

### OPCS Response to Comments Received

The first Medical Diagnostic Equipment Workshop held in Washington DC. on 8 December, 2016 proved to be a success. A number of comments and feedback have since been received from the attendees. See below a breakdown of each comment received, what section, theme or point from the workshop summary pack the comment is in reference to, and a response from the Operations Policy and Country Services team.

REFERENCE	COMMENT	OPCS RESPONSE
Point 3.2 of Workshop Summary - <i>Approach to Market and Contract Award</i> - Technical expertise needs to be bolstered to support improved evaluation of proposals.	Specify who needs to have this improved expertise? Client procurement professionals?	The improved expertise needs to be both Borrower and Bank.
Point 5.1.1 of Workshop Summary - <i>Project design and dialogue with the private sector should focus on clinical outcomes</i> - Dialogue should be encouraged with the private sector with a focus on clinical need and desired outcomes	Who is leading these discussions? World Bank client procurement professionals?	The Borrower will lead these discussions. OPCS will consider whether there is a need to undertake industry wide engagement on developing a methodology and guidance to support Borrowers in leading such discussions.
Point 5.1.2 of Workshop Summary - <i>Expanded early-Market engagement is key to understanding value-based solutions that exist in the market</i> - Clients and the Bank should expand stakeholder engagement beyond those involved in service delivery	It would be helpful to provide an example of other stakeholders to include. Also are those involved in service delivery referring to users of equipment being purchased (e.g., imaging technicians and radiologists)?	At the workshop there was discussion on whether the stakeholders should include representation from country government staff. Service delivery was referring to Borrower staff and direct managers of the service/equipment e.g. clinicians
Point 5.1 Suggested Outcomes Point 3 - Operationalize and formalize a process for Task Team Leaders (TTLs) to engage with the private sector to receive impartial advice	Does private sector refer to product vendors, consultants, or both? Others?	For clarification consultants are referring to procurement and project consultants. Private sector engagement is referring to equipment and service providers.
Point 5.2.1 of Workshop Summary - <i>Sector Solutions should begin as far upstream as possible at the project design phase or earlier</i> - The Bank should prequalify technical experts to participate on panels to peer review needs assessment	I think we also talked about having a process for prequalifying consultants.	The reference to technical experts will be expanded to include procurement and project consultants.
Point 5.2.1 of Workshop Summary - <i>Sector Solutions should begin as far upstream as possible at the project design phase or earlier</i> - International standards should be set for equipment specifications and import regulations. These standards should be segmented by risk class, taxonomy of device and application	It might be helpful to distinguish in this document between international standards for procurement specifications vs. specification in general international device standards. They may overlap but won't necessarily be the same.	Agreed. Will update accordingly.
Point 5.2.2 of Workshop Summary - <i>Best procurement practices on specification design and value for money should be employed as part of the client's approach to market</i> - Working practices should include an independent review of specifications and "lot" bundling to validate whether competition will be created. Value for money guidance should include advice on the bundling of equipment purchase with operation and maintenance costs across the lifecycle of the product	Not clear from this wording as to whether or not competition is desired. I believe the intent is to create competition and not develop specifications or bundles to inappropriately lock out a vendor/product. Also, it may be helpful to distinguish between bundling of product with operation and maintenance costs in contracts vs. bundling of multiple product types in one contract.	Agreed. Will update accordingly.

