

1 Introduction

As part of the implementation of the World Bank (Bank) Procurement Framework (launched on July 1, 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:

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

As part of the Bank's IEP for Large Medical Diagnostic Equipment, a workshop with industry experts was held on June 19, 2017, in Tokyo. The workshop was the final face-to-face engagement with industry and it involved Japanese based manufacturers and industry experts.

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.

4 Workshop Format

The workshop opened with remarks from the Bank's IEP Program Lead Procurement Specialist providing background and context on the IEP. The identified sector issues and proposed solutions were outlined along with a high-level program timeline.

The workshop was structured in three different plenary sessions to discuss sector specific issues and solutions based on the three procurement themes. Each session was facilitated by a Bank representative.

- **Theme 1 - Identification of Procurement Opportunities and early-Market Engagement**
- **Theme 2 – Approach to Market and Contract Award**
- **Theme 3 – Capacity and Capability Building**

Annex 1 provides a list of all workshop attendees.

5 Plenary Session Discussions

A summary of the session discussions are detailed below:

Theme 1 – Identification of Procurement Opportunities and Early-Market Engagement

1. **Industry is unable to respond directly to procurement opportunities.** Many procurement opportunities are split into lots that include multiple items and not just imaging equipment. This means that industry must bid through a trading house.
2. **Industry does not have input during Project design phase, or earlier.** Currently, industry is not engaged until bidding opportunities are advertised. At this point specifications are already defined. Industry should be engaged at a much earlier stage, to help define what equipment is best suited based on actual clinical needs. As it stands, equipment could be procured that is not the best solution for meeting the needs of patients.

Theme 1 – Suggested Outcomes

- There should be improved publication, access and visibility of MDI equipment requirements (not just a consolidated project view) should be provided.
- Earlier and more regular engagement should take place with industry, with more interaction across the whole procurement process.
- Industry involvement at an earlier stage of project preparation should take place to enable discussions and input on specifications, requirements and Request for Proposals prior to issue for the formal Request for Proposals.
- Trade associations should be used to help promote procurement opportunities and support market engagement to receive constructive and impartial feedback on draft requirements.
- Use of external technical experts (i.e. trade associations or a panel of approved experts) should be made to define the clinical needs of a project at the earliest possible stage in the project cycle. The role of the experts should also include identifying opportunities for continuous improvement in the procurement process, as well as helping to guide the selection of appropriate technology based on a country's individual circumstances.
- Lotting strategies which do not consolidate multiple medical equipment requirements (that are restrictive to suppliers who specialize only in MDI equipment) should be considered to avoid blocking these suppliers from bidding.
- Lotting strategies should also consider how any local supply arrangements could operate.
- Medical Imaging Equipment should be procured separately so that OEM's have the option to respond directly to the procurement and not through a trading house.

Theme 2 – Approach to Market and Contract Award

1. **Technical specifications.** Local procurement teams have a lot of power on the setting of specifications that can be too detailed, which leads to accusations of bias. Specifications should be centrally controlled and reviewed to ensure they are unbiased and have the right level of detail.
2. **Input/output specifications.** The use of input and output specifications should be carefully considered and used under the right circumstances. Output specifications can lead to too much variety if not designed in the right way.

3. **Country requirements need to be considered.** When the specification is being drafted the country requirements need to be considered. For example, high resolution imaging for early diagnostic is only needed if the country has the medical knowledge and capability to treat early diagnostic.
4. **The use of Trade Associations to review specifications.** Using Trade Associations to review specifications could be useful but the associations would have to be fully independent and transparent so a reasonable amount of time will need to be given, 6 weeks would be enough time to provide the right input. The Trade Associations would also be able to provide feedback on the balance between output and input specifications.
5. **Service and maintenance costs are important as is usage.** In the bidding process service and maintenance costs should be included and how these will be evaluated. Focusing on service and potential equipment usage is critical. Initial equipment costs can be low, maintenance fees are where the industry makes the most margin as equipment can be heavily discounted.
6. **Medical equipment maintenance.** Many hospitals don't want to learn how to operate new equipment or deal with spare parts from multiple suppliers. When equipment is changed, the equipment must be linked to the information system which means additional training is required.
7. **Refurbished equipment.** Refurbished equipment should be considered for developing countries due to its lower price point, however, some developing countries don't allow import of second hand products. Currently there is no international standard for refurbished equipment which could cause safety issues. DITTA have prepared a process standard for refurbished standards and testing which should be to the same standard as the OEM's.
8. **Over what period should whole life costs be calculated.** It is difficult to determine the right period that whole life costs should be calculated. This is due to many varied factors such as the type of imaging equipment and its usage. The typical life cycle for imaging equipment is 10 years but manufacturers have indicated that they would only offer support for seven years' maximum as the industry standard for maintaining spare parts by the OEM's is seven years.
9. **Standard terms and conditions for the industry.** There are no standard industry terms and conditions for imaging equipment. The introduction of agreed terms and conditions would reduce the time to procure the equipment as there wouldn't be a need to negotiate already agreed terms.

