CAVEAT EMPTOR:
Decision Making on Clinical Technology Acquisitions

Wednesday, April 15 – 11:30am-12:30pm

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Conflict of Interest

Stephen L. Grimes, FACCE FAIMBE FHIMSS
Has no real or apparent conflicts of interest to report.

Jacob B. Johnson, MS CCE
Has no real or apparent conflicts of interest to report.
Session Description

Capital budgets for clinical technology acquisitions today is often 8 to 10 times larger than what same organization spent 10 years ago.

This session provides a description of a structure, process, and tools that decision makers (CEOs, COOs and CFOs) should avail themselves of when determining which clinical technologies to adopt and how to measure a successful implementation.
Learning Objectives

1) Explain why the challenge of clinical technology acquisitions today represents a major shift from acquisitions of only a few years ago

2) Identify best sources of objective information that decision makers should typically consult before selecting and deploying new clinical technologies

3) Describe a scalable structure, process, and set of tools that facilitates the smart selection and adoption of new clinical technologies

4) Describe how to establish key objectives related new clinical technologies under consideration and how to assess the level of success achieved following deployment
Today’s Challenge

- trend in annual spend for biotech and related purchases (as reported by CEO of KP) for One Health Plan has increased > 9 times ($62.3M to $580M) between 1997 and 2007 †... and that trend is likely to continue rising for healthcare organizations

- implementation of new medical technology accounts for between 38 percent and 65 percent of health care spending increases between 1985 and 2006.‡

- rapid evolution of new and complex technologies (e.g., hybrid ORs, radiosurgical systems, robotic surgical systems, 3D imaging, real-time vital sign monitoring for general patient population, etc.) poses significant challenges for organizations who strive to adopt technologies that both broaden and improve patient care services while better managing costs

† Source: Halverson, George C., “Healthcare will not reform itself.” CRC Press. 2009. pg 22
‡ Source: http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2011/rwjf71331
What’s driving the increases?

**Complexity Drives Higher Implementation and Support Cost**

- **Medical Devices**
- **Networked Systems**
- **System Integration**

**Complexity**

- Simple
- Complex

**Total Cost**

**Trends:**
- System/System Bi-Directional
- Automated Workflows
- Business Intelligence

- **WAN Functionality**
- **Customer Supported Network**
- **Mobile & Wireless Use Cases**

- **Increasing Customization Options**
- **Software Subscription Model**
- **Wearable & Disposable sensors**

Features Sold as “Value Added Capabilities” often drive cost for Implementation and Support

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What’s driving the increases?

*Acquisition Cost is Only the Tip of the Iceberg*

Costs Relatively Stable

- Commonly Evaluated and Negotiated by Sourcing Teams

Source of Spending Increases

- Costs less Commonly Managed by Sourcing Teams
- More Specialized Resources required to Assess
Technology Acquisitions
Impact from *Discrete* (one patient one device) to *Enterprise*

Across Continuum of Care
A Structure for Making Effective Clinical Technology Acquisition Decisions
To address the challenge of identifying healthcare technologies for acquisition, this organization should establish a *Healthcare Technology Assessment (HTA) Committee*. 
Rationale for HTA Committee

- increasingly new technologies are having a ripple effect on an organization’s clinical, support, and business operations
- new technologies can also have a major impact on the organization’s financial resources.
- growing need to give appropriate consideration to the strategic, clinical, safety, operational, and financial implications prior to acquisition
HTA Committee Purpose

- take a strategic view
- focus on evidence-based consideration of technology acquisition
- engage appropriate stakeholders ... including those who
  - understand how to analyze and plan deployment and workflow processes
  - can identify required support infrastructure & associated costs
- establish appropriate justification process & metrics relevant to organization’s goals
Example of HTA Committee Structure

Multidisciplinary team *(with ad-hoc representation)*:

- Department Chairs/Directors (owner/operators of equipment)
- Chief Medical Officer (CMO)
- Chief Medical Informatics Officer (CMIO)
- Chief Nursing Officer (CNO)
- Chief Executive or Operating Officer (CEO/COO)
- Chief Financial Officer (CFO)
- Director of Supply Chain / Materials
- Director of Healthcare Technology Management / Clinical Engineering
- Chief Information / Technology Officer (CIO/CTO)
- Additional committee support staff includes senior experts in information services, quality, compliance and risk management.
Example HTA Committee Structure

Leadership Team
- CEO
- COO
- CTO
- CMO
- CFO

Clinical
- Department Chairs/Managers
- Clinical End Users
- Medical Informatics

Technical
- Clinical Engineering
- Information Technology
- Supply Chain

Finance
- Financial Analyst
- Revenue Cycle
- Property Accounting

Sourcing, Risk & Quality
- Sourcing
- Quality
- Compliance
- Risk Management
- Legal
Example HTA Committee Roles

Leadership Team
- Defines Strategy, Goals & Objectives
- Allocates Resources to Committees
- Ensures Balanced Decision Making
- Approves Contracts & Expenditures

Clinical
- Defines Clinical Needs & Opportunities
- Provides Clinical Workflow & End User Expertise
- Defines Clinical Training Requirements
- Champions Patient Perspective

Technical
- Forecasts & Plans for New Technologies
- Defines Technical Requirements
- Assesses Capabilities & Value-Adds
- Defines Installation and Support Strategy
- Provides Inventory & Cost of Service Data

Finance
- Analyzes and Validates Financial Benefits & Risks
- Manages & Reports Spend Forecast
- Supports year-over-year investment strategy & budgeting
- Sets Metrics to analyze HTA performance

Sourcing, Risk & Quality
- Manages Vendor Engagement, Negotiation, Compliance
- Provides Risk and Quality data for analysis
- Ensures adherence to policy, regulations and requirements
- Advises on Risks & Business Continuity

Champion Implementation of Strategies
Example: HTA Committee Structure at Kaiser Permanente
HTA Committee Goals & Metrics

The HTA committee considers goals and establishes metrics that can demonstrate progress to goals. Examples of goals include:

- improved care outcomes
- improved patient/staff safety
- reduced data security risks
- improved regulatory compliance
- improved efficiency & workflow processes
- improved revenue, particularly improvements with P4P initiatives
- reduced costs
- improved technology reliability
- improvements in utilization & longevity
- greater technology & vendor standardization to reduce support costs
- broader patient demographic served
- improved market perception (reputation)
A Process for Making Effective Clinical Technology Acquisition Decisions
The Acquisition Process

The Joint Commission Comprehensive Accreditation and Certification Manual (EC.02.04.01, EP1)

“The hospital solicits input from individuals who operate and service equipment [e.g., HTM/CE services, IT] when it selects and acquires medical equipment.”

Acquisition process should be systematic & meaningful ... the acquisition process should consider

- is proposed equipment new or replacement?
- does similar equipment already exists in organization?
- who and what areas will be affected by acquisition?
- what goals are to be achieved by the acquisition and how is successful achievement of those goals to be measured (metrics)?
The Acquisition Process

- Prospective owner submits a request for new (or replacement equipment) along with justification to COO/CFO for preliminary approval.
- If preliminary approval given by COO/CFO, request/justification form is submitted to HTA committee.
- HTA committee conducts an appropriately detailed assessment of request & justification, evaluates the degree to which the requested equipment meets one or more organizational goals and makes recommendations to the COO/CFO.
The Acquisition Process

- if an acquisition is approved by the COO/CFO, materials management /supply chain works with users, HTM/CE services and other relevant stakeholders (e.g., IT, facilities) to
  - ✓ establish an acquisition timetable
  - ✓ determine detailed requirements (to be incorporated in RFP purchase order) and
  - ✓ evaluate/select the product and vendor (thru RFP)
- the selected vendor is given an order including established specifications/requirements
- roles & responsibilities for deployment, installation, workflow design, training & support are detailed & formalized
Tools
for Making Effective
Clinical Technology Acquisition Decisions
Key Acquisition Tools

Capital Medical Equipment Request & Justification Form

Acquisition Requirements for Medical Equipment
## Medical Equipment Request and Justification Form

### 1.0 Requestor Information

<table>
<thead>
<tr>
<th>Request Date:</th>
<th>Date Product Needed:</th>
<th>Requestor / Title:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dept Name:</td>
<td>Cost Center:</td>
<td>Phone #</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 2.0 Product & Vendor Information

<table>
<thead>
<tr>
<th>Product:</th>
<th>Manufacturer:</th>
<th>Model:</th>
<th>Anticipated Cost</th>
<th>$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Does other equipment of this manufacturer &amp; model already exist within the organization?</th>
<th>If yes, approximately how many exist?</th>
<th>If yes, where in organization does equipment exist?</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ yes ☐ no</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vendor</th>
<th>Has this vendor been subjected to this organization's vetting process and approved?</th>
<th>Does this vendor participate in one of this organization's joint purchasing groups (i.e., Premier, Yankee, Novalon, HPG, SFRC)?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>☐ yes ☐ no</td>
<td>☐ yes ☐ no</td>
</tr>
</tbody>
</table>

### Requestor Info

- **Product & Vendor Info**
  - **✓ Description, Manufacturer, Model, Cost?**
    - **✓ Does other equipment from this manufacturer & model already exist?**
      - If yes, how many & where?
  - **✓ Vendor**
    - **✓ name**
    - **✓ is this vendor already vetted?**
    - **✓ is this vendor a participant in one of organization’s group purchasing organizations?**
### Medical Equipment Request and Justification Form

#### 3.0 Funding Source

<table>
<thead>
<tr>
<th>Capital Budget?</th>
<th>□ yes □ no</th>
<th>If yes, what fiscal year?</th>
<th>FY</th>
<th>Budgeted Amount:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foundation?</td>
<td>□ yes □ no</td>
<td>Contribution</td>
<td>$</td>
<td>Other Source?</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$</td>
<td>□ yes □ no</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>$</td>
<td></td>
</tr>
</tbody>
</table>

#### 4.0 Other Costs Beyond Acquisition (estimated)

<table>
<thead>
<tr>
<th>Initial costs</th>
<th>Operator training</th>
<th>Maintenance training</th>
<th>Facility modifications</th>
<th>Additional equipment</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Projected Annual Costs</th>
<th>Maintenance (post warranty)</th>
<th>Software upgrades &amp; license fees</th>
<th>Supplies &amp; Consumables</th>
<th>Utilities</th>
<th>Operators</th>
<th>Operator Support</th>
<th>Other (describe)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
<td>$</td>
</tr>
</tbody>
</table>

#### Funding Source
- Additional staff
- Operator training
- Maintenance training
- Facility modifications
- Additional equipment

#### Projected Annual Costs
- Maintenance (post warranty)
- Software upgrades/license fees
- Supplies & Consumables
- Utilities (electric, water, gas, network, etc.)
- Operators & operator support ... including cost of on-going user training
# Medical Equipment Request and Justification Form

## 5.0 Justification for New or Replacement equipment

<table>
<thead>
<tr>
<th>New Equipment</th>
<th>Justification: Does new equipment</th>
<th>Check all that apply</th>
<th>Explanation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ yes ☐ no</td>
<td>• provide new (or expand existing) service or provide needed new features?</td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• facilitate patient care and/or workflow improvements?</td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• provide important safety improvements?</td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• have other justifications? <em>explain</em></td>
<td>☐ yes ☐ no</td>
<td></td>
</tr>
</tbody>
</table>

**New equipment?**

- Does new equipment
  - ✓ provide new (or expand existing) service or provide needed new features?
  - ✓ facilitate patient care and/or workflow improvements?
  - ✓ provide important safety improvements?
  - ✓ other justifications?

- Will there be a sufficient amount of utilization to support its acquisition and allow for user proficiency to develop? *Users get good at what they do frequently (practice or live).*
5.0 Justification for New or Replacement equipment

<table>
<thead>
<tr>
<th>Justification: Existing equipment ...</th>
<th>Check all that apply</th>
<th>Explanation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>has insufficient features/functions for current or projected clinical needs?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>has insufficient capacity for anticipated workload?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>has unresolvable safety issues?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>is technically unreliable?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>is too costly to support?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>is clinically and/or technically approaching obsolescence?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>is at or is approaching end of manufacturer support (manufacturer’s date for end of support _______)?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Descrip of outgoing Equip</th>
<th>Manufacturer</th>
<th>Model</th>
<th>Serial or Site #</th>
<th>Asset #</th>
<th>Proposed disposition</th>
<th>Residual value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>transfer □ dispose □ sell □ sell</td>
<td>$</td>
</tr>
</tbody>
</table>

Replacement equipment?

