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Connectivity Summit

Infusion Therapy and Information
Technology—Taking IV Therapy to
New Levels of Safety with IT Integration

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National Conference on Infusion Therapy and Information Technology

The 11th invitational conference at the CareFusion Center for Safety and Clinical Excellence in San Diego, held on June 2-3, 2011, brought together more than 40 experts and practitioners to share information, offer perspectives and address issues on the topic of infusion therapy and information technology. The day and a half of presentations and round-table discussions included individuals representing academic institutions, large health care systems, professional associations and industry. This conference report summarizes 17 presentations by nationally recognized experts.

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The following presentations were pre-recorded and are available at:
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**Auto-programming of Infusion IV Pumps:
Idealized Work Flow Process**

Kristen O’Shea, RN
Wellspan, York, PA

**Auto-programming of Infusion Pumps:
Learnings from an Early Adopter**

Tina Suess, RN, BSN
*Lancaster General Hospital
Lancaster, PA*

**Episodic versus Continuous Wireless Connectivity:
Are Medical Devices Ready for Real Time?**

Jim Welch
*formerly with Masimo
Irvine, CA*

PROCEEDINGS

Medical Device Interoperability From 30,000 Feet

Tim Gee, Principal and Founder

Medical Connectivity Consulting

Beaverton, OR

Key Points

- *There are preexisting models of medical device interoperability that can provide models for point-of-care device interoperability*
- *Point-of-care device interoperability includes requirements that differ from past interoperability models*
- *Specific barriers to adoption exist and must be overcome to facilitate infusion pump interoperability*
- *Medical device interoperability has been divided into five levels of interoperability*

Interoperability Experience

Point-of-care medical device interoperability is desirable as a means to improve patient safety and staff productivity by automating error-prone, time-consuming and sometimes complex manual tasks. Due to chronic patient safety issues with infusion pump medication administration, interoperability between the pumps and the information systems used to order and manage patient medications has existed for some time. Currently existing infusion pump interoperability is done via purpose-built interfaces between specific pump systems and information systems. These existing integrations are more like prototypes—expensive and not particularly intuitive or easy to use or support—than they are released products.

There do exist medical device interoperability solutions that have achieved significant market adoption that can provide useful models in considering infusion pump interoperability. These examples are

laboratory information systems (LIS) and picture archiving communications systems (PACS).

The typical LIS includes products from many different vendors. The diagnostic instruments, interfaces, and robotics that handle the samples are from different manufacturers. There are complex automated workflows driven by orders that generate diagnostic reports delivered to clinicians.

Likewise, PACS include diagnostic imaging modalities, diagnostic workstations for analysis and report generation, workflow engines, archives, and other system components, all from different manufacturers. As in the clinical laboratory, no single manufacturer makes all the components that could be found in a PACS.

The interoperability of these systems is supported by a set of specific characteristics. Most of the medical devices and other equipment are permanently installed, and communications are accomplished via

wired Ethernet networks. As a result, the challenges of mobility and portability are avoided. While these systems are large, they are contained in localized departments, making system design and management easier. Most of the components, including the medical devices, include industry standards to facilitate communications and interoperability. The maturity of these standards and their implementation makes these systems virtually plug-and-play, since minimal configuration is required. Test and certification bodies support both of these large interoperable systems, resulting in proven and reliable system configurations.

Point-of-Care Complexity

Taking the same two examples, the PACS and LIS, and extending them to the point of care highlights challenges similar to those faced by interoperable infusion pumps.

By removing medical devices from established departments such as the clinical laboratory and diagnostic imaging, the devices are used in new environments in ways that are different from conventional department-based devices.

Mobile or portable devices are often wirelessly enabled, which provides the best usability and convenience for device users. Besides the necessity of properly integrating a wireless radio and antenna into the medical device, the enterprise wireless local area network must be designed to support the application of wireless medical devices in all the locations in which they may be used. This often

entails a site survey to establish a baseline of wireless performance, and a redesign and modification of the existing network. The more widely these mobile devices may be used in the enterprise, the greater the scope of network modifications and validation testing.

Point-of-Care Challenges
Portable or mobile – wireless
Increased area of use
New workflow
Insufficient standards
Crosses organizational silos

When considering medical device interoperability or connectivity, the first thing most people think about is the connection. While the ability of medical devices to communicate to their respective computer systems is critical, it is the workflow—the series of steps required by the user to successfully complete a task with the mobile medical device—that is often most difficult. The workflow to order, draw, test and return a result for a conventional lab test is well established, as are similar workflows in radiology. The workflow for point-of-care medical device use is being created with every new point-of-care testing device and software release that comes to market. And it appears that the industry is still quite a distance from establishing the optimal workflows.

One advantage that clinical laboratory and diagnostic imaging modalities used at the point of care have over conventional point-of-care devices (patient monitors, infusion pumps, ventilators, etc.) is the broad adoption of industry standards by medical device and information technology (IT) manufacturers. Standards equivalent to DICOM in diagnostic imaging or ASTM in the lab do not exist

for infusion pumps and other point-of-care medical devices.

The LIS and PACS exist mostly within their diagnostic departments, providing an organizational advantage. Even support departments like IT often have specialized resources housed in the laboratory and radiology to support their interoperable systems. Mobile and portable medical devices that are broadly deployed in the enterprise cross numerous organizational silos in a more overt way, complicating the management and support of infusion pump interoperability.

All of these challenges must be overcome before infusion pump interoperability becomes a widely adopted commercial success. Besides these challenges, there are other barriers to entry for both manufacturers and providers.

Infusion pump interoperability is a system of systems. The first system is the infusion pump itself, referred to as an embedded system by engineers. Next is the smart pump system that incorporates the infusion pumps themselves and the related network, servers and software to provide the drug error reduction system, clinical documentation into electronic medical records (EMRs), and other advanced infusion therapy management features. The penultimate system provides interoperability between medication administration orders

Barriers to Adoption
Confluence of IT and regulated medical devices
Uncertainty how to regulate interoperable systems
Coordinating workflow across silos
Insufficient standards
Uncertain integration strategies: one-off or plug and play