Theme 2 – Suggested Outcomes:

- Specifications should be reviewed centrally or by an independent panel of experts approved by the Industry.
- Industry and trade associations / bodies should be sent draft specifications and request for proposal documents to provide independent and non-attributable feedback on the draft documents.
- Timescales for consultations on requirements and submitting proposals needs to be extended. As a minimum, consultations should start six weeks before Requests for Proposals are issued.
- A move away from input specifications towards output specifications or ideally outcome based specifications should take place. However, output specifications should not be too wide or high level. A good balance between output and input will ensure compliance with minimum standards.
- The use of refurbished equipment should be considered more often and bidding / proposal documents should explicitly state if refurbished equipment is an option for the contract.
- Standards of universal applicability need to be set for the procurement of refurbished MDI equipment. (Note: DITTA are in the process of finalizing a standard).

- Risks associated with procuring refurbished equipment need to be understood and mitigated through effective requirement setting.
- More focus should be put on Value for Money to ensure that service and maintenance costs are considered, not just the price of the equipment.
- Value for money should be evaluated on a whole life cost basis to avoid issues of low cost of initial equipment but disproportionately high operational costs over the equipment's life time.
- In evaluating MDI equipment proposals, detailed cost models should be used to deliver transparent value for money and drive consistency in how clients evaluate proposals.
- Support and maintenance should be based on set parameters, which supports industry in establishing more comprehensive country or region based service offerings.
- The packaging of equipment supply, support and maintenance and consumables supply could be separated out.
- Visibility of contract award decisions should be improved with bidders being provided with debriefings on their bid and the successful contract award.
- Framework agreements could be utilized to reduce bidding costs, speed up procurements and mitigate lengthy negotiations over contractual terms and conditions, but they need to be designed in such a way that new products can be added easily.
- Pricing varies at a country, regional and international level, however opportunities to package multiple requirements across countries and regions may provide opportunities for volume discounts.
- Framework agreements need to be established in a flexible manner in recognition of this lack of unity and conformity of pricing.

Theme 3 – Capacity and Capability Building

1. **Governments should look at total solutions.** Total solutions covering the purchase, operation, maintenance and training should be looked at for emerging markets. However, this would only work if high utilization rate due to the investment costs.
2. **Government officials and World Bank expertise in medical technology is low.** This sector is highly dynamic, with fast moving technology. Implementing agencies and Bank staff do not have the knowledge on the latest innovations within the med-tech industry.

Theme 3 – Suggested Outcomes:

- An evaluation should be made of the opportunity of establishing an industry standard set of contract terms and conditions agreed by all manufacturers through direct engagement with manufacturers and trade associations / bodies.
- Standardization on requirements such as manufacturer warranties, spare parts support and service levels should be considered to help ensure a more equitable and realistic balance of risk is established.
- Engagement should take place early with the private sector to ensure the correct technology is being procured based on clinical needs.
- Industry should be given the opportunity to provide support to capability building of Borrowers and Bank staff.

- As part of the client planning process, an assessment of post contract award client capability requirements should take place to ensure adequate client capability exists to successfully implement the contract.
- Guidance to clients on procuring MDI equipment and how to specify and evaluate requirements would be beneficial. The Guidance should also offer advice on how specific requirements based on a country's individual circumstances are considered.
- Greater awareness and transparency of the Bank's complaints mechanism would build industry confidence in the MDI equipment supply market.
- Continuous monitoring of a contract's implementation should be put in place and a feedback mechanism should be established with industry to share any lessons learnt (positive and negative).
- Standard and consistent terms and conditions should be used to make the procurement process more efficient for all and drive fair and equitable risk transfer.

The Bank will continue to engage with the Large Medical Diagnostic Equipment Sector as part of our engagement plan during 2017. Outcomes of all workshops will be posted on the Industry Engagement Program website.

6 Priority of issues/solutions (based on individual participant feedback)

- Early and interactive engagement with industry and the use of pre-bid conferences.
- Independent evaluation panel as a filter for specifications and to support bid and proposal evaluation.
- Output based specifications that meet local needs.
- Framework agreements, including flexibility for local supplier participation.
- Total cost of ownership evaluation of bids, with a focus on linking equipment evaluation and performance.
- More information and feedback given post contract award.
- Consistency and standards set for support and maintenance.
- Standard and consistent terms and conditions for the sector used to make the procurement process more efficient for all and drive fair and equitable risk transfer.

Annex 1 - List of Workshop Attendees

Representation	Organization	Attendee name
Government	Ministry of Economy, Trade and Industry	1. Kazuyuki Oda
Trade Association	Japan Association for the Advancement of Medical Equipment (JAAME)	2. Takashi Suzuki
Trade Association	Japan Industries Association of Radiological Systems (JIRA)	3. Susumu Uchiyama 4. Satoshi Kimura
Supplier	Fujifilm Holdings Corporation	5. Masaharu Morita
Supplier	Hitachi Medical Corporation	6. Yukio Matsuda 7. Kenji Wada
Supplier	Shimadzu Corporation	8. Yusuke Kondo 9. Yoko Sasaki
Supplier	Olympus	10. Kaz Nishihashi
Supplier	Toshiba Corporation	11. Atsushi Habara 12. Tomoki Koshizawa 13. Hiroyuki Kusaka
World Bank	Standards, Procurement, and Financial Management (OPSPF)	14. Christopher Browne 15. John Williams 16. Barnaby Wiles
World Bank	WBG External and Corporate Relations	17. Koichi Omori 18. Yasusuke Tsukagoshi