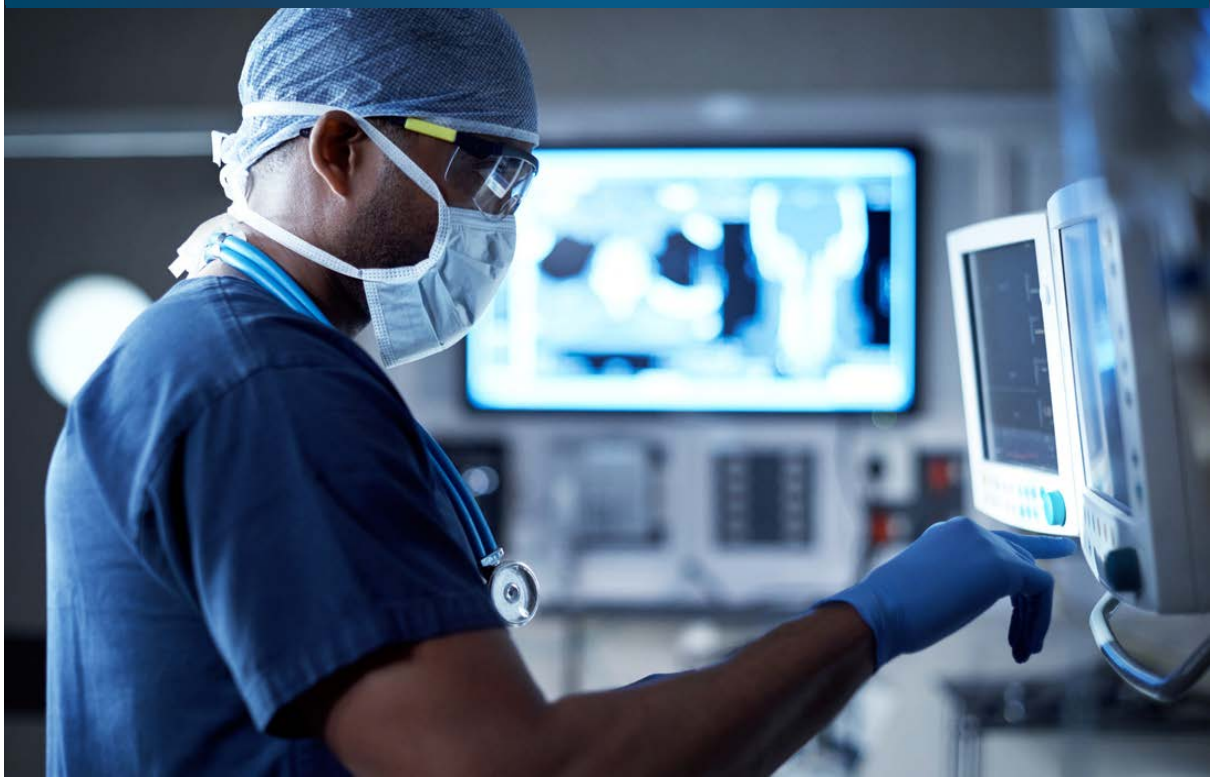
PROCUREMENT GUIDANCE



Medical Diagnostic Imaging (MDI) Equipment

Understanding how to procure Medical Diagnostic Imaging equipment

THE WORLD BANK
IBRD • IDA

Published February, 2019 – First Edition

The authors of this document would like to recognize the contribution and support received from the World Bank Health, Nutrition and Population Global Practice and from the health industry.

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Common Abbreviations and Defined Terms

This section explains the common terms and abbreviations used in this guidance. Defined terms are written using capital letters.

Abbreviation/term	Full name/ definition
AFR	Bank region: Africa
Bank	The World Bank, comprising IBRD and/or IDA (whether acting on its own account or in its capacity as administrator of trust funds provided by other donors).
CAGR	Compound Annual Growth Rate
CAT	Computerized Axial Tomography
CMS	Centers for Medicare & Medicaid Services
COCIR	The European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
CPF	Country Partnership Framework
CR	Computed Radiography
CT	Computed Tomography
DICOM	Digital Imaging and Communications in Medicine
DIMS	Digital Image Management System
DITTA	Global Diagnostic Imaging Healthcare IT & Radiation Therapy Trade Association
DR	Digital Radiography
DSV	Diameter of Spherical Volume
EAP	Bank region: East Asia and Pacific
ECA	Bank region: Europe and Central Asia
ECRI	Emergency Care Research Institute or ECRI Institute
EMMP	Equipment Maintenance Management Program
EPI	Echo-Planar Imaging
ESR	European Society of Radiology
FDG	Fluorodeoxyglucose
FOV	Field of View
GHTF	Global Harmonization Task Force
GP	Global Practice
GPO	Group Purchasing Organizations
HTA	Health Technology Assessment
IDA	International Development Agency
IDN	Integrated Delivery Networks

IEP	The Bank's Industry Engagement Program
IHE	Integrating the Healthcare Enterprise
IHN	Integrated Health Networks
IMDRF	International Medical Device Regulators Forum
IPF	Investment Project Financing
IPR	Intellectual Property Rights
IVD	In Vitro Diagnostic
LAC	Bank region: Latin America and the Caribbean
Lots	Where a single procurement process is divided into packages or lots. The use of lots potentially allows for multiple providers to be appointed following one procurement process.
MAB/P	Most Advantageous Bid/Proposal
MEAT	Most Economically Advantageous Tender
MES	Managed Equipment Services are long-term partnerships between healthcare facilities and technology providers.
MHUs	Million Heat Units
MNA	Bank region: Middle East and Northern Africa
MOS	Monthly Operational Summary
MRA	Magnetic Resonance Angiography
MRI	Magnetic Resonance Imaging
MRIO	Multi-Region Input-Output system
MS	Managed Services
NCB	National Competitive Bidding
NCD	Medicare National Coverage Determination manual
NNP	Health Nutrition Population
nsec	Nanosecond
O&M	Operation and Maintenance
OECD	Organization for Economic Co-operation and Development
OEM	Original Equipment Manufacturer
PACS	Picture Archiving and Communication System
PAD	Project Appraisal Document
PDOs	Project Development Objectives
PEP	Patient Encounter Pricing
PET	Positron Emission Tomography
PFI	Private Finance Initiative

PID	Project Information Document
PMU	Project Management Units
PPP	Public-Private Partnership
PPSD	Procurement Project Strategy for Development
R&D	Research and Development
RF	Radio Frequency
SAR	Bank region: South Asia Region
SCC	Special Conditions of Contract
SPECT	Single Photon Emission Computed Tomography
TCO	Total Cost of Ownership
TOF	Time of Flight
VfM	Value for money
WHO	World Health Organization

Contents

Section I. Introduction

Guidance Overview

This guidance has been prepared to assist Borrowers and Bank staff responsible for implementing Investment Project Financing projects involving the procurement of Medical Diagnostic Imaging (MDI) equipment. It provides detailed advice on how to procure the different types of equipment. It covers aspects of project preparation, procurement, and project delivery and is designed to support both technical and procurement specialists.

The document has been written in a modular form so that readers can either read the whole document, which is recommended, or just the section related to their area of interest.

There are nine sections in the guidance:

Section I	Introduction to the guidance and details of its purpose.
Section II	Outline of the scope of the guidance and its objectives.
Section III	Overview of the Bank's Industry Engagement Program (IEP) and an outline of the recurring procurement issues that result in sub-optimal procurement and project outcomes.
Section IV	A brief introduction to the Bank's Project Cycle and ideas on how engagement with the MDI equipment industry can provide input and support in developing the optimum solution for a project.
Section V	Precis of the procurement process.
Section VI	Detailed explanation on drafting specification and a technical overview of some of the key parameters associated with different types of MDI equipment.
Section VII	Comprehensive explanation of how to design a procurement approach for MDI equipment, with specific focus on different commercial models, pricing and costing mechanisms, selection arrangements, bid / proposal evaluation, total cost of ownership (TCO), and contract management.
Section VIII	Industry Engagement Program Market Analysis. A synopsis of the Bank's market research undertaken as part of the IEP, providing information that can be used to support the preparation of a Project Procurement Strategy for Development (PPSD).
Section IX	In conclusion, a summary of the key information and analysis provided in the guidance and how a procurement arrangement could look when applying this best practice.

The guidance has been designed to supplement the Bank's existing procurement guidance and other sources of information such as Public-Private Partnerships at https://pppknowledgelab.org/

Purpose

This guidance is non-mandatory and is designed to serve as a practical guide to undertaking procurement in the MDI equipment sector, in order to achieve Value for Money (VfM) and improve overall project outcomes.

This guidance should be used in conjunction with the Bank's *Procurement Regulations* and other guidance documents, such as *Project Procurement Strategy for Development*, *Value for Money* and *Contract Management*.

This guidance is one of the priority interventions that has been identified as part of the Bank's Industry Engagement Program (IEP) with the MDI equipment sector. The Bank acknowledges and expresses its thanks to the firms, trade bodies and industry associations for their contributions.

Section II. Scope

MDI Equipment

The scope of this guidance is the MDI equipment sector. MDI equipment refers to several different technologies that use various imaging methods to scan and image the human body to diagnose, monitor or assess treatment of medical conditions. This guidance covers different types of procurement approaches, such as: lease, buy, and service-based delivery, including the procurement of support and maintenance.

Objectives

The primary objective of this guidance is to highlight, and help fix, recurring challenges in the procurement of MDI equipment. This guidance provides:

1. A practical guide on how to undertake MDI equipment procurement and how to deliver optimal procurement solutions, VfM, and enhanced project outcomes;
2. An overview of the Bank's Project Cycle, stages in the procurement process and the procurement approaches available to Borrowers;
3. An overview of the MDI equipment market;
4. An analysis of market research findings, with a focus on the issues identified, including procurement-related complaints;
5. Procurement risk analysis, and tools and techniques to support the development and analysis of bids/proposals.

Market Scope Classified by Products

The range of MDI equipment products covered by this guidance include:

1. **X-Ray Systems:** X-Ray technology is the oldest and most commonly used form of MDI equipment. X-Rays use ionizing radiation to produce images of a person's internal structure by sending X-Ray beams through the body, which are absorbed in different amounts depending on the density of the material. Also included in X-Ray devices are mammography, interventional radiology, computed radiography (CR) and digital radiography (DR);
2. **CT Scanners:** CT, is also known as a Computerized Axial Tomography (CAT) scan. It is a medical imaging method that combines multiple X-Ray projections taken from different angles to produce detailed cross-sectional images of areas inside the body. CT images allow doctors to get very precise, 3-D views of certain parts of the body, such as soft tissues, the pelvis, blood vessels, the lungs, the brain, the heart, abdomen and bones. CT is often the preferred method of diagnosing many cancers, such as liver, lung and pancreatic cancers;

3. **Ultrasound Systems:** Diagnostic ultrasound, also known as medical sonography or ultrasonography, uses high frequency sound waves to create images of the inside of the body. The ultrasound machine sends sound waves into the body and can convert the returning sound echoes into a picture. Ultrasound technology can also produce images of internal organs and structures, map blood flow and tissue motion, and provide highly accurate blood velocity information to assess patient's health;

4. **MRI Systems:** Magnetic Resonance Imaging (MRI) is a medical imaging technology that uses radio waves and a magnetic field to create detailed images of organs and tissues. MRI has proven to be highly effective in diagnosing many conditions by showing the difference between normal and diseased soft tissues of the body;

5. **Nuclear Imaging Systems:** Positron Emission Tomography (PET) and Single Photon Emission Computed Tomography (SPECT) are the primary nuclear imaging systems comprising this type of product. PET is a nuclear imaging technique that provides physicians with information about how tissues and organs are functioning. PET, often used in combination with CT imaging, uses a scanner and a small amount of radiopharmaceuticals which are injected into a patient's vein to assist in making detailed, computerized pictures of areas inside the body. SPECT is a nuclear tomographic imaging technique that uses gamma rays.

These products can be further segmented by technology, portability, architecture and functionality into individual products (See Figure I).

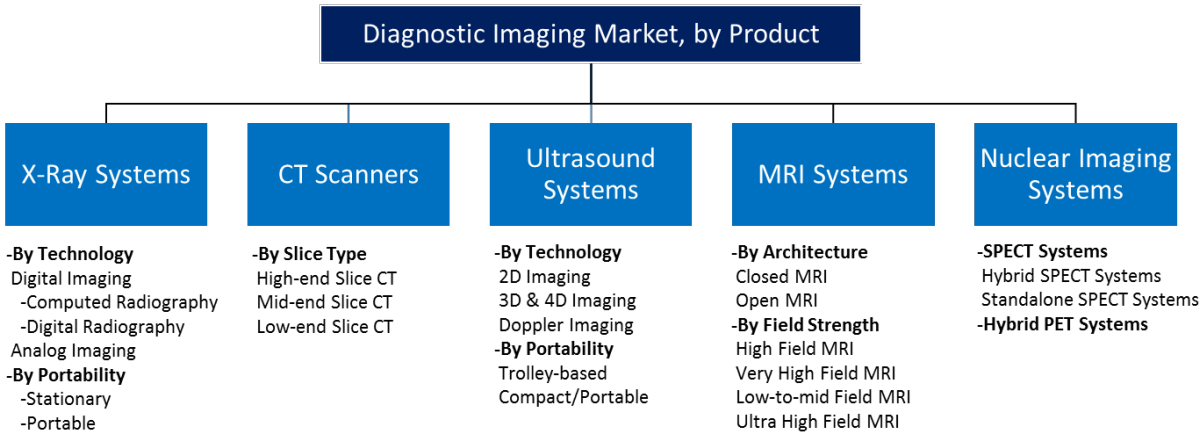

Figure I - MDI equipment by products

Section III. Industry Engagement Program

Industry Engagement Program

The Industry Engagement Program (IEP) has been established by OPCS to fix recurring procurement challenges in important, specialist project areas to improve readiness for project implementation, and drive better overall value for money. It was set up as part of Management's commitment to the Board (July 2015) to establish an IEP to improve procurement outcomes.

The Bank's IEP worked closely with industry sector experts (both on the client and the supply side) to identify and address recurring procurement challenges in Bank financed projects. The principal objective is to achieve improved procurement and development outcomes. The other IEP objectives are to:

1. Motivate the right companies to bid;
2. Speed up procurements;
3. Improve readiness for project implementation;
4. Reduce complaints;
5. Reduce the costs of bidding (for Borrowers and suppliers);
6. Achieve VfM in delivering better outcomes and results;
7. Bring greater transparency to the bidding process.

The IEP involved detailed market research following the principles and approach contained in the Bank's Long Form Project Procurement Strategy Document Guidance (PPSD). MDI industry feedback was sought through a series of global outreach events. The analysis of the market research provides the Bank and Borrowers with the necessary information to identify the key risks and issues that constrain the delivery of effective project outcomes, undermine procurement processes, and limit the achievement of optimum VfM. The outputs of the market research and industry consultation have been to identify a series of interventions designed to improve VfM, as well as procurement and project outcomes.

Procurement-Related Complaints

This guidance has been written to help provide solutions to recurring procurement issues that have been identified through market research and industry engagement. Such issues result in sub-optimal procurement outcomes and have led to procurement-related complaints. Complaints slow down the procurement process, damage the integrity of individual procurements, cause reputational damage to both the Bank and Borrowers, and undermine the delivery of VfM, better outcomes and enhanced results.

An essential element of delivering sustained improvement in the procurement of MDI equipment requires understanding of procurement problems at the right level of detail to develop appropriate fit-for-purpose procurement interventions to fix them.

The Bank captures procurement-related complaints and tracks information regarding the opening and closing of a complaint, the nature of the complaint, and any documentation related to the complaint.

Table I shows the results of a recent review (2017) of the total number of MDI equipment procurement related complaints by region. The highest was Latin America and the Caribbean Region and the lowest was Africa. Projects with medical equipment procurement within the Middle East and Northern Africa (MNA) and East Asia and Pacific (EAP), did not have procurement related complaints, and are not included in this analysis.

Bank Region	Percentage of total complaints
Latin America and the Caribbean Region (LAC)	31%
Europe and Central Asia (ECA)	30%
South Asia Region (SAR)	27%
Africa (AFR)	12%

Table I – Breakdown of total complaints by region

Table II shows the total number of complaints by procurement method. These results indicate that since these projects typically involve higher-value medical equipment, international competitive bidding is the most commonly used procurement method.

Procurement method	Percentage of total complaints
International Competitive Bidding	84%
National Competitive Bidding (NCB)[1]	8%
Other methods	8%

Table II – Breakdown of total complaints by procurement method

Table III shows the percentage of complaints related to each stage of the procurement process.

Procurement stage	Percentage of total complaints
Specific Procurement Notice	2%
Bidding/Procurement Documents (as issued by the Borrower)	25%

[1] NCB as under Procurement Guidelines

Bid opening/minutes	4%
Opening of Technical Proposals/minutes	2%
Bid Evaluation Report and Recommendation for Award	53%
Signed Contract	8%
Contract Completion	6%

Table III – Breakdown of total complaints by stage in procurement process

The two procurement stages that account for over 75% of complaints are:

1. Bidding/Procurement Documents (25%);
2. Bid Evaluation Report and Recommendation for Award (53%).

Complaints on Bidding/Procurement Documents mostly focused on the technical specifications. The complainants stated they were either too specific or targeted/biased towards certain manufacturers and/or distributers. Concerning the bid evaluation and recommendation for award stage, complaints focused on disqualification of bids, qualifications of other/awarded firm, technical specifications, and irregularity in bid/financial evaluation, where criteria were either not objectively neutral or the evaluation was biased towards a particular equipment supplier. These factors are further considered in this guidance.

The average time from when a complaint is first received by the Bank to when it is considered closed, is 78 calendar days. This means that, on average, a complaint can add an additional 2.5 months to a procurement process in order to resolve any issue brought forward by bidders/proposers and before the contract can be awarded.

Engagement with MDI equipment manufacturers has provided further insight into issues observed from a supplier's perspective. Table IV below contains a summary of the main points raised.

Procurement stage	Issue
Specific Procurement Notice	The procurement notice does not provide the full scope i.e. a comprehensive description of the type of MDI equipment to be procured.
	More detailed market research is needed by qualified staff, including vendor input, to develop clearer specifications and understand the most appropriate clinical solution.
Bidding/Procurement Documents (as issued by the Borrower)	Bids ask for references that sometimes cannot be provided due to confidentiality of contract data.
	Bids ask for references where the contract amount is considered too high.

Procurement stage	Issue
	The Special Conditions of Contract (SCC) should include specific wording for the Letter of Credit and detail how liquidated damages are to be fixed.
	Electronic bidding should be used more widely, as document delivery can take, on average, an additional three working days.
	The specifications lack clarity as to the intended use and what MDI equipment needs to be provided.
	Product specific specifications are used which limit/restrict competition as opposed to specifications that describe the technical requirements, clinically relevant, salient characteristics and desired performance, outputs and outcomes.
	Performance Based Specifications are preferable, but are not frequently used.
	Lack of transparency, as not all suppliers are notified of the procurement and specifications.
	Limited opportunity for suppliers and vendors to ask clarifying questions, provide feedback or take exception to unclear specifications.
Bid Evaluation Report and Recommendation for Award	Not always a clear statement on the technical and clinically relevant evaluation factors (e.g., training, implementation, past performance, efficiency, workflow, cost savings, service costs, life cycle ownership costs, etc.) which inhibit a supplier's ability to be able to provide innovation and good value.
	Lack of use of two-envelopes and two-stage bidding which means that the provision of more expensive but technically more advanced MDI equipment is constrained, limiting the use of effective VfM evaluation that uses rated criteria.
	There is limited transparency in providing: the justification for the contract award, VfM evaluation, information on other losing suppliers, and the process for protest or redress. There is an opportunity (when sending the Notification of Intention to Award) to notify suppliers of the decision, the identity of the successful supplier, contract award amount, specific product purchased, justification for award (with

Procurement stage	Issue
	redacted confidential information), and the relative strengths and weaknesses of the unsuccessful supplier's proposal.
	Risk transfer is not balanced as a Manufacturer's Authorization Form puts liability on the manufacturer for risks that should be considered as the accountability of the distributor / value added reseller.
	Escalation processes are not clear for a supplier to inform the Bank of any complaints.

Table IV – Issues at different stages in the procurement process

In addition, engagement with industry and Bank staff has identified multiple procurement problems that are consistent across all product lines[2]. These include:

1. Procurement opportunities are not always publicly available in advance;
2. Specifications lack definition and can be biased;
3. Capacity to undertake technical evaluation can be low across both Borrowers and the Bank.

[2] World Bank Large Medical Diagnostic Equipment Workshop, December 8, 2016, Washington, DC, input from industry.

Bank's Project Cycle

The Bank provides support, oversight and supervision as projects progress through the various stages of the Banks' project cycle. This guidance focusses on stages 1-5 of the project cycle (see Figure II).

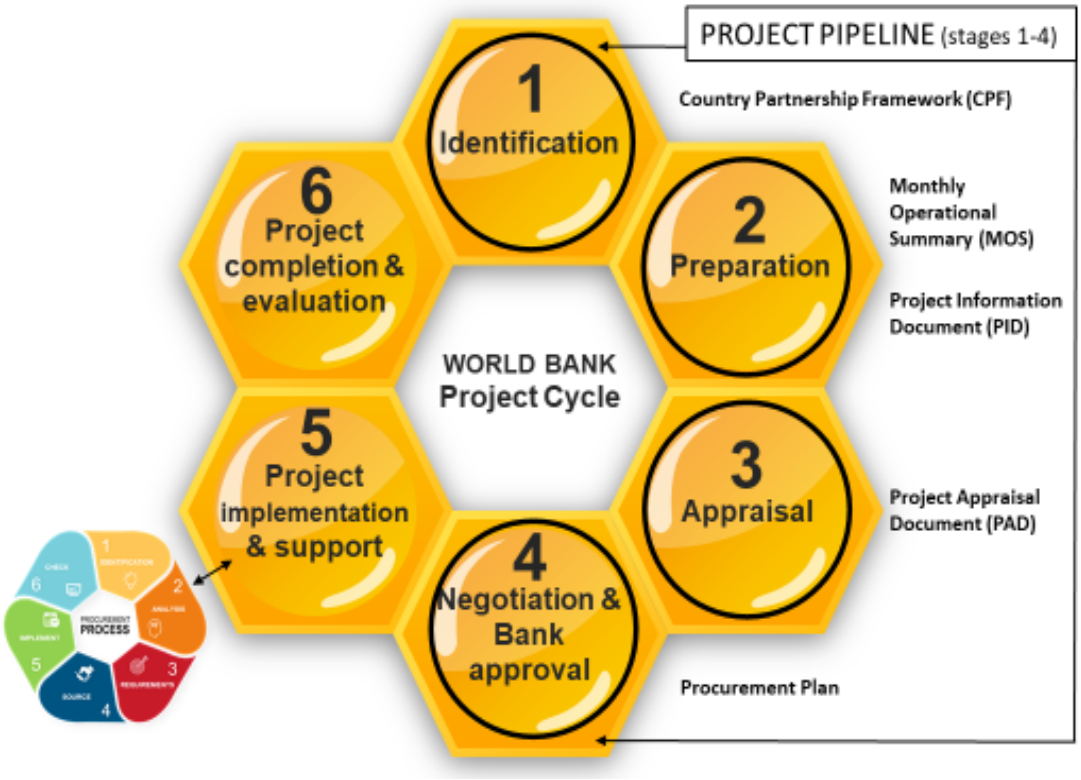

Figure II – World Bank's project cycle

Collectively, the first four stages of the project cycle are known as the "project pipeline". This pipeline comprises projects at various stages of development, before obtaining Bank approval for funding, and before going to the bidding, selection, contracting and implementation (at stage 5).

The MDI equipment sector is rapidly evolving, not only in terms of technology, but also in terms of how industry provides MDI equipment to its customers. For that reason, Borrowers and Bank staff are encouraged to involve industry at the earliest possible stage in the project cycle. Early engagement with industry will help establish the optimum solution for a particular project, based on its unique requirements and operating environment.

Table V summarizes the procurement processes during the first five stages in the project cycle.

Stage	Procurement process
STAGE 1 **Identification**	1. During this stage, the Borrower and the Bank are involved in defining the concept and scope of the project. This is to clarify and confirm that the proposed project development objectives effectively contribute to, and address, the Borrower's development objectives, and are aligned with the Country Partnership Framework (CPF). 2. When the project identification is completed, a Project Information Document (PID) will be published on the World Bank's *Project Database* (at Stage 2). 3. The PID includes contact information for the Borrower's project implementing agency, as well as identifying the Bank's Team Leader. 4. For health sector projects, which may involve procurement of MDI equipment, this stage presents a unique opportunity for the Bank to engage with industry experts to determine project outcomes based on clinical needs.
STAGE 2 **Preparation**	1. The Borrower is responsible for the work done at the preparation stage. This is when the technical and institutional alternatives for achieving a project's objectives are identified and discussed. 2. Preparation usually requires feasibility studies followed by more detailed studies of the alternatives that promise to yield the most satisfactory results. An environmental assessment is usually carried out during this phase. 3. Market analysis and preparation of procurement strategies (i.e., the PPSD) usually start at this stage. During market analysis the Borrower will research the supply market to identify: a. the number and types of suppliers available (nationally and/or internationally, if appropriate); b. pricing structures; c. total costs of ownership; d. new or emerging solutions or technologies. 4. The Borrower may also test its proposed solution by undertaking market soundings and getting feedback from suppliers. Such direct engagement with the market at this early stage needs to be carefully managed to ensure that it is done in a fair and transparent way and does not advantage or disadvantage one supplier over another. Threshold values for procurement approaches and methods vary by category and country. For details see Bank Guidance: *Thresholds for procurement approaches and methods by country*. 5. Industry experts and independent trade bodies should be consulted during this stage, as they are well suited to advise on fit-for-purpose equipment which best satisfies the clinical needs of the project. The Bank has also established a Framework Agreement (MDI equipment Expert

Stage	Procurement process
	Panel) with several consulting firms and individuals, from which Borrowers can source, and pay for, technical and procurement support. Reference the Bank's guidance *How to select and contract a Medical Diagnostic Imaging MDI specialist*.
STAGE 3 **Appraisal**	1. At the appraisal stage the Bank is responsible for undertaking a comprehensive review of all aspects of the project (technical, institutional, economic, and financial). This lays the foundation for implementing the project and evaluating it when completed. 2. Project appraisals are conducted by Bank staff. In addition, staff may be supplemented by external expert advice. The Bank has established a Framework Agreement (Expert Panel), from which the Bank staff can source, and pay for, technical support and procurement advice. 3. At the end of Stage 3, a Project Appraisal Document (PAD) is published and is available from the *World Bank website*. 4. Market engagement can take place in this stage as details of the procurement approaches to deliver the project are included in the PAD. The Borrower may engage with the market as part of market research to ensure that the Borrower has developed procurement approaches that fit with the market. 5. Market engagement can be done in several different ways including concept viability exercises, supplier questionnaires, market sounding exercises, supplier conferences, trade events, paid for market research, and publication of preliminary (outline) procurement strategies for consultation. 6. At this stage, some Borrowers may start procurement before the Bank loan has been approved. This is called "advance procurement". Such opportunities are advertised on the *UNDB website*.
STAGE 4 **Negotiation and Bank approval**	1. During stage four the Bank and Borrower negotiate the Investment Project Financing (IPF). The agreement reached is recorded in the draft loan, credit or grant documents. 2. These documents are required for IPF funded projects. The Bank reviews the PPSD and Procurement Plan as part of the project appraisal. The Bank and Borrower agree on the Procurement Plan no later than completion of loan negotiations. 3. Upon completion of negotiations, the project is then presented to the Executive Directors of the Bank for their consideration and approval. Following approval, the loan, credit or grant agreement is signed.
STAGE 5 **Implementation**	1. Following Bank approval, the loan, credit or grant is declared effective. Implementation gets underway normally a few months after signing.

Stage	Procurement process
	2. Contract opportunities during the project implementation stages are called Operations Procurement. This procurement is led by the Borrower, who is the buyer. 3. Continuous engagement with the private sector during this phase will ensure the procurement process and contract execution will run smoothly.

Table V – Procurement process during the project cycle

Country Partnership Frameworks

Engagement with industry should start as early as possible and the Country Partnership Frameworks (CPF) provide the first opportunity. The CPF addresses the most important challenges and opportunities a country faces in advancing towards the Bank's twin goals of ending extreme poverty and increasing shared prosperity in a sustainable manner. It is developed in partnership between the Bank and the Borrower and is created using a model which is systematic and evidence-based.

During preparation of the CPF, the Bank engages with businesses, and other key stakeholders, to seek their views. The CPF typically covers a 5-year period and details an indicative pipeline of future projects, which lead to future procurements.

The MDI equipment sector will be very enthusiastic about engaging at this stage as this provides the earliest, and potentially the most effective, opportunity to align Bank and Borrower thinking around what the optimum solution is for delivering the health outcomes, how these can align with strategic medical outcomes for a country, and the range of procurement solutions available for meeting these outcomes.

Engagement at this stage also assists in providing industry with visibility of future procurement opportunities and allows individual companies to start planning on whether they are interested in bidding for opportunities, how they may approach bidding and how they will ensure ongoing engagement with a project.

Table VI provides a hypothetical example of projects listed in a CPF lending program.

Indicative FY16-20 IDA Lending Program		
Fiscal Year	**Project Name**	**Amount (US$ million)**
FY16-17	Skills and Training Enhancement	100
	Siddhirganj Power	176
	Ghorashal 4 Power Generation	217
	Private Sector Development	130
	River Management Improvement 1	600

Indicative FY16-20 IDA Lending Program		
Fiscal Year	**Project Name**	**Amount (US$ million)**
	Pro-poor Slums Integration	50
	Regional Waterways	170
	Colleges	100
	Modernization of State-owned Financial Institutions	150
	Insurance and Pensions	80
	Regional Weather and Climate Services	75
	Public Procurement Reform II	9
	Leveraging ICT (AF)	26
	Health Sector Development Program	150
	TOTAL	**2,033**
Note: pipeline project amounts are provisional and subject to change		

Table VI – Example project listing from CPF

Table VII is an example of individual projects developed from the CPF listing.

Project P1234A Health Sector Development Program procurements	
1.	New hospital design, construction and supervision
2.	Existing hospital refurbishment
3.	Large medical diagnostic imaging equipment e.g., MRI's, X-Ray etc.
4.	Medical staff training/education

Table VII - Example health sector projects developed from CPF listing

Monthly Operational Summary

Projects in the pipeline are tracked and publicly reported in the Bank's *Monthly Operational Summary* (MOS). This is a report on the status of each project. Projects appear in the MOS from the point they are identified, up to the signing of the loan/credit agreement (i.e., stages 1 to 4 in the Project Cycle, Figure II). After the loan/credit agreement is signed, entries for projects are dropped from the MOS.

For the MDI equipment sector, the MOS is a valuable summary of upcoming opportunities and provides an early indication of bidding opportunities and timing. This allows the sector to start planning in more detail on how they intend to approach bidding.

Table VIII provides an example of how health projects appear in MOS.

Extracts from MOS April 2018:

Russia

Regional Cancer Care Modernization Project: The proposed Project Development Objective (PDO) is to contribute to the Regional government's effort to improve early access to detection and quality treatment of cancer care services in Tyumen Oblast. Concept completed on 6 July 2016. Environmental Assessment Category B. Project: P151953. US$140.0 (IBRD). Consultants will be required. Federal Ministry of Health, Contact: Mikhail Kramorov, Head of Division, Dept. of Organization of Medical Care; RUSSIAN FEDERATION, Contact: Andrei A. Bokarev, Director, Dept. for International Financial Relations, MOF.

Uzbekistan

(R) Additional Financing for Second Serbia Health Project: The PDO is to contribute to improving the efficiency and quality of the public health system of the Republic of Serbia through the strengthening of: (i) health financing, purchasing, and maintenance systems; and (ii) quality improvement systems and management of selected priority non-communicable diseases. Approval completed on 29 March 2018. Environmental Assessment Category B. Project: P166025. US$31.1 (IBRD). Consultants will be required. Ministry of Health.

Bangladesh

HSDP Additional Finance: To enable the Government of Bangladesh to strengthen health systems and improve health services, particularly for the poor. Approval completed on 24 June 2016. Environmental Assessment Category B. Project: P151070. US$150.0 (IDA Credit). No consultants are required. Ministry of Health and Family Welfare.

Chile

Public Health Sector Support Project: The objectives of the Project are to: (i) improve the efficiency of the public health care sector; and (ii) improve the quality of Non-Communicable Diseases-related health care services. Approval completed on 8 June 2017. Environmental Assessment Category B. Project: P161018. US$80.0 (IBRD). Consultants will be required. Ministry of Health.

Samoa

(R) Samoa Health System Strengthening Program: The Program Development Objective (PDO) is to improve the quality and capacity of the service delivery in Samoa for tackling the rising NCDs. Concept completed on 18 April 2018. Project: P164382. US$ 10.0 (IDA Credit). No consultants are required. Ministry of Health.

Table VIII - Example Health Sector extracts from MOS listing

Stages in the Procurement Process

The Procurement Process is defined in the World Bank's Procurement Regulations as:

> *"The process that starts with the identification of a need and continues through planning, preparation of specifications/requirements, budget considerations, selection, contract award, and contract management. It ends on the last day of the warranty period."*

While each procurement is unique, they broadly follow a similar process. This can be simplified as six key stages. Figure III is a theoretical representation of the procurement process. It shows the common stages and their usual sequencing. Actual procurements may differ.

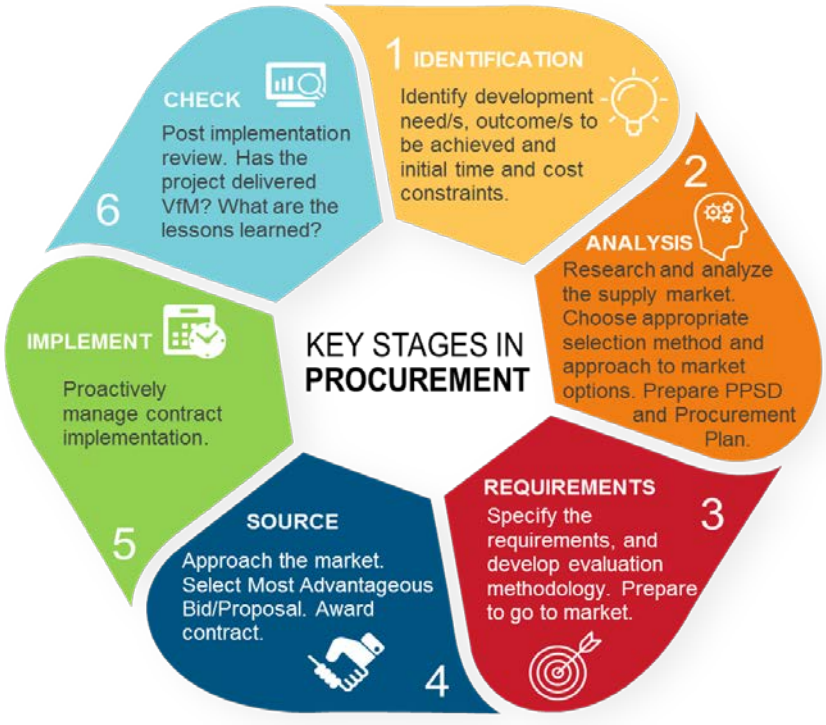

Figure III – Key stages in the procurement process

As mentioned in Section II, the Bank and Borrowers should seek to engage early with the market, e.g., during project identification and preparing the specification of requirements (stages 1 to 3 above). The purpose of such engagement is to carry out market soundings and gain market intelligence to identify what solutions are available or are about to be launched, what technological advances have been introduced, and to identify opportunities for innovation or sustainability, within the MDI equipment sector.

Needs Assessment for MDI Equipment

As part of the project identification in stage 1 (Figure III) a needs assessment should be undertaken. Before initiating the procurement of any MDI equipment, it is important to consider the overarching goals of the health facility. Most well-run hospitals and hospital systems have a multi-year strategic plan that clearly defines priorities and guides major procurement decisions. While the obvious general goals may be the reduction of death and the burden of disease, there will be other more specific goals, determined by the type of hospital.

For example, a general hospital is meant to serve a wide cross section of the population, while a specialty hospital will have a high volume of patients around certain diseases or conditions and require more specialist equipment. If the hospital is a teaching facility, or is used for clinical research and studies, the most current and more sophisticated versions of MDI equipment will be desired.

With the increasingly rapid speed of innovation and commercialization of medical technologies, and their rising costs as a percentage of hospital budgets, some hospital administrators, clinicians and public policy officials rely on Health Technology Assessments (HTA). An HTA is a scientific examination and report on the use of a particular technology for a specific health problem. The HTAs review various aspects of the technology, including alternatives, efficacy and cost, including the analysis of the evidence associated with a technology and whether the evidence supports its use for a given application or condition.

National and international professional medical societies, organizations and practice groups focus around various specialties, e.g., cardiology, oncology and trauma, issue a wide range of reports and studies, including the use of MDI for particular conditions. These expert findings and experiences may shape a hospital's equipment selection.

Some healthcare systems are centrally regulated and must follow prescribed practices established by the Ministry of Health, or another government body, in determining which modalities of equipment are needed, and within each type, what level of sophistication.

In OECD countries, there are generally accepted recommendations for how many units of a certain modality make sense for a given population size. For example, for every [X ,000] people, one CT scanner makes economic and operational sense. Given the diversity across country demographics, epidemiology patterns and healthcare systems, there is currently no global standard in place.

In planning for rehabilitation or modernization versus a greenfield site, it is important to conduct an audit of existing equipment, including age, condition and usage. Equally important is an inventory of the existing human resource capabilities and identification of gaps.

The following questions can further guide the decisions around MDI equipment needs:

1. **Type of facility:** general or specialty, teaching/research;
2. **Location of facility:** rural or urban;
3. **Size of facility:** including any plans for expansion;

4. **Special infrastructure needs**: including floor loading for heavy scanners (MRI) and power quality requirements of high end MDI systems;
5. **Number of patients**: current and forecast;
6. **Number of exams**: per day/month/year for the specific MDI modality being considered;
7. **Epidemiological data**: and trends;
8. **Other facilities**: nearby or planned;
9. **Adequate staff**: and if not, what are the plans to bring on additional staff;
10. **Hospital standards**: which local, regional or international standards are applicable to the hospital;
11. **Personnel standards**: which standards apply for health professionals;
12. **Cultural considerations**;
13. **Maintenance**: technology maintenance requirements, including staffing requirements for maintenance activities and current and future capacity;
14. **Training and education**;
15. **Specific needs**: is there a need for pediatric imaging? Are there any obese patients?

Regarding technical specifications for each piece of equipment, it is important to involve specialized hospital planners, biomedical engineers, medical physicists, and end-users. A variety of software tools and fee-based subscriptions are available that provide planning templates for configurations based on inputs of variables. For example, tools are available from ECRI or Attainia.

Pre-market Engagement and Reverse Marketing

Pre-market engagement is a procurement technique that enables Borrowers to engage, and consult with potential bidders, and suppliers across the market, before a procurement opportunity goes to market. The purpose is to inform the specification of requirements, help identify the best procurement approach, and to attract the right level and type of supplier participation. It is particularly useful if there is a need to create a market or increase supplier participation because of a lack of market interest, especially where there is an incumbent supplier, or the requirement are new and warrants innovation. This engagement can continue until bidding documents are issued or made available for purchase by project implementing agencies. Once bidding documents are issued any subsequent engagement is part of the procurement bidding process.

Reverse marketing refers to the situation in which a Borrower encourages a market place and suppliers within it, to enter that market and bid for opportunities that they had not planned to bid for, normally for reasons of awareness or "attractiveness" of the opportunity. The term is based on the concept that marketing involves creating demand for something that can be sold, while reverse marketing involves stimulating supply for a pre-existing demand.

The MDI market research and feedback from the marketplace indicates that there is a need for both activities to reposition MDI procurements as a more attractive proposition for potential bidders.

For more information on pre-market engagement, including methods and tools, see Annex 2.

Fit-for-Purpose Procurement

Fit-for-purpose is one of the Bank's Core Procurement Principles. These Principles are listed in the Bank's *Procurement Policy*. Fit-for-purpose means:

> "*…the effective, efficient, and economic use of resources, which requires an evaluation of relevant costs and benefits, along with an assessment of risks, and non-price attributes and/or life cycle costs, as appropriate. Price alone may not necessarily represent value for money.*"

The Bank's Procurement Regulations provide a variety of selection methods, and market approach options, that allow each Borrower a degree of flexibility in designing individual procurement processes that are proportional and fit-for-purpose (see *Procurement Regulations* Sections VI and VII). For each IPF financed project, the Borrower is required to prepare a PPSD and Procurement Plan. This is done as part of the initial scoping and planning. The PPSD analysis determines the optimal way to approach the market and conduct the procurement to deliver the best procurement results.

The Borrower and Bank staff (HNP Global Practice and Procurement Global Practice) work together to undertake the analysis and develop the most appropriate procurement approach.

Section VI. Specifications

Overview

Drafting specifications for MDI equipment is critical to delivering the required project outcomes. An analysis of complaints made to the Bank's Borrowers associated with the procurement of MDI equipment indicates that 25% of complaints relate to concerns of biases and weaknesses in specifications and bid documents.

Finalizing the project's procurement specification should take place after the market analysis has been completed. However, considerations of how requirements could be specified should take place as early as Stage 1 of the Project Cycle (Figure II). This helps ensure adequate information is available to allow requirements to be fully developed. For health sector projects, which may involve procurement of MDI equipment, this stage presents a unique opportunity for the Bank and Borrower to engage with industry experts to determine the project outcomes based on clinical needs. As the project moves into Stage 2 of the Project Cycle (Figure II) clear specification of the clinical need becomes even more acute. At this stage it is important to consider the range of technical and institutional alternatives for achieving the project's objectives.

Market analysis and preparation of procurement strategies (i.e., PPSD) for MDI equipment usually start at this stage. The PPSD is linked with the drafting of specifications because it identifies the risks and risk management plans associated with procurement of the MDI equipment and as such the selection of the appropriate type of specification has critical impact on the procurement approach, and subsequent level of market interest.

During market analysis the Borrower will research the supply market to identify aspects such as new or emerging solutions or technologies, understanding of the different commercial approaches (such as purchase, lease or service-based solutions), and approaches to assessing whole-life costs. These types of decisions have a significant impact on the approach to specification writing and the type of specification that may be most appropriate. At the conclusion of the analysis stage (in the PPSD), Borrowers should have an overview of the following information, which they will consider when finalizing specifications.

1. Lead-time before going to market;
2. Selection of procurement methods (bidding approach and the appropriate Standard Procurement Document (SPD));
3. Transfer of risk between the Borrower and the supplier;
4. Level of supplier innovation;
5. Bid/proposal evaluation method and complexity;
6. Likelihood of delivering the Project Development Objectives (PDOs);
7. Level of supplier flexibility in design and delivery;
8. The level of Borrower control over design and delivery.

As part of this research phase, the Borrower may also test its proposed solution by undertaking pre-market engagement and getting feedback from suppliers operating in the marketplace (refer page 23).