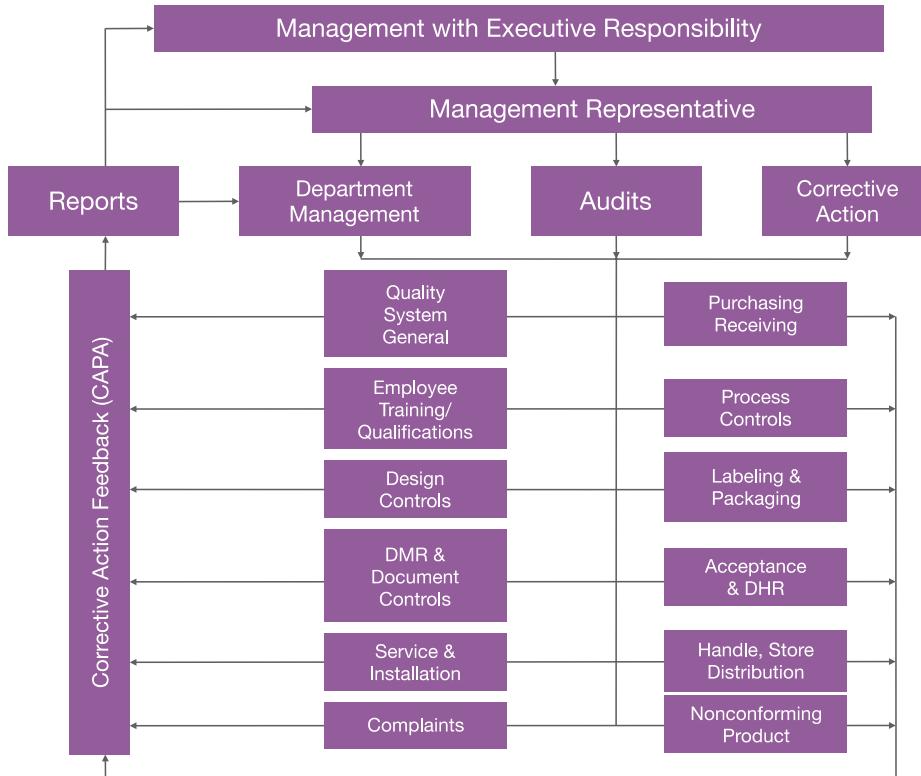
in one system, the pharmacy information system, medication administration record management and the smart pump system and infusion pumps themselves.

This confluence of enterprise IT—both infrastructure and hospital information systems—and regulated medical devices presents a substantial regulatory challenge. Existing regulations were crafted for conventional stand-alone medical devices. As medical device systems such as patient monitoring networks and smart pumps have caused regulators to make adjustments for systems, an established regulatory framework for a system of systems incorporating regulated medical devices has yet to be developed.

Likewise, the IT and biomedical governance in hospitals do not fully address this confluence of IT and medical devices. Regardless of whether the biomedical department (Biomed) reports to IT or not, almost all hospitals in the US lack sufficient rigor in risk management, configuration management, change control and several other areas to support interoperability or other life-critical systems of systems.

The best model for an optimal hospital governance framework for medical device interoperability is how the Food and Drug Administration (FDA) regulates manufacturers. In IEC 80001, a recently promulgated standard targeting hospitals intended to address risk management of networked medical devices, the risk management portion is based on the standard used by medical device manufactures to manage risk, ISO 14971. As provider organizations deploy their own life-critical systems of systems for which they assume primary responsibility for support and management, providers will need a basic quality system to ensure ongoing safe and effective operation of interoperable medical device systems.

Basic Quality System



DMR – Device Master Record; DHR – Device History Record

Due to the broad deployment of infusion pumps, hospitals will have to grapple with the organizational challenges that come with initiatives or operations that span organizational silos. Many hospitals are experimenting with matrix organizations, committees and cross-functional working groups in an effort to successfully resolve the issues that impact multiple groups.

The resulting workflows, which cross organization silos, are both an organizational and operational challenge. A cross-silo workflow is not a success until it benefits (or at least does not negatively impact) everyone that uses that workflow. Hospitals and manufacturers have yet to establish reliable and efficient methods for documenting existing workflows and qualitatively comparing them to automated workflows. Trial and error

seems to be the dominate technique for optimizing workflow.

As noted above, the scarcity of workable standards implemented in point-of-care devices is a major barrier to realizing medical device interoperability. For point-of-care medical device manufacturers, the long-standing product strategy is the creation of proprietary end-to-end systems. The advancement of workflow automation at the point of care, necessitating a patient- rather than device-centric focus, is perhaps the biggest factor pulling manufacturers away from their cherished proprietary end-to-end solutions.

The good news regarding standards for use at the point of care is that there are many suitable standards that could be adopted; no reinventing the wheel is required. All manufacturers have to do is

agree on which standards will be adopted and then adopt them. Given the lengthy life cycle of medical devices, this adoption will take some years. For an interim period, separate interface devices will be used to provide an industry standard interface to legacy medical devices, much like image acquisition modules were used in the early days of DICOM and PACS.

Once standards are decided upon and implemented in some way, a mechanism is required to test and certify that implementations are in conformance with the standards and that the desired workflow has been enabled. In diagnostic imaging, this function is provided by the test and certification organization Integrating the Healthcare Enterprise (IHE). The IHE has a similar workgroup targeting infusion pump interoperability. Many industries and market segments utilize test and certification bodies to facilitate the effective creation of device interoperability across manufacturer's products. It is possible that new standards or test and certification bodies may evolve to address infusion pump interoperability and/or other point-of-care devices.

The Continua Health Alliance is a test and certification body created several years ago to address the ambulatory market, or what is often called "mHealth" (mobile health) or "healthcare unbound." Continua does not address the acute care market, though at some point products with Continua certification may be adopted for use in hospitals.

Medical Device Interoperability

The term "medical device interoperability" brings many things to mind. One of the challenges of interoperability is defining it in a succinct way that has clear meaning. Clear definitions are also essential for the regulation of medical device interoperability.

Some time ago the FDA, Continua, the Center for Integration of Medicine and Innovative Technology (CIMIT) Medical Device Plug-and-Play Lab, and others convened a group for the purpose of developing an efficient and effective regulatory framework for interoperability. This group is currently known as the Medical Device Interoperability Safety Working Group. This group has developed an ontology of interoperability and defined five levels or degrees of interoperability.

A key objective of this work group is to enable medical devices and systems to operate in a patient-centric way. This contrasts with the LIS and PACS that are more specimen- or exam-centric. A regulatory goal is to avoid pair-wise medical device regulation. The FDA typically regulates medical device systems as one complete solution. Only one manufacturer can be cleared by the FDA to market the device/system, regardless of how many manufacturers' products are integrated into the system. There are exceptions to this, for example, PACS. Early in their inception, PACS were regulated as a system, but over time the FDA came to regulate individual components of the system as separate medical devices. The Medical Device Interoperability Safety Working Group is attempting to facilitate the same transition for interoperable systems targeting the point of care.

Pair-wise regulation means that an interoperable infusion pump system would have to get cleared for integration with Cerner and then get cleared again for integration with McKesson, and for every additional integration. The goal is to receive clearance once and then be able to connect with any other system that has been cleared, too. Under this framework, an infusion pump manufacturer would get cleared once for integration with cleared

EMR interfaces, rather than individually for each EMR vendor. Otherwise, if there were five pump manufacturers and five EMR vendors, every company would have to gain FDA clearance five times.