- Does the existing equipment
  - ✔ have insufficient features/functions for current or projected clinical needs?
  - ✔ have insufficient capacity for anticipate workload?
  - ✔ have unresolvable safety issues?

- ✔ technically unreliable?
- ✔ too costly to support?
- ✔ approach clinical and/or technical obsolescence?
- ✔ approach end of manufacturer support?
### Other considerations

**Medical Equipment Request and Justification Form**

**6.0 Other considerations**

<table>
<thead>
<tr>
<th>Are there:</th>
<th>Check all that apply</th>
<th>If yes, describe relevant requirements ...</th>
</tr>
</thead>
<tbody>
<tr>
<td>• special security needs (including physical and/or technical safeguards) related ePHI or other data?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>• monitoring needs (e.g., are there alarms/alerts that may require action)?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>• space needs (i.e., square and cubic foot requirements, reinforced flooring, enlarged entrance, etc.)?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>• environmental needs (i.e., controlled temperature, humidity)?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>• special utility needs (i.e., electric, gas, water, medical air/oxygen/vacuum, etc.)?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>• network or internet access needs (including interface to EMR or other applications)?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
<tr>
<td>• special cleaning or infection control needs?</td>
<td>□ yes □ no</td>
<td></td>
</tr>
</tbody>
</table>

- Other considerations – Are there

- ✓ special data security needs?
- ✓ monitoring needs (important alarms/alerts)?
- ✓ space needs?
- ✓ environmental needs?
- ✓ special utility needs?
- ✓ network or internet access needs?
- ✓ special cleaning or infection control needs?
- ✓ appropriate guidelines for alarm/alert settings
## Medical Equipment Request and Justification Form

### 7.0 Metrics (acquisitions should have clear / demonstrable benefits)

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe principal benefit(s) of acquiring equipment</td>
</tr>
<tr>
<td>Describe timetable for achieving benefit(s) after acquisition</td>
</tr>
<tr>
<td>Describe means of measuring benefit(s) gained (i.e., what metrics?)</td>
</tr>
</tbody>
</table>

### 8.0 Pillars

<table>
<thead>
<tr>
<th>Service</th>
<th>People</th>
<th>Quality</th>
<th>Financial</th>
<th>Growth</th>
<th>Community</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>How will the new equipment impact one or more pillars?</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Metrics**
- ✓ description of principal benefit(s) of acquiring equipment
- ✓ projected utilization
- ✓ description of timetable for achieving benefit(s) after acquisition?
- ✓ description of means to measure benefits gained

**Pillars**
- ✓ service
- ✓ people
- ✓ quality
- ✓ financial
- ✓ growth
- ✓ community
Required reviews /sign-offs ... does the proposed system

☑ require a network or internet connection, software, integration to EMR?
☑ represent a device/system used in treatment, diagnosis or monitoring?
☑ represent a device/system that either is new technology or has a broad effect on care?
☑ requires installation, facility modification, special environmental considerations, utilities?
## Requirements for Acquisition of Medical Equipment

Next 3 slides should be considered “minimum” requirements

<table>
<thead>
<tr>
<th>Check</th>
<th>Required (if checked by HTM/CE Services) for new acquisition</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1. Vendor agrees to provide two sets (preferably on disk in PDF) of</td>
</tr>
<tr>
<td></td>
<td>a. User manuals</td>
</tr>
<tr>
<td></td>
<td>b. Service manuals including:</td>
</tr>
<tr>
<td></td>
<td>• a description of manufacturers recommended scheduled maintenance procedures, parts replacements and schedules</td>
</tr>
<tr>
<td></td>
<td>• troubleshooting guides</td>
</tr>
<tr>
<td></td>
<td>• list of equipment/software necessary for testing, troubleshooting, repairing</td>
</tr>
<tr>
<td></td>
<td>2. Vendor agrees to provide a completed Manufacturers’ Disclosure Statement for Medical Device Security (MDS²) - HIMSS/NEMA Standard HN 1-2007</td>
</tr>
<tr>
<td></td>
<td>3. Vendor agrees to provide any service keys or passwords and any required diagnostic software to clinical engineering</td>
</tr>
<tr>
<td></td>
<td>4. Vendor agrees to provide a description of any special utility requirements (e.g., electrical, water, HVAC, etc) or any IT requirements</td>
</tr>
<tr>
<td></td>
<td>5. Vendor agrees to provide their 24x7 technical support contact information</td>
</tr>
<tr>
<td></td>
<td>6. Vendor agrees to provide a description (including schedules and additional cost of any) of training available for</td>
</tr>
<tr>
<td></td>
<td>a. equipment users</td>
</tr>
<tr>
<td></td>
<td>b. for technical service staff (i.e., HTM/CE Services)</td>
</tr>
<tr>
<td></td>
<td>7. Vendor agrees to provide a service contract proposal (12 month term) for post-warranty</td>
</tr>
<tr>
<td></td>
<td>• scheduled maintenance (according to manufacturer’s recommended procedures and schedule) and</td>
</tr>
<tr>
<td></td>
<td>• corrective maintenance (for normal business hours) including full parts but excluding consumables</td>
</tr>
<tr>
<td></td>
<td>8. Vendor agrees to supply credentials (e.g., relevant degrees, training certificates, certifications) of staff the vendor will use for servicing the equipment</td>
</tr>
</tbody>
</table>
9. Vendor agrees to provide a warranty for ________ months beginning on date of incoming inspection and acceptance by clinical engineering. Vendor also agrees to provide service documentation for all warranty, contract or time & material services performed on this device/system which documentation will include:

1) Vendor service report reference number
2) Date/time service request received for non-scheduled service (or date/time work performed if scheduled service)
3) Description of relevant device(s)/system including manufacturer, model and at least one of the following:
   - Asset number
   - Site number
   - Serial number
4) Description of reported problem or service issue
5) Description of action taken by vendor
6) On-site labor (including any breakout of normal and overtime hours)
   a) hours expended
   b) value of labor
   c) labor charge to be invoiced (if any)
7) Travel
   a) hours expended
   b) value of labor
   c) travel charge to be invoiced (if any)
8) Materials (including hardware/software/supplies)
   a) description of material used
   b) value of material
   c) material to be invoiced (if any)
9) Date/time returned to service
10) Final device(s)/system status
11) All completed service reports are to be e-mailed to ______________
Requirements for Acquisition of Medical Equipment

Signed/agreed to by vendor ... and stakeholder who will be responsible for verifying compliance

☐ 10. Vendor attests that the equipment has been approved for marketing in US by the FDA and that system carries an OSHA required NRTL certification (e.g., UL, IEC, TUV, CSA, CSL, ITSNA, MET, NTS, SGSUS, TUVAM).

Signed by HTM/CE Services representative: ___________________________ Date: ___________________________

Signed by authorized vendor representative: ___________________________ Date: ___________________________
Post Acquisition - Close the Loop

- Review the justification & metrics 6 -12 months after acquisition in order to inform and refine process.

Identify need, Define goals & Prepare justification (including metrics to measure achievement of goals) → Review Justification & Make Decision → Deploy approved system → Monitor system performance (do metrics confirm goals are being achieved?)

Feedback – improve justification process & metrics
Conclusion

Sophistication, Complexity and Broad Impact (operational & financial) of today’s clinical technologies on an organization is too significant not to include informed stakeholders in the acquisition process and decision.

Strategic, systematic, objective evidence-based approach with input from informed stakeholders needs to be norm for future clinical technology acquisition decisions.
Conclusion: Rationale for Investing in Healthcare Technology Assessment

- Ensure Acquisitions align with Organizational Strategies and Financial Goals
- Evaluate Technology Capabilities, Benefits, Risks and Risk Mitigation strategies.
- Understand Impact to Clinical and Business Workflows
- Understand infrastructure and resource needs to achieve Benefits Realization
- Define Implementation and Ongoing Support Requirements
- Balance Total Cost of Ownership with Business and Clinical Needs
Thank You!

Questions?

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