Impact of MDI on Device Assessment & Acquisition

Presented by: American College of Clinical Engineering

June 4, 2016 | Tampa, FL

PART 2
Topic 2: Impact of MDI on Device Procurement
Sub-Topic 1: Changing Process Considerations

Rob Maliff, Director Applied Solutions, ECRI Institute
Steve Juett, Sr. AVP, CallisonRTKL
Tobey Clark, Director ITS & Adjunct Faculty, University of Vermont
Angela Mulinix, Biomedical Engineer, VHA
Acquisition Programs in an MDI World

Presented by Rob Maliff

Director, Applied Solutions

ECRI Institute
Evolution of the Connected Medical Device

**Past**
Self contained device per bed space

**Present**
Interoperable therapy/diagnosis system with data exchange to various information systems.
New Acquisition Concerns

• Hospital Merger Mania

Hershey Med and PinnacleHealth fight with feds over merger; first-round knockout expected

UT Southwestern, Texas Health Resources form huge health care network
New Acquisition Concerns

• *Hospital Merger Mania*

• Multiple EMRs

• Multiple model “standards” and preferences
  • Five preferred physiological monitoring providers!

• Multiple service arrangements
  • If various arrangements are known beforehand!
New Acquisition Concerns

• **Cybersecurity**

• What does a hospital ask for in an RFI/RFP?
• Using a Common Vulnerability Scoring System (CVSS)?
• How does the supplier disclose vulnerabilities?
• How do you guarantee access to vulnerability fixes?

In Contracts with Device Vendors, Mayo Clinic Emphasizes Security
New Acquisition Concerns

• *Capital Planning and Budgeting Woes*

• Acute Care versus Community/ACO Health

• Telemedicine/telehealth/mHealth
• Wearable sensors
• BYOD and PCDs
• MDS2- Require It!

Personal Connected Health Alliance
New Acquisition Concerns

• Next Up.....

• Steve Juett - CallisonRTKL

• Tobey Clark – University of Vermont Medical Center

• Angie Mulinix – Minneapolis VA Health Care System
Thank You

Rob Maliff
Director, Applied Solutions

ECRI Institute

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rmaliff@ecri.org

AAMI Booth #
Medical Equipment Connectivity Acquisition

Presented by Steve Juett, PE
Introduction

- Clinical Engineer 35+ Years
- Consultant 15+ Years
- Complex Clinical Systems – Connected Medical Equipment (CME)
- Acquisition – Procurement Services
- Vendor and Client Neutral
Complex Clinical Systems

Acquisition Challenge

• Understanding the Task
  • Connecting the dots
  • Diverse Stakeholders
  • Making Connectivity Work
• Validating the Requirements
  • Confusing data and available information
CME Project Example

• Understanding - What am I Procuring?
Complex Clinical Systems

Validating for Levels of Connectivity

- Device / Room
- Service Line
- Across Service Line
- Hospital Sharing
- Community of Health Information
- Proactive Lifestyle Monitoring
Confusing Data and Available Information

Managing the Procurement Detail

• Vendor RFI/ RFQ/ RFP
  • File Types – Mixed Content
  • Physical Connection
  • Proprietary Communication
  • Network
  • System
Managing Complexity

- Process Brings Clarity
- Process Enables Informed Decisions
- Process Develops Priority
- Process Enables Success

### Technology Connection Report

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<th>Atta ID</th>
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**Room: Electronics, Hybrid OR**  
**Room#: C-161B**  
**Room Sign:**  
**Area/Phase: Phase 1**

Comments: OR18 Stryker router goes here

| 5470-015  |        | 1   | Power Supply, Uninterruptible (UPS)                                       | Stryker Communications (0100-224-409)       | D - Data                    | Available |
| POW0030   |        |     | Tripplite SMART1200XLHG                                                    |                                             |                             |           |
| 7673-005  |        | 1   | Router, Surgical Suite Integration                                         | Stryker Communications ( )                  | V - Video                   | Confirmed |
| RTR0014   | VIRO-01| O/V | SwitchPoint Infinity 3                                                     | Stryker Communications ( )                  |                             |           |
| 5655-015  | C279585 | 1   | Shelving, Wire, Wall, Double                                               | InterMetro Industries Corporation ((2x)SW43C/(2x)2124NC) | None                        | N/A       |
| SHL0585   |        |     | Super Erecta Post-Type Chrome 24W x 21D                                    | InterMetro Industries Corporation ( )        |                             |           |
Managing Complexity

- Results – Budget Forecasting
- Results – Smooth Acquisition

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<th>Clinical Integration Categories</th>
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Complex Clinical Systems

Summary

• CME Acquisition is COMPLEX!
  • Many Diverse Stakeholders
  • Attention to:
    • Technical Connection detail
    • Interfaces and software – Device and IT
  • Big Budget impacts
Thank You
Medical Device Integration: Acquisition
Focus on Request for Information and Replacement Planning

Tobey Clark, CCE FACCE
Technical Services Partnership
University of Vermont

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AAMI: Top Ten Medical Device Challenges

#1 - Managing devices on the network
#2 - Integrating data into the EHR
#4 - Cybersecurity
#7 - Wireless spectrum

ECRI: Top Ten Patient Safety Concerns

#1 - Health IT Configurations/and Organizational Workflow That Do Not Support Each Other

ACQUISITION MUST ADDRESS THE ISSUES!
Medical Device Integration: 
*University of Vermont Medical Center*

- Organization wide Philips Bedside monitors, central stations, telemetry access points, telemetry transmitters and associated components.
- Organization wide imaging systems.
- Organization wide B-D Alaris large volume infusion pumps.
- Organization wide endoscope cleaners
- Masimo pulse oximeters on Medical/surgical floors.
- Invasive Cardiology Cathlab, Evoked Potential diagnostic systems, and Pacemaker programmer systems.
- Non Invasive Cardiology EKG carts, Holter and stress test systems.
- Anesthesia Machines.
- Radiation Oncology planning and treatment systems.
- Dialysis Machines.
- Neurology EEG and Sleeplab systems
- Pulmonary function systems.
- Respiratory Ventilators.

*Also unidentified equipment in the Clinical Laboratory*
Critical Acquisition Step:
Request for Information

- Technical Standards Questionnaire
  - Purpose of this Document
  - Intended Audience
  - Introduction and Instructions
- Basic Information
  - Name of Organization/Company
  - Name of System
  - Functional Overview of System
  - Technical Overview of System
- Detailed System Information
  - Infrastructure
    - Servers
    - Disk Storage
    - Network
    - Why does it need to be conn...?
    - Desktop Client
    - Devices (printers, scanners, m...)
    - Telecommunication
    - Does the system communicate w...
  - Software
    - Architecture
    - Components
    - Web Environment
- Database
  - Architecture
  - Management System
  - Size and Configuration
  - Backup and Recovery
  - Updates and Patches
  - Schema
- Security
  - Architecture
  - HIPAA Compliance
  - PCI Compliance
  - Data Security
  - User Authentication and Acco...
  - Application Administration an...
  - Auditing
- Interoperability
  - Data Transfer
  - Interfaces
- Cloud and Hybrid System
  - Infrastructure
  - Policy
- System Maintenance
  - Support
  - Can you provide manuals on phy...
RFI Detail: *Networking Questions*

1. Describe the connection method between end users and supporting infrastructure; include required bandwidth and a network diagram.

2. Does the system require greater than 100 Mbps network bandwidth to the client or 1Gbps network bandwidth to the server? If so, please explain the requirements.

3. Are any network protocols other than TCP/IP required?

4. Do you use IPv6? If so, do you support dual-stack mode with IPv4?

5. Is an isolated network segment required for any servers or workstations associated with this system?

6. Does your system support load balancing? Do you have a preferred vendor?

7. Are there any requirements for wireless network connectivity for servers, workstations, or mobile devices associated with this system? If so, please describe.

8. If you require/support wireless connectivity, what forms of wireless security do you support (WPA/WPA2/WPA Enterprise, 802.11x)?