Level	
1	Virtual device display
2	Synthesis of derived notices or alarms
3	Virtual device control
4	Conditional device control
5	Programmable device control

To achieve this regulatory goal (and at the same time provide plug-and-play interoperability rather than custom integrations between manufacturers), the work group needed to define specific degrees of interoperability based on risk and how a technology might be implemented.

The first level is *virtual display*, whereby data from medical devices and systems are aggregated and displayed in a clinically significant way. There are many different applications for this, but the best description comes from the IT industry: dashboards. By extending the display of data from the device to another location, perhaps combining it with additional related data from other sources, and displaying that data changing over time, you have a dashboard of information.

The *synthesis of derived notices or alarms* applies control and knowledge to alarms and events from multiple devices. When the devices are attached to the same patient, this synthesis may eliminate duplicate alarms where the same physiological change generates alarms from multiple devices without adding any additional clinical information. When devices are attached to different

patients, synthesis may normalize alarms across the same type of device from different manufacturers. For example, physiological parameters and alarms can vary considerably across ventilator manufacturers. In an environment using ventilators from more than one manufacturer (a common occurrence in hospitals), the resulting dissimilar alarms can be confusing. Synthesis can normalize these variations, so the user only has to consider ventilator performance and patient condition framed by one set of common alarms.

Virtual device control means the remote control of the medical device. Many medical device systems allow caregivers to silence alarms or to adjust alarm parameters from a central location, in addition to the bedside. Virtual device control would provide a common interface, so that this central location could make these kinds of changes across devices from different manufacturers.

Level four takes remote control a step farther, to *conditional device control* where a system controls multiple devices based on "if/then" types of logic. A system that can suspend drug administration automatically, if and when a specific parameter on a patient monitor falls below a value controlled by the clinician, is using conditional device control.

Programmable device control represents the most complex and automated level of interoperability. Here an algorithm configured by the clinician makes decisions that affect the control of the various devices attached to the patient. The work group is using ventilator weaning as an example of programmable device control.

Summary

Perhaps the biggest challenge to interoperability is getting manufacturers to move past proprietary end-to-end solutions and work together to create a framework that will result in plug-and-play interoperability that is affordable, easy to deploy and maintain, and reasonable to get through regulators such as the FDA. There are many pressures driving manufacturers in this direction—customers, meaningful use requirements and the Office of the National Coordinator for Health Information Technology and others. How things will ultimately evolve remains a mystery.

PROCEEDINGS

Infusing Patients Safely: Priority Issues from the 2010 AAMI/FDA Infusion Device Summit

Mary Logan, JD, CAE

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Key Points

- *In 2010, the Food and Drug Association (FDA) made infusion system safety a high priority, because of 87 pump recalls, 56,000 adverse incidents and 710 deaths reported to the FDA in a five-year period.*
- *The Association for the Advancement of Medication Instrumentation (AAMI) and the FDA co-hosted a summit meeting of diverse experts from across healthcare to develop consensus on 13 priorities for infusion safety improvements. Some of the priorities need to be addressed by industry, others by healthcare systems; some with stronger device standards, others with standardized practices. The entire healthcare community's engagement will be needed to turn the corner on significantly reducing adverse incidents.*
- *Ten volunteer working groups are addressing the 13 priorities from the AAMI-FDA Summit under the direction of an infusion steering committee in the AAMI Foundation's new safety council.*
- *Five changes will be tested, assessed and validated that, if on target, could reduce IV medication errors by up to 90%.*

On October 5-6, 2010, a remarkable group of diverse experts on infusion system safety came together at the AAMI-FDA Infusion Device Summit, determined to change the world of infusion safety. The event was sparked by the FDA's announcement that more than 56,000 adverse incidents and 710 deaths associated with infusion devices were reported to the FDA from 2005-2009, more than with any other healthcare technology. There were 87 pump recalls during that same period. The FDA's Bill Maisel acknowledged that "adverse events are amplified because

of the number and frequency of use of infusion pumps. Failures can occur whenever pumps are used, with every type of pump, with any manufacturer. Many problems are due to deficiencies in design and engineering. But it's not just an issue of devices; it's about users and user interfaces."

Some of the priorities emerging from the Summit need to be addressed by industry; others require attention by healthcare systems. Some of the priorities suggest the need for stronger device standards; others are likely to lead to recommended standardized practices. The entire

healthcare community's engagement in these 13 priorities will be needed to turn the corner on significantly reducing adverse incidents.

13 Priority Issues and 5 Clarion Themes

The AAMI-FDA Infusion Device Summit was framed by expert presentations. Then summit participants from across the healthcare spectrum spent most of the two days building consensus on a list of 13 priority issues that they believed were the most critical for improving patient safety. AAMI then synthesized these 13 priority issues into 5 clarion themes (Table 1).

These issues were no surprise to anyone. The time was simply right for the issues to gain traction, because summit participants heard the FDA's call to action. Everyone knew that the time had come to change infusion safety throughout the healthcare system. Summit participants believed the healthcare community was capable of and would prefer to address the issues together, rather than react to regulatory action. Nat Sims, MD, said it best: "There is no way this issue can sink back into obscurity, because the FDA has made it a priority."

At the summit, AAMI announced the formation of a safety council to spearhead action on the 13 priority issues. Ninety-one summit attendees volunteered to be a part of the follow-up work.

Working Group Projects and Progress to Date

Fast forward to the summer of 2011, and the AAMI Foundation's Infusion Systems Steering Committee oversees ten working groups and a vision of "No patient will be harmed by a drug infusion." Volunteer working group members have developed charters and action plans around the 13 priority issues. Their progress in six months of working together is remarkable:

- **Alarm Survey.** In order to better understand the nature and frequency of pump alarms, the Alarms Management working group is surveying first responders. Results will be shared at the AAMI-FDA-ECRI-ACCE-Joint Commission alarms summit in October 2011.
- **Gaps in Connectivity.** The Connectivity Working Group is studying gaps in existing connectivity standards and activities.
- **Failure Mode Study for Multiple Line Infusions.** The Multiple Line Management Working Group is supporting a study by the University Health Network in Toronto to analyze failure modes in administering multiple infusions.
- **Standardized Terminology.** The working group on Standardized Terminology is developing a table of terms and definitions related to infusion systems and will propose these terms to industry and clinicians for comment and ultimately adoption.
- **Library of Resources.** The Information Clearinghouse Working Group is building a library of resources.
- **Ideal Reporting System.** The Incident Reporting/Listening Systems Working Group is defining and describing the ideal reporting system and its requirements.

- **Drug Formulary.** The Drug Library Working Groups are: (a) developing a formulary of medications with standardized data elements and (b) developing checklists on maintaining and updating drug formularies in infusion systems.
- **Matching Environments with Safety Features.** The Working Group on Environment of Use is developing a tool that will help match use environments with specific device safety features, in order to help reduce the risk of prescribing inappropriate equipment.

- **Training Gaps.** The Training Working Group is developing a plan to collect information from vendors, manufacturers and healthcare providers on current training practices, in order to address gaps.

In separate but related work, AAMI's Infusion Device standards committee continues toward its goal to improve the ANSI/AAMI ID26:2004(R) (2009) standard for infusion devices. A task group is developing a new Technical Information Report (TIR) on how to develop a safety assurance case report to support a 510(k) application.

Table 1. Infusion Device Summit: 13 Priority Issues, 5 Clarion Themes

Standardize systems and processes for reporting, aggregating, and analyzing infusion device incidents

1. Poor (incomplete and inadequate) system for reporting data on adverse events.
2. Reported incidents do not convey the bigger picture in terms of the volume of incidents involving infusion devices (eg, close calls, near misses, and root causes).
3. Manufacturers often cannot determine root cause due to the difficulty of accessing and analyzing incident data from all sources.
4. No process for collaborative failure analysis ("safe space").
5. Improve the integration of infusion devices with information systems and drug libraries
6. Incompatibility across devices and with systems (eg, consistent bar coding, wireless, power supply, HIT systems).
7. Lack of formulary and standards for drug libraries.
8. Uploading, managing, and maintaining drug libraries can be difficult.

Mitigate use errors with infusion devices

9. A high percentage of sentinel/adverse drug events are due to use errors. It is imperative to figure out how to develop design safety features that make it easy for the user to do the right thing.
10. Lack of standardization of terminology used in infusion systems.
11. Lack of knowledge/familiarity with infusion devices and lack of effective training.

Improve management of multiple infusions

12. Difficulty in infusion line management

Reconcile challenges and differences in the use environments of infusion devices

13. Alarm management is not effective
14. Injuries are caused by a lack of differentiation between the use of infusion devices in hospitals and in other environments.

How Will We Know We Have Been Successful?

It is one thing to have an inspiring vision that no patient will be harmed by a drug infusion. It is quite another thing to answer the question, “How will we know we have been successful?” The AAMI Foundation infusion systems steering committee developed an early list of success measures to keep front and center (Table 2).

Looking at this list of success measures, the steering committee during the spring of 2011 started discussing a possible list of five priority changes that, if implemented, could eliminate up to 90% of all IV-infusion-related errors. Following the Infusion Therapy and Information Technology conference hosted by CareFusion on June 2-3, 2011, the steering committee developed the dream list of 5 items (Table 3).

The next steps will be to test, assess and validate this list with several elite healthcare institutions. While the entire

healthcare community in theory would want to embrace five changes, if they knew those five changes could reduce IV-drug related incidents by 90%, this list no doubt will create some angst, if not controversy. “Proof” that this is the right list and how much reduction in incidents actually can be achieved will be critical to make the list compelling.

The Continuing Challenge

The challenge for all will be to keep the momentum going, to nurture the spark that gave the FDA, AAMI, the summit participants, and the working group volunteers the energy to get this far so fast. If the going gets tough, it will be important to reach out for that common bond shared by the entire healthcare community: improving patient safety.

Table 2. Infusing Patients Safely: Success Measures

- Improved design and manufacturing of devices
- Secure wireless networks
- Safety no longer depends on human accuracy
- No more “no fault found” errors
- Training, protocols, checklists and reporting are standardized
- Liability insurance premiums are reduced
- FDA, industry and hospitals are congratulated on their collective success of reducing infusion-related incidents

Table 3. Infusing Patients Safely: Priority Changes

The following changes, if implemented, could eliminate up to 90% of IV-infusion errors:

- Standardized drug nomenclature
- Auto documentation: closing the loop with computerized prescriber order entry (CPOE)
- Commitment to standardized critical drug hard stops across all care environments
- Standardized competencies: clinician training, checklists and competency assessments and audits
- All pumps on secure wireless networks

PROCEEDINGS

One or More Errors in 67% of the IV Infusions: Insights from a Study of IV Medication Administration

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Key Points

- *An observational, prospective investigation evaluated the type, frequency, and severity of IV infusion pump-related errors and whether these errors could have been prevented by stand-alone smart pumps not interfaced to other systems.*
- *Four teams, each with a pharmacist and a nurse, observed IV infusions and compared the infusing medication, dose and programmed rate on the infusion device to the ordered medication, dose and rate in the paper medical chart.*
- *In one nine-hour shift a total of 426 IV medication infusions were observed; of these 285 (66.9%) infusions had one or more errors associated with their administration, and three of these were judged to be due to a programming mistake.*
- *Further analysis showed that only one of these errors would have been prevented by a stand-alone smart infusion device.*
- *To provide maximum protection against all errors associated with IV infusion device use, seamless bi-directional communication is necessary among smart pumps and other devices (electronic medical record, computerized physician order entry [CPOE] system, barcode medication administration system, and pharmacy system), so that all nodes of the medication use process communicate with one another electronically in real time.*

In 2002 a multidisciplinary group comprising pharmacists, nurses and biomedical engineers at Northwestern Memorial Hospital in Chicago undertook the challenge of performing a failure modes and effects analysis (FMEA) around the use of bedside intravenous (IV) infusion devices to infuse IV medications to patients at a controlled rate. This methodology is used to analyze potential failure modes within a process for potential severity,

frequency of occurrence and effects of the failure on the overall process output. Infusion devices were chosen to be subjected to the FMEA methodology due to the increasing evidence both in the literature and at the organization that infusion device use was resulting in unintended harm to patients.

The FMEA identified the suspected root cause of patient harm as device

misprogramming leading to severe life-threatening overdoses of high-alert medications such as heparin and insulin that are more likely to cause patient harm if administered incorrectly. To validate this suspected root cause and gain a better understanding of the actual nature and root cause of such errors, an observational, prospective investigation was performed using a point prevalence approach.¹ The objectives were to determine the type, frequency, and severity of errors associated with IV infusion pumps, and to evaluate the likelihood that stand-alone smart pumps without an interface to other systems could have prevented the errors.

In January 2003 four teams, each comprising one pharmacist and one nurse, observed IV infusions at the bedside and compared the infusing medication, dose and programmed rate on the infusion device to the ordered medication, dose and rate in the paper medical chart. An error was defined as “any preventable event that may cause or lead to inappropriate IV medication use via an IV pump or to patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures and systems, including order communication, product labeling, compounding, dispensing, administration, education, monitoring and use.” This definition, although slightly modified

for the methodology of this study, was established in 1995 by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). It includes deviations in the administration of a drug from the physician's prescription or from the hospital's policies. NCC MERP error definitions (Table 1²) were used to determine the specific type of each error documented by the teams. For each "rate deviation" error, the team also estimated the likelihood that stand-alone smart pump technology could have prevented the error.

Results

A total of 426 medications infusing via an IV infusion device were observed by the teams in one nine-hour shift (0800–1700). Of the 426 medications observed, 285 (66.9%) had one or more errors associated with their administration, for a total of 389 errors overall. Of these, only 37 were deemed "programming errors," and only three of these were judged to be due to a programming mistake. Further analysis showed that only one of the documented programming errors would have been prevented by a non-integrated smart infusion device.

The other types of administration errors were not the result of device misprogramming, which the FEMA team had determined was the major root cause of IV infusion device-related errors. Instead, the other errors were the result of lack of system integration or lack of sufficient knowledge of the patient that could have been mitigated by appropriate integration with other clinical systems. For example, half of the medication labels were erroneously missing medication dose and rate information; pumps integrated with a pharmacy information system would have intercepted this type of error. Additionally, stand-alone smart infusion devices could not warn a clinician that a patient was allergic to a medication about to be infused or that a medication was about to be administered to the wrong patient.

Reference:

- 1 M Husch, C Sullivan, D Rooney, et al. Insights from the sharp end of intravenous medication errors: implications for infusion pump technology. *Qual Saf Health Care*. 2005;14:80-6.
- 2 National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP).

Study Conclusion

The use of stand-alone smart infusion devices will prevent a small number of programming errors that have the potential to harm patients; however, in order to achieve meaningful improvements in patient safety, more advanced technology is required. Such technology would provide seamless bi-directional communication among smart pumps and (a) an electronic medical record (EMR); (b) a computerized physician order entry (CPOE) system with sophisticated rules and alerts and solid human factors engineering; (c) a barcode medication administration (BCMA) system that assures correct patient/ drug/medication/dose/route/ schedule per the original order; and (d) a pharmacy system that allows pharmacists to verify orders, dispense accurately, monitor infusion rates and volumes, and better anticipate patients' needs. To provide maximum protection against all errors associated with IV infusion device use, all nodes of the medication use process from prescribing through administration and monitoring should be able to communicate electronically with one another in real time.

Table 1. Error Types: Definitions²

- **Rate deviation:** a different rate is displayed on the pump from that prescribed in the medical record. Also refers to weight-based doses calculated incorrectly, including using a wrong weight.
- **Incorrect medication:** a different fluid/medication as documented on the IV bag label is being infused compared with the order in the medical record.
- **Delay of rate or medication/fluid change:** an order to change medication or rate not carried out within 4 hours of the written order per institution policy.
- **No rate documented on label:** applies both to items sent from the pharmacy and floor stocked items per institution policy.
- **Incorrect rate on label:** rate documented on the medication label is different from that programmed into the pump. Applies both to items sent from the pharmacy and floor stocked items.
- **Patient identification (ID) error:** patient either has no ID band on wrist or information on the ID band is incorrect.
- **Unauthorized medication:** fluids/medications are being administered but no order is present in medical record. This includes failure to document a verbal order.

PROCEEDINGS

Computerized Physician Order Entry and IV Infusions: Current Status and Future Opportunities

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Key Points

- *In six community hospitals, the average rate of adverse drug events (ADEs) and the percent of ADEs that were preventable were much higher than what had been found in prior studies in academic medical centers.*
- *The drug-safety benefits of implementing computerized prescriber order entry (CPOE) represent only a small portion of the potential financial benefit.*
- *In another study, user acceptance of interruptive safety alerts positively correlated with frequency of the alert, quality of display and level of the alert level, making it abundantly clear that institutions should be tiering alerts.¹⁰*
- *In a simulation study CPOE systems detected only 53% of orders that would have been fatal and 10% to 82% of orders that would have caused serious ADEs, with no relationship between CPOE vendor and error detection.¹¹*
- *Key opportunities to improve IV medication safety include standardizing IV orders across institutions and systems, including dose ranges and titration orders; sending orders directly to smart pumps, eliminating the need for re-entry and linking smart pumps with monitoring devices such as end-tidal CO₂, patient movement and respiratory data.*

One key reason for establishing interconnectivity among various medical devices is to improve medication safety, as this has the potential to reduce the incidence of adverse drug events (ADEs) and related patient harm. Two of the most important technologies to link are computerized prescriber order entry (CPOE) and computerized intravenous (IV) infusion pumps (smart pumps).

This article includes brief reviews of the recent evidence on CPOE and medication safety, including data on epidemiology and prevention of ADEs especially in community hospitals; a brief overview of the “meaningful use” requirements; a summary of the risks of CPOE; new evidence about clinical decision support and human factors; and the current status and future opportunities with respect to CPOE and IV infusions in particular.

Frequency of ADEs

Most of the data on the frequency of ADEs have come from studies conducted at large, academic medical centers. A recent study¹ sought to determine the baseline rate of ADEs in six community hospitals in the greater Boston area, compare the ADE rates among the hospitals and estimate the potential benefit and savings associated with ADE rate reduction.

The average ADE rate in the six community hospitals was 15 per 100 admissions (range, 11 to 19.5),¹ about twice what it was in academic centers.² On average 75% (range, 68% to 85%) of these ADEs were preventable,¹ which is much higher than in academic centers, where 28% of ADEs were preventable.² Moreover, ADEs are very costly, with the estimated cost to the U.S. healthcare system \$3.8 billion in 2008 for inpatient ADEs alone.³ As reimbursement changes, hospitals will likely no longer be able to charge for the treatment of preventable ADEs, so it will be in their financial interest to invest in solutions to prevent them.

Impact of CPOE on Medication Safety

A study done in 2003⁴ found five trials of the impact of CPOE implementation on medication safety. Two showed a large decrease in the serious medication error rate; one showed improvement in the use of corollary orders (for example, if you order an aminoglycoside, the system suggests

you check renal function). One study showed improvement in five prescribing behaviors, and one showed improvement in nephrotoxic drug dose and frequency.

A subsequent meta-analysis found a 66% reduction in prescribing errors on average.⁵ Yet another meta-analysis evaluated 10 studies of CPOE and ADEs: five found decreases in the ADE rate, four showed non-significant trends, and one showed no effect.⁶ Most individual studies to date have not had sufficient statistical power to look at the frequency of ADEs, which are relatively rare.

Taken together, though, it appears that CPOE clearly reduces the frequency of medication errors, and probably also decreases the frequency of preventable ADEs; the results for the latter are more mixed. However, the drug-safety benefits of implementing CPOE represent only a small portion of the financial benefit. In addition, getting full value from CPOE requires building in good decision support, ensuring that you have the ability to modify the system and then iteratively improving it. It is important to identify and track problems, and address them one at a time.

Meaningful Use and Medication-Safety-Related Decision Support in Hospitals

In 2011, financial incentives for providers with regard to meaningful use of an electronic health record (EHR) were introduced. The medication-related targets focused on the following:

1. have an active medication list and an allergy list
2. for more than 30% of patients, have at least one drug ordered using CPOE
3. have drug-drug interaction and drug-allergy checks.

By far the most controversial of these provisions was including CPOE on the list, as a large proportion of the public comments about the regulations focused on this area.

The 2013 recommendations are under consideration, although it appears likely they will be released soon. The latest iteration directs hospitals to use CPOE for all order types. The target for CPOE use has been increased to 60% of patients. Other requirements are to use evidence-based order sets, do medication reconciliation at 80% of key transitions and implement electronic medication administration record (eMAR).⁷

CPOE Risks

Any new technology can introduce new errors, and CPOE is no exception. The use of CPOE can make it possible to write orders that are unclear or that have internal conflicts. Almost all new implementations have some issues, which typically are more profound for IV medications than for other types of orders. The issues need to be identified, tracked and eliminated one by one.

Human Factors and Alarms

A recent study of human factors and alarms in relation to medication safety made a number of recommendations based on the evidence in this area.⁸ Uniform alerting mechanisms and standardized alarm responses are needed. An institution's alarm philosophy should be established, and one key is to minimize the number of false positive alerts. Extensive evidence shows that if there are too many alerts, people start to ignore even the important ones. Other factors that emerged include that visibility is critical—placement of the alerts substantially impacts the likelihood that users will see them. The font size should be large enough to be readily legible.

Visual alerts should be prioritized, and color should be used to help cue the user to the importance of a specific alert. In many systems, the life-threatening alerts look exactly the same as ones that are not at all important, making it easy to miss the critical ones. The number of colors used should be kept to a minimum. To make visual alerts more distinct, it is important to minimize the number of shared visual features, so they do not look alike. Text-based information should be succinct.

Human Factors Principles and Alert Acceptance

To examine how alerts affect behavior, another study⁹ looked at almost 51,000 drug-drug interaction (DDI) alerts, both inpatient and outpatient. Providers accepted only 1.4% of non-interruptive alerts. For interruptive alerts, user acceptance positively correlated with frequency of the alert (OR 1.30), quality of display (OR 4.75), and alert level (OR 1.74). Alert acceptance was higher in inpatients (OR 2.63) and for drugs with dose-dependent toxicity (OR 1.13). The textual information influenced the mode of reaction, and providers were more likely to modify the prescription if the message contained detailed advice on how to manage the DDI.

Impact of Tiering on Inpatient DDI Alerts

Another study by our group looked at the impact of tiering (differentiating DDI alerts in CPOE by level of severity) at two academic medical centers in Boston that were using the same knowledge base.¹⁰ Site A displayed alerts using three tiers, including hard stops for the most severe alerts (Level 1), and Site B had all the alerts as interruptive (or Level 2), and Level 3 was non-interruptive—informational only. The information systems group at

Site B did not want to structure things in this way, but technical issues made it impossible to implement tiering, so we took advantage of this natural experiment.

The findings were striking. At Site A, 100% of the most severe warnings were accepted, because they were basically hard stops, versus only 34% at non-tiered Site B. In essence, people “ran stop signs” 66% of the time. Overall alert acceptance was higher at the tiered site (29% vs 10%, $p < .001$). These data make it abundantly clear that institutions should be tiering alerts.¹⁰

Safety Results of CPOE Decision Support Among Hospitals

Another important issue is how hospitals at large are doing with respect to implementing alerts. In a study done jointly with the Leapfrog Group which was led by Metzger, we evaluated the alerts hospitals had implemented, using a CPOE “flight simulator.” Overall, 62 hospitals around the country voluntarily participated.¹¹ The hospitals were given a few simulated patients, and then orders that had either actually killed or seriously injured someone to enter into their CPOE systems, so they could check whether or not warnings would display. All results were entered into a website, and the hospitals received their scores. The results were alarming: the CPOE systems detected only 53% of orders that would have been fatal, and only 10% to 82% of orders that would have caused serious ADEs. Furthermore, there was almost no relationship between CPOE vendor and error detection.¹¹ Even though some people think that picking the right vendor will solve their medication safety problems, this finding shows that belief is not correct. How a system is implemented, especially the decision support put in place, is probably much more important—all the vendors had

hospitals which scored well, but also all had hospitals which scored poorly. This underscores the need for such testing on an on-going basis, so that hospitals can assess where they are with respect to decision support implementation.

CPOE and IV Infusions: Current Status

Currently linkages between CPOE and smart infusion devices are rare. IV infusion orders vary widely and pumps typically are programmed manually, creating many opportunities for errors to occur between placing an order and programming it into a pump. Enormous variability in practice also increases opportunities for errors. Smart pumps have documented many errors that previously were unknown. As noted above, the rates of IV medication errors are much higher than many suspected.

Analyses of smart pump data have identified shocking behaviors such as a nurse overriding a fatal overdose alert six times or toxic medications being infused without an order in place. A 100-hospital study¹² found huge variation in practice, with an average across hospitals of 8.5 names per drug, three different dosing units per drug, and 15 different continuous dosing units per hospital (range 8 to 24), not including bolus dosing.¹² Thus, there is substantial potential to improve IV medication safety.

CPOE and IV Infusions: Key Opportunities

Key opportunities to improve medication safety include standardizing IV orders across institutions and systems, including dose ranges and titration orders. Orders should be sent directly to smart pumps, which would eliminate the need for re-entry. Another key opportunity is to link the pumps with monitoring devices such as end-tidal CO₂, patient movement

and respiratory data, which could enable the pumps to stop infusions if a patient’s breathing appears to be slowing or to notify a nurse to intervene.

As noted earlier, CPOE appears to be highly beneficial in the aggregate, but it clearly can create new problems that need to be identified and engineered out. That also holds true for IV infusion safety systems. It is important not only to have a technology but also to implement it well and serially refine the decision support.

As Einstein said, “Insanity is doing the same things the same way and expecting different results.” We have to change the way that we are doing things, if we are to achieve dramatically different results in preventing harmful ADEs.

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PROCEEDINGS

How Well Does Bar Code Medication Administration Address the IV Process?

