The Development of an Interoperable Roadmap for Medical Devices

Tracy L. Rausch [a], Thomas M. Judd [b]

Abstract-**It is believed that *interoperability* between medical devices and electronic medical records (EMR) is one key to developing a system of higher quality, safer, and efficient healthcare delivery. Interoperability speaks to either wireless or hard-wired streaming of two-way patient and related data between devices and EMRs. An analysis of a large integrated delivery system's medical devices and EMR was conducted to demonstrate this potential. This integration has significant impact on future care delivery processes and cost of health technologies involved.**

I. Introduction

Technology has been used to reduce error and increase efficiency in every industry. Why has the integration of technology become so complicated in the medical industry?

Healthcare focuses on quality of care, providing the best care possible for patients, at the most appropriate cost. With a focus often solely on the clinicians and patients, technology historically has been an after-thought. As healthcare industry moves into the age of electronic medical records (EMR), this is clearly changing as the integration of medical devices with information systems has become a necessity.

Interoperability between medical devices and between devices and the EMR is the key to developing a system of safer and more efficient healthcare delivery. Will interoperability allow improved care quality, efficiency, and safety? Healthcare is unique in the fact that the product and the producers are people. Contrary to some fears that the increase of technology will dehumanize healthcare, the more efficient use of medical devices will provide more time for clinicians to interact with the patients while decreasing administrative tasks and allow them to focus on the patient's needs and for technology to assist with diagnosis.

The application of engineering principles to the practice of medicine is a challenge, but a systems approach can be applied to medical devices to achieve interoperability. Medical devices, information systems, infrastructure, and clinicians cannot be seen as sole entities but as a piece of a system. Analysis of clinical requirements by device types, input types, output types, and priority of need produce a roadmap of how interoperability can be achieved.

The goal of this analysis is to guide in the selection and development of interoperable medical devices that are cost-effective, generate a more efficient work environment, allow for situational customization of devices, improve patient safety and quality, allow for clinical informatics in real-time, and decrease end-user network complexity.

[a]Tracy L. Rausch is a Clinical Systems Engineer with Kaiser Permanente (KP) Eastern Hub, Rockville, MD 20852 USA (email: tracy.rausch@kp.org).

[b]Thomas M. Judd is a Health Technology (HT) Consultant with KP, Atlanta, GA 30305 USA, and a World Health Organization HT Consultant (phone: 678-612-3837; fax: 404-364-4732; e-mail: tom.judd@kp. org).

II. Interoperability Roadmap

Manufacturer Interoperability Requirements: The main focus of this analysis is not to specifically determine how each device is interoperable but to gain a general understanding of what is required to make these devices interoperable. This will provide insight into the level or economic impact the implementation of interoperable medical devices would be required for the healthcare organization. Healthcare organizations are dependent on manufacturers to provide interoperable devices, and this analysis gives the manufacturer a typically required set of clinical interoperability requirements.

Interoperability Roadmap: Medical devices will be categorized by device type. Each type will then be analyzed with the characteristics of organizational device counts (volumes), device model and manufacturer variations, data input, data output, criticality of input and output, long and short term storage requirements, real time functionality requirements, current communication methods, hardware and software characteristics, display requirements, timing and syncing abilities, device alarm requirements, built in safety locks, HIPAA requirements and safeguards, and replacement cost. After this interoperability analysis, devices are also assessed from quality of care and patient safety perspectives; see Tables 1A and 1B for examples.[1]

III. Quality and Efficiency Through Interoperability

Clinical Work Flows: This analysis is then developed into a toolbox which will allow for device technical information to be then plugged into clinical use cases. Use cases are workflows of specific clinical processes. By using the tool box and the work flows, the requirements for different types of medical devices' interaction needs with either other medical devices and or information systems can be developed, resulting in improved quality and efficiency.[2]

An example of device interaction would be the use case involving syncing of a ventilator to cease briefly for a C-Arm to take an X-Ray, and then the ventilator to continue its use.[3]

Another use case example is accessing vital signs from any location, and viewing and periodically processing vital signs from any location. Work flows demonstrate that patient vital signs and identification are measured, transmitted and stored for access for any user interface on demand. The main actor is the device, and flow of information - patient blood pressure, temperature, heart rate, and SPO2 - are collected and transmitted to a gateway and then transmitted to an EMR, central station or storage, and then transmitted to a be displayed and/or stored by any end user device (e.g., personal digital assistant-PDA).

Quality is improved by eliminating transcription and reading errors, more accurate data is recorded to the EMR. This use case can be used in outpatient clinic, home health, medical / surgical inpatient settings, emergency room, physician office, and possibly anywhere a patient would see multiple clinicians. This system could eventually be attached to a "smart system". This system would then alert clinical staff in major changes in vitals from previous visits or vitals that appear to be out of the range of normal.

Efficiency is improved as follows: On an average patient visit to an outpatient clinic, the staff spends five minutes obtaining patient information and five minutes transcribing this information. By eliminating the transcription time through interoperability, one is saving five minutes per patient of clinical time. A physician spends five minutes reviewing this information and with the integration of interoperability you are saving this physician two minutes of time per patient. In the inpatient setting, this device-EMR automatic charting and analysis of vital signs and related procedure information is expected to save 50% of current support staff current charting time and 20% of current practitioner charting time.

IV. PATIENT SAFETY THROUGH INTEROPERABILITY

How can interoperability make a difference in patient safety? Here is a listing of possible impacts[4]:

1. Surgical Site Incidents
   - Using integrated information systems, the EMR would display the correct site on a visual display in surgical suite and not just on a paper medical record. EMR would be used to verify the correct patient.
2. Foreign Body Retention
   - Using bar coding scanned before and after surgery; a system is created that counts and keeps track of medical supply use in the operating room (OR) for quality, safety, and accounting uses.
3. Death/Serious Disability via Medication Management
   - This can be accomplished through "smart alarms" on infusion pumps, catheters with increased safety locks, and not allowing infusion past previously set dosing limits, or multiple (inappropriate) infusions within a given time period.
   - Infusion pumps can be connected to the EMR to cross reference drugs re drug interactions, drug-condition issues, drug allergy alerts, never-use meds, oncology, and anticoagulation issues.
   - Verification of patient, right person, right dose, right administration method, can be verified by the EMR.
   - Interoperability information can assist medication reconciliation – a JCAHO national patient safety goal[5] - across care settings.
   - Prevention of Adverse Drug Reactions (ADR), Adverse Drug Events (ADE), and medication medical errors can be accomplished through cross referencing infusion drugs with the EMR. One unpublished study of impact of medication medical errors by Kaiser Permanente in 2005[6] demonstrated the following medication error sources: 39% in prescribing; 12% in transcription; 11% in dispensing; and 38% in medication administration.
4. Hemolytic Transfusion
   - Using integrated information systems, the EMR would display the correct site is on a visual display in the OR/surgical suite and not just on a paper medical record or by bar code cross referencing of information. Verification of patient - right person, right transfusion - would be done by the EMR.
5. Work Place Safety / Workers Compensation
   - There can be integration of "Smart Rooms/OR/ICU" in order to decrease the amount of cords and wires throughout the work environment.
6. Medical Errors (device-related)
   - "Smart Systems" transfer of information with the EMR can allow devices to synchronize and communicate in order to decrease the human interaction for events to occur.
7. Implantable Devices
   - Appropriate verification and tracking can be accomplished through the EMR.

V. CONCLUSIONS

By performing this medical device-EMR interoperability analysis in collaboration with a healthcare facility and information system infrastructure analysis, a roadmap can be developed that demonstrates the potential cost impact of interoperability in the healthcare environment.

The analysis validates cost of purchasing equipment that is interoperable, and allows for a clear set of clinical needs for interoperability.

The addition of quality, safety, and efficiency factors in the analysis is vital to show the expected contribution of these technologies in changing the way medicine is practiced.

REFERENCES

[1] T.L. Rausch, and T. M. Judd, "Interoperability Roadmap", study for KP Biomedical Equipment Steering Committee, August 2005, unpublished.

[2] J.M. Goldman, and S. Whitehead, CIMIT Operating Room of the Future Plug and Play Project Use Cases, www.cimit.org/orfpnp.html, Boston, June 2005, unpublished.

[3] T.L. Rausch, CIMIT Operating Room of the Future Plug and Play Project Use Case, October 2005, unpublished.

[4] T. M. Judd, T.L. Rausch, and D. Bonacum, Discussion with national KP Vice President for Safety and Risk, November 2005, unpublished.

[5] JCAHO/www.jointcommission.org/patientsafety/nationalpatientssfetygoals/, 2005.

[6] D. Bonacum, KP national medication safety study, unpublished, 2005.

TABLE IA

EXAMPLE INTEROPERABLE ROADMAP

Device	Why Critical	QRS Now 5 yrs	# Now	5 Yr. Incr.
Diag-nostic Ultra-sound (US)	Increased demand over next 5 years as US replaces other modalities; widely used now in OB, OR /Anesthesia, Urology, Radiology, ER, Cardiology; in the near future: more PT, Oncology, advanced forms of current US, and in Primary Care	3 / 2 - 3 / 2	A per H; B per MOB; Mix of high and low end devices	30% ***
ECG	Aging population; widespread CV disease; use in primary care, inpatient care settings	1 / 1 - 1 / 1	C per H D per MOB Mix of devices	20% ****
Physio-logic monitor	Includes temperature, heart rate, pulse oximetry, respiration. Includes fetal monitoring. For OR/Anesthesia, ER, ICU, Primary Care. eVitals versus manual vitals and in future	1 / 1 - 1 / 1 *	E per H F per MOB Mix of high and low end	15% growth overall *****
Ventila-tors	Acute care focus - OR/Anesthesia, ER, ICU	2 / 2 - 1 / 1	G per H H per MOB Mix of devices	10% ******
Infusion Pumps	Excludes PCAs and injectors; used at every level of care; key quality and safety/risk factors; used as part of treatment.	2 / 2 - 2 / 2 * **	I per H J per MOB Mix of high and low end	10% *******

Table 1A Notes:
Why Critical: Why clinically critical now and in the future.
Quality Issues / Risk / Safety Issues (QRS): Equipment availability allowing adherence to evidence-based medicine clinical practice guidelines or emergency care needs; Now/5 Yrs; 1=high; 5=low / Equipment related to Adverse Events or Malpractice Related-National Patient Safety focus.
 # (Device Volumes Present) Now: Total devices organization-wide: H= Hospital/inpatient care, MOB=clinic/med. office building-primary care.
5 Year Increase: *National patient safety focus on clinical alarms;
**National patient safety focus on infusion pumps;
***Rapidly increasing applications while technology is improving and costs are dropping.
****Expected wider use in various care settings due to aging population with Cardiovascular Disease (CVD).
*****20% mostly low end as most monitoring occurs at lower acuity.
*****Increasing acuity of population for modest growth

TABLE IB

Interoper-ability Futures	Current Interoper-ability Rating	Current Device Costs	Expected 2006 & 2010 Cost Impacts
EBS	3	High end ~$150-200,000 (K) (probe dependent); Low end ~$20-50K each	Life Cycle: 10% low end (10 years) & 20% High End (5 years) replaced annually
ES	2	High end: $11K now; Low end: $5-8K	Life Cycle 7 years: 14% low & high end replaced annually
EBS	2 for High End 4 for Low End	$20K high and $5K low; manage-ment of data will be a huge challenge	Life Cycle 10 years: 10% high and low end replaced annually
EB	5	$50K high (anesthesia vent), $25K mid (ICU), $15K low (portable)	Life Cycle 7 years; 14% replaced annually
EB	3/4	$6K high end (hospital use), $3K low end (MOB use)	Life Cycle 5 years: 20% replaced annually

Table 1B Notes; continuation of Interoperability Roadmap:
Interoperability Futures:
E = interoperable with electronic medical record
S = interoperable with data storage system
B = interoperable with another device,
Current Interoperability Rating:
1– 100% open source communication standard
2 – Proprietary Communication to 3rd party storage system
3 – Prioprietary Communication with vendor storage system
4 – No communication but device contains hardware
5 – No Interoperability
Current Device Costs:
Typical organizational device costs
Expected 2006 & 2010 Cost Impacts:
% replacement or purchase noted based on device life cycle.