Medical Devices Management Workshop

Facilitator: Ismael Cordero,
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"A Clinical Engineer is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology."
ACCE Definition, 1992
Workshop Objectives

• Briefly introduce basic HTM concepts and framework

• Briefly introduce available tools and resources for managing HT/MD

• Learn from countries about their successes and challenges in managing HT/MD

• Provide specific recommendations to:
  • WHO
  • Medical Device Industry
  • NGOs and Donors
## Agenda/Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Title</th>
<th>Speaker</th>
</tr>
</thead>
<tbody>
<tr>
<td>14:00</td>
<td>Introduction</td>
<td>Ismael Cordero</td>
</tr>
<tr>
<td>14:05</td>
<td>Presentation of Basic HTM concepts and Available Tools and Resources</td>
<td>Ismael Cordero &amp; Others</td>
</tr>
<tr>
<td>14:20</td>
<td>Presentation on Country Experiences</td>
<td>Country Representatives</td>
</tr>
<tr>
<td>15:00</td>
<td>Group Discussions</td>
<td>Groups of no more than 10 people each</td>
</tr>
<tr>
<td>15:40</td>
<td>Presentations on Group Discussions</td>
<td>Group Representative</td>
</tr>
</tbody>
</table>
Providing healthcare effectively and efficiently involves putting together a great variety of resource inputs, commonly described as healthcare technology.
Healthcare Technology

The devices, equipment, systems, software, facilities, supplies, pharmaceuticals, biotechnologies, and medical and surgical procedures used in the intervention, diagnosis, rehabilitation and treatment of disease in humans
Problem Tree

- Poor awareness
- Absence of clear policy
- Inadequate information
- Insufficient training
- Poor maintenance
- Poor budgeting
- Poor procurement
- Inadequate HR
- Poor state of devices
An accountable and systematic approach to ensure that cost-effective, efficacious, appropriate and safe equipment is available to meet the demands of quality patient care
HTM Inputs and Outputs

**INPUTS**
- Coordination with other Departments
- Budget
- Policy
- Planning
- Transport support
- Logistics Support
- Spare parts
- Training
- Facilities
- Service Infrastructure
- Telecomm
- Installation and Commissioning
- Selection and procurement of equipment and spares

**OUTPUTS**
- Decommissioning
- Selection and procurement of equipment and spares
- Installation and Commissioning
- Training
- Budgeting
- Repair
- Routine Maintenance
- Safety
- Planning
- Inventory
- Policy
- Planning
- Coordination with other Departments
## Framework for HTM

<table>
<thead>
<tr>
<th>Phase</th>
<th>Process</th>
<th>Activities</th>
</tr>
</thead>
</table>
| **Acquisition** | Planning | • Strategic Planning & Programming  
• Budgeting & Resource Allocation  
• Requirements Planning / Needs Assessment  
• Feasibility & Option Appraisal / Prioritization  
• Technology Scanning / HTA |
| | Procurement | • Requisition / Specification / Evaluation  
• Provisioning (tender/purchase/lease/hire)  
• Delivery / Installation  
• Commissioning / Acceptance  
• Training (users & maintainers, initial) |
| **Utilisation** | Asset Management | • Inventory / Asset Registers / Audit Checks  
• Utilization & Performance Monitoring  
• Maintenance & Spare Parts Management  
• Training (users & maintainers, ongoing)  
• Replacement Planning & Decommissioning |
| | Risk Management | • Risk Profiling & Assessment  
• Post-Market Surveillance / Hazard Notification  
• Inspection / Calibration / Safety Checks  
• Training (users & maintainers, ongoing)  
• Adverse Event Monitoring & Analysis |
You cannot manage what you don’t understand

Equipment Inventory

<table>
<thead>
<tr>
<th>INVENTORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID or Control #</td>
</tr>
<tr>
<td>Description</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Model #</td>
</tr>
<tr>
<td>Serial #</td>
</tr>
<tr>
<td>Location/Cost Center</td>
</tr>
<tr>
<td>Acquisition Date/Cost</td>
</tr>
<tr>
<td>Maintenance requirements (frequency/schedule)</td>
</tr>
</tbody>
</table>

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You cannot manage what you don’t understand

Centralized Documentation System

© SHCTA / slg - 16
Available Tools and Resources

- WHO tools
- “How to Manage” Series
- ACCE- ACEWs
- IFMBE CED
- INFRATECH
- Biomedtalk
- AAMI
- ECRI Institute
Forum CD- Technical Advisory Group on Health Technology Documents

- Medical Device Lists
- DRAFT - Introduction to Medical Device Procurement
- DRAFT - The Advancement of Health Technology Assessment in D
- PUBLISHED - Guidelines for Health Care Equipment Donations

PUBLISHED - Medical Device Regulations Global Overview and...
These spreadsheets will be consolidated into a searchable database
## Medical Device Lists

### Equipment List of District Hospital - Inpatient

<table>
<thead>
<tr>
<th>Area</th>
<th>Unit</th>
<th>Subunit</th>
<th>Type</th>
<th>Equipment name</th>
<th>GMDN</th>
<th>Specific Type</th>
<th>UMNDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Stretcher Station</td>
<td>ME</td>
<td>Wheelchair</td>
<td>14449</td>
<td>Wheelchair, attendant driven, collapsible</td>
<td>14-449</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Stretcher Station</td>
<td>MF</td>
<td>Stretcher</td>
<td>13814</td>
<td>Stretcher, general-purpose</td>
<td>13-814</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>ME</td>
<td>Clinical electronic thermometer</td>
<td>14028</td>
<td>Thermometer, electronic</td>
<td>14-032</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>ME</td>
<td>Patient-Nurse Communication System</td>
<td>NA</td>
<td>NA</td>
<td>15-614</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Bed mattress</td>
<td>12475</td>
<td>Mattress, bed, general-purpose</td>
<td>12-475</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Bedrail</td>
<td>15852</td>
<td>Rail, side-support, bed</td>
<td>10-341</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Bedside cabinet</td>
<td>10526</td>
<td>Cabinet, bedside</td>
<td>10-531</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Electric bed</td>
<td>41436</td>
<td>Bed, general-purpose, electrically-powered</td>
<td>10-347</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Footstool</td>
<td>11771</td>
<td>Footstool, conductive</td>
<td>11-621</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Intravenous stand</td>
<td>40509</td>
<td>Fluid delivery mount, general-purpose</td>
<td>12-177</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Kick bucket</td>
<td>41111</td>
<td>Kick bucket</td>
<td>14-427</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Overbed light</td>
<td>12347</td>
<td>Light, overhead</td>
<td>15-660</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Overbed table</td>
<td>13949</td>
<td>Table, over-bed</td>
<td>13-963</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Patient record</td>
<td>15567</td>
<td>Chart, patient record</td>
<td>15-962</td>
</tr>
<tr>
<td>Inpatient</td>
<td>General Attention</td>
<td>Wards</td>
<td>MF</td>
<td>Screen for examination table</td>
<td>13513</td>
<td>Screen, bedside</td>
<td>13-514</td>
</tr>
</tbody>
</table>
American College of Clinical Engineering (ACCE)  http://accenet.org

Welcome to the World Wide Web home of the American College of Clinical Engineering (ACCE). Founded in 1991, ACCE is committed to enhancing the profession of clinical engineering. With members in the United States and abroad, the ACCE is the only internationally recognized professional society for clinical engineers.

AAMI and FDA SUMMIT ON INFUSION DEVICES
OCTOBER 5-6, 2010 - SILVER SPRING, MD

AAMI and the U.S. Food and Drug Administration (FDA) are teaming up this fall to co-host a summit on infusion pumps in an effort to improve patient outcomes.

What's New
- ACTE covered in \textit{Salvation Press}
- The first CE-IT \textit{Community webinar} held in June 2010
- Student Papers from the 2010 ACCE Awards competition
- JOB OPPORTUNITIES in the Clinical Engineering field

The First Global Forum on Medical Devices
Convened by the World Health Organization
9-11 September, 2010, Bangkok, Thailand

Read more...
ACCE- Advanced Clinical Engineering Workshops (ACEWs)

- Three Levels of ACEW

Main Topics:
- Healthcare Technology Management
- Health Technology Assessment
- Human Resources Development
- Patient Safety, Risk Management & Use Error
- Maintenance Service Management
- Technology Management Shared Services
- Utility Systems in Healthcare Facilities

New Issues:
- Electro Magnetic Interference (EMI/EMC)
- Medical Telemetric Systems/ Wireless Communications
- Patient Care Device Interoperability
- PACS, RIS, HL7, DICOM
- Medical Devices Regulation
- Medical Device Incident Investigation
- Donated/Refurbished Medical Equipment
- Reuse of Single-Use Medical Devices
- Integrated Health Technology Package - IHTP
Acew- Statistics

- 21 Years
- 46 ACEW
- 29 Countries Hosted ACEW
- 16 from Latin America and the Caribbean (LA&C)
- 63 Countries have Participated in ACEW
- 32 from LA&C
- 4,075 Attendees
- 3,350 from LA&C
- 72 Faculty Members of ACCE- 20 Former ACEW Attendees
- 1,850 Hours of Lecture
- 2 Certification Boards on CE (Brazil & Mexico)
ACEW- Contact

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INFRATECH Discussion Group
http://infratechonline.net
Thank You

Innovation
Affordability
Safety
Equity
Effective

Improving access to safe, effective and innovative quality medical devices

Research
Assessment
Training
Maintenance
## Group Discussions

<table>
<thead>
<tr>
<th>Group</th>
<th>Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Procurement</td>
</tr>
<tr>
<td>2</td>
<td>Donations</td>
</tr>
<tr>
<td>3</td>
<td>Inventory and Maintenance Management</td>
</tr>
<tr>
<td>4</td>
<td>HR development for HT managers and equipment maintainers</td>
</tr>
<tr>
<td>5</td>
<td>Patient and User Safety</td>
</tr>
<tr>
<td>6</td>
<td>Monitoring and Evaluation (indicators)</td>
</tr>
<tr>
<td>7</td>
<td>National HT Policy/ National HT Institutions</td>
</tr>
</tbody>
</table>

3 Recommendations for:  
- WHO  
- Medical Device Industry  
- NGOs and Donors