<p>Point 5.2.2 of Workshop Summary - <i>Best procurement practices on specification design and value for money should be employed as part of the client's approach to market</i> - Advice on fit-for-purpose procurement approaches should include considerations for lifecycle costs (LCC) and alternatives for equipment purchase or ownership (e.g. lease options, and refurbished equipment)</p>	<p>One thing that we talked about that could be specified here is to make sure that contracts include sufficient support to make sure that the product can be used effectively throughout its whole life cycle. For example, if a contract only includes the standard one-year maintenance warranty vs. longer term maintenance support then there is a good chance that product will have a limited useful life – if life-time maintenance support is not otherwise planned for. Another issue may be the lack of confirmation of qualified service providers in the region where the product is to be used.</p>	<p>Agreed. Will update accordingly.</p>
<p>Point 5.2.2 of Workshop Summary - <i>Best procurement practices on specification design and value for money should be employed as part of the client's approach to market</i> -</p>	<p>I added support in reference to my above comment about making sure product is supported from a maintenance point-of-view so that it does not become a “dust collector” after it breaks for the first time.</p>	<p>Agreed. Will update accordingly.</p>
<p>Point 5.3 Suggested Outcomes point 6 - 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</p>	<p>Generic operating procedures are very useful but having technology-specific and/or application-specific procedures would be more valuable and would effectively become training tools for clients and bank staff.</p>	<p>Agreed. Will update accordingly.</p>
<p>Annex 1 - <i>Approach to Market and Contract Award</i> - Contract award decisions that focus on price alone</p>	<p>Note that at some point price negotiations will be required during the procurement process. Resources are available like from ECRI to help procurement specialists determine if they are getting a good and fair price.</p>	<p>Agreed and Noted.</p>
<p>Annex 1 - <i>Capacity and Capability Building</i> - Lengthy negotiations on contractual terms and conditions”</p>	<p>Engage <b>private (?)</b> sector for input into solutions for contractual terms and conditions - Also develop standard Bank-approved terms and conditions for various contract types (e.g., for MRI)?</p>	<p>Agreed. The key here will be to balance the need for Borrower contractual protection versus appropriate and balanced allocation of risk between the contractual parties.</p>
<p>Point 5.2.1 of Workshop Summary - <i>Sector Solutions should begin as far upstream as possible at the project design phase or earlier</i> - 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.</p>	<ul style="list-style-type: none"> <li>• To support regional/country specific engagement with industry, one idea would be to pilot workshops with medical diagnostic equipment providers (either in country or in Washington) during the formulation of Country Assistance/Partnership Strategies, to ensure that considerations for health programming are taken into account.</li> <li>• This consultative approach at the early stage would align with the concept of “Horizon Scanning,” by helping borrowing countries understand what is possible, i.e. what could be procured, based on the intersection of two factors: <ol style="list-style-type: none"> <li>1. Benefits which could accrue to the borrowing countries from the current status of innovation in devices;</li> <li>2. Disease burden as it affects the borrowing countries’ potential for growth in their national economy. <ul style="list-style-type: none"> <li>• Broadly, this same approach would help to ensure greatest value for any lending program that is to identify the greatest disease burden as assessed by impact on growth in the national economy, and the devices which offer the greatest benefit in mitigating that impact. The proposed expansion of access by the WB to medical expertise would optimize such a process of matching devices to disease burden.</li> </ul> </li> </ol> </li> </ul> <p>”</p>	<p>Yes we agree in principle, however we would like to obtain further feedback from future consultations to determine the most effective method of managing engagements such as those described.</p>

Point 5.2.1 of Workshop Summary - <i>Sector Solutions should begin as far upstream as possible at the project design phase or earlier</i> - International standards should be set for equipment specifications and import regulations. These standards should be segmented by risk class, taxonomy of device and application.	Our understanding was that ECRI might be able to support here.	Yes noted.
Point 5.2. 2 of Workshop Summary - <i>Best procurement practices on specification design and value for money should be employed as part of the client's approach to market</i> Value for money guidance should include advice on the bundling of equipment purchase with operation and maintenance costs across the lifecycle of the product.	Suggest to add "provision of spare parts" to the phrase on operation and maintenance costs to be taken in account.	Agreed.
Theme 2: Suggested Outcomes - Create guidance for clients on complaint response and escalation process.	We strongly support this provision, particularly guidance that would ensure bidders receive feedback from the Customer/Bank on complaints prior to contract award.	The new Procurement Framework has already enabled this provision through its revised complaints handling procedure which includes the introduction of a Standstill period prior to contract award for all International Competitive Bidding (ICB) procurements.
Theme 3 – Suggested Outcomes - Operationalize arrangement to develop and provide industry supported training (via industry associations to maintain neutrality)	Medical device industry representatives (through MITA) previously worked with HNP to develop a draft training concept for modular webinars which the World Bank could implement using its online training platforms. We suggest revisiting this; MITA/Andrew Northup should have the latest version of the Concept Note available.	Thank you, we will follow this up.
Theme 1 – Suggested Outcomes - Operationalize and formalize a process for Task Team Leaders (TTLs) to engage with the private sector to receive impartial advice	Not impartial if received from industry. Suggest consider focusing on breadth of engagement to neutralize partiality and that not simple cut and paste one supplier's technical spec sheet.	Agree. Engagement will be on a multi stakeholder basis e.g. industry, Borrowers and other experts. Any documentation produced by OPCS will be quality assured to remove any unintentional bias.
Theme 1 – Suggested Outcomes - 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.	What is the "right" information?	The right information will need identification but could include how to undertake life cycle costing, validation of projects development objectives/procurement objectives, market research and cost/price benchmark data.
Theme 2 – Suggested Outcomes - Operationalize early involvement of probity oversight of procurement	What does this mean?	This means that procurement oversight will ensure that procurement approaches, specifications and Borrower capability are all appropriate to the complexity, value and risk of a project. Oversight will start early in the project cycle and will continue through to contract award.
Theme 2 – Suggested Outcomes - Designate a focal point at the Bank to work with industry to find and test solutions	Also should work with governments. How will these be tested? What is the risk to the integrity of the procurement and the level of competition if the test fails?	Agreed. The focal point should work with a variety of stakeholders such as suppliers, governments and industry groups. It is envisaged that consultation with identified key stakeholders would help test these solutions. Our thinking is still at an early stage but one idea could be to set up a multiply stakeholder advisory group. OPCS will take responsibility for managing integrity issues associated with the overall external sectorial engagement program. We believe OPCS are far enough removed from operational delivery that integrity can be managed accordingly. There is always a risk that procurement exercises don't result in adequate levels of competition. However the interventions being considered as part of this program are primary designed to improve competition, ensure that

		capable suppliers are motivated to bid and the program is open and transparent enough to give suppliers confidence that there is no bias in Bank funded projects. For example market engagement and open dialogue with suppliers prior to commencing a procurement should enable both the borrower and the Bank to have early insight into any potential issues and to whether suppliers will bid for work.
Theme 2 – Suggested Outcomes - (e.g. framework agreement for a panel of sector and procurement experts)	Do you want to emphasize that they need to be impartial?	Agreed.
Annex 1 – <i>Identification of Procurement Opportunities and early-Market Engagement</i> - procurement opportunities need to be publicly accessible in advance	In advance of what? The publication of the procurement notice or release of tender documentation? You could also get at this by specifying a best practice amount of time to allow for submission of offers	The reference to in advance would normally be prior to issue of the final tender documentation but could happen far earlier in the project cycle. We can consider indicating time scales for stages of the procurement process.
Annex 1 - <i>Procurements need to be better planned to suit the circumstances of the project</i> - Set up accessible repository of analysis for specific equipment (e.g. MRI)	How will this be kept current?	We are currently considering how the Bank can collate such information and how this would be kept relevant and contemporary.
Annex 1 - <i>A lack of fair and transparent early market engagement</i> – Work with internal Bank and external sector specialists to plan for assistance with identified Bank pipeline projects	Need to have strong integrity and conflict provisions.	Any assistance would be in accordance with the Banks approach to hands on expanded implementation support as detailed in the Regulations and associated guidance.
Annex 1 - <i>Poorly defined or biased specifications</i> –Engage with sector to identify specification standards (e.g. MRI)	Suggest requiring broad engagement. Engagement with sector could be limited to European firms.	Engagement will be on a multi stakeholder basis e.g. industry, Borrowers and other experts and be subject to quality assurance by OPCS to ensure there is no bias.
Annex 1 - <i>Poorly defined or biased specifications</i> – Identify a knowledge-base to enable procurers to test the appropriateness of specifications	Needs to be impartial. Needs to be current.	Agreed.
Annex 1 <i>Complaints handling</i> - Set up specific monitoring and evaluation of complaints relating to Bank Large Medical Diagnostic Equipment procurement with a clearly defined escalation process	What does this mean? Bank monitoring, or domestic monitoring systems? Who evaluates, on what basis, and for what purpose (merit of compliant and ruling on it, or for oversight)?	The new Procurement Framework has enabled a revised complaints handling procedure. The program will monitor the complaints database to understand emerging issues to consider any further action that needs to be taken e.g. market intervention, additional guidance for Borrowers and alternative procurement approaches. Any escalation would be in accordance with the complaints handling procedure.
Annex 1 - <i>Lengthy negotiations on contractual terms and conditions</i> – Engage sector for input into solutions for contractual terms and conditions	And governments too.	It is envisaged that the program would engage with multiple stakeholders to establish how contractual terms could be improved. The Bank would then determine how any amendments could be made to its standard procurement documents (SPBs) following nits normal protocols.
Annex 1 <i>Lack of technical capability amongst procurement personnel</i> – Make available and promote technical support from industry	Impartial?	Agreed.
Introduction – Program Objectives	Program objectives should include bringing greater transparency to the bidding process.	Agreed.
Point 5.1.1 of workshop summary - <i>Project design and dialogue with the private sector should focus on clinical outcomes</i> - Current procurements are mostly input based (e.g. requirement for 10 MRI scanners), when they should be focused on clinical outcomes (e.g. reduction of a disease)	We agree with this statement, but believe it would be enhanced by greater specificity surrounding clinical need – i.e., to add at the end of this sentence: “...as well as the disease profile at the national or regional level (e.g. the specific challenges faced by clinicians and patients in-country),	Agreed.

