Using Integrated Clinical Environment Data for Health Technology Management

Tracy L. Rausch\textsuperscript{a}, Thomas M. Judd\textsuperscript{b}

\textit{Abstract}— Ten years ago the authors presented \textit{The Development of an Interoperable Roadmap for Medical Devices}.\textsuperscript{1} The premise was that interoperability between devices and electronic medical records (EMR) is essential to developing higher quality, safer, and more efficient healthcare delivery. An analysis of a large integrated delivery system’s medical devices and EMR was conducted to demonstrate this potential. Successful medical device integration was believed to be important to enable future care-delivery processes and reduce the cost of health technology management (HTM).

Since publication of the initial paper, the utilization of medical device data is starting to provide the granularity necessary to improve quality and completeness of EMRs. Adding contextual metadata has the potential to enable improvements in patient safety, quality, and operations and logistics (O&L, including HTM). Utilizing the Integrated Clinical Environment (ICE)\textsuperscript{2} architecture and data model, these data have the potential to provide detailed analysis of adverse events.

Therefore, the questions to be asked must include: What are the benefits of interoperable medical device data? How will the data be used? How do we use this data to contribute to the goal of developing a Learning Healthcare System?

\section{I. Introduction}

When this initial paper was presented EMR (and EHR) implementations were in their infancy. The promise of what capabilities EMRs could be provide was still uncertain. The initial paper discussed systems in healthcare but still focused primarily on device-to-device and device-to-EMR / EHR communication. Over the past ten years of research and evolution in this space, many of the technology gaps that are required to achieve the vision articulated in the initial paper have evolved.

Current health IT and medical device solutions fall short of providing the technical capabilities necessary create a learning healthcare system. A Learning Healthcare System (LHS)\textsuperscript{3} is defined as follows: to generate and apply the best evidence for the collaborative (and personalized) healthcare choices of each patient and provider; to drive the process of discovery as a natural outgrowth of patient care; and to ensure innovation, quality, safety, and value in healthcare.

A LHS must enable decisions utilizing data that is collected in the hospital or other care delivery environments. Health systems must choose technology solutions that are best in breed to implement heterogeneous ‘systems of systems’ continually evolving to meet changing technologies and needs. Data acquisition and decision-support technology solutions must be open and modular to enable iterative contributions by the healthcare community. Modularity allows even large health systems the agility to make improvements once the data is analyzed and improvements are identified.

Well specified, as well as contextually complete bedside data, is necessary for the development of a LHS. The data necessary extends beyond infrequent periodic documentation in the EMR, to hospital O&L data, and automation to create improved safety. [The bedside data as outlined is not EMR / EHR data per se, but the interaction with existing EMR / EHR communication protocols / standards such as HL7 CDA, HL7 FHIR, ISO 13606, or openEHR, is implied. The bedside data is bi-directional with the EMR; the EMR data is a subset of the data that is required.]

An App which monitors patients that are high risk for opioid overdose could enable an infusion to be paused, and a multi-source (smart) alarm to be enunciated if a patient has respiratory depression. Other examples include: (1) a real time O&L dashboard which allows for routing of new patients to the hospital with appropriately available equipment; and (2) long term modeling of ICE data which includes diagnoses and procedures, plus devices and supply utilization based on accurate historical data, for more efficient supply chain and capital equipment purchasing.

The data required for a LHS must be complete and accurate. In order to achieve that goal, the data collection technologies must integrate seamlessly, be automated and continuous. The data that is collected from an ICE will be required to be used for various functions simultaneously and therefore is required to be open and contextually complete.

\section{II. Health Technology Management}

HTM historically had various functions in the clinical environment such as maintaining the fleet of medical devices in the hospital, adverse event and medical device failure investigations, and equipment maintenance. HTM personnel now work closely with and provide technical expertise to hospital departments of Quality, Safety, and Nursing. HTM has evolved over the past 10 years as it has become more responsible for interfaced / integrated medical devices (MDI) and have become responsible for clinical system design, usability, and maintenance. Therefore, the benefits of HTM for a data driven healthcare system are profound.

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HTM is not limited to, but often has responsibilities to:
- Evaluate and determine MDI requirements
- Clinical systems design
- Device surveillance of all devices in inventory
- Device corrective and preventive maintenance (PM)
- Clinical staff training
- Tracking device recalls
- Investigation of device-related adverse events

### III. ICE ARCHITECTURE

The ICE Architecture is a functional architecture which was defined in 2009 in ASTM standard F27613, see Figure 1. This standard outlines several areas of requirements that are necessary to gather complete and contextually rich clinical data. An ICE system can enable an open platform to create interoperable systems of devices and applications (Apps). It is important to note that the ICE standard did not specify one data communication standard but provides examples of various standards that will be required to create an ICE. One key piece of the ICE Standard calls for data logger functionality similar to a black back recorder for forensic analysis. The ICE architecture is scalable (one ICE per patient) and the combination of multiple ICEs provides complete, well specified, as well as contextually complete bedside data for an entire hospital system.