9. What wireless protocols do you support (802.11a/b/g/n/ac)?
Health Care Technology Life Cycle

Planning
- Budgeting
- Assessment
- Replacement

Management
- Education
- Compliance
- Safety
- Maintenance
- Disposal

Data Collection & Analysis

Deployment

Outcomes

Copyright Univ of Vermont
Technology Replacement

- **Quantitative Method**
- Analyze technology database for:
  - Obsolescence
    - Technological
    - Clinical
  - Cost-effectiveness
  - Safety and Reliability
  - Support
  - Condition
  - MDI capability
Equipment Database: 
*Network Integration*

- Will the device data go to the electronic health record?
  - 30+% of medical devices?\(^1\)
  - Legacy devices must be replaced or upgraded
  - I/O port
    - Analog or no output
    - Digital output translatable by middleware to EHR
    - HL7 output

\(^1\) Kaiser Permanente
Technology Replacement – When?

- When it fails at a critical time?
- When the physician returns from a conference and states the current technology is obsolete?
- When the department manager complains “*my equipment never works right*” at the capital budget meeting?
- When undergoing repair, it is found that parts and support are no longer available?
- *When you try to interface the device with the network and find that it will need to be replaced?*

**NOT! Need a plan for technology replacement!**
Medical Technology Acquisition: 
Emerging Process Considerations

Presented by Angela Mulinix, MS, CCE
Department of Veterans Affairs
Areas to consider during Acquisition

Cyber security

Strategic sourcing

Data analytics
Cyber Security

- VA-wide initiative to provide a safe and secure operating environment for networked medical devices that provide direct care to our nation’s Veterans.

- **Directive 6550 - Pre-procurement Assessment**
  - Conducted prior to acquisition of medical devices/systems
  - Medical devices/systems that will be connected to networks
  - Medical devices that store sensitive patient information
  - Multi-disciplinary technical review
  - Biomedical Engineering, Information Technology, Information Security, Privacy Officer, and Contracting
  - Ensure compliance with TJC requirements
Cyber Security

- Risk Analysis Process
- Medical Device Isolation Architecture (MDIA)
- Incident Reporting & Remediation
- Ongoing Medical Device Protection
  - NMDD - Networked Medical Device Database
  - WSUS - Windows service update system
  - Antivirus
  - Mobile media scanning
  - Patching policy
- End of life decommissioning
Interoperability

Number of Networked Medical Devices

- 2011: 34,438
- 2012: 
- 2013: 
- 2014: 
- 2015: 
- 2016: 81,000
Strategic sourcing

- Making plans, projections, and decisions based upon the life cycle of equipment

Method the VA uses:

- **Step 1:** Analyze current equipment
- **Step 2:** Develop equipment specific lifecycle models
- **Step 3:** Apply lifecycle model to equipment type
- **Step 4:** Align equipment acquisition schedules across VISN
- **Step 5:** Adjust schedule to effectively and practically distribute costs over time and two phase implementation
Data Analytics

• Use data from maintenance histories
  • Assess reliability
  • Safety
  • Use issues
  • Applications training
VISN 23 Digital Radiography (DR) Initiative
VISN-wide Evaluation, Implementation, and Optimization of State-of-the-Art Radiographic Imaging Technology

Results
- 23 Systems Implemented within 2 years
- Standardized Technology Across VISN
- Acquisition Cost Savings over $3.0 Million
- Consistent Image Production & Standardized Processing Algorithms across all Facilities
- Customized Applications & Physics Training
- 50% Reduction of Radiation Dose to Patients
- Increased Patient Throughput x2
- Images to Radiologist Almost Instantly
- High Level of Staff Satisfaction
- Collaborative Problem Resolution
- Consistent Integration to PACS
- Maintenance Efficiencies

Project AIM
Upgrade conventional radiographic equipment to digital radiographic at all facilities across VISN 23.

What is DR?
- Digital radiography process replaces the film and cassette used in conventional radiography system with a digital detector.
- The digital system provides clearer images of patient anatomy - very quick to radiologist.

Biomedical Expert Group
- Market Research - Product Demonstrations, Site Visits, RSNA Conference
- Consultant - Optimize Images, Physics Training

Establish Maintenance Program
- Continuous Protocol Refinement
- Corrective and Scheduled Maintenance

Implementation Team
Biomedical Engineering, Construction Engineers, Vendor Partner

Plan
- Project Management - Weekly Conference Calls
- Establish Implementation Timeline

Do
- Commission Implementation Team
- Evaluate Proposals - Clinical Function, Technical Specs, Price, Value - Order Equipment

Study
- Define Clinical and Technical Requirements

Competitive
- Procurement - Issue RFP, Obtain Vendor Proposals

Capital Investment
$10.2 Million
Equipment Cost: $8.5M
Construction Cost: $1.5 M
Consultant/Other: $200k
Thank You

I would like to publicly acknowledge the following contributors to this presentation:

Kurt Finke
Megan Friel
Jim Witting
Jennifer Gersten
Sub-Topic 2: Integrated Systems Support Considerations

Michael Fraii, Exec Director Biomedical Engineering, BWH
Roberto Torres, Jr., CE Manager, Cedars-Sinai Medical Center
Samantha Jacques, Director CE, Penn State Milton S. Hershey Medical Center
Integrated Support for Systems

L. Michael Fraai, MS, CCE
Executive Director Biomedical Engineering and Device Integration

BWH
BRIGHAM AND WOMEN’S HOSPITAL
Brigham and Women’s Hospital

- 793 Licensed beds
- 146 ICU beds
- Patient care network ~ 1600 devices
- 489 Telemetry beds
- 43 Operating rooms
- BMDI integrated into EHR system
BWH History going from Devices to Systems

Monitoring Device Integration Strategy – Inpatient

Patient Care Network
BWH History going from Devices to Systems

• ECG machines to ECG archival system
  o Results and Billing interfaces, now orders

• Fetal Monitor strip archival system

• Integrated video systems

• IV delivery platforms
  o Wireless connectivity
Providing Support for Clinical Systems

• Seamless for clinicians
• Multi-disciplinary teams
  o IS & Application teams
  o Multiple vendors
• Clinical competency
  o Workflow understanding
• Technical Competency
  o Knowledge and understanding
    o Device function
      ▪ Parameters & how it works
    o Device output
      ▪ Network, analog output
• Device Redundancy
• Troubleshooting across the BME domain
Integrated Workflow Support

Start

Clinician/department admin calls BWH Biomed

Clinician/Department Admin calls the IS Helpdesk

Clinician/Department Admin inputs request online

Ticket is opened in ServiceNow

Onsite BWH Biomed team takes 1st call: Troubleshoots issue

Determine if the support call requires vendor support

Onsite BWH Biomed team: Troubleshoots & determines escalation path (Call is reassigned to BWH CE)

NOTIFICATION Add PeC BMDI team via ServiceNow watch list

ESCALATION Add PeC BMDI team via ServiceNow ITASK

Establish a bridgeline for collaborative troubleshooting

ESCALATION PeC BMDI team includes other teams via ServiceNow ITASK, as needed

ESCALATION Determine if an all user update needs to be sent out

Contact GE (contact info needed)

Contact Nanthealth (contact info needed)

Contact OBIX (contact info needed)

Resolve issue and notify users

Close ticket/iTask in ServiceNow/TMS with resolution

End

Seamless process regardless of where the call originates there is the same outcome
How do you develop the skills?

• Device competency
  o Technical training on the device

• Device output
  o What is the output?
  o How does the device interface?
    o Network, Analog output

• Network fundamentals

• Integrated network

• Use of data flow
  o Help understanding
  o Troubleshooting tool
BWH Example

• Technical Training
  • Network basics
  • Data flow schematics
• Scenario based training
  • Use a clinical call to learn the skills to troubleshoot
Systems Data Flow

Connectivity Legend:
- MC Network
- IX Network
- IS Network
Example of a scenario

• Telemetry Scenario #2: Nursing staff call helpdesk due to tele patient data not populating in the patients flowsheet. Information on ticket states “Patient returned from being off-unit and telemetry data is no longer showing in their flowsheet”.

• Biomed Checkpoint: Demonstrate ability to check patient admit location in EHR. Once conflict identified (patient moved in EHR, but left admitted to old location in tele) move patient @ CIC and show data transfer over. Verify data showing in patients chart before leaving

• Follow-up Questions with Scenario: Did staff move patient @ central or discharge/re-admit. Make sure staff knows different approaches and implications with respect to data @ CIC/bedside monitor.

• Once patient moved, staff asks about pulling demographics to monitor/CIC. Also ask about data for last 10 minutes that was going into wrong patients chart.
  o Biomed Checkpoint: Demonstrate knowledge/ability of pulling ADT to the CIC.
  o Biomed Checkpoint: Identify data flowchart fix as non-biomed . Direct user to EHR analyst team (verify correct team this type of issue should go to).
Challenges

• Sustain knowledge of systems
  o As calls ↓
    o In addition to the other Biomed expectations

• Resources to develop, maintain, implement and track a training syllabus

• Staff turn over
Take Away

Teach me and I shall forget
Show me and I shall remember
Let me do it and I shall understand

~ Adapted from Benjamin Franklin
Thank You
A Collaborative Approach to Supporting Integrated Devices

Presented by:
Roberto Torres, Jr.
Manager, OR Clinical Engineering
Cedars-Sinai Medical Center
Cedars-Sinai Medical Center

- Established in 1902 and located in Los Angeles, CA.
- 886 licensed beds, Level I Trauma Center
- Expanding scientific and medical knowledge through research that benefits patients
- Educating healthcare professionals for the future
- Improving the health status of the community
- HIMSS Analytics Stage 7 facility
- Primary service area includes 3.3 million people
In close collaboration with clinicians, administrators, and other technology groups, Clinical Engineering and Device Integration (CEDI) promotes quality patient care through the appropriate and safe use of medical device technology.

Clinical Engineering and Anesthesiologists meeting to discuss the hardware mounting related to CS-Link Anesthesia Record implementation.

We strive to be a center of excellence for innovative and robust solutions that promote leadership in delivering healthcare related services.
Clinical Engineering & Device Integration (CEDI) Mission Statement

Darren Dworkin
S.V.P & CIO

Jennifer Jackson, Director

Roberto Torres, Jr, OR and Procedural Clinical Engineering

Curt Rodriguez, IP & OP Clinical Engineering

Vere Davis, Device Integration

(open), Device Integration
Cedars Sinai
Not All Our Heroes Practice Medicine

From the HIMSS Analytics Press Release:
"Cedars-Sinai is one of the most fully deployed and automated facilities we have encountered in the HIMSS Analytics Stage 7 program. With all of their progress on device integration, including fully integrated smart pumps, Cedars-Sinai has approached a new level of patient safety, even among stage 7 facilities."

- John Hoyt, executive vice president of HIMSS Analytics
Agenda

• Review a case study in supporting an integrated device system - Anesthesia Record in the OR’s
• The Challenge
• The Approach
• The Outcome
The challenge

• Deploy Anesthesia Record
  • Add a workstation, keyboard and mouse to an already crowded anesthesia device system. Total of 95 anesthesia machines.
  • Develop a cross-functional support solution.
  • Train anesthesiologists (approx. 180) and anesthesia techs (approx. 16)
The Approach

Device integration overview – understanding the path of the data.

Possible Trouble Spots
- Total malfunction
- Wire/sensor
- Power
- Configuration

General Technical
Anesthesia Machine
Vitals Data Aggregator
Data Processing/Interface Engine
Epic Bridges
Epic Anesthesia (EMR)

What happens at this stage?
- Single device
  Expired Desflurane = 4.8 L/min
- Multiple devices
  Expired Desflurane, BP, RR, Temp, ST
- Message Processing
  OBX[6][ST][593][4.8][19][ ][F][ ][201 31050050000]
- Message Translation
  OBX[6][ST][593] → FLO 593
- Front End Presentation
  Expired Desflurane = 4.8 L/min

Technical Possible Trouble Spots
- Total malfunction
- Connection
- Power
- Network
- Configuration
- Translation
- Network
- Server
- Configuration
- Application
- Network
- Server
- Configuration
- Application
- Workflow/Training
- Desktop
The Approach