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Key Points

- *The need for and benefits of using bar code medication administration (BCMA) extend far beyond medication administration.*
- *In the pharmacy, bar-code scanning can help ensure accurate, efficient storage and retrieval of outsourced intravenous (IV) preparations, and for in-house preparations, help ensure that the right components are being admixed and matching labels are generated automatically.*
- *At the point of infusion, in addition to positive identification of patient and medication, mobile BCMA computing devices provide the means by which data are retrieved from and stored in the electronic medication administration record (eMAR), helping ensure accurate pump programming and infusion documentation.*
- *For “meaningful use,” BCMA can help ensure accurate reading and feeding of the eMAR portion of the larger electronic health record (EHR)*
- *For IV infusions, both BCMA and smart pumps are necessary: with smart pumps alone, nurses could administer the wrong medication the right way; with bar coding alone, the right medication the wrong way. Each technology is incomplete without the other.*

Bar code medication administration (BCMA) is often thought of in terms of helping prevent medication errors and adverse events at the point of care. However, the need for and benefits of using this technology extend far beyond medication administration itself. The idea is not simply to catch errors at the point of care but to prevent as many errors as possible before they ever reach patients. In this article, the importance of using bar coding on the path to infusion, the value of BCMA at the point of infusion, and some nuances of the infusion process with BCMA will be addressed.

BCMA on the Path to Infusion

The efficacy of bar-coding at the point of infusion starts with the accuracy of IV medication preparation and labeling. IV medications arrive in hospital pharmacies from manufacturers and outsourced compounding services with bar-coded labels that must be mapped to hospital drug formularies. The use of bar-code scanning in the pharmacy can help ensure the accuracy and efficiency of the storage and retrieval process of these pre-mixed preparations.

When IV medications are prepared in the pharmacy, it is possible for IV medications to arrive at points of care with labels that match the patients receiving them, but with IV medications that have been inaccurately mixed. To avoid this, bar-code verification safeguards are increasingly being used during in-house IV preparation. Pharmacy personnel scan each ingredient to ensure that the right components are being admixed and that matching order labels are generated automatically. It is difficult to understand why any hospital would drag its feet on exercising this option; no point-of-care system can catch a pharmacy's admixture error.

In the future, scanning will also to be used to help validate the integrity of IV products against expiration dates, lot numbers, and even cold-storage histories. The simple, printed, 2D bar codes used today include lot number and expiration dates. Other industries demonstrate other possibilities. The Department of Transportation and the Environmental Protection Agency require manufacturers to put more detailed labels on new car windows for energy consumption ratings. The labels include quick-response (QR) codes, which, when scanned with smart phones, take consumers to detailed information about mileage, ratings, etc. More complex solutions such as radio frequency identification (RFID) can monitor product temperatures; however, less expensive

and equally effective solutions are on the horizon. Coors is making beer-can labels that change colors as the product temperature hits ideal. The grocery industry is testing meat and produce product labels printed with temperature-sensitive inks. If a product's temperature goes outside safe ranges, the bar codes change to an unreadable color.

BCMA at the Point of Infusion

At the bedside, BCMA offers far more than just barcode scanning. Mobile BCMA computing devices give caregivers access to the eMAR, and scanning is the means by which data are retrieved and stored. Scanning devices may be handheld devices, wall-mounted screens, or computers on wheels. iTouch, iPhone and iPad devices are starting to be used, as well.

It is worth noting that hospitals may have eMARs without bar-coding, but it would be senseless and perhaps impossible to have medication administration bar-coding without eMARs. In referring to BCMA, eMARs are assumed. Some hospitals even call their barcode initiatives "eMAR."

Arguably the most important value of BCMA is positive patient identification. BCMA assists caregivers in positive patient identification, in keeping with the first National Patient Safety Goal from The Joint Commission calling for hospitals "to improve the accuracy of patient identification." By scanning a patient's wristband, the caregiver retrieves that patient eMARs, which display prospectively what is to be administered and retrospectively what has been administered to that patient.

Scanning a medication confirms that what is in the clinician's hand matches the patient's order. The screen also provides additional information such as what the

caregiver is to do with the drug in hand (eg, give five of the 10 mL, and then the other five). The screen also indicates route and site. When IV medications are involved, the dose, rate and other important information for properly programming the infusion pump also may be involved.

Finally, bar-code enabled eMARs assist in achieving more accurate documentation. BCMA documents medication administration where and when it actually happened, rather than documenting it later, down the hall. Too often, even when eMARs without bar coding are employed, nurses jot administration notes on scraps of paper at the point of care and attempt to recall what they did, later in the day at a computer 20 yards away.

BCMA and Meaningful Use

While bar coding is not explicitly included in the phase one and phase two requirements of Meaningful Use of EHRs, it is difficult to imagine how hospitals can meet the expectations in the American Recovery and Reinvestment Act (ARRA) without eMARs. The question is not whether or not use of eMARs will be expected, the question is where eMARs will be utilized and how data will be retrieved and entered. For hospitals that have eMARs down the hall at nursing stations, BCMA is a tool for bringing them to the point of care, using bar code scanning as a data-retrieval and data-entry mechanism.

Early in his communications on Meaningful Use, David Blumenthal, MD, MPP, former National Coordinator for Hospital Information Technology, sent a compelling message: "By focusing on meaningful use, we recognize that better healthcare does not come solely from the adoption of technology itself,

but through the exchange and use of health information to best inform clinical decisions at the point of care. Meaningful use in the long term is when EHRs are used by healthcare providers to improve patient care safety and quality." This refers to bringing this electronic record to the point of care and using it during the process of care. BCMA can be thought of as the "synapse" between the patient and the EHR for reading and feeding the electronic record.

BCMA enables faithful reliance upon and reliable population of the medical record. Whatever Meaningful Use definitions CMS may evolve, for EHRs to be meaningful they must be fed real-time all the time—thoroughly and accurately. And if they are going to be used meaningfully, they need to be used at the point of care.

BCMA and Smart Pumps

In past years, there has been some debate over which technology hospitals should implement first, BCMA or smart pumps? That seems rather like Orville and Wilbur arguing at the drawing board over which wing of the airplane was more important. With smart pumps alone, nurses could administer the wrong medication the right way (within the dosing parameters for that drug). With bar coding alone, caregivers could administer the right medication the wrong way. Each technology is incomplete without the other. The yin of scanning and the yang of smart pumps are both needed.

The good news is that smart pumps are becoming more communicative. Not only are pump drug libraries being updated remotely, some hospitals are actually auto-programming smart pumps from eMARs via mobile computing devices and scanners. In these instances, smart pump systems not only are respecting the drug

library's parameters for each drug but also ensuring that the exact order is sent to the pump for dose, rate and flow. Equally exciting, the pump is feeding the eMAR with real-time infusion information, which can be read not only at the point of care but also remotely by caregivers, even alerting pharmacy when it is time to send up more product.