One key component of the ICE that was not defined in the standard is an ICE Data Model. This model is emerging but, it is important to know that interoperability cannot exist without an effective data model. This model links together physiological data with clinical context. It ties the relationships of various types of data together to tell a story. It is a key finding in the research that sources of data are unaware of the intended use of the data and therefore must provide enough metadata to ensure the data is usable for future applications. The ICE data model’s foundation leverages the fact there is one ICE per patient, which enables a patient-centric organization of data. The reason for basing the foundation with the patient is that the patient is the one component of the ICE system that - by definition - will be always present within the ICE. In contrast, a patient monitor or therapeutic device may not be used at every patient encounter.

### IV. ICE AND HTM

The subset of data from existing medical devices - that have been transformed utilizing translation tables to comply with IEEE 11073-10101, 10101a and 10201 and additional non-device data components - are in compliance with the data model that has been created. According to the ICE standard, these devices are considered model compliant devices. Although there is still additional information which is required from the devices, we can begin to see the benefits of the ICE architecture in HTM. Additional standards are used in the model for the collection of non-device data such as diagnosis (SNOMED CT^4) and clinical activities (ISO 18104^5).

### V. METHODS

The DocBox ICE platform was used to automatically collect data on patients as part of regular medical care. Data was collected at Medanta the Medicity in Gurgaon, India [http://www.medanta.org/]. Clinical staff added devices and patients to the system and logged in and out as part of the normal clinical documentation. The data model was incorporated into the development of DocBox’s ICE platform and creation of DocBox’s platform Apps^6. Cardiac ICU data was continuously acquired by an ICE platform and transmitted every few minutes to a Cloudera Hadoop cluster. The data was then analyzed for various operations metrics related to HTM. The preliminary report of the findings of this data will be used to provide examples of what is possible within an ICE and what is can provide to HTM to enable data-driven decision making.

### VI. RESULTS

Pilot data was collected from 2 beds over 6 days. This pilot is ongoing as of January 2016. See Figures 2-4.

#### Hours of Device Use by Device Type

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventilator</td>
<td>124.4</td>
</tr>
<tr>
<td>Patient Monitor</td>
<td>84.9</td>
</tr>
<tr>
<td>Infusion Pump</td>
<td>72.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>281.9</strong></td>
</tr>
</tbody>
</table>

Figure 2: Device Hours by Type for 7 days for one bed in the cardiac ICU

#### Bed/Manager

<table>
<thead>
<tr>
<th>Bed/Manager</th>
<th># of Unique Devices</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICE Manager 31</td>
<td>11</td>
</tr>
<tr>
<td>ICE Manager 32</td>
<td>6</td>
</tr>
</tbody>
</table>

Figure 3: Unique Device Count per bed
VII. CONCLUSIONS

The results of analysis of the data over 6 days showed that we could evaluate how many devices were utilized at each bed (Figure 3) and the unique ID of each of these devices (Figure 4). As a result, we can document device utilization by care unit, patient procedure, and patient condition because the information is contained in the ICE data model. This information can provide data on hospital device utilization resulting in more precise capital equipment planning that could provide substantial savings in capital equipment and life cycle costs. The results of this study are preliminary and quantification of these numbers will be generated after additional data is achieved.

Device utilization hours can be tracked per specific device ID. This enables targeted PM to be completed on devices that are used most frequently. This can reduce the workload on the Biomedical Equipment Technicians (BMETs) on the HTM staff, allowing them to do more important tasks or support more devices. Usage data could also explain why some devices are requiring more frequent repairs.

These preliminary results demonstrate that acquiring ICE-based, contextually rich, time-synchronized data enables rich HTM analysis.

It is anticipated that future data will be analyzed to develop predictive HTM models. For example, if a hospital is planning to open a new ICU in order to support a specific number of surgical procedures, ICE data could be utilized to analyze the anticipated type of procedures and capacity to determine how much of each type of equipment to buy. This would be far more accurate than the usual method of “how much did we buy before?”

Utilizing ICE data to develop data-driven decision making is only a portion of the development of a LHS but is a key to the development of a smarter, less expensive, higher quality system through advances in HTM.

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REFERENCES