vendor would be responsible for providing all products and services to each patient, including any offered by the competitor. If more than one vendor was selected, this provision simplified care for each patient, who did not have to deal with more than one vendor providing products and services. The one-stop shop option enabled clinical choice without additional systems or negative patient impact.
- **Value-Add Requirements:** Vendors were asked to provide suggestions on how they could bring additional value to the health organizations (typically in the form of volume rebates or training opportunities).

In early 2012, following clinical evaluation and sequential negotiations, the contract was awarded to a primary and secondary vendor. Within two years, an outcomes-based procurement approach had already delivered significant benefits. As a result of negotiated volume rebates, costs dropped and continue to do so, even as usage has increased. Clinicians have more choice and flexibility to introduce clinical innovation. Above all, the patient experience has improved. Under the one-stop-shop concept, patients have a single point of contact for integrated service and support, regardless of which of the two vendors produces the products for their care. Services have also subsequently improved by expanding call centre hours and support and adding delivery options for international travel.

By collaborating with clients and expanding the scope of the procurement process, HSSBC Supply Chain is able to go beyond buying products to provide added value through procuring for solutions that meet patient and clinical needs.

Procuring for solutions has enormous potential to drive innovation in health systems. However, it involves greater complexity and sophistication in the application of tendering principles and requirements. Its use is not widespread currently. As health systems become increasingly constrained by public budgets, procuring for solutions can be expected to gain in importance and favour as a tool in the policy tool kit.

CHAPTER 7

Collaboration and Risk Management

Chapter Summary

- Multi-sector or cross-sector institutional and organizational cooperation has the potential to advance the procurement of innovation.
- Different types of risks could be managed or mitigated through collaboration between payers, health care organizations, and industry. Mechanisms to manage risk include third-party guarantees, private finance initiatives, and public-private partnerships. These approaches allow industry to invent and test solutions within certain budget ranges.
- While collaboration between hospitals and industry is not yet widely in place, several delegates to the International Roundtable indicated that their organizations were moving in that direction.

Collaboration is an emerging best practice that came up repeatedly at the International Roundtable. Collaboration is more than just bringing together different stakeholders to draft specifications or to engage in value analysis of medical devices and related technologies. As vital as such practices are, collaboration can go beyond such multidisciplinary forms of engagement to include genuine multi-sector or cross-sector institutional and organizational cooperation to advance the procurement of innovation.

Collaboration can involve academic centres. In some countries, academic centres, usually affiliated with universities, act as independent intermediaries between public buyers and private sellers in health systems. Academic centres can offer services that range from research and development to clinical testing, and from health technology assessment to on-site training of medical practitioners in the use of innovative products. Two or more of these services can be integrated into a single program. (See Case 7.)

Case 7: EndoCAS

EndoCAS is a multidisciplinary research and education centre in full operation since 2005 in Pisa, Italy. Its original funding came from Italy's Ministry of Education, Instruction and Research and from Tuscany's Regional Health Service. It is located on the grounds of the main Teaching Hospital of Cisanello in Pisa, which is associated with the University of Pisa and the Scuola Superiore Sant'Anna. EndoCAS's workforce includes engineers, computer scientists, software engineers, economists, and physicians—most of whom are surgeons and radiologists.

The centre's mission is to "develop breakthrough technologies based on engineering and information technologies," which will improve "current surgical procedures and reduce their invasiveness by means of an optimal use of medical imaging."[1] EndoCAS conducts research in patient-specific 3D models; surgical navigation systems for mini-invasive treatments; robotic surgical guidance; and simulators for training and planning of surgical interventions.

EndoCAS does not just experiment with various computer assisted surgery (CAS) systems. It seeks to determine their relative cost-effectiveness so as to facilitate their transfer into the market. The centre is able to draw upon human and material resources already on the campus of the Cisanello Teaching Hospital in pursuit of this goal. What is more, it offers surgical training to students and residents of the hospital in the use of new technologies. In this way, it facilitates market entry both in conducting HTA in conjunction with R&D and in diffusing the necessary skills for widespread adoption of new technologies. These services are integrated in the same facility.

Collaboration between industry and hospitals can help develop evidence of technology performance and help manage the risks involved in purchasing new medical devices. Through collaborations, vendors can test and demonstrate performance of their innovative technologies, while collecting evidence of outcomes and cost-effectiveness. This approach decreases the risks of non-completion, underperformance, or false performance that may concern tenders in cases of radical innovation. It also decreases risk aversion due to fear of failure or the exposure of failure among civil servants.[2] By creating the right structural incentives, risk-averse attitudes among public contracting authorities can be mollified, opening the way for more creativity.[3]

In some cases, it may be appropriate to include risk-sharing criteria in a tender, so that both purchaser and vendor appropriately share rewards from meeting or beating expected results, and fairly apportion

1 EndoCAS, *Mission*.

2 See, for example, House of Lords, *Public Procurement as a Tool*, 25; Koller, Lovallo, and Williams, *Overcoming a Bias Against Risk*.

3 Howell, "The Right Stuff."

consequences from failing to meet results. Mechanisms to manage risk include third-party guarantees, such as surety bonds and letters of credit, and private finance initiatives (PFIs), in which the private sector is responsible for keeping within a budget allocated by public managers. Forms of public-private partnership (PPP or P3) also exist. For example, industry can agree to provide funds to a hospital so that a clinical unit can experiment with a promising new medical device to gather data on outcomes. The hospital, in turn, commits to the possibility of long-term procurement if cost-effectiveness is established.[4]

No case study on risk-sharing was presented at the International Roundtable, for there is very limited experience in this cutting-edge practice for procuring innovative medical devices. Nonetheless, several participants, especially from hospitals in Spain, indicated internal movement toward risk-sharing ventures with industry. As purchasing staff become more comfortable with risk-sharing mechanisms, they will be better able to present documented evidence of its operation.

4 European Commission, *Risk Management in the Procurement,* 41–42.

CHAPTER 8

Transferring Ideas Across Jurisdictions: Importance of Context

Chapter Summary

- The type of procurement policies pursued and instruments used in various jurisdictions depends on the context.
- Transparency and objectivity are challenging when procuring innovations.
- This report has suggested best practices that can uphold the integrity of public procurement while leading to health systems that are more open and receptive to health innovations.

The type of procurement policies pursued often depends on the context. What may work in one country may not work in another. What may be preferred in one region or hospital may be avoided in another. Procurement policies can differ between one jurisdiction and the next as the result of purely idiosyncratic factors, such as the vagaries of local administrative evolution and decision-making, or local clinical capacity and practice. Mainly, however, public procurement policies tend to respond to, and be shaped by, the degree of perceived corruption in a given society. This tends, in turn, to reflect the extent of macroeconomic development and bureaucratic maturity.[1]

The challenge for the procurement of innovative medical devices is that it requires input and judgment from various stakeholders, often without definitive data to prove the value of differentiated products.[2] Engaging the judgment of stakeholders can raise questions of transparency and objectivity. This stakeholder judgment comes into play both in drafting the specifications and applying award criteria that include significant weight for qualitative factors as well as price. The application of judgment also comes into play in the more complex tender process of procuring for a solution rather than just products.

1 For a recent, comparative look at various public procurement systems around the world, see Lember, Kattel, and Kalvet, *Public Procurement, Innovation and Policy*.

2 Burguet and Che, "Competitive Procurement With Corruption," 50–53.

However, this report has suggested best practices that can mitigate concerns about transparency and objectivity in the procurement of innovation. (See Appendix B.) These best practices include:

- the use of multidisciplinary committees to draft specifications and assess value;
- rotation of the KOLs who are chosen to work with purchasing staff;
- the publication of regional or national guidelines on procurement procedures;
- use of a fairness commissioner or monitor to ensure competition in a tender;
- a commitment to market research to render generic specifications;
- a clear indication of the weights assigned to criteria in an RFP;
- the establishment of complaint mechanisms.

In the final account, these and other best practices can help to sustain a fair system of public procurement, but they will not eliminate all concerns about transparency and objectivity or avoid all corruption.[3] Studies indicate that a culture of honesty, trust, and self-restraint is the single most effective insurance against corruption. This culture emerges not from any set of guidelines or policies, but from the existence of strong social norms and the example of ethical conduct on the part of role models and leaders or managers.[4]

It is beyond the ability of any procurement system per se to ensure this kind of disciplined societal culture.[5] Nonetheless, careful, incremental implementation of best practices can help improve process, step-by-step, toward a system that is more open and receptive to health innovation, including new medical devices.[6] In this way, greater social and economic value for patients, health care providers, industry, and society as a whole will be created to the improvement and the long-term sustainability of health systems and the betterment of living standards.

3 See, for example, Williams, “The Use of Exclusions.”

4 See, for example, Ntayi, Ngoboka, and Kakooza, “Moral Schemas and Corruption.”

5 World Trade Organization, *Report (2003) of the Working Group*, Section 14.

6 See, for example, Mosoti, “Reforming the Laws.”

CHAPTER 9

Conclusion

Chapter Summary

- This report captures the essential conversation of the International Roundtable on Innovation Procurement, held in Toronto on December 2 and 3, 2013.
- Methods of and best practices in innovation procurement of medical devices and related health technologies ensure value-for-money.
- Case studies in this report provide concrete detail of how best practices are implemented in the developed world.
- Public procurement is a powerful tool for advancing cost-effective innovation in health care systems.

This report aimed to capture the essential conversation of the International Roundtable on Innovation Procurement, held in Toronto on December 2 and 3, 2013.

A common thread that runs throughout these pages is that the methods by which new medical devices and related health technologies are procured can prove decisive with regard to value-for-money. Recognition of this fact is key to ensuring the sustainability of health systems throughout the world while advancing medical practice.

The case studies presented in this report demonstrate how best practices are put to work at various stages of the innovation procurement process: from determining value and capturing these in technical specifications written by committees of end-users, to awarding tenders on the basis of both price and non-price criteria. They also present other cutting-edge practices that are being developed in various countries to move innovation procurement forward. These practices include harmonizing the regulatory and HTA process pre-market to boost uptake of innovations, as well as using alternative procurement approaches that better support the purchase of state-of-the-art technology and allow for the procurement of solutions rather than products.

Procurement lies at the juncture between invention and successful innovation. The true extent of the power of public purchasing to bring life-saving, as well as cost-effective, innovation into health systems is only now coming to be fully appreciated by policy-makers, administrators, and industry representatives. Increasing attention is being paid to concepts and models of total value, health technology assessment, and ways of aligning new medical devices with the overall goals and visions of health systems. As emphasis on this topic continues to grow, the innovation procurement tool kit will likely become more robust and sophisticated. We will continue facilitating dialogue across countries to expand knowledge, cross-pollinate ideas, and speed up the adoption of

these innovation procurement practices. This is our commitment to the support of health care system performance and sustainability and greater social and economic development.

APPENDIX A

List of Attendees

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Director of Health System Strategies and Chief Marketing Officer
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APPENDIX B

List of Best Practices

During the International Roundtable, participants were asked to write down examples of best practices that were discussed at the conference and that they felt were important. Some examples follow:

- Engaging multidisciplinary stakeholders in writing specifications.
- Using KOLs to manage change of clinical practice, when required by the procurement of new medical devices.
- Indicating how measure is to be valued in the tender document.
- Procuring for solutions with attention to risk-sharing.
- Involving physicians in managing departmental budgets to encourage quality assessment.
- Weighting price and quality.
- Limiting contracts to a maximum of two years to facilitate technology upgrades.
- Paying attention to total cost of ownership.
- Using a fairness advisor to ensure all interests are balanced during a tender.
- Conducting HTA to drive recommendations for procurement within health systems.
- Allowing negotiations prior to final selection for the purpose of rectification.
- Writing specifications to include the broader goal of a health system as a category of assessment.
- Creating tools to make innovation procurement less risky.
- Implementing NRFPs.
- Allowing end-users to determine value.
- Ensuring dialogue between industry, administrators, and physicians in order to obtain outcomes-based evidence.

- Sharing risk as a solution to a lack of evidence in very innovative technologies.
- Making sure that specifications are generic.
- Engaging HR when transforming procurement practices.
- Training procurement professionals in critical thinking and dialogue.
- Adopting new technology while the industry partner continues to collect data (with option to raise price if or when value is established).
- Sharing a code of ethics with all stakeholders in the procurement process.
- Including all available evidence, without excluding data that has been sponsored by industry (use design criteria to exclude low-quality study, instead of falling back on anti-industry bias).
- Weighting each element of procurement assessment transparently.
- Negotiating with industry before writing specifications.
- Allowing fairness commissioners within the supply chain to review specifications for a medical device tender to ensure competition.
- Favoring solutions rather than mere products in procurement.
- Borrowing specifications that have already been written from a neighboring province or region for efficiency and as a basis for comparison.
- Publishing specifications online for transparency.

APPENDIX C

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