The great value of patient safety technologies is that they make it easier for caregivers to do the right thing and harder for them to do the wrong thing. Interfacing eMARs and smart pumps as discussed above also makes it easier for caregivers to do their work and removes the incentives for them to create work-arounds, simply because doing things the right way is easier than doing them the wrong way. The impressive safety and efficiency gains realized with the WellSpan BCMA/Pump integration project, discussed elsewhere in these proceedings, provide excellent examples.

Conclusion

Bar code medication administration (BCMA) is often thought about in terms of preventing errors and adverse events in administering medications at the point of care. However, BCMA provides benefits not only at the point of infusion but also in the pharmacy, between the point of care and the electronic record, for meaningful use, and for smart pump auto-programming and auto-documentation. BCMA provides a safety net at the point of care and also a means of helping ensure safe processes throughout the IV process.

PROCEEDINGS

Have Smart Infusion Pumps Reached Their Full Potential?

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Key points

- *Early intravenous (IV) infusion pumps were one-size-fits-all devices that allowed a 10,000-fold range of infusion rates and a 100,000-fold range of volumes-to-be-infused that contributed to serious medication errors.*
- *In the last 10 years, computerized “smart” infusion pumps with dose error reduction software (DERS) have greatly improved IV infusion safety by providing more advanced technology and requiring hospitals to create comprehensive drug libraries with dose limits and other important safeguards.*
- *A major safety contribution has been the smart pumps’ continuous quality improvement (CQI) logs, which provide actionable data that can help hospitals improve practice and better manage their drug libraries, and help manufacturers improve the technology.*
- *Taking IV infusion safety to the next level will come through interoperability and system integration, as smart infusion pumps seamlessly become a fully functioning component of a hospital’s information technology (IT) systems.*

Intravenous (IV) infusion pumps have been in widespread clinical use for almost four decades, but computerized infusion pumps with dose error reduction software (DERS) have only been available in the last 10 years. Commonly referred to as “smart” infusion pumps, these devices have added many new safety elements to IV infusion therapy, and their adoption across the hospital market has been significantly faster than that of any other medication safety technology, such as bar code medication administration (BCMA), computerized physician order entry (CPOE), etc.

Improving IV Infusion Safety

To appreciate how smart pumps have improved medication safety, we need to briefly describe the previous “dumb” infusion pumps and how they were used. For the first 30 years, the typical IV infusion pump was a one-size-fits-all device designed to meet the needs of the entire hospital, from the smallest neonate to an adult patient in intensive care. Unlike the medications they infused, the pumps were not individualized for each patient. The typical pump dispensed by biomedical engineering could deliver anywhere from a few drops to a full

liter over the course of an hour with no safeguards, and any dose or rate was OK. The 10,000-fold infusion-rate ranges and 100,000-fold volumes-to-be-infused ranges of these early pumps contributed to serious medication errors. A missed decimal point, an extra zero, switching the rate and volume entries—these types of errors could go undetected and result in serious medication over- or underdoses.

Unlike the administration of tablets and injections, which are discreet events, infusions are a process. Infusions often continue for hours or days, are programmed by multiple caregivers and subject to starts, stops, titrations, etc. Every change increases the opportunities for errors. Without additional safety features to help avert such errors, the entire IV infusion system left much to be desired.

Smart Pumps’ Contributions

Ten years ago, one of the first important contributions of smart pumps was not the technology itself but the requirement that hospitals create comprehensive drug libraries for their pumps. For every drug in the library, a hospital had to determine what dose was too low or too high, and what type of alert and subsequent clinician action should be required if a programmed dose exceeded the drug library limits. Creating the drug libraries, which today include virtually 100% of IV drugs, is typically the most challenging aspect of smart pump implementation.

Recommended doses are available in reference texts and package inserts, but these same sources do not provide dose limits. In titrating a drug to increase blood pressure, when is the dose too high? To meet the challenge of making such determinations, clinical pharmacists, working with nursing and the medical staff, assumed responsibility for creating and managing the smart pumps' multiple drug libraries, including the determination of dose limits, whether these should be "soft" or "hard" (can or cannot be overridden), what drugs can be used safely in specific care areas, what concentrations and dosing units are permitted, etc. Standardizing IV infusion therapy across the hospital greatly reduced the opportunities for serious medication errors.

A second, often overlooked contribution is that instead of one-size-fits-all, smart pumps provide 10 or more configurable "profiles" that are customized for different patient types or care areas such as neonatal intensive care unit (NICU), adult ICU or medical-surgical. When a smart pump is powered on, it requires the clinician to select a profile. This automatically configures the pump for use with that patient type or in that patient care area with the appropriate drug library and 40 or more pump-performance settings such as maximum flow rate, air detection limit, maximum occlusion pressure, alarm tone, etc. Simply selecting the profile customizes the smart pump's configuration in ways the engineering department never could.

An unexpectedly powerful contribution of the smart pumps has been their continuous quality improvement (CQI) logs, which have proven to be a treasure trove of information. The logs capture any pump programming that results in an alert and record the clinician's subsequent action. In addition to documenting "good

catches" whereby unintended under- or overdoses were identified and averted, the logs help clinicians identify previously unrecognized, unsafe clinical practices; help hospitals improve their drug libraries and help manufacturers identify ways to improve the technology.

When smart pumps were first introduced, uploading the drug library and downloading CQI data required physically connecting each pump to a laptop, one by one. This was a very labor-intensive process, and often CQI data were collected and libraries updated only during the annual preventive maintenance. Wireless connectivity, which has become standard, greatly simplified this process. Now CQI data can be collected wirelessly every day, and drug libraries can easily be updated as frequently as required.

Opportunities for Further Improvements

Despite smart pumps' many important contributions, their full potential has not yet been realized. With few exceptions, today's smart pumps cannot yet ensure the traditional five "rights" of drug administration (right patient, right drug, right dose, right route and right time) or other "rights" such as right response and right documentation.

Pumps typically are not assigned to individual patients and have no patient information beyond location or patient type. Although the pumps are wirelessly connected, the physician's orders are not sent directly to the pumps, and programmed pump settings are not compared to the physician's order. With few exceptions, current pumps do not communicate with the electronic medication record (EMR) or the hospital's BCMA systems.

Given these issues, the current pumps have advanced about as far as they can. However, multiple advances are creating exciting opportunities to go from smart infusion

pumps to smart infusion systems that will take infusion safety to the next level.

Reaching the Next Level of Infusion Safety

Attaining the next level of safety is currently a work in progress, with a major focus on interoperability between medical devices and information technology (IT) systems. A major challenge is that infusion pumps are unique in the medical device world. Unlike monitors and many other devices, IV infusion pumps are programmed and their future capabilities depend on bidirectional communication. Future infusion systems will most likely have the following attributes:

- Every infusion pump, regardless of type, will be wirelessly connected to the hospital's information network, enabling bi-directional communication with the enterprise-wide IT system and other systems that provