

## 1 Introduction

As part of the implementation of the World Bank (Bank) Procurement Framework (launched on 1 July 2016), the Bank committed to establishing an **Industry Engagement Program** (IEP) to improve procurement outcomes in targeted sectors. In FY17, two sectors have been targeted; Large Medical Diagnostic Equipment and High Voltage, Direct Current (HVDC) electricity transmission.

The IEP has been designed to work closely with industry sector experts (both client and supply side) to identify and address recurring procurement problems in Bank financed projects to achieve improved procurement and development outcomes.

Program objectives are to:

- Motivate the right companies to bid;
- Speed up procurements;
- Improve readiness for project implementation;
- Reduce complaints;
- Reduce costs of bidding (clients and suppliers);
- Achieve Value for Money (VfM) to deliver better outcomes and results;
- Bring greater transparency to the bidding process.

The Large Medical Diagnostic Equipment industry actively participated in the consultations on the Bank's new Procurement Framework providing written comment on proposed changes to the Bank's Procurement Regulations for Borrowers. This included identification of specific procurement issues and initial proposed solutions relating to Large Medical Diagnostic Equipment.

## 2 Large Medical Diagnostic Equipment Industry Engagement Workshop – Washington D.C.

As part of the Bank's IEP for Large Medical Diagnostic Equipment, an initial workshop with industry experts was held on **8 December 2016, in Washington DC**. The workshop was the first of three proposed face-to-face engagements with industry and it primarily involved US based industry experts. Subsequent workshops are planned to be held in Asia and Europe from the second quarter of calendar year 2017. Dates are to be confirmed.

The objectives of the workshop were to:

1. Provide attendees with a clear understanding of the IEP;
2. Obtain input on procurement issues in the sector;
3. Obtain input on proposed solutions, including input on how the sector could assist the Bank and clients in implementing proposed solutions;
4. Identify emerging trends and innovation that may influence a procurement approach;
5. Understand how clients and industry operate in the sector.

The primary focus of the workshop was to discuss procurement issues and proposed solutions previously raised by industry and Bank staff, and achieve a common understanding.

### 3 Large Medical Diagnostic Equipment Procurement Identified Issues and Proposed Solutions

A high level set of issues and proposed solutions have been identified based on prior engagement with industry. One objective of the workshop was to move towards a more granular understanding to develop more effective and precise solutions.

The issues broadly fall into three distinct themes, which map to the procurement process outlined below:

- **Theme 1 - *Identification of Procurement Opportunities and early-Market Engagement***
  - Procurement opportunities need to be publicly available in advance;
  - Procurements need to be better planned to suit the circumstances of the project;
  - Fair and transparent early market engagement with industry needs to be put in place.
- **Theme 2 - *Approach to Market and Contract Award***
  - Specifications need to be better defined and not biased;
  - Contract award decisions need to focus less on price;
  - Borrower and Bank technical expertise needs to be bolstered to support improved evaluation of proposals;
  - Complaints handling, management and escalation needs to be improved.
- **Theme 3 - *Capacity and Capability Building***
  - Allocation of risk between parties needs to be more realistic and equitable;
  - Lengthy negotiations on contractual terms and conditions need to be avoided;
  - Client capacity needs to be strengthened for procuring Large Medical Diagnostic Equipment.

Annex 1 provides more detail on procurement issues and proposed solutions identified during engagement prior to the workshop.

### 4 Workshop Format

The workshop opened with remarks from the Bank's Chief Procurement Officer providing background and context on the IEP. The identified sector issues and proposed solutions were outlined along with a high-level program timeline, including future global engagement events in Asia and Europe in 2017.

The workshop was structured around breakout sessions to discuss sector specific issues and solutions based on the three procurement themes. Each breakout session was facilitated by an industry representative, supported by a member of the Bank's procurement team as detailed below:

- **Theme 1 - *Identification of Procurement Opportunities and early-Market Engagement***
  - Joseph Gatewood – AdvaMed
- **Theme 2 – *Approach to Market and Contract Award***
  - Gisela Abbam – DITTA / GE
- **Theme 3 – *Capacity and Capability Building***
  - Trevor Gunn - Medtronic

Post-breakout session, a summary of discussions, findings and suggested outcomes was presented back to the full workshop. Annex 2 provides a list of all workshop attendees.

## 5 Breakout Session Discussions

A summary of breakout session discussions are detailed below:

### Theme 1 – Identification of Procurement Opportunities and early-Market Engagement

1. ***Project design and dialogue with the private sector should focus on clinical outcomes.*** Dialogue should be encouraged between the Borrower and the private sector with a focus on clinical need and desired outcomes. Current procurements are mostly input based (e.g. requirement for 10 MRI scanners), when they should be focused on clinical outcomes, as well as the disease profile at the national or regional level (e.g. the specific challenges faced by clinicians and patients in-country), such that the most appropriate equipment can be procured given the country-specific context. Dialogue with the private sector should begin at the project design phase and should be focused on understanding client needs and discussing solutions, not detailed specification planning.
2. ***Expanded early-Market engagement is key to understanding value-based solutions that exist in the market.*** Clients and the Bank should expand stakeholder engagement beyond those involved in service delivery. A broader and higher level engagement could be a good way to identify value, taking into account social aspects and overall country healthcare system needs. The Bank should look to international examples of how governments engage early with industry (e.g. Sources Sought in the United States, and recent medical equipment procurement in Kenya).
3. ***Early-market engagement with the private sector should include input into terms of reference for project and procurement consultants.*** Consultants are used in the preparation and implementation of projects and are a key part of the Project Implementation Unit. Given the importance of their role, early-market engagement with the private sector should include discussions on Terms of Reference (ToR) for project and procurement consultants. If the client or consultant does not have the requisite medical sector expertise, the Bank should work with the client to provide or help obtain the required expertise.

### Theme 1 Suggested Outcomes:

- Identify which documents/tools from the World Bank's new Procurement Framework should be adapted for use with the healthcare sector, initially considering the following procurement documents: Project Procurement Strategy for Development (PPSD) and the supporting assessment tools, including the Market Engagement Approach, Market Analysis and Stakeholder Management Plan;
- Guidance on the creation of Terms of Reference (ToR) for consultants involved in project preparation, project implementation and/or project procurement;
- Operationalize and formalize a process for Task Team Leaders (TTLs) to engage with the industry, Borrower, and other experts to receive impartial advice;
- Develop standard operating procedures and check-lists for use by TTLs and clients to ensure they are guided towards obtaining the right information on which to base decisions.

## Theme 2 – Approach to Market and Contract Award

1. ***Sector Solutions should begin as far upstream as possible at the project design phase or earlier.*** Industry engagement should occur regionally or at the Bank portfolio level to inform buyers of market options and to provide input into needs assessment. The Bank should prequalify technical experts, as well as procurement and project consultants to participate on panels to peer review needs assessment. Where available, equipment specifications and import regulations should favor international standards. This may include international standards developed in accordance with the WTO TBT Committee's 2002 Decision on international standards, as well as national regulations and other relevant guidance from the World Health Organization and the International Medical Devices Regulators Forum (IMDRF). These standards should be aligned with clinical pathways to treat prioritized medical diagnoses and treatments and IMDRF-defined risk classes.
2. ***Best procurement practices on specification design and value for money should be employed as part of the client's approach to market.*** Working practices should include an independent review of specifications and "lot" bundling to validate whether effective competition will be created. Value for money guidance should include advice on the bundling of equipment purchase with operation and maintenance costs, as well as the provision of spare parts, across the lifecycle of the product. Advice on fit-for-purpose procurement approaches should include considerations for lifecycle costs (LCC) (such as servicing for the entire useful life of the equipment) and alternatives for equipment purchase or ownership (e.g. lease options, remote diagnostics/service delivery, and refurbished equipment).
3. ***An overall framework for value for money and technical assistance should be established to guide the approach to market from the beginning of project design.*** Approach to market should include clinical scenarios (e.g. operating room for a hospital) and not be driven by detailed product specifications. The value for money framework should be specific to equipment (e.g. X-ray) and mapped to lifecycle cost elements. Hands-on support should be provided early on in the project to enable innovation in the market and procurement approach (e.g. using Requests For Proposals or a Competitive Dialogue procedure).

