Patient Safety and Interoperability: Are We There Yet?

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and
CMIO  Pascal Metrics
October 2, 2012
A Patient Safety Interoperability Case

69 year old women admitted for elective colon resection for Divetriculi

2 days Post op she develops pneumonia and is transferred to the ICU

On the second ICU day the patient suffers a prolonged period of unrecognized hypotension and is ultimately found to be septic

On review of the case a malfunction in the bedside monitor/EHR Interface led to an inaccurate blood pressure reading in the EHR blood pressure display
Lessons from a Recent Recall

Posted by William Hyman on Dec 18, 2011 in connectivity, Patient Safety, Standards & Regulatory | 0 comments

A recent Class I recall (not pictured) of a medical monitor with a hospital network connected central station stimulating some generalities about software, “fixes”, and connectivity. (Class I recalls are defined by the FDA as a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.) The use of the product in question was given as:

- a networked solution system used to monitor a patient’s vital signs and therapy, control alarms, review Web-based diagnostic images, and access patient records. The number of monitored vital signs can be increased or decreased based on the patient’s needs.
Before the 9/11 attacks, interoperability was not high on Washington’s agenda. A little-noticed federal program had studied the issue, recommending a handful of “best practices,” and the few bureaucrats who took an interest in the problem worked without much encouragement.

“My boss said, ‘If that’s what you want to work on — interoper … whatever it is — go ahead,’” recalls David Boyd, who now heads a Department of Homeland Security division focused on improving communications. “It was at a meeting three years later that he finally said, ‘I get it. This is kind of important.’”
Health IT and Patient Safety:
Building Safer Systems for Better Care
Committee membership

GAIL L. WARDEN (Chair)
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PHILIP SCHNEIDER
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Medical Associates Clinic and Health Plans
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*Resigned from committee March 2011
The New Challenge: Measuring Harm

Department of Health and Human Services
OFFICE OF INSPECTOR GENERAL

15,000 Medicare beneficiaries per month experience adverse events contributing to death

State with Safety Program Flat-line Improvement

The NEW ENGLAND JOURNAL of MEDICINE

HEALTH AFFAIRS
The Policy Journal of the Health Sphere
Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Selected Counties

Daniel R. Levinson
Inspector General

December 2008
OEI-06-08-00220
### Sample for National Incidence Study

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>October 2008</strong></td>
<td>• Sample month</td>
</tr>
<tr>
<td><strong>999,645</strong></td>
<td>• Medicare beneficiaries discharged from acute care hospitals</td>
</tr>
<tr>
<td><strong>780</strong></td>
<td>• Sample Medicare beneficiaries</td>
</tr>
<tr>
<td><strong>661</strong></td>
<td>• Hospitals represented</td>
</tr>
</tbody>
</table>
Incidence Rates – of all beneficiaries

- **13.5%**
  - Adverse Events (NQF, HAC, F–I Level)

- **0.6%**
  - NQF Serious Reportable Events

- **1.0%**
  - Medicare Hospital-Acquired Conditions

- **13.5%**
  - Temporary Harm Events (E Level)
Is safety improving in the US?

SPECIAL ARTICLE

Temporal Trends in Rates of Patient Harm Resulting from Medical Care

Christopher P. Landrigan, M.D., M.P.H., Gareth J. Parry, Ph.D.,
Catherine B. Bones, M.S.W., Andrew D. Hackbarth, M.Phil.,
Donald A. Goldmann, M.D., and Paul J. Sharek, M.D., M.P.H.
Results-Demographics

• Hospital descriptors
  – AHA size: 2 Small; 3 Medium; 5 Large
  – 8 Urban vs 2 Rural
  – 10 hospitals--3 Teaching vs 7 Non-teaching

• 2341 patient records from 5 year period
• 588 harms detected
  – 25 / 100 admissions
Slope: 0.98 (95% CI 0.93, 1.04  p = 0.47)

Landrigan et al., New Engl J Med 2010; 363: 2124-34
Global Trigger Tool’ Shows That Adverse Events In Hospitals May Be Ten Times Greater Than PreviouslyMeasured

