Biomedical Device Integration into an Electronic Health Record
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Conflict of Interest

L. Michael Fraai, M.S, C.C.E.
Has no real or apparent conflicts of interest to report.
Agenda

• Overview of the Brigham and Women’s Hospital (BWH)
• Scope of BWH’s Biomedical Device Integration
  • Planning stages
  • Project testing stages
• Support
• Lesson learned
Learning Objectives

• Outline of a collaborative Biomedical Device Integration process
• Application of the methodology used for Biomedical Device Integration for EHR implementation
• Use of proposed template for EHR implementation
• Outline of the critical steps during the planning stages for Biomedical Device Integration with EHR implementation
STEPS: Treatment/Clinical

Devices being integrated
Increase in number of devices supported

Manual data entry of vital signs
Decrease in data omissions due to automation
Brigham and Women’s Hospital

- 793 Licensed beds
- 146 ICU beds
- 489 Telemetry beds
- 43 Operating rooms
Brigham and Women’s Hospital

• National leadership in patient care, quality improvement and patient safety initiatives, and its dedication to research, innovation, community engagement, educating and training

• BWH employs ~16,000 people; 3,000 physicians, fellows and residents; more than 1,000 researchers and 3,113 nurses

• In 2011, performed the first full face transplantation in the US

• Inpatient admissions totaled approximately 46,000

• Biomedical Engineering supports ~26,000 patient care devices

• BWH went live on 05/30/15 with one of the largest EHR installations in the US that included Biomedical device integration
Partners eCare Goals

• One Patient, One record, One Bill
• ↑ Consistent (standardized) processes
• One system integrated across the enterprise
  – 2 Academic Medical Centers
  – 17 Community hospitals
• Project completed in phases
• Intricate Governance structure
  – Enterprise decisions
  – Entity provided subject matter experts and had some autonomy
Biomed Device Integration Scope

• Goal
  – Standardized approach that can be scaled across the enterprise
• Brigham and Women’s Hospital

<table>
<thead>
<tr>
<th>Patient Care Area</th>
<th>Device Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>OR</td>
<td>Anesthesia Machines, Physiologic Monitors</td>
</tr>
<tr>
<td>ICU</td>
<td>Physiologic Monitors, Ventilators</td>
</tr>
<tr>
<td>ED</td>
<td>Physiologic Monitors, Ventilators</td>
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<td>L&amp;D</td>
<td>Fetal Monitors, Physiologic Monitors</td>
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<td>Procedural Units</td>
<td>Physiologic Monitors</td>
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<td>Inpatient (Non-ICU)</td>
<td>Physiologic Monitors</td>
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</table>
Planning stages

• Leverage our device integration strategy

• Develop a project plan that can be integrated across the hospital and enterprise as a master project plan

• Determine the scope of what will be needed
Leverage the Device Integration Strategy

Clinical Informatics (Nursing, Physician and Anesthesia)

- Identify team of RNs, MDs and Biomed to work on the process
- Identify clinical parameters for documentation in EHR (leverage ACD & PIMS work)
- Determine workflow impact relative to medical device integration from EHR
- Provide solutions for work flow changes needed due to EHR architecture

Clinical need mapping on Biomedical patient care technology

- Identify the devices relative to the parameters
  - Inventory & document manufacturers, models and software versions
  - Determine device output and connectivity method
  - Identify gaps between clinical needs and technology capabilities
  - Determine cost impact to integrate parameters not available on current devices

Develop middle ware approach/strategy

- Develop a decision matrix and cost comparison to determine approach
  - Identify potential areas not covered with current connectivity
  - Infrastructure
  - Identify middle ware to use
  - Develop cost estimate to remediate gaps
  - Identify additional workflow impacts based on middleware solution

Infrastructure Plan

- Identify infrastructure needs:
  - Cabling
  - Power
  - Network hardware
  - Mounting
  - IS connectivity
  - Patient care network
- Develop a project timeline leveraging low census periods

Middleware selection

- Collaborative work with Biomed, EHR and IS for selection
- Identify potential long-term implication
- Determine the specifications needed
- Select middleware to use
- Develop cost estimate to remediate gaps
- Address potential gaps in clinical need

Middleware installation & device connectivity corrections

- Network provisioning needs:
  - Network requests (firewalls, routers etc)
- Purchasing process to address the gap analysis performed (software upgrades and replacements)
- Perform (potential) software upgrades for connectivity
- Perform (potential) device replacements

Testing

- Develop the testing scenarios based on identified workflow
- Scenario validation with a broader clinical group
- Technical testing of the system
- Technical testing based on the scenarios

Validation and Verification Testing

- Develop solutions to address unanticipated testing outcomes
- Verify accuracy of the system
- Technical testing to address the gap analysis performed (software upgrades and replacements)

Clinical testing of the scenario and work flow implications

Identify unintended outcomes

- Develop solutions to address unanticipated testing outcomes

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Process to build this plan

- Develop a strategy that meets the hospital’s evolving clinical needs and goals
- Develop a multi-year vision to complete the project
- Understand the clinical drivers and the hospital’s strategic vision
- Technology understanding
  - Map clinical needs on the available technology
- Plan for standardization
- Build relationships (Vendors, clinicians, contractors)
- Collaborate with IT
- Plan for scaling and continuous improvement
Project plan

• Timelines aligned with:
  – EHR Vendor
  – Integration Partners
  – BWH
  – Partners

• Thorough, robust and complete specification planning
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Stages of the EHR Biomed Device Integration

• Project Cost estimate
• Infrastructure preparation
• Make Model Variable (MMV) testing
• Room readiness
• Production readiness
• Production Validation