Drafting specifications for MDI equipment requires significant technical knowledge to accurately define the project requirements in clear, concise language. Industry experts and independent trade bodies can be consulted to assist. They are well suited to advise on a fit-for-purpose solution which best satisfies the clinical needs of the project and the marketplace's ability to meet or satisfy these needs. In addition, as MDI equipment is highly technical in nature, external specialist support may be needed to augment in-house capacity. Such support may include assistance in writing the specifications. The Bank has established a Framework Agreement Expert Panel to support both the Bank and the Borrower in undertaking such tasks. Information at [hyper link]

Types of Specifications

Figure IV illustrates the two main approaches to specifying requirements and how these can influence the factors described above. The two main types of specification are:

1. **Conformance specifications:** sometimes known as technical, detailed, input or design specifications;
2. **Performance specifications:** sometimes known as outcome-based specifications.

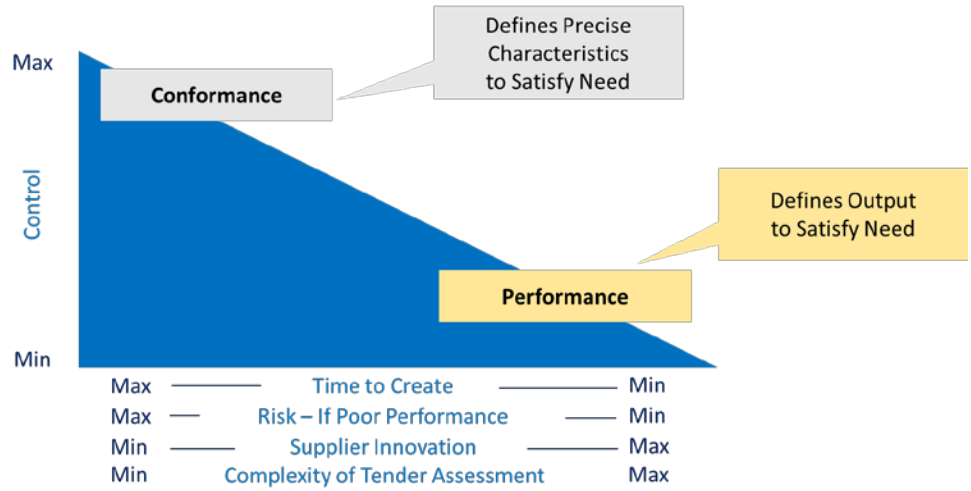

Figure IV – Types of specification ranging from conformance to performance

As a general rule, conformance-based specifications focus on design and resources, whereas performance-based specifications focus on results and outcomes.

Conformance Specification

Conformance-based specifications are used where a full understanding of the requirements already exists. In these circumstances, the Borrower normally has a comprehensive understanding of the need and how it will be met and is able to describe the requirements in

detail. This includes the technical, design, and functional requirements. The Borrower will also be able to describe exactly how the supplier must perform and deliver the requirements.

Conformance specifications generally work best for purchases of goods, services, and works, where there is a focus on defining, e.g., specific quantities, unit price costing, the specifics around the time, place, and manner of delivery and acceptance. Generally, conformance specifications exclude flexibility, unless alternative bids are permitted.

Conformance specifications are suitable to be used for the procurement of MDI equipment. However, there are risks associated with their use. These include:

1. If the specification is incorrect or inadequate, then all the risk lies with the Borrower because the Borrower specified exactly what it wanted:
2. If the specification is written based on the author's personal knowledge, and that knowledge is imperfect, limited or not fully up to date;
    a. The specification may be based on old technology and the Borrower will fail to receive the benefits of new functionality;
    b. The standards set in the specifications may fall below that which the marketplace currently offers (i.e., offers at no extra cost);
    c. The Borrower may be directed towards a type of technology that a facility or environment cannot support.
3. By strictly controlling the technical requirements there is no ability for suppliers to better meet the Borrower's needs, as they are not permitted to:
    a. Identify the best solution, based on their own expert knowledge;
    b. Propose new technology;
    c. Propose innovative solutions.
4. Locking out suppliers from the bid process by producing potentially biased specifications or specifications that inadvertently request a particular technical attribute, that is not widely available, and doesn't add value to the overall requirement.

Many of these risks can be mitigated by accessing specialist support from the Bank's Expert Panel and through pre-market engagement where suppliers may point out any inadequacies in the proposed specification and suggest improvements in the description of requirements.

Performance Specification

Performance specifications should be drafted in a way that provides suppliers the maximum flexibility in meeting the requirements. Performance specifications are used where the understanding of what is required, in terms of outcomes, can be described, but;

1. The Borrower is uncertain of the best process or method to deliver the requirements; or
2. The Borrower wishes suppliers to propose their own solutions; or

3. Suppliers have the capability to design fit-for-purpose innovative solutions.

Performance specifications focus on outcomes or results rather than detailing the precise process of production, construction, and delivery. They are particularly effective in allowing MDI equipment suppliers to bring their own expertise, technology, creativity, and resources to the bid process without restriction. This allows MDI equipment suppliers to propose the best VfM solution, potentially reduce costs and improve quality outcomes. It also passes the risk of both cost and performance (supplying something that delivers the desired outcomes) to the supplier.

Borrowers should consider whether they need to utilize independent experts with the knowledge to specify requirements and assess the utility and the VfM of the different solutions proposed by suppliers.

Using performance specifications for MDI equipment will involve a step change in how Borrowers specify requirements, design procurement approaches and reward suppliers. The use of performance specifications is starting to emerge in Medical Equipment Services (MES) type contracts where patient outcomes are defined as the performance elements of the specification. Suppliers are invited to offer solutions that deliver those outcomes. Performance specifications don't describe the equipment requirements, but rather the key parameters of the required outcomes, along with expected volumetrics. The benefits of this approach include the following:

1. Suppliers are allowed to propose their own design solutions (technical and operational) that result in the full delivery of the required patient outcomes;
2. Demand driven approach that elicits innovation from suppliers;
3. Drives solutions from industry rather than prescribing the equipment and service;
4. Places accountability with the supplier to deliver the outcomes and all the requirements necessary to achieve those outcomes, often linking payment to the supplier on delivery the outcomes;
5. Leads to shared risks associated with some variables, such as volumes of patients (these can be difficult to ascertain accurately over the life time of the contract).

Drafting Specifications

In practice, it is expected that Borrowers will use specifications for MDI equipment that are a combination of conformance-based elements and performance requirements. In drafting specifications Borrowers should consider making as many elements as possible performance-based because this will give the industry freedom to provide the optimum solution.

Irrespective of the specification type, Borrowers should consider the following key points:

1. **End-Users:** The skill levels of the technicians using the MDI equipment needs to be considered. If you are purchasing the most technologically advanced CT scanner for example, determine whether the end-users require additional training on how to properly and safely operate the equipment or how to optimize clinical protocols. Is

training to be provided online or offline and at what cost? Will the end-users have unlimited access to online usage, maintenance, and vendor performance reports? Will these reports be provided at no cost?

2. **Usage:** How often and in what environment will the MDI equipment be used?
3. **Product features:** The circumstances in which the MDI equipment will be used will help determine the list of product features necessary to achieve the desired medical outcomes. Borrowers should ideally undertake a quick survey of the technicians to determine the true needs of the patients;
4. **Needs analysis:** A formal needs analysis can help identify the right equipment to deliver the required project outcomes. Needs should not be constrained by the complexity or integrated nature of identifying a holistic solution to diagnosis and treatment. This can sometimes drive Borrowers towards service-based solutions;
5. **Scope:** Ensure the scope of the specifications reflects the full requirements. It should include all elements, such as installation, training, technicians support, ongoing regular maintenance services, and parts and materials, including the availability of fully trained to support this maintenance. This should also include obtaining information from suppliers on any new or specific safety concerns with the use of the required MDI system;
6. **Innovation:** The market is developing rapidly through significant innovation, not only in terms of technology, but also in how the market delivers value to the customer and end-user.

Specifically, the Borrower should address the points below when drafting and quality assuring specifications:

1. Risks identified in the procurement risk assessment;
2. Key deliverables based on the PDOs;
3. Requirements based on the PDOs;
4. Future needs identified, especially where the contract, project delivery, or asset/service operation is spread over a number of years;
5. Use of plain language, that is precise and unambiguous;
6. Technical accuracy;
7. Clear timescales;
8. SMART performance criteria;
9. Application of appropriate standards, where they exist;
10. Whole-life costing is applied, as appropriate;
11. Availability of replacement parts to support the full operational life;
12. Upgrade availability and technology roadmaps;

13. Health and safety considerations;
14. Flexibility and compatibility for subsequent requirements and/or increased volumes.

Equally, when drafting specifications avoid:

1. Breaching copyright or propriety rights;
2. Excluding areas of risk that are best addressed in the specification;
3. Using trade names;
4. Using brand names;
5. Excluding site information where it is critical that the supplier is aware of health and safety implication, access arrangements, security arrangements, etc.;
6. Using needless acronyms or technical language;
7. Discriminating on the basis of nation, state, or region;
8. Being ambiguous;
9. Being biased towards any particular supplier, brand, or country.

In the end, due diligence will help determine the specifications including the product features required to best serve the needs of the patient. It's important to ensure that the specifications are designed correctly when making such a significant purchase. The final purchase will ultimately come down to the right piece of MDI equipment, that meets the greatest number of the Borrower's needs, offers the best VfM and is the most beneficial to the Borrower and its citizens.

Consider Emerging MDI Market Innovations

Specifications should consider emerging themes with the MDI market, which have been identified as part of the market research undertaken on the MDI equipment sector. Detailed below are an overview of some of these main themes.

Emerging Technologies

The MDI equipment sector is constantly investing in new and emerging technologies to increase their product offering and attractiveness. These emerging technologies may enhance MDI equipment by, e.g., providing better resolution, enabling new modalities, or facilitating portability. The acceptance of emerging technologies varies across the world.

Information Availability

As new technologies are commercialized, MDI manufacturers, distributors, and industry associations have increased efforts to keep clients, in areas where the industry maintains a strong market presence, informed. This is aided by the advances in communication and media, though it still leaves most of the outreach focused in developed countries, where the largest MDI equipment markets are located.

Information on the latest technology, correct use of products, and equipment preservation is not as wide spread or easily assessable in countries that are not considered target markets by MDI manufacturers and distributors.

In some countries research has noted that there is a trend for over-use of patient testing and treatment with MDI equipment. This leads to increased costs for healthcare systems. This could be due to greater access to patient information possible with this equipment, leading health practitioners to avoid any ambiguity by over testing, with several types of MDI equipment.

Pace of Change

All research in MDI equipment technological advances conclude that the pace of change is rapidly accelerating overall. This pace is not only due to advances in core imaging techniques, but also the integration of new digital and analytical technology and overall technology cost efficiencies.

This pace of change does vary when looking at separate markets based on geography. The type of technology, as well as the knowledge base of imaging professionals, seems to change quicker over time in larger MDI markets than does with smaller MDI manufacturer and distributor presence.

Patents and Intellectual Property

Intellectual Property Rights (IPR), patents and counterfeiting have not posed as significant a problem for MDI firms as they have in the pharmaceutical industry. However, the sector is beginning to face related revenue losses with increasing frequency. IPR violations include using medical device firms' patented technology to manufacture a competing medical device or unauthorized use of a registered trademark. Similarly, counterfeit medical devices are copies of patented medical devices that are manufactured and marketed without following the requisite approval process, which can result in unsafe products on the market. There is limited data on counterfeit medical devices, but research has shown that the most frequent incidences are in IVD reagents and solutions, contact lenses, medical test kits and components parts, such as semiconductors used in MDI equipment.

R&D Expense

For MDI equipment manufactures to keep up with new technologies, and to keep competitive in the market, they spend, on average, between 3.5% and 37.7% of their annual revenue on R&D. This is recovered through mark-up on manufacturing cost.

Low Cost Options

MDI equipment manufacturers have been launching new products, at varied price points and across all modalities, to strengthen their presence in the MDI market. MDI manufactures are focusing geographic expansion in emerging markets (such as India, China, and Brazil), and the development of low-cost equipment specifically for developing countries.

Factors such as reimbursement cuts, high competition, and increasing demand for refurbished devices may propel MDI manufacturers to provide technologically advanced MDI systems at low costs for mature markets in coming years.

Refurbished Products

Refurbishment involves restoring equipment to its original condition without altering any of the product's main specifications. The process ensures maintenance of the safety and efficacy of the MDI equipment without altering its performance. Therefore, refurbishment varies from the replacement of worn parts to cosmetic changes.

Usually, the replacement cycle depends on the agreement between the vendor and end-user, but normally this decided mainly by the end-user. New equipment has a life span of about 10 years. Spare part availability is normally available for 7 years from when the equipment is discontinued by the manufacturer. Often equipment replacement is not driven by equipment unreliability, but by technological obsolescence in the world's richer countries. This helps create the supply market for refurbished equipment.

Refurbished equipment tends to have a lifecycle of between 3-5 years. However, as the marketing is relatively immature, it is expected that this will change and extend as the latest equipment with improved operational performance and reliability enters the refurbished market.

When purchasing new or refurbished MDI equipment, price is always a major concern. Not only should the purchase price be taken into consideration but in addition, it is critical to consider how much it will cost to properly operate and maintain the equipment over its lifetime using a Total Cost of Ownership (TCO) model. Considerations such as the cost of replacement parts or consumables, and comparison with other similar makes and models on the market should be factored in. Using a TCO template which compares the whole-life costs of each piece of MDI equipment helps with the decision-making process.

Technical Requirement Considerations for MDI Equipment Categories

Drafting technical specifications for MDI equipment requires specialist technical knowledge. The sections below provide an overview of the technical aspects of each type of equipment and can be used to assist Borrowers in undertaking quality assurance of specifications produced by technical experts. The overview also provides details on other factors that should be considered when making decisions on the exact content of a specification.

CT Scanners

CT scanners work by acquiring imaging data as the scan gantry rotates. Scanner models are for the most part categorized in terms of number of slices that a scanner is capable of processing and this gives an indication of the scanner's capability in terms of speed of coverage. The current scanner ranges are 16 slices, 64 slices, 128 slices, and 256 slices or greater. However, for technical reasons, some manufacturers 'double sample' each detector row resulting in a doubling of the number of slices, but not doubling the volume coverage.

Therefore, some scanners categorized as 64-slice have half the volume coverage of other 64-slice models. The maximum number of detector banks on a CT is currently 160. Both 256-slice and 320-slice technologies achieve this by double sampling. Therefore, Borrowers should be aware of the distinction between the number of detector rows and the number of slices on a CT scanner.

There are also several other factors that can influence a CT scanner's specification. For complex applications, including cardiac, CT require a higher slice technology to enable a larger volume of data to be obtained in a shorter scan time. Other factors that should be considered include patient throughput, but it should also be recognized that this can be heavily influenced by an individual institution's approach to the adoption of skills mix, teamworking, complexity of the examination and patient condition, together with patient referral patterns. In addition, scanner use can be constrained by staffing recruitment and retention issues (radiographic and other clinical staff). Borrowers should also note that a faster examination time does not translate to higher patient throughput, because only a very small proportion of the time a patient spends in a scanner, is used for image acquisition.

Most routine clinical examinations can be adequately performed using a 16-slice scanner. Similar systems with larger gantry apertures, called wide-bore scanners, are appropriate for oncology examinations, scanning bariatric patients and interventional procedures. Systems that acquire more and thinner slices in one rotation allow for more complex examinations (e.g., cardiac) and more varied patient populations (e.g., pediatric, trauma). However, as the number of slices acquired increases, the incremental benefit decreases. The number of slices has a significant effect on the cost of a system.

Many factors affect the radiation dose received by patients, and it is often incorrectly believed that lower-channel systems lead to lower patient radiation doses than higher-channel systems. In fact, if two scans are performed with exactly the same parameters on a 16-channel system and a 64-channel system, the 64-channel system will likely expose the patient to a lower dose. However, the difference is small and is not reason enough to purchase a 64-channel system.

Another major consideration is the system's integration with the picture archiving and communication systems (PACS) already in use in the health-care facility. All digital systems should be compliant with relevant country standards for Digital Imaging, Communication and Integration protocols / profiles

Other Considerations

Whilst comparable scanners from manufacturers differ little in their clinical applications, there are several factors that should be considered in specifying and evaluating CT scanners.[3] These include:

1. Advanced applications, such as cardiac, perfusion, and dual energy imaging;

[3] The CT scanner model being evaluated should be examined while in use and this should ideally be during actual or simulated clinical use rather than in a manufacturer's demonstration room.

2. Dose control technology;
3. Future proofing which means Borrowers should consider whether they anticipate a need to upgrade their CT capabilities in the future. For example, the technological move from a 16-slice system to a 64-slice system requires significant changes in design of the scanner. The detector, analog-to-digital converters, x-ray tube, and processing computer require upgrading;
4. Upgrades, especially as most manufacturers offer intermediate systems e.g., 32-slice and 40-slice systems, especially as the high-specification components are already included or can be easily fitted, thus upgrading to full specification is easier. However, purchasing lower-specification equipment and upgrading later will normally be more expensive overall, but the initial capital investment is lower. There no given rules that govern the upgradability of a system, and some systems may be more easily upgraded than others, but it is essential compatibility standards associated with compliance with relevant country standards for Digital Imaging, Communication and Integration protocols, including cyber-security statements, are considered;
5. Equipment life. For example, the European Society of Radiology (ESR) published a statement about renewal of radiological equipment in 2014, which reported that radiological equipment has a definite lifespan. It recommended replacement of equipment of more than ten years old, citing obsolescence and reduced image quality. Older equipment has a higher risk of breakdown and increased operating costs;
6. Space requirements. Although distributed processing in the construction of CT scanners has eliminated the need for specially air-conditioned computer rooms in some cases, however, airconditioned rooms are often still required. Failure to provide adequate air-conditioning for the computer equipment severely compromises the reliability of the scanner system and ultimately shortens its useful life. CT scanners can be modified for mobile use in trailers, (removing high installation costs and siting problems), with normally only a power source required. However, it is essential that Borrowers consider the quality of images produced by the mobile system as well as any special siting requirements. The ability of a scanner to make artifact-free images often depends on the electrical power energizing the equipment. Surge suppressors and means for automatic disconnection in the event of power failure should be installed. Some scanners that are water-cooled may have special plumbing requirements;
7. Training. The complexity of CT scanners makes adequate training essential. Training normally consists of one or more visits to the healthcare facility by a suppliers' trainer. Initial training periods are usually three to four days, with longer visits available, depending on the in-house expertise and experience. Follow-up training should be arranged three to six months after the initial installation. It should be noted that technician and physician training vary by supplier and therefore being about what is required or being offered is important;
8. Patient groups and examination type. There are advantages to using a 64-slice CT scanner, which is often stated as the optimal size, but this comes at a higher cost. A

16-slice system is adequate for trauma and angiographic applications and can acquire a peripheral angiogram with 2 mm slices (with a scanned length of 5 feet) in less than 30 seconds.

CT technology is mature, and it is unlikely that there will be any major new advances in the near term. However, technical aids to improve clinical interpretation, reporting and display continue to be developed.

Key Specifications

Table IX outlines the key attributes to consider when preparing specifications for this type of MDI equipment.

Category	Measurement	Description
Number of slices	Number	The maximum number of unique slices acquired per single rotation. Conventional thinking is that the greater the number of slices, the better the image quality
Number of detector channels	Number	The components that change the analog signal to a digital value and transfer it to the computer to reconstruct the image
Coverage area	Total detector width, z-axis, mm	The overall coverage for each rotation. This is significant because the image area determines how much stitching of images is required to image an entire organ. The total detector width also determines the number of rotations required and hence scan times. Thus, wider coverage equates to less rotations and faster scan time without compromising image quality
Image resolution	Reconstructed slice width options, mm	The width of the x-ray beam that passes through the patient. Image resolution and patient dose are affected by slice thickness. Smaller slices provide greater spatial resolution but require a larger radiation dose. Manufacturers tend to work on the principle of the lowest as reasonably possible and the benefit outweighs the risk. The size of the slice is dependent on the systems, which can limit the minimum slices that can actually be achieved e.g., a 64-slice system may only acquire ten 0.3 mm slices
Gantry rotation speed	Seconds for a 360° rotation	The time required for the gantry / x-ray tube to rotate once around the patient, with shorter rotation times leading to shorter scan times. Faster rotation times mean shorter temporal resolution with less blurring from the motion.

Category	Measurement	Description
		However, shorter rotation times require higher-power x-ray generators
Contrast resolution	Mm at % at ≤20 mGy (2 rads)	The system's ability to resolve objects with a small difference in density. It is generally measured from a contrast-detail curve, which plots the minimum contrast detectable at various diameters of detail. It reflects overall image quality and defines dose and reconstruction kernel
Tube heating	MHU	The capacity of the x-ray tube anode to store heat generated during its operation. In examinations which require many thin slices, the heat storage capacity of the anode can be a limiting factor in the time between scans[4]
Tube cooling	Heat dissipation rate, kHU/min	The rate at which the anode, in the x ray tube, cools. Faster cooling rates are required for high heat loads generated during rapid multiple-slice acquisition such as high-volume scanning
Image reconstruction interval	Milli-seconds	The time it takes for the computer and associated processors to turn the scan data into an image. Shorter times are better
Maximum image reconstruction rate	Inches per second	The time taken to reconstruct a whole image. When multiple slices (10 to 20) are required, the time can significantly affect patient throughput. Image reconstruction must be fast enough to support workflow and optimum patient throughput
X-ray generator power	kW	Electrical power required to operate the scanner

Table IX – Specification attributes

MRI Scanners

There are a wide range of systems available, from non-enclosed (open) systems that increase patient comfort, to high field strength systems which provide the best image quality. However, different designs, system configurations and functionality involve trade-offs associated with scanning speed, image quality and costs. For example, a higher-strength magnet produces faster and clearer images, but costs more.

The latest imaging techniques are confined to high field strength systems, where certain examinations are only possible using 3.0T or higher systems, while routine examinations are

[4] Heat storage and tube cooling should be considered together.

possible with lower strength systems such as 1.5T but take longer and result in a poorer quality image.

Four major components should be considered when specifying an MRI scanning system:

1. **Static Magnet Field:** The magnet needs to produce a homogeneous magnetic field that covers as wide a field of view and provides as much patient space as possible. The main magnet strengths in use are 1.5T and 3.0T. The major difference between the two is that 3.0T systems offer an improved signal to noise ratio compared to 1.5T systems, but this needs to be considered because 3.0T systems offer better quality, spatial, temporal resolution and reduced acquisition times. The most commonly used magnets are superconducting electromagnets. These consist of a coil that has been made superconductive by helium liquid cooling and immersed in liquid nitrogen. They produce strong, homogeneous magnetic fields, but are expensive and require regular upkeep, namely topping up the helium tank. Other magnet types are resistive electromagnets, which are less costly (whole life cost) and easier to maintain than superconducting magnets. These are far less powerful, use more energy and require a cooling system. The final magnet type is permanent magnets, of different formats, composed of ferromagnetic metallic components. Although they have the advantage of being inexpensive and easy to maintain, they are very heavy and weak in intensity;
2. **Gradient system:** When an MRI system is in a resting state and not actually producing an image, the magnetic field is quite uniform or homogeneous over the region of the patient's body. However, during the imaging process the field must be distorted with gradients. A gradient is just a change in field strength from one point to another in the patient's body. The gradients are produced by a set of gradient coils, which are contained within the magnet assembly. The faster the gradient system, the higher the image resolution, but the smaller the field of view. This is reflected in MRI scanners with a cardiac focus, which sacrifice field of view for faster gradients. Gradient performance primarily depends on strength and slew rate, which is the rate at which the gradient can be switched to the required strength;
3. **Radiofrequency:** The radiofrequency coil on an MRI are the receivers, and sometimes also the transmitters, of radiofrequency (RF) signals in equipment used in magnetic resonance imaging. They can be compared to the lens on a camera. Radiofrequency coils transmit the excitation pulse which rotates the net magnetization in the z plane into the transverse (x-y) plane. Coils also receive the radiofrequency energy from the imaged object. Radiofrequency coils can be divided into three general categories; transmit and receive coils, receive only coils, and transmit only coils. The sensitivity to the MRI signal as well as the amount of global coverage is dependent on the type of radiofrequency coil used for signal reception and the number of channels. Channels are independent, complete electronic chains required for processing information received from a coil segment. Channels include amplifiers, filters, analog-to-digital conversion circuitry, demodulation/mixer devices, and image processing capability. The output of each channel is generally a partial view of the entire anatomy being imaged,

subsequently combined with output from the other channels to produce the final MR image;

4. **Computer system:** The computer system must be able to keep up with the magnet so that images are instantly available while the scan progresses. The most common type of upgrade to an MRI system is via software.

Other Considerations

There are several factors that should be considered in specifying and evaluating MRI scanners.[5] These include:

1. Physical location such as the extent of the magnetic field, the physical footprint of the magnet and the magnet weight;
2. The number of channels of the system. Channel numbers are directly related to a system's image quality or the effectiveness of its parallel imaging capability, with at least 16 channels recommended as the minimum specified requirement;
3. Being aware that resistive and superconducting magnet systems are usually designed and installed to offer a specific, fixed field strength and that changing a field's strength in an electromagnet is time consuming and disturbs the homogeneity of the field. In addition, the radio frequency component is finely tuned and changing the field strength can make radio frequency adjustment impossible, short of replacing the radio frequency component. Although they are not as costly to purchase as other magnet systems, they are also expensive to operate because of higher electrical power consumption;
4. The availability of low-field strength and specialized MRI systems, where these niche systems can be used for examining just head, limb, and joint imaging. This has the advantage of reduced cost and physical footprint (up to 13.9 foot squared), as well as making installation easier because of the smaller size and shield requirements;
5. Non-enclosed systems, low field strengths up 1.2T making patient use easier and less intimidating, as well as helping with the examination of critically ill patients;
6. Non-enclosed systems are also being used for interventional and therapeutic MRI procedures such as catheter insertions, biopsies, cryosurgery because they allow hands-on access to the patient. The 3-D capabilities of MRI systems are useful in planning and performing stereotactic procedures, in which precise correlation between the MR image and the surgeon's field of view is essential. Additionally, the quality of MR images is generally considered superior to that of intraoperative CT images. However, the lower field strength of non-enclosed MRI systems requires longer acquisition times and often sacrifices image quality compared to high field strength MRI systems;

[5] The MRI scanner model being evaluated should be examined while in use and this should ideally be during actual or simulated clinical use rather than in a manufacturer's demonstration room.

7. Stand-up or upright MRI systems offer weight-bearing examinations of patients in standing, seated, or lying positions and can be particularly beneficial for examinations of spinal conditions. Prostate imaging with patients seated on an antenna coil/cushion is another favorable application.

MRI scanners can be modified for mobile use in trailers, removing high installation costs and siting problems, with normally only a power source required. However, it is essential that Borrowers consider the quality of images produced by the mobile system as well as any special siting requirements. For this particular type of equipment, Borrowers should compare costs of service-based contracts (e.g. cost per scan), leasing and purchasing.

Another major consideration is the system's integration with the picture archiving and communication systems (PACS) already in use in the health-care facility. All digital systems should be compliant with relevant country standards for Digital Imaging, Communication and Integration protocols / profiles.

Upgrades and compatibility standards associated with compliance with relevant country standards for Digital Imaging, Communication and Integration protocols, including cyber-security statements, should be considered. These cooperative standards assist communication between various image-based modalities and accessories to each other. Broadly, they focus on workflow of images and provide reliable protocols for integration of image data between imaging, non-imaging modalities, devices and systems, as well as the operations that a Borrower wants to perform on data from a modality. Borrowers should require suppliers to explain in detail what information objects, service classes, and data encoding are supported by their systems. The conformance statements should be requested in the same format using the same vocabulary to facilitate comparisons among suppliers. By specifying data and interface requirements, this helps ensure that devices, particularly those made by different suppliers, can communicate with one another.

Key Specifications

Table X outlines the key requirements to consider when preparing specifications for this type of MDI equipment.

Category	Measure	Description
Patient aperture at narrowest	Type	Apertures vary with non-enclosed (open systems) or closed bore systems, in addition to wide-bore, vertical, or horizontal field design. Closed MRI scanners have higher field strengths and, for comparable image quality, require less scan time than open systems. Systems such as compact, short bore, and ultrashort are closed systems, although some have open

Category	Measure	Description
		sides. Wider-bore (70 cm) and true open designs are also available
Gradient system	Type	The gradient system / technology used to localize the MRI signal and the RF system
Maximum field of view (FOV)	Mm	Field of View (FOV) determines the amount of coverage or usable imaging volume available. This affects the resolution of an image. Good practice is to obtain the smallest FOV as practical
Minimum field of view (FOV)	Mm	Field of View (FOV) determines the amount of coverage or usable imaging volume available. Good practice is to obtain the smallest FOV as practical
Maximum field of view and homogeneity	Cm (x, y, z)	Field of View (FOV) determines the amount of usable imaging volume available. FOV is defined as the size of the two or three-dimensional spatial encoding area of the image. This affects the resolution of an image
Helium / nitrogen refill period	Years	Helium / nitrogen cools the coils, which carry electric current for superconducting magnets, to a temperature close to that of the liquid
Body mass limit	**Kg or lbs.**	The maximum load a scanner can bare
Amplitude / gradient strength	Milliteslas per meter (mT/m) or gausses per centimeter (G/cm); 10 mT/m = 1 G/cm.	Gradient strength is the amplitude of the gradient field. Amplitude is the signal height. The greater the amplitude of the signal, the larger the number of protons in the image and the brighter it will appear. The gradient strength and slew rate must be considered together. Higher gradient strengths increase the spatial resolution possible. They also require faster slew rates, which control the imaging speed and technically demanding pulse sequences. Today, high specification gradient systems are essential for facilities performing advanced studies

Category	Measure	Description
Slew rate	Z-axis, T/m/sec	Slew rates are the speed at which a gradient can be turned on and off and is calculated as the maximum gradient strength of the gradient divided by the rise time. MR imaging is a product of magnetic field gradients which are created by magnetic gradient coils. The quality and performance of a gradient coil will directly impact the quality and resolution of the final image. One of the more important characteristics or specifications of a gradient coil is its slew rate (along with strength of the gradient). The slew rate will help define the maximum scan speed of the system. Therefore, the gradient strength and slew rate must be considered together. Higher gradient strengths increase the spatial resolution possible. They also require faster slew rates, which control the imaging speed and technically demanding pulse sequences. Higher performance systems are required for cardiac imaging.
Number of independent FR receiver channels	Number	The RF systems' number of elements that can be connected simultaneously is important. More elements enable higher density coils (better image quality) and wider area coverage, so patient throughput can be increased. The number of channels significantly affects image quality and scanning speed possible.
Minimum installation area	M^2	Footprint required to house the MRI scanner

Table X – Specification attributes

PET Scanners

PET scanners are used to obtain good quality, detailed images of a body and/or organ and so specifications need to detail and evaluate parameters that will influence how the scanner

performs in image formation. These include spatial resolution, sensitivity, noise, scattered radiations, and contrast. These parameters are interdependent, and if one parameter is improved, one or more of the others is compromised.

The spatial resolution of a PET scanner is a measure of the ability of the scanner to accurately reproduce the image of a body and/or organ, clearly showing the variations in the distribution of radioactivity in the body and/or organ. It is empirically defined as the minimum distance between two points in an image that can be detected by a scanner.

The sensitivity of a PET scanner is defined as the number of counts per unit time detected by the device for each unit of activity present in a source. The higher the sensitivity, the more efficiently the detector can use the available radiation.

Image noise is the random variation in pixel counts across the image. It can be reduced by increasing the total counts in the image. More counts can be obtained by imaging for a longer period, injecting more radiopharmaceutical, or improving the detection efficiency of the scanner. All these factors are limited by various conditions e.g. too much activity cannot be administered because of increased radiation dose to the patient, random coincidence counts, and dead time loss. Imaging for a longer period may be uncomfortable to the patient and improving the detection efficiency may be limited by the design of the imaging device.

The scatter fraction (SF) is another parameter that is often used to compare the performances of different PET scanners. Scatter reduces image quality and must be minimized in all PET imaging. Unlike other nuclear medicine devices, scatter in PET devices is minimized electronically. Lower scatter fraction increases image quality.

Contrast of an image arises from the relative variations in count densities between adjacent areas in the image of an object. Several factors affect the contrast of an image, namely count density, scattered radiations, type of film and patient motion. Each contributes to the contrast to a varying degree.

All PET scanners will provide adequate image quality, but patient throughput will vary. It is impossible to specify patient throughput, since this will depend on the types of exams being performed and the size of the patient. Instead, the sensitivity of a PET scanner is used as a guide to estimating patient throughput. In general, the higher sensitivity correlates to shorter examination time. However, scatter fraction must also be considered, because a higher scatter fraction indicates reduced image quality. Energy resolution can affect the scatter fraction as it is one of the ways PET discriminates between true and scattered photons. Narrow energy resolution reduces the scatter fraction and improves image quality. Recommended values for these attributes include a system sensitivity of >5 cps/kBq, scatter fraction of ≤38%, and energy resolution of ≤15%.

Improvements to the quality of PET images are made by increasing the sensitivity and spatial resolution of the image, which requires an array of detectors that can capture the largest possible fraction of the photons emitted by the target object at the highest possible rate and with the best possible spatial accuracy. In addition, the detectors should possess the highest possible energy resolution to reduce the effects of scattered radiation.

Another major consideration is the system's integration with the picture archiving and communication systems (PACS) already in use in the health-care facility. All digital systems should be compliant with relevant country standards for Digital Imaging, Communication and Integration protocols / profiles.

For facilities looking to conduct PET scans using isotopes with very short half-lives, high detector performance is essential. Low-contrast resolution will detect soft tissue contrast in the image to improve diagnosis and treatment. Borrowers should consider the number of slices acquired, not for image quality, but for those scans affected by patient movement. Exams benefit from higher slice counts, with experts recommending ≥16 slices.

Systems should be capturing true events, which are images that are not effected by loss of detection because of interference.

Other Considerations

There are several factors that should be considered in specifying and evaluating PET scanners. These include:

1. Planning and construction, special permits, and rigorous training for technical staff;
2. Capital costs for establishing a PET center are estimated to range from US$2.5 million to US$5 million. Borrowers should consider that the payback on PET scanners can be more unpredictable than other scanning types;
3. Arranging the supply of isotopes, which can be expensive and very difficult in countries that do not have a local supplier because of the issues of the half-life of isotopes.

Key Specifications

Table XI outlines the key attributes to consider when preparing specifications for this type of MDI equipment.

Category	Measure	Description
Scanner sensitivity	Counts per second per microcurie or megabecquerel	Measures the counting efficiency of the scanner, recorded in counts per second, for a given radioactivity concentration. Sensitivity describes the efficiency of the detector
Scatter fraction	Percentage	The ratio of scattered to total events, reported as a percentage
Image noise	Noise equivalent / effective count rate (NECR)	Image noise is the random variation in pixel counts across the image. The NECR is a measure of image quality
Maximum count rate, cps @ 50% dead time	Percentage	The ratio of scattered to total events. As the number of events (counts) increases, the efficiency of any photon-counting

		device (such as a PET camera) decreases due to dead time. The higher the maximum count rate, the more accurately the system can detect high signal regions, which are very important in PET imaging
Energy resolution	Full width at half maximum FWHM	The ability to accurately isolate and identify the radionuclide photopeak and distinguish it from random or scattered radiation events. Energy resolution is one of the ways that PET discriminates between true and scattered photons, narrow energy resolution reduces the scatter fraction and improves image quality. Full width at half maximum (FWHM) is an expression of the extent of function given by the difference between the two extreme values of the independent variable at which the dependent variable is equal to half of its maximum value
Compliance	Statement	Country standards (often legal standards due to radiological nature of the equipment) in the country of use.

Table XI –Specification attributes

Digital Radiography

Digital X-ray also known as digital radiography (DR), uses X-ray-sensitive plates that directly capture data during the patient examination, immediately transferring the data to a computer system.

Detector-based digital radiography uses different types of solid-state detectors (flat panel detectors and charge coupled devices) as image receptors and an X-ray source for producing high-quality radiographs. The detectors are compact, lightweight and come in various sizes including portable versions. The advancements in detector technology have been the hallmark of digital radiography systems, increasing dose efficiency, image quality, ease of equipment handling and, ultimately, image throughput. It is often considered a complete digital solution for radiography, as it eliminates the need for replacing and processing image receptors, unlike film-based or phosphor-based radiography.

Digital flat panel x-ray detectors dramatically reduce the cost per x-ray image produced, as well as the processing time per image, allowing for potentially instant interpretation for an expedited diagnosis. However, considerable initial investment is associated with installation of such units due to the expensive detector technology. Nevertheless, the long-term cost-

benefits and the reduced dependency on highly skilled operators favor the initial investment in DR technology for the purpose of most diagnostic needs.

DR is more expensive than traditional x-ray (film) technology, but the images are of the highest quality and are seamlessly sent to a computer display. DR has become the "gold standard" for general radiography imaging. Despite all the advances being made across various other imaging modalities, general radiography continues to account for between 40% and 45% of diagnostic imaging examinations performed globally.

Using DR efficiently is influenced by three key elements and these need to be considered when drafting specifications:

1. Producing the highest possible image quality, which is a combination of high resolution, sharp detail, and high contrast;
2. Keeping radiation dose as low as reasonably achievable (ALARA – an acronym used to refer to the guiding principles of radiation safety);
3. Achieving high workflow productivity to accommodate high patient volumes and staff availability as cost effectively as possible and it is for this reason that DR is typically recommended only for high workflow situations.

DR systems are made up of several key components:

1. **A digital image receptor.** The device that intercepts the X-ray beam after it has passed through the patient's body and produces an image in digital form, that is, a matrix of pixels, each with a numerical value;
2. **A digital image processing unit.** The source of a major advantage of DR systems is the ability to process images after they are recorded, and various forms of digital processing can be used to change the characteristics of the digital images. For digital radiographs, the ability to change and optimize the contrast is of great value, and it is also possible to use digital processing to enhance the visibility of detail in some radiographs;
3. **An image management system.** A function performed by the computer system associated with the digital radiography process, consisting of controlling the movement of the images among the other components and associating other data and information with the images. Some of these functions might be performed by the computer component of a specific digital radiology device or by a more extensive Digital Image Management System (DIMS) that serves many imaging devices within a single healthcare facility. It should be noted that it is not unusual for the DIMS to be referred to by an older acronym, PACS (Picture Archiving and Communications System);
4. **Image and data storage devices.** Digital data storage provides multiple advantages to film-based image archiving including rapid storage and retrieval capabilities; the requirement for less physical space for storage, and the ability to copy and duplicate images without the loss of image quality;

5. **Interface to a patient information system.** Known as the Radiology Information System, this is an adjunct to the DR system wherein information such as patient ID, scheduling, actual procedures performed, and other data are transferred;
6. **A communications network**. The ability to transfer digital images from one location to another very rapidly provides for sharing of information within the imaging facility to the storage and display devices across departments and to other locations (including the ability to leverage teleradiology resources off-site);
7. **A display device with viewer operated controls.** These systems deliver the ability of the viewer to adjust and optimize image characteristics such as contrast, and they also provide the ability to zoom, compare multiple images easily, and perform a variety of analytical functions while viewing the images.

Specification for DR should consider:

1. Detector technology (direct vs. indirect);
2. Technical specifications (active area, pixel array, pixel pitch, limiting resolution, MTF, DQE);
3. Communication interface (image acquisition time, exposure control, wireless option);
4. Environmental condition (operating and storage temperature, humidity);
5. Mechanical (dimension, weight, housing material);
6. Power (power dissipation, power supply, frequency, battery backup option);
7. Regulatory requirements ensuring compliance with applicable international standards and regulatory directives;
8. Use and allow for 4-5 hours of uninterrupted work in situations of unreliable or unavailable electrical supply;
9. Resistance to high temperature, humidity and dust, depending on the climate/conditions in which the solution will be implemented;
10. User-friendly operation making best use of available staff skills;
11. Size, for example, small sizes allow for mobile installations, such as in a truck or van, if applicable;
12. Robustness of design and maintenance requirements.

There are two types of detectors which are indirect conversion systems or opto-direct systems, which use a scintillator layered on top of an array with light-sensitive photodiodes with thin-film transistors.

The performance of detectors is determined by several parameters such as spatial resolution, edge spread function, line spread function, modulation transfer function, noise power spectrum and detective quantum efficiency.

The cost of detectors depends upon several factors, such as whether the system is fitted with a born digital machine (complete DR), comes with retrofit version (docked with analogue equipment to convert into DR) or is purchased independent of the other components. Based on the technology, indirect capture detectors are more expensive and more recent than direct capture detectors. Features such as the size of detector, a wireless option and extended battery life are also contributors to variable prices.

For better resolution, a pixel size of at least 150 µm is recommended. Automatic positioning of the detector and x-ray tube, as well as including positioning controls on the x-ray tube, enhance ease of operation and increase workflow.

Another major consideration is the system's integration with the picture archiving and communication systems (PACS) already in use in the health-care facility. All digital systems should be compliant with relevant country standards for Digital Imaging, Communication and Integration protocols / profiles, including cyber-security statements;

DR systems generally perform upright examinations or table-based examinations, for which detector mounting is crucial. Borrowers should assess all types of examinations being performed before deciding which type of system will best benefit their health-care facility.

Other Considerations

The number and types of procedures to be performed will influence the selection of features for the system. Smaller focal-spot sizes provide better spatial resolution on the image receptor for certain studies, and options such as tomography and table tilt can increase the system's overall procedural capabilities.

Elevating tables allow easier patient access and are especially beneficial to health-care facilities handling trauma and emergency cases because the table height can be adjusted to facilitate patient transfer from a mobile stretcher or wheelchair. Generator options should also be considered, as high-frequency generators require less space and often eliminate the need for high-voltage cables.

DR offers many potential advantages over film-based radiography, including storage space reduction, enhanced image processing, and off-site diagnostic capabilities. Some technologists say that exams can be completed three to four times faster with DR than traditional systems.

Key Specifications

Table XII outlines the key attributes to consider when preparing specifications for this type of MDI equipment.

Category	Measure	Description
Table weight capacity	Kg/lb.	Maximum table weight limit should accommodate special clinical needs and requirements (i.e., bariatric).

Focal spot sizes	Mm	The size of a concentrated stream of electrons directed at the target area. A smaller focal spot size produces images with higher resolution, but a larger spot size allows heat to dissipate more quickly, which promotes longer tube life and decreases lag time between exposures.
Control panel on x-ray tube	Control panel	Positioning controls on the x-ray tube enhance ease of operation, thus increasing workflow.
Automatic tube positioning	Yes or No	Automatic positioning of the detector and x-ray tube enhances ease of operation and increases workflow.

Table XII – Specification attributes

Ultrasound Scanning Systems

Medical ultrasound imaging is widely used for diagnostic imaging of internal body structures. It works by transmitting acoustic energy into the body and receiving and processing the returning reflections to generate images of internal organs and structures, map blood flow and tissue motion, and provide highly accurate blood velocity information.

An ultrasound system is normally made up of a beamformer, a central processing unit, a user interface, probes, a video display, a digital recording device and a power unit.

The digital transmit beamformer generates the necessary digital transmit signals with the proper timing and phase to produce a focused transmit signal. High-performance ultrasound systems will generate complex transmit waveforms using an arbitrary waveform generator to optimize image quality.

A critical component of this system is the ultrasound transducer. A typical ultrasound imaging system uses a wide variety of transducers optimized for specific diagnostic applications. Typical transducers can have 32 to 512 elements and operate at frequencies from 1MHz to 15MHz. The higher the frequency of the ultrasound wave, the less it can penetrate, and the lower the frequency, the deeper it can penetrate. The higher the frequency, the higher the axial resolution resulting in better image quality. The lower the frequency, the lower the axial resolution resulting in lower image quality.

The types of transducers used with these scanners include mechanical probes, electronic phased arrays, linear arrays, curved arrays, two-dimensional arrays, and three-dimensional scanning probes based on a combination of the above types. Most ultrasound systems provide two to four switchable transducer connectors to allow the clinician to easily switch among the various transducers for each exam type.

General-purpose scanners are normally equipped with a wide variety of transducers, including:

1. **High-frequency small-parts flat linear array probes** which are used for examinations of the thyroid, breast, scrotum, and musculoskeletal system;
2. **Convex array probes** which are used for abdominal and obstetrical applications;
3. **Microconvex linear array probes** which are primarily used for neonatal brain and other pediatric examinations;
4. **Endocavity transducers** which are designed for prostate imaging and to guide prostate biopsies;
5. **Full-featured systems** are used for general-purpose abdomen and small-parts studies and are used in a hospital's radiology department or in a free-standing imaging center;
6. **General-purpose scanners with vascular capabilities** are used to evaluate blood vessels throughout the body, enabling clinicians to diagnose arterial and venous abnormalities and their causes;
7. **Doppler ultrasound modes** are used for thorough assessments of vascular structures to detect and characterize blood flow in organs and tumors as well as the neck and extremities.

The probes attach to a central processing unit (CPU) or the main computer of an ultrasound machine. The CPU transmits electrical currents that makes the probe emit sonic sound waves. The CPU analyzes these electrical pulses that the probe makes in response to reflected waves coming back. It then converts this data into images that can then be viewed on an accompanying monitor, stored on disk or printed. The display processor performs the computations necessary to map the image as well as performing other spatial-image-enhancement filtering functions.

Ultrasound scanners also include controls or user interfaces that enable the CPU to make adjustments and save images.

Received, beamformed, digital ultrasound signals are processed for visual and audio output using a wide variety of DSP and off-the-shelf PC-based computer solutions. This process can generally be separated into B-mode or 2D image processing, and Doppler processing associated with color-flow image generation and both PWD and continuous-wave Doppler (CWD) spectral processing.

The power unit for an ultrasound scanner is typically a High Voltage Power Supply which provides voltages to drive the probe's elements (array) in the range of +150V/-150V, while a Low Voltage Power Supply provides +3.3/+5/-5/+12/-12/+15/-15 VDC to the back-end and front-end sub-systems. Mobile scanners also have the ability to use battery power or electric power.

Other Considerations

When purchasing an ultrasonic scanning system, Borrowers need to consider the following basic issues:

1. **Functions and features.** There is a general trend towards smaller, lower cost, and more portable imaging solutions. However, it is recommended that the end-users are consulted during the purchase process and users should perform appropriate in-person assessments of the scanners being considered;
2. **Cost.** Ultrasound scanners are relatively low in capital cost compared to other imaging equipment approximately $20,000 to $250,000, depending on system configuration. This means they are normally purchased as leasing is more expensive, while renting is not normally a cost-effective alternative;
3. **Ease of use.** Operator ergonomics should enable height positioning of the keyboard and minimize repetitive strain. Standard operations should be provided by means of remote controls to reduce strain and promote easy use. The scanner must conform to appropriate formal standards for safety and performance;
4. **Upgradeability.** Updates and upgrade pathways should be based on clear and guaranteed pathways for updates and upgrades. Updates should normally be viewed as a form of maintenance and be provided free of charge. It is important to note upgrades will add functionality to the system and so will usually need to be purchased;
5. **Standards.** It is essential compatibility standards associated with compliance with relevant country standards for Digital Imaging, Communication and Integration protocols, including cyber-security statements, are considered;
6. **Image storage.** The scanner should include on-board image management and a storage facility (via CD-RW, DVD or USB port);
7. **Customer support.** Full clinical applications support from the supplier is essential during the commissioning of the scanner. Ideally, this should be provided with minimal reliance on local cascade training and instead be based on continuous support with the initial clinical cases through the scanner. Clinical applications support should be maintained throughout the lifetime of the equipment, both in response to any reported difficulties and for scheduled reviews. Engineering support should be timely and well-informed. Consideration should be given to the inclusion of remote diagnostics, downtime guarantees (or penalties) and a readiness to respond to issues highlighted during local quality assurance procedures. Technical and operating manuals must be provided with comprehensive documentation covering scanner operation and technical support.

Key Specifications

Table XIII outlines the key attributes to consider when preparing specifications for this type of MDI equipment.

Category	Measure	Description
Detail/Spatial Resolution	Transducer specification	The ability of the ultrasound system to detect and display structures that are close together. Since an ultrasound image displays depth into the patient

		and width across a section of anatomy, consideration should be given to two types of spatial resolution, axial and lateral. The ability of an ultrasound system to distinguish between two points at a particular depth in tissue, that is to say, axial resolution and lateral resolution, is determined predominantly by the transducer.
Focus	Transducer specification	The focus is the area within the beam where lateral spatial resolution is at its optimum. Sector width is one of the factors which may affect lateral resolution. The pulse of ultrasound can be manipulated to be at its narrowest at a particular depth, the focal position. This means that image quality including lateral resolution is maximized at that level. The focal zone is typically positioned at, or just below, the object being examined. In some cases, reducing the sector width may permit a higher lateral line density, reducing the number of interpolated pixels, thereby improving the image quality. Most modern transducers have electronic focusing to allow adaption of the aperture to specific requirements (dynamic focusing)
Image Uniformity	Visual	Image uniformity is an essential parameter of image quality, with comparable detail and contrast throughout the image being required
Contrast resolution	Control on user interface	The ability to differentiate different tissue types without introducing noise. Contrast resolution refers to the ability to distinguish between different echo amplitudes of adjacent structures. Contrast resolution may be enhanced at various stages in the imaging process, these include compression, image memory, and the use of contrast agents. Gain controls how bright the image appears by altering the amplification applied to the received signal. The operator can alter this with the overall gain control and/or with the time gain control, where gain at certain depths within the tissue is altered. Increasing the gain leads to brighter display of echoes with an increase in image noise and artefact and also a possible loss of contrast
Temporal Resolution / Frame rate	Image generation / frame rate	The rate to acquire frames and display them. Anatomical structures are displayed on the screen of the ultrasound machine, in two or three dimensions, as sequential frames over time. Each frame is created from repeated pulses that form

		scan lines. These may be duplicated depending on the number of focal points. Temporal resolution is the time from the beginning of one frame to the next. It represents the ability of the ultrasound system to distinguish between instantaneous events of rapidly moving structures. A high frame rate, and hence enhanced temporal resolution, may be improved by reduced depth of penetration, since pulses have to travel a short distance, reduced number of focal points, since scan lines do not have to be duplicated, and reduced scan lines per frame, using narrow frames rather than wide frames
Dynamic range	Ratio of the largest echo to the smallest echo or dB	Largest and smallest signals acquired and displayed. Dynamic Range refers to the range of ultrasound intensities that can be displayed by the ultrasound machine. The dynamic range adjustment can make an image look either very gray or very black and white. Dynamic Range acts more on the weaker echoes and has a lesser effect on the stronger reflections. The DR is the range of useful US signals expressed as the ratio between largest and smallest signals. It refers to how the range of received signal strength is displayed from maximum brightness to darkness. This may also be referred to as compression or contrast. The effect of compression or contrast controls on the image may vary between different manufacturers depending on what additional factors, other than dynamic range, are included in the processing
Spatial Discrimination	Elimination	The ability to limit artifacts and reflections from other locations.
Bandwidth	MHz	The system's ability to reproduce signals appropriately. Ultrasound transducers contain a range of ultrasound frequencies, termed bandwidth. Higher frequency improves spatial resolution, at the expense of penetration

Table XIII – Specification attributes

The above individual requirements for consideration when drafting a specification for ultrasound scanners basically translate into the following functionality and /or features on equipment:

1. Brightness mode;
2. Frequency adjustment range on transducers;

3. Ability to swop between transducers without physical reconnection;
4. Gain and time compensation;
5. Operator controlled and multiple adjustable focal zones;
6. Color and power Doppler;
7. Measurement of linear and curved distances, areas and volumes;
8. Cine loop facility;
9. Magnification using read and write zoom.

Finally, it should be noted that signal processing and functions on an ultrasound scanner are not universally of value for all examinations as different medical practices / specialties require different emphasis and functionality. Good spatial and contrast resolution are universally important, but opinions differ on the optimization of dynamic range, grey-scale transfer and smoothing for example. As with other MDI equipment, trade-offs have to be made.

Specifications and Purchase Price Considerations

MDI equipment entails ongoing maintenance and operational costs. These costs can be substantial. For that reason, the initial acquisition cost does not accurately reflect the total cost of ownership (TCO) to the buyer. The purchase decision should therefore be based on a comprehensive assessment of TCO. Aspects of maintenance and operational costs provide opportunities to minimize and contain ongoing expenses. These need to be explored and fully determined during the evaluation of proposals and clearly articulated in the contract/s.

Different types of equipment may have different TCO elements. Some of the common elements include:

1. **Acquisition**
    a. Purchase price;
    b. Discounts rates;
    c. Duties / taxes;
    d. Delivery costs (freight, insurance);
    e. Initial license;
    f. Warranty;
    g. Accessories (e.g., headrests, footrests) and special features;
    h. Initial consumables;
    i. Initial spare parts (stock items to be kept on site).
2. **Commission**
    a. Building works (building consents, alterations, cabling, systems integration);

b. Installation and calibration;
c. Testing and initial inspection;
d. Staff training.

3. **Operation and maintenance**
   a. Personnel (number of staff required to operate);
   b. Consumables;
   c. Utilities;
   d. Contribution towards overheads;
   e. Annual licenses;
   f. Software upgrades;
   g. Ongoing staff training;
   h. Annual maintenance;
   i. Preventative maintenance;
   j. Spare parts;
   k. Cost of on-call support services;
   l. Planned maintenance outages (hire of replacement equipment/service);
   m. Regular overhaul (including recalibration and testing).
4. **Decommission**
   a. Deconstruction and restoration of original site;
   b. Transportation of equipment from site;
   c. Disposal costs (e.g. hazardous substances).
5. **Commercial model**
   a. Cost implications of the commercial model (purchase/lease) and ongoing operation (levels and types of service contracts) and other financial accounting contributions through revenue flows or capital investment etc.

However, there are other factors which can influence the purchase decision. These are non-TCO considerations such as:

1. User preference;
2. Users' current levels of experience and training (e.g. shorter learning curve by going with an existing supplier);
3. Ease of integration with an existing system/s;
4. Availability and suitability of local service support;

5. Non-price-related benefits offered by the supplier;
6. Reduced costs through standardization with existing equipment.

To maximize bargaining leverage, the Bank recommends that Borrowers discuss and agree, where possible, all aspects of the TCO as part of the contract negotiations. This may include the service contract, if offered by the supplier. Where appropriate agree prices as far ahead as possible (e.g. up to five years in advance) for goods and services which are likely to sustain price increases in the future.

The cost discount or containment achieved will depend on such factors as the:

1. Borrower's negotiating skills;
2. System configuration and model to be purchased;
3. Previous experience with the supplier;
4. Extent of concessions granted by the supplier, such as extended warranties, fixed prices for annual service contracts, and guaranteed on-site service response.

It is essential to ensure that arrangements are made for ongoing, regular maintenance. Borrowers can arrange service contracts or service on a time-and-materials basis from the supplier or third-party providers. The equipment servicing decision should be carefully considered as poor servicing impacts on the quality of the performance and constant availability of the equipment over the required duration. A service contract ensures that preventive maintenance will be performed at regular intervals, reducing unexpected failures and maintenance costs. Although the solid-state electronics of modern medical instrumentation are very reliable, the complexity of such equipment makes it critical to ask potential suppliers to demonstrate their equipment servicing offerings and capability. Manufacturers often provide software updates, which enhance the system's performance, at no charge to service contract customers. Furthermore, software updates are often cumulative, that is, previous software revisions may be required to install and operate a new performance feature.

Service and spare parts must be available without significant delay to ensure the cost-effective use of the equipment with minimum down-time. Additional service contract discounts may be negotiable for multi-year agreements or for service contracts that are bundled with contracts for other equipment in the healthcare facility. Also, many manufacturers do not extend system performance and uptime guarantees beyond the length of the warranty unless the system is covered by a service contract.

Borrowers should also negotiate a non-obsolescence clause stating that the supplier agrees not to introduce a replacement system within one or two years and that if a replacement system is introduced during this time period, 100% of the purchase price can be applied to the purchase of the new system.

Borrowers should ensure that staff training is included in the purchase price. Some manufacturers offer more extensive on-site or off-site training programs at an additional cost. Standardization of equipment can make staff training easier, simplify servicing and parts

acquisition, and provide greater bargaining leverage when negotiating the purchase of new equipment and/or service contracts.

The following describes specific cost containment factors that relate to the different types of MDI equipment.

CT Scanner

As a guideline, a first-year full-service contract (without tubes) typically costs approximately 10% to 12% of the scanner's purchase price. This cost may increase after the first year. Contracts with tubes cost more. With the current replacement-based CT market, hospitals may receive a discount on the list price if replacing a working system. However, the resale value of a 4-slice or 16-slice system is significantly less than its original purchase price.

PET

Improved scanner design and the usefulness of the unique images of in vivo biological processes have resulted in increased interest in the clinical use of PET. However, other costs associated with installation and operation make PET the most expensive diagnostic imaging technology. A typical single PET scan can cost from $1,400 to $2,400. Because the initial acquisition cost is only a fraction of the total cost of operation, Borrowers should consider operating costs over the lifetime of the equipment rather than making a purchase decision based solely on the acquisition cost.

Annual operating costs include scanner and cyclotron supplies. When added to the cost of salaries, service and maintenance, and overheads the total costs can range from $1.2 million to more than $2 million depending on the facility. Other costs may include additional shielding.

To reduce the expenses associated with purchasing and operating a PET system and cyclotron, facilities can share the expenses of operating a regional cyclotron. The short half-lives (e.g. 24 hours) of PET radionuclides limit the possible locations of regional cyclotrons or require that radionuclides be shipped (e.g. by air) daily for use during procedures performed that day. Cyclotrons cost between $1 million and $2 million, and installation costs another $2 million. Therefore, many hospitals have opted to use radiopharmaceutical distributors. The recent development of smaller, self-shielded, less expensive cyclotrons and automated PET radiochemistry systems may reduce the costs associated with producing radiopharmaceuticals for PET studies.

An additional payment option is patient-encounter pricing (PEP), which is a leasing option offered by some suppliers. PEP, also known as pay-per-use, allows healthcare facilities to pay for PET scans based on the number of scans performed. When deciding whether to buy, lease, or pay-per-use, Borrowers should consider the following:

1. Effectiveness of PET technology;
2. Length of time that the PET camera will be used;
3. Frequency of PET scans, either per patient or on a given day;
4. Financial limitations.

DR

Although the initial acquisition cost of a DR system is greater than that of a traditional film-based system, the elimination of x-ray film and film processing can substantially lower costs, including processing costs resulting from hazardous waste removal and silver recapture. However, adding to the costs of implementing DR is the need for high-speed networks and diagnostic-quality computer workstations to archive and read digital images, as well as the need for PACS and film digitizers. Borrowers considering digital systems for the first time should begin planning the steps, including ancillary equipment purchases, that will be needed to implement a DR system.

Ultrasound

In today's competitive ultrasound market there are, in general, few significant technical differences between high-end ultrasound scanners manufactured by the market leaders. As a guideline, full-service contracts for ultrasound equipment typically cost approximately 6% to 8% of the system's purchase price.

Because ultrasound systems tend to be highly reliable (many suppliers have a 99% to 100% uptime guarantee during a warranty period), the financial risk associated with not purchasing a service contract may be minimal. However, the decision to purchase a service contract can be justified for several reasons. Most suppliers provide routine software updates that enhance the scanner's performance, at no charge to service contract customers. Because transducers and hard-copy imaging devices are the components of the system most prone to failure or damage, they should be included in the service contract.

In addition, given the current highly competitive market for ultrasound systems, Borrowers should negotiate for a significant discount on the capital purchase. Many suppliers discount new, fully configured systems from 15% to 60%.

Buyers should consider the number and types of ultrasound studies performed at their healthcare facility before deciding on a specific system configuration. Also, if multiple scanners are necessary, hospitals should determine the types of scanners and capabilities required in order to avoid paying for unnecessary analysis packages, transducers, and features. For instance, a hospital may want to purchase three scanners:

1. One dedicated to obstetrics and gynecology;
2. One to general radiology;
3. One for cardiac scanning.

In this case, purchasing all three scanners from one supplier could result in a significant discount. Standardization of equipment can make staff training easier, simplify servicing and parts acquisition, and provide greater bargaining leverage when negotiating the purchase of new equipment and/or service contract costs. Given their relatively low capital cost compared to other imaging equipment, ultrasonic scanners are typically purchased outright. However, leasing more expensive, high-performance systems may be a viable option for some facilities. In general, renting is not a cost-effective alternative.

Magnetic Resonance Imaging

Before purchasing an MRI unit, Borrowers should consider the costs associated with the following:

1. Building structure, RF shielding, and fringe-field shielding required at the chosen site;
2. Storage and replenishment of cryogens and other cooling system requirements;
3. Special surface coils for different imaging procedures, obtained from the MRI manufacturer or third-party suppliers;
4. Optional software packages and accessories;
5. Contrast agents used for certain procedures;
6. Consumables and monitoring equipment used during exams;
7. Computer hardware and software upgrades;
8. Service and/or preventive maintenance contracts.

Before purchasing an MRI unit of a particular field strength, facilities should consider the associated siting, access, and construction costs and the number and types of procedures to be performed. Magnets with field strengths less than 0.5T have greatly reduced fringe fields, decreasing the cost of shielding. However, because they are usually heavy permanent magnets, special construction required during installation may be costly. Hospitals that perform a large number of cardiac examinations should consider systems with field strengths of 1.5T and higher. Facilities interested in MRI spectroscopy, neurological, and advanced applications that are still experimental, should consider systems with field strengths of 3.0T.

Although 3.0T systems represent an advance in MRI technology for highly specialized imaging applications, they are not necessary for general-purpose imaging. Hospitals considering upgrading to a 3.0T MRI system should be aware of the possible siting, construction, and safety changes, as well as associated costs. Equipment that is MRI-compatible at 1.5T may not be safe at 3.0T, and magnetic gradients close to the magnet are steeper and more dangerous. These issues are not insurmountable, but the cost adds to the initial purchasing price of a 3.0T system. The market share of 3.0T systems has been increasing since 2000 despite these higher purchase and construction costs.

Because of the heat they produce, resistive systems exhibit less field uniformity and stability than superconducting systems. Although they are initially less expensive, resistive magnets have high operating costs (electricity and cooling water) and generate only limited field strengths. Superconducting magnets provide greater stability and higher field strengths but at a higher initial cost. They may also require periodic replenishing of cryogens and regular monitoring of cooling system integrity.

Some improvements to image quality, workflow, or range of clinical applications necessitate replacing the entire system at great expense. However, many improvements can be obtained by upgrading the existing system through software upgrades, installation of new electronics, or small hardware purchases. MRI safety training needs to be included.

Section VII. Designing the Procurement Approach

Procurement Approach

The "procurement approach" encompasses the procurement processes and methodologies that are applied when implementing the procurement strategy. Designing the procurement approach involves deciding the right combination of: pre-market engagement, selection method, market approach option, Standard Procurement Document (SPD), evaluation methodology and criteria, contract type, and contract management plan, to deliver the optimal procurement results. Getting the right design increases the likelihood of the best suppliers submitting good quality bids/proposals and increases the chance of achieving the best VfM solution. The PPSD analysis informs these design decisions and details the justification for the chosen procurement approach.

Designing the Best Procurement Approach

For MDI equipment procurement, the following are key considerations that should be taken into account when designing the best procurement approach:

1. **Contract Strategy**
    a. Contract scope;
    b. Commercial model;
    c. Lotting strategy;
    d. Pricing and costing mechanism.
2. **Selection Methods**
    a. Bank approved selection methods;
    b. Optimal combination for MDI equipment;
    c. Considerations for Medical Equipment Service contracts.
3. **Evaluation methods**
    a. VfM and non-price attributes;
    b. Most Advantageous Proposal;
    c. Rated criteria;
    d. VfM evaluation.
4. **Contract management**
    a. Key performance indicators.

These key considerations are analyzed the following four sub-sections.

Designing the Procurement Approach

A. Contract Strategy

Contract Strategy

Contract Scope

This guidance covers in detail the equipment, maintenance and service requirements of the contract scope. It also introduces the concept of Medical Equipment Service (MES) contracts and outlines how they operate. Deciding the contract scope is critical. It fundamentally determines the contract type and influences other essential elements of the procurement approach.

The following five components are key factors in the procurement of MDI equipment. Each component can be procured individually or as part of an integrated solution. The composition of the contract scope will influence the choice of contract type.

1. **Equipment:** This is the physical equipment required to undertake the imagery. This includes software and accessories;
2. **Installation:** Each procurement will need to address how the equipment will be installed in the location where it is to operate. The requirements and scope for installation will vary depending on the project. Options can range from connecting to existing mechanical and electrical infrastructure and medical systems, modifying or upgrading infrastructure as part of building renovations, through to incorporating new infrastructure into hospital construction projects;
3. **Maintenance and servicing:** This means the ongoing maintenance and support services required to operate the equipment and keep it functioning. It includes the ongoing supply of consumables and the provision of spare parts;
4. **Training:** The staff who use the equipment need to be trained, including any on-site service personnel. Training on how to operate the equipment can include training on the premises, the provision of operations manuals, and remote support. Training can be one-off or provided on an on-going basis;
5. **Operation:** The machine operator and technician are normally provided in-house by the medical institution. However, the MDI equipment market is moving to service-based solutions and this requirement is often offered by suppliers, with the machine operator having modality specific credentials.

Commercial Model

The MDI equipment market continues to evolve, including how it supplies equipment and delivers related services. Borrowers have options on how to configure their contract scope to best meet their needs. Selecting the right commercial model will help determine the contract type. The most common commercial models are:

1. Purchase;
2. Lease;
3. Managed Equipment Services (MES).

The type of health-care facility does not lead to the selection of a particular commercial model. In deciding which commercial model will be most effective, Borrowers should consider the pros and cons of each model, as described below.

Purchase

Purchasing involves the Borrower obtaining ownership and title of the equipment outright. In this case, the Borrower is responsible for how the equipment is used and ensuring that it is properly maintained. The equipment will usually have a warranty period during which time the supplier is responsible for fixing any defects. However, ongoing support and maintenance of the equipment is normally contracted separately with either the OEM or specialist maintenance suppliers.

Purchasing equipment can be beneficial where:

1. The equipment has a long lifespan;
2. The Borrower does not have capacity and/or systems to track assets and manage leases with each supplier;
3. Ongoing funding is limited or uncertain.

The risks associated with purchasing include:

1. Increased maintenance costs as the asset ages;
2. New technology making the asset obsolete before it's fully depreciated;
3. Competitors with more current technology (where the health-care facility is in competition for patients) can out-market facilities that have older technology;
4. An initial high capital outlay, which may not be financially feasible.

Lease

Leasing is different from buying. In buying equipment the Borrower obtains outright ownership of the capital asset on payment of the purchase price. Leasing involves a financial arrangement between a leasing company (lessor) and the Borrower (lessee).

In general, businesses lease equipment to secure the use of the equipment without having to finance a capital purchase. This means that a Borrower can avoid tying up funds in an outright purchase. However, the drawbacks are that leases are usually more expensive overall.

Types of Lease

The MDI Equipment market offers both capital and operating leases. Each is used for different purposes and results in differing accounting treatment.

1. **Capital lease:** Capital leases are generally used for long-term financing arrangements for equipment that is unlikely to become technologically obsolete. The lessee is essentially paying the cost of the equipment over the term of the lease. However, the lessee will be paying much more, in the form of lease charges, than the original cost of the equipment. The lessee bears all costs associated with the use of the equipment, including servicing and maintenance. The lessor does not provide any services. Critically, a capital lease is irrevocable.

   For accounting purposes, a capital lease is treated as a purchase from the standpoint of the Borrower. The equipment is reflected on the Borrower's balance sheet as an asset. The capital asset may be depreciated in the books. The lease is considered a debt of the lessee. From the standpoint of the lessor it is treated as a loan.

   In most jurisdictions, conditions apply for a lease to qualify as a capital lease. Examples include the:

   a. Ownership and title to the equipment passes automatically to the lessee by the end of the lease term;

   b. Lease contains an option to purchase the equipment at the end of the lease;

   c. Term of the lease is greater than 75% of the useful life of the equipment;

   d. Present value of the lease payments is greater than 90% of the fair market value of the equipment.

2. **Operating lease:** Operating leases are often short-term, commonly less than one year, but sometimes up to five years. They are generally used for assets that are high-tech or equipment that is subject to rapid technological change, quickly becoming obsolete.

   In this type of lease, the lessee has the right to use the property, but ownership is retained by the lessor. The lessor bears the risk of obsolescence and undertakes maintenance and servicing. Generally, there is an option for either party to terminate the lease after giving notice.

   For accounting purposes, the rental cost of an operating lease is considered an operating expense.

Types of Lessors

There are three basic types of lessors:

1. **Banks**: which offer leases as an alternative to other types of credit;
2. **Manufacturers**: who lease the products they produce instead of selling them outright;
3. **Leasing companies**: who will purchase equipment so that they can lease it out.

Irrespective of the type of lessor, they always remain the legal owners of the leased equipment for the duration of the lease. In the MDI equipment market manufactures often act as lessors.

Lease Term Options

There are typically three flexible options at the end of a term. The lessee can:

1. Return the equipment, without further obligation;
2. Purchase the equipment from the leasing company;
3. Extend the lease for an additional period.

Whether a capital or operating lease, a monthly payment is made over the term and a buy-out option is normally available after the conclusion of the lease term.

End of lease terms can be:

1. **$1 buy-out lease**: A $1 buy-out lease requires monthly payments and allows the lessee to buy the equipment for $1 when the lease is over;
2. **10% buy-out lease**: a 10% buy-out lease allows the lessee to buy the equipment for 10% of its market value when the lease is over;
3. **Fair market value buy-out lease**: with a fair market value lease, the lessee has the option to purchase the equipment at its fair market value, or renew the lease, or return the equipment.

Lease buy-out decisions often hinge on the anticipated value and usefulness of the equipment at the end of the lease period. For example, it doesn't make sense to pay more for a low buy-out lease on a MRI scanner you don't expect to keep beyond the lease period. Of course, the tendency to keep equipment longer also affects the lease/purchase decision.

Benefits of Leasing

Leasing is often used where a Borrower provider doesn't have much capital funds but does have revenue funds. Leasing involves less initial expense, has the potential to be tax deductible (as an operational expense), and makes it easier to upgrade equipment. MDI equipment manufacturers can tailor a lease to a customer's needs. Leases can be either short or long term. Purchasers that apply TCO in the procurement of assets often lease equipment. Leases provide payment flexibility as payments to be structured to meet cash-flow considerations.

Leasing also can be favored because it passes the risk of ownership of the asset to the lessor or MDI equipment manufacturer. Leasing may introduce flexibility in managing assets, right-sizing capacity, and driving standardization or utilization based on other environmental factors, such as reimbursement changes or industry consolidation.

Since a lease often does not require a down payment, it can be equivalent to 100 percent financing. Borrowers can conserve the capital that would have been used for such a down payment.

As healthcare facilities grow and needs change, the lessee may be able to add or upgrade MDI technology at any point during the lease term.

At the end of the lease, if the Borrower elects to return the equipment, the leasing company is responsible for the disposing of the asset.

Technology solutions that could depreciate quickly should be leased to limit a Borrower's risk of getting caught with obsolete equipment. Leases make it easier to upgrade or add technology solutions to meet ever-changing needs.

An expensive services contract will often bundle support and maintenance, and system updates in the terms and conditions. It will often be advantageous to negotiate this support and system updates at the initial leasing stage. Support and maintenance should be easily accessed via a toll-free number and system updates should be provided at no cost, since their goal is to eliminate a manufacturer malfunction or enhance the overall performance of the equipment.

Leasing can allow Borrowers to respond quickly to new opportunities with minimal documentation. Many leasing companies approve applications within a few hours.

Leasing allows Borrowers the ability to accurately forecast the cash requirements for equipment since they know the amount and number of lease payments required. With leases there are normally no floating fees.

Disadvantages of Leasing

While some Borrowers may like the opportunity to buy a piece of equipment at the end of a lease, this is not always considered a benefit. Purchase options at the end must be both clear and feasible.

Many governments are reluctant to invest in new equipment due to cash constraints and financial concerns. Because of such budget constraints, MDI equipment leasing is a viable alternative to purchasing. Equipment leasing makes it easy for Borrowers to obtain the MDI equipment required to provide patient care, increase throughput and work more efficiently, while conserving cash and remaining flexible.

Considerations for Leasing

Specifically, the Equipment Leasing and Finance Association, a trade group representing financial services companies and manufacturers, recommends Borrowers consider the following questions before signing a lease. Such questions consider the "before", "during" and "after" stages of a lease.

1. How will the MDI equipment be used?
2. Who will meet the costs of maintenance and ongoing servicing?
3. What technical support and system updates are offered?
4. How is the Borrower responsible if the MDI equipment is damaged or destroyed?
5. What are the Borrowers obligations for the MDI equipment (such as insurance, taxes and maintenance) during the finance agreement?
6. Can the Borrower upgrade the MDI equipment or add additional MDI equipment under the lease agreement?

7. Does the finance company/manufacturer understand the Borrowers requirements and how this transaction helps the Borrower to do deliver health care?
8. How much are the periodic payments and what is the total finance payment over the term of the lease?
9. Are there any other costs that the Borrower could incur before the lease ends?
10. What happens if the Borrower wants to change the financing agreement or end it early?
11. What are the Borrower's options at the end of the finance agreement?
12. What are the procedures the Borrower must follow if it chooses to return the MDI equipment?
13. Are there any extra or hidden costs at the end of the finance agreement?

Managed Equipment Services

Managed Equipment Services (MES) contracts outsource the provision and operation of MDI equipment to a third-party specialist provider. The MES provider owns the equipment and provides all the necessary services to support the effective use by the Borrower. MES providers have the specialist knowledge and expertise to manage the procurement, commissioning, training of users, servicing, maintenance and planned replacement of the equipment throughout the life of the contract.

A MES arrangement typically lasts 10–25 years. Instead of incurring significant capital outlays, Borrowers spread the costs through regular payments over the years. Payments can be tied to the provider meeting agreed performance parameters. This arrangement allows Borrowers to spread costs over the life of the contract, and facilitates long-term, sustainable financial management and planning. MES allows a Borrower's medical facilities to focus on taking care of their patients, whilst the MES provider takes care of the technology.

MES arrangements represent innovation in financial and business planning. MES is sometimes expressed as a partnership with a private sector service provider. MES are occasionally structured as Public-Private Partnerships (PPPs). They are designed to allow governments to provide access to care, without the burden of detrimental levels of debt.

Key benefits of MES contracts include:

1. **Procurement and asset management**: renewal, replacement and maintenance of MDI equipment;
2. **Ownership and management**: of all MDI equipment requirements, by a specialist supplier. This service can cover one or more medical facilities over the life of the contract;
3. **Initial provision**: delivery, installation and commissioning of MDI equipment;
4. **Technology**: use of the technology available that is the best fit at any time to increase the quality of care as well as improve clinical outcomes for patients;

5. **Replacement**: structured plan of on-going replacement of equipment, to ensure that it remains state-of-the-art;
6. **Disposal**: disposal of parts and equipment;
7. **Flexibility**: flexibility to adjust MDI equipment placement and technology if requirements change;
8. **Upgrades**: timely equipment modernization and maintenance;
9. **Ownership**: the cost risk associated with ownership and planned replacement;
10. **Choice**: clinical freedom of choice of brand - the supplier's role is to procure the equipment on behalf of its client, no matter what brand;
11. **Solutions**: additional solutions to support the healthcare facility's operational and clinical efficiency;
12. **Existing equipment**: transfer of legacy MDI equipment over the contract period;
13. **Range of services**: financing, professional services, room planning, training for clinical users, and onsite technical support;
14. **Service levels**: pre-agreed service level agreements;
15. **Performance levels**: performance and attainment of service levels incentivized (risk and reward) through payments based on the quality of service delivered;
16. **Availability**: guaranteed availability and uptime;
17. **Training**: training including on-the-job user and maintenance training, technical training and specialized training, and clinical training in specified fields;
18. **Support**: onsite technical support;
19. **Financial planning**: predictable, fixed financial planning and fixed monthly OPEX monetary fee.

The scope of an MES contract can include all or some of the above features. The scope usually describes requirements as a performance-based specification. This approach provides the flexibility for MES providers to use their expertise to determine the optimum operational solution in delivering the quality of service required, at the most economical cost.

Benefits of MES

In a MES solution, the risk is shared between both parties. The MDI and technology infrastructure service provider takes responsibility for the availability, quality, maintenance and upgrades over the lifetime of the technology. This enables Borrowers to benefit from future enhancements and innovations and any other modifications needed to align their MDI infrastructure with changes to the health care environment.

This approach can optimize the use of technology and can improve operational performance. MES can make healthcare more sustainable and allow for smarter capital expenditure and ongoing VfM.

Adopting a MES model can allow a government to shift current capital expenditure to operational expenditure. This spreads the same budget over a much longer period, providing the financial flexibility to adapt to a rapidly changing environment.

Moving from capital purchases to a long-term strategic partnership involves shared risk and facilitates the adoption of ongoing innovative technologies for a predictable annual outlay. It can also provide the reassurance that more patients will benefit from current and future innovation.

The use of a MES can optimize available budgets which can offer major benefits to governments and healthcare facilities and contributes to addressing fundamental healthcare challenges. MES solutions offer:

1. **Predictability:** predictable operational costs and cash-flow giving certainty that a healthcare facility cans source the equipment it needs at a fixed cost for the contract duration;
2. **Performance guarantee**: knowing that the equipment supplied will perform as required, or be replaced at the provider's expense;
3. **Cost reduction**: reduction in prices if the performance of a piece of equipment does not meet the agreed standard;
4. **Ongoing upgrades**: automatic access to equipment upgrade cycles and future innovations;
5. **Efficiency**: improved efficiency through standardization and sharing of best practice;
6. **Support:** consultancy services offered including education and training;
7. **Workflow management**: optimization of workflow and reduction of the integration risk;
8. **Single supplier**: having a single technical partner motivated throughout the contract to ensure the equipment supplied is operating optimally.

The benefits of MES solutions is having a growing impact of the MDI equipment market, with contracts being awarded in a variety of jurisdictions. Although such contracts have the potential to transform healthcare equipment supply, each jurisdiction will need to adapt them to suit their own healthcare structures. As well as the UK, where the concept is most developed, MES contracts are also established in Spain, with the Netherlands currently implementing the required enabling legislation. Germany, too, has a parallel structure to the MES contract, although, as it is lease-based, the emphasis on the service aspects of MES contracts are somewhat downgraded. Kenya has entered into one of the largest sustainable healthcare projects through an MES arrangement involving the provision, management and servicing of medical equipment in almost 100 hospitals throughout the country, at an estimated cost of US$9m.

MES delivers much more than the supply and maintenance of MDI equipment. Partnership agreements can be tailored to fit the specific needs of both users and patients. For example, MES arrangements can include:

Item	Detail
Financing	Long-term solutions allowing capital expenditure to be spread over several years Limited or full asset replacement Flexible variation process to add or remove assets to meet changing clinical demands
Capital Asset Planning	Ensures flexibility and sustainability
MDI Equipment Selection	Vendor/brand neutral Output based specifications development so that equipment meets the health facility's needs
Optimizing Technology Management	Optimizing the full range of services (e.g. parts replacement, upgrades, installations) in terms of both time and quality and avoiding obsolescence
Enabling and Pre-Installation	Patient/workflow optimization
Support Staff	On-site engineering staff Interim mobile service Completion risk
Managed Maintenance	Extended hours Upgrade programs Single point of contact
Training and Continuous Education	To ensure the optimal use of MDI equipment
Integrated Services	The use of technology to support hospital's broader strategic vision and objectives
Optimizing Workflow Management	Improving the efficiency of healthcare provided (in terms of quality and human resources management)
Sharing Best Practice	The use of continuous shared mentorship programs

Table XIV – Elements of MES arrangements

MES Success Factors

MES arrangements are complex service delivery solutions that require careful procurement planning and implementation. Some of the success factors include:

1. Capturing the views of all stakeholders in the development and implementation;
2. Ensuring sustainable healthcare through an adequate, well-trained health workforce;

3. Managing responsibility and risk to ensure that both the public and private sector entities meet their obligations;
4. Resourcing contract management to deliver sustained efficiency in providing the expected health gains;
5. Monitoring performance and capturing data to guide the calculation of payments (and payment deductions) made under the contract;
6. Mobilizing skilled and capable procurement staff especially as MES providers usually deploy highly capable staff in putting together MES offers;
7. Ensuring that the public procuring entity is equally well-represented in developing and letting the contract.

Selecting the Commercial Model

Recognizing the many factors that go into a purchase, lease and service decision, many MDI manufacturers have taken steps to help their customers make the best choice for their individual health care facility through an ability to offer all three commercial models. The selection of the commercial model can be complex, and the points should be considered in identifying the most appropriate commercial model include:

1. Duration of need;
2. Frequency of equipment use;
3. Evidence to support the use of technology is the environment / setting of the country of the healthcare facility;
4. Consistency of use;
5. Required "up time";
6. Condition of existing equipment and facilities;
7. Total cost of ownership (TCO);
8. Funding availability (revenue and capital);
9. Consumables;
10. Training need (one-off or ongoing);
11. Equipment support and maintenance;
12. Speed of technological change, innovation and obsolescence;
13. Upgrades roadmap;
14. Accountability for delivery of outcomes and/or requirements;
15. Availability in the market place of different commercial models;
16. Service standards and response times;

17. Spare part availability;
18. Warranty cover and duration;
19. Scope of need e.g. technicians to operate the equipment;
20. Inhouse capability to maintain and service equipment;
21. End of life disposal.

The commercial decision model may not necessarily be based on one method being more cost-effective than the other over the long term. For example, some purchasers have always considered leasing a more expensive option, however, when considering TCO leasing can be less expensive than purchasing in certain circumstances. This is especially true if the procurement approach maximizes competition, has a clear output-based requirement, evaluation is undertaken on a total cost of ownership basis, and contract management is used to ensure the lease is managed properly. Conversely, some purchasers find that ownership of their assets, even those prone to technological obsolescence, outweighs the flexibility of maintaining a state-of-the-art equipment portfolio that leasing may provide.

Maintenance and Servicing

MDI Equipment Servicing

The management of MDI equipment has become more complex in recent years because of increased sophistication and specialization of the equipment, integration with electronic networks, dependence on outsourcing for specialized maintenance and repair, and ever-increasing requirements for compliance, safety, reliability and accuracy. However, effective support and maintenance is essential for long term operation, and high utilization.

Types of Maintenance

There are a number of options available for both the level and type of support and maintenance that Borrowers may need.

Corrective Maintenance

Corrective maintenance (sometimes referred to as "breakdown maintenance"), is maintenance that is carried out only when equipment fails and/or needs repair. A maintenance task is carried out to identify, isolate or separate and rectify a particular fault. This is performed to restore damaged or failed equipment to an operational condition. Corrective maintenance can be either planned or unplanned. Corrective maintenance can be subdivided into:

1. **Immediate corrective maintenance:** in which work starts immediately after a failure;
2. **Deferred corrective maintenance:** in which work is delayed in conformance to a given set of maintenance rules.

Whilst unplanned corrective maintenance can be a low-cost option, it is not recommended for MDI equipment due to the importance of clinical needs, and the associated costs and impact on service of any unscheduled down time.

Inspection and Preventive Maintenance

This is regular scheduled maintenance based on the manufacturer recommendations. Preventative maintenance is used proactively to keep equipment operational and avoid failure. It is designed to prevent deterioration of equipment, through regular servicing, periodic inspection, condition diagnosis to measure deterioration and guide any required maintenance. It is further divided into:

1. **Periodic Maintenance (time-based maintenance)**: periodic, time-based maintenance consists of scheduled inspections, servicing and cleaning including replacing parts to prevent sudden failure;
2. **Predictive Maintenance:** is a method in which the service life of important parts is predicted based on inspection, failure history of parts or diagnosis. This allows the use the parts to the limit of their service life, but not beyond;
3. **Risk Based Maintenance:** preventative maintenance procedures based on risk helps minimize both the clinical and financial risks associated with clinical equipment. Reducing the frequency of preventive maintenance inspections not only reduces labor hours but can move a facility from preventive maintenance to predictive or reliability-centered maintenance.

Preventive and corrective maintenance are mostly concerned with frequency-scheduled activities as well as repairs after the equipment is out of service, but they miss opportunities for optimization, including the ability to set maintenance intervals based on meaningful data. In addition to labor hours saved, moving to predictive or reliability-centered maintenance will prevent equipment failure, optimize reliability and save costs.

Compared to periodic maintenance, predictive maintenance is condition-based maintenance. It manages trend values, by measuring and analyzing data about deterioration and can employ a surveillance system, designed to monitor conditions through an on-line system. Preventive maintenance is essential to equipment up-time and operational life time, but does mean considerable ongoing cost, however, it is normally seen as the optimum option.

Equipment Maintenance Management Program (EMMP)

Equipment Maintenance Management Programs (EMMP) have been around for more than 25 years. Most hospitals' maintenance plans have evolved from a "fix-it-when-it-is-broken" inspection and maintenance program, to one that is time-based, then to predictive, then condition-based, and finally, risk-based.

EMMP broadens the maintenance scope and integrates other services so that asset management and utilization is maximized. These additional services can include all or some of the following:

1. OEM contract management;
2. Provision of spare parts inventories to ensure fast, effective care;
3. On-site technical staff;

4. Management program for all equipment, including equipment under warranty and vendor service agreements;
5. Asset planning and management to reduce equipment life-cycle costs and maximize the capital investments. This includes analysis of the costs and useful life of current equipment and weigh that against the investment in new systems and overall patient care goals;
6. Advice on equipment space, layout, design and utilization;
7. Technical assistance for the evaluation of potential cost effectiveness of new medical equipment including reliable and objective information about the latest technological developments, assistance with equipment purchase negotiations in regard to training, service and operational manuals, consignment equipment and part;
8. Assistance in the training of clinical personnel on basic operation, patient and operator safety and best practices;
9. Ensuring all equipment meets safety and performance to manufacturers' specifications;
10. Assistance with equipment disposal. As clinical technology becomes more complex and stores protected health information, the need to properly dispose of aged equipment is becoming an increasingly important issue. EMMP can include the disposal process, ensuring both regulatory and environmental standards are followed and documented.

