Benchmarking: Clinical Engineering Departments & Medical Device Quality Assurance

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http://its.uvm.edu/tsp

President, Healthcare Technology Foundation
www.thehtf.org
University of Vermont Technical Services Partnership

- Clinical Engineering program started in 1973
- Non-profit university department
- Staff of 52 - BMETS, Clinical Engineers, IT, managers, and administrators
- Contracts with 32 hospitals in Vermont, New Hampshire and New York; 400+ private practice offices, schools, and labs; 60,000 medical devices
Why Do We Need Clinical Engineering for Medical Technology Management?

- **Patient safety**
  - Medical device failures account for 13% of all types of adverse events (Frost & Sullivan)
  - 100,000+ medical device adverse event reports are received by the FDA each year (FDA Recall Study)
  - The total national costs from preventable adverse events range between $20 billion to $75 billion annually. (IOM report)

- **Cost**
  - $94.9 billion in 2010 for equipment expenditures (Espicom)
  - Medical technology responsible for half the increase in healthcare spending since 1975 (Congressional Budget Office 2008)

USA data
## Lack of Management and Maintenance

<table>
<thead>
<tr>
<th>Deficit Area</th>
<th>Cost Increases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inability to correctly specify total needs during bid and procurement</td>
<td>10-30%</td>
</tr>
<tr>
<td>Purchase of underutilized/unused technology due to lack of operator and technical staff training</td>
<td>20-40%</td>
</tr>
<tr>
<td>Extra modifications or additions to equipment and facilities due to poor planning</td>
<td>10-30%</td>
</tr>
<tr>
<td>Reduced life of equipment due to improper use</td>
<td>30-80%</td>
</tr>
<tr>
<td>Lack of standardization leading to high parts costs</td>
<td>30-50%</td>
</tr>
<tr>
<td>Poor maintenance leading to increased downtime</td>
<td>25-35%</td>
</tr>
</tbody>
</table>

*Ziken International for WHO*
Why Do We Need Clinical Engineering for Medical Technology Management?

• Rapid change
  • 50% of all diagnostic and treatment methods used today did not exist 10 years ago

• Complexity
  • FDA evaluated more than 10,000 new products 2003-2005
  • Over 2 million articles on healthcare technology
  • Convergence of technologies – medical devices, information technology, and telecommunication
  • Device / pharmaceutical questions, e.g. drug eluting stent

• Efficacy
  • Effectiveness of technology to improve outcomes
    • Example 1: 1980 Medical lasers, must have technology → 1990 and on, limited success, no better than other less expensive methods
    • Example 2: 2000 daVinci Robotic surgery → 2013 1900 installed in the US @ $1-2 million, hospital marketing push; AMA article - no better than laparoscopic hysterectomy, 25 product liability of lawsuits

USA data
Quality management program

1. Ensure the ongoing quality, safety and effectiveness of medical devices
2. Avoid medical device failures during critical medical procedures
3. Improve clinical effectiveness and device availability
4. Reduce total cost of device ownership
5. Uphold staff morale and professionalism through positive patient experience
6. Reduce patient and staff risk and improve patient confidence
7. Comply with regulations and OEM recommendations

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Harm prevention

Medical device technology should:

1. Help sustain high quality of care provided to each patient
2. Facilitate faster/easier diagnoses to improve patient care/outcomes
3. Be safe to use at all times for both patients and staff
4. Maintain functionality and effectiveness throughout the life of the device

How do we ensure the continuous safety and effectiveness of medical devices in an systematic, repeatable way?
Quality Assurance:
Clinical, Safety and Criticality Factors

Device function

- What function does the equipment perform in a clinical environment?
  - Highest risk → life-support devices
  - Lowest risk → patient contact only, example
    - electrically powered patient bed

Risk of misuse or failure

- What are the possible consequences to the patient or staff of a device malfunction or misapplication?
  - Range from “no significant risk” to death

Mission criticality

- What is the impact on overall hospital patient care, workflow, or income?
  - Most critical → CT Scanner
  - Less critical → Non-invasive blood pressure monitor
Quality assurance: Maintenance Factors

Manufacturer maintenance requirements

- Recommendations based on device type, design, and the components inside
- Compliance with standards

Equipment maintenance history

- How prone to failure is this device or group of devices?
  - Failures found during testing and in patient use.
- Maintenance sensitivity
  - What devices become more reliable and accurate with maintenance?
Organization and keeping track

Computerized maintenance management systems (CMMS)

All USA hospitals have Clinical Engineering services and most use a CMMS to track/organize/analyze and plan with quality assurance data.

Hospital Engineering Management System (HEMS) EQ2 Inc. Vermont USA

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DEFINITION: A measurement of the quality of an organization's policies, products, or programs, and their comparison with standard measurements, or similar measurements of its peers.

