A Practical Approach To Medical Technology Capital Planning

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Conflict of Interest

Chris Gutmann, MS
Ilir Kullolli, MS

Has no real or apparent conflicts of interest to report.
Agenda

✓ Introductions
✓ Learning Objectives
✓ Technology Challenges
✓ Organizing Clinical Engineering
✓ Assessment and Planning
✓ Capital Strategy
✓ Modernization with Security
✓ Execution of Capital Planning
✓ Total Cost of Ownership
✓ Process in Flowchart
✓ Device Security – FDA influence
✓ Closing Remarks
Learning Objectives

- Identify ways to drive Capital Medical Systems acquisitions
- Analyze two approaches to Capital Planning while keeping in mind Cybersecurity, Integration, TCO, and Interoperability
- Define a path to proper planning while considering Clinical, IT, Clinical Engineering and Administrative needs
- Detect nuances on the effects of Cybersecurity, Integration, and Interoperability on Long Term Capital Planning
Stanford Children’s Health

Stanford Children’s Health (SCH) is the only medical network in the area, & the country, exclusively dedicated to pediatric & obstetric care. Network of more than 1,000 physicians across 60 locations. At the heart of our healthcare system is Lucile Packard Children’s Hospital Stanford, which is internationally recognized for advancing leadership & innovation with family-centered care of newborns, children, & expectant mothers. Multiple Awards (Davies, Stage 7, Most Wired, Best IT Department, etc.)
VISION
Yale New Haven Health enhances the lives of the people we serve by providing access to high value, patient-centered care in collaboration with those who share our values.

MISSION
Yale New Haven Health is committed to innovation and excellence in patient care, teaching, research and service to our communities.

VALUES
- INTEGRITY: Doing the right thing
- PATIENT-CENTERED: Putting patients and families first
- RESPECT: Valuing all people
- ACCOUNTABILITY: Being responsible and taking action
- COMPASSION: Being empathetic

YaleNewHavenHealth
Technology challenges

Financial Constraints:
- Economic Forces and Regulations
- Technological Advances
- New Technologies (i.e. Telehealth, nanomedicine, imaging technologies, etc.)
- Place of Healthcare Delivery (home, hospital, clinics, etc.)
- Complex Technologies to Deliver Appropriate Care (integration, security, etc.)
Clinical Engineering
Roles and Responsibilities
Previous Org Structure (no CSE)

• Status Quo Clinical Engineering org structure
  – Focus on preventive maintenance, repairs, and technology replacements and equipment breaks/no longer functional
• CSE Team of 6 created due to:
  – Device integration
  – Networking of systems
  – Technology planning
  – CyberSecurity Focus
  – Highly skilled
  – Quick escalations
  – SWAT interventions
Technology assessment and planning

- Managing Equipment Lifecycle
- Medical Equipment and Technology Assessment
- Medical Equipment and Technology Replacement Planning
- Execution of Replacement Plan / Communication
- Project Management
- Communicating with Senior/Executive Leadership
Assumption of Chief Executives - their clinical engineering team has been built with the tools to facilitate their planning activities.

Executives’ strategy is based upon macro-economics of the overall long term objectives for the Health System.

Clinical Engineering planning has support aspects in each service line that are unique, often clashing with macro algorithms and over simplification. CE must package projects that serve both needs.
Medical Technology in Future tense

Humans are the only creatures with the ability to dive deep in the sea, fly high in the sky, send instant messages around the globe, reflect on the past, assess the present and imagine the future.

- Sylvia Earle
Finite capital allocations burdened with financial constraints such as measures of cash flow, carryover from previous years, strain of growth strategy, physician recruitment, etc.

Look to your CE department to be open to all inputs/distributions needed from “capital pie”

1. Replacement
   - Patient Safety, Liability, End of Life
2. Growth
   - New construction, Acquisition agreements
3. Strategic
   - Physician Recruitment, Local Government
Modernization is the Goal

How are Business Cases built in your Health System?

• Patient Experience

• Ensure all costs are included:
  – Equipment
  – Resources
  – Licensing (interfaces, database, inter-vendor)
  – Virtualization in the data center
  – Barcode Scanners?
  – Access to an EHR workstation?
  – Mobile access to EHR?

• Total Cost of Ownership

Clinical Systems:
- Infrastructure (Transport)
- FDA approved Medical Device?
- Compute: Virtual/Physical

Life Cycles of equipment are not all created equal:
PC: 3-4 years
Med Device: 7-12
Server: 5 years
Upgrade v. Replace?
Medical Device Security

- Threats to our medical information across the health system occur both in the physical and logical movement of patient information.

- Medical device systems provide a unique risk through some:
  - Operating systems’ age (FDA approvals)
  - Ports on devices for peripherals
  - Emerging consumer device platforms
  - Configuration files
  - Software updates

- Financial burden in both updating old as well as ensuring security on the new devices.
Mechanics of Execution

• Utilize Software and ERP, to consolidate equipment purchasing. This allows execution of the C-suite strategic vision without administrative waste (delays).

• Stratification of equipment in multi factorial method
  – 250% life expectancy – Primary Care Environment
  – 150% life expectancy – Med/Surg, ICU, HVC
  – 75% life expectancy – Translational Medicine

• Anecdotal drivers - safety incidents, statistical deviation of cost

• Delivery Network capital committees aligning
  – Each Delivery Network: different lens at similar issues

• Information Security
  – Added costs to the project that need accounting up front
# Mechanics of Execution

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![Bar Chart](image)

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# Capital Plan by the Numbers

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<th>FY21</th>
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<td>CT Scanners</td>
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<td><strong>$31,445,000</strong></td>
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Vendor Partnership v. Transaction

Many large OEM vendors have business markets in different clinical service lines.

Ask yourself are our clinical service lines aligned in efforts of technology? Is the presenting OEM truly aligned to us and our multi-disciplinary needs?

The balance of when to strike partnership level (agreed revenue targets) vs. transactional (health system determines purchase based on available capital)

What are the tipping points? $, cross over, Analytics, Infrastructure, Clinical Alignment
Operating Costs Considerations

- Cost of Service Ratio (COSR)
  - Yearly Service Cost / Acquisition Cost

- Total Cost of Ownership (TCO)
  - Yearly Service Cost x LE + Acquisition Cost
Keeping the TCO Mindset

**Upfront Investment**
- Purchase Price
- Installation Costs
- Clinical and Biomed Training
- Networking/Integration
- Configuration

**Continued Support**
- Parts Costs
- Consumables costs
- Biomed Support
- IT/Integration Support
- Security Patching and Upgrades

**Hidden Costs**
- Power and Networking expenses
- Replacement Planning
- Security issues as equipment gets older
- Negotiating service with Manufacturer as equipment gets older
- Change Management
Development of Plan

1. Develop Technology Plan
2. Review with Department Leaders, IT, Facilities, etc.
3. Adjust Technology Plan
4. Submit for Approval
5. Make Final Adjustment
6. Execute Technology Plan
Technology Planning Committees

Physician Co-Chair and Nursing/Operations Co-Chair

- Lead Strategic Planning
- Determine clinical outcomes
- Collaborate on creation of business cases
- Promote the Technology Plan with their peers
- Determine impact (financial and/or operational)
- Define utilization and help adhere to it
- Determine initiatives to be funded (research, etc.)

Clinical Technology and Biomedical Engineering

- Manage current Medical Equipment Inventory and provide Service History Data
- Provide replacement recommendations based on allocations and service history
- Work with Analytics team and/or vendors to obtain Utilization Information (when available)
- Facilitate technology evaluations (coordinate with vendors, department, etc.)
- Communicate, coordinate, and implement Technology Plan
- Obtain data from IS, Construction, vendor to provide TCO
- Facilitate committee meetings
Process Driven Planning

- Download List from CMMS based on AHA Life Expectancy
- Review List and Repair Orders/Service History for these devices
- Based on inventory count and allocation, do we need to replace it?
- Does service history show need for replacement?
- Is Equipment at End of Life?
- Is there a new Clinical Initiative that warrants replacement?
- Do not Include in Replacement. Mark device for Next Year Review
- Additional Equipment and New Initiatives
- Equipment with known issues and extensive Service History, but not at Life Expectancy
- Include in Clinical Technology Plan
- Remove from Service and Decommission Device
- Yes
- No
- Yes
- No
- Yes
- No
- Yes
- No
- Yes
Planning for replacement

1. Additional Equipment and New Initiatives
2. Equipment with known issues and extensive Service History, but not at Life Expectancy
3. Download List from CMMS based on AHA Life Expectancy
4. Review List and Repair Orders/Service History for these devices
5. Do not Include in Replacement. Mark device for Next Year Review
6. Include in Clinical Technology Plan
7. Is Equipment at End of Life?
8. Does service history show need for replacement?
9. Based on Inventory count and allocation, do we need to replace it?
10. Remove from Service and Decommission Device
11. Is there a new Clinical Initiative that warrants replacement?
12. Equipment with Security Risks

#HIMSS19
Planning for Security Risks

- **Download List from CMMS with Equipment that has outdated software/Security Risks**
- Can the Software be Updated in these Devices? **Yes**
- Are they on the network? **Yes**
- Proceed to Clinical Technology Plan
- **Is there a contingency plan for them (i.e., Cisco ISE, restrictions, etc.)?** **Yes**
- Do not Include in Replacement. Mark device for Next Year Review and work on restricting access
- **No**
- **Can the Software be Updated in these Devices?** **No**
- **Are they on the network?** **No**
- **Download List from CMMS with Equipment that has outdated software/Security Risks**
Developing the Plan

- Equipment Lifecycle – Process
  - New Technologies
  - Existing Refresh
- Create Committees to Review Capital Needs
- Create a List of “Must Do” vs. “Nice to Do”
- Rank Equipment Needs
  - Criticality
  - Utilization Data
  - Service History Data
  - Inventory and Allocation Data
- Develop a Long Term Plan (5-10 year Plan)
Shift in Blame – Device Security

“The FDA won’t let us fix it”
- Medical Device Vendors

“No one is enforcing safe biomedical devices”
- Information Services Department

“Vendors don’t create secure biomedical devices”
- FDA + Every Biomed Engineer

2012

2016

Feb 2019
FDA involvement and what we can do to help

- Very expensive to keep replacing equipment every time they get old
  - FDA getting involved to hold manufacturers accountable to make updates available for older equipment
  - Cannot replace devices like PCs/Laptops (every 3 years)
- Plan for worst case scenario (equipment will not be updatable/upgradeable in 3-5 years)
  - Appliance that can restrict device communications and monitor communication to and from devices
  - Include these appliances in technology refresh planning for medical equipment
- Get your department involved with professional organizations that are the voice of the profession with FDA/TJC
  - American College of Clinical Engineering, etc.
Questions

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Please complete online session evaluation