	such that the most appropriate equipment can be procured given the country-specific context.”	
Point 5.1.1 of workshop summary - <i>Project design and dialogue with the private sector should focus on clinical outcomes - “e.g. reduction of disease”</i>	We agree with the reduction of disease goal, but believe it should include improved patient outcomes. One example would be reducing mortality attributable to sudden cardiac arrest.	Agreed.
Point 5.2.1 of Workshop Summary - <i>Sector Solutions should begin as far upstream as possible at the project design phase or earlier - The Bank should prequalify technical experts to participate in panels to peer review needs assessment</i>	We believe that technical experts should be vetted with significant input from industry to ensure they have a sufficiency of relevant expertise.	To ensure impartiality the Bank would carry out the vetting process, however the need for sufficiency of relevant experience is essential to both the credibility and effectiveness of the proposal.
Point 5.2. 2 of Workshop Summary - <i>Best procurement practices on specification design and value for money should be employed as part of the client’s approach to market - Value for money guidance should include advice on the bundling of equipment purchase with operation and maintenance costs across the lifecycle of the product</i>	We agree with this statement, and would add that, in the field of radiotherapy, World Bank procurements of radiotherapy equipment have in the past encompassed extended warranties. However, these warranties do not extend for the full useful life of the equipment, which may be used for over ten years in the development world in particular. From a budgeting perspective, countries may be unprepared to purchase service and maintenance contracts at the conclusion of these warranties, and may not have a full understanding of the value of doing so. We would further add that value for money guidance should also include advice on the bundling of equipment purchase with training and education for clinicians. Given the complexity of the equipment in question, and the fact that procurements often encompass newer-generation technology, it is essential for clinicians to receive the necessary training to ensure safe and effective use of the procured equipment.	Agreed. These points will be considered in any guidance produced.
Point 5.2.3 of Workshop Summary - <i>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 - 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</i>	While we agree with this statement and approach, we would also note that the creation and implementation of such a framework will take an extended period of time, given that it is only one element of the World Bank’s medical equipment procurement reform – a multi-year process – and given the diversity of medical equipment to be considered, which consequently has distinct ways of contributing value and impacting clinical outcomes that must be reflected in such a framework. As such, we discussed during the workshop the possibility of implementing certain measures in the near term, which would greatly enhance existing and forthcoming World Bank tenders for medical equipment while the overall framework is still in inception.  As a concrete example, the current state of World Bank procurement for radiotherapy equipment was considered. The radiotherapy industry is relatively small, with three main players – only two of which compete regularly in international tenders, and the equipment produced by each company is distinct and cannot be considered via an apples-to-apples comparison. As such, procurement initiatives undertaken under the umbrella of World Bank projects have traditionally stripped down equipment specifications to the lowest common denominator in order to enable competition, and the lowest bid wins. This thereby does not encourage or permit tenderers to consider which additional technical capabilities are most appropriate and beneficial to their patient	Once the consultations have been completed it is envisaged that a plan combining short, medium and long term interventions will be implemented prioritized on the ease of implementation, impact and resource requirements. The plan will also consider whether interventions are market wide or need to focus specifically in a particular niche. At this time out thinking is that it is likely to be a combination of both.

	<p>populations, which can lead to sub-optimal solutions being procured. However, some countries (not under the auspices of a World Bank project) have created tender evaluation frameworks that address this by assigning points to technical capabilities that go above and beyond the lowest common denominator specifications, and which are determined by the tender committee to be essential to achieving the clinical goals of the country or public institution in question. These points then translate to a certain percentage discount on the bid, such that offers may be considered to be X% lower than the actual bid price, and thereby enabling bids that are higher in price but with more advanced clinical offerings to be successful.</p> <p>During the IEP Workshop, the above was discussed, and it was suggested that the World Bank could implement similar tender evaluation frameworks as a “quick fix” – an interim step before the final overall framework is completed. Industry is able and willing to share examples of such frameworks with the World Bank to further this effort.</p> <p>We would also suggest that there may be existing frameworks in some cases that may be fit for these purposes, and if so, these can be vetted and utilized. Continuing efforts to work with the medical technology industry to leverage existing frameworks would be advantageous to the stated goals.</p>	
<p>Theme 2: Suggested Outcomes - Create guidance for clients on complaint response and escalation process</p>	<p>We would strongly favor not only the creation of guidance documents, but also a World Bank framework for intervention in procurements in which there is clear evidence of unfair manipulation of specifications (e.g. when specifications unfairly benefit one manufacturer and lock out competition, or other examples of undue bias). In the past, we have had negative experiences in which complaints and objections to tendering authorities on the basis of unfair specifications have been ignored, and thus tenders have gone through in which specifications have been copied directly from the website of one manufacturer, thereby preventing other companies from bidding. While we understand the desire of the World Bank to empower clients to tender for and select equipment that is most relevant and needed in their countries, we believe that the World Bank should provide a stop-gap and intervene in cases of clear corruption or unfair practice.</p>	<p>The new Procurement Framework has enabled a revised complaints handling procedure. The program will monitor the complaints database to understand emerging issues to consider any further action that needs to be taken e.g. market intervention, additional guidance for Borrowers and alternative procurement approaches. Any escalation would be in accordance with the complaints handling procedure. We believe the introduction of a Standstill period prior to contract award for all International Competitive Bidding (ICB) procurements will help address the issues highlighted.</p>
<p>Point 5.3.1 of workshop summary - <i>Lack of technical expertise perceived as a key barrier to achieving improved project outcomes</i> - Lack of market and procurement expertise contributes to a limited approach to market and procurement rules</p>	<p>Training programs would be invaluable to enhance the expertise of World Bank and client personnel, as reflected in this section. One example of an existing best practice is the Reverse Trade Mission (RTM) model utilized by the U.S. Trade and Development Agency (USTDA). RTMs bring delegations from other countries who are responsible for procuring medical equipment (or other goods and services, depending on the targeted industry) to the United States to visit health institutions where this equipment is in use; to visit relevant manufacturers in order to understand the types of equipment offered and distinct advantages of different models; and to receive training by USTDA on value procurement. These trade missions greatly enhance the expertise of participants.</p>	<p>Agree. We will consider this particular type of approach as part of developing the action plan, once all the consultations have been concluded.</p>

Point 5.3.1 of workshop summary - <i>Lack of technical expertise perceived as a key barrier to achieving improved project outcomes</i> - The Bank should augment existing expertise through hiring or use of prequalified technical experts.	We believe that experts should be vetted with significant input from the medical technology industry to ensure all experts utilized have a sufficiency of relevant expertise.	To ensure impartiality the Bank would carry out the vetting process, however the need for sufficiency of relevant experience is essential to both the credibility and effectiveness of the proposal.
Annex 1 - <i>Lack of technical capability amongst procurement personnel</i> - Develop training and targeted capacity building programs to increase expertise in procurement of Large Diagnostic Medical Device Equipment. Make available and promote technical support from industry."	We believe the training encompassed in the 'World Bank Institute (WBI) E-Learning Course Concept Note: Medical Technology Policy Planning, Regulation and Management' offers potential benefits to address some of these issues. Please find it attached to our submission.	Agreed and thank you.

Document Reference	Suggested Language	Comment	OPCS Response
p. 3 Theme 1: Suggested Outcomes: Guidance from the Bank for clients advocating consultation with a wide group of stakeholders during product design	Identify which documents/tools from the World Bank <i>New Procurement Framework and Regulations for Projects After 7/1/2016</i> should be adapted for use with the healthcare sector, initially considering the following procurement project/contract requirement documents: Project Procurement Strategy for Development (PPCD) and the supporting assessment tools, including the Market Engagement Approach, Market Analysis and Stakeholder Management Plan	Similar to the infrastructure sector, projects in health care represent a significant share of the World Bank's project portfolio. Achieving changes in a country's health outcomes requires a focus on the clinical profile of the targeted population, as well as an understanding of other local social and economic conditions. The current procurement tools focus primarily on an economic analysis and stakeholder mapping that seem better suited to projects in infrastructure or industrial development. This may result in a poor characterization or insufficient understanding of local capacity and patient needs in the health care sector. At worst, this may result in project procurements that are ineffectual, while also limiting innovations in potential health care solutions and health outcomes proposed by bidders.	Agree, will update accordingly.
p. 4 Theme 2 Approach to Market and Contract Award 1. Sector Solutions should begin as far upstream... International standards should be set for equipment specifications and import regulations. These standards should be segmented by risk class, taxonomy of device and application.	[Insert: Where available,] [delete text International standards] [Insert text: equipment specifications and import regulations should favor international standards. ] [delete text: be set for] [insert text: This may include international standards developed in accordance with 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 segmented [insert: aligned with clinical pathways to treat prioritized medical diagnoses and treatments] and IMDRF-defined risk classes] [delete text: taxonomy of device and application]  Final sentence: Where available, equipment specifications and import regulations should favor international standards. This may include international standards developed in accordance with 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	Nomenclature: The Bank may wish to insert language in its <i>New Procurement Framework and Regulations for Projects After 7/1/2016</i> that explains the difference between how the term standard is used in the context of the World Bank's lending requirements and international standards used by industry, such as those codified in accordance with ANSI, ISO and other relevant standards making bodies.  Perhaps in the consultations with industry to design the new procurement guidance for large scale medical devices, as well as in relevant procurements industry's input could be solicited on the relevant international industry standards.	Agree, will update accordingly.

	prioritized medical diagnoses and treatments and IMDRF-defined risk classes.		
p. 4 Theme 2 Approach to Market and Contract Award  2. Best procurement practices on specification design and value for money...	...(e.g. lease options, [insert text: remote diagnostics/services delivery...])	Acknowledges that there are a variety of solutions that industry can offer in providing large scale medical equipment, including provision of services such as remote interpretation/review of medical images and information collected	Agree, will update accordingly.
p. 4 Theme 2 Suggested Outcomes	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	An initial consultation and ongoing discussion with industry on these specific tools could result in adaptations to the frameworks to bring and then continue to introduce healthcare best practices into World Bank health sector projects	Agree, will update accordingly.