• The objectives of benchmarking are to:
  – determine what and where improvements are called for
  – analyze how other organizations achieve their high performance levels, and
  – use this information to improve performance.
AAMI Benchmarking Solutions—Healthcare Technology Management

- Web-based product
  - Budgets, personnel, practices, and policies against other facilities
    - Number of devices maintained by a CE program
    - Percentage of scheduled inspections that identify a need for corrective maintenance
  - Internal or external comparisons
    - Differing bed, size, responsibilities, academic/community, location, adjusted discharges, acquisition cost, peer cluster
  - Cost of service ratio
    - Annual service cost = X %
      Acquisition cost
  - Staffing *
    - Devices per technician: 1,087
    - Hourly Cost of In-house Maintenance: $89.85 USD
    - Maintenance Cost to Acquisition Cost Ratio (COSR): 5.46%
- [http://www.aami.org/abs](http://www.aami.org/abs)

Ted Cohen, *Staffing Metrics: A Case Study*, Biomedical Instrumentation & Technology July/August 2011

*Average of all 2010 respondents (135)
AAMI Benchmarking Solutions
Healthcare Technology Management

Staffing Metrics

<table>
<thead>
<tr>
<th>CE Program Staffing by Professional Titles</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total FTEs</strong></td>
</tr>
<tr>
<td>Total number of FTEs in the CE program.</td>
</tr>
<tr>
<td>17.00</td>
</tr>
<tr>
<td><strong>Number of Clinical Engineers</strong></td>
</tr>
<tr>
<td>Total number of clinical engineers (CEs) in the CE program.</td>
</tr>
<tr>
<td>Include only those personnel with actual engineering credentials.</td>
</tr>
<tr>
<td>Examples: Professional Engineer (PE) license, BS or higher degree in engineering (not engineering technology), Certified Clinical Engineer (CCE) credential.</td>
</tr>
<tr>
<td>2.25</td>
</tr>
<tr>
<td><strong>Number of BMETs</strong></td>
</tr>
<tr>
<td>Total number of biomedical equipment technicians (BMETs) in the CE program (FTEs).</td>
</tr>
<tr>
<td>14.00</td>
</tr>
<tr>
<td><strong>Number of Other Personnel</strong></td>
</tr>
<tr>
<td>Total number of other personnel (not CEs or BMETs) in the CE program (FTEs). Examples: clerical staff, contracts administrator, etc.</td>
</tr>
<tr>
<td>1.00</td>
</tr>
</tbody>
</table>

Device Metrics

| Devices - Total |
| Total number of all devices managed or maintained by CE. |
| 10,325 |
| Devices - Imaging and Therapeutic Radiology |
| Total number of all imaging equipment and therapeutic radiology equipment managed or maintained by CE. Examples are x-ray equipment, ultrasound equipment, CT systems, nuclear medicine systems, MR systems, linear accelerators, and other radiation treatment equipment. |
| 138 |
| Devices - Laboratory Equipment |
| Total number of all clinical laboratory equipment managed or maintained by CE. This category includes devices used for the preparation, storage, or analysis of patient specimens and pharmaceuticals. |
| 295 |
| Devices - General Biomedical Equipment |
| Total number of all the general biomedical equipment (devices not included in the two categories above) managed or maintained by CE. These are devices that provide monitoring, diagnosis, treatment, or life support. Examples: physiological monitors, infusion pumps, dialysis equipment, surgical equipment, scales, clinic equipment, ventilators, etc. |
| 8,940 |
| Devices - Other |
| Total number of all other devices (patient care and non-patient care devices not included in the three categories above) managed or maintained by CE. Examples: beds, stretchers, wheelchairs, nurse call systems, patient entertainment systems, general purpose computers, communications equipment, TVs, etc. |
| 952 |

**Devices - Error Check**

The fields to the right are automatically calculated. The "Total of Above" and the "Expected Total" (Devices-Total entered above) should match. The "Difference" should be zero. This will display after you click Submit below.

Total of Above: 10,325
Expected Total: 10,325
Difference: 0
AAMI Benchmarking Solutions—
Healthcare Technology Management

On Demand Charting

Cost of Service Ratio (COSR)

Values

25th Percentile | Median | 75th Percentile

3.45% | 4.02% | 4.78%

My Facility (83rd Percentile)

Selected Metric | Filter Settings
ECRI Institute Biomedical Benchmark

- Inventory
  - Risk levels, inspection procedures & frequencies, service costs, life expectancy, cost of service ratio
- Staffing
- Workspace
- Service contracts
  - Imaging, clinical laboratory, biomedical

- [https://www.ecri.org/Products/Pages/BiomedicalBenchmark.aspx](https://www.ecri.org/Products/Pages/BiomedicalBenchmark.aspx)
• Anticipate equipment life cycles to improve efficiency
• Identify and evaluate options for equipment service
• Compare staffing levels to other similar facilities
• Determine if manufacturers' inspection frequencies can be reduced
## Table of IPM Procedure Frequencies

Many of the procedures provide additional guidance on inspection intervals.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>No.</th>
<th>Times/ Yr</th>
<th>Procedure</th>
<th>No.</th>
<th>Times/ Yr</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambulatory Infusion Pumps</td>
<td>490</td>
<td>1</td>
<td>Mini C-arms</td>
<td>478</td>
<td>2</td>
</tr>
<tr>
<td>Anesthesia Units</td>
<td>400</td>
<td>2</td>
<td>Mobile C-arms</td>
<td>463</td>
<td>2</td>
</tr>
<tr>
<td>Anesthesia Vaporizers</td>
<td>436</td>
<td>2</td>
<td>Mobile High-efficiency- filter Air Cleaners</td>
<td>475</td>
<td>6</td>
</tr>
</tbody>
</table>

### High-risk devices:
- Life-support, key resuscitation, critical monitoring, energy emitting, and other devices whose failure or misuse is reasonably likely to seriously injure patients or staff.
- Anesthesia Units and Vaporizers
- Apnea Monitors
- Argon-Enhanced Coagulation Units
- Irrigation/Distention Units
- Laparoscopic Insufflators
- Lasers (Surgical)

### Device Term | Dev. Code | No. Data Points | Avg Service Cost ($/unit/yr) | Avg Acquisition Cost ($/unit) | Service Cost/Acquisition Cost (%)
--- | --- | --- | --- | --- | ---
Aerators, Ethylene Oxide | 10045 | STD | $1,925 | $19,399 | 9.9
Analyzers, Laboratory, Blood Gas/pH | 15709 | STD | $4,224 | $43,311 | 10.3
Analyzers, Laboratory, Blood, Glycated Hemoglobin | 17109 | STD | $6,650 | $69,506 | 10.2
Analyzers, Laboratory, Body Fluid, Amino Acid | 15090 | LTF | $10,800 | $98,920 | 10.9
Analyzers, Laboratory, Body Fluid, Lead | 15300 | LTF | $630 | $13,050 | 4.8
Analyzers, Laboratory, Breath, Carbon Dioxide | 10588 | LTF | $1,700 | | |
Which of the following best describes your current employer?

- Hospital: 60% (Orange)
- Independent Service Organization: 20% (Blue)
- Equipment Manufacturer: 10% (Purple)
- Government (non-military): 5% (Red)
- Military: 5% (Green)
- Educational Institution: 5% (Yellow)

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Average respondent’s team is responsible for an inventory of more than 1000 medical devices
Average medical device technology team

- One BMET I
- Two BMET II
- Two BMET III
- One Radiology Equipment Specialist
- One Manager
- One Director

Level of compensation generally increases with each title.

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Does your current employer use a risk management approach to testing?
Maintenance strategies

Internally-managed for both preventive maintenance and repair; PM testing every six months:

- Anesthesia systems
- Defibrillators
- Diagnostic ultrasound
- Electrosurgical devices
- External pacemakers
- Radiographic & fluoroscopic X-ray
- Ventilators

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Internally-managed for both preventive maintenance and repair; PM testing every 12 months:

- Apnea monitors
- Aspirators
- Cardiac output units
- Central station monitoring systems
- Compression units
- Enteral feeding pumps
- Fetal monitors
- Hypo/hyperthermia units
- Infant incubators
Internally-managed for both preventive maintenance and repair; PM testing every 12 months:

- Infusion devices
- Patient monitors
- PCA Pumps
- Phototherapy units
- Pneumatic tourniquets
- Pulse oximeters
- Radiant warmers
- Sphygmomanometers
- Therapeutic stimulators
- Therapeutic ultrasounds
Preventive maintenance and repair handled by service contract with the manufacturer; PM testing every six months:

- Computed tomography (CT)
- Magnetic resonance imaging (MRI)
- Mammography devices
- Positron emission tomography (PET)
Medical Equipment Quality Assurance and Metrology Guidance Document

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Ventilator procedure
Estimated time: 30 minutes

General information
Control number: Hospital:
Manufacturer: Model:
Serial number: Location:

Test Information
Technician: Date:

Test equipment needed: EA 1500 (Electrical Safety Analyzer [equivalent])
VT-PULS HP Ventilator Analyzer (or equivalent)
Test lead such as AC/DC (0.1)
Fuses and connections to connect to VT-PULS HP:

Test results

Physical condition

Grout and tile:
< 0.1 mm

Water leakage:
< 10 V

Power leakage:
< 5 mA

Temperature:
< 50 °C (86 °F)

Resistance:
< 600 Ω

Soldering:
< 0.2 mm

Isolation:
< 50 MΩ

Insulation test applied: DC 50 V
< 2 MΩ

Optional tests

Test results (continued on page 19)
• Inspection program
• Procedures
• 2nd Edition soon!
THANK YOU!

谢谢

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