Service Options

There are six primary supply options in providing service and maintenance arrangements. These are:

1. **OEMs**: Offer a maintenance plan for a set period. There are usually multiple options, that can be tailored for the level of coverage required;
2. **A Third-Party Service Organization**: Can cover all equipment irrespective of manufacturer, but some limit their offering to a technology type or one or more manufacturers;
3. **Insurance Company**: Can write a policy to cover the equipment and to combine two costs: the policy's premium and a fixed equipment-repair fund. The insurance company will provide data on the best prices for parts and services. At the end of the year, if actual costs are less than the repair fund's pool of money, the Borrower will retain the saving. If the year ends with actual costs exceeding the pool of money, there are no additional out-of-pocket costs, since the risk has been capped;
4. **In-House Maintenance Team:** Hiring a dedicated in-house maintenance team is a solution that usually operates best when managing a large health care facility and/or multiple sites. However, in-house maintenance teams may still put in place external service contracts for certain types of equipment;

5. **Self-Insure:** A Borrower can take the risk and pay for service and parts as needed. Usually, the health care facility will create a risk pool that is based on the past two years' failure rates for equipment. With this method, costs are paid from the pool as they are incurred;
6. **Hybrid Mix:** Using a mix of the other five service options. For example, buying a full-service contract on one machine (because it has high failure rates) and buying an insurance product for everything else.

Service Contract Considerations

It is important to find out the duration of the manufacturer warranty as it varies from manufacturer to manufacturer. After the warranty period expires, it is essential to consider what service contract terms and conditions are available and at what cost because negotiating leverage is completely lost after the service contract has been signed or auto renewed. In addition, if the equipment is leased, normally the only option for service is a full-service maintenance contract from the supplier.

Before entering into any contract with the OEM or third-party vendor, it is vital to understand exactly what is covered in the agreement. For example:

1. Is the service contract long or short-term?
2. Is there an auto-renewal clause?
3. What are the cancellation fees?
4. Is there a guaranteed response time?
5. Are parts and travel included in the contract cost?

Availability of Parts and Consumables

It is important to decide whether you prefer OEM certified parts and new consumables versus refurbished parts and consumables. The pros and cons for each need to be considered. Which parts and consumables are more readily available, new or refurbished, and do the prices fall within the Borrower's equipment maintenance budget. It's important to review the language concerning parts and consumables in the service contract.

Lotting strategy

For many procurements, Borrowers need to consider the best way to package requirements to achieve the right response from the market. Packaging requirements are primarily informed by end-use dynamics and market characteristics, which together are used to determine whether the procurement is bid as one package, or as a number of lots, and if lots, the bundling of activities within each lot.

One-Package Procurement

A one-package procurement combines all requirements for a particular procurement into one bidding/procurement document, with bidders/proposers required to deliver all component parts of the specification in its entirety e.g. award a single contract to one Bidder/Proposer that can do all of design, supply, install, train and maintain. In a one-package approach, the contract is awarded to the Bidder/Proposer that offers the best single solution that meets the Borrowers requirements and is evaluated as the Most Advantageous Bid/Proposal.

Lots

A lotting approach divides the Borrower's procurement requirements into separate lots identified within the bidding/procurement document. Examples of lots include:

1. **Geographic area:** e.g. Lot 1 supply, install, and maintain MRI scanners in hospitals in the capital city and capital region. Lot 2 same for the country's northern region. Lot 3 same for the country's southern region etc.;
2. **Type of activity:** e.g. Lot 1 to design, supply and install an MRI machine. Lot 2 to maintain the machine over a 5-year period;
3. **Product type:** e.g. Lot 1 is for the supply of MRI Scanner. Lot 2 is for the supply of X-Ray machines;
4. **Size:** e.g. 60% of the need in Lot 1 and 40% in Lot 2 (used when the Borrower needs to spread the business across more than one Bidder/Proposer to maintain or build competition).

When lotting is used, the Borrowers may permit a Bidder/Proposer to Bid/Propose for one, or a combination, or all lots defined within the bidding/procurement documents. The final award decision is then determined on a lot by lot basis to assess the best overall combination of Bidders/Prospers to meet the Borrower's requirements. In some instances, a Borrower may permit a Bidder/Proposer to offer a cross-discount that will be applied in assessing their Bid/Proposal if more than one lot is awarded to them.

Bundles

Bundling usually refers to specific activities that may be bundled together within a specific lot. In example 1 above (geographic region), lot 1 is to supply, install and maintain MRI scanners to the hospitals in the capital city and capital region of a country. In this example, the lot is based on the geographic area whereas the bundle is the combination of activities within that lot i.e. supply, install, and maintain the MRI machine. In this example the award decision will be taken on a lot by lot geographic basis, requiring that bidders/proposers must be able to complete all the activities that have been bundled together in that geographic area. The Borrower will award the contract to the optimum number of bidders/proposers that deliver the best overall value across all lots.

In example 2 above, (type of activity), the bundling decision has been to bundle design, supply and install into lot 1. Lot 2 is purely for maintenance. Such an approach may be optimal when

the OEM does not have the capacity to perform maintenance in a given locale. The final award decision could then be to different bidders/proposers: one to design, supply and install, and another to maintain. An OEM could bid for both, if they have capacity (unknown to the Borrower) or are committed to invest to deliver the capacity.

Deciding between one-package and multiple lots

Determining the right way to package the requirements is a crucial decision that will have many consequences. It can affect both the number of bidders/proposers participating in the procurement and their behavior. If the packaging is correct, then the right bidders/proposers are more likely to participate, there will be effective competition, the Borrower is more certain of attaining best VfM, and it is more probable that the procurement will be sustainable over the long-term. To determine the right packaging approach Borrowers, need to pay particular attention to the:

1. Complexity and criticality of the procurement;
2. Market structure, by geography, activity, supplier, user and size, including the role and use of sub-contractors and added value added resellers (as opposed to OEMs);
3. Supplier specialism and cost competitiveness e.g. is there a supplier that has a unique specialist knowledge, piece of equipment or innovation that no one else in the market has, or does a supplier have a more competitive pricing structure, but only in limited markets or areas of supply;
4. Whole-life cost and where the cost and profit exist for suppliers e.g. the capital cost of equipment does not represent the majority of cost over the operational life of a piece of equipment. Operations costs such as support, training, spare part supply, consumables etc. are often higher;
5. Degree of competition vis a vis buyer influence (buyer attractiveness), including the risk of creating future dependency by creating lock-in to a single supplier;
6. End-user need and structure, by geography, activity, user and size, including compatibility with existing equipment;
7. Critical mass of procurement necessary to lever economies of scale. This motivates bidders/proposers to participate, and provides a fair chance that they will make a profit if they win;
8. Dis-economies of scale where fragmentation increases the overall cost of purchase and/or supply through increased transport costs, loss of volume discounts, increased administrative overheads, the need to have a single delivery or service start date, etc.;
9. Risk allocation, where fragmenting responsibility for supplying the Borrower's requirements across multiple contractors can lead to the risk of failure being spread over more supply chains. This has the potential to impact other contractors involved in supplying elements of the Borrower's requirements.

The nine issues highlighted above are not mutually exclusive and must be considered together to inform the optimal method to package the procurement.

A high value, critical piece of equipment, from a specialized market, that operates as an oligopoly is more likely to receive competitive bids/proposals if procured as one package. So long as the bidders/proposers have the capacity to deliver all activities required e.g. supply, install, and maintain. In this situation, the use of a one-package approach may attract the right bidders/proposers as they will benefit from the bundle of follow-on added-value services after installation. However, such an approach only works if the bidders/proposers have the capacity and infrastructure to support this (e.g. they have maintenance staff in the locality or are willing to invest to develop it).

Using the same scenario, but with a more mature, diverse and competitive market, separating the procurement into lots may deliver a better result. For example, if the market has maintenance specialists (that may be better value than the equipment manufacturer) then dividing the procurement into lots based on activity, allows those specialist maintenance bidders/proposers to submit for that activity lot, and perhaps offer the Borrower a better overall combination of suppliers and optimum VfM. It equally allows the OEMs to submit too, which then allows the Borrower to make an informed decision based on all factors and options.

In summary, determining how best to package a procurement is informed by analysis in the procurement strategy. The final decision on the use of a one-package approach, or use of lots, and the bundling within the lot, is crucial as it will directly impact competition, and the nature of suppliers that Bid/Propose. Packaging a procurement based purely on how the supply market is structured will ensure appropriate competition, and can be used as an initial guide on the packaging options available e.g. geographic, activity, size etc. These initial packaging options, based on how the market is structured and operates in the Borrower's locale, should then be contrasted with the degree of competitiveness present, the degree of buyer influence/attractiveness, end-user needs/structure, and the critical mass of procurement needed to make the contract economically viable. Selecting the final packaging option which reflects how the market operates, and best meets the other factors will likely result in the optimum procurement outcome.

Pricing and Costing Mechanisms

The choice of the price and costing mechanism when procuring MDI equipment should be made based on the:

1. Requirements stated in the specifications;
2. Procurement risk assessment;
3. Market analysis;
4. Operational environment;
5. Commercial model selected;
6. Standard procurement document being used.

This will help ensure that the selected price and costing mechanism provides clarity on the risk allocation between the Borrower and the supplier, motivate suppliers to bid, as well as helping to mitigate any identified risks.

The pricing and costing mechanism will vary depending upon the commercial model, but the mechanisms that are likely to be most suited are a combination of:

1. Lump-sum for equipment purchase;
2. Schedule of rates for leasing and MES solutions, support and maintenance, training, etc.;
3. Performance-based costing for MES solutions.

MES solutions can make use of either a schedule of rates and/or performance-based costing. Performance-based costing is best suited when MES solutions have an incentivization mechanism whereby the supplier payment is determined by achievement of specific targets, performance or outcomes. These can be volume, service and quality based, or a combination of all three.

Table XV provides an overview of the main advantages and disadvantages of each of the three pricing and costing mechanisms.

Type	Requirements	Advantages	Disadvantages
Lump Sum/Firm Price	• Requirements can be accurately specified • Volume and durations are known with relative certainty • Risk can be reasonably identified	• Full extent of cost & liability known • Straight forward to contract manage • No hidden costs	• Supplier may include excessive contingency to cover risks • Supplier may seek to "cut corners" to meet price • Borrowers pay irrespective of usage
Schedule Rates	• Services can be accurately foreseen but not accurately measured at outset • There is an indication of the extent of the services at tender stage	• Borrowers only pay for what they use • Price is known per "unit" • Allows services to be "called-off" quickly	• Overall cost is unknown unless volumes are known • Suppliers need accurate volumes to be able to price effectively • Requires higher level of ongoing contract management

Performance-Based Costing	• Requirements are defined on an outcome basis • High confidence and trust in the supplier • Data to measure performance is readily available	• Suppliers incentivised to deliver to the highest standard • Fewer constraints allow suppliers to determine the best way to deliver • Incentive to improve productivity	• Overall cost can only be calculated on a range basis • High contract management requirement • Setting the wrong performance targets results in the wrong behaviours or poor delivery

Table XV – Costing mechanisms advantages and disadvantages

Pricing Considerations for Purchases

During the drafting of a pricing and costing schedule for the outright purchase of MDI equipment, the following should be used as a guide to determine its content:

1. Line-item price schedule that individually lists all the components for the purchase, installation, start-up, calibration, and testing of the MDI equipment;
2. Individual line items (including equipment and services) based on the standard list price;
3. Installation costs included in the price for the MDI equipment;
4. Prices for the number of years support provided under warranty services;
5. Prices on an installed inclusive basis (freight prepaid and included in price), including rigging and inside delivery;
6. Prices guaranteed firm, with a reasonable time period of about 120 days after the bid opening;
7. Prices include all costs associated with delivery in accordance with the proposed delivery schedule;
8. Price changes covered by a pre-agreed mechanism (if any) if a long delivery date is requested.

Pricing Considerations for Support and Maintenance

During the drafting of a pricing and costing schedule for support and maintenance of MDI equipment the following should be used as a guide to determine its content:

1. Full description of the annual service contracts covering the different service offers, examples are provided in tables XVI to XVIII below;

2. Cost information and contract language for preventive maintenance and equipment repair service after regular business hours;
3. Price for each yearly period to be binding;
4. Cost-saving service options, including screening of service calls and/or preventive maintenance by Borrower for post-warranty years;
5. Service agreements for a five-year period, including all agreement terms, conditions and fees, minimum and maximum remedial maintenance response times;
6. Amount of service credit if the supplier fails to meet guaranteed response time;
7. Availability of trained technicians and parts, system hardware enhancements and upgrades, software maintenance, engineering support, software license.

A. Full-Service Package (24 hours)
1. Labor rate for 24-hour service
2. Parts
3. Transportation charge for either personnel or parts, regardless of time of day
4. Overtime charges and the hours that would apply.

Table XVI – Costing mechanisms advantages and disadvantages

B. Full-Service Package (8 a.m. to 5 p.m.)
1. Labor rate for 8 a.m. to 5 p.m. service
2. Parts
3. Transportation charge for either personnel or parts, regardless of time of day
4. Overtime charges and the hours that would apply

Table XVII – Costing mechanisms advantages and disadvantages

C. First-Screen Package
1. Hospital-trained personnel for first response
2. Provision of A.2, A.3, and A.4 above
3. Assistance in troubleshooting and repair, when required, at reduced, specified labor rates

Table XVIII – Costing mechanisms advantages and disadvantages

Pricing Considerations for Leasing

During the drafting of a pricing and costing schedule for leasing MDI equipment the following should be used as a guide:

1. Full description of the contract, including equipment, and support and maintenance, plus any other services;
2. Single charge per machine;
3. Cost information and contract language for preventive maintenance and equipment repair service after regular business hours;
4. Price for each yearly period to be binding;
5. Cost-saving service options, including screening of service calls and/or preventive maintenance by Borrower for post-warranty years;
6. Service agreements for at least a five-year period, including all agreement terms, conditions and fees, minimum and maximum remedial maintenance response times;
7. Amount of service credit if the supplier fails to meet guaranteed response time;
8. Availability of trained technicians and parts, system hardware enhancements and upgrades, software maintenance, engineering support, software license;
9. Equipment replacement schedule and impact on cost.

Pricing Considerations for MES

During the drafting of a pricing and costing schedule for MES arrangements the following should be used as a guide:

1. full description of the contract, including method of service for equipment, support and maintenance, plus any other services and guaranteed service levels;
2. single charge per machine or per unit of measurement (e.g. outcome or output) for all the MES services;
3. price for each yearly period to be binding;
4. cost-saving service options;
5. amount of service credit if the supplier fails to meet guaranteed service levels;
6. equipment replacement schedule and impact on cost.

General Considerations for Commercial Models

During the drafting of a pricing and costing schedule the following factors should be considered to ensure that all information required to establish that the schedule is realistic and comprehensive (i.e. all items of costs have been identified and stated):

1. Proposed delivery and installation schedule for each piece of equipment;

2. Costs, if any, of installation planning, design, and construction services;
3. Time required for installation, start-up, acceptance testing, and removal of existing equipment details of subcontractor(s)' equipment installation, equipment calibration;
4. Payment terms, including any cancellation fees and any alternatives that result in a cost saving;
5. Substitution, at the Borrowers discretion, for new equipment introduced by the supplier after the award of contract, but before delivery, that more suitably meets the Borrowers clinical requirements;
6. Methodology for dealing with potential cost differences;
7. Proposed equipment layouts for all equipment including all options;
8. Information on the conformance of the proposed layouts with stated room sizes and layout;
9. Information on functional adequacy of the designs including provision of adequate space for normal work activities;
10. Policy for newly developed hardware and software, equipment and software modifications for improved performance and reliability, and correction of design, component, or manufacturing defects;
11. Confirmation that modifications, upgrades, and enhancements are no-charge items and, if so, for what period of time (e.g., warranty period only, extended period, or for the life of the equipment);
12. Detailed description of the in-service training for clinical personnel and the technical training;
13. Information on the training program length and format, content, the qualifications of the instructors, and written and electronic materials;
14. Training covering both supplier equipment and other firms' equipment, if applicable;
15. Information on refresher training and training for new Borrower employees over the lifetime of the equipment;
16. List of all (if any) original equipment manufacturer (OEM) items not specifically manufactured by the supplier but provided as part of the equipment systems;
17. Copy of standard warranty agreement and a description of proposed warranty terms, including any partial (less than one year), pro rata, or extended warranties;
18. Description of local and regional factory-based service capabilities, including the number and qualifications of service engineers, as well as their training, their base locations, the locations of backup service engineers;
19. Approximate response time for emergency repairs (both during and outside of regular business hours);

20. Location of primary and backup spare-parts locations;
21. Time for delivery of parts after notification;
22. Description of factory engineering backup capabilities.

Total Cost of Ownership (TCO)

As MDI equipment is used over a long period of time it is essential to understand the full costs of ownership and operation. This helps determine the best VfM solution when evaluating alternative proposals. A Total Cost of Ownership (TCO) methodology can be used to make this determination.

Definition

TCO is an estimate of the total costs associated with a solution over the whole of the operational life including final disposal. It includes the purchase price or initial fees and all the other costs a Borrower incurs, less any benefits received. For example, the TCO of MDI equipment could include the initial purchase price, and the cost of installation, operation and ongoing maintenance, less the residual value upon disposal. TCO may also include non-quantifiable components, such as reduced patient waiting times and physician time as opportunity costs.

Core Procurement Principles

The Bank's Procurement Framework encourages the Borrower to make balanced procurement decisions taking into account the Core Procurement Principles which include: VfM, efficiency, economy and fit for purpose. TCO as a methodology considers all these principles and ultimately helps ensure VfM over the life time of the MDI equipment and/or services.

One element of good procurement is achieving the right price, not just the lowest initial purchase price. VfM using TCO is expressed as the lowest whole-of-life cost. This involves identifying the initial purchase price and estimating all future costs and returns. Consequently, for many types of MDI equipment, TCO analysis finds a very large difference between purchase price and total life cycle costs, especially when ownership covers a long-time period.

A contract award decision based on the initial purchase price only, rather than the TCO, often fails to recognize the true cost to the Borrower. TCO is a versatile methodology and can be used to support both project planning stages, such as production of the PAD and the procurement itself, through to identifying the true cost to Borrowers of the MDI equipment and services. This can be particularly significant in helping Borrowers ensure they have future revenue budget funding available to keep the MDI equipment in full operational use.

TCO can be considered in the following activities:

1. Being a part of project design to assess the costs, benefits and risks associated with the investment;
2. Assessing different business models, maintenance options or solutions on a comparable cost basis;

3. Understanding the different cost drivers over the life of a procurement;
4. Demonstrating that a bidder's/proposer's TCO for their solution has greater total benefits and value, especially where the initial purchase price is higher than competitors, but the TCO is lower;
5. Selecting the best Bid/Proposal by assessing the comparative whole-of-life costs of all competing bids/proposals;
6. Managing the contract to track actual expenses and income against budget;
7. Making up part of benefits realization planning and execution.

TCO analysis begins when the Borrower identifies or defines two things:

1. The specific type of MDI equipment to be procured;
2. The "ownership life" for the equipment. Ownership life is almost always given as a number of years with known starting and ending dates. However, it can be described as the number of scans or the usage of the equipment.

TCO analysis continues when the analysis identifies important cost categories likely to have cost impacts during ownership. To ensure sure the TCO analysis includes all important costs, the Borrower should consider two kinds of cost categories, "known costs" and "hidden costs".

How does TCO compare to Price?

TCO highlights the difference between the initial purchase price and the long-term costs of operating the equipment over its useful life. There are a number of different commercial models (such as lease or purchase) and TCO analysis can help make cost comparisons between those commercial models.

Known Costs

Known costs in TCO analysis are:

1. **Purchase price**: The actual price of the piece of MDI equipment;
2. **Maintenance costs**: Warranty costs, maintenance labor, contracted maintenance services or other service contracts.

Hidden Costs

Hidden costs are the less obvious costs that are easy to overlook or omit from purchase and planning decisions. Hidden costs may include:

1. **Purchase costs**: These can include costs due to identifying, selecting, ordering, receiving, and inventorying. Any of these costs can signal the start of the ownership life for analysis;
2. **Set up and deployment costs**: Costs due to configuring space, transporting, installing, setting up, integrating, and outside services;

3. **Upgrade, enhancement, refurbishing costs**: These can include known upgrades or refurbishment costs through the life of the equipment;
4. **Reconfiguration costs**: These should include any known reconfiguration costs as per the MDI manufacturers guidance through the life of the equipment;
5. **Operating costs**: For example, salary cost for operators and energy costs and fuel costs;
6. **Change management costs**: Costs due to user orientation, user training, and workflow or process change;
7. **Infrastructure support costs**: Costs of heating, lighting, cooling, or IT support costs;
8. **Environmental impact costs**: Costs due to waste disposal, clean up, and pollution control. These may also include costs due to environmental compliance reporting;
9. **Insurance costs**: Costs incurred to insure the MDI equipment;
10. **Security costs**: Physical security, for example, costs due to building locks, secure entry doors, closed circuit television, and security services;
11. **Electronic security**: Costs due to security software, offsite data backup, and disaster recovery services etc.;
12. **Financing costs**: Costs due to loan interest and loan origination fees;
13. **Disposal or decommission costs**: Costs associated with the disposal and decommissioning of MDI equipment;
14. **Depreciation**: Costs associated with expense tax savings (a negative cost).

Calculating TCO

The following items in Table XIX should be considered in deciding which costs will be included in the TCO methodology to be used in calculating bidders'/proposers' costs.

Initial Purchase Costs	**Purchase Price**	Purchase price of the MDI equipment including accessory items and customization. If the equipment is procured via a lease arrangement, identify the annual lease payments in a leasing costs section.
	Duties and Taxes	Costs associated with any duties or tax paid as part of the MDI equipment purchase.
	Delivery and Transportation Costs	Costs associated with having the equipment delivered. This includes freight, foreign exchange costs and transit insurance.

	Installation Cost	Costs associated with having the equipment installed (including getting access), integrated and calibrated on site.
	Integration Cost	Costs associated with integrating and interfacing the equipment with existing systems and other equipment such as software updates and connections to IT systems.
	Facility Modifications	Costs associated with modifying the facilities to accommodate the MDI equipment such as floor reinforcement, air conditioning upgrades, filtering systems and protective linings. These costs may also include any costs to remove the equipment being replaced.
	Initial Training	Initial training costs such as train the trainer, course materials, biomedical engineering, engineering and technical support, training and service manuals.
	Initial License Costs	Any costs associated with any initial licensing costs for the MDI equipment or software to operate the equipment.
	Trade-In	Discounts or allowances provided by the MDI supplier for any equipment traded in. Only include actual discounts received. Do not include the written down value of the item being replaced.
Leasing Costs	**Lease Payments**	Annual leasing costs for the item of MDI equipment being acquired (if purchased via lease arrangement).
	Residual Lease Payments	Identify (if applicable) any lump sum residual payments payable at the end of the lease term.
Maintenance Costs	**Maintenance Agreement(s)**	Costs associated with a 3rd party maintenance agreement to cover routine maintenance of the MDI equipment.
	Scheduled/Preventative Maintenance	Regular activities that need to be undertaken to maintain the equipment in safe working order such as preventative service kits. This would include additional resources required for in-house maintenance and/or maintenance contracts with external service providers.

	Decontamination and Waste Disposal	Costs associated with cleaning, sterilization, disinfection, decontamination and the disposal of hazardous waste such as radioactive materials or chemicals. Only include costs that are directly related to the item of equipment such as specific chemicals or decontamination equipment.
	Service/Repairs, outside of a Maintenance Agreement	Costs associated with any service or repairs that aren't covered by a maintenance agreement or if a maintenance agreement isn't in place.
	Spare Parts	Costs to acquire spare parts needed for the upkeep of the MDI equipment.
	Other Maintenance Costs	Other significant maintenance costs associated with this type of equipment.
Operating Costs	**Staffing Costs**	Salary and related on-costs associated with employing additional staff to operate and maintain the MDI equipment.
	Accreditation and Certification	Costs associated with undertaking certifications and compliance audits and ensuring that the MDI equipment meets professional standards.
	Supplies and Consumables	Costs of supplies and consumables directly used in operating the equipment.
	Ongoing Training	Costs for undertaking train the trainer, in-house biomedical engineering / engineering / technical support training, refresher course and the production/acquisition of training material.
	Facilities and Infrastructure	Ongoing costs for facilities and infrastructure such a building rent and maintenance.
	Software Upgrades	Fees and charges associated with any software upgrades required to operate and maintain the MDI equipment.
	Utilities	Energy costs directly associated with operating the equipment where these costs are material and can be reliably estimated.

	Insurance	Costs associated with the insurance of the MDI equipment.
	Licenses	Fees and charges associated with licenses required to operate and maintain the equipment such as software.
	Other Operating Costs	Other significant operating costs associated with this type of equipment.
Repair Costs	**Repairs and Unscheduled Maintenance**	Unanticipated costs to maintain the effective life and safe working order of the MDI equipment. For simplicity, and given that repairs are unforeseen, an annual 'best' estimate of possible repairs is satisfactory. This estimate should be based, where possible, on past-experience for the type/brand of MDI equipment and reliability cited by the manufacturer.
	Upgrades and Refurbishments	Periodic updates to the MDI equipment to maintain the equipment in accordance with statutory or the manufacturer's requirements.
	Spare Parts and Accessories	Costs of replacement spare parts and accessories over the life of the MDI equipment such as monitor cables.
	Other Repair Costs	Other significant repair costs associated with this type of equipment.
Downtime Costs	**Planned Maintenance Outages - Additional Costs**	Any costs as a result of any planned maintenance outage(s).
	Unplanned Outages - Additional Costs	Other estimated additional costs as a result of any unplanned outage(s).
	Unplanned Outages - Lost Revenue	Any lost revenue as a result of any unplanned maintenance outage(s).
End of Life Disposal Costs	**Decommissioning or Deconstruction Costs**	These are costs to decommission, remove from service and safely dispose of the equipment at the end of its useful life such as removal costs, freight, 'make good' repairs to the facility. This should be the best estimate at the time of purchase. Where possible, disposal costs of

		similar items may provide a suitable guide to provide an estimate of these costs.
	Cost of Transportation of Equipment	These are the costs associated with the transportation of the MDI equipment to the health-care facility.
	Disposal Costs	Any costs that relate to safe disposal of the MDI equipment, particularly any hazardous components.
Disposal Income	**Resale / Salvage value of Equipment**	The forecast value of the item either as re-sale or salvage.
	Resale / Salvage value of Parts	The forecast value of any parts expected to be held in stock by the Borrower at the end of the equipment's life, either as re-sale or salvage.
	Resale / Salvage value of Operational Items	The forecast value of any operational items (consumables) expected to be held in stock by the Borrower at the end of the equipment's life, either as re-sale or salvage.

Table XIX – Key specifications

Obtaining TCO Bids/Proposals and evaluation

As part of the procurement process, the Borrower should compare bids/proposals using TCO. As such the above information needs to be requested in the RFB/RFP. Annex 3 contains a standard TCO template. It can be used to request bidders/proposers prepare an appropriate TCO schedule. Using a standard template will make it easier for the Bidder/Proposer to compile the requested information and for the Borrower to analyze all bids/proposals on a comparable basis.

If a TCO approach is to be used as part of the evaluation of bids/proposals the Borrower should ensure that:

1. As part of early market engagement, it is made clear that Bid/Proposal evaluation will be on a TCO basis and that detailed TOC information will be sought;
2. Their needs are made clear so that bidders/proposers can produce accurate TCO information that is customized to meet these needs;
3. Bidders/proposers are given sufficient time to prepare a detailed, comprehensive TCO calculation;
4. They are able to answer bidder's/proposer's questions about TCO in a prompt manner and ensure that all bidders/proposers are provided with the same information at the same time.

Designing the Procurement Approach

B. Selection Methods

Bank Approved Selection Methods

The Procurement Regulations offer a number of approved selection methods, selection arrangements, and market approaches for the procurement of MDI equipment, associated services and MES contracts.

Selection method example include:

1. Request for Proposals (RFP).

Selection arrangement examples include:

1. Public-Private Partnerships (PPPs);
2. Competitive Dialogue.

Market approach examples include:

1. Open competitive or limited source;
2. Single stage or multi-stage;
3. Use of rated criteria;
4. Use of BAFO or negotiations.

Designing the optimum, fit for purpose procurement process involves selecting the right combination of these options. The PPSD, which is prepared for each individual project, will determine the optimum fit for purpose process for that project.

Drawing on the analysis and findings in this guidance document, a number of conclusions can be drawn on the key features and options in undertaking the procurement of MDI equipment and services. These conclusions are based on the level of competition within the MDI equipment market, the number of capable suppliers available, the specificity of the requirements, and the inherent risks involved in delivery.

The main sources of information for determining the optimum combination of these options are the:

1. Market analysis;
2. Market engagement strategy;
3. Procurement risk analysis.

To complete the full contract strategy and procurement approach the Selection Methods elements need to be combined with pre-market engagement, the choice of specification type, the pricing and costing mechanism, the TCO methodology and the evaluation methodology.

Optimal Combination for MDI Equipment

For most MDI equipment procurements, the optimum combination of selection methods, selection arrangements, and market approaches will include the following key features:

1. Request for Proposals;
2. Open Competition;
3. International Competition;
4. Approaching International Market;
5. Initial Selection;
6. Two Stage following Initial Selection;
7. Rated Criteria;
8. Negotiations.

The following tables describes each of these features as they apply to MDI equipment.

Selection Method / Arrangement / Market Approach	Justification
Request for Proposals	An RFP should be used as it allows suppliers the opportunity to offer more innovative solutions and provides the Borrower with greater opportunity to receive improved VfM through evaluating the relative merits of proposals, especially those that exceed any minimum requirements stated. It also provides suppliers the opportunity to offer customized solutions that may vary in the manner in which this is achieved. It provides enough flexibility for suppliers to offer the most up-to-date solutions and harnesses the Borrower's ability to take advantage of the newest technology available, if appropriate.
Open Competition	The use of Open Competition is essential to ensure a wider range of options from the market. However, suppliers need to be given adequate notice and time to fully respond to the Borrower's requirements and submit their best proposals. Therefore, the deadline for submission of proposals must be reasonable. Providing adequate notice helps tackle the issue the market place has with not being given enough notice to respond to opportunities.

Approaching International Market	The MDI equipment and services market is international by nature and therefore using International Competition will maximize the choice of suppliers, the breadth of different types of solutions (both technical and commercial) and ultimately competitiveness.
Initial Selection	Initial Selection is normally used with RFPs. It enables the Borrower shortlist from the initial response and invite only the best suppliers to submit full proposals. It also has the added benefit of reducing the number of proposals received at RFP stage as well providing confidence that the proposals that are received are likely to be of a higher quality. This will also save the Borrower time in that it will not have to undertake detailed evaluation of proposals that prove to subsequently non-compliant or of poor quality.
Two Stage following Initial Selection	A Two Stage selection process is best suited to complex information technology, which characterizes MDI equipment. It also works very effectively with the use of more performance-based specifications. This approach also integrates well with pre-market engagement as it provides Borrowers and suppliers with the opportunity to have discovery meetings to refine the business or functional performance requirements and suppliers to submit modified proposals based on these refined needs. This also helps address feedback from the market place that procurements are undertaken at arm's length and it is not always possible to get total clarity on what is required, which ultimately leads to complaints.
Rated Criteria	Rated criteria are an integral element of an RFP. The justification for using rating criteria is provided in detail in Section VI, sub-section 3 of this guidance.
Negotiations	The supply, installation, commissioning and operation of MDI equipment and services has many variables. The use of negotiation provides the opportunity to explore those variables and, through discussion with a supplier, understand the impact of these on their cost proposal. This may provide the opportunity for the Borrower to receive a reduction in cost or improvement in service. In addition, the Bank has access to other pricing proposals from other projects and this information can be used to benchmark pricing and where a negative discrepancy exists, negotiate on price.

Table XX – Key specifications

Where a project or country is likely to have a continuing need for supply of Equipment MDI equipment and associated services, the best option may be to establish a Framework Agreement. The same contract strategy as detailed above should be followed.

Considerations in Medical Equipment Service Contracts

The use of the approved selection methods, selection arrangements, and market approaches described for the supply of MDI equipment and services can be used for Medical Equipment Service Contracts (MES). However, for complex MES contracts the use of Competitive Dialogue should also be considered.

The Regulations state that Competitive Dialogue is most suitable for undertaking procurements where:

1. *A number of alternative solutions, that satisfy the Borrower's requirements, may be possible, and the detailed technical and commercial arrangements required to support those solutions require discussion and development between the Borrower and Proposers;*
2. *Due to the nature and complexity of the procurement, the Borrower is not objectively able to:*
    a. *Adequately define the technical or performance specifications and scope to satisfy its requirements; or*
    b. *Adequately specify the legal and/or financial arrangements of the contract.*

MES contracts meet all these requirements as by nature they are novel, complex, long term and have many variables, including complex costing and pricing mechanisms designed to incentivize suppliers to deliver high quality services and can often be linked to medical outcomes.

The tests used to establish if a Competitive Dialogue is the optimum fit for purpose procurement approach include:

Test	Justification
Are the "needs" clear, but the "means" of delivering these "needs" undefined?	MES contracts can be linked to the delivery of clinical outcomes, where the supplier is free to innovate on how to deliver those outcomes. MES contracts use performance-based specifications that do determine how MES solutions are delivered.
Does the Borrower want to encourage and allow innovation, and refrain from defining the "means" through which the "needs" should be delivered?	A fundamental objective of MES contracts is to harness the knowledge and innovation of suppliers in the market place on how to deliver best solution to meet outcomes while maximizing VfM.

Test	Justification
Could the "needs" be met through several different solutions?	There are multiple different operational, technical, legal and commercial solutions to delivering MES contracts.
Are there several potential options that could be adopted to provide the commercial element of the overall solution?	There are multiple different commercial solutions to delivering MES contracts such as charge linked to clinical outcomes through to charges based on through-put and efficiency. In addition, under a value-based procurement approach which encompasses a Competitive Dialogue, pricing mechanisms can be established that pass risk to the supplier and provide incentives for them to manage those risks as well as incentivization for delivering a high quality of service.
Is the contract unique or unusual, e.g. no previous procurements have been undertaken by the Borrower for similar requirements?	MES contracts are novel and the Bank has yet to award a contract requiring this type of service.
Is the Borrower sure that other procurement selection methods and arrangements do not allow for the required level of collaboration between the Borrower and proposer to allow the development of an acceptable solution?	The use of the procurement arrangements described for the supply of MDI equipment and services can be used for MES contracts. However, for complex MES contracts the use of competitive dialogue should be considered.
Does the Borrower have sufficient resource to devote to an intensive procurement process that may last 12 to 18 months, and require a high level of input, resource and cost (especially in relation to preparation, rounds of dialogue and proposal evaluation)?	It is unlikely the Bank or Borrower would have sufficient capacity to use Competitive Dialogue for an MES contract as both the use of MES contracts and Competitive Dialogue are new to both the Bank and Borrower. Any use of these approaches would require substantial capability building, augmented with expert external resources.
Is there the potential for a high level of market interest and therefore strong competition?	MES contracts for MDI equipment are a market driven innovation. A number of large suppliers in the market place are already providing these solutions to projects that aren't funded by the Bank. The market place is also actively encouraging the Bank to consider MES solutions and is providing information and data to demonstrate how the delivery can improve VfM.
Have other procurement selection methods and arrangements, such as the use of a RFPs, with a negotiation stage, been assessed and discounted as not appropriate for the contract?	The use of the procurement arrangements described for the supply of MDI equipment and services can be used for MES contracts. However, for complex MES contracts the use of competitive dialogue should be considered.

Table XXI – Competitive Dialogue tests

The application of the Competitive Dialogue "tests" described above provide a strong indication that Competitive Dialogue is a viable procurement arrangement for MES contracts, as long as due consideration is given to the capacity issues associated with delivering such a complex procurement.

As with an RFP, the procurement arrangements for Competitive Dialogue need to be combined with pre-market engagement, the choice of specification type (performance), the pricing and costing mechanism, the TCO methodology and the evaluation methodology to complete the full contract strategy.

Designing the Procurement Approach

C. Evaluation Methods

VfM and Non-Price Attributes

The Bank's Procurement Policy defines VfM as follows:

> *"The principle of value for money means the effective, efficient, and economic use of resources, which requires an evaluation of relevant costs and benefits, along with an assessment of risks, and non-price attributes and/or life cycle costs, as appropriate. Price alone may not necessarily represent value for money."*

The procurement of MDI equipment is moving rapidly towards value-based purchasing. This brings the focus on MDI equipment that achieves the best healthcare outcomes. Rather than equipment that simply satisfies the technical requirements.

VfM in MDI equipment has a close link to innovation. Innovation often improves the quality and efficiency of health services, thereby contributing to improved population health (social value). For example, innovation can decrease waiting times, length of hospital stays, morbidity and mortality rates. In addition to the obvious social and patient care benefits, innovation also contributes to the affordability of healthcare services (economic value).

VfM is a holistic concept. Ideally bid evaluation should try to reflect, as close as possible, the MDI equipment's expected impact on healthcare outcomes, including financial, clinical and societal factors. As already indicated, cost analysis needs to consider more than price and take into account life-cycle costs and the broader efficiencies which may be generated by sourcing high-value products.

This guidance has already considered the assessment and management of risk as well as why, what and how to calculate whole-life costs through determining TCO. Of significant importance in the procurement of MDI equipment, are non-price attributes and how these can be evaluated to help establish total VfM. Clearly VfM is not just about cost, but also about the broader delivery of patient outcomes. VfM therefore encompasses both cost and non-cost factors.

Most Advantageous Bid/Proposal

The Procurement Regulations require that contracts are awarded on the basis of identifying and selecting the supplier that submits the Most Advantageous Bid/Proposal (MAB/P). The definition of MAP in the Regulations when rated criteria are applied is

> *"When rated criteria are used, the Most Advantageous Bid/Proposal is the Bid/Proposal of the Bidder/Proposer that meets the qualification criteria and whose Bid/Proposal has been determined to be:*
>
> *a. Substantially responsive to the request for bids/request for proposals document; and*

b. The highest ranked Bid/Proposal."

Rated Criteria

The IEP market analysis provides a strong indication that the optimum procurement approach when evaluating MDI equipment is through the use of rated criteria.

The rational for this is:

1. Quality is an important consideration. The quality of a product or service may have a high impact on the overall cost as regular repairs or maintenance (additional to the purchase price) may add to the overall cost, with regular breakdowns resulting in loss of productivity until the item is fixed;
2. MDI equipment has different functional and technical capabilities, where certain features may provide additional value to Borrowers above and beyond their minimum requirements;
3. The quality of the MDI equipment can also impact on its life. A higher quality product may be more likely to last longer than a poorer quality one. A longer lasting quality product provides increased operational benefits and means the purchase price can be spread over more years;
4. Equipment that is coming to the end of its life can be inexpensive but may lack the capacity to meet Borrower ongoing needs;
5. The market is dynamic and continues to develop innovative solutions. Rated criteria can allow evaluation of the relative benefits of different ways of delivering the Borrower's requirements. Innovation is about value creation and, within the healthcare system, innovation can improve the quality and efficiency of health services, thus contributing to improved population health (social value);
6. The effective operational use of MDI equipment is dependent on the quality of support and maintenance services. These can be provided in different ways and with different levels of proven success, making an assessment of these factors essential in identifying the optimum overall solution;
7. The market can now supply additional services from training on the use of the MDI equipment through to providing the technicians to operate the equipment. This means bid evaluation needs to cover the relative merits of each supplier in a more qualitative way;
8. The move to service-based solutions, such as MES, means that bid evaluation in these circumstances is far less about the functionality and technical merit of the MDI equipment being used and more about the methodology that individual suppliers will be using to deliver the total managed service function and achieve the specified outcomes;
9. The use of performance specifications provides suppliers more freedom to propose innovative solutions that are best assessed against qualitative requirements using

rated criteria. Suppliers can better demonstrate that their solution is robust and can effectively and efficiently deliver the Borrower's requirements;

10. Traditional procurement approaches, based on lowest price conforming bid, have led to a failure in managing the risks associated with buying and operating MDI equipment. The use of rated criteria can tangibly assess these risks and how these are going to be managed and mitigated by a supplier's solution;
11. Feedback from the market states that manufacturers and suppliers are unable to offer the most innovative and optimum solutions where the buyer's focus is on the lowest cost conforming bid. This precludes them from offering valued-added features to their bids as these are not recognized or credited. With a focus on lowest capital cost suppliers are disadvantaged if their innovation involves short-term investment to implement.

Benefits of Rated Criteria

In summary the benefits of using rated criteria include:

1. Allowing Borrowers to rank proposals in order of merit;
2. Setting a minimum score which Proposers must meet. This supports selecting only the best quality proposals;
3. Applying rated criteria rewards proposals that exceed minimum requirements;
4. Enabling consideration of non-price attributes where price is not the key determining factor;
5. Using requirements that are based on performance and outputs, not functions or inputs;
6. Comparing the merits of alternative proposals;
7. Enabling sustainable procurement, benefits such as the ability to offer products or services with low environmental impact or the ability to reduce costs over the life of contract, including e.g. disposal, power efficiency, reduction in waste, avoiding hazardous substances.

Developing Rated Criteria

In developing the rated criteria to be used Borrowers need to decide the following:

1. Balance between price and quality (rated criteria) in the overall evaluation. Based on market research the range for the qualitative assessment should be weighted from 30% for simple purchases and 70% for complex services such as MES solutions;
2. Quality attributes (the rated criteria) that will be used for the evaluation making sure questions are included in the bidding/procurement document to obtain that information;

3. Relative importance and priority of each individual qualitative criteria through the allocation of an individual weighting;
4. Minimum threshold scores for each individual rated criterion or for the aggregate rated criteria score.

Consideration should also be given to the list of features which could contribute to the MDI equipment's value as detailed below. The actual rated criteria used will vary from contract to contract depending on an individual project's requirements, scope, complexity, risks and market dynamics in a particular geographic region. Considerations include:

1. Delivery and installation schedule for each piece of equipment;
2. Equipment layouts for all equipment including all options;
3. Conformance of the proposed layouts with stated room sizes and medical facility layout;
4. Time required for installation, start-up, acceptance testing, and removal of existing equipment, including details of subcontractor(s) equipment installation, equipment calibration;
5. Substitution for new equipment introduced by supplier after the award of contract, but before delivery, that more suitably meets the Borrowers clinical requirements;
6. Operational service delivery and efficiency methodology;
7. Technical benefits/merits from information on functional adequacy of the designs including provision of adequate space for normal work activities;
8. Newness of technology being used e.g. is it leading edge or bleeding edge and what are the test results;
9. Standards to determine quality;
10. Safety, i.e. ability to lower or minimize adverse events or complications;
11. Clinical effectiveness, including reductions in morbidity or mortality rates or as measured by patient-reported outcomes and patient satisfaction and preference;
12. Reliability and service level of the vendor/manufacturer, including warranty, maintenance, customer care and clinical training and support;
13. 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).
14. Policy on newly developed hardware and software, equipment and software modifications for improved performance and reliability, and correction of design, component, or manufacturing defects;
15. In-service training for clinical personnel and technical training;
16. Training program length and format, content, the qualifications of the instructors, and written and/or electronic materials;

17. Standard warranty agreement and a description of proposed warranty terms, including any partial (less than one year), pro rata, or extended warranties;
18. Local and regional factory-based service capabilities, including the number and qualifications of service engineers, as well as their training, their base locations, the locations of backup service engineers;
19. Approximate response time for emergency repairs (both during and outside of regular business hours);
20. Location of primary and backup spare-parts locations;
21. Time for delivery of parts after notification;
22. Description of factory engineering backup capabilities;
23. Environmental effects including sustainability.

VfM Evaluation

AdvaMed have produced a helpful guide on Good Practices for the Procurement of Innovative Medical Technology[6]. This document offers a number of hints and tips on how to effectively undertake bid evaluation on a VfM basis. These include:

1. Value-based award criteria should be routinely used in medical device procurement (as opposed to the simplistic recourse to procurement based on lowest price). This means "best value for money" procurement which for the Bank and Borrowers is the Most Advantageous Bid/Proposal;
2. Procurement authorities under no legal obligation to implement MEAT or best value criteria, should normalized their use as the most appropriate method of procuring innovative healthcare technology;
3. Award criteria should be verified against value-based checklists;
4. Checklists should be consulted on in advance with industry;
5. Rated criteria as set out in the proposal documentation, should clearly delineated cost and non-cost criteria;
6. Relative weightings of cost and non-cost criteria and sub-criteria should be transparent;
7. Award criteria should not be so prescriptive that innovative solutions are penalized;
8. Incentives should be used to encourage innovation;
9. Decision-making throughout the procurement process, from design to award, should involve a diverse range of stakeholders, including medical experts and other end-users;

6 https://www.advamed.org/sites/default/files/resource/809_good_practices_for_the_procurement_of_innovative_medical_technology_final_tagged.pdf

10. Decision-makers should have the right to review and amend criteria in advance of the release of tender documentation and, subsequently, to review award decisions to guarantee the application of award criteria;
11. Compliance of each proposal with the value-based policy should be recorded;
12. Procurement authorities choosing to purchase according to price or where the award weighting is mainly accounted for by price should be exceptional and the reasons for this choice should be set out in a written report;
13. Each national jurisdiction, fixed value protocols should be agreed between industry, healthcare key opinion leaders and procurement authorities to ensure certainty and a value-based policy.

Designing the Procurement Approach

D. Contract Management

Contract Management

Good contract management is critical to the successful delivery of projects. Its purpose is to ensure that the contract delivers the right quality and quantity in the right place and time for the right price. Contract management requires systematic and effective planning, execution, monitoring, and evaluation. It aims to ensure that both the supplier and the Borrower fulfil their contractual obligations and commitments.

Contract Management Need Analysis

Contract management is essential in ensuring MDI equipment contracts deliver the expected outcomes. The Supply Positioning analysis (IEP Market Analysis, Section VII) categorizes MDI equipment as "Strategic Security" (i.e. lower value, but high risk). This means that the Borrower needs to secure reliable ongoing supply through highly motivated suppliers, while not necessarily being able to use the contract size/value as an incentive or lever. This makes the use of contract management essential in ensuring suppliers deliver as per contract.

The Supplier Preferencing analysis (Section VII) categorizes the Borrower as of low interest to suppliers (i.e. lower value, and unattractive to suppliers). This can mean suppliers are not highly motivated to provide their best service to Borrowers. The misalignment between the Bank's supply positioning of "Strategic Security" (high risk procurements that need to succeed), with the markets view of the procurements as a "Nuisance" is of great concern.

This guidance addresses (Section IV) how the Bank and Borrower can work to raise the attractiveness to a level where the market treats these procurements as a business development opportunity. This means they will be more positively engaged and likely to bid more competitively. In addition to these strategies, contract management is another procurement technique that improves this attractiveness as it provides a forum for Borrowers to manage its suppliers, but also for suppliers to manage Borrowers to ensure they deliver on their obligations as well as providing a communication mechanism for issues to be discussed and remedial actions agreed.

The importance of contract management should not be under estimated. The IEP market analysis (Section VII) has already identified that up to 70% of MDI equipment may not be used, for a range of reasons including spare parts shortages, lack of regular maintenance and poor support and maintenance services. In addition, the procurement risk analysis also identified key risks to both the supply and ongoing operation of MDI equipment including:

1. Equipment reaching the end of its useful life time;
2. Equipment too technically advanced for full use;
3. Equipment not future proofed;

4. Delays in the provision of spare parts;
5. Delays in the provision of support and maintenance;
6. Lack of compatibility with existing equipment;
7. Software failure;
8. Software requires regular upgrades;
9. Delays in the provision of consumables;
10. Delays in the provision of mechanical and electrical requirements;
11. Delays to civil works;
12. Delays to equipment supply.

Contract Management as a Risk Management Tool

Effective contract management should help mitigate or manage these risks as it involves:

1. Tracking and monitoring cost, time, place, quantity and quality of deliverables;
2. Clear understanding of the roles and responsibilities by both the Borrower and supplier;
3. Managing relationships with the supplier and key stakeholders;
4. Managing payments in accordance with agreed terms;
5. Being proactive throughout the contract to anticipate problems and issues before they arise;
6. Managing problems and issues as they arise, quickly, effectively, fairly, and in a transparent manner;
7. Collaborating to improve performance and promote opportunities for ongoing innovation.

From the Borrower's perspective, effective contract management also:

1. Ensures the supplier delivers upon its commitments;
2. Obtains best value for money (VfM) during the life of the contract;
3. Manages supply risks for the duration of the contract;
4. Continually challenge and drive best value in contract delivery;
5. Ensures contracts deliver to the requirements;
6. Demonstrates best procurement practice in the management of contracts.

Plan, Execute, Manage

A significant feature of contract management is that it provides an end-to-end view of a contract's lifecycle. The quality of contract management directly impacts how the Borrower

delivers health services to its citizens, controls cost, ensures compliance, and reports of results. Contract management primarily focuses on creating, executing and managing contracts across three key implementation phases. These are:

1. **Plan**: planning how the procurement will be undertaken in order to award the contract, and planning how the contract will be implemented;
2. **Execute**: executing contract implementation as per the plan;
3. **Manage**: proactively managing delivery during contract implementation, including effective management of emerging risks and issues.

Plan

This guidance describes how to design the optimum, fit-for-purpose, proportionate procurement approach for MDI equipment. Part of designing the procurement approach involves considering how the contract will need to be managed. The information and data collected at the PPSD stage can inform contract management planning. For example:

1. **Supply positioning:** this helps determine how critical the procurement is to the Borrower and informs how much resource and effort the Borrower should spend on contract management. Based on the challenges associated with successfully delivering MDI equipment and services, the conclusions drawn, on a general basis, are that contract management resource and effort should be high;
2. **Supplier preferencing:** this helps to determine how focused and committed the supplier is likely to be in delivering the contract. Including, how much time and effort they are likely to apply in resolving unanticipated problems and working with the Borrower in a collaborative manner. Based on this knowledge, the Borrower can decide the best approach to managing the supplier, including supplier meetings, reporting, communications etc. The MDI equipment industry states their commitment to Bank funded projects is high and they are committed to fostering an ongoing collaborative approach to delivery. On this basis Borrowers should consider having regular contract management meetings throughput the contract term, with frequency being highest during set up and installation and the first six months of operation;
3. **PPSD**: this provides information that assists in the preparation of the Procurement Plan and the subsequent contract management. Key elements of the contract management plan are Key Performance Indicators (KPIs) and milestone events. The sections on the Commercial Model (Section VI, sub-section 1), Pricing (Section VI, sub-section 1), and Bid Evaluation (Section VI, sub-section 3), provide suggestions on the information required from bidders/proposers during the sourcing stages. Some of this information forms key components in the contract management plan, such as:
    a. Delivery and installation schedule for each piece of equipment;
    b. Equipment layouts for all equipment;

c. Time required for installation, start-up, acceptance testing, and removal of existing equipment details of subcontractor(s) equipment installation, equipment calibration;

d. Standards to determine quality such as service level agreements;

e. Safety, i.e. the ability to lower or minimize adverse events or complications;

f. Clinical effectiveness, including reductions in morbidity or mortality rates or as measured by patient-reported outcomes and patient satisfaction and preference;

g. Reliability and service level of the vendor/manufacturer, including warranty, maintenance, customer care and clinical training and support;

h. In-service training for clinical personnel and the technical training;

i. Standard warranty agreement and a description of proposed warranty terms, including any partial (less than one year), pro rata, or extended warranties;

j. Environmental effects, e.g. sustainability.

The Procurement Regulations, Annex XI Contract Management, identifies other factors to be included in a contract management plan, such as:

1. Identified potential risks (such as delays in the contractor's right of access to site, payment delays, and other defaults in the Borrower's contractual obligations that could potentially lead to contractual disputes), and their mitigation;
2. Key contacts and roles and responsibilities of the parties;
3. The names and contact details of the key contacts for each party;
4. Ensuring that each party has established the necessary authorizations and delegations for its personnel at the beginning of the contract is an important prerequisite to ensuring that all contracting decisions are valid and enforceable;
5. Communication and reporting procedures;
6. Key contractual terms and conditions;
7. Contractual milestones, including critical path (identified to ensure early detection and mitigation of issues), and payment procedures consistent with contractual provisions;
8. Key contract deliverables identified and properly described, and updated to account for change orders during the execution of the contract;
9. KPIs and a description of the measurement process;
10. Formal contract variation/change control mechanisms;
11. Record-keeping requirements and systems to be applied.

Execute

The Borrower should use the information, approach and methodology set out in the contract management plan to regularly and consistently monitor the actual performance and progress of the contract against what has been planned. Progress, risks and emerging issues need to be reported to key stakeholders and the Bank with copies being given to the supplier. The Bank may use the information gathered to benchmark performance.

A contract management plan should be initiated during the period when the contract is being written. It is good practice to discuss and agree the final terms of the plan with the supplier. The plan should be completed and signed at the same time as contract signature. It is essential that all parties have a shared understanding of what is required to be delivered and how progress will be tracked, measured and reported, in particular in relation to how performance against KPIs will impact on payment.

Manage

Managing the contract is the most critical stage because all the value that has accrued through planning only materializes if the supplier is held to account in delivering against the contract. The management and monitoring of contract implementation can be considered as a form of risk management in that it puts in place a series of controls that should stop potential risks becoming real issues. Contract monitoring may also include Bank supervisory activities.

Risk Management

All risk management processes begin with identifying possible risks, assessing the probability of their occurring and the impact if they do occur. A plan is then developed to avoid the risks occurring and, if they do occur, mitigating their impact. These strategies are recorded in a risk management plan, which the contract manager will monitor during contract implementation and adjust, if needed. The risk management plan is a fundamental tool to practical contract management.

Poor risk management preparation can lead to ongoing sub-standard delivery. For MDI equipment and services this can result in increased costs, delays, and poor provision of health services and patient care. Actions Borrowers can take to tackle these risks include:

1. **Start-up Implementation**: All implementation aspects of the contract should be reviewed to ensure proper preparation for managing implementation is done. A contract management team needs to be formed and staffed with sufficient resource and capability relative to the size, scope complexity and importance of the contract. Systems and management methodologies need to be put in place. For example: communication plans, operational procedures, management decision making controls, working instructions, documentation and record keeping, systems including data access controls (administrative, operational, technical, reporting, financial etc.), management performance reports, nominated contact persons for the Borrower and supplier, and training of supplier, as require. The Borrower's staff who will manage the contract need to become familiar with the contract requirements and contract management plan,

methodologies and systems. The supplier staff need to become familiar with the healthcare facility and Code of Conduct;

2. **Control**: The supplier's performance should be frequently monitored, including regular inspections and audits. The Borrower should monitor (standard) performance through regular reporting, to satisfy themselves that the contract is being delivered as per the requirements and to check that the management control system is efficient and effective. Meetings should be organized in line with contract specifications to prevent avoidable loss or delay without consuming excessive time. Actions and agreements resulting from meetings should be properly documented. This should help minimize the opportunity for contract variations and budget creep. It is essential that deviations and modifications are agreed as per the contractual change procedure. They must be properly authorized and recorded. Any provision of MDI equipment or services outside the scope of the contract should not be provided without prior costing and agreement (using agreed contractual change procedures). Borrowers should have a complaints or disputes procedure in place, as agreed with the Bank. The complaints process should, at a minimum, document grievances and incidents and record how they have been resolved. It is essential that timely, and appropriate action is taken recover losses or mitigate claims, as agreed with the Bank;

3. **Performance Management**: The KPI's should be recorded in the contract and monitored by the Borrower. The supplier's achievements against KPIs must be based on actual delivery and results. For a KPI to be met there must be evidence of, for example, efficiency and effectiveness improvements, budget or cost reductions, or realization of more fixed prices and services in a specified time. The Borrower should also ensure the supplier performs sufficient work or job preparation to avoid subsequent safety or competence claims, incidents or other inefficiencies such as ESHS briefings and relevant "authority-to-work" permits are given or issued to supplier staff prior to commencement of work, required staff headcount and competences are determined, and/or required sequence and critical path of activities (incl. inspections) are determined and assigned;

4. **Enforcement Action**: Borrowers can incur avoidable loss by not appropriately enforcing the contract terms and conditions or activating contractual sanctions during implementation. This can happen where there has been insufficient monitoring or incorrect or overpayments. By requesting the information in the sections on Pricing, TCO and Evaluation will help ensure sufficient breakdown of contracted work is available to manage and monitor aspects, such as specified performance standards, analysis of activities, functional and technical specifications, consideration of relevant standards, regulations and warranties, failure/malfunction solving procedures, research into modification or improvement possibilities and concept evaluation, review and improvement. This should include where suppliers purchase equipment and services from subcontractors;

5. **Monitoring**: Borrower's staff should monitor supplier activity to ensure that all work is carried out in accordance with the agreed order or contract specification. This prevents losses to the Borrower and subsequent contractor claims. Measures such as having

logistics arrangements and procedures in place at the healthcare facility and actively managing these to avoid congestion, downtime/demurrage and claims;

6. **Asset Use and Management**: MDI equipment should be recorded as an asset, on receipt, in a standard asset management system and tracked to avoid unauthorized use or disposal. The system should include records of consumable goods, spare parts, items removed from site for repair or storage, and any supplier equipment brought onto the healthcare facility;
7. **Accepting Equipment**: Before handover of equipment and release to the Borrower occur, the MDI equipment should be formally checked, inspected or tested to ensure that it complies with functional and technical specifications. The release should be formally authorized by the appropriate official, including ensuring any inspection, testing and verification work performed by the supplier complies with contract specifications;
8. **Invoicing and Payment**: Supplier claims for payment should be adequately verified by the Borrower in accordance with the contract terms. For example, work invoiced is confirmed by the Borrower via comparison with activity and progress measurements (e.g. Gantt charts, milestone charts or time sheets) and then signed off for authorization at the agreed level. Invoices should be checked prior to payment against the supporting documentation and authorized for payment by a responsible officer. That person should verify that the amounts charged are correctly calculated against the quality of service delivered etc. In addition, this should also include checking that previous controls have been fully performed and that the supplier has provided all necessary documentation as specified in contract;
9. **Communication**: It is critical that internal and external contract information is captured, reported and communicated in a productive, consistent, confidential and timely manner. Borrowers should determine the format, content and frequency of reported information in accordance with defined objectives, KPIs and other agreed actions. Borrowers should act quickly in relation to reporting problems (e.g. full reporting, on time, in the correct format, sent to the correct people etc.). Good, clear communications are essential to enable adequate performance control;
10. **Contract Management Meetings**: Inefficient and ineffective contract management meetings may frustrate the monitoring and achievement of the contract management objectives, cause avoidable conflict between parties, and frustrate the overall communication process. Therefore, Borrowers should implement a contract management meeting schedule and structure to enable efficient and effective communications and process performance control. Controls can include: description of relevant department and process participants, frequency, standard agenda listing in-line with defined the procurement strategy and policy plans, required management reports and action plans and minutes and 'action & decisions overview';
11. **Supervision**: The Borrower's senior staff, and the Bank's staff, as appropriate, should supervise the contract management process in a sufficiently detailed manner to ensure adherence to applicable policies, procedures, contract and Service Level Agreement. These

reviews should cover actual performance against planned, actual cost against budgeted, and quality of performance against agreed objectives and standards (including analyses of deviations). A detailed action plan (which includes the responsible person(s), due dates, follow up etc.) helps ensure effective follow-up of any improvement actions.

Key Performance Indicators (KPIs)

Key performance Indicators (KPIs) are the primary method by which supplier performance is measured. KPIs are measures of contract performance that are aligned to the key outcomes that the procurement approach has been designed to deliver. The KPIs should be "SMART" indicators (Specific, Measurable, Attributable, Relevant, and Time-bound). In medium to long terms contracts they can also be "SMARTER", which adds two further steps, namely: Evaluate the effectiveness and relevance of the KPIs and readjust as necessary. They should also be directly linked to the Project Development Objectives and the Procurement Objectives and this will help ensure contract delivery is fully aligned with the desired outcome. The KPIs should be included in the contract management plan, and if they link to incentive mechanisms/payment decisions, they will need to be agreed and included as part of the contract before it is signed. It is vital that the KPIs reflect the key deliverables in the contract and the method proposed to measure the performance is understood and provides meaningful data on which to gauge performance.

KPIs for MDI Equipment Supply and Services

Table XXII outlines typical KPIs for supply of MDI equipment and services.

KPI Description		KPI Measurement
1. Delivery		
a. On-Time Delivery	Provide contractually obligated deliverables and outcomes on agreed dates	• On time delivery of contractually obligated deliverables as per mutually agreed plans
b. Document Deliverables	Information is managed (shared, stored and communicated) in line with expectations defined in contract or as agreed between the parties	• Deliverables uploaded to knowledge system according to agreed timeframe. • Supporting/ working documents uploaded (Templates, weekly status reports, minutes of meetings, training manual, project progress etc.)

2. Support		
a. SLA Performance	Successfully meets contractual requirements relating to agreed SLAs.	• Number of SLA breaches, based on contractually agreed limits (e.g. service/hardware calls are completed on time)
b. SLA Documentation	Information is managed (shared, stored and communicated) in line with expectations defined in contract or as agreed between the parties	• Deliverables uploaded to knowledge system according to agreed timeframe. • Supporting/ working documents uploaded (Templates, weekly status reports, minutes of meetings, training manual, project progress etc.)
3. Quality		
a. Delivery Quality	Product/service meets quality acceptance criteria	• Number of deliveries that have met acceptance criteria (e.g. Number of defects, functionality of application, User Interface)
b. Supplier Personnel	Teams are made up of members with expertise relevant to our business including input from Subject Matter Resource (SMR)	• Number of people proposed, rejected or replaced due to performance issues or not meeting the expectations • Number of key project resources leaving and joining for the contracted services
c. Customer Satisfaction	Level of satisfaction received from service recipients / business users	• Rating received by service recipients / business users
4. Partnership and Innovation		
a. Relationship	Committed to building and maintaining effective relationships with senior executives.	• Number of no shows of supplier senior executives in steering committee meetings etc. • Number of dedicated supplier account management visits
b. Flexibility & Responsiveness	Demonstrates willingness and ability to respond to non-forecasted demand and ensure timely response to sourcing requirements	• Number of requests met without raising CRs • Timely response to sourcing and ad-hoc requirements "

c. Continuous Improvement and Innovation	Improved processes, products and services that are credible and implementable (quick wins). New product development (services) and innovative ideas for discussion and strategic decision making	• Number of improvement and innovation recommendations that are accepted • Adherence to supplier development plan
5. Governance and Risk		
a. Governance	Adheres to supplier performance management principles and meets requirements for governance	• Number of missed deadlines for inputs (agenda and pre-reads) and outputs (reports) • Actions closed from previous review meeting as agreed timeline • Disputes resolved amicably as per dispute resolution framework
b. Risk Management Compliance	Understands and adheres to requirements for risk management. Establishes and implements adequate controls to mitigate risks	• Risks are communicated as part of governance process. Risks raised with effective mitigation plans: – Project related risks – Supplier related risks
c. Contractual Compliance	Successfully meets legal contractual requirements and statement of work specification	• Number of contractual breaches identified
6. Financial		
a. Invoicing	Contractually compliant with the time and quality for submission of invoices	• On time submission of invoices with supporting documents as agreed • Number of invoice errors identified in the past period
b. Cost Transparency	Supplier provides transparency into its cost breakdowns	• Cost (invoices, financial proposals) is provided with a detailed breakdown of activities, services, products, quantities, etc.
c. Travel Spend	Amount spent on travel with and/or Partner Airlines.	• Amount spent on travel using qualified and/or Partner Airlines.
d. Price Reduction/ Discount/ Saving Opportunities	Price reductions/ discounts/ savings are consistently applied	• Number of instances of price reductions/ discounts/ savings and the amount • Identified volume discounts and other price-reducing options

e. Penalties	Financial penalties applied due to non-compliance to SLA, delivery schedule, product quality, etc.	• Number of instances of financial penalties applied and the amount
f. Change Requests/ Contract Amendments	Number and value of CRs/ Contract Amendments initiated since the previous scorecard or over the reporting period	• Total number of CRs raised/ Contract Amendments, value & scope of each CR / Contract Amendment

Table XXII – KPIs for MDI equipment

KPIs for MES Contracts

When considering an MDI service contract, it is important that the right KPI's are set and agreed between both parties to ensure effective management of the agreement.

The KPI's should cover financial, environmental, clinical efficiency, development and operational performance.

Example KPI's are listed in Tables XXIII to Table XXVI.

Financial

KPI	Definition	Measurement Method	Hospital Objective	Healthcare Objectives
Return on Investment	Return on MS investment	Cumulative (Cum.) Profit (Earnings) of hospital - Cum. MS Investment / Cum. MS investment	To maximize impact of the quality of investments	Sustainable and affordable care
Case efficiency	The results of the MS average case	Revenues of case - Costs of case/Costs of case	To obtain increased gains and savings resulted from operating efficiencies of the particular clinical case	Affordable care

Table XXIII – Financial KPIs

Environmental

KPI	Definition	Measurement Method	Hospital Objective	Healthcare Objectives
Energy Consumption	Amount of energy consumed by all MDI equipment contemplated in the MES system	Energy consumption per MDI device / system	To decrease the carbon footprint in the hospital	Sustainable care
Re-Use and Recycling	Use of re-used parts and recycled material in the supply chain of all equipment contemplated in the MS system	Amount of re-used parts and recycled material in the MS system	To reduce waste and foster a sustainable healthcare environment	Sustainable care

Table XXIV – Environmental KPIs

Clinical Efficiency

KPI	Definition	Measurement Method	Hospital Objective	Healthcare Objectives
Use of Standard protocols	The users' conformity to the standard protocols set by the hospital	On-site equipment data analysis (Utilization Management)	To fully comply with high quality healthcare standards	High quality care
Average Applied Dose	The average dose quantity applied for radiological protection	Total average applied for patients / Effective dose applied for patients	To improve patient safety	High quality care
Average Room Occupation Time	The amount of time required for patients to occupy clinical rooms in the hospital	Average (hrs.) and days of occupation	To reduce idle times, increasing patient throughput	High quality care
Gold Standard Use	The best-performing equipment use	Benchmark of best equipment use and hospital's average utilization	To ensure best in class treatment for patients	High quality care

Table XXV – Clinical Efficiency KPIs

Development

KPI	Definition	Measurement Method	Hospital Objective	Healthcare Objectives
Patient Satisfaction Rate	Overall patient satisfaction with the hospital's service (clinical department and sites)	Average level of satisfaction survey responses in patient population	To improve the patient experience with the services delivered by the hospital	High quality care
Employee Satisfaction Rate	Overall employee satisfaction with the equipment, maintenance and all extended services included in the MS solution	Average level of satisfaction survey responses in patient population	To retain long-term qualified employees committed to delivering high quality care	Transformation of health Services
Training Level of Staff	The number of staff trained within an MS, impacting on the clinical knowledge of the employees	The number of staff trained within a period of time by the MS partner for each equipment device in a clinical department	To have, and retain, high-qualified clinical and technical personnel in the clinical departments/units of the hospital	Training and lifelong Learning
Continuous Improvement and Value Add	Value-adding activities within a MS contract (mainly improvement actions, improvement suggestions)	Number of improvement actions/Number of improvement suggestions or Number of improvement projects implemented / Number of improvement actions raised	To perceive and materialize improvements that contribute to the hospital's competitive strategies and results	Integrated care and transformation of health services

Table XXVI – Development KPIs

Section VIII. IEP Market Research Analysis

This section details market research undertaken as part of the Bank's IEP. It can be used to support the preparation of a PPSD for an individual project. However, in doing so, the Borrower should validate that the information is still current and reflects the individual circumstances of their project.

Market Size

In 2015, the MDI global equipment market was worth US$24,722.9 million. It is forecast to grow by up to 6% year on year, up to 2020[7]. The global MDI equipment market is broken down into four regions, North America, Europe, Asia-Pacific and the Rest of the World (which includes Africa). In 2015, North America accounted for the largest share at 33.4%, with Europe accounting for 30%, Asia-Pacific 25.4% and the Rest of the World with 11.2%. The Asia-Pacific region is expected to grow at the highest rate of approximately 7.2% year on year until 2020, while the Rest of the World is expected to grow by 6% year on year. This growth is being driven by improving healthcare infrastructure, associated expenditure, and improving reimbursement and insurance coverage facilities.

Table XXVII shows the value of the MDI equipment market in the four regions by year. Amounts are in US$ million.

Region	2013	2014	2015	2020
North America	$7,403.6	$7,814.8	$8,253.5	$11,068.4
Europe	$6,668.8	$7,027.2	$7,406.8	$9,782.1
Asia-Pacific	$5,507.6	$5,883.5	$6,288.1	$8,912.4
Rest of the World	$2,491.1	$2,629.4	$2,774.5	$3,657.5
TOTALS	**$22,071.1**	**$23,354.9**	**$24,722.9**	**$33,420.4**

Table XXVII –MDI market size by region (US$ million)[8]

Global MDI expenditure is projected to reach US$33,420.4 million by 2020. The growth against each product is not uniform, with X-Ray systems forecast to grow the most, by US$4,524.7 million (approximately 50%), followed by MRI systems, Ultrasound systems and CT systems, which are all forecast to grow by approximately 25%. Nuclear Imaging systems, which is the smallest product category, with expenditure of under US$2,000 million, is forecast to grow by 20%.

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7 Markets and Markets, Diagnostic Imaging Market: Global Forecast to 2020 (2016)

8 *Source: Annual Reports, Press Releases, Investor Presentations, Journals, World Health Organization (WHO), Centers for Disease Control and Prevention (CDC), Organization for Economic Co-operation and Development (OECD), GLOBOCAN, Company Websites, and Markets and Markets Analysis*

X-ray systems are the largest spend product in the MDI market, accounting for approximately 33% of expenditure across the five product lines, while MRI Systems, Ultrasound systems and CT systems each represent something in the order of 20% each, leaving Nuclear Imaging systems with approximately 7%.

The chart at Figure V shows the value of MDI equipment by product. Amounts are in US$ million.

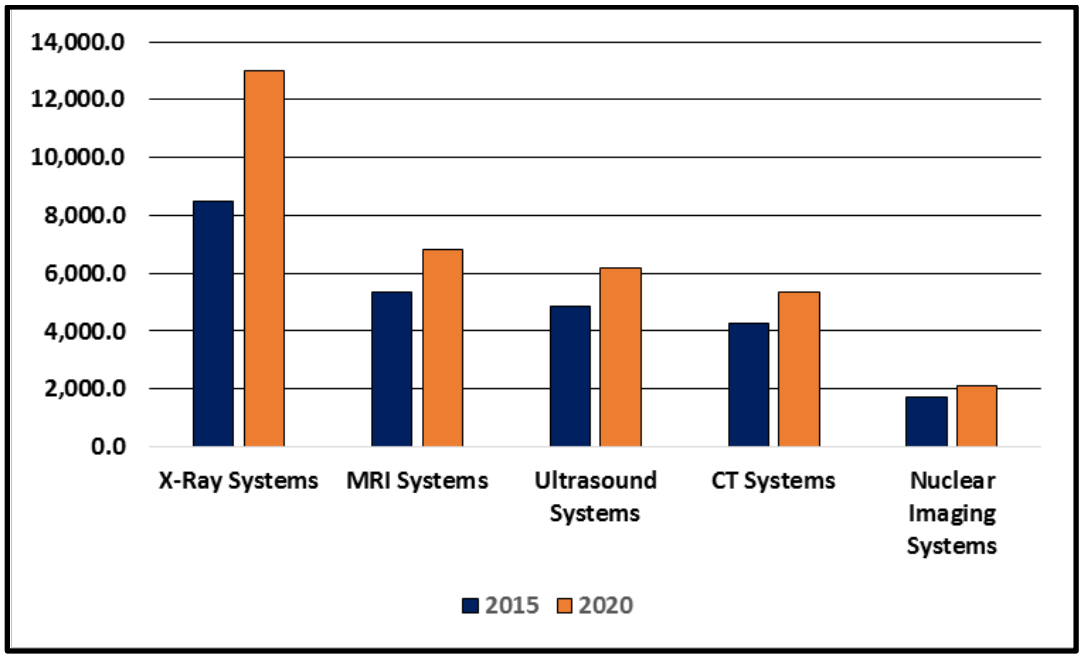

Figure V – MDI equipment market by product (US$ million) (2015 vs. 2020)

Table XXVIII shows MDI equipment global expenditure by product and compares 2015 to forecast figures for 2020. Amounts are in US$ million.

YEAR	X-Ray Systems	MRI Systems	Ultrasound Systems	CT Systems	Nuclear Imaging Systems
2015	$8,498.4	$5,338.0	$4,865.8	$4,292.5	$1,737.2
2020	$13,014.1	$6,802.7	$6,159.3	$5,356.2	$2,088.1

Table XXVIII – MDI market size by product (US$ million) (2015 vs. 2020)[9]

It can be concluded from this data, that the primary geographies in which Bank funded projects operate (Asia Pacific and the Rest of the World) are those that will see the highest level of growth. In addition, based on market trends, it is likely that most of this expenditure will be in the X-Ray system market.

9 Source: *Diagnostic Imaging Market: Global Forecast to 2020, Markets and Markets*

Supplier Market Share

From a supplier perspective, the MDI equipment market is global. Most market leaders across all product lines are in Japan, China, Western Europe, and North America (See Figure VI below)[10].

Siemens (Germany), GE (United States), Philips (Netherlands) and Toshiba (Japan) are the market leaders across all MDI equipment product lines. These four suppliers consistently dominate the MDI equipment market with 65-90% of the market share. The other supplier which has a reasonable market share across several the product lines (less than 10%) is Hitachi. Other suppliers such Shimadzu have a reasonable market share but have less than 10% in a single product line. There are other emerging suppliers, but in relative value, they have yet to impact significantly on the global market.

Emerging markets

Emerging markets have been researched in more detail to better understand the existence and development of the supplier market for MDI equipment[11].

1. **Brazil**: The domestic market production of medical equipment in Brazil is approximately US$100 million, with only a portion of that market being in MDI equipment. Most domestic companies are producing electro diagnostic equipment, with only a few producing radiology equipment. There are no significant domestic manufacturers of other MDI equipment;
2. **China**: Two Chinese companies, Neusoft and Mindray, are market-leading suppliers in the global marketplace. Neusoft is among the top ten global market leaders in MRI and Nuclear Imaging manufacturing. Mindray is among the top ten in ultrasound manufacturing. There is a significant number of smaller emerging companies in the marketplace that manufacture MDI equipment. There are also significant manufacturing facilities for global market leaders in China via joint ventures with multi-national firms;
3. **India**: Indian domestic suppliers currently target mainly low-tech medical equipment, disposable equipment and consumables markets. MDI equipment is produced either as a joint venture with multi-national firms, or MDI manufacturers have set up manufacturing operations, such as GE in Bangalore[12];
4. **Mexico**: The medical equipment production market value is approximately US$2.8 billion across the entire sector. Mexico produces MDI equipment either as a joint venture or produces components that feed into the larger manufacturing operations of multi-national firms;

10 Markets and Markets, Diagnostic Imaging Market: Global Forecast to 2020 (2016)
11 BMI reports for Brazil, China, India, Mexico, Thailand and Turkey
12 http://www.indiainfoline.com/article/news-business/ge-healthcare-expands-india-manufacturing-operations-113100901004_1.html

5. **Thailand:** In Thailand over 90% of MDI equipment comes from imports. Thailand is not a major producer of MDI equipment. Domestic manufacturers produce medical supplies and consumables.

Emerging suppliers in multiple product lines include Esaote (Italy) in X-Ray, MRI and Ultrasound, while Neusoft (China) and Mindray (China) are the emerging market suppliers across all product lines. However, in contrast to the four market leaders their market shares are very small. It is unlikely that they can significantly change this position or how the market operates in the short to medium term. However, their growth is expected to be largely driven by emerging markets. More specifically, as demonstrated in Figure VI, by 2017 the global market for MDI equipment will mainly grow because of emerging markets such as India, Latin America, Russia and China.

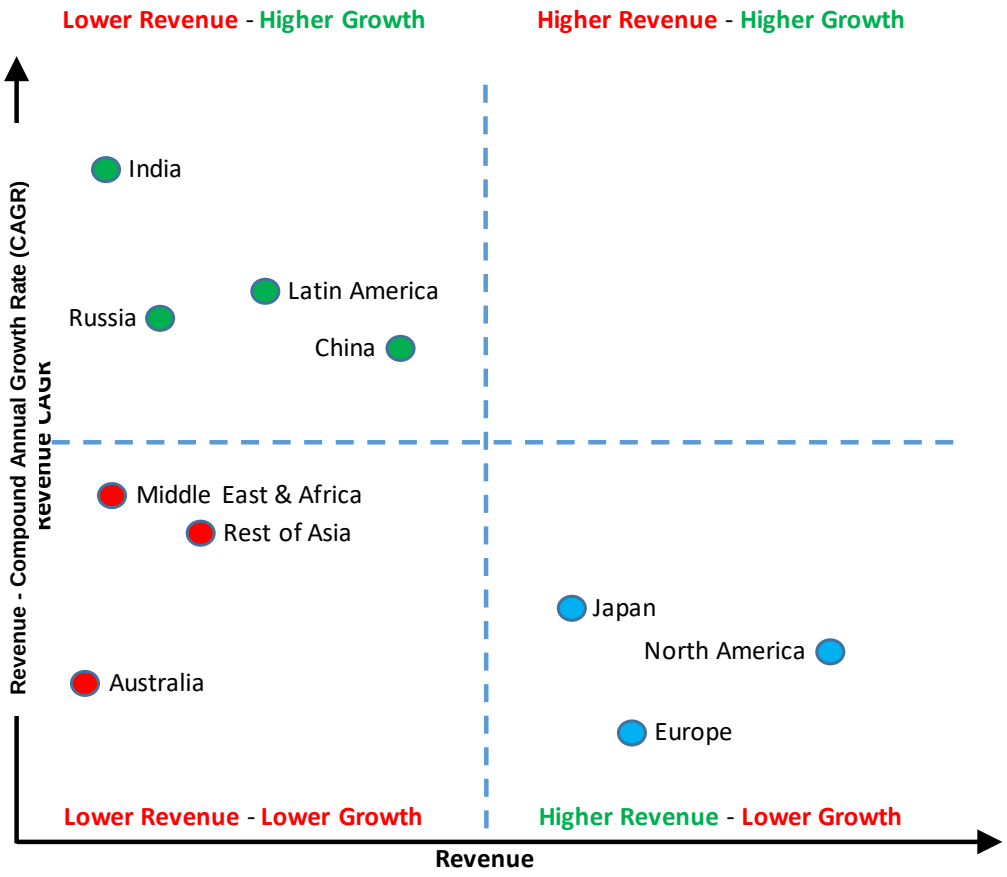

Figure VI - Global MDI equipment market, revenue outlook by geographic region, world 2012-2017[13]

13 https://www.siemens.com/innovation/en/home/pictures-of-the-future/health-and-well-being/medical-imaging-facts-and-forecasts.html

Product	Company	Country	Market Share (%)	Total Market (USD M)
X-Ray Imaging	Siemens	Germany	19%	$8,439
	GE	United States	18%	
	Phillips	Netherlands	18%	
	Shimadzu	Japan	10%	
	Toshiba	Japan	9%	
	Carestream	Canada	8%	
	FujiFilm	Japan	8%	
	Varian	United States	2%	
	Esaote	Italy	<2%	
	Hitachi	Japan	<2%	
	Samsung	South Korea	<2%	
MRI Systems	GE	United States	28%	$5,338
	Siemens	Germany	27%	
	Phillips	Netherlands	18%	
	Toshiba	Japan	11%	
	Hitachi	Japan	6%	
	Esaote	Italy	<6%	
	Auroa	United States	<6%	
	IMRIS	Canada	<6%	
	Fonar	United States	<6%	
	Neusolf	China	<6%	
Ultrasound	GE	United States	25%	$4,865
	Phillips	Netherlands	20%	
	Toshiba	Japan	18%	
	Siemens	Germany	11%	
	Hitachi	Japan	9%	
	Samsung	South Korea	7%	
	Esaote	Italy	<7%	
	FujiFilm	Japan	<7%	
	Mindray	China	<7%	
	Analogic	United States	<7%	
CT Scanners	GE	United States	23%	$4,292
	Siemens	Germany	22%	
	Toshiba	Japan	19%	
	Phillips	Netherlands	12%	
	Hitachi	Japan	7%	
	Hologic	United States	<7%	
	Samsung	South Korea	<7%	
	Shimadzu	Japan	<7%	
Nuclear Imaging Systems	Siemens	Germany	33%	$1,737
	Phillips	Netherlands	31%	
	GE	United States	29%	
	Toshiba	Japan	7%	
	Neusolf	China	<7%	
	Mediso	Hungary	<7%	
	Digirad	United States	<7%	
	CMR Naviscan	United States	<7%	
	SurgicEye	Germany	<7%	
	DDD	Denmark	<7%	

Table XXIX –MDI Equipment: top suppliers, country of origin and market share

Conclusions

In summary, the MDI equipment market is relatively straight forward, in that it is dominated by four main suppliers across all product types (GE 23%, Siemens 21%, Philips 18% and Toshiba 13%), with the emerging suppliers being very small by comparison. Most spend is concentrated

on one product line, X-Ray systems. The four dominant suppliers work in all the individual product lines.

Analysis of Supplier Market Share by Product Line

The MDI market is dominated by a small number of suppliers who manufacture (and maintain) most MDI equipment across all product categories. The level of concentration varies slightly by product, but consistently four suppliers (GE, Philips, Toshiba and Siemens) represent approximately 65-90% of market share on a consolidated basis.

The initial purchase of capital equipment is the first step in establishing a multi-year relationship as a service provider producing long-term revenues. GE reported that 44% of its annual revenue from its healthcare division came from services for both 2014 and 2015[14]. As the industry business models continue their move towards value-based services, it is expected the percentage of division revenue derived from services will increase substantially. Engagement by the Bank with industry has also identified a lack of contracting for Operation and Maintenance (O&M) or proper O&M management, as a key issue in Bank-financed MDI equipment procurement.

Driven by a continuing need to deliver value to the healthcare marketplace, the medical sector is evolving business models to deliver connected health services. This contributes to the increasingly blurred lines of where MDI equipment sits within medical technology, healthcare IT and healthcare services markets[15]. The following is an analysis of the MDI market by product lines.

X-Ray Imaging Market

The global X-Ray imaging systems market in 2015 was dominated by four main players. The top three of which had market shares of over 18%. These were, Siemens Healthcare (18.7%,) GE Healthcare (18.4%), Philips Healthcare (18.2%), and Toshiba Medical Systems (8.6%).

After the four main players, the rest of the X-Ray market is made up of Shimadzu Corporation, Toshiba Medical Systems, Carestream Health and Fujifilm Medical systems each with a market share of between 8% and 9.6%. Other major players such as Esaote S.p.A (Italy), Hitachi Medical Corporation, and Samsung Medison (South Korea) accounted for 8% of this market

14 GE Annual report 2015 - http://www.ge.com/ar2015/assets/pdf/GE_AR15.pdf
15 Ernst & Young, Pulse of the Industry: Medical Technology Report 2016

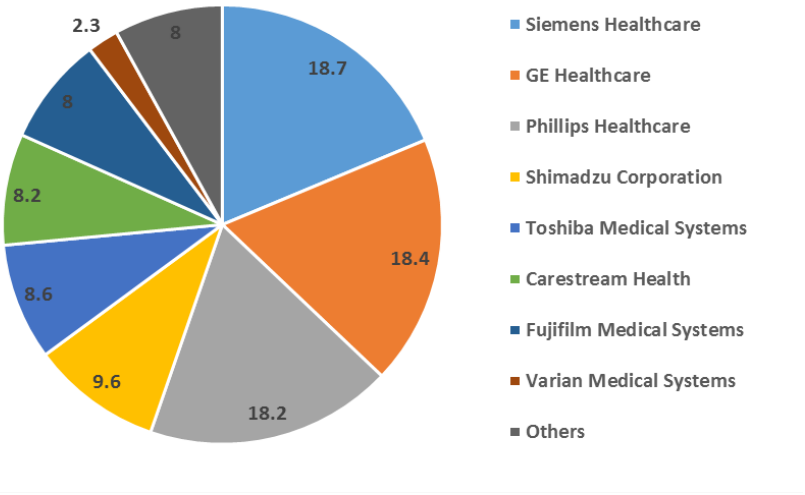

Figure VII- X-Ray Imaging Market Share 2015

MRI Market

The global MRI market in 2015 was dominated by two main players, each with a market share of over 27%. GE Healthcare (28%) and Siemens Healthcare (27%).

After the two main players, the rest of the MRI market is made up of Philips Healthcare (18%), Toshiba Medical System (11%) and Hitachi Medical Corporation (6%).

Other major players such as Esaote (Italy), Aurora Medical Imaging (U.S.), IMRIS (Canada), Fonar (U.S.), and Neusoft (China) accounted for approximately 10% of this market.

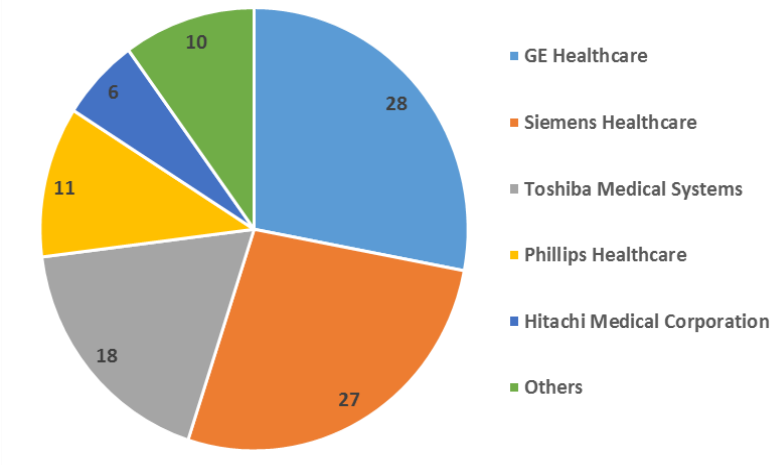

Figure VIII- MRI Market Share 2015

CT Scanners Market

The global CT scanners market in 2015 was dominated by three main players, each with a market share of between 19-23%. GE Healthcare (23%), Siemens Healthcare (21.5%) and Toshiba (19%).

After the three main players, the rest of the CT scanners market is made up of Philips Healthcare (12%) and Hitachi Medical Corporation (7.5%). Other major players such as Hologic, Inc. (U.S.), Samsung Medison (South Korea), and Shimadzu Corporation accounted for 17.0% of this market.

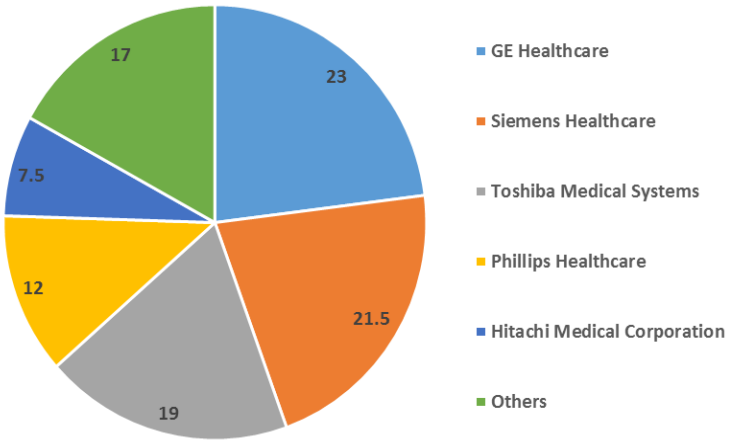

Figure IX- CT Scanners Market Share 2015

Ultrasound Market

The global Ultrasound market in 2015 was dominated by one main player, GE Healthcare, who took 25%.

Other major players were Koninklijke Philips (20%,) TMSC (18%), Siemens Healthcare (11%), Hitachi Medical Corporation (9%) and Samsung Medison (7%.)

Other players in this market include FUJIFILM Holdings Corporation (Japan), Esaote S.p.A. (Italy), Mindray Medical International Ltd. (China), and Analogic Corporation (U.S.). These players together accounted for a share of 10.0% of the market.

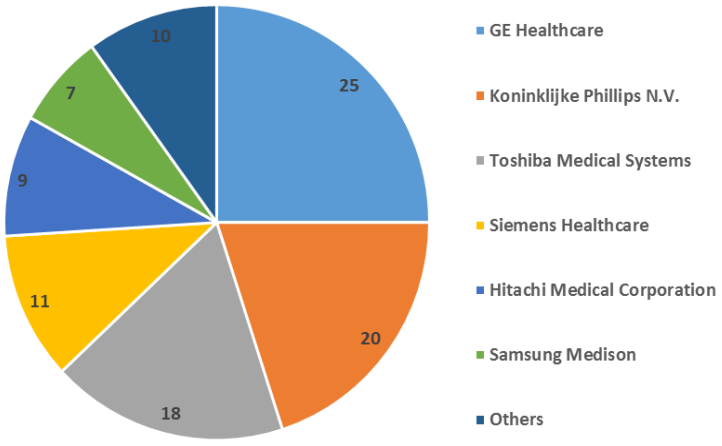

Figure X- Ultrasound Market Share 2015

Nuclear Imaging Market

The global Nuclear Imaging market in 2015 was dominated by three main players, each with a market share of between 29 – 33%. Siemens Healthcare took 33%, Philips Healthcare took 31% and GE Healthcare took 29%.

Other players in this market include TMSC (Japan), Neusoft Medical Systems Co., Ltd. (China), Mediso Medical Imaging Systems Ltd. (Hungary), Digirad Corporation (U.S.), CMR Naviscan Corporation (U.S.), SurgicEye GmbH (Germany), and DDD Diagnostics (Denmark). These players together accounted for a share of 7.0% of the market.

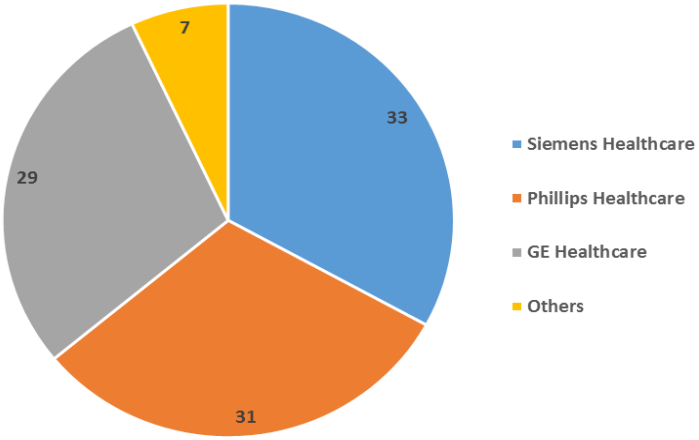

Figure XI- Nuclear Imaging Market Share 2015

Conclusions

A small number of Original Equipment Manufacturers (OEMs) dominate the MDI equipment market across all product categories (accounting for over 65% market share). The major OEMs found across all product categories include Siemens Healthcare, GE Healthcare, Philips Healthcare and Toshiba Medical Equipment.

The X-ray imaging market is the most fragmented market with eight major OEMs accounting for over 90% of market share and several other international businesses accounting for less than 10% of the remaining market.

The nuclear imaging market is the least fragmented market with three major OEMs accounting for 93% of market share and several other international businesses accounting for just 7% of the remaining market.

These market fragment characteristics across product lines may correlate to the age and complexity of the technology, hence older technology will have a greater fragmented market compared to newer technology. As the Bank supports newer medical device technology within project procurement, it is important to understand that there may not be many available suppliers due to the newness of the technology.

These MDI equipment OEMs focus their business strategy on developing customer relationships through the sale of equipment and maintain those relationships and continued

revenue generation by providing services. Revenue generated through services can account for almost half of the total annual revenue for the major MDI equipment OEMs. It is important to understand that continued service is a strategic business area for these entities when structuring Bank financed procurements to attract these types of suppliers.

An emerging trend across MDI equipment product lines, and the overall medical equipment sector, is internet-connected healthcare. By 2020, internet-connected healthcare products will be worth an estimated US$285 billion. However, connectivity comes with a price, principally the vulnerability to hackers and criminals. An estimated 85% of large health organizations experienced a data breach in 2014, with 18% of breaches costing more than US$1 million to remediate.

The emergence of internet-connected healthcare is leading to a further change in the selection of goods and scope of services that OEMs can provide. When undertaking market analysis at a project level, research should be undertaken to understand how this trend is affecting healthcare systems, especially in emerging economies and how it can be beneficial to Bank financed procurements of MDI equipment and overall health focused projects.

SWOT

Introduction

A Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis is a helpful decision-making tool. It aims to identify everything that could potentially impact the success of a new project. Failure to consider a key strength, weakness, threat or opportunity could lead to poor procurement decisions and outcomes. Strengths and Weakness commonly focus on internal factors. Whereas Opportunities and Threats commonly focus on external factors.

1. **Strengths**: characteristics of the project that give it an advantage over others;
2. **Weaknesses**: characteristics of the project that place it at a disadvantage relative to others;
3. **Opportunities**: elements that the project could exploit to its advantage;
4. **Threats**: elements that could cause trouble for the project.

Figure XII below outlines a high-level SWOT analysis that examines the MDI equipment market for Bank funded projects. It details the factors that affect the market, Borrower and suppliers. A more in-depth analysis provided in the narrative that follows.

Strengths	Weaknesses
• World Bank brand • Disciplined procurement process • Low project funding risk • Higher investment, funds and grants from government, public-private partnerships and development organizations • Flexibility to amend procurement approach (Improved specifications and different lotting strategies)	• Cost of Diagnostic Imaging • Lack of capacity and capability in the Bank and Borrowers • Lengthy and costly procurement processes • Lack of suitably qualified consultants to support projects • Accessibility of project information and lack of clarity of future contracts
Opportunities	**Threats**
• Emerging markets, increase in demand for diagnostic imaging and improving healthcare • Development in low-cost, technologically advanced imaging systems with applications in multiple fields • Increase in refurbished equipment • Industry initiatives • Growth in the number of private diagnostic centers • Diagnostic imaging technological advances • Aging population and the increase in various diseases	• Shortage of helium • Budget cuts • Government regulations • Refurbished regulations • Emerging manufactures a threat to established players • High radiation exposure risk • Lack of trained professionals

Figure XII- MDI equipment SWOT analysis

Strengths

World Bank Brand

As an international organization, a strong brand name is a major strength of the World Bank, and this is recognized the world over. World Bank financed projects are attractive to suppliers due to the strength of its brand and because, in some cases, winning World Bank projects can help the supplier to build long term lasting relationships with the Borrower country's government.

Disciplined procurement process

A strength of procurements financed by the Bank is that Borrowers are required to follow a transparent uniformed procurement approach which includes the application of the Bank's Standard Procurement Documents. All procurements comply with Bank's *Procurement Regulations* which clearly define how the procurement should be run and gives clear guidance on such issues as eligibility, procurement approaches and evaluation, fraud and corruption provisions and complaint mechanisms. These regulations are open published in the public domain. This enables MDI manufacturers and suppliers to fully understand how Bank financed projects are procured.

Feedback following the IEP consultations has identified that the flexibility that exists in Bank's Procurement Regulations needs to be applied fully. Borrowers are encouraged to design procurement approaches that reflect the needs of their individual requirement based upon their market and risk analysis. Examples may include warranty requirements and special contract terms to enable medical equipment supply contracts.

Low project funding risk

Prior to a project being approved by the Bank, a comprehensive project appraisal is carried out and agreed with the Borrower which includes funding. This gives potential suppliers confidence that the procurement will not be stopped part way through the process due to lack of funding. This can sometimes happen when projects are funded solely by the government. Procurements that are cancelled part way through the process can cost suppliers thousands of dollars due to the high internal costs of responding to these types of procurements.

Higher investment, funds and grants from government, public-private partnerships and development organizations

One of the main factors driving the demand for MDI equipment is the greater awareness about the benefits of early diagnosis of diseases among patients. A related driver is the rise in mortality and morbidity from chronic, non-communicable diseases (e.g., cardiovascular disease and cancer), compared with communicable diseases, especially in developing countries. Due to this increase in demand and usage of MDI equipment investment by governments and international organizations has increased.

The high capital investment required for MDI equipment is a major challenge for hospitals and medical centers. Some hospitals, due to budget constraints, refrain from purchasing or upgrading their current equipment.

Investments by public-private partnerships for the modernization of hospital infrastructure enable hospitals to purchase high-end MDI equipment.

In SAR, significant investment has taken place. For example, in June 2013 the Government of Maharashtra entered an agreement with GE Healthcare (U.K.) and EnsoCare (India) to encourage investments from these companies for improving MDI services in India[16].

In March 2013, the Government of China invested US$103 million on basic research and US$82.9 million in the molecular, biochemical, immunological, and physical diagnostic sectors. Owing to a significant growth in the geriatric population, coupled with unmet medical needs in the country, authorities in China are increasingly focusing on investments and the rapid development of innovative sensing technologies.

Flexibility to amend procurement approach (improved specifications and different lotting strategies)

The Bank's *Procurement Framework* (introduced in July 2016) provides greater flexibility in designing fit-for-purpose procurement. It has a range of procurement methods and has moved away from the traditional one size fits all approach. The Procurement Framework also separated the policy from the regulations enabling management to amend the regulations as needed to deal with recurring procurement issues. Previously there have been cases in Bank financed projects in which the Borrower has struggled to attract a high enough number of bids in this market to ensure competition. This is due to several factors, but poor specifications or

[16] http://www.genewsroom.com/press-releases/ge-technology-powers-government-maharashtras-ppp-initiative-healthcare-219319

how the procurement has been packaged into lots, is a recurring complaint. Industry feedback stated that technical specifications can be overly prescriptive, lacking clinical relevance or performance-based criteria, outdated, and, in some instances, written in a manner that favors a unique product or supplier.

This indicates a need to improve the quality of specifications and to ensure that procurements are lotted correctly to enable the best providers in the market to respond. These aspects will be covered later in this guidance.

Weaknesses

Cost of diagnostic imaging

MDI equipment is relatively expensive with the average cost of MRI equipment around US$1.5 to US$2 million, while CT systems cost around US$1 to US$1.5 million. Healthcare facilities that purchase such costly systems often depend on private third-party payers (such as Medicare, Medicaid, Southern Cross, BUPA etc., or other private health insurance plans) to get reimbursements for the costs incurred in the diagnostic, screening, and therapeutic procedures performed using these systems. However, factors such as continuous cuts in the reimbursement for nuclear imaging scans and the increasing cost of radiotracers due to their shortage/limited availability are preventing imaging centers from investing in nuclear imaging modalities. Due to the high cost of MDI equipment, most hospitals in developing countries struggle to afford MDI systems.

Lack of capacity and capability in the Bank and Borrowers

Capacity of the Bank and Borrowers to manage highly technical procurements can be limited with a heavy reliance on individual external consultants. This can result in inconsistent approaches and an inability for the Bank to build, share and retain institutional knowledge. The Bank has established a Framework Agreement Expert Panel to support both the Bank and the Borrower in undertaking procurements for MDI equipment. Information at [hyper link]

Lengthy and costly procurement processes

Procurements financed by the Bank can sometimes be a lengthy and costly process. Whereas the Bank's Procurement Regulations provide a structured and transparent approach for all procurements financed by the Bank, this also leads the Borrower to seek the Bank's "no-objection" at critical stages of the procurement process, such as reviewing the bidding documents, specifications and the bid evaluation reports. Compared to procurements run by a Government on their own procurement system, it can add delays in the process and increase costs to suppliers.

Lack of suitably qualified consultants to support projects

As capacity in both procurement and the MDI equipment market can be limited, Project Management Units (PMUs) take on external consultants to develop the appropriate procurement framework and corresponding bidding and evaluation documents. This reliance on external consultants can result in an initial increased cost for the procuring entity, although this practice needs to be balanced with the expected decrease in overall cost of the

procurement through streamlining the process and making it less prone to errors, while also increasing the project's potential of attaining its Project Development Objectives. Sourcing the right external consultant with the right knowledge is challenging, as there aren't many in the market. Currently the Bank only uses one consultant and his availability is limited. The Bank has established a Framework Agreement Expert Panel to support both the Bank and the Borrower in undertaking procurements for MDI equipment to mitigate this issue. Information at [hyper link]

Accessibility of project information and lack of clarity of future contracts

Information on Bank financed projects is accessible on the Bank website. However, this information can be confusing to suppliers and it can be difficult to determine what will be procured as part of the project. Feedback received from MDI manufacturers indicates that in many circumstances, information is gained on procurements of MDI equipment when the tender notice is published on UNDP.

Bank projects vary in size and complexity and many different procurements can be needed to deliver the overall project. For example, the project might be to improve access to health care provisions, which includes the building of a medical facility and then procuring the equipment for the facility. It might not be clear, e.g., that MDI equipment will need to be procured for the new facility, until the tender notice is published.

Opportunities

Emerging markets, increase in demand and improving healthcare

Emerging countries with limited healthcare markets such as Brazil, China, India and South Africa offer significant growth opportunities for MDI suppliers. In these countries, the high cost of MDI equipment is a major issue. However, due to their huge population base, especially in India and China, this offers a sustainable market for MDI suppliers, since company profit targets can be achieved through volume growth.

The increase in chronic diseases, such as cancer, is considerable in these countries. It is estimated that more than 60% of the total number of new cancer cases annually occur in Africa, Asia, and Central and South America[17] and account for 70% of the global cancer deaths. In India, it is estimated that there are 2 to 2.5 million cancer patients at any given point of time. Every year about 0.7 million new cases are added, and half of these individuals die each year[18]. In China 3.5 million people are diagnosed with cancer every year. The huge untapped market in these countries can be targeted with cost-effective diagnostic procedures, along with conventional cancer diagnosis.

A 2012 report by Bloomberg stated that Brazil was expected to be the sixth most popular destination for medical tourism, in the same year it registered circa 180,000 overseas patient visits. India was expected to be the fifth-most popular destination for medical tourism, with

17 http://www.dw.com/en/world-health-organization-calls-for-action-after-predicting-rise-in-cancer-cases/a-17405987

18 http://www.nihfw.org/NationalHealthProgramme/NATIONALCANCERCONTROLPROGRAMME.html

an estimated 400,000 foreign patients visiting the country for various treatments. Healthcare treatments cost up to 90% less in India as compared to the U.S.[19].
Manufacturers and suppliers are adopting various strategies to strengthen their foothold in these markets, such as mergers and acquisitions, expansion, development of low-cost equipment specifically for developing countries, increasing headcount, and entering joint ventures. In September 2012, Royal Philips signed an agreement with Al Faisaliah Medical Systems, (a subsidiary of the Al Faisaliah Group (Saudi Arabia)), to set up a joint venture to sell Philips' Healthcare solutions and services in the Kingdom of Saudi Arabia[20]. Similarly, GE Healthcare increased its workforce in India by 10% by the end of 2012[21] and in June 2014, TMSC established a new manufacturing company in Penang, Malaysia[22]. Through this new manufacturing base, Toshiba will produce MDI devices and printed wiring boards. In January 2014, Toshiba established a fully owned subsidiary, Toshiba Medical System R&D, in China to develop highly competitive products in a timely manner to meet global needs[23]. In June 2012, Philips Healthcare commenced its operations in its Greenfield manufacturing facility in India[24]. This new facility was developed to focus on diagnostic and interventional imaging solutions for the Indian market. Furthermore, in 2011, GE Healthcare (U.K.) moved its X-Ray business headquarters to China to accelerate sales in this fast-growing market, and in 2010 the company invested US$2 billion in China for the development of its X-Ray business.

China announced in 2009 a US$124 billion healthcare reform plan with a focus on reducing urban-rural healthcare disparity. Through these funds, China plans to build around 2,000 county hospitals and 29,000 township centers, upgrade or expand 5,000 township health centers and build or upgrade 3,700 urban health service centers and 11,000 community health service stations[25].

The increased competition in mature markets will also further compel MDI equipment manufacturers to focus on emerging markets.

Development in low-cost, technologically advanced imaging systems with applications in multiple application fields

The requirement for MDI equipment that is both cost effective and provides high quality results in multiple application fields has increased. The adoption of these advanced systems is expected to increase significantly in the coming years due to budget constraints and reimbursement cuts. For instance, the general radiography market has been witnessing a

19 http://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/international-medical-tourism-industry-pegged-at-40-billion-a-year/articleshow/20790062.cms
20 http://www.philips.com/a-w/about/news/archive/standard/news/press/2012/20120929-philips-and-al-faisaliah-medical-systems-enter-healthcare-joint-venture.html
21 http://www.healthcareasia.org/2012/ge-healthcare-to-add-400-jobs-in-india/
22 http://www.toshibamedicalsystems.com/news/2015/150211.htm
23 http://www.toshibamedicalsystems.com/news/2014/140120.htm
24 http://www.philips.com/a-w/about/news/archive/standard/news/press/2012/20120614-Greenfield-Healthcare-manufacturing-facility-India.html
25 http://www.nytimes.com/roomfordebate/2011/11/01/is-china-facing-a-health-care-crisis/chinas-health-care-reform-far-from-sufficient

steady shift from film technology to the digital flat-panel detector technology due to its higher efficiency and image quality and lower lifetime costs.

Increase in refurbished equipment

In developing countries, many hospitals are unable to invest in MDI equipment due to budget constraints, higher cost of equipment, and poor reimbursement rates. However, due to the high demand for MDI procedures in these countries, hospitals that cannot afford to invest in new imaging systems prefer to opt for refurbished ones. Refurbished systems are priced lower than new systems (40% to 60% of the price of new equipment).

Owing to this, many market leaders are now promoting refurbished devices through various programs. For instance, Siemens' Medical Proven Excellence Program, GE Healthcare's GoldSeal Program, and Philips' Diamond Select Program are some noteworthy global refurbishing programs that promote the use of refurbished diagnostic imaging systems.

The increasing demand for refurbished devices poses a major challenge for market players, especially for small manufacturers. To strengthen their position in the market and create a strong user base for their imaging systems, market players will either have to position their products at lower prices or will have to come up with better or more advanced technologies that will address the unmet needs in the market.

Industry initiatives

Several manufacturers of MDI equipment focus strongly on innovation. Efforts by new and established manufacturers have led to the development of a strong pipeline of products that are expected to offer better and more effective functionalities. This rich pipeline of innovative products is expected to open an array of opportunities in the MDI equipment market.

Growth in the number of private diagnostic centers

Increased demand for MDI services and increased burden on public hospitals has led to many private MDI centers being set up across the world. For example, in Russia, in 2003, Dr. Arkady Stolpner opened his first diagnostic center which included a Multi-Region Input-Output (MRIO) system. By 2013 he had 77 centers which accounted for 20% of all MRI exams (circa 1.2 million MRI exams) performed in Russia per year[26].

With a significant growth in the number of MDI centers in major markets across the globe, the volume of MDI procedures is expected to increase in the coming years.

Diagnostic imaging technological advances

MDI manufacturers are constantly looking for technological advancements and new products that can be launched. Product innovations and new product launches mainly deal with the development of more economical, technologically advanced, and easy-to-use MDI equipment. Examples include:

[26] https://www.healthcare.siemens.com/news-and-events/medical-solutions-online-archive/category-healthcare-access/mri-center

1. **TMSC** introduced its latest MDI equipment, Aquilion ONE CT system and Vantage Elan MRI system in 2016;
2. **FUJIFILM SonoSite** introduced its new portable ultrasound system called the SonoSite Edge II with CE mark and FDA 510(k) clearance in 2016. This system features a revolutionary transducer technology, which can deliver a better imaging experience for the most rugged environments;
3. **Shimadzu** launched EZy-Rad Pro EFX Version in December 2015. This is a diagnostic radiography system equipped with functions to navigate radiography procedures. With this technological advancement, clinicians can now clearly look at specific areas of the heart that were previously compromised either by a patient's movements, high heart rate, or inability to hold their breath;
4. **Philips Healthcare** launched the EPIQ Ultrasound System in August 2013. This features a new imaging technology called nSIGHT, which delivers a powerful combination of velocity and image clarity when combined with Philips' Anatomical Intelligence technology. The Anatomical Intelligence technology provides superior organ modeling, image slicing, and quantification. This helps in easy execution of exams that are more reproducible.

Aging population and the increase in various diseases

As health care and living standards improve across the world so does life expectancy and the number of age-associated diseases, such as Alzheimer's, cardiovascular, cancer, arthritis, and dementia. For example, in China, the population of individuals aged 60 years and above is estimated to increase two-fold by 2030 from 178 million in 2010[27].

The number of new cancer cases diagnosed globally each year has increased from 12.7 million cases in 2008 to 14.1 million cases in 2012. It is estimated that by 2025, the number of new cancer cases diagnosed per year will reach 19.3M million due to the rapid growth in the global geriatric population[28].

The increase in cancer and other diseases is expected to increase the demand for MDI equipment, as MDI plays a crucial role in the initial diagnosis, treatment planning, and palliative therapies through interventional techniques.

Threats

Shortage of helium

Helium plays an essential role in MRI systems. About 28% of the world's helium supply is used for the production and maintenance of MRI systems[29]. The use of helium has increased by about 25% since 2003, which is mainly driven by the increasing use of MRI in diagnostic

27 Source - World Population Statistic
28 http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx
29 Source - Plant Energy Biology, ARC Center of Excellence

imaging. Helium is currently the only element known that can be effectively used to cool down the superconductive magnetic coil to a temperature below 10 Kelvin.

Helium reserves are expected to run out within 25 to 30 years with the current rate of consumption[30].The U.S. currently produces 75% of the world's helium, of which more than 50% comes from the U.S. Federal Helium Reserve. In May 2012, Mr. Walter Nelson, the director of helium sourcing for Air Products and Chemicals, Inc., told the U.S. Senate Energy and Natural Resources Committee that by the end of 2014, the reservoir is expected to have around 10 to 12 billion cubic feet of recoverable helium, and at the current production rates, helium will decline to around 1 billion cubic feet per year after 2014[31]. This has raised concerns among MRI manufacturers, as the shortage of helium may damage the magnet permanently or raise the need for replacing it, which is a costly and time-consuming process.

In addition, the shortage of helium supply is driving up prices. For example, the U.S. federal government increased the price of helium to US$84 per thousand cubic feet in 2013 from US$75.75 per thousand cubic feet in 2012. These factors have the potential to create significant challenges in the MRI systems market in the next five years.

Budget cuts

Due to the economic instability that many countries have faced over the last five years, governments have been trying to reduce healthcare costs. To meet these cuts several purchasers have aligned themselves with group purchasing organizations (GPOs), integrated health networks (IHNs), and integrated delivery networks (IDNs). These organizations aggregate the purchasing volume of their members to get a more competitive price with suppliers and manufacturers of MDI equipment. GPOs, IHNs, and IDNs negotiate heavily for bulk purchase of diagnostic imaging devices.

Government Regulations

The MDI market is very tightly regulated, varying in degree from country to country. Suppliers must comply with the latest international standards to remain competitive. For the MDI sector to fully realize its potential in developing markets, standards for regulatory approval, risk management and quality must improve and continue along the path of international convergence to meet global standards. The Global Harmonization Task Force (GHTF), formed as a voluntary organization comprised of regulators and industry with five founding members consisting of the United States, Canada, Japan, the European Union and Australia, with its core objective of streamlining and harmonizing regulatory standards.

The International Medical Device Regulators Forum (IMDRF) is a voluntary group of MDI regulators from around the world who have come together to build on the strong foundational work of the GHTF. IMDRF aims to accelerate international medical device regulatory harmonization and convergence. The enhanced participation of developing countries' medical device regulatory agencies in IMDRF activities, coupled with guidance issued by GHTF, has

30 http://lifeboat.com/blog/2013/09/space-mining-for-our-fastest-depleting-resource-helium

31 http://www.networkworld.com/article/2161183/servers/helium-gas-shortage-risks-popping-wd--39-s-drive-plans.html

been be critical in establishing regulatory regimes for MDI devices that are distinct from traditional pharmaceuticals.

Refurbished Equipment Regulations

Regulations covering refurbished equipment can act as a barrier to countries and hospitals purchasing such equipment. For example, in Mexico, public hospitals which cover approximately 70-80% of total medical services provided cannot by law buy used or refurbished products.

Another threat to the refurbished equipment market is that there currently are no international standards or regulations that cover how such equipment should be refurbished. This can mean that equipment isn't being refurbished to the highest standards, which can be dangerous to patients.

Emerging manufacturers a threat to established players

Emerging manufacturers of MDI equipment are slowly appearing from countries like China and India. This is good for the industry as these new manufacturers are challenging the traditional manufacturers. However, for the established manufacturers this is seen as a threat to the market share they currently enjoy.

High radiation exposure risk

CT scans account for around 12% of diagnostic radiological procedures in large U.S. hospitals and CT imaging is the major source of medical radiation exposure, according to the National Cancer Institute. For instance, in the U.S., According to a study published in the New England Journal of Medicine in August 2009, it is estimated that about 4 million U.S. citizens receive radiation doses higher than 20 mSv from medical imaging, each year[32]. After analyzing the data from the U.S. National Council on Radiation Protection and Measurements and the United Nations Scientific Committee on the Effects of Atomic Radiation, a report, published in Radiology in November 2009, established that the annual effective radiation dose per capita from medical imaging has doubled globally in the past 10 to 15 years and the increase in the U.S. was much greater than other parts of the world[33]. However, the clinical benefits of CT scans outweigh the risk of over radiation exposure.

Lack of trained professionals

According to the Bureau of Labor Statistics in the U.S., radiologic technicians may witness an employment growth of about 21% between 2012 and 2022 and 41,500 new positions will need to be filled during the same period[34]. However, there is a huge gap between the demand and supply of diagnostic imaging technicians around the world.

In case of ultrasound imaging, physicians largely depend on the skills of the sonographer for examinations. The skill and experience of the sonographer conducting an ultrasound is critical for the use of ultrasound devices in the diagnosis of abnormalities in patients, as poorly

32 http://www.nejm.org/doi/full/10.1056/NEJMoa0901249#t=article
33 http://pubs.rsna.org/doi/full/10.1148/radiol.2532090494
34 https://www.bls.gov/ooh/healthcare/radiologic-technologists.htm

captured images may lead to misdiagnosis or unnecessary repetition of ultrasound examinations. Furthermore, in imaging procedures, there are certain differences between how sonographers and other imaging technologists operate. Other technologists may reject a scan owing to suboptimal technical quality. However, sonographers reject over 95% of images because they do not provide a diagnosis.

According to the Society of Medical Diagnostic Sonography, Sonography Canada, and Australasian Sonographer Accreditation Registry, there is a severe ongoing shortage of sonographers in the U.S., Canada, and Australia.

Conclusion

Overall the MDI equipment market is growing with the introduction of new technologies and the ability for healthcare systems across different economic settings to find new ways of accessing MDI equipment to meet their populations' growing demand. Issues do exist that can potentially limit the purchasing and use of MDI equipment, but by understanding what they are, the Borrower can develop measures to mitigate any potential weaknesses or threats.

In terms of strengths, the MDI equipment market is growing globally across all product lines mainly due to the increase in awareness of the technologies and their respective usefulness to improving healthcare outcomes. This awareness has led to the development of external and private diagnostic centers that deliver MDI services to support the efforts of both public and private healthcare systems. Growth in the market is also due to rapid technological advances that seek to treat an overall aging population afflicted with new diseases, as well as a global increase in efforts for cancer prevention. These strengths are advancing the continued growth of the MDI equipment market in middle and high-income countries, as well as the introduction of MDI equipment and services into certain low-income countries. The growth in demand for MDI equipment and services in low income countries has led to growth in the refurbished MDI equipment market. However, this can hinder the development of new technology and new players in the market. The Bank could conduct outreach with stakeholders to understand in which setting refurbished equipment can be useful, and in which settings new equipment is necessary, while also addressing regulatory barriers that prevent high quality refurbished products from entering the local market.

A major weakness of the MDI market is the high cost of diagnostic imaging, which can act as a barrier to introducing MDI equipment into certain developing healthcare systems and middle and low-income countries. Health issues do exist in the handling of MDI equipment, and include the risk of high radiation exposure from certain technologies. This can pose a serious risk in healthcare settings where staff are not properly trained to handle the MDI equipment. Limitations to the technology are arising due to shortages of key raw material such as helium. Another limitation is the development of standalone systems that do not offer interoperability with other systems due to technological differences as well as manufacturers' designs.

Opportunities do exist as many developing countries are providing suitable environments for MDI equipment manufacturers to reach large populations for revenue generating as well as economies to support cost efficient manufacturing. Many major MDI manufacturers are developing joint ventures to support product distribution as well as product development in

several World Bank Borrower countries. At the same time the MDI equipment market is strongly focused on innovation that leads to not only a healthy pipeline of new technology, but also development of low-cost alternatives to fill in the market gaps found within financially constrained healthcare systems.

Threats to this market stem from the overall economic instability that is present in many countries that are demanding MDI equipment. This instability leads to budget cuts within public healthcare systems, not only hindering the purchasing of equipment, but also the proper training of personnel to safely use the equipment.

Supply Positioning

Introduction

The Supply Positioning matrix is a way that purchasers rank their sources of supplies, based on the amount of money spent with each supplier and the level of vulnerability the purchaser has if that supply/supplier fails. This matrix helps in prioritizing effort and developing procurement supply strategies.

The Supply Positioning matrix has been applied to establish the risk or vulnerability of Bank funded MDI equipment procurement by Borrowers.

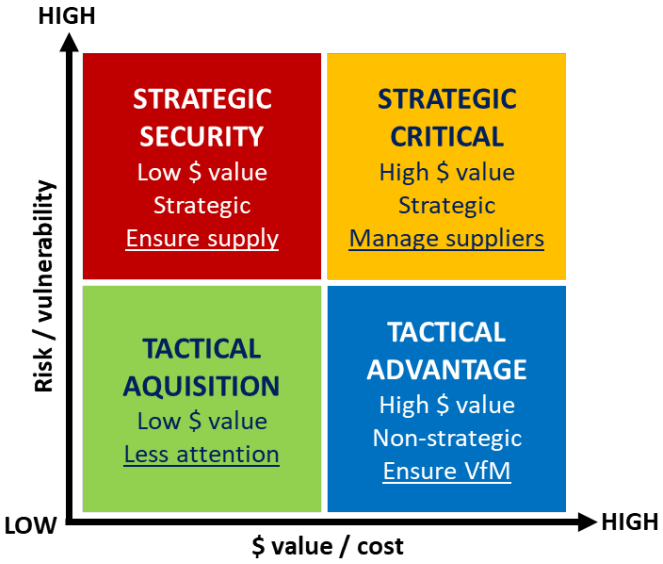

Figure XIII –Supply Positioning matrix

Result: Following analysis of various factors, the Supply Positioning matrix demonstrates that MDI equipment can be classified as "strategic security" (top left quadrant in Figure XIII) because whilst the expenditure is relatively low, MDI is important to the sound operation of a hospital.

Table XXX summarizes features identified in relation to the total spend and the levels of vulnerability, if the supply of MDI equipment fails.

$ value / cost	Risk / vulnerability
Relatively low-value contracts for capital equipment.	Knowledge imbalance between buyer and supplier.
Support and maintenance contracts are low annual value, but over the lifetime of the equipment represent the higher cost element.	Diagnostic imaging often part of larger supply contracts for a broader range of medical equipment.
Funding is through a mix of capital and revenue.	Multiple vendor supply models, including direct supply from original equipment manufacturers through to multiple distributors.
Bank only fund capital.	Market generally dominated by four large suppliers (GE, Philips, Toshiba and Siemens).
Market changing to more service-based offerings, combining capital and revenue costs into a single regular charge.	Brand recognition, patents and significant research and development investment requirements create real barriers to entry.
	Support and maintenance in developing countries often provided through distributors/third parties.
	Products that deliver best clinical outcomes tend to be costly as they are at the beginning of the product life cycle.
	Logistical issues associated with remoter geographies and non-physical presence in a country results in security of supply risks.
	Scarcity of technical resource, capability and capacity to operate and use the equipment.
	Rapid rate of innovation.

Table XXX – Supplier Positioning Analysis

Conclusions

The Supply Positioning analysis demonstrates that the overall expenditure on MDI equipment is relatively low-value, when considered in the context of the Bank's overall IPF (approximately US$20 billion), an individual Borrower's overall spend, and relative to the overall spend at a project level. Consolidating all expenditure from the Bank's MDI equipment portfolio, which is estimated to be US$10 million per annum, is relatively insignificant when compared to total industry sales of US$24.7 billion. This position is compounded by the fact that the consolidated Bank portfolio expenditure is relatively insignificant when compared to the sales turnover of the major suppliers "health tech" divisions. For example, Philip's Diagnosis and Treatment division has sales of US$3.6 billion, and GE sales are approximately US$3 billion.

The Bank's Health Global Practice portfolio spend is fragmented and projects are offered to the market on a piecemeal basis, often based on an individual location or a limited number of locations in a country. Furthermore, MDI equipment is often procured as part of a larger

package, either as a refurbishment of a hospital, building of a hospital or part of an upgrade to, or expansion of, an existing facility.

There are also several factors that indicate a higher risk to the Borrower operating in MDI equipment markets. The markets are technically complex and dynamic, with multiple supply sources determined by environmental complexity. Technical skills to specify and operate the equipment are at a premium and the rationale for specific specifications can be obfuscated by other factors such as familiarity with equipment and established ways of working, leading to the high number of complaints the Bank receives at the specification and bid evaluation stage of the procurement process.

It has already been established that MDI equipment has several market segments based on a more granular analysis of the product market. Whilst this may be the case, the issues considered in the Supply Positioning analysis have been applied at a consolidated market level i.e., diagnostic imaging. The rationale for this approach is that the general points considered, and the conclusions drawn, are for the most part, applicable to all segments within the market.

In summary, applying these various factors to the Supply Positioning matrix demonstrates that MDI equipment can be classified as strategic security because whilst the expenditure is relatively low, MDI is important to the sound operation of a hospital. This classification is substantiated by the fact that in the vast majority of projects the Borrower is in a relatively weak position, because of contract size, the lack of technical knowledge and the factors as demonstrated by the SWOT analysis, in that the negative factors (and their impact) outweigh the positives by a quantum.

Recalibrating and resolving this imbalance would suggest that the Bank should be focusing at a generic industry level, to implement the interventions to fix the recurring procurement issues identified. It is predicted that successful implementation of the interventions will reduce the overall risk and MDI equipment will move towards a tactical acquisition categorization. Borrowers should seek to lever these macro interventions and this guidance provides details on the actions Borrowers can take to strengthen their position and influence at an individual project level.

Supplier Preferencing

Introduction

Often suppliers will evaluate a customers' worth to determine the amount of effort they will exert to obtain and/or maintain the account. Supplier Preferencing analysis allows a purchaser to recognize how they are viewed by suppliers. It can help identify changes it may need to make to be seen as a more attractive customer. This can, e.g., result in more competition among suppliers to win their business.

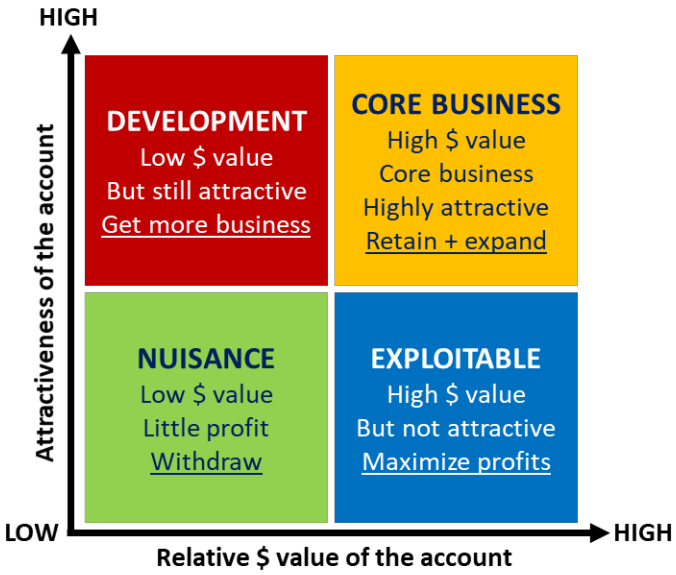

Figure XIV –Supplier Preferencing matrix

Supplier Preferencing analysis (as detailed in Table XXXI), has been applied to provide an indication of how suppliers may view the Bank, Borrowers and Bank funded projects in terms of attractiveness of doing business and the behaviors suppliers may exhibit in bidding and delivering contracts.

Result: On face value, Supplier Preferencing analysis indicates that Bank funded projects are not generally attractive, and in terms of relative value have little to offer suppliers relative to the size of the market and other customers in the market place. This places these projects in the "nuisance" category (lower left quadrant in Figure XIV).

POSTIVES	NEGATIVES
Blue chip organization which provides suppliers with a prestige account for references and promotional activity	Restrictive specifications limit competition
Opportunities for growth as the Bank's spend increases through additional financing and increased projects as clients look to replace earlier generation equipment	Slow and inconsistence decision making during the procurement process add cost and increase uncertainty
Security of payment (although there is a recognition that it can be delayed)	Poor visibility of the contract / project pipeline hinders business and bid planning
Doing business on Bank funded projects provides a high profile stepping stone to winning business from governments and other multilateral development banks	Changing needs and specifications impacts creditability and confidence in the management of the bid process and the freedom to deliver without undue encumbrance
A combination of the procurement reform and the launch of the Industry Sectorial Engagement Program demonstrates a willingness to listen, change and improve	Fragment customer base leads to inconsistency in requirements and higher costs of sale
Equipment often purchased as part of a larger overall package, providing the opportunity to cross sell a broader portfolio of medical devices and equipment	Decisions made on the basis of lower cost can result in sub-optimal decisions in terms of valuing innovation, driving value (as opposed to cost) in delivery and effective clinical outcomes
Supply of capital equipment leads to long term income stream (which over the life time of the equipment) exceeds the capital purchase price	Lack of consistency and convergence on the required standard and level of support and maintenance increases cost, non-standard processes and therefore a greater risk of non-compliance with service (level) agreements
Conditions of contract provide for a reasonable approach to sharing risk	Clinical preferences based on users experience and "customer and practice" can lead to barriers to entry
Transparent complaints handling system provides increasing confidence in the integrity of procurement processes and demonstrates a more open approach to listening	Lack of transparency of decision making impacts integrity and confidence in the procurement process
	Specifications are often prescriptive and conformance based restricting the opportunity to offer value added solutions
	Specifications are often prescriptive and conformance based restricting the opportunity to out sell the competition
	Opportunities to sell value added services that increase profitability are limited
	Combining equipment supply, installation and support into a single contract provides a long term legal and commercial risk in more volatile economies
	Country security issues create in tolerable risk for employees
	Significant supply chain challenges serving remote and / or hostile geographies
	Business opportunity values are relatively low and fragmented
	Decisions not made on the basis of whole life cost distort the value offering and de-incentivize investment in efficiency
	Funding treatment between capital and revenue can over complicate and distort normal commercial models
	The level of bureaucracy in procurement and project deliver results in a significant cost overhead / cost to doing sales
	Terms and conditions vary from contract to contract and require repeated review per contract adding to the cost of sales
	Poor investment in contract management increases the resource required to support deliver and increases the changes of protracted contractual delays and disputes
	Low margin business as equipment procured is earlier generation and further through its product life cycle

Table XXXI – MDI equipment sector Supplier Preferencing analysis

Conclusions

On face value, Supplier Preferencing could indicate Bank funded projects are not generally attractive, and in terms of relative value have little to offer suppliers relative to the size of the market and other customers in the global market place.

The annual value of Bank funded contracts is low, although the value could reasonably be expected to increase. In addition, the majority of business is the X-Ray systems market which could be viewed as lower profitability (for the capital purchase) as this market is very mature, with many product lines entering the latter stages of the product life cycle. This is further compounded by the fact that Bank funded clients are also not at the forefront of adopting new technology so opportunities to increase profitability by selling additional value products remains more limited than markets in Europe and the U.S for example. In addition, in the Bank Regions where the most significant expenditure is forecast, the largest manufacturers tend to use distributors, which puts further pressure on profit margins.

The overall profit margin position is partially offset using more lucrative (higher profit) support and maintenance contracts that have a longer duration covering the lifetime of the equipment. In addition, obtaining business in a single hospital location can help produce a "lock in" position where there is a significant change that future purchases of equipment will be with the same manufacturer. This "lock in" is driven by compatibility both with other pieces of equipment and staff knowledge of that equipment.

In terms of the operating environment, suppliers are likely to view Borrowers less favorably compared to the mature markets of the Europe and the U.S. Demotivating attributes include the use of traditional procurement processes, biased specifications, institutional capacity, logistical challenges and extended payment terms. However, while market growth across all geographies and product lines is expected up to 2020, Bank funded contracts are forecast to be awarded in the highest growing markets. Therefore, if suppliers are building the larger customer portfolios in these countries, winning Bank funded contracts may be more attractive.

Although the Supplier Preferencing indicates that the Bank and Borrower could be considered unfavorably, the one massive counter measure to that is that the Bank is seen as prestige, blue chip partner/customer. Driven by the Bank's convening power, and its ability to set good global practice in the developing geographies, make it easier for suppliers to do business. In addition, working on Bank funded projects provides suppliers with access to senior government stakeholders is these countries, which helps open future contract opportunities to wider government.

The Supplier Preferencing analysis reinforces many of the issues already established in the market analysis report and reinforces many negative drivers that could demotivate suppliers to win and deliver effective medical solutions for Borrowers. However, the Bank's redeeming strength is that it drives improved professional behaviors and standards in growing markets, provides access to influential stakeholders and is operating in the fastest expanding markets. These attributes provide a strong driver for suppliers to want to engage with the Bank and bid for Bank funded contracts.

To conclude, Supplier Preferencing analysis indicates that the Bank and Borrowers are considered as a "nuisance", while Supply Positioning analysis indicates that the Bank and Borrower view MRI equipment as "strategic security". This imbalance demonstrates that the Bank needs to engage with the market and implement changes that moves the Bank and Borrowers into the Supplier Preferencing categorization of "develop". The Supplier Preferencing analysis reinforces the position that there are several opportunities available for the Bank, at a macro level, to make significant improvements to how the Bank and Borrowers engage with the market. As with Supply Positioning, Borrowers should seek to lever these macro interventions and this guidance provides details on the actions Borrowers can take to strengthen their position and influence at an individual project level.

Porters 5 Forces

The Porters 5 Forces model (see Figure XV) has been applied to identify the competitive intensity that exists in the MDI market and, therefore the market's overall attractiveness. Attractiveness, in this context, means overall profitability. MDI equipment would be an unattractive industry if a combination of the five forces act together to drive down profitability. Whereas, MDI equipment would be a more attractive industry if there was "perfect competition" (a market where there are limited barriers to entry to the market, and in which buyers and suppliers are so numerous and well informed that all elements of monopoly are absent, and the market price of a commodity is beyond the control of individual buyers and suppliers), allowing new entrants to compete and make profit. The nature of competition in the MDI market has been analyzed based on the following five forces:

1. Bargaining power of suppliers (supplier power);
2. Bargaining power of buyers (buyer power);
3. Rivalry among current competitors (competitive rivalry);
4. Threat of substitute product/services (product and technology development);
5. Threat of new potential entrants (new market entrants).

Figure XV - Porters 5 Forces

Bargaining power of suppliers (supplier power)

The MDI market is a concentrated market, with four major players (GE, Siemens, Philips and Toshiba), that have large market shares in all the equipment lines. Suppliers to this market are mainly comprised of component and subcomponent manufacturers. Availability of substitutes is limited, as these components and subcomponents are technologically advanced, and often protected by patents and intellectual property rights (IPR). However, there is a growing risk for manufacturers in countries that have more limited intellectual property protection laws where reverse engineering is creating a threat of technology copying.

Competition in this area is due mainly to the "make or buy" decision of each manufacturer. Market leaders such as GE, Philips, Siemens and Toshiba, have large R&D budgets and are fully capable of producing each component in-house, therefore the bargaining power of suppliers in this market is low.

Bargaining power of buyers (buyer power)

The size of the MDI equipment market is considerable. In 2015 the market was worth US$24.7 billion and is set to reach US$33.4 billion by 2020 at a CAGR of 6.2%. Annual spend on this type of equipment by projects financed by the Bank is in the region of US$100 million to US$200 million, therefore the Bank's portfolio in relation to overall market size is small. Bearing in mind the market capitalization of any of the four largest suppliers in this market is more than US$3 billion, the Bank or its Borrowers are unlikely to exert any kind of influence over suppliers in this market from a strictly financial point of view. However, the Bank has a unique brand and international standard setter role, and kudos associated with its name, which puts it in a position of its own from a buyer's perspective. It also has unique relationships with governments worldwide, which may be of interest to any supplier looking to build long-term strategic partnerships, or indeed seeks the Bank to influence global procurement practice. Therefore, the bargaining power of buyers in this market is medium.

Rivalry among current competitors (competitive rivalry)

The MDI equipment market is oligopolistic in nature. Only four firms have a large share of and dominate the market. The degree of competition varies slightly for each market segment, but in these segments the four largest players have a combined market share of over 65%-90%. Barriers to entry such as high fixed costs, patents, multiple regulatory regimes and brand loyalty bring down the competitive rivalry and make it difficult for new suppliers to emerge.

Threat of substitute product/services (product and technology development)

MDI equipment manufacturers have been launching new products at varied price points and across all modalities to strengthen their presence in the MDI equipment market owing to significant opportunities in the emerging markets. MDI equipment manufacturers have also been focusing on nations such as India, China, and Brazil, through geographic expansions and development of low-cost equipment specifically for developing nations.

Factors such as reimbursement cuts, high competition, and increasing demand for refurbished devices may propel MDI equipment manufacturers to provide technologically advanced MDI systems at low costs for mature markets in coming years.

The threat of substitute products varies between market segments:

1. **Ultrasound segment:** This segment features a more mature technology with a higher degree of competition in the market. There are more suppliers' active in this segment, with a broader choice of products on offer, from stand-alone Ultrasound equipment, to lower cost portable devices that plug into external monitors;
2. **X-Ray segment:** This segment also features mature technology. However, modern digital X-Rays are gradually substituting analogue machines in more mature markets;
3. **MRI segment:** This segment features a technologically advanced product, with low threat of substitute products. While innovations in this segment are continuous, the underlying technology used to capture images stays the same.

In conclusion, the threat of substitute's products for the broader MDI equipment market is low, and innovations are generally due to size and functionality of the product, rather than the performance of the product.

Threat of new potential entrants (new market entrants)

The threat of new entrants into the MDI equipment market is medium to low. There are numerous barriers to entry into this market which makes entry to the market a challenge.

1. **Brand Loyalty:** Established brands such as GE, Siemens and Philips hold an advantage in this market, as recognition is linked to quality, which directly affects clinical outcomes, therefore buyers are less likely to take a gamble on a new unknown brand;
2. **Customer switching costs:** In many cases in this market, purchases are linked to service contracts or IT equipment, which has the potential of making a switch to another brand costly;
3. **Capital Investment:** This is a very high-tech industry, with a large amount of capital required for R&D costs;
4. **Government Regulations:** This market is very tightly regulated, varying in degree from country to country. Suppliers must comply with the latest international standards to remain competitive;
5. **Patents:** Suppliers in the market strive for continual innovation and protect their investment and market position through aggressive patent registration and enforcement. However, there is a growing risk for manufacturers in countries that have more limited intellectual property protection laws where reverse engineering is creating a threat of technology copying.

Conclusion

The MDI market size is considerable. In 2015 the market was worth US$24.7 billion and is set to reach US$33.4 billion by 2020 at a CAGR of 6.2%. An aging population and an increasing incidence and prevalence of chronic diseases (such as Cancer and Alzheimer's) are the main driving forces behind this growth rate.

The size of this market, coupled with a high projected growth rate makes it seem an attractive proposition for companies across the globe, however, the market is dominated by a small number of very large players. Buyer power is low in general, as there are many independent buyers, which have a very limited influence on price. Supplier power is also low, as the main manufacturers in the market are large companies with high capabilities for R&D, and potentially possess the ability to produce their own components and subcomponents, which are the main inputs in this market. The threat of new entrants is medium to low, the main threat being other large electronics companies looking to move into new industries through acquisitions, due to falling profitability in other product lines (e.g., Samsung, with revenues from their core TV segment decreasing year on year). The threat of substitute products is also low in this market.

In conclusion, this market is an oligopoly in structure, with a handful of large companies that dominate the market in each segment. Profitability will remain high for the established companies, with new entries to this market being limited.

PESTLE Analysis

Introduction

The following PESTLE analysis (see Figures XVI and XVII) has been applied systematically to draw together many of the issues described in the market analysis. It helps to summarize the key findings.

Figure XVI – PESTLE

Figure XVII –PESTLE analysis for MDI equipment sector

Political

Regulations

The MDI sector is heavily regulated. That can affect market growth. For the MDI sector to fully realize its potential in developing markets, standards for regulatory approval, risk management and quality must improve and continue along the path of international convergence to meet global standards. The GHTF's core objective is to streamline and harmonize regulatory standards.

The IMDRF has built on the strong foundational work of the GHTF. IMDRF aims to accelerate international medical device regulatory harmonization and convergence. The enhanced participation of developing countries' medical device regulatory agencies in IMDRF activities coupled with guidance issued by GHTF has been be critical in establishing regulatory regimes for MDI devices that are distinct from traditional pharmaceuticals.

International or Domestic

Some Borrower countries have policies that encourage a domestic preference to domestic providers. Domestic preference could reduce competition in the procurement process if a preference is given as this could lead to sub-optimal MDI devices being procured. This shouldn't be an issue in most cases with Bank financed projects as the value of the procurement would

be over NCB thresholds and will therefore need to be advertised internationally without a domestic preference being given.

Acceptance of New Technology

MDI manufacturers are continually investing in R&D to develop new technologies to enhance their product offerings and to differentiate themselves from the competition. This has many benefits to health care providers and enables them to offer the highest level of medical care. However, in some developing countries the acceptance of new technologies is low, and many choose to purchase older technology MDI devices.

Trade Barriers

Regulatory and reimbursement requirements for MDI devices vary from country to country, creating complications for MDI exporters. Certain countries, including India, some Latin American countries and parts of Asia, still maintain high tariffs on some medical products, reducing the net sale price of MDI devices.

The MDI device industry is highly regulated, and regulatory environments in the U.S., Europe and the rest of the world have serious implications on industry performance. An increasingly common practice among developing countries is the establishment of national regulatory requirements above and beyond the requirements of developed countries. MDI firms tend to devote tremendous amounts of time and money to determine such requirements, conduct additional clinical trials and pay additional user fees. These national requirements may sometimes be established to protect the domestic industry or to be a source of revenue for the government or both.

Public-Private Partnerships

New hospitals, including fit-out and equipment, are more commonly being funded through Public-Private Partnership (PPP) arrangements, and a range of approaches to healthcare PPPs has emerged. The UK was the leader in hospital facility PPPs under its Private Finance Initiative (PFI), focusing on development/rehabilitation of facilities and facilities management. Several countries have followed a similar approach to hospital PPPs, focusing on facilities, including Australia where several states continue to follow this approach.

India, by contrast, has adopted more comprehensive service delivery PPPs, where not only are the facilities developed and improved but services are provided as well. This approach is more one of a private hospital built on public land with a requirement to make a certain number of beds/treatments available to publicly funded patients. The rest of the facilities can be used for private patients. In some cases, the concessionaire will pay the government a fee for the right to operate the concession, in others it will require a subsidy. Typically, the bids are evaluated based on the lowest cost to government.

Local authorities, often with fiscal difficulties, are looking to PPPs to allow them to provide the health facilities that they find unaffordable. As with many sub-national PPPs, they utilize land available to them to develop a partnership with the private sector that they expect to benefit their citizens.

Total Health Care Solutions

Organizations have emerged that state they can provide total health care solutions to communities from the national level down to the sub-national level. These solutions include providing the space, staff, and equipment needed for a healthcare system to function. Generally operating initially off public financing, these organizations go a step further than PPPs in the fact that they completely control all aspects of the healthcare system and it is overall privately run.

Closer Government Involvement

In some countries, the government is more involved in how the MDI equipment industry operates with regulations, policies or tariffs. Governments can also have more involvement in the procurement process and can influence the award decision.

Economic

Growth

The MDI market is experiencing a high level of growth. In 2015 "MarketsandMarkets" indicated that the X-Ray segment was expected to account for 34.3% of the global MDI equipment market followed by MRI systems and ultrasound systems with a market share of 21.6% and 19.7%, respectively. However, the X-Ray systems market is expected to grow at the highest rate of 8.9% from 2015 to 2020, primarily due to new product launches with technological and software modifications, the growing use in various medical applications, and strong support/preference from obstetricians and gynecologists across the globe.

Inflation

Inflation is defined as a sustained increase in the general level of prices for goods and services. It is measured as an annual percentage increase as reported in the Consumer Price Index (CPI), generally prepared monthly. As inflation rises, purchasing power decreases, fixed-asset values are affected, companies adjust their pricing of goods and services, financial markets react and there is an impact on the composition of investment.

Exchange Rates

One of the many risks that come with the global nature of supply chains is the risk of currency fluctuations. Foreign exchange rates can fluctuate dramatically over the course of a supply agreement and it is important to consider their impact upfront. To mitigate this risk, an exchange rate fluctuation provision can be included. If there is a conversion risk, then the Borrower and the Bank should consider:

1. The likely size of any fluctuation in the exchange rate between the Borrowers currency and the foreign currency during the term of the contract;
2. The impact of the potential exchange rate fluctuation given the value of the contract;
3. Mitigating the risk of exchange rate fluctuations by hedging, considering the availability and cost of hedging.

Shortage of Qualified Medical Staff

There is a lack of suitably qualified MDI equipment professionals across the world. As MDI increases around the world, and particularly in developing countries, the lack of qualified professionals could reduce access to diagnostic imaging. In India, a recent study by Public Health Foundation of India for the Ministry of Health and Family Welfare found that radiography and imaging alone account for 88.7% of the skills gap amounting to a huge shortage of medical laboratory technicians. The greatest need of radiology and imaging professionals is in Uttar Pradesh (adjusted estimate 3,600). Other states witnessing these huge skill gaps are Maharashtra, Bihar, West Bengal, Andhra Pradesh, Gujarat, Assam followed by Delhi.

Workforce shortages pose a serious challenge to timely access of healthcare services around the world.

Developing Countries

According to the World Health Organization (WHO), more than 70% of MDI equipment acquired by developing countries, or donated, will never actually be used. This is due, e.g., to insufficient knowledge or expertise to install the device, missing electrical cables, or the absence of qualified personnel. And the remaining 30% often can no longer be used when it becomes necessary to order accessories or spare parts. The vast majority of the inhabitants of these countries have no access to such essential equipment as X-ray machines, incubators for newborn babies or equipment for anesthetics.

In many cases, for an MDI device to be effective, the device must be adapted to the context in which it is to be used. This can mean having to completely re-think each device, integrating in its design effective solutions to the recurring problems in these countries. These can include, an electricity network that is often defective, resulting in excessive voltages that damage the device, a lack of financial resources for the purchase of the device and the accessories necessary for its functioning and the complexity of utilization for poorly trained personnel.

Economically Volatile

The overall healthcare sector of many Borrower countries is highly reliant on public funding. If countries' economies take unexpected downturns, this can lead to a shortage of funding to healthcare systems and in turn a decrease in the level of healthcare service. Many private healthcare systems also have some reliance on the public financing, either through grants or policies for subsidies, hence they can also be at risk for the same downturns in the economies.

An economical volatility also increases the difficulty in which healthcare systems can properly plan and implement their own growth that is needed to meet the needs of patients over time. Long-term strategies, which can include the procurement of new MDI equipment, can sometimes not be realized due to the lack of received funds due to an economic downturn.

Reimbursement Payment Environments

Reimbursement is the act of compensating someone for an out-of-pocket expense by giving them an amount of money equal to what was spent.

Reimbursement is also used in insurance, when a provider pays for expenses after they have been paid directly by the policy holder or another party. This is especially relevant in health insurance, due to urgency, high costs, and administrative procedures which may cause a healthcare provider to incur costs pending reimbursement by a private or public provider. Segments of the healthcare industry, such as MDI, rely on reimbursement for income[35] and produce resources assisting their customers (hospitals, physicians, etc.) in obtaining reimbursement[36].

Social

Life Expectancy Increasing

The dramatic increase in average life expectancy during the 20th century ranks as one of society's greatest achievements. Although most babies born in 1900 did not live past age 50, life expectancy at birth now exceeds 83 years in Japan. Less developed regions of the world have experienced a steady increase in life expectancy since World War II, although not all regions have shared in these improvements. (One notable exception is the fall in life expectancy in many parts of Africa because of deaths caused by the HIV/AIDS epidemic.) The most dramatic and rapid gains have occurred in East Asia, where life expectancy at birth increased from less than 45 years in 1950 to more than 74 years today.

These improvements are part of a major transition in human health spreading around the globe at different rates and along different pathways. This transition encompasses a broad set of changes that include a decline from high to low fertility, a steady increase in life expectancy at birth and at older ages, and a shift in the leading causes of death and illness. As the MDI equipment manufacturers keep improving their product offerings, and more people get access to this equipment, early diagnostic has increased which increases the chances of effective treatment of the illness or disease.

Demographics (Young vs Old)

As well as increased life expectancy, increasing the demographics of young and old has also changed. In the next four years, the global population who are 65 and older will surpass those under 5 for the first time, according to a new report from the U.S. Census Bureau. This crossing is just around the corner, before 2020, says the report. These two age groups will then continue to grow in opposite directions. By 2050, the proportion of the population 65 and older (15.6 percent) will be more than double that of children under age 5 (7.2 percent).

The changing demographics means that demand and access to MDI equipment is also likely to increase in the same period.

Lack of Focus on Medical Outcomes

Healthcare systems' spending, including MDI equipment, often focuses on short-term, supply-driven solutions. This practice uses success metrics based on volume and profitability of services provided, which in fact does not go far enough to determine the actual health

[35] http://clinicaldevice.typepad.com/cdg_whitepapers/2011/05/reimbursement-strategies.html
[36] https://www.vascular.abbott/us/professional-resources/reimbursement.html

outcomes attained by the targeted patient population. The current strategy can lead to purchasing of MDI equipment that does not fit the need of the patient population or does not support the services offered by the purchasing healthcare entity. Overall, this can cause unnecessary or redundant costs within a healthcare system.

A change in strategy has been developed by leading economists over the past decade to redefine healthcare system's goals as achieving the best medical outcomes at the highest value and lowest cost[37]. Value in this case is defined as the health outcomes achieved that matter to patients relative to the cost of achieving those outcomes. Examples of this new type of strategy can be found in some developed economies, but it is still not transitioning quickly into developing economies.

Emerging Health Care Systems

The growth of health care systems across developing countries has led to innovating methods for health care delivery. For example, in Mexico a telephone-based health care advice and triage service is available to more than one million subscribers and their families for $5 a month, paid through phone bills. In India, an entrepreneur has proved that high-quality, no-frills maternity care can be provided for one-fifth of the price charged by the country's other private providers[38].

These innovations are driven by existing providers and entrepreneurs improvising due to lack of existing adequate healthcare and by decreased oversight by existing healthcare regulatory institutions. This has allowed some healthcare systems to bypass traditional healthcare models.

Emerging health care systems tend to be localized and developed to tackle a specific need within the targeted population. As these systems continue to grow, lessons can be compiled to develop broader, patient-specific strategies for health care systems across different economic and social settings.

Technology

Emerging Technologies

The MDI equipment sector is constancy investing in new and emerging technologies to increase their product offering and attractiveness. These emerging technologies could enhance MDI equipment by providing better resolution, enabling new modalities, or facilitating portability.

The acceptance of emerging technologies varies across the world. Acceptance is higher in the developed world compared to the developing world. Many countries in the developing world do not possess the infrastructure or knowledge capacity ready for these new technologies and MDI manufacturers produce low cost options for this market.

37 https://hbr.org/2013/10/the-strategy-that-will-fix-health-care

38 http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/the-emerging-market-in-health-care-innovation

Information Availability

As new technologies are commercialized, MDI equipment manufacturers, distributors, and industry associations have increased efforts to keep informed clients in areas where they maintain a strong market presence. This is aided by the advances in communication and media. Though it still leaves most of the outreach focused in developed country settings where the largest MDI equipment markets are located.

Information on the latest technology, correct use of products, and equipment preservation is not as wide spread or easily assessable in country setting that are not considered target markets by MDI manufacturers and distributors.

In-country setting, where information is widely available, research has noted that there is a trend for over-use of patient testing and treatment with MDI equipment, leading to increased cost for healthcare systems. This could be due to the ease of access to patient health information possible with this equipment, leading health practitioners to avoid any ambiguity by over testing with several types of MDI equipment.

Pace of Change

All research in MDI equipment technological advances conclude that the pace of change is rapidly accelerating overall. This pace is not only due to advances in core imaging techniques, but also the integration of new digital and analytical technology and overall technology cost efficiencies.

This pace of change does vary when looking at separate markets based on geography. The type of technology, as well as the knowledge base of imaging professionals, seems to change quicker over time in larger MDI markets than does with smaller MDI manufacturer and distributor presence.

Patents and Intellectual Property

IPR, patents and counterfeiting have not posed as significant a problem for MDI equipment firms as they have in the pharmaceutical industry. However, the sector is beginning to face related revenue losses with increasing frequency. IPR violations include using medical device firms' patented technology to manufacture a competing medical device or unauthorized use of a registered trademark. Similarly, counterfeit medical devices are copies of patented medical devices that are manufactured and marketed without following the requisite approval process, which can result in unsafe products on the market. IPR violations occur in markets that may not fully respect or enforce patent protection, such as China. There is limited data on counterfeit medical devices, but research has shown that the most frequent incidences are in IVD reagents and solutions, contact lenses, medical test kits and components parts, such as semiconductors used in MDI equipment. U.S.

R&D Expense

MDI manufactures to keep up with new technologies and to keep as competitive in the market spend on average between 3.5% and 37.7 % of their annual revenue on R&D. So, this is recovered through a high mark-up on manufacturing cost?

Low Cost Options

MDI manufacturers have been launching new products at varied price points and across all modalities to strengthen their presence in the MDI market. Owing to immense opportunities in the emerging markets, MDI manufactures have also been focusing on nations such as India, China, and Brazil, through geographic expansions and development of low-cost equipment specifically for developing nations.

Factors such as reimbursement cuts, high competition, and increasing demand for refurbished devices may propel MDI manufacturers provide technologically advanced MDI systems at low costs for mature markets in coming years.

Refurbishment / Refurbished Products

Refurbishment involves restoring equipment to its original condition without altering any of the product's specifications. The process ensures maintenance of the safety and efficacy of the MDI equipment without altering its performance. Therefore, refurbishment varies from the replacement of worn parts to cosmetic changes. Usually, the replacement cycle depends on the agreement between vendor and end-user. New equipment has a life span of about 10 years, with spare part availability being 7 years from when a piece of equipment is discontinued. Often equipment replacement is not driven by equipment unreliability, but by technological obsolescence in the world’s richer counties. This helps create the supply market for refurbished equipment.

Refurbished equipment tends to have a lifecycle of between 3-5 years, however, as the marketing is relatively immature, it is expected that this will change and extend as the latest equipment with improved operational performance and reliability enters the refurbished market.

Legal

State Involvement

In general, each national government is involved in the MDI equipment industry from a regulatory perspective. In certain countries, there are also regulatory practices conducted on the subnational level. Apart from regulation, state involvement can also be in the form of grants and/or tax subsidies to MDI manufacturers to improve technology, competitiveness, and their health care system.

In some developed countries, some cases of involvement exist in terms of acquiring feedback to support policy decisions. Agencies are established that use information gathered from MDI equipment use and results to inform future healthcare and medical technology policy decisions.

Regulations

There are many regulations at a country level that need to be considered as part of the PESTLE analysis. These regulations will differ from region to region and country to country. The common regulations and legal factors that need to be considered are:

1. Employment regulations;
2. Competitive regulations;
3. Health and safety regulations;
4. Product regulations;
5. Antitrust laws;
6. Patent infringements.

Price Controls

Price controls are governmental restrictions on the prices that can be charged for goods and services in a market. The intent behind implementing such controls can stem from the desire to maintain affordability of goods, to prevent price hiking during shortages, and to slow inflation. There are two primary forms of price control, a price ceiling, the maximum price that can be charged, and a price floor, the minimum price that can be charged.

For example, in India the government is considering regulating the MDI sector, a task force has recommended a separate price control order by putting them under the *Essential Commodities Act*. Once the devices come under the Act, the government will be able to keep tabs on the price of equipment. The Task Force on Medical Devices has also recommended formulation of the *Medical Device Regulatory Act*.

Contract/Commercial Law

Contract and commercial law refer to the legislation that is put in place at either the national or sub-national level and that applies to the rights, relations, and conduct of persons and businesses engaged in commerce, merchandising, trade, and sales.

In the case of MDI equipment, international trade between manufacturers and distributers, and sometime manufacturers directly to end customers, falls under the laws of multiple country's contract and commercial laws. International and regional conventions do exist with the goal of standardizing and harmonizing trade between countries, with the most widely accepted being the framework developed through the World Trade Organization.

Health and Safety

MDI equipment manufacturers must operate under legislation and regulations concerning safety in medical equipment design and use. These legislations and regulations are generally imposed at a national level, although efforts to create a set of standards are in progress by organizations such as the Medical Imaging and Technology Alliance (a U.S.-based organization).

Environment

Local Legislation

The MDI equipment industry is regulated on the national level, and in some cases on the sub-national level. Although efforts for international standardization do exist, local legislation can be different in areas of commercial law, product development, and even health and safety.

Local legislation may also be a barrier for entry for non-local suppliers, forcing them to not take part in local procurements or to do so through local distributers.

Radiation Concerns

In general, the amount and duration of radiation exposure affects the severity or type of health effect. There are two broad categories of health effects: chronic (long-term) and acute (short-term).

Chronic (long-term exposure): This is continuous or intermittent exposure to radiation over a long period. With chronic exposure, there is a delay between the exposure and the observed health effect. These effects can include cancer and other health outcomes such as benign tumors, cataracts, and potentially harmful genetic changes.

Acute (short-term exposure): This is low levels of radiation exposure. Current science suggests there is some cancer risk from any exposure to radiation. However, it is very hard to tell whether a particular cancer was caused by very low doses of radiation or by something else. While experts disagree over the exact definition and effects of "low dose," U.S. radiation protection standards are based on the premise that any radiation dose carries some risk, and that risk increases directly with dose. This method of estimating risk is called the "linear no-threshold model". The risk of cancer from radiation also depends on age, sex, and factors such as tobacco use.

Waste Disposal

The average lifecycle of MDI equipment can be up to 10 years and is shorter for refurbished equipment. MDI manufacturers guarantee to keep parts available for MDI equipment for 7 years after a model is discontinued. Specific regulations around medical device disposal exists in most countries and include specific criteria for medical imaging equipment. In developed country settings, large industry exists to support the proper disposal, and even refurbishment, of MDI equipment.

Although certain technology can be subject to specific treatments, the general avenues for waste disposal include:

1. Donating the equipment to an entity that is legally able to use the equipment;
2. Transfer of ownership to an entity that is legally able to use the equipment;
3. Sell the whole machine, or parts, to a waste disposal company that is licensed to safely and legally dispose of nuclear waste materials.

Falling Helium Reserves

Helium plays an essential role in MRI systems, as it is currently the only element on earth that can be effectively used to cool down the superconductive magnetic coil in MRI equipment. About 28% of the world's helium supply is used for the production and maintenance of MRI machines. The use of helium has increased by 25% since 2003, which is majorly driven by the increasing use of MRI in MDI.

According to the Lifeboat Foundation, with the current rate of consumption, helium reserves are expected to run out within 25 to 30 years. Currently, the U.S. alone produces 75% of the world's helium, of which more than 50% comes from the U.S. Federal Helium Reserve. However, in the past few years, even the U.S. helium reserves have faced shortage. This has raised concerns among MRI manufacturers, as the shortage of helium for MRI systems may damage the magnet permanently or raise the need for replacing it, which is a costly and time-consuming process. In addition, the shortage of helium supply is driving up its price across the globe. For instance, the U.S. federal government increased the price of helium to US$84 per thousand cubic feet in 2013 from US$75.75 per thousand cubic feet in 2012. These factors have the potential to create significant challenges in the MRI systems market in the next five years. The shortage of helium is a major area of concern for MRI manufacturers.

Security

As medical equipment is becoming more connected, issues concerning internet connected devices and software should now be considered when dealing with MDI equipment. Specifically, these issues can include privacy and safety concerns to patients as well as cyber security threats such as malware. The responsibility for security is still not fully defined across the industry on whether liability rests with the manufactures and vendors or with the purchasers and end-users. This liability is also subject to regulation and can differ from country to country.

Also, due to some MDI equipment containing radioactive materials, a secure procedure is needed to ensure that radioactive material is disposed of in a safe and secure manner.

Conclusions

The MDI equipment market is defined as a sub-section of the overall medical equipment market. MDI equipment manufacturers include the various activities as part of this market, such as: O&M, user training, and other activities required to effectively operate equipment. There are several influences into this market that can have an impact in the outcomes of Bank financed projects that procure MDI equipment and related services.

Regulations play a large role in the manufacturing and the procurement of MDI equipment, yet these regulations are often country specific, with some regional standards in place. It is important for Bank financed project teams to understand the regulations specific to their country setting to assess any limitations that may be placed on the available technology.

Since some country healthcare systems are burdened with economic instability, it creates a market place that would often be considered unfavorable for OEM to operate in. Hence, distribution networks and joint ventures are often put in place to shield the OEMs from economic risk, while making MDI equipment available to these healthcare systems. Unfortunately, these solutions can lead to lack of attention to areas such as training qualified staff to properly use MDI equipment, leading to the WHO's observation that more than 70% of MDI equipment acquired by developing countries, or donated, will never actually be used. The Bank needs to ensure that procurement of MDI equipment fits into the capacity of the end-users and that any knowledge transfer/training is included in the procurement.

Emerging healthcare systems are beginning to tackle issues arising from increased life expectancy, as well as new patient demographics that demand services involving MDI equipment. To sufficiently meet this demand and provide the appropriate fit-for-purpose, Bank financed projects should develop procurement strategies that tackle the desired medical outcomes rather than purely supply-driven solutions. Reflecting the values outlined in the Bank's *Environmental and Social Framework* into the project's procurement strategy can support this drive for desired medical outcomes and ensure the best use of MDI equipment throughout its entire lifecycle.

The MDI equipment market has many new technologies continually emerging, and its pace of change seems to be accelerating. Bank and Borrowers must make a conscious effort to ensure that information on MDI equipment solutions is available for a project's market, in order to procure the best solution for a particular healthcare system. Depending on the environment, this may mean that refurbished equipment is the best fit to attain a particular medical outcome.

Risk Analysis

An evaluation of the risks associated with the procurement MDI equipment indicates a close correlation with the issues that have been identified by both the market research and industry consultation. Certain risks can have a major impact on the procurement of MDI equipment.

In summary, the following key risks were identified:

1. **Needs analysis:** The identification of the right equipment to deliver project outcomes is constrained by the complexity and integrated nature of identifying a holistic solution to diagnosis and treatment;
2. **Attractiveness of Bank financed projects:** Projects have struggled to attract a high enough number of bids in this market due to factors such as; location of the Borrower, poor specifications, and aggregate requirements as part of a hospital refurbishment projects;
3. **Competition:** The market for MDI equipment is highly concentrated and dominated by a small number of large suppliers, that compete strongly for market share through competitive pricing and developing propriety functionality;
4. **Innovation:** The market is developing rapidly with significant innovation, not only in terms of technology but also in how the market delivers value to the customer and end-user;
5. **Capacity of the Borrower:** MDI equipment is highly technical in nature and requires external specialist support, to augment in-house capacity' to deliver projects;
6. **Requirements (equipment use, infrastructure, purchase type):** Specifications are often not fit-for-purpose because they are technically inadequate, leading to significant volumes of complaints from the market place;
7. **Cost:** Purchase decisions do not always recognize that the operational costs of running MDI equipment out-weigh the capital cost/purchase cost of MDI equipment;

8. **Budget:** Budgets do not make adequate provision for revenue costs associated with keeping equipment operational over its life time;
9. **Quality of service (equipment up-time):** Operational effectiveness of equipment, in terms of availability and utilization, is negatively impacted by the availability of machine technicians, continuity of knowledge, effective support and maintenance contracts with appropriate incentives that ensure equipment is fixed promptly.

The primary mitigations to address these risks include:

1. **Project Development Outcomes:** Accurate identification of project outcomes is essential in determining the best purchase type (e.g., lease, buy or service);
2. **Technical Capacity:** Ensure expert advice and support on technical input, covering equipment functionality and infrastructure requirements;
3. **Scope:** Specifications to reflect the full requirements, such as training, technicians support and maintenance services;
4. **Reverse Marketing:** Enhanced engagement with the market to increase visibility and attractiveness of Bank funded opportunities;
5. **Procurement Approach:** Take a considered approach to developing an appropriate procurement strategy. Consider options such as: lotting, use of Request for Proposals, and incentive-based payment mechanisms;
6. **Supplier Selection:** Utilize evaluation methods based on merit rating systems (rated criteria), balancing cost and quality;
7. **Cost:** Undertake a whole-of-life cost analysis to understand the full cost and budgetary implications;
8. **Ongoing Management:** Institute strong contract management to maintain system availability.

For more information on risk identification and analysis in procurement see Annex 1.

Summary of Findings

This market analysis informs Bank staff and Borrowers of the that risks, issues and factors that should be considered in developing effective procurement strategies when purchasing MDI equipment. The key elements to consider can be summarized as:

1. **Market engagement**: Focus on the marketplace and demonstrate to suppliers the benefits of working with the borrower;
2. **Specification**: Make sure the Borrower clearly states the detailed specification or performance requirements and provides the supplier with freedom to use its expertise to be innovative in its delivery;
3. **Procurement approach** (contract type, conditions of contract, pricing mechanisms, etc.): Make sure bids are competitive and ultimately deliver demonstrable VfM;

4. **Evaluation**: Make sure the most appropriate supplier is selected and all risks are identified, understood and managed;
5. **Environmental and Social Framework**: Make sure the procurement approach better manages environmental and social risks of projects to improve development outcomes;
6. **Legal**: Make sure suppliers fulfil their contractual obligations and that any issues are dealt with efficiently and effectively in a fair and transparent manner.

Table XXXII below provides a summary of the findings of the market research and analysis and identifies mitigation strategies.

Market Research and Analysis – Key Findings	Mitigation	Procurement Stage
1. Recurring procurement problems include challenges to the bid evaluation process and award decisions (53% of complaints), and concerns on biases/weaknesses in specifications and bid documents (25% of complaints).	• Provide expert independent advice to quality assure specifications • Provide guidance on specifications for different MDI equipment types • Establish a standardized format for bid evaluation models	• Specification • Procurement approach • Evaluation
2. The Bank's expenditure data is likely under reported[39] as MDI can be combined into a broader civil engineering project e.g., hospital construction or refurbishment.	• Work with the Health GP to help identify the potential pipeline • Provide regular updates to the market place • Undertake regular pre-market engagement to help mitigate issues in pipeline visibility • Ensure use of effective lotting strategy	• Pre-market engagement • Specification • Procurement approach
3. The Bank has 45 active projects in its HNP portfolio. 50% of projects are in Europe and Central Asia (ECA) and Africa. $470 million of medical equipment procurement is identifiable. The Bank's MDI financing is relatively low to the total value of all MDI procurement globally.	• Share analysis with the market place • Focus early capacity building in these 2 Regions	• Pre-market engagement • Procurement approach
4. Due to the complexity of the procurement, Bank financed projects usually hire an external consultant to support procurements. The availability of technical MDI consultants is limited, and they can often be accused of biases by the MDI sector.	• Establish a Framework Agreement to provide efficient and effective access to individual consultants and firms with expertise in MDI equipment	• Specification
5. The average total cost (purchase, operation and maintenance) over the life of an MRI scanner is circa US$3.08 million, an X-Ray is US$344 thousand, and an Ultrasound is US$6 million.	• Regularly benchmark Bank funded projects to ensure market pricing remains competitive	• Specification • Procurement approach • Evaluation

[39] At the time of finalizing this report the Bank financed a major MDI program in Romania, which is not included in the data shown.

Market Research and Analysis – Key Findings	Mitigation	Procurement Stage
6. The ratio of initial purchase price to operation and maintenance cost is 1:1 for MRI, 1.5:1 for X-Ray and 2:1 for Ultrasound.	• Develop a model on total cost of ownership	• Specification • Procurement approach • Evaluation
7. Typically, MDI equipment has a 10-year life span (longer or shorter depending on O&M). The optimal age profile for a set of MDI equipment is 60% should be less than 5 years old, 30% between 6 to 10 years, and less than 10% over 10 years old. Due to fiscal constraints, the life of equipment is generally being extended. This progressive aging of equipment may lead to a surge in demand following economic growth.	• Develop a model on total cost of ownership • Ensure project appraisal considers lifetime costs and funding • Ensure spare parts are contractually available for the life time of the equipment • Continue engaging with the market to monitor activity • Update market analysis every 3 years to ensure it remains contemporary	• Pre-market engagement • Specification • Procurement approach • Evaluation
8. The MDI market is segmented between Original Equipment Manufacturers (OEM), distributors and suppliers of refurbished equipment (latter, with some OEM approved, others not).	• Market engagement should be aimed at all sectors of the MDI equipment industry • Lotting strategies should consider the optimum supply approach for their requirement	• Pre-market engagement • Specification • Procurement approach
9. GE (North America) (23%), Siemens (Germany) (21%), Philips (Netherlands) (18%) and Toshiba (Japan) (13%) hold between 65% to 90% of MDI OEM market share (MRI, X-Ray, Ultrasound and Nuclear Imaging). Following these major four OEMs, Hitachi (Japan) holds under 10% market share, across multiple product categories, with Shimadzu (China) holding less than 10% market share in a single product category (X-Ray).	• Continue to engage with the market to develop joint solutions • Create an IEP website	• Pre-market engagement
10. The market is an oligopoly, substitutions are not evident, but the development of lower cost MDI equipment is being driven by developing markets and the need to penetrate, secure and grow market share. Buyer power is generally low, due to fragmentation. Profitability remains generally high for established OEMs, although high R&D costs	• Continue to engage with the market to develop joint solutions • Create an IEP website • Regularly benchmark Bank funded Projects to ensure market pricing remains competitive	• Pre-market engagement • Procurement approach

Market Research and Analysis – Key Findings	Mitigation	Procurement Stage
impact the bottom line. Due to this there are limited opportunities for new entrants.		
11. The typical business strategy of OEMs is to develop customer relationships through the sale of equipment, then grow the relationship and revenue through O&M, and other services. Some may also seek to "lock-in" clients by offering integrated services, software, or other equipment that interfaces for increased benefits. This can be summarized, much like other technology companies as a "capture, secure, grow, reap and protect" market strategy.	• Standardized documents should be developed for MDI equipment to make the procurement as efficient as possible for both the Borrower and supplier • Conditions of contract should be reviewed and amended as necessary to reflect market place and Borrower need, and balanced risk allocation • Develop a model on total cost of ownership	• Pre-market engagement • Specification • Procurement approach
12. Most Bank financed MDI equipment is procured through distributors (usually OEM certified) and is mainly focused on X-Ray equipment. The largest distributors who have been awarded Bank financed procurements are based (rank order) in the Russian Federation, Switzerland, Vietnam, China and Bangladesh.	• Market engagement should be aimed at all sectors of the MDI equipment industry • Lotting strategies should consider the optimum supply approach for their requirement • Undertake regular pre-market engagement to engage all potential suppliers	• Pre-market engagement • Specification • Procurement approach
13. The MDI sector is represented by Industry Associations, most notably Global Diagnostic Imaging Healthcare IT & Radiation Therapy Trade Association (DITTA) and Emergency Care Research Institute (ECRI), both of which are not-for profit bodies that, among other things, gather good practice, give sample specifications, analyze and publish market data, and lobby for the sector. However, compared to other Industry Associations they have not set any harmonized legal conditions.	• Continue to engage with industry and seek advice and support on collaborative working to identify and solve issues	• Pre-market engagement • Procurement approach
14. Refurbished MDI equipment varies between 16% to 25% of market share for individual product lines. Procurement of refurbished equipment is most prevalent in North	• The availability and suitability of refurbished equipment should be considered as part of the PAD development	• Specification • Procurement approach • Evaluation

Market Research and Analysis – Key Findings	Mitigation	Procurement Stage
America. However regulatory frameworks in many countries prevent the use of refurbished MDI equipment.		
15. MDI sector is moving from a supplier of equipment, to a provider of medical care solutions, with a service delivery model being preferred. For example, General Electric reported in 2014/15 that 44% of its Healthcare division revenue came from service delivery. It is logical to assume that other manufacturers have a similar revenue distribution model.	• The project appraisal process should evaluate buy, lease and managed service solutions • Engage with the market to identify how the *Procurement Regulations* can support service solutions • Provide expert independent advice to support specification drafting for managed service solutions • Specifications should be drafted on a performance basis	• Specification • Procurement approach • Evaluation
16. The MDI industry is therefore concerned that the Bank's tendency to not finance or support procurement of O&M services is a critical problem that needs resolution.	• Develop a model on total cost of ownership • Ensure project appraisal considers lifetime costs and funding	• Specification • Procurement approach • Evaluation
17. WHO observes that 70% of MDI acquired by developing countries will never be used due to a lack of technical capacity and insufficient O&M.	• Specifications should consider ongoing needs such as training, support, maintenance and technician supply • Support and maintenance contracts should ensure key elements like response times and fix times are contractually enforceable • Develop a model on total cost of ownership • Ensure project appraisal considers lifetime costs and funding • Ensure spare parts are contractually available for the life time of the equipment	• Specification • Procurement approach • Contract Management
18. The global MDI market is valued at US$24.7 billion, with annual growth expected to be at least 6% till 2020. The highest levels of growth are forecast in EAP at 7.2%, with X-Ray forecast to grow the highest at 50%. Growth is	• Continue to engage with industry and seek advice and support on collaborative working to identify and solve issues	• Pre-market engagement

Market Research and Analysis – Key Findings	Mitigation	Procurement Stage
impacted by increasing patient numbers, aging populations and increased detection of chronic diseases such as cancer, Alzheimer's, cardiovascular disease etc..	• Update market analysis every 3 years to ensure it remains contemporary	
19. Licensing of MDI equipment and regulatory standards at a country level is a critical barrier to entry and can limit competition. Regulatory convergence is progressing through IMDRF but is someway off completion.	• Provide access to expert advice that can ensure specialist advice on appropriate standards in a region is available	• Specification
20. Due to the relatively low expenditure on MDI (as a percentage of the Bank's IPF instrument), coupled with the high levels of complexity, difficulty to specify and criticality for medical outcomes the procurement is positioned as "Strategic Security" on the Supply Positioning Matrix (lower value, but high risk). This means that the Bank needs to secure effective supply, while not necessarily being able to utilize contract size/value as an incentive lever.	• Standardized documents should be developed for MDI equipment to make the procure as efficient as possible for both the Borrower and supplier • Conditions of contract should be reviewed and amended as necessary to reflect market place and Borrower need, and balanced risk allocation • Fix recurring procurement problems • Motivate the best suppliers to bid	• Pre-market engagement • Specification • Procurement approach • Evaluation
21. Reflecting the relatively low value of Bank financed procurement compared to the total MDI market, and the industry feedback that Bank financed procurements can be with unattractive clients (e.g., with low capacity, lack of O&M, lowest purchase price decision-making, poor payment track records etc.). The Supplier Preferencing is categorized as "nuisance" (lower value, and unattractive).	• Standardized documents should be developed for MDI equipment to make the procure as efficient as possible for both the Borrower and supplier • Conditions of contract should be reviewed and amended as necessary to reflect market place and Borrower need, and balanced risk allocation • Fix reoccurring procurement problems • Motivate the best suppliers to bid	• Pre-market engagement • Specification • Procurement approach • Evaluation
22. The misalignment between the Bank's Supply Positioning of "Strategic Security" (high risk procurements that need to succeed), with the markets view of the procurements as a "Nuisance" is of great concern. The Bank therefore needs to work to increase the attractiveness of its financed MDI procurement to	• Borrowers should undertake pre-market engagement • Borrowers should consider a market engagement approach based on reverse marketing • Continue engaging with the market to monitor activity	• Pre-market engagement • Specification • Procurement approach • Evaluation

Market Research and Analysis – Key Findings	Mitigation	Procurement Stage
raise the attractiveness to a level where the market treats the procurements as a business development opportunity – meaning they will be more positively engaged and likely to bid.	• Fix recurring procurement problems • Motivate the best suppliers to bid	

Table XXXII – Summary of market analysis findings

Section IX. Conclusion

Conclusion

This guidance supports World Bank staff and Borrowers when procuring Bank funded MDI equipment and services. It provides an overview of the different types of MDI equipment, their use and application. It describes how to design a fit-for-purpose strategic procurement approach and contains information, data, analysis and practical advice on how achieve the best VfM results.

The guidance objectives are to provide:

1. A practical guide on how to undertake MDI equipment procurement and how to deliver optimal procurement solutions, VfM, and enhanced project outcomes;
2. An overview of the Bank's Project Cycle, stages in the procurement process and the procurement approaches available to Borrowers;
3. An overview of the MDI equipment market;
4. An analysis of the market research findings, with a focus on the issues identified, including procurement-related complaints;
5. Procurement risk analysis, and tools and techniques to support the development and analysis of bids/proposals.

The information is structured chronologically and provides a step-by-step guide through the various stages in the procurement of MDI equipment. Particular emphasis is given to robust procurement planning, including pre-market engagement, market and data analysis, and the preparation of a comprehensive PPSD. It stresses the importance of using outcomes-based specifications and rated criteria that evaluate the optimal combination of quality and cost over the life of the equipment.

Although the guidance is comprehensive it doesn't prescribe the exact procurement process to be followed. Each procurement must be dealt with on a case-by-case basis and the procurement approach must address the unique facts and circumstances of the project. The guidance therefore supports the user to develop a fit-for-purpose and proportionate procurement approach that is appropriate for the individual project.

The guidance gives the user a "head start"! Much of the research to determine the range of solutions available has been done, as well as the analysis of the various considerations in designing the optimum procurement approach. For example, detailed information is provided on the current market, the various purchase options and their relative advantages, while taking into consideration the different procurement tools, techniques, and methods available as part of the Bank's *Procurement Framework.* All of this should accelerate the initial procurement planning stages.

Although, this guidance is non-mandatory, and is designed as practical advice only, it is recommended that Bank staff and Borrowers use it whenever procuring MDI equipment. It will greatly support achieving the best VfM and improving overall project outcomes. It also

specifically addresses key issues that can lead to complaints, and in particular, issues that were identified by manufacturers and suppliers through the Bank's industry engagement program.

This guidance should be used in conjunction with the Bank's *Procurement Regulations* and other guidance documents, such as *Project Procurement Strategy for Development*, *Value for Money* and *Contract Management*.

Table XXXIII summarizes key information and analysis, and demonstrates how a procurement arrangement could look using much of the good practice contained in this guidance.

Attribute	Selected Approach	Justification
REQUIREMENTS		
Specifications	Performance	• Performance (as opposed to conformance specifications) allows suppliers to use their knowledge and experience to offer innovative solutions to best meet the required project outcomes.
Sustainability Requirements	Yes	• Energy use is an important aspect of sustainability and is considered as part of whole life cost analysis. Equipment disposal can also be an issue especially if the MDI equipment contains hazardous materials.
CONTRACT STRATEGY		
Contract Type	Traditional	• The contract type is traditional supply of goods and services, which covers all aspects of equipment supply and associated services.
Pricing and Costing Mechanism	Schedule of Rates/Admeasurement	• The pricing mechanism should be a schedule of rates, which shows list price and the appropriate discount for equipment. Any associated services should be stated on the same basis. This approach provides the necessary breakdown of costs to support negotiations and ongoing contract management.
Selection of Cost and Price Mechanism	1. Specification Type 2. Contract Type 3. Required Allocation of Risk 4. Operational Environment 5. Capacity of Borrower 6. Type of Market	• The specification to be used is performance as stated above. • The commercial model to be used is purchase. Ownership is the preferred method to provide optimum cost effectiveness, with a support and maintenance contract for the 8-year expected life of the equipment. • As technical knowledge is specialized, the Expert Panel Framework agreement will be used to source additional technical knowledge and experience to help draft the specification and

Attribute	Selected Approach	Justification
		undertake contract management, up to and including installation. • A detailed risk register has been prepared and the risk of keeping the equipment operational has been passed to the supplier with the use of incentivization in the pricing mechanism to support optimum utilization of the equipment. • The supplier will also be responsible for regular ongoing training during the contract's start up and duration to ensure the technical knowledge required to operate the equipment is transferred to the client's staff. • The market is both competitive and dynamic and MES solutions were considered, but the current capacity doesn't exist to undertake a competitive dialogue procurement method and for such contract management.
Supplier Relationship	Collaborative	• The suggested contract management approach is based on working collaboratively with suppliers to deliver ongoing improvements and proactively manage any delivery issues. • Pre-market engagement will be undertaken to maximize marketplace interest and demonstrate the collaborative approach.
Price Adjustments	Percentage	• Any price adjustments should be based on a percentage uplift and this should be included as part of the contract and cover as many years as required, especially for service contracts that may be required for the equipment life.
Form of Contract (Terms and Conditions)	State any special conditions of contract	• Special conditions of contract should consider the use of incentivization mechanisms on pricing and liquidated damages, as necessary.
SELECTION METHODS		
Selection Method	Request for Proposals (RFP)	• The use of an RFP will allow suppliers to demonstrate how their capability and innovation can best develop solutions that exceed the minimum requirements and deliver greater VfM.
Selection Arrangement		• There are no Selection Arrangements being used in addition to the Selection Method and Market approach as none of the arrangements are required for this type of market.

Market Approach	Type of Competition a. Open b. International	• The market analysis indicates that a competitive international market exists. • Open competition is the best approach.
	Number of Stages a. Single stage, or b. Multi Stage	• A two-stage selection process is best suited to complex information technology, which characterizes MDI equipment. • It also works very effectively with the use of more performance-based specifications. • This approach also integrates well with pre-market engagement as it provides Borrowers and suppliers with the opportunity to have discovery meetings to refine the business or functional performance requirements and suppliers to submit modified proposals based on these refined needs. • This also helps address feedback from the market place that procurements are undertaken at arm's length and it is not always possible to get total clarity on what is required, which ultimately leads to complaints.
	BAFO or Negotiations a. BAFO (No) b. Negotiations (Yes)	• Negotiations are to be used in conjunction with price benchmarking to ensure the cost of the equipment is comparable to the best offers in the market. • The negotiations will be used to maximize the service levels and obtain an extended warranty.
Qualification	Pre-Qualification	• Initial Selection will be used as part of the RFP, which will allow a shortlist of between 4 and 7 companies to be invited to submitted proposals. • This will provide the necessary competitive tension but will not provide overburdensome during proposal evaluation.
EVALUATION SELECTION METHOD		
Evaluation of Costs	Life-Cycle Costs	• Whole life costs are being used to evaluate proposals because the revenue costs for associated services such as support, and maintenance will exceed the capital purchase cost many times.
Domestic Preference		• N/A

Rated Criteria	List the type of criteria to be used (mandatory/desired)	• A 50% rating for quality is being used to encourage a high level of innovation and quality in the solutions offered by suppliers to meet the requirements in the performance specification. • The criteria being used are: 1. delivery and installation schedule for each piece of equipment; 2. equipment layouts for all equipment including all options; 3. conformance of the proposed layouts with stated room sizes and medical facility layout; 4. time required for installation, start-up, acceptance testing, and removal of existing equipment, including details of subcontractor(s) equipment installation, equipment calibration; 5. operational service delivery and efficiency methodology; 6. technical benefits/merits from information on functional adequacy of the designs including provision of adequate space for normal work activities; 7. reliability and service level of the vendor/manufacturer, including warranty, maintenance, customer care and clinical training and support; 8. In-service training for clinical personnel and technical training; 9. Training program length and format, content, the qualifications of the instructors, and written and/or electronic materials; 10. Standard warranty agreement and a description of proposed warranty terms, including any extended warranties; 11. Local factory-based service capabilities, including the number and qualifications of service engineers, as well as their training, their base locations, the locations of backup service engineers; 12. Response time for emergency repairs (both during and outside of regular business hours).
CONTRACT MANAGEMENT		
Contract Management Approach	Outline the approach to be used	• Contract management, up to installation of the equipment, will be managed by the consultant selected from the expert panel. The requirements will be managed in strict accordance with the

		delivery and installation schedules in the contract. • The client will be responsible for contract management of the support and maintenance contract and will undertake this on the basis of monthly performance reviews with the supplier, supported by data measuring the KPIs delivered below. • Incentivization pricing will be monitored on a quarterly basis.
Key Performance Indicators (KPIs) – Measures	List the key measures of success for contract management:	• Key measures include: 1. delivery and installation timeliness; 2. adherence to service levels; 3. machine utilization and up time; 4. energy use; 5. training and client staff skills; 6. continuous improvements; 7. accuracy of invoicing; 8. achievement of incentivization metrics.

Table XXXIII – Summary procurement analysis

ANNEX 1: Risk Analysis Tools

Risk Analysis

Procurement risk analysis is the process of identifying and taking steps to reduce the likelihood of a risk occurring, as well as minimizing the impact should it occur. It aims to assess the impact on the overall objectives of the project.

The risk analysis in Table XXXIV defines procurement risks, assesses their impacts, describes the mitigation actions, and at what procurement stage the mitigation should be applied.

The analysis has identified the key risks and has assessed them based on likelihood, duration and impact, and has used this information to rank the risks in terms of criticality and therefore their overall threat to projects in delivering their intended outcomes.

The risk assessment is a generic assessment and therefore Borrower's need to review this assessment and establish whether these individual risks are relevant to their specific project and review the risk scoring reflects so that it reflects the individual circumstances of their project. Borrowers should also assess their project for any additional risks and undertake the assessment and rank all applicable risks. The following headings provide a useful structure for undertaking this analysis:

1. Market complexity and competitiveness;
2. Delivery and supply security;
3. Suppliers and supplier relationships;
4. Borrower capacity and capability;
5. Cost trends;
6. Technical innovation – the degree and rate of change;
7. Sustainability (environmental, economic, social);
8. Business and operating environment.

This individualized procurement risk assessment should also be used to create the Risk Management Plan by summarizing and recording the overall risk management analysis and used throughout the Project Life Cycle.

Procurement risk management is primarily concerned with managing impacts on the contract schedule, cost, and performance (including the delivery of the stated requirements). Through a structured approach to risk management, Borrowers should identify how opportunities and risks will be managed at different stages of the procurement process.

Table XXXIV - Procurement Risk Analysis

Key: L= low M= medium H = High

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
1	**Equipment too technically advanced for full use**	H	H	H	27	• Specification • Procurement arrangements • Evaluation • Contract management	• Ensure capability assessment is undertaken as part of identification • Use Expert Panel to QA specifications • Use expert to evaluate bids • Build client capacity • Ensure requirements include provision for training
1	**Whole of life costs not considered**	H	H	H	27	• Procurement arrangements • Evaluation	• Make bidders aware that whole of life costs will be used to determine the most advantageous bid • Use of whole of life costs evaluation model
1	**Consumables expensive relative to capital cost of equipment**	H	H	H	27	• Procurement arrangements	• Consider managed service offering • Use of whole of life costs evaluation model • Use benchmark data to establish optimum cost • Use negotiation to reduce costs • Fixed costs of consumables for long duration and use index to cap any price increases
1	**Bidders propose un-necessary accessories or functionality**	H	H	H	27	• Procurement arrangements • Evaluation	• Use benchmarking data to establish need • Use expert advice • Negotiate
1	**Future funding for equipment operation is not secured**	H	H	H	27	• Evaluation	• Ensure funding via Bank or Government • Consider managed service and leasing options
1	**The market is dominated by a few large suppliers**	H	H	H	27	• Specification • Procurement arrangements	• Undertake pre-market engagement to encourage full market participation • Use output or performance-based specifications to not limit competition

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
							• Consider lotting strategy to facilitate optimum market attractiveness
1	**Technical capacity or capability is not available**	H	H	H	27	• Specification	• Engage expert advice and support
2	**Wrong type of specification**	M	H	H	18	• Specification	• Use Expert Panel to QA specification
2	**Too detailed specification**	M	H	H	18	• Specification	• Use Expert Panel to QA specification
2	**Not detailed enough specification**	M	H	H	18	• Specification	• Use Expert Panel to QA specification
2	**In appropriate standards specified**	M	H	H	18	• Specification	• Use Expert Panel to QA specification
2	**Technicians don't know how to use the equipment**	M	H	H	18	• Specification • Contract management	• Consider managed service offering providing full service including technicians • Secure budget for long term training • Ensure training requirements are part of the requirement • Ensure ongoing training requirements are part of the contract
2	**Price paid for equipment too high**	M	H	H	18	• Procurement arrangements • Evaluation	• Use of whole of life costs evaluation model • Use benchmark data to establish optimum cost • Use negotiation to reduce costs • Fixed costs for additional equipment during a set period in the contract and use index to cap any price increases
2	**Consumables prices too high**	M	H	H	18	• Procurement arrangements	• Use of whole of life costs evaluation model • Use benchmark data to establish optimum cost

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
						• Evaluation	• Use negotiation to reduce costs
2	**Consumables prices increase**	M	H	H	18	• Procurement arrangements • Contract management	• Use of whole of life costs evaluation model • Use benchmark data to establish optimum cost • Use negotiation to reduce costs • Fix costs for consumables for long duration in the contract and use index to cap any price increases
2	**Spare part prices too high**	M	H	H	18	• Procurement arrangements • Evaluation	• Use of whole of life costs evaluation model • Use benchmark data to establish optimum costs • Use negotiation to reduce costs
2	**Spare part prices increase**	M	H	H	18	• Procurement arrangements • Contract management	• Use of whole of life costs evaluation model • Use benchmark data to establish optimum costs • Extend warranty period on equipment • Use negotiation to reduce costs • Fix costs for spares for long duration in the contract and use index to cap any price increases
2	**Support and maintenance prices too high**	M	H	H	18	• Procurement arrangements • Evaluation	• Use of whole of life costs evaluation model • Use benchmark data to establish optimum costs • Extend warranty period on equipment • Use negotiation to reduce costs • Fix costs for support and maintenance for long duration in the contract and use index to cap any price increases • Consider the use of other suppliers (distributor -v- manufacturer)
2	**Support and maintenance prices increase**	M	H	H	18	• Procurement arrangements • Contract management	• Fix costs for support and maintenance for long duration in the contract and use index to cap any price increases • Consider the use of other suppliers (distributor -v- manufacturer)

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
2	**No interoperability between equipment**	M	H	H	18	• Specification	• Inventorize existing equipment and include in specification • Engage expert advice and support
2	**Slow procurement processes**	H	M	H	18	• Pre-market engagement • Procurement arrangements	• Provide requirements to market place for review prior to inviting bids • Use standardized evaluation methodology • Use Expert Panel • Use expert advice
2	**Lack of compatibility with existing equipment**	M	H	H	18	• Specification • Evaluation	• State existing equipment in requirements and place obligation on supplier to ensure compatibility • Use Expert Panel to QA specification • Use expert to evaluate bids • Ensure supplier offers guarantee for equipment supplied, spare parts, support and consumables to expected life time of equipment use
2	**Biased specification**	M	H	H	18	• Specification	• Use Expert Panel to QA specification
3	**Equipment reaching the end of its useful life time**	L	H	H	9	• Specification • Procurement arrangements • Evaluation	• Use Expert Panel to QA specification • Use Expert to evaluate bids • Ensure supplier offers guarantee for equipment supplied, spare parts, support and consumables to expected life time of equipment use
3	**Equipment not future proofed**	L	H	H	9	• Specification • Evaluation	• Use Expert Panel • Ensure requirements cover future use (volumes of use, upgrades, etc.) • Use expert to evaluate bids
3	**Equipment life cycles short as**	L	H	H	9	• Procurement arrangements • Evaluation	• Consider leasing options • Consider managed service offerings • Future proof standards

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
	technical obsolesce is high						
4	**Delays in the provision of spare parts**	M	L	H	6	• Procurement arrangements • Contract management	• Put service level agreement in contract • Use liquated damages clause • Evaluate as part of the bid how support is provided (location, size of team, track record)
4	**Delays in the provision of support and maintenance**	M	L	H	6	• Procurement arrangements • Contract management	• Put service level agreement in contract • Use liquated damages clause • Consider the use of other suppliers (distributor -v- manufacturer) • Evaluate as part of the bid how support is provided (location, size of team, track record)
4	**Delays in the provision of consumables**	M	L	H	6	• Procurement arrangements • Contract management	• Consider managed service offering • Put service level agreement in contract • Use liquated damages clause • Consider the use of other suppliers (distributor -v- manufacturer) • Evaluate as part of the bid how supply is provided (location, size of team, track record) • Use liquidated damages clause
4	**Leading suppliers do not bid**	M	L	H	6	• Pre-market engagement • Procurement arrangements	• Undertake pre-market engagement • Ensure early warning to the market of requirements • Consider lotting strategy
5	**Delays to civil works**	M	L	M	4	• Procurement arrangements • Contract management	• Put service level agreement in contract • Use liquated damages clause

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
5	**Procurement process delayed by complaints**	M	L	M	4	• Procurement arrangements	• Provide requirements to market place for review prior to inviting bids • Use standardized evaluation methodology • Use Expert Panel • Use expert advice
5	**Use of propriety requirements**	M	L	M	4	• Specification	• Use Expert Panel to QA specification
6	**Software failure**	L	L	H	3	• Procurement arrangements • Contract management	• Ensure contract covers software operating standards • Use liquidated damages clause • Ensure support and maintenance contract covers software • Ensure support and maintenance provider has access key to software code
6	**Software requires regular upgrades**	H	L	L	3	• Procurement arrangements • Contract management	• Ensure contract covers software upgrades and how they are delivered • Ensure service level agreement determines the timing of software upgrades (frequency, duration, etc.) • Use liquidated damages clause
6	**Protection of confidential information**	L	L	H	3	• Specification • Contract management	• Ensure appropriate standards of data protection are stated in the contract • Ensure security software patching is covered in the requirements • Ensure contract covers supplier obligation to report security breaches
6	**Wrong mechanical and electrical requirements**	L	L	H	3	• Specification • Procurement arrangements • Contract management	• Procurement strategy to cover all requirements for supply and installation (design and build) • Consider managed service offering • State each party's roles and responsibilities • Use specialist to define requirements

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
							• Ensure bidders survey site before bidding
6	**Equipment doesn't function on installation**	L	L	H	3	• Specification • Contract management	• Use acceptance testing • Use payment milestones • Hold significant retention sum payable on success operation
7	**Mechanical and electrical requirements not considered**	L	L	M	2	• Specification • Procurement arrangements	• Procurement strategy to cover all requirements for supply and installation (design and build) • Consider managed service offering • Use specialist to define requirements • State each party's roles and responsibilities • Ensure bidders survey site before bidding
7	**Delays in the provision of mechanical and electrical requirements**	L	L	M	2	• Procurement arrangements • Contract management	• Ensure a project delivery time table is included in the contract • Put service level agreement in contract • Use liquated damages clause
7	**Civil works requirements not considered**	L	L	M	2	• Specification	• Procurement strategy to cover all requirements for supply and installation (design and build) • Consider managed service offering • State each party's roles and responsibilities • Use specialist to define requirements • Ensure bidders survey site before bidding
7	**Wrong civil works requirements**	L	L	M	2	• Specification	• Procurement strategy to cover all requirements for supply and installation • State each party's roles and responsibilities • Use specialist to define requirements • Ensure bidders survey site before bidding

#	Risk	Likelihood	Duration	Impact	Score	Procurement Stage	Mitigation
7	**Delays to equipment supply**	L	L	M	2	• Procurement arrangements • Contract management	• Put service level agreement in contract • Use liquated damages clause
7	**ICT infrastructure required for equipment operation**	L	L	M	2	• Specification	• Procurement strategy to cover all requirements for supply and installation (design and build) • State each party's roles and responsibilities • Use specialist to define requirements • Ensure bidders survey site before bidding
7	**Bid price above project budget**	M	L	L	2	• Procurement arrangements • Evaluation	• Use benchmark data to establish cost estimate • Consider market engagement to establish estimate costs • Undertake market research to understand cost trends

ANNEX 2: Pre-market Engagement Tools

Pre-market Engagement and Reverse Marketing

Pre-market engagement describes a range of activities undertaken by the Borrower to engage the market before starting a procurement process. These activities may include both a technical dialogue to inform specification drafting and discussions on the fit-for-purpose procurement approach proposed by the Borrower. Reverse Marketing refers to the situation in which a Borrower encourages a market place, and suppliers within it, to enter that market and bid for opportunities that they had not planned to, normally for reasons of awareness or "attractiveness" of the opportunity.

The MDI market research and feedback from the marketplace indicates that there is a need for both activities to reposition MDI procurements into a more attractive proposition for potential bidders.

The *Procurement Regulations* encourage talking to potential suppliers before starting the formal procurement process of inviting bids. Pre-market engagement is not subject to any detailed procedures. However, pre-market engagement must be based on the *Core Procurement Principles*, particularly those associated with transparency, fairness, fit-for-purpose and integrity. Engaging with the market before starting the formal procurement process is best practice and helps to maximize VfM from the resulting procurement.

Market analysis, particularly, Supplier Preferencing, should be used to inform the approach to pre-market engagement. The MDI equipment market analysis has identified several generic issues, which relate directly to how suppliers negatively perceive opportunities in the MDI equipment sector, their potential willingness to participate in bids, and their ability to put forward their optimum bid that gives the Borrower best VfM. An individual project should consider this analysis and identify which of these aspects may apply to their contract and how these specific issues could be addressed.

Guide to Pre-market Engagement

The key issues identified as part of the MDI market analysis and the desired outcomes to be achieved from the pre-market engagement are described in the following table.

Issue	Outcome
1. **Specifications and requirements**	• Definition of the requirement by informing the business case and helping to identify or develop the requirements of what is needed • Better understanding of the feasibility of the requirement, the best procurement approach, the capacity of the market to deliver and possible risks involved • Informed potential solutions and viable options to meet the Borrowers required outcomes and objectives

Issue	Outcome
	• Project designed to best meet Borrowers required outcomes and objectives • Contemporary information to inform the PPSD (in particular market analysis) • Assessment of the marketplace's ability to meet the Borrower's requirements • Potential risks identified early in the Project Cycle, and the initial stages in procurement, as well as potential mitigations • Supply base that understands exactly what the project is trying to achieve • Specifications that are clear and relevant and address any points that suppliers have said were unclear • Ideas on alternative approaches for meeting the requirements • Requirement clarity before bidding commences as a result of an iterative and participatory process with the market to share information on risks, issues. Where ambiguity exists, clarify before the bidding process commences • Clarity on requirements and procurement approach from the outset so time and energy are invested early by all parties focused on gaining a common understanding, avoiding abortive effort, and allowing suppliers to make appropriate bid or not bid decisions and plan resource for bidding with greater certainty
2. Procurements speed	• Reduced procurement timescales by minimizing the dialogue needed during the formal procurement process • Procurement approach and timelines design that have a realistic understanding of the pressures and drivers on the supplier market • Early marketplace awareness of planned procurement allowing suppliers to schedule resources to submit bids with the need to request extended bid return dates • Eliminate unnecessarily complex procurement procedures, unless circumstances dictate
3. Planning	• Informed PADS and PPSDs through greater understanding the market place, requirements and potential procurement solutions • Realistic timescales for the bidding process informed by marketplace feedback
4. Bid evaluation and whole of life cost	• Marketplace aware that rated criteria/best VfM approach is being used as well as increasing attractiveness of bidding • Indicating the use of whole of life costs to ensure bidders recognize all costs will be evaluated

Issue	Outcome
	• Demonstration that service aspects post equipment supply is important • Budgets are available for the life time of the equipment • Market understands that all suggested ancillaries will be evaluated for need • Integrated thinking about how the requirement, pricing and quality can be evaluated to demonstrated best value for money
5. Procurement approach	• Range of options in terms of procurement approaches to deliver the requirements • Informed design of the procurement approach, including lotting approach, selection methods and market approach • Procurement approach and timelines design that understand the pressures and drivers on the supplier market • Integrated procurement approach that manages risk in the right way for all parties • Greater competition through improved bidder participation as a result of listening to the marketplace's needs • Supplier solutions reflect the best options for delivery the market place has to offer, to meet the requirements
6. Lotting strategy	• Understanding of the factors associated with an individual procurement that will influence the optimum lotting strategy • Optimum lotting strategy to ensure best supply and value proposition
7. Contract management	• Information to support the key components of the contract management plan • Identification of key performance indicators and provide a draft of these in the bidding documents • Identification of features that need to be included in bidding documents to enable and support active contract management
8. Profitability and Pricing	• Full visibility of pricing information • Benchmarking data to be used to evaluate pricing information to ensure consistency of pricing and transparency • Improved and realistic understanding of how much the requirements may cost (budget and cost) • Informed identification of any factors that may influence pricing • Realistic budget • Understanding of risk and any potential impacts on pricing
9. Market participation	• Stimulate increased competition, thereby reducing the dependency on a limited number of suppliers

Issue	Outcome
	• Potential bidders identified • Market capacity building (as needed) • Right suppliers motivated to bid • Best suppliers submit strong bids • Insight into likely marketplace interest • Attractive procurement opportunity for the marketplace
10. Communications and pipeline visibility	• Early warning to the market place that a bidding opportunity is coming up • Opportunity for supplier to ask questions/raise queries and highlight any issues addressed at an early stage • Market engagement leading to increase visibility and attractiveness of opportunities • Clearer requirements to publish to potential bidders • Contracting authority and potential suppliers benefit from early two-way communication. • Responsive market having given the market sufficient time to prepare to meet demand e.g., by ensuring the right skills and resources are in place

How to Undertake Pre-Market Engagement

The steps in undertaking pre-market engagement are to:

1. Establish a clear understanding of the required MDI equipment outcomes and ensure that the Borrowers needs are agreed and clearly stated through structured engagement with key Borrower stakeholders;
2. Use this information to develop sufficiently detailed specifications to test with the marketplace;
3. Determine the method of pre-market engagement to be used;
4. Undertake pre-procurement market engagement with prospective suppliers and use structured and potentially time-boxed advertised industry days to test out and refine thinking on the business requirements and target outcomes, before the formal procurement process begins;
5. Ensure proper readiness to go to market by publishing a full draft bidder's pack (specification, selection and award criteria, terms and conditions and timescales) as part of the pre-market engagement, as this will further assist potential suppliers in making informed decisions as to whether they wish to tender for the requirement;
6. Streamline the pre-market engagement with suppliers to make best use of limited time and expensive resources.

When conducting pre-procurement market engagement:

1. Identify how the pre-market engagement is going to be operated and advertise the approach in the same manner as a Specific Notice;
2. Engage early and widely with the market to give potential bidders an opportunity to shape the requirement (in a non-biased manner) and get ready to meet the demand;
3. Discuss the contract outcomes and objectives to inform the specification;
4. Ensure that suppliers are aware that any resulting procurement will be conducted competitively;
5. Ensure that all potential bidders are offered the same opportunity to be part of the pre-market engagement;
6. Maintain the commercial confidentiality of information received during discussions with potential suppliers, in-line with applicable laws, the *Core Procurement Principles* and the *Procurement Regulations*.;
7. Discuss whether splitting a contract into smaller contracts/lots will stimulate greater competition and deliver better VfM or whether this can be achieved through encouraging a more diverse supply chain;
8. Minute discussions and feedback as necessary.

Information Required for Pre-market Engagement

When advertising a pre-market engagement approach, the following information should be included in both the advertisement and any written material produced to support the engagement.

1. Organization name and department;
2. Background to the organization and project;
3. The objectives and outcomes to be delivered by the procurement;
4. Project/contract location;
5. Target contract start date;
6. The issues on which feedback is being sought;
7. The date by which suppliers need to respond on the specific issues highlighted;
8. The information required, e.g., how much the work may cost, how long it may take to complete the contract and feedback on specifications;
9. Any next steps.

Approaches Pre-market Engagement

There are various approaches to undertaking pre-market engagement with the MDI equipment sector. These approaches can either be used individually or in combination. Borrowers will need to

select the most appropriate pre-market engagement approach based upon the individual circumstances of their project and contract. Factors to consider include:

1. The stage of the project life cycle and procurement cycle;
2. The size and complexity of the requirements;
3. Project or contract specific problems;
4. The level of innovation required to deliver the solution;
5. Timescales for the procurement;
6. The Borrower's capacity in terms of both procurement and technical knowledge;
7. The location of the project;
8. The budget available to undertake pre-market engagement.

Detailed below is an overview of the main methods of pre-market engagement including consideration of the advantages and disadvantages of each approach.

Reference Groups using Industry Trade Bodies

Reference groups are a way of facilitating supply-side consultation before bids are invited. Their composition should include recognized Industry Trade Bodies such as DITA, and AdvaMed. These groups can inform the feasibility and technical advice (including on specifications) on relevant aspects of market performance. But they can be invaluable in seeking supplier input/buy-in to the upcoming procurement.

They have the benefit that the Trade Association coordinates the feedback to their industry members. They also provide anonymized comments from not only their own experts, but also their industry members. The Trade Association can also take on the role of resolving conflicting pieces of feedback.

The disadvantage of this type of approach is that the feedback is not normally attributed to a source. So, it can be difficult to establish if the comments are un-biased. In addition, this method may not be as inclusive or as open as using other methods, as stakeholders must be a member of a particular Trade Association to comment. Therefore, it is important that Trade Associations consulted are representational of the MDI equipment geographical supply base.

Market Soundings

Market sounding is the process of assessing the reaction of the market (that is, all potential suppliers considered collectively) to a proposed requirement and procurement approach.

It brings a supplier perspective to procurements at an early stage, offering potential benefits in terms of making the subsequent procurement process more focused and efficient. Market sounding focuses on suppliers as a whole, rather than the merits of individual suppliers. It includes no element of supplier selection (choosing suitable contractors) or bid evaluation (looking at proposals and prices). There is no commitment of any kind involved on either side.

There is no defined process for market sounding. The approach taken will vary from project to project. Market sounding is not part of regulated procurement and is not subject to any detailed *Procurement Regulations*, procedures, rules. A market sounding exercise will not take the form of a sequence of prescribed steps. It is a question of selecting the approaches that will provide the most useful, balanced view of the market and its likely attitude to the requirement. It is vital to ensure that the market sounding process remains open, and that all suppliers involved are treated with fairness and equality. All possible efforts should be made to preserve a "level playing field" and the process should be formally documented.

Market sounding is beneficial at both strategic and project/program specific levels and involves gathering knowledge in the following key areas:

1. **Feasibility**: Whether what is sought is actually feasible or has ever been done;
2. **Capability**: The ability of the market (whether through a single supplier or a consortium) to achieve what is required;
3. **Maturity**: Whether there is an established market for the requirement, and whether there are enough suppliers in existence for a competitive procurement;
4. **Capacity**: Whether the market can achieve what is required quickly enough, or on a large enough scale. Other additional areas of interest include the way supply chains work in the market, cultural concerns, and attitudes towards customers.

A market sounding is an interactive approach that has the advantage of allowing real time, face-to-face dialogue between the Borrower's purchasing entity and 'the market'. It aims to clarify and refine the content of the requirement. One of its real strengths is seeking input into issues that the Borrower is uncertain about. The helps identify the best solution and allows such issues to be discussed collectively with the supply market. It also has the benefit of being a very inclusive approach, as all potential suppliers are made aware of the market sounding and are free to attend and contribute. Furthermore, as the process is interactive Borrowers can ask immediate follow up questions or ask for greater clarification on points made, so market soundings often provide content rich feedback.

The disadvantage of a market sounding is that they can involve a lot of logistics, be time consuming and potentially costly to arrange. Because the event takes place at a fixed geographical location, they can be restrictive in terms of which suppliers are able to attend, or may find it financially beneficial to attend, if they are not represented in that geography.

Concept Viability Exercises

Concept Viability is a particular type of market sounding that is designed to maximize the benefits of market feedback, normally at the very early stage of a project. Projects and contracts can be tested for the 'do-ability' of their ideas at an early stage. A workshop with suppliers is arranged to explore a project brief that outlines the development objectives. It is often less focused on specific issues than a market sounding and the feedback from the event tends to be higher level and strategic in nature. Following the workshop, a summary report is collated which captures the views of suppliers into a 'market view'.

The benefits of this approach include:

1. It provides useful insights into possible solutions;
2. It is anonymous, so suppliers tend to be more open with ideas;
3. Concepts that are technically unfeasible, flawed or high risk can be identified at an early stage;
4. It helps ensure that an analysis of risks and implementation options has taken place;
5. It informs any subsequent work on feasibility or proof-of-concept but is not intended to replace these activities.

The disadvantages are the same as market sounding, with two additional points. Firstly, feedback from the event tends to be higher-level and strategic in nature. Secondly, it is often necessary to run a second market sounding just before the procurement commences to get more focused and specific feedback.

Supplier Questionnaires

Supplier questionnaires are a form of survey where suppliers are invited to provide written comments and feedback on specific documents, issues, or a procurement approach, in response to specific questions raised by the Borrower.

The main advantage of using questionnaires is that a large number of suppliers can be reached relatively easily, quickly and economically. This approach benefits from the fact that a standard questionnaire provides quantifiable answers for a topic and these answers should be relatively easy to analyze.

Questionnaires by nature are not iterative so opportunities to immediately clarify a point do not exist. In addition, if questions are not precise and clear, respondents may misunderstand or misinterpret the question. The use of a questionnaire can also have limited effectiveness because of poor response rates.

ANNEX 3: Example of Technical Specification

Example: Magnetic Resonance Imaging Equipment

TECHNICAL REQUIREMENTS	Recommended Parameters
FDA CLEARANCE	YES
CE MARK (MDD)	YES
Superconducting Magnet 1.5T	
Active screening System of the Magnet against outside interference	YES
Magnetic field Intensity:	minimum 1.5T
Description of gantry: diameter	minimum 60 cm
Field of vision (FOV) on the 3 axes (x, y, z)	min. 45 cm
Helium evaporation rate zero (Zero boil-off technology)	He l/min < 0,05 / DA
Guaranteed minimum magnetic field homogeneity inside a spherical volume 45 cm in diameter	maximum 5,0 ppm
Guaranteed minimum magnetic field homogeneity inside a spherical volume 40 cm in diameter	maximum 1,4 ppm
Guaranteed minimum magnetic field homogeneity inside a spherical volume of 30 cm in diameter	maximum 0,30 ppm
Guaranteed minimum magnetic field homogeneity inside a spherical volume of 20 cm in diameter	maximum 0,08 ppm
Guaranteed minimum magnetic field homogeneity inside a spherical volume of 10 cm in diameter	maximum 0,02 ppm
Gradient System	
Gradient system with active screening	YES
Gradient amplitude on each axis (for maximum FOV):	minimum 33 mT/m on axis
Growth rate (slew-rate) on each axis (for maximum FOV):	minimum 120 T/m/s
RF transmission/reception System	
RM signal digitization and digital signal transmission to reconstructor (DirectRF, OpticalRF, dStream or equivalent technologies)	YES
RF Amplifier with solid state technology:	YES
Number of RF standalone channels:	minimum 16
Patient table	
To support the maximum weight of patient (including during vertical movement of the table):	minimum 150 kg
Minimum height of patient table:	maximum 61 cm
Methods for minimizing the patient' anxiety:	
Protective system against the noise in the magnet room	YES
Ventilation and lighting adjustable in the tunnel	YES
Patient Monitoring:	
Patient Alarm	YES

TECHNICAL REQUIREMENTS	Recommended Parameters
Communication between patient and operator	YES
Automatic voice commands (e.g. commends to stop breathing)	YES
Voice commands programmable by the user	YES
Measuring System for physiological parameters	
Synchronizing the measurement with the physiological cycle of the respiratory and/or cardiac movement	YES
Gating pulse	YES
ECG Triggering	YES
Breath Triggering	YES
Scanning Parameters:	
Minimum field of vision (Min FOV):	maximum 1.0 cm
Minimum thickness of 2D section:	maximum 0.5 mm
Minimum thickness of 3D section:	maximum 0.1 mm
Maximum field of scanning on X, Y axes:	minimum 48 cm
Console for acquisition	
Processor:	minimum quad core, of minimum 2,5 GHz
RAM memory:	minimum 32 Gb
Color LCD Monitor with diagonal:	minimum 19"
Hard disk for image storage:	Minimum 300 Gb, or minimum 300.000 images in 256x256 format
Screen resolution:	minimum 1280 x 1024
Storage unit on CD-R/ DVD	YES
Acquisition Matrix	≥1024x1024
Image reconstruction Computer	
Processor:	minimum dual core, of minimum 2,4 GHz
RAM memory:	minimum 16 Gb
Image reconstruction speed: (matrix 256 x 256, 100% FOV)	minimum 11.000 recon/s
Post-processing station independent of the acquisition system	
Processor:	minimum dual core, of minimum 2,0 GHz
RAM memory:	minimum 16 Gb
Maximum image storage capacity on hard disk	minimum 600 Gb
Monitor color LCD, with diagonal:	minimum 19"
Screen resolution:	minimum 1280x1024
Professional imagery monitors with contrast and high brightness	YES
DVD – RW writer unit	YES
Acquisition, detection and correction techniques	
Parallel acquisition Algorithm	Minimum one

TECHNICAL REQUIREMENTS	Recommended Parameters
Calibration techniques	Minimum one
Motion correction compatible with the parallel acquisition technique with radial blades (Propeller, Blade, MultiVane or equivalent type)	YES
Motion correction with radial blades available in all directions	YES
Spin-echo (SE) type sequences	YES
Gradient-echo type sequences	YES
3D sequences of BFFF/3D-FIESTA/True FISP type, or equivalent	YES
Gradient-echo sequences of multi- echo type (mFFE, MERGE, MEDIC, or equivalent)	YES
Turbo/fast spin echo (TSE/FSE) sequences	YES
Turbo/fast spin echo sequences with quick restore (DRIVE, RESTORE, FRFSE, FSE T2 type, or equivalent)	YES
3D TSE/FSE sequences with variable flip angle (CUBE/SPACE/VISTA type, or equivalent)	YES
Spectral fat saturation	YES
APPLICATIONS	
Imagery for Neurology	
EPI sequences and protocols for diffusion and perfusion	YES
3D sequence for cervical spine	YES
Optimized protocols for internal ear examination	YES
Single Voxel Spectroscopy	YES
Magnetic susceptibility sequence with phase reconstruction for determining microhemorrhages and their possible discrimination from potential calcified lesions.	YES
Evaluation of perfusion studies with contrast on the acquisition console with calculation of rCBV and rCBV type maps as well as Mean Transit Time, Time To Peak	YES
Diffusion sequence with multiple values of b parameter	YES
3D sequences with isotropic voxel	YES
Automatic processing of ADC maps	YES
Body Imagery:	
2D and 3D acquisitions	YES
Dedicated protocols for fat suppression	YES
Imagery techniques allowing examinations with/without holding breath during scanning	YES
Protocols for MRCP, abdomen, pelvis	YES
Dynamic liver Imagery (THRIVE, LAVA, VIBE or equivalent type)	YES
Diffusion sequences for abdomen	YES
Breast Imagery:	
Dedicated sequences with fat suppression	YES
2D and 3D protocols	YES

TECHNICAL REQUIREMENTS	Recommended Parameters
Simultaneous bilateral scanning of both breasts	YES
Possibility for loading curve analysis in dynamic examination	YES
Sequences with spectral excitation water/fat	YES
Imagery Orthopedics:	
High resolution 3D protocols	YES
Fat suppression protocols	YES
Sequence for incipient viewing of cartilage lesions	YES
Imagery Angiography:	
2D/3D angiography with phase contrast	YES
Automatic tracking of contrast material throughout the scanned area	YES
Peripheral angiography with automatic table motion	YES
Artery and vein viewing with and without contrast material enhancement	YES
2D, 3D TOF	YES
Peripheral angiography without contrast medium enhancement	YES
Angiography without contrast medium available anywhere in the body	YES
Renal artery angiography without contrast medium enhancement	YES
Other applications	
Automatic image compounding of data sets acquired in various stages	YES
3D imagery volume viewing (volume rendering)	YES
Distance and angle measurements	YES
Minimum / Maximum Intensity Projections, MPR	YES
Software applications available on the postprocessing console	
Applications for assessing RM neuro perfusion studies allowing processing and calculations of cerebral blood flow maps (CBF), time to peak value - TTP (Time To Peak), cerebral blood volume (CBV), mean transit time - MTT (Mean Transit Time)	YES
Applications for breast analysis with analyzing of the time curve and the possibility to create color maps for studies with contrast material.	YES
Software for spectroscopy post-processing	YES
Dynamic load curves	YES
Antennae	
Head and neck antenna	minimum 16 elements
Spine antenna	minimum 12 elements
Antenna used for abdominal/pelvic examinations	minimum 12 channels
Breast antenna	minimum 7 channels
Antenna for shoulder examinations	minimum 16 channels
Antenna for ankle and foot examinations	minimum 16 channels
Antenna for hand/ wrist examinations	minimum 16 channels
Knee dedicated antenna	minimum 8 channels
Interconnection	

TECHNICAL REQUIREMENTS	Recommended Parameters
DICOM functions: Send/Receive; Query/Retrieve; SC (Storage Commitment), Modality worklist, Print	YES
Accessories	
Furniture for the acquisition console and the post-processing one (including chairs for operators),	
Accessories for patient communication:	
- bidirectional intercom	
- relaxation system with music and headphones for acoustic noise reduction	
- call button	
- mattress and positioning accessories	
- Gantry video surveillance camera	
Keyboard, mouse for all computers	
Faraday cage (RF cabin)	
Chiller sized according to system requirements	
Quench pipe	
Switch panel for electric supply network connection (electric switchboard)	
Voltage stabilizer with rated power corresponding to the tendered generator	
Post-processing station independent of the acquisition console and connected with the appliance and PACS system.	
UPS systems both for the acquisition console and for the post-processing station	
Injector for contrast material RM compatible	
Ferromagnetic mobile stretcher and non-ferromagnetic carriage	
Patient monitoring apparatus	
- critical state	
- pediatric and	
- coronary	
Compatible with RM appliance	
Oxygen socket and accommodation of oxygen adduction in Faraday cage near the patient table	
Air conditioning station for: gantry chamber; utility room (will ensure temperature maintenance < 18 degrees C regardless of the outside conditions); control room; image interpretation/ processing room	
Professional DVD/CD plotter	
User Manual in Romanian	
System Warranty	2 years
TRAINING: 2 weeks training for radiologists, 1-week training for radiology technicians	


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