## Theme 2 Suggested Outcomes:

- Develop case examples of best practice for end-to-end procurement of Large Medical Diagnostic Equipment;
- Create a knowledge base to share project lessons using talent pools or a Community of Practice (CoP);
- Operationalize early involvement of probity oversight of procurement, specification development and evaluation criteria, where risk is anticipated and mitigation is designed into the procurement process;
- Designate a focal point at the Bank to work with industry to find and test solutions;
- Use the Project Procurement Strategy for Development (PPSD) document as an entry point to trigger analysis and design of fit-for-purpose solutions;
- Create guidance for clients on complaint response and escalation process;
- Provide hands-on support or technical assistance to fill any client capability gaps in approaching markets (e.g. framework agreement for a panel of impartial sector and procurement experts);

- Review with industry and other relevant stakeholders the World Bank “Guidance on Value for Money” and “Guidance on Sustainable Procurement” to determine how these frameworks could be adapted and kept evergreen for the healthcare sector.

### Theme 3 – Capacity and Capability Building

1. **Lack of technical expertise perceived as a key barrier to achieving improved project outcomes.** There is a lack of client technical expertise and a perception of a lack of technical expertise at the Bank across key areas relevant to project design such as understanding national healthcare priorities, strategy and health technology assessments (HTAs). The Bank should augment existing expertise through hiring or use of prequalified technical experts.
2. **Lack of market and procurement expertise contributes to a limited approach to market and procurement results.** The lack of understanding of emerging market trends, business models, new technologies and healthcare delivery models results in a limited approach to market. The approach to market overlooks Total Cost of Ownership (TCO), including appropriate consideration of operation and maintenance cost over the lifecycle of the equipment. The Bank should augment market expertise through the use of prequalified experts and/or existing knowledge platforms.
3. **Industry should assist the Bank to help close the knowledge gap for both clients and Bank staff.** Industry informed curriculum should be used to develop understanding of the key elements to proper management and use of Large Diagnostic Medical Equipment. Guidelines and tools required for the selection, procurement, management and use training of Large Diagnostic Medical Equipment should be created. Training should be delivered in-person, via webinars and/or through e-learning modules. Existing knowledge platforms (e.g. ECRI) should be used by the Bank and clients to provide access to market research and knowledge.

### Theme 3 Suggested Outcomes:

- Create an industry advisory committee to provide advice on curriculum relevant to building technical and market expertise in the Bank and clients;
- Operationalize arrangement to develop and provide industry supported training (via industry associations to maintain neutrality);
- Explore options to provide access to existing industry knowledge platforms for Bank and clients;
- Share internal Bank expertise via internal knowledge sharing platform or CoP;
- Replicate the specialization model used at the Bank for IT procurement expertise for Large Medical Diagnostic Equipment;
- Develop standard operating procedures and check-lists for TTLs and clients to ensure they are guided to the right information on which to base decisions.

The Bank will continue to engage with the Large Medical Diagnostic Equipment Sector as part of our engagement plan during 2017. Information on workshops in Asia and Europe will be posted on the Industry Engagement Program website as soon as the dates and locations are confirmed.

**Annex 1 – Identified Issues and Proposed Solutions**

Procurement Theme	Procurement Issue	Proposed Solutions
<b>Identification of Procurement Opportunities and early-Market Engagement</b>	Procurement opportunities need to be publicly accessible in advance.	<ul style="list-style-type: none"> <li>Understand what specific information is needed and timing of availability</li> <li>Explore options for publication in advance of procurements (e.g. World Bank sector specific website)</li> </ul>
<b>Identification of Procurement Opportunities and early-Market Engagement</b>	Procurements need to be better planned to suit the circumstances of the project	<ul style="list-style-type: none"> <li>Work with industry specialists to develop a suite of information to inform project preparation</li> <li>Set up accessible repository of analysis for specific equipment (e.g. MRI)</li> </ul>
<b>Identification of Procurement Opportunities and early-Market Engagement</b>	A lack of fair and transparent early market engagement	<ul style="list-style-type: none"> <li>Identify a framework for fair and transparent early-Market engagement on Bank projects</li> <li>Analyze the Bank pipeline for projects that may be suitable to trial the approach</li> <li>Work with internal Bank and external sector specialists to plan for assistance with identified Bank pipeline projects</li> </ul>
<b>Approach to Market and Contract Award</b>	Poorly defined or biased specifications	<ul style="list-style-type: none"> <li>Engage with sector to identify specification standards (e.g. MRI)</li> <li>Identify a knowledge-base to enable procurers to test the appropriateness of specifications</li> <li>Establish a protocol to ensure standards and knowledge-base is utilized</li> </ul>
<b>Approach to Market and Contract Award</b>	Contract award decisions that focus on price alone	<ul style="list-style-type: none"> <li>Develop VFM Guidance specific to Large Medical Diagnostic Equipment procurement</li> <li>Test with industry and revise as needed</li> </ul>
<b>Approach to Market and Contract Award</b>	Lack of technical expertise for evaluation of proposals	<ul style="list-style-type: none"> <li>Identify industry experts to provide unbiased technical support</li> <li>Identify projects to trial and promote the technical support</li> </ul>
<b>Approach to Market and Contract Award</b>	Complaints handling	<ul style="list-style-type: none"> <li>Set up specific monitoring and evaluation of complaints relating to Bank Large Medical Diagnostic Equipment procurement with a clearly defined escalation process</li> </ul>



Procurement Theme	Procurement Issue	Proposed Solutions
<b>Approach to Market and Contract Award</b>	Allocation of risk between parties	<ul style="list-style-type: none"> <li>Identify specific areas of concern and identify a best practice approach to balanced risk allocation</li> <li>Reflect in bidding documents and contract terms and conditions as necessary</li> </ul>
<b>Capacity and Capability Building</b>	Lengthy negotiations on contractual terms and conditions	<ul style="list-style-type: none"> <li>Identify specific projects and contractual terms and conditions that have been an issue</li> <li>Engage private sector for input into solutions for contractual terms and conditions</li> </ul>
<b>Capacity and Capability Building</b>	Lack of technical capability amongst procurement personnel	<ul style="list-style-type: none"> <li>Develop training and targeted capacity building programs to increase expertise in procurement of Large Medical Diagnostic Equipment</li> <li>Make available and promote impartial technical support from industry</li> </ul>

**Annex 2 - List of Workshop Attendees**

Representation	Organization	Attendee name
Non-Profit	ECRI	1. Jim Keller
Non-Profit	PATH	2. Todd Dickens
Supplier	Becton Dickson	3. Michael Reiner
Supplier	Boston Scientific	4. Carr Slayton
Supplier	General Electric	5. Mary Ann Ring 6. William Elliott
Supplier	Johnson & Johnson	7. Steve Phillips
Supplier	Medtronic	8. Trevor Gunn 9. Justin Koester
Supplier	Philips	10. Will Center 11. Diane Wilkins
Supplier	Siemens	12. Richard Frank 13. Julia Jeffrey
Supplier	Varian Medical Systems	14. Julia Sheehy-Chan
Trade Association	AdvaMed	15. Joseph Gatewood
Trade Association	DITTA	16. Gisela Abbam
Trade Association	MITA	17. Patrick Hope 18. Andrew Northup
Trade Association	US Chamber of Commerce	19. Gary Littman
US Government	Dept. of Commerce (International Trade Administration)	20. Selina Milligan 21. Tracy Gerstle 22. Denise Carpenter
World Bank	Integrity Vice Presidency (INT)	23. Steve Burgess
World Bank	World Bank Health Sector Specialists (HNP)	24. Marcelo Bortman 25. Kara Adamon
World Bank	Standards, Procurement, and Financial Management (OPSPF)	26. Christopher Browne 27. Simon Mckinley 28. Michael Osborne 29. Justin Valentine 30. Barnaby Wiles 31. John Williams
US ED Office	ED Advisor	32. Aaron Held