

# **Table of Contents**

3 Introduction

6 Part One

Redesigning of public procurement and collaboration with stakeholders will foster innovation and enhance healthcare value

**11** Part Two

Utilizing the "Four Favorables" has enhanced healthcare value in China

**16** Part Three

Utilizing Jiangsu Province tendering practices that demonstrate a willingness to move beyond price can add value

**20** Part Four

Industry/Government partnership and harmonized purchasing approaches can increase value and lead to new healthcare solutions

23 Part Five

Utilizing a robust legal framework that provides transparency, clear rules and paths for stakeholder collaboration enhances value in tendering

**28** Conclusion

# Introduction

# The importance of innovation and value in medical device procurement

As discussed in the November 2014 paper, deciding which healthcare technologies to procure and how to procure them is one of the most pressing policy concerns in the majority of countries. Governments have to try to achieve sustainable health systems in the face of increasing demand for healthcare services and limited budgets – either from governments or by patients paying out-of-pocket expenses. AdvaMed is seeking "operational good practices" to help policy makers address this crucial issue.

This document summarizes the key insights from the latest in a series of conferences sponsored by AdvaMed in conjunction with global healthcare and procurement experts. The first meeting was an International Innovation Procurement Roundtable in Toronto on December 2-3, 2013, hosted by the Conference Board of Canada, which issued its report "Innovation Procurement for Medical Devices: Driving Health System Improvement" in April 2014.

The Second International Innovation Procurement Roundtable in Barcelona that AdvaMed sponsored was held on June 26-27, 2014, and was co-hosted by the Conference Board of Canada and ESADE University. This conference continued to explore and deepen understanding of assessing value and procuring for outcomes and solutions.

The Barcelona conference addressed the importance of multi-stakeholder value assessment and broadened the number of countries represented in the discussion. A white paper, "Good Practices for the Procurement of Innovative Medical Technology," was issued in November 2014, building on the Toronto findings and detailing the concepts discussed at the Barcelona conference. This paper defined a number of key concepts – including value – that formed the foundation for the China conference.

The overarching purposes of the AdvaMed conferences are: (1) to continue to refine how to derive value and innovation from healthcare systems in the context of procurement of medical technologies; and (2) to identify operational good practices that allow these concepts to be more readily applied consistently in each country – taking into account the unique features of that country. That is, the goal is to have a menu of good practices for each country to consider.

Accordingly, this most recent conference in Beijing brought together a panel of experts from several countries to meet with Chinese officials and discuss their latest views on the current status of procurement for medical technology within the context of policies that are being implemented globally to enhance value. Chinese officials explained the challenges they face on a national and provincial basis and indicated how they are addressing cost and value.

This paper reflects key learnings from the Beijing conference and builds on the previous conferences. The recommendations on effective healthcare tendering contained in this paper are primarily intended to promote the procurement of innovative medical technology products, as well as service and delivery models, to achieve greater value and ensure that limited public resources are spent wisely. An informed focus on innovative, constantly evolving technology, procured with full awareness of societal benefits and healthcare outcomes, is a crucial factor in sourcing successful, long-term healthcare solutions.

### Value

Our discussion of value in this paper uses the same definitional concepts that are contained in our previous work. In the November 2014 paper. In particular we noted:

#### What is Value?

Value can be defined as patient health outcomes per unit of currency spent. Value, therefore, encompasses both cost and non-cost factors. The list of features which could contribute to a device's value will vary from case to case, but we list here some of the most typical features of value.

Value encapsulates cost-related factors which go beyond the initial purchase price. These factors are life-cycle costs and those relating to ownership, such as:

- Direct medical costs, e.g. laboratory or diagnostic tests, provider services (including physicians and allied caregivers), as well as hospitalization and post-acute care.
- Costs of maintaining, cleaning, and storing the device.
- Other ongoing operating costs, including efficiencies achieved in other areas due to introduction of the device.
- Upgrade costs.
- Staff training and other employment costs.
- Disposal costs.

Equally important are factors associated with patient outcomes or those involving total budget savings. All of the following should form part of the value assessment of a medical device:

- Delivery efficiencies.
- Technical benefits/merits.
- Safety, i.e. ability to lower or minimize adverse events or complications.
- Clinical effectiveness, including reductions in morbidity or mortality or as measured by patient-reported outcomes and patient satisfaction and preference.
- Reliability and service level of the vendor/manufacturer, including warranty, maintenance, customer care and clinical training and support.
- Societal benefits, e.g. improved patient quality of life, reduction in spend outside the health budget (i.e. productivity and social care gains due to fewer missed days of work).
- Environmental affects, e.g. sustainability.

. . . Value is a holistic concept that covers all aspects of a device's expected impact on healthcare outcomes, recognizing that financial, clinical and societal factors are, in almost all cases, important features of a value assessment and on an equal footing with cost factors. The cost analysis itself should go beyond price and take into account life-cycle costs and the broader efficiencies which may be generated by sourcing high value products — even a device with a high initial price could well end up saving money when its overall economic and clinical impact is considered.

# The Beijing Conference: Lessons Learned

On May 15-16, 2015, AdvaMed hosted the International Medical Devices Procurement and Supply Administration Conference in Beijing, in conjunction with the China Health Economic Association (CHEA). CHEA is a non-governmental organization led by DG Zhang Zhengzhong and has an interest in economic and policy research relating to healthcare in China.

This paper is not intended to be a verbatim transcript of discussions held during the conference, but rather a distillation of the key concepts relating to innovation and value in medical technology procurement discussed during the conference. This paper focuses on broader, institutional and governmental strategies to ensure medical technology procurement is conducted in a manner to enhance value. We have attempted to summarize the key learnings from the conference and take the next step in refining the concepts embodied in the white paper that resulted from the Barcelona conference.

We express our sincere appreciation to our conference host, as well as the conference presenters, participants and organizers, in supporting and furthering this important discussion.

## Guidance

This paper provides discussion and guidance in five key areas – the major "lessons learned" from the conference:

- Part 1 Redesign of procurement in collaboration with stakeholders will foster innovation and enhance healthcare value;
- Part 2 Use of the "Four Favorables" in China has enhanced value;
- Part 3 Elements of Bidding Criteria in Jiangsu can add value;
- Part 4 Industry/Government partnership and a harmonized purchasing approach can increase value and lead to new healthcare solutions; and
- Part 5 Utilizing an appropriate, robust legal framework that provides transparency, clear rules and paths for stakeholder collaboration enhances value in tendering.

### Part One

# Redesign of public procurement and collaboration with stakeholders will foster innovation and enhance healthcare value.

We examined in detail many concepts in our last two papers (Toronto and Barcelona). The concept of value remains a key focus of our discussion, as policymakers in every market are keen to discuss and learn how to achieve better value in their healthcare purchasing.

In China, experts continued to explore the concept of value, with additional and more specific lessons learned about its application to specific public procurement initiatives and efforts. Several of the presenters provided powerful messages regarding the effort of governments to redesign procurement systems to enhance value.

Much of the impetus to examine innovation in procurement has been provided by policy makers' efforts to address spiraling healthcare costs. Many governments' initial efforts to obtain better value often targeted bottom-line cost reduction as the central goal. This is often still the case.

More recently, procurement policy is adopting a more holistic approach. There is greater collaboration between government, industry and key stakeholders. There is more recognition that systemic solutions supported by the appropriate framework can yield effective long-term solutions to a much greater degree than bottom-line cost cutting.

The Director of the Strategic Policy and Innovation Branch of the Ontario Ministry of Government and Consumer Services presented a number of concepts, discussed below, that were developed for use in Ontario and can be utilized in other markets to enhance value. These concepts are able to be applied to all levels and scales of the procurement process, from a revamp of an entire regional or provincial system to the procurement of a single clinical solution.

#### Concept 1 - Engage in robust stakeholder discussion with meaningful input into project design

This concept was described in detail in our last paper. However, it is worth noting that healthcare authorities are focusing more attention and effort into designing inclusive processes that attempt to address rising healthcare cost -- not by cost-cutting only, but by increasing the value of what is provided. The presenters in Beijing repeatedly observed that an aging population, sustainability, greater demand for services, as well as capital investment and service/delivery issues, all provided impetus for policy activity in the procurement of healthcare services.

#### Concept 2 - Establish a baseline of what is working and what is not working

An initial step in looking at how to bring about better procurement is a comprehensive review of existing systems and mechanisms, and an honest assessment of their efficacy. Case studies or examples of innovations that have been introduced onto the market and not done well can be instructive in this regard. If a procurement system has not been updated or revamped in a long time, chances are fairly good that it does not conform to modern, state-of-the-art standards and focuses too much on bottom-line pricing.

Comprehensive review of the existing system includes having extensive dialog with officials who manage and work in the existing procurement system, governmental entities that regulate it, and suppliers and manufacturers that sell products to it. Physicians and nurses play a vital role in providing services, and input from them is essential to achieve greater awareness of the existing strengths and weaknesses of the system. Hospital staff and administration also are important to consult. Manufactures know the latest technologies to enable procurement officials to make informed decisions.

Examining the traditional supply chain functions can help determine what needs to be improved. Probing and recognizing where the system's weaknesses are will lead to the appropriate remedy to address them. Identifying the success metrics and mechanisms the current system uses to evaluate its performance can point to ways to improve it. Also, fragmentation and redundancy issues in the current system should be found, with an eye toward learning and reconfiguring them if there are redundant responsibilities or too diffuse responsibilities such that no one takes ownership of the issue.

#### **Concept 3** - Move to strategic purchasing that incorporates efficiency and innovation

Entities generally do not undertake review of existing systems unless there is impetus to do so, and that impetus often includes the notion that that existing performance is lagging and can be improved. While comprehensive review of existing functions is essential, so too is a plan to improve. Presenters at the conference highlighted various approaches that were different in detail, but were all concerned about redesigning procurement to get better results, via improved efficiency and value.

Examination of existing systems revealed problems with regard to fragmentation, different metrics and standards. Also problematic within existing systems was the lack of solution-oriented approaches. Procurement systems tend to be transactional in nature, and while transactional metrics may be helpful in purchasing routine or commodity-type products, they are significantly less useful in purchasing innovative healthcare solutions. Procurement for innovative medical technology must be more strategic and incorporate innovative procurement concepts if it is to be more successful.

The movement to improved procurement does not necessarily have to disregard strengths of the current system. Our presenters noted that when they examined existing systems, they found them to be good at some key, necessary skills, such as administrative and process execution. But, the vision and day-to-day execution needed to be improved. This can be accomplished by using collaborative purchasing and improving logistics to drive improvements in supply chain management, service delivery and cost. This in turn

moves the system toward more strategic purchasing with a focus on total quality, value and innovation. Having a good legal framework to either mandate some changes or to ensure that the necessary dialog can occur is important.

The Director from Ontario noted that a key initial step was is to undertake sufficient study to have a good understanding of leading supply chain practices. This enables the case to be made to procurement officials that they should adopt these practices to improve their results. The process used to perform these types of reforms in Ontario was not mandatory. It was specifically chosen to be voluntary; in other words, it had to be a good process on its own to encourage adoption of these procurement best practices.

Improvements can be phased in in stages. The initial phase is to offer best practices and studied improvement via an initial voluntary collaboration to improve procurement in healthcare (and other sectors). The second phase is the issuance of guidance based upon the assessments done, collaborative discussion and agreed upon guidelines to improve. This phase includes the adoption of leading practices by facilitating and funding transformation. Performance measurement criteria, with clear definitions and performance measurement benchmarks are issued and adopted.

**Concept 4** - Adopt key principles that embody the changes necessary and address the entire scope of the desired changes.

In one example given, the Ontario government has issued procurement policy to ensure that hospitals and other public entities acquire publicly funded goods and services through a process that is fair, open and transparent. The guiding principles of the policy are as follows:

- Accountability Organizations must be accountable for the results of their procurement decisions and the appropriateness of the process.
- Transparency Organizations must be transparent to all stakeholders. Whenever
  possible, stakeholders must have equal access across information on procurement
  opportunities, processes and results.
- 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.
- **Quality Service Delivery** Front-line services provided by organizations, such as patient care, must receive the right product, in the right place, at the right time.
- **Process Standardization** Standardized processes remove inefficiencies and create a level playing field.

This policy includes a code of ethics. Ethical behavior generates trust, good will and confidence in the system. Undertaking meaningful reform is of little value if unethical conduct occurs and undermines confidence. Ontario has formulated a code of ethics that applies to public procurement officials and their customers. The goal is to make everyone aware of potential issues and perceptions of issues that may undermine processes. The pillars of this code of ethics are: personal Integrity and professionalism; accountability and transparency; and compliance and continuous improvement.

The Ontario procurement policy also has 25 mandatory requirements that must be considered for conducting tendering processes and managing contracts. While this may seem like a large number of requirements, these were imposed only after extensive research on supply chain best practices. Having these requirements helps ensure the procurement landscape remains in accordance with best practices for being strategic, achieving value and promoting confidence in the system.

**Concept 5 -** Continually assess the landscape and ensure flexibility to overcome barriers and implement change based on that assessment.

Benefits that are accrued through reform and implementation of new and best practices are somewhat fragile, and may be lost if continuous assessment and feedback do not occur. One mechanism to address this is to have a meaningful feedback mechanism from stakeholders and to use it regularly to assess current practices. Operational and policy changes may be seen as barriers by those conducting or supporting procurement. These should be constantly addressed.

Another mechanism that can be useful is to use pilot projects for assessment and learning purposes. Pilots are generally more limited in scope and duration than standard procurements and thus can be more flexible and designed specifically to address issues of concern or to assess system performance.

But the work does not stop there. Part of procurement strategy lies in identifying barriers to the uptake of innovation. Ongoing, honest assessment found that the Ontario government was accumulating a great deal of skill at doing pilots, but that innovations were still failing to take hold in the procurement landscape, and thus not being adopted in healthcare. Investigation to determine the cause of innovation failing to take hold revealed a gap between product development and commercial sales -- termed the "valley of death." Addressing the issues that were causing this gap was a key step to remove barriers to innovation. The recognition of this issue and subsequent plan to address it are among the more unique and promising aspects of Ontario's approach.

Specifically, many companies with promising products encounter challenges at the demonstration and scale-up stage, or fail to be procured and adopted in sufficient volume or scale for the procurement to realize long term value. Intensive study into this issue revealed the problem: there was no mechanism to ensure adoption of innovation. This was a natural consequence of assuming that an innovative product will find its way into the market in sufficient number to foster the competition and uptake necessary for a long-term sustainable model. However, study indicated this is not often the case – an innovative product that is good on its merits is not guaranteed of being adopted or procured.

Ontario will address the "valley of death" issue by promoting demand-pull strategy and value-based procurement. "Demand pull" refers to encouraging hospitals, physicians, nurses and other consumers of medical technology to consider their short- and long-term procurement needs. The switch to a demand-pull model begins with the health system articulating their procurement needs to the industry, researchers and the market to "pull" the development of innovative solutions, instead of attempting to determine where an innovative product fits into the procurement landscape at the last minute. By involving the users and procurement officials earlier on in the development of innovative solutions, consideration will be given upfront to the specific drivers of adoption for that type of technology, such as clinical practice changes. By doing so, it ensures that those things are in place to enable the technology to succeed.

Experience has shown that, in many cases, the barrier to adoption of a promising health technology is outside of the procurement process. For example, reimbursement policies may favor older or less efficient technologies, or personnel may simply need to be made more aware of clinical uses or provided with training to use the new technology effectively within existing systems.

Regardless of the reason, the remedy is to study and change incentives and/or remove barriers that are leading to inadequate uptake of new or innovative technology. Working with key thought leaders, such as healthcare professionals, helps ensure there is a vision for a long-term, sustainable model of innovation, and that those innovations will have a better chance of being adopted at scale.

A number of concepts emerged during discussion, and these are utilized in Ontario to assist in innovation uptake and in creating demand pull:

- Creation of an office of the chief health innovation strategist
- Appointment of innovation brokers to connect innovators with resources
- Investment in made-to-Ontario technologies
- Acceleration of the shift to strategic, value-based procurement
- **Development** of incentives and removal of barriers to innovation
- Optimize the pathways to adoption and diffusion of innovation

Specific implementation tactics for accelerating the shift to strategic, value based purchasing, have been developed. These include:

- Broad spectrum involvement from stakeholders and procurement professionals to define healthcare procurement needs and strategies on an early and ongoing basis;
- Stakeholder focus on addressing health system priorities and population needs rather than day-to-day purchasing of specific goods and services;
- Individual healthcare providers working with shared service organizations to procure innovative technologies; and
- Health system investment in skills, knowledge and competencies needed to enable strategic procurement.

Use of these concepts and strategies will change the innovation procurement landscape and lead to increased uptake of innovation in Ontario. Ontario's goal is to stimulate innovation development and adoption, achieve economic growth and provide quality and sustainable healthcare services.

Ontario's innovative, holistic approach to address many of the most difficult issues in procurement has greatly enhanced value.

# Utilizing the "Four Favorables" has enhanced healthcare value in China.

Presenters from China noted large increases in recent years in China's healthcare expenditures, as well as the vast diversity of the market, particularly on the pharmaceutical side. For example, in 2013 China had 15,000 kinds of drugs on the market and about 168,000 licenses for drugs, over 436,229 retail pharmacies with a retail market of RMB 2607 Billion (roughly \$400 billion). While most of the discussion centered focused on the pharmaceutical market, presenters stressed that they used lessons learned there for medical devices.

Prior to 2000, Chinese purchases of pharmaceuticals and medical technology were highly decentralized at the hospital level. Since 2000, China has been moving to more centralized purchasing in an attempt to harmonize the market and obtain better value for purchasing pharmaceuticals and some medical technology products, with the former being used as a model for purchases of the latter.

In 2010, China introduced the grass-roots essential drug program. This has led to improvements in both drug quality and safety, allowed the government to better regulate the behavior of drug purchasing and promote national policies for the administration and use of clinical drugs. It also helped to relieve some of the financial burden associated with families having to pay for a key part of their medical expenditure. Many of the stated gains from this more harmonized purchasing approach were due to greater central control to better harmonize clinical practices for drug utilization, and focus on improved drug quality with more standardized dosages and packaging. As a result, the Chinese Government realized large improvements in both drug quality and clinical usage.

Presenters noted that China has made many improvements in clinical practice and drug safety due to greater centralized control, greater emphasis on quality, standardized packaging and dosage, and harmonization of drug purchasing and clinical utilization. Presentations focused on the "Four Favorables" as mechanisms to address some of the remaining key issues and enhance value in China's procurement of pharmaceuticals and medical technology.

#### The Four Favorables are:

- Elimination of the compensation system that relies on resale markups by hospitals to generate profit and cover operating cost;
- Elimination of "falsely high" drug prices and commensurately relieving the patient's burden to pay for drugs at falsely inflated prices;
- Prevention and reduction of commercial bribery; and
- Promotion of healthy development and competition in the pharmaceutical industry.

These important concepts are outlined below as descriptive of current healthcare procurement initiatives in China.

**Favorable One** - Elimination of the compensation system that relies on resale markups by hospitals to generate profit and cover operating costs would add tremendous value, but remains something that needs to be addressed for the foreseeable future

The issue of hospital markup and patient's payment burden was frequently discussed and emphasized by all of the China presenters. In China, the patient often pays out-of-pocket for the pharmaceuticals or devices the hospital uses to treat their conditions. The reference to a markup system refers to the price of drugs and medical technology being marked up by hospitals or intermediaries which is then passed along to the patient. The hospitals use the money to meet operating costs, treat patients, pay physician fees, and make profit. The Chinese government is keenly aware of the markup practices undertaken by hospitals. Elimination of this system has been one of the key goals of the initiatives around centralized procurement and consolidated purchasing arrangements.

Presenters repeatedly emphasized that while progress has been made in reducing overall government expenditures on pharmaceuticals, hospital markup practices remain firmly in place. This is due in part to the lack of a substitute source of revenue for the hospitals. Success to date has come in the form of overall reductions in the amount of budget that is allocated to the purchase of pharmaceuticals. Expenditures on hospital drugs was approximately 70% of total health expenditure prior to implementation of centralized procurement and other reforms (such as increased harmonization of clinical utilization practices, drug quality and packaging standards, standard dosage packaging and electronic transactions and payment).

Centralized procurement for pharmaceuticals was implemented in the late 1990s and was slowly rolled out to urban areas and the provinces. Procurement reform and efficiency gains from the other reforms have resulted in a large decrease in the percentage of the total healthcare budget that China spends on pharmaceuticals -- now accounting for under 40% of total health expenditure. Presenters described that the purchases tended to be better value than in the past, due to a focus on drug quality, standardized packaging and quantity, and better harmonized clinical usage standards.

However, while intermediary and hospital markup practices have been the focus of much of the Government's policy efforts, the reforms presented and discussed at the forum in Beijing only indirectly targeted them. Presenters did not foresee that the hospital markup model would be eliminated in the foreseeable future unless some alternative funding mechanism was provided to the hospitals that would allow them to better cover operating expenses.

Presenters from China emphasized this second of the Four Favorables as a mechanism to deal with what they termed "falsely high" prices of drugs. The terminology "falsely high" refers to prices the Chinese government believes to be unnaturally high (noncompetitive), presumably due to a perceived lack of competition among manufacturers as well as inefficient or uninformed purchasing practices. It also encompasses prices that are paid to providers who are offering substandard or low-quality products in response to government tenders. Strategies to overcome these issues focus on reformed procurement practices, better clinical and quality standards, greater transparency, and some degree of flexibility to increase value.

Although China's implementation of large scale tendering has been using price-focused criteria, China is focusing more on quality than in the past, and the trend is expected to continue. For example, China's use of invitation-to-bid processes, particularly in the pharmaceutical context, has become increasingly more specific regarding technical requirements, quality standards, dosages and projected quantity. Technical requirements are specified in detail and bids that are too low require quantity assurance or a secondary bid to ensure sufficient quantity (and quality) at the agreed-upon price.

Presenters also discussed flexibility in the bidding mechanisms based on market conditions. While many of the processes are applied on a large scale with limited flexibility, purchase-by-negotiation principles have been applied to niche or small quantity manufacturers where the product is clinically unique or has a special application and is not well suited to large scale invitation to bid mechanisms. Another example of flexibility is the allowance of direct hospital purchasing in the context of generic pharmaceuticals, gynecological drugs and supplies, and emergency rescue drugs. Hospitals can procure these products directly, generally through online tendering processes.

Several mechanisms were discussed that have helped increase value to pharmaceutical (and some medical technology) procurement. Presenters noted that China had a large problem with pharmaceutical quality – pharmaceuticals being sold that were unable to meet basic quality standards and related issues of non-standard dosages and packaging. The non-standard dosages and packaging led to a lot of wasted product.

The Chinese government implemented pharmaceutical quality standards to ensure pharmaceuticals offered for sale in China are of high quality. The goal was to eliminate poor quality providers from the bidding process or get those that did participate to ensure their products were of high quality. Additionally, the current procurement rating mechanisms frequently provide favorable consideration in the form of points to bidders who can demonstrate a history of good quality and timely delivery of their medicines. Such considerations are also becoming more common in medical technology procurement.

Another issue that was addressed was the lack of standardization in packaging. Presenters referenced situations in which there was a significant mismatch between the dosage sizes that were being sold and the standard dosage that would normally be prescribed and administered to the patient. This mismatch led to waste of product and inefficiency in ordering. According to the presenters, this issue has been much improved through formulation of standard dosage protocols and their use in the procurement process to disfavor bidders that offer non-standard sizes or doses of pharmaceuticals in the bidding process.

#### Favorable Three - Prevention and reduction of commercial bribery

Presenters noted strong initiatives by the Chinese government to address bribery and corruption. While these efforts were not discussed in detail, some key aspects were highlighted. The speakers agreed that these initiatives have improved China's ability to purchase and procure healthcare for its citizens. Presenters indicated that the Chinese government has been taking an increasingly hard line with regard to corruption in procurement and provision of healthcare services, with stiff penalties for problematic activities. Problems with fraudulent invoices and unlicensed businesses were specifically mentioned, as were historical problems with inferior quality goods, kickbacks to hospital purchasing and decision-making personnel, and excessive sales commissions.

Several anti-corruption mechanisms were mentioned, including a policy of rotating officials who are in positions of authority. According to the presenters, government officials who are engaged in procurement of healthcare services are routinely rotated and re-assigned as a means to reduce the risk of participation in corruption. The underlying notion seems to be that familiarity over a period of time will present temptation to participate in unethical behavior.

Discussion of anti-corruption efforts in China also revealed alignment with formally issued clinical guidance, used by hospitals, as a means to reduce potential corruption by ensuring that pharmaceuticals are used and prescribe correctly. These guidelines are designed to reduce over-prescription or over-use of medication as well as usage of inappropriate medication as potential sources of corruption. Presenters indicated that reductions of this type of activity have brought about significant savings to China's healthcare budget.

#### Favorable Four - Promotion of healthy development and competition in the pharmaceutical industry

Presenters discussed policies that encourage innovation in procurement. Some, such as quality and clinical standards, and more flexible bidding practices for clinically unique or limited use products, were discussed above.

Key guiding principles to achieve better results and value in tendering have been: transparency, fairness, quality and measurement of results. One example is in the purchase of "special drugs." Presenters noted that pharmaceuticals – such as anesthetics, psychotropics, those targeted at the prevention of infectious and parasitic diseases, family planning medications and vaccines for the national immunization program – are purchased according to national regulations to guarantee transparency. The use of internet auctions was described in the context of direct purchasing by hospitals for generic drugs and medication used to treat emergency room patients. These practices were said to have enhanced value.

In addition, hospital-based mechanisms have been developed and implemented to address irregular purchasing practices and promote proper clinical use of medicines, promote better inventory linkages between supply and demand and strengthen comprehensive clinical evaluation of pharmaceuticals and pharmaceutical pricing policies. Some of these practices could be adopted for medical technology.

Another tool to enhance value was the use of past-performance or performance-assessment mechanisms. Companies that do not sufficiently support their products or honor the terms of their contracts, or who have demonstrated inability to deliver in a timely manner, can be disqualified from participating in tenders. Barriers to entry into tenders, including documented ability to meet the economic and technical criteria as well as quantity, were noted as requirements that have improved quality and therefore added value. Awarding contracts to multiple suppliers instead of simply one supplier was discussed as a policy that ensures the market remains fair, diverse and competitive.

Finally, the topic of encouraging innovation was discussed. Presenters noted that, for now, China's major focus is on price competition. However, there does seem to be an increasing focus on innovation and a small degree of flexibility to consider quality depending upon the nature of the procurement. For example, presenters described pilot reforms that enable public hospitals to purchase by themselves using the provincial centralized tendering platform, albeit with price capping. There has also been some encouragement of joint purchasing arrangements between hospitals and even provinces. Use of distribution centers has helped reduce transport cost and provided greater efficiencies for pharmaceutical distribution across some rural provinces. Increasing use of electronic transactions has increased efficiency as well.

In the medical device arena, China is categorizing and classifying products into expansive catalogs to better standardize purchasing, much as they have done with pharmaceuticals. For example, one province's database for high-value medical supplies (medical devices) contained 10 categories, 29 classifications, 13,800 registered certificates, 84,100 components, 86,400 kits, and 399,800 pieces of information.

Presenters also indicated that the Chinese government is continuing to examine and explore innovative methods to ensure timely supply, reliable quantity and reasonable price of pharmaceuticals. However, they did not provide any concrete examples of real incentives within the framework for innovative medical technology, other than the most basic quality measures. Past performance measures are present, but only to the extent of meeting predefined quality and delivery standards that are fairly generic. It seems that for the time being, China's fundamental focus is on consolidating the more basic procurement functions, with a focus on price, using a model that is primarily derived from their experience with drugs.

There was some discussion that a truly innovative medical device would be recognized by clinical experts and may qualify for its own product tendering, but no examples were provided. Although aware of the significant differences between pharmaceuticals and medical technology, the presenters did not offer any predictions that the procurement models for each of these areas will diverge greatly in the near future.

# Part Three

# Utilizing Jiangsu Province tendering practices that demonstrate a willingness to move beyond price can add value.

The Jiangsu Provincial Government's plan to coordinate hospital purchases of medical devices, which are then resold to patients at a profit, offers an interesting attempt to introduce sophisticated quality factors. While the Jiangsu representative noted the use of ceiling price, he claimed that in future more emphasis should be placed on quality.

In Jiangsu, tenders are held every two years with supplementary tenders on an 'as-needed' basis. For medical devices, the price data are evaluated for each device offering including six different sources of actual price data compiled from purchasing information for devices in Jiangsu and other geographic areas (provinces, cities, etc.). A mechanism for introducing quality into the process is the separation of imported and domestic devices into separate track. Each type is compared only to others in its track. Imported devices are rated and priced and compared in an import-only category and devices manufactured in China are priced and compared to other Chinese manufactured products. This is an implicit recognition of higher quality of imported medical technology and, therefore, the need for them to compete only with each other.

The Purchase Center announces a request for bids for devices that contain specifications for the products to be purchased, including quantity. There is a formal consultation with experts, including clinical, procurement and management experts who provide advice in constructing the tenders and who can also recommend specific products for consideration in the tender.

Prospective sellers respond with bids containing the specifications and documentation required by the Purchase Center's electronic portal. Bids must contain the catalog number of the product in the central catalog. Sellers of imported medical devices must also submit import declarations and receipts for customs duties and VAT.

Evaluation of the bids occurs in two stages. In the first stage, a Purchase Center evaluation committee evaluates what are referred to as 'economic technology' factors. These include sales volume and market reputation, market coverage and product quality, assigning points for each up to a total of 60 points. The Chinese authorities claim that 15 of the 60 points are 'subjective' while 45 are objective. Examples of points assigned include:

- Up to 8 points for higher sales volume;
- Up to 4 points for tax compliance;
- Up to 4 points for quality based on presence or absence of both CE and FDA approvals;
- Up to 3 points for holding a patent to the product, up to 9 total points for being registered for bidding in each provincial city;
- Up to 3 points for clinical evaluation indicating it is better than comparator products; 2 points for clinical evaluation indicating it is equivalent to comparator products;
- Up to 3 points for good clinical safety;
- Up to 3 points for clinical convenience and packaging compared to other products;
- Up to 3 points for service reputation;

At the conclusion of the first stage, the purchase center publishes a list of the scores calculated from the point assignments listed above.

In the second stage, a 'comprehensive review' is conducted. In this stage the focus is primarily on price. The evaluation of price criteria proceeds and points are awarded to the product based on comparative price factors. Total calculations are up to 60 points for 'economic technology' factors (listed above) and up to 40 points for price criteria, for a total of 100 possible points. Products must score at least 60 points to be shortlisted and be eligible to be purchased by hospitals. The bid price and quality point score for each bid are then aggregated and compared for each clinical category of device.

The seven economic technology factors listed below can provide a bidder extra points in the evaluation process in Jiangsu. By including these seven elements as weighted criteria in the bidding process, Jiangsu has recognized these criteria add value and that price alone cannot lead to best value.

#### Higher sales volumes

Higher sales volumes in China are a favorable economic technology factor in the Jiangsu process. Jiangsu awards up to eight points in the bidding evaluation process based on the volume of sales in China. The level of points awarded ratchets down incrementally to a minimum three points awarded to those products with the lowest sales volumes. All bidding participants receive at least three points this category. While use of sales volume in the calculation could potentially disadvantage newer products, the mechanism does appear to attempt to increase value based on the assumption that a product that has gained a large degree of approval and utilization in China has done so because it has demonstrated its effectiveness through practical experience.

#### Tax compliance

Jiangsu rewards tax compliance with up to four points, with every bidder receiving a minimum of one point. The specifics of this factor appear to be in part a form of reward for good citizen behavior and in part a reward for greater amounts of tax paid. Payment of tax of \$4 million RMB or more gains the highest point total of 4 points, with amounts progressively decreasing to an award of one point for bidders who pay less than 1 million RMB in tax. This encourages legal compliance and enhances value.

#### EU and/or FDA approvals

Jiangsu awards additional points to bidders whose products have been approved in other markets. A product that has obtained both CE and FDA approvals is awarded four points. A product having either CE mark or FDA approval is awarded two points, and a product with neither FDA nor CE approval is not awarded any points. This criterion adds value by recognizing the time, effort and expense undertaken by manufacturers to get their product approved in the EU and US. It is appropriate that a product that has undergone more rigorous pre-market testing and gained approvals in multiple markets be awarded a higher score in tendering.

#### Patented Devices and Certified Bidding Participants

Jiangsu awards up to three points if the product being submitted for bid has a patent, with three points awarded if the device has a patent, zero points are awarded if the device does not have a patent. This criterion is designed to recognize and reward innovation and thereby add value. Jiangsu also awards up to eight points to bidders who are certified to bid in various regions in China on a sliding scale based on engagement in specific markets. This recognizes and rewards manufacturers who are able to make larger scale commitments to China's medical technology market.

#### Demonstrated clinical evaluations that indicate they are equal to or better than comparable products

Jiangsu awards additional points based upon clinical effectiveness, with products that have demonstrated superior clinical effectiveness to similar products receiving three points and products that have demonstrated clinical equivalency to similar products receiving two points. All products in this criterion receive at least one point. While these are subjective assessments, it is commendable that there is recognition that greater clinical efficacy increases value.

#### High levels of clinical convenience and packaging

Up to three points are awarded in the Jiangsu tender evaluation process based on the subjective assessment of the package quality and convenience (ease of use) of the product compared to similar products. One point is awarded for 'ordinary package quality and convenience,' two points are awarded for good and three points for excellent. Accounting for value in the form of packaging quality and ease of use of the medical device is one of the more unique aspects of the Jiangsu process.

#### Service reputation

Up to three points are awarded if the subjective assessment indicates an excellent service reputation. Two are awarded for a good service reputation and one is awarded to all bidders who are deemed to have an 'ordinary' service reputation. By taking into account the reputation for service and support products, Jiangsu rewards manufacturers who are the most committed to supporting their products, and adds value.

The Jiangsu system has several elements to commend it for emerging markets. In particular, recognizing the higher value of imported products is a straightforward means of rewarding innovation. In addition, the product evaluation phase of the process (economic technology factors) contains some criteria that add value and merit consideration.

## Part Four

# Industry/Government partnership and harmonized purchasing approaches can increase value and lead to new healthcare solutions.

The importance and value gained from the use of collaborative approaches between government and industry was addressed. The presenter from Health Shared Services in British Columbia (HSSBC) described how these collaborative approaches can enhance health system value and lead to innovative healthcare solutions. HSSBC's goal was to enhance value to the healthcare system through efficient and effective delivery of support services. This vision was formulated in response to budget pressures from rising healthcare expenditures and fragmented, inefficient procurement.

In response to these challenges, the authority undertook a comprehensive review to examine cooperation with Canadian provincial authorities to develop effective healthcare solutions. Factors such as sustainability, aging population, capital investment and service delivery models were examined as potential drivers of cost increases. Non-labor expenditures were aggregated and managed to create greater opportunities for systemic efficiency and savings.

Stakeholder engagement processes lead to service redesign and increased value through more efficient and effective delivery of healthcare support services

HSSBC conducted an intensive study of the market and current conditions for providing health care. They concluded that consolidation of services leads to greater transparency. They also discovered that, for British Columbia, centralization of services and an integrated health care delivery model provided opportunities for greater predictability, capacity and decreased cost and risk.

They attempted to harness these opportunities to provide unique, innovative and cost-effective solutions, all with improved customer service. Broad-based processes were used to obtain input from all stakeholders on potential solutions. These included the utilization of comprehensive stakeholder engagement, integration of services models and realigned supply chain structure. The key facet was to utilize these efficiencies in a system that was responsive to customers' needs. Extensive stakeholder (including vendor) engagement, including roundtable discussions were conducted that allowed a wide range of ideas to be discussed and utilized to develop a model to reorganize services to add value. Engagement included discussions with vendors around innovation, engagement of CEOs and managers to discuss ideas and systemic redesign, consideration of public-private partnerships, and of course engagement with clinicians and patient groups.

In examining its inventory processes, HSSBC decided to consolidate inventory more centrally, with incorporation of regional warehouses to better respond to patients, and consider entering into distribution agreements instead of having government do the work in this area. In hospital settings, the model added value by removing the burden of staff from doing procurement and thus freeing up more staff time to devote to patient care and clinical services.

What emerged from the process was an integrated service delivery model. It was found to be more efficient to remove inventory from each local provider or hospital, and instead have vendors ship directly to distribution centers. HSSBC would deliver the goods from the distribution centers to the hospitals. HSSBC found that having one system of this type, and using e-procurement to reduce paperwork, reduced excess stock and waste, while promoting greater transparency and compliance, thus adding value. In the near future, it is expected that a cloud-based system containing all procurement information and single payment mechanisms are expected to be implemented, further driving efficiency and adding value.

Key lessons from HSSBC's study and redesign show that broad-based vendor and stakeholder engagement are keys to success. Use of these processes not only allows the procurement authority to become more knowledgeable about the vendors, but also increases the knowledge regarding potentially available clinical solutions.

Without this input, there may be innovative clinical advancements or systemic approaches available but that would be missed. Utilization of common standards, clinical best practices and standardized equipment also were found to enhance value, and were incorporated into procurement practices. Additional learning came in the form of development of metrics that accurately reflect success or lack of success and that may reveal areas where improvement is necessary. It was also discovered that obtaining value required the use of performance metrics that would measure vendor performance over time, including clinical performance, to give a more accurate picture of total life cycle cost as a measure of which products offered best value.

#### Consolidation of purchasing and clinical needs within hospitals can enhance value

There was discussion of models that allowed hospitals within a foundation trust in the UK to consolidate purchasing power for the purpose of adding value while maintaining high standards of care and good clinical outcomes in a cardiac catheterization unit.

The presenter from the UK described a case involving a group of three hospitals within an NHS trust consolidating services in this manner. The hospitals did a survey of available options to achieve a much-needed refurbishment of cardiac capital equipment and related cardiac lab services, with a goal to attempt to capture efficiencies over a period of years. The traditional manner of piecemeal purchasing was examined and discarded in this instance as being too inefficient and unaffordable.

An essential initial step in this process was a landscape evaluation. The hospitals undertook a lengthy process to identify customer needs, assess the innovation landscape and consider a variety of models to address these issues. They used this information to develop a tender that would define desired outcomes and efficiencies that they needed to stay within their budget. Potential mechanisms for efficiency gains, including outsourcing, were examined. Various levels of purchasing equipment, supply and support services were

considered, with varying levels of external support. Key to the process was flexibility, as the presenter indicated what they thought they wanted as a solution at the outset of the process evolved as they learned more through a rigorous and involved engagement and assessment process of customer needs, their own business and clinical needs and the market solutions offered.

The analysis indicated that efficiencies could be obtained in the following areas so that clinical outcomes could be improved or maintained: better management of cardiac catheter lab functions and staffing; improvements in start times to allow more efficient use of clinical time; better purchasing strategies for equipment; and supply chain and inventory control processes that made stocking and ordering of supplies more efficient (and also making it less likely for stock to expire before being used).

Ultimately, the hospitals chose to consolidate all services and clinical needs through an external provider. However, although consolidation occurred primarily with one partner, the hospital retained full clinical decision-making authority and control, and also retained the ability to make product choices from whatever supplier they wanted, not just the preferred supplier. In this manner clinical control and flexibility were maintained even though the overall goal was to some extent to consolidate control and demand.

Incorporating freedom on clinical choice and clinical control in the model worked to ensure best clinical outcomes could be maintained while increasing efficiency. This efficiency added value since it enabled the hospitals to treat a greater volume of patients in a given day, again while maintaining high clinical standards. Clinical management and supply chain efficiencies from the model also enhanced value by freeing up staff time and resources.

## Part Five

# Utilizing a robust legal framework that provides transparency, clear rules and paths for stakeholder collaboration enhances value in tendering.

An appropriate legal framework that provides transparency, clear rules and paths for stakeholder collaboration enhances value in tendering. Legal trends in global tendering were presented and discussed in detail. Policymakers seem to have an increasingly strong awareness that an appropriate legal framework plays an essential role in ensuring tendering practices are transparent and fair. However, more recently, there has been greater interest by policy makers that appropriately designed legal processes can add value to the tendering process. The presentation and discussion at the conference centered on this point: the necessity for a legal framework and how that framework can add value to global tendering processes.

Tendering Authorities are Changing Procurement Mechanisms to Allow for Greater Industry Dialog and Better Incorporation of Procurement for Value Concepts.

One example of this trend is the United Nations Commission on International Trade (UNCITRAL), which revised its tendering model procurement law in 2011 to incorporate value principles. UNCITRAL also published a guide to enactment in 2012, and subsequent guidance on implementation in 2013.

Other examples were described, including the European Union's (EU) revision to its Procurement Directive in 2014, which adopts the concept of "best price/quality ratio" — as opposed to low price — as a method for selecting contractors. Also, the World Bank is currently undertaking a process to revise its procurement policy and is expected to publish a final rule before the end of 2015 that will likely include value for money principles.

Many individual countries are revamping their procurement laws to address a variety of issues. In some cases, the revisions are in part attributable to dissatisfaction with the results of using only low price as the basis for choosing contractors. These revised mechanisms are designed to ensure that value for money is obtained in tendering and not simply the lowest price. Evidence is mounting that in many markets experiences with tendering policies focused on obtaining lowest price have not always been successful.

Participants devoted some time in both Toronto and Barcelona defining value (which can be found in the report of those meetings). For this paper, the definition can be simplified to mean the highest quality at the selling price. Value has multiple dimensions, including price, quality, service and support, and warranty.

The discussion in Beijing focused on the importance of all three stages of procurement – acquisition planning, competition and award, and contract execution – in ensuring value. Each of those three phases is discussed below, with a focus on the risks and opportunities at each stage related to achieving value. Corruption is a risk during all three phases.

#### 1) The Acquisition Planning Phase

In the acquisition planning phase, the purchasing entity must decide what it wants to purchase and set the ground rules for awarding the contract. Critical to determining what to purchase is an understanding of what the commercial marketplace offers; market research must be undertaken. Engagement with industry can help educate the purchasing entity, although that engagement needs to be conducted in a way that is fair to all those who may want to compete for the resulting contract. Specific value criteria are often hard to define and incorporate into tenders unless extensive stakeholder communication and information gathering is undertaken.

A key decision point in the acquisition planning phase is deciding which procurement mechanism to use, since that may enhance or reduce the likelihood of obtaining value. A good example is the decision to use an electronic reverse auction in conducting the procurement, a method that is being increasingly used around the world. In a reverse auction, the roles of buyer and seller are reversed. In an ordinary auction, buyers compete to obtain a good or service by offering increasingly higher prices. In a reverse auction, the sellers compete to obtain business from the buyer and prices will decrease as sellers undercut each other. In the U.S. and many other places, the reverse auction tends to be more common in tenders for non-complex commodity-type products. The method has more limited applicability to complex technology, including medical technology, where factors beyond price are becoming even more of an increasing priority. Since reverse auctions are focused only on price, their use in procurements for complex or innovative medical technology may lead to poor value being obtained.

Relating this concept back to the acquisition planning phase, a determination as to whether to set up a tender as a reverse auction should involve considerations of the complexity of the product and whether price alone is a factor that will lead to best value. If the expectation is to compare complex and innovative technology on price alone, the reverse auction is not generally a satisfactory choice.

Another critical step in acquisition planning is the drafting of the specifications to be included in the tender documents. Well-drafted specifications will make clear to potential tenderers precisely what the purchasing entity wants to purchase. The precision with which the tender documents are drafted will affect value. Insufficient clarity with regard to bidding criteria or in defining the desired outcome may cause potentially qualified bidders not to compete. Also, proposals may be submitted that do not offer what the contracting officials are seeking.

As noted in our Barcelona and Toronto papers, the planning phase of the tender is potentially the most critical. This applies to the contracting entity undertaking the review and to allowing sufficient stakeholder discussion to enable them to be sure that they are making an informed decision in drafting specifications for the winning tender.

A consistent theme that has echoed through all of our conferences is that the drafting of tender specifications for a particular product should be managed by tender officials, but that the actual drafting of the specs should be primarily done by clinical experts, physicians, key opinion leaders, and industry – those with direct knowledge of the clinical goals that are attempting to be achieved. Tender officials who draft their own specifications for the tendering of complex medical technology potentially risk not achieving best value.

Well-written specifications should set the bar high enough that a tender that meets them will provide value to the procuring entity. If the specifications set the bar too low, a tender may win based on low price, without providing adequate quality. However, if the specifications set the bar too high, they may unduly restrict competition -- thus potentially unjustifiably increasing the cost paid and excluding alternative, innovative solutions.

Finally, during acquisition planning, the purchasing entity must decide on the criteria to be used in selecting the winning tender. The most traditional (and most conservative) method is to rely solely on low price. As discussed in more detail below, the international trend is toward use of non-price factors, in addition to price. Whatever award criteria are selected, the purchasing entity needs to ensure that the criteria are clearly stated in the tender documents.

#### 2) Competition and Award Phase

In the competition and award phase, a key to obtaining value is to have in place processes that ensure the competition is conducted as fairly and transparently as possible. The specifications stated in the tender documents must be the standard for evaluating tenders, and the award criteria must be complied with. A contract awarded based on a bid that does not meet tender specifications is improper, even if the non-conforming tender would provide better value. Similarly, ignoring non-price factors, or adding new ones not specified in the tender documents, is improper. This again underscores the importance of ensuring that tender specifications and award criteria selected at the outset of the process are transparent and suited to finding the best value. "Remedying" mistakes and omissions during the competition and award phase is improper.

#### 3) Contract Execution Phase

The contract execution phase is the phase of the contract where the goods or services are actually delivered. The theme here is to ensure that the contract performance lives up to the promise made by the contractor in terms of price, schedule, and quality. The contracting authority must have in place mechanisms to ensure that contract performance is monitored and meets expectations that are laid out in the contract.

Critical during this phase is frequent and meaningful communication between the purchasing entity and the contractor, during which the contractor's performance is monitored and problems that arise are promptly addressed. Even the best process, one that is carefully constructed at the outset to ensure broad-based input from all stakeholders and key opinion leaders and includes appropriately drafted criteria and processes, will fail if the contracting authority does not ensure that the contract delivers the promised quality and quantity at the specified price and at the specified time. On certain occasions it is justified for the contracting authority or the contractor, to make changes to promised quality, price or schedule. However when a change occurs it should be transparent, that is, made in accordance with a process that is specified in advance and ensures that value is not lost without justification.

#### 4) Price and Non-Price Award Criteria

Price is always one of the award criteria for a contract, and virtually always has a significant weight in the final award criteria. Price is a familiar concept for every party engaged in tendering and is easy to measure. From the perspective of officials engaged in procurement, it is easier at first glance to assess price factors as these are more straightforward and more predictable, and can offer an attractive means to defend decision-making process. For many stakeholders, a focus on low price is appealing, since it would appear to offer the most transparent selection method, the one ensuring that taxpayer funds are spent prudently, and the one most resistant to corruption.

Two current international trends, however, were discussed at length during the conference. One is to evaluate price in a more sophisticated way, and the second is to complement the focus on price with the use of non-price factors. Both of these trends are driven by the desire to ensure value in the spending of public funds through the procurement process.

In the effort to develop more sophisticated ways to evaluate price, the trend is to expand the focus beyond the initial purchase price to include additional elements. These may include: the cost of delivery or installation, expected repair and maintenance cost (knowable but less certain because it is a projection of expected cost), and life cycle cost, or total cost of ownership. These additional elements can be viewed as a continuum, ranging from the easiest to identify (the initial purchase price) to the most challenging to assess (total cost of ownership).

Despite the challenges of assessing the additional elements, many stakeholders around the world are promoting a more inclusive assessment of price, because an exclusive focus on the initial purchase price — as objective and certain as it is — may lead to the selection of a solution that ultimately does not offer the best value over time. This is particularly true when the equipment being procured is meant to be used for a substantial period of time, such as implantables and medical equipment.

It is for this reason that the EU, for example, in its 2014 revisions to its Procurement Directives, highlights the importance of assessing life cycle cost. Life cycle cost can be the most sophisticated way to evaluate the cost of competing tenders, but also the most difficult to undertake. It works best if there is an independent third party that can verify life cycle cost claims; unfortunately, in many cases this information simply does not exist. In addition, whatever method for evaluating price is to be used, including life cycle cost, must be clearly spelled out in the tender documents and then followed during the evaluation of tenders.

As noted above, the second global trend is that price is often no longer the sole award criterion. Instead, non-price evaluation factors are being widely used. Some examples of non-price criteria include: technical quality, or some other measure of quality; environmental considerations; energy efficiency; and past performance.

Some non-price criteria lend themselves to objective assessment better than others. For example, length of warranty is a non-price factor that is easy to assess using objective criteria, the term of the warranty. Quality of warranty and quality of past performance are non-price factors that do not lend themselves easily to objective assessment. However, few would deny that quality of warranty and quality of past performance are very important factors to assess, with the potential to add significant value to a tender.

Non-price award criteria can be viewed as "value criteria," since they are meant to identify what quality elements the purchasing entity is seeking and, accordingly, how the purchasing entity will evaluate tenders. They have been used in the U.S. procurement system for more than 50 years, and seem to be gaining credibility and momentum around the globe for greater use in tendering. In particular, the EU's revised Procurement Directive Article 67 endorses non-price award criteria as a mechanism to enhance value, recognizing that EU member states may decide to restrict the use of price-only criteria in order to promote a focus on quality — essentially, value. Also, as mentioned above, many expect that the World Bank will be incorporating some use of non-price criteria in its forthcoming revised procurement guidelines, which are due to be issued sometime late in 2015.

A common theme echoed by many of the presenters was that non-price criteria need to be developed and utilized to an even greater extent than they are currently, because these criteria offer the promise of unlocking the most value in future procurements. Dissatisfaction with price-only tenders has been one of the key drivers in this push.

Value criteria can be incorporated into procurements in various ways. The simplest way is to identify a non-price factor in the tender documents (for example, a two-year warranty) and then to assess the presence or absence of the factor in each tender. This is a pass/fail type of evaluation, so an assessment of the presence or absence of the specific value criterion is the extent of the analysis.

A more sophisticated system allows evaluation of value criteria on a comparative scale, rather than simply pass/fail. When that approach is adopted, the evaluation frequently occurs as part of a points matrix, with certain points in the tender process allocated to meeting certain criteria. For example, a certain number of points may be available under a specified quality factor, with more points awarded to tenders that are assessed as excelling in that factor. The points method of assessment should be set out in the tender documents, so bidders can craft their tenders to achieve high scores on the value criteria. China is currently utilizing this type of process in some of its tendering and is allocating points for value and performance criteria.

When a point-based comparative rating system is used, the purchasing entity may find that two or more tenders are acceptable, and it will need to have a basis to select between them. This often leads to a tradeoff situation, in which the purchasing entity will need to choose between a higher-scored, but higher-priced tender, and a lower-scored, but lower-priced one. Most tendering systems that allow use of value criteria require some type of objective formula to perform the tradeoff to determine the winning tender. The use of a mathematical formula reflects concern that otherwise there would be a loss of transparency and the potential for bias to enter into the selection of the winner.

Objections to the use of non-price factors are often driven by the fear of corruption and loss of transparency. While it is true that the use of non-price criteria may increase subjectivity and can in theory lessen transparency, both risks can be managed by designing and adhering to a process that is developed and known in advance of the tender process and that describes in as much objective detail as possible the criteria that will be used to assess the non-price factors.

Additional concerns around use of non-price criteria were discussed, including that the use of such criteria risks favoring certain bidders and reducing competition. However, this does not need to be the case, and simply underscores the importance of the criteria and processes being properly crafted and sufficiently robust.

The movement to greater use of value criteria, as embodied both by the recent EU and World Bank initiatives, may place greater global emphasis on utilizing value criteria in markets that have not traditionally favored them.

# Conclusion

As noted in the Introduction, this paper reflects the third stage of AdvaMed's efforts to bring together procurement experts to determine "best operational practices." The goal of this stage was to further refine recommendations on medical technology procurement and also learn more about China's strategies for addressing these issues in an emerging market.

The consensus of our work remains that procurement of medical technology – done properly, with an eye toward factors other than short-term price – will greatly enhance value and efficiency in healthcare systems. Our specific learnings from this conference have been helpful in outlining even more specific mechanisms that can be utilized by governmental entities and industry to enhance value and innovation.

In comparison to our Barcelona paper, which addressed institutional issues but had a strong focus on local practice, this paper has a strong focus on broader, institutional and governmental strategies to ensure medical technology procurement is done in a manner to enhance value. Presentations during the session revealed that China has taken some important initial steps in this area to enhance value but is still attempting to harmonize a more basic market and maintains a strong focus on price. We believe as the China market matures (and it is maturing rapidly), the strategies outlined and discussed here will offer instructive tools that can be incorporated to unlock greater value and innovation.

We view this third White Paper as another important step in our commitment to support improvement in healthcare system performance, access, quality and sustainability as well as greater social and economic development. We continue to believe that robust, meaningful engagement between industry, policy makers and stakeholders holds the most promise for improving global procurement processes and enhancing healthcare system value. The stakes are high, with healthcare systems across the globe facing pressures from increased demand and declining budgets. Utilizing the tools we have discussed to unlock greater value in healthcare systems will help to ease this problem, by freeing resources to enable more patients to be treated more effectively – a goal we all share. We hope to continue to enhance our understanding of practical applications by holding additional conferences on this topic.