➢ There are more testing stages involved for interfaces
Project estimate

• Gap analysis of current vs. future state
  – What is in the inventory?
    • Make, model, software version
  – Requirements to standardize devices in project scope
    • Can the device be upgraded?
  – BMDI Resource calculation
<table>
<thead>
<tr>
<th>Item</th>
<th>Device Type</th>
<th>Qty</th>
<th>Time (Hrs)</th>
<th>Total Time</th>
<th>Now 9/35</th>
<th>Later</th>
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Total time to get devices EHR ready:

<table>
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<tr>
<th>Location</th>
<th>Total Time</th>
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<tbody>
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<td>BWH</td>
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<td>850 Boylston</td>
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<td>FXB</td>
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OR Areas
Inpatient & other areas

Assumptions:

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
<th>Hrs/wk</th>
<th>Total hrs/wk</th>
<th>Duration</th>
<th>Time to complete</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1 Internal group&lt;br&gt;3 technicians for 10hrs/wk, 2 CE interns for 20 hrs/wk, 1 CE resource for 20</td>
<td></td>
<td>108.00</td>
<td>18</td>
<td>4.59</td>
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<tr>
<td>2</td>
<td>1 Internal group + additional 2 dedicated (contract) BMETs full time</td>
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<td>188.00</td>
<td>10</td>
<td>2.64</td>
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<td>3</td>
<td>3 contract BMETs backfill</td>
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<td>120</td>
<td>16</td>
<td>4.13</td>
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<tr>
<td>4</td>
<td>6 Internal BMET using OT</td>
<td></td>
<td>90</td>
<td>21</td>
<td>5.51</td>
</tr>
</tbody>
</table>
Project estimate

- Infrastructure cost
  - Cabling
  - Power
  - IS closet work
  - Mounting
- Middleware cost
- Vendor configuration cost
- BME resources
  - In-house, OT, backfill
High level architecture
NOTE: 4 High availability spare Gateway not reflected
Make Model Variable Testing

• Parameter mapping for interfaces into EHR

• Does the make and the model generate the variable output in the format that is expected or desired?

• Map the values into EHR through the middle ware

• *MMV Testing through the stages*
Make Model Variable Testing stages
Room Readiness

• Each location is EHR ready
  – Monitor model
  – Software version
  – Network and redundant network connection
  – Power
  – Mounting
### Device specific time allocation

<table>
<thead>
<tr>
<th>Task</th>
<th>Time</th>
<th>Task</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monitor Software Upgrade</td>
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<td>Unity ID check or replace mounts</td>
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</tr>
<tr>
<td>Unity ID function check</td>
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<td>Verify monitor configuration (Unit &amp; Label)</td>
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</tr>
<tr>
<td>Unity ID software Upgrade</td>
<td>0.25</td>
<td>Misc. tasks (Gowning, travel, cover up unused jacks, label jacks &amp; documentation)</td>
<td>0.65</td>
</tr>
<tr>
<td>Unity ID configuration</td>
<td>0.10</td>
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<table>
<thead>
<tr>
<th>Device Type</th>
<th>Task</th>
<th>Time (Hrs)</th>
<th>BMET</th>
<th>Non Technical</th>
<th>Now</th>
<th>Later</th>
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<tr>
<td>Solar/B850</td>
<td>Software Upgrade</td>
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<td></td>
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<td></td>
<td>Unity ID function check</td>
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<td>Unity ID software Upgrade</td>
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</table>
Production readiness

• One parameter from each location through all the integration stages and into the EHR test environment
  – Device mapping is being tested
  – Configuration testing
  – Test ADT in-bound (bed mapping)
  – Labeling
• Planning around a functioning hospital
  – Census!
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<th>Mon</th>
<th>Tues</th>
<th>Wed</th>
<th>Thurs</th>
<th>Fri</th>
<th>Sat</th>
<th>Number of beds</th>
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<th>Days needed with 2 teams</th>
<th>Best days</th>
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Production Validation

• Test environment moved to production environment
• Test to ensure that migration was successful
• Validate critical areas
• Repeat test of areas that failed during production readiness
EHR Support

- Build a collaborative plan that illustrates how support will be handled between BME, IS and application teams
- Seamless call response for clinicians regardless of where the call starts
  - BME
  - IS
- Call triage schematic
Seamless process regardless of where the call originates, there is the same outcome.
BME Training

• ↑ focus from device to system approach
• Some concepts are abstract
  – Servers are not on-site
  – Pictures or even bring the staff to the location
• Use of schematic diagrams
• Allow staff to participate in the clinical training
  – Hear questions that will be asked
• Scenario based training
Schematic Diagram

- Correct

  Monitor
  Monitor Name: PACU-01

  Gateway
  PACU-01 = BWHPACU_01

  Integration Engine
  BWHPACU_01

  EHR
  BWHPACU_01 = MON 1012 BWH

- Incorrect

  Monitor
  Monitor Name: PACU-01

  Gateway
  PACU-01 = BWH PACU_01

  EHR
  BWHPACU_01

  EHR
  BWHPACU_01 = MON 1012 BWH

From: Prakhar Kapoor
Example of 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.
  - **Biomed Checkpoint**: Demonstrate knowledge/ability of pulling ADT to the CIC.
  - **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).
STEPS: Treatment/Clinical

Following a methodical process

Reduces variability and project timeline creep
Lesson Learned

• Importance of documentation along the process
• Develop a thorough and methodical approach
• Project plan and timelines
• Cost estimates
• Collaborative approach
  – EHR vendor
  – Information Systems and Biomedical Engineering
  – Application teams
  – Clinicians (MDs and RNs)
Questions

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