ABSTRACT Identification and measurement of adverse medical events is central to patient safety, forming a foundation for accountability, prioritizing problems to work on, generating ideas for safer care, and testing which interventions work. We compared three methods to detect adverse events in hospitalized patients, using the same patient sample set from three leading hospitals. We found that the adverse event detection methods commonly used to track patient safety in the United States today—voluntary reporting and the Agency for Healthcare Research and Quality’s Patient Safety Indicators—fared very poorly compared to other methods and missed 90 percent of the adverse events. The Institute for Healthcare Improvement’s Global Trigger Tool found at least ten times more confirmed, serious events than these other methods. Overall, adverse events occurred in one-third of hospital admissions. Reliance on voluntary reporting and the Patient Safety Indicators could produce misleading conclusions about the current safety of care in the US health care system and misdirect efforts to improve patient safety.
**EXHIBIT 4**

Adverse Event Detection, By Severity Level And Hospital

<table>
<thead>
<tr>
<th>SEVERITY LEVEL</th>
<th>IHI Global Trigger Tool</th>
<th>AHRQ Patient Safety Indicators</th>
<th>Hospital voluntary reporting system</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>204</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>F</td>
<td>124</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>G</td>
<td>8</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>H</td>
<td>14</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>I</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>354</td>
<td>35</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HOSPITAL</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital A</td>
<td>161</td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Hospital B</td>
<td>92</td>
<td>13</td>
<td>3</td>
</tr>
<tr>
<td>Hospital C</td>
<td>101</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>354</td>
<td>35</td>
<td>4</td>
</tr>
</tbody>
</table>
Features of safer health IT

Health Professionals, Health Care Organizations, Vendors

Features of Health IT
- Workflow
- Usability
- Balanced Customization
- Interoperability

Design and Development
- Software requirements and development
- User interface design
- Testing
- Deployment
- Maintenance and upgrade

Implementation
- Planning and goal setting
- Deployment
- Stabilization
- Optimization
- Transformation

Safer Systems for Health IT

FIGURE 4-1
Interdependent activities for building a safer system for health IT.
<table>
<thead>
<tr>
<th>Aspects of Interoperability</th>
<th>Definition</th>
<th>Impact on Patient Safety</th>
</tr>
</thead>
</table>
| Ability to exchange the physical data stream of bits (Hoekstra et al., 2009) that represent relevant information | Allows for electronic communication between software components | Software components that cannot communicate with each other force users to reenter data manually, which  
- Detracts from time better used attending to patient safety and  
- Increases opportunities to enter misinformation |
| Ability to exchange data without loss of semantic content | Ability for software system to properly work when modules from different vendors are “plugged in” | The loss of meaning in received data compromises patient safety |
| Accept “plug-ins” seamlessly | Semantic content refers to information that allows software to understand the electronic bits |  
- The inability to use multiple modules within one organization decreases the likelihood that the user can provide their patient information to another health IT product  
- Lack of “plug-in” interoperability means that the user does not have the ability to select modules from multiple vendors that may perform a specific function more safely |
| Display similar information in the same way | - Different health IT products display similar information in similar ways  
- Systems are consistent in matters such as screen position of fields, color, and units | When information is displayed inconsistently across organizations, the user must reconcile the different representations of the information mentally, which  
- Requires an increased cognitive effort that could be better used toward safe care and  
- Increases the chance that a user may make a mistake |
BOX 4-2
Potential Guidelines for Safe Interoperability

The committee believes guidelines for safe interoperability are needed, such as the following:

- All health IT products should be able to export data in structured and standard formats, ready for use in other modules or systems, without loss of semantic content.
- All health IT products should provide their documentation without fee and in an easily read form. All products should publicize their adherence to relevant standards.
- All health IT products should be able to display imported data in a way compatible with data generated internally, so that users need not exert additional mental effort to deal with data arriving from other software packages.
- Use of standards for data representation should be strongly encouraged, as should support for both the completion of important standards still being developed, such as the RxNorm drug nomenclature effort at the National Library of Medicine, and the adoption of standards which exist but lack adequate adherence, such as SNOMED (Systematized Nomenclature for Medicine).
Patient Safety: Achieving A New Standard of Care

Institute of Medicine Committee on Data Standards for Patient Safety
November, 2003
Recommendation 3

**Federal Leadership for Data Standards**

- Congress should direct, authorize and fund HHS to lead and maintain a public-private partnership for the promulgation of data standards for patient safety:
  - CHI should work with NCVHS to identify data standards for adoption and gaps needed to be filled
  - AHRQ and NLM and others:
    - Provide administrative and technical support to CHI/NCVHS
    - Provide financial support and oversight for standards development activities
    - Ensure development of tools to implement data standards
    - Coordinate activities, maintain clearinghouse
  - NLM responsible for mapping and distributing terminologies
Recommendation 4

Work Plan for Standards Development, I

- Accelerate development and adoption of patient safety data standards:
  - Clinical data interchange standards
    - Incorporate CHI standards (HHS, VAH, DoD) into contracts and regulatory requirements
    - AHRQ support accelerated completion of:
      - HL7 version 3 (within 2 years)
      - CDA specifications and implementation guides
      - Analysis to address unique health identifier for individuals
Recommendation 4

Work Plan for Standards Development, II

- Clinical terminologies
  - AHRQ should support creation of an integrated, non-redundant core terminology set that includes patient safety requirements
    - Begin with 20 IOM priority areas
  - NLM should provide mappings from existing terminologies to core terminology set
  - NLM should accelerate completion of RxNorm
Recommendation 4

Work Plan for Standards Development, III

- Knowledge representation
  - NLM should support development of standards for evidence-based knowledge representation
  - AHRQ, NIH, FDA, and other agencies should support development of generic guideline representation model to facilitate use by EHR decision support tools
NQF HIT Critical Paths: Patient Safety Technical Expert Panel

Conference Call/ Web Meeting
July 20, 2012
Background

Critical Paths Project

Patient Safety

- **Scope** focused on “acute care infusion devices”
  - 90% of hospitalized patients receive intravenous IV medications*.
  - 35% to 60% of adverse drug events involve pumps and the majority are the result of incorrect programming*.

- **Goals**
  - To assess the readiness of electronic data to support acute care infusion device quality reporting
  - To recommend actionable steps to address gaps and barriers.

- **Future State**: Integrate Unique Device Identification (UDI) and associated meta-data into existing quality measurement methods using point of care data capture within electronic systems

* Enhanced Notification of Infusion Pump Programming Errors, Medinfo 2010, Evans, Carlson, Johnson, Palmer and Lloyd
Patient Safety TEP: End to End Intravascular Infusion System

* Devices with static information only

& Devices that produce and manage information
Workflow
Fully Automated and Integrated IV Interoperability

Order placed in CPOE
- Data captured: Medication, rate, dose, route, concentration, volume to be infused, frequency

EHR combines all data that can be queried by clinicians and patient safety initiatives in near real time
- Alert data, patient information, drug information, infusion information (rate, route volume, frequency), nurse ID, pump ID, vital signs (including O2 saturation, BP, HR), patient location, infusion time stamps (start/stop, rate changes)

IV Interoperability Workflow and Data Capture

Reviewed by pharmacist
- Pharmacist validates order in EHR or pharmacy system

Bedside verification
- Pump user scans barcode of: patient, drug, IV pump and channel (if an infusion), nurse ID
- Patient values (e.g., location)
- Patient location
- Verifies 5 Rights and pump ID

Pump captures and sends data to EHR:
- Time of infusion, start/stop (log certain stop infusion codes)
- Drug, dose, rate (current and previous), concentration, volume to be infused, infusion duration, patient weight
- Alarm data: soft or hard, how many times limit/dose intended is the value programmed, what was initially programmed and what was it changed to, over-rides, rationale for over-rides, clinician ID

Pump programmed and validated by nurse:
- BCMA/EHR pushes orders to pump and programs drug name, volume TBI, dose, rate, bag #, concentration, infusion duration, weight of patient
- Pump matches order with drug library limits
- Nurse validates pump parameters and confirm

Pump sends alarm data including source, priority, patient, location, etc. to a secondary alarm system (e.g., a paging or system that that communicates the alarm to clinicians)
The interoperability at the user level problem: Each health IT vendor has its own “look and feel” and individual implementations are customized so that each facility has unique features. Many health professionals work in more than one facility and encounter these different products on a regular basis.

Is it possible to make health IT interoperable at the user level so that clinicians moving from one facility to another do not have to learn a new way of doing things each time? Can systems be designed so that clinician profiles developed in one system can be used in another? What are the consequences of having every implementation be different from every other implementation?
IOM – Improving Safety Requires a Learning System Built from a Sociotechnical Approach

- Safety is a characteristic of a sociotechnical system
- System-level failures occur almost always because of unforeseen combinations of component failures

**FIGURE 3-1**
Sociotechnical system underlying health IT-related adverse events.

SOURCE: Adapted from Harrington et al. (2010), Sittig and Singh (2010), and Walker et al. (2008).
Questions?

Comments