Procurement of medical devices

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Date
Introduction

- Definition of procurement
- The importance of good procurement
- The process of procurement
- Challenges for good procurement
- Resources available
- Case study
To ensure improved access of safe, quality medical devices

Research and development

- Innovative technologies
- Research and development based on needs
- Approved high cost Medical devices
- Health Technology Assessment

Assessment

- Regulations of medical devices
- Approved Medical devices lists
- Needs Assessments
- Selection

Policies

- Policies of medical devices
- Human resources for Medical devices
- Glossary on Medical devices

Management

- Procurement
- Donations
- Post market surveillance and Adverse event reporting
- User training and clinical effectivenes
- Installation
- Inventories; CMMS, Maintenance
- Decommissioning, Replacement
Definition

- **Procurement:**
  - “the acquisition of property, plant and/or equipment, goods, works or services through purchase, hire, lease, rental or exchange”

- **and is taken to include**
  - “all actions from planning and forecasting, identification of needs, sourcing ......, evaluation ..........., contracting and all phases .......until delivery of the goods.”

  - (UN Office for Project Services)
Importance

- Good procurement brings:
  - safe, quality healthcare services
  - the best deal for the organization’s needs
  - timely delivery and handover
  - satisfactory delivery, installation, commissioning and training
  - effective payment and warranty
  - satisfactory after-sales service
  - greater interest in submitting offers in the future
  - transparent and trustworthy systems

- The right product of the right quality at the right price of the right quantity at the right place and time (Bailey, 1994)
Purpose of document

- To summarize published health technology procurement guidelines
- To be a planning aid and checklist for system development
- To give a set of indicators for procurement performance assessment

Audience
- procurement division or hospital management of a national or regional government health service body
Key elements

- Process
  - Technology assessment
  - Device evaluation
  - Planning and needs assessment
  - Procurement
  - Installation
  - Commissioning
  - Monitoring

- All these are summarized in a flow chart.
Key elements

Figure 2. Summary flow chart of standard procurement procedures

Technology assessment
- Review of existing reports
- Review of International Network of Agencies of Health Technology Assessment (INAHTA) website for available reports
- Assessment commissioned, if required, from health technology assessment (HTA) agency

Device evaluation
- Market research
- Review of existing product evaluations
- Specialist input if local market information not available
- Reporting on function and performance

Planning and needs assessment
- Establishment of multidisciplinary team and development of work plan
- Data gathering and definition of strategic areas
- Development of a list of required supplies, quantities and specifications (i.e. needs assessment)
- Costing and specification of site requirements
- Funding and budget analysis
- Definition of purchase method
- Finalization of plan and management indicators

Procurement
- Issuance of bid documents
- Receipt and opening of bids
- Evaluation of technical and financial aspects, as well as of supplier
- Award of contract or order
- Definition of payment schedule

Installation
- Site preparation
- Pre-dispatch inspections
- Shipment and customs
- Storage, transport and delivery
- Receipt and checking
- Assembly and construction
- Stocking of disposables and consumables

Commissioning
- Document verification
- Function, safety, calibration and acceptance tests
- Training (use, maintenance and follow-up)
- Registration and handover

Monitoring
- Equipment performance measurement
- Supplier performance measurement
- Technology suitability assessment
- Cost-effectiveness assessment
- Forecast review
- Procurement process review
- Patient safety monitoring

Note: HTA and device evaluation are helpful preparatory steps to good procurement, although they are separate from the procurement process itself.
Each stage of the process

- **Definition of each stage**
- **Inputs**
  - what is needed before this stage
- **Actions**
  - how to accomplish each stage
- **Assurances**
  - how to be sure each stage is completed
- **Outputs**
  - what you expect to see at each stage
Special considerations

- Local regulations
- replacement of equipment
- Refurbished equipment
- Radiological equipment
- Information technology
- Infrastructure
- Emergencies
- Sustainability
- E-procurement
- Grievances
- Ethical considerations
Assessing performance

- **Performance measures for:**
  - Efficiency of the competitive process
  - Cost reduction and containment
  - Supplier management
  - Efficiency of internal systems and processes
  - Procurement management
  - Quality control of equipment and facilities

- **References for:**
  - System development
  - Check sheets
Challenges

- **Vested interests**
  - transparent systems and clear rules needed

- **Poor monitoring**
  - keep track of every stage, use assurances

- **Poor planning**
  - know what quality, quantity, timing is needed

- **Lack of feedback**
  - ‘close the loop’, users know the issues

- **Poor logistics**
  - careful handling, transport and storage needed
Resources available

- 63 references, grouped under:
  - system development guidelines
  - medical device guidelines
  - country or organization documents
  - pharmaceutical guidelines
  - assessment tools
  - web resources
Case study

- **India**
- **Ministry of Health and Family Welfare**
  - Empowered Procurement Wing established
  - National Procurement Manual published
  - Warehousing and cold storage assessed
  - Equipment specifications formulated
  - E-procurement enabled
  - Procurement Management Information System developed
  - Test houses for quality assurance assessed
Working group session
Discussion questions

- Why can one stage of procurement not be used alone?
- Which challenges listed are greater, which are less?
- Which stage of procurement has been effective here?
- Which stage of procurement is absent here?

End
WHO Medical Device technical Series

Training module of:

- Procurement process resource guide
- Developed by Andrew Gammie
- April 2011
- Global Initiative on Health Technologies, WHO
- Supported by the Bill & Melinda Gates Foundation
Thanks!

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Objective: to ensure improved access, quality and use of medical devices.