• The Support Team

• Continuum was critical for success
• Implementation team members were retained in active roles
• Clinical Engineering Team
  – OR Clinical Eng
  – Device Integration Team
• Epic Optime/Anesthesia Team
• MD Champion, ad hoc collaborators
• Help Desk
• Epic Team (vendor)
• Ad-hoc resources from Desktop Engineering, Bridges, Systems Integration
Leveraging Clinical Engineering for in-OR issue triage

Success criteria:
- Leadership support
- Clear expectations
- Continuous training
- Clin Eng on-site
The Outcome

Devices integrated per machine:
- Philips monitor
- Anesthesia machine
- BIS monitor
- CCO monitor
- INVOS monitor
- Tangent workstation
- Neuron (as the data concentrator)

Total devices integrated/communication with EPIC – 490

In the first 3 months - total calls since go-live – 132
  - Tangent computer issues – 65
  - Neuron reset – 24
  - Server – 12
  - Neuron failure – 12
  - Damaged cables – 11
  - Operator Error – 8

A specific phone number was deployed to the end users for first call support and a quick reference card was installed on all anesthesia machines providing instructions on how to access device on/off/reset buttons.
The Outcome

- Clinical Engineering is able to respond faster to calls than the I.T. staff.
- Because the workstation was on an anesthesia machine the Clinical Engineering staff were seen as the responsible team for this new computer.
- Clinical Engineering staff have access to the read-only template in Epic.
- Our Clinical Engineers were taught how to resolve the most common issues to include user errors and navigating the application.
- This additional training allowed our Clinical Engineering team to resolve over 95% of calls related to this new application both from hardware and user sides.
- Supporting the application even at a limited capacity educated and empowered our staff and raised their confidence levels.
- Clinical Engineering is now seen not only as a hardware support team but a system support team.
- An unexpected outcome was that other Applications teams have reached out to us for support for their systems such as PACS and Imaging support.
- Collaboration is good for everyone.
Thank You

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Pre-Procurement Support Considerations for Integrated Systems

Penn State Health
Milton S. Hershey Medical Center

Samantha Jacques, PhD, FACHE
Equipment Lifecycle

Pre-Procurement Evaluations

Capital Planning/Project Planning

Testing and Installation

Preventative Maintenance (PM) and Repair

End of Life (Replacement) Planning

De-installation and Disposition
Normal Support Plans

SO, NOW WE HAVE ASCERTAINED WHO IS RESPONSIBLE....
Roadmap for Support Plan

- 4 W’s and H
- End User
- Technical

Roles Responsibilities
- People
- Process
- Technology
- Vendor Management

- Workflow Development
- Documentation

Scope
Support Plan
Getting Scope Understood

- Who, What, Where, When, How of system needs
- End User Scope – processes, regulatory requirements, business needs, support needs
- Technical Scope - Servers, Database, Interfaces, Hardware, Software, Security, Access, etc.
- Take-Away
  - Ideal State Workflows and Architecture Diagrams
Defining Roles/Responsibilities

• People
  • System Admin, IT Help Desk, Clinical Engineering, IT 2nd Tier Support, Vendor Support

• Process
  • Ordering supplies, add users, run reports, escalating issues, replaces hardware, downtime process

• Technology
  • Upgrades, Lifecycles, System Enhancements
Understanding Vendor Management

• Ultimately one owner for vendor management
  • Vendor negotiation
  • Project Management and Implementation
  • Contract Management (T’&C’s as well as $$)
  • Support Management
  • Vendor Scorecards
Draft Support Plan

- Document History and Revisions
- System Application Overview/Vendor Contacts
- Technical Information
  - Server/Appliance Overview
  - Database Overview
  - Interface Overview
  - VPN/Firewall Overview
  - Network Overview
  - Workstation Overview
  - Application Overview
  - Storage Overview
  - Biomedical Equipment Overview
- Technical/Application/Architecture Diagrams
- Data Flow Overview
- Roles/Responsibilities
  - IT Service Areas
  - Clinical Engineering
  - End User
  - Vendor
- Support Processes
- Knowledge Articles
- Sign Offs
Thank You

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Q&A

Come to the microphone OR
Submit questions to:

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Closing Remarks & Thank You!

...And thanks again to our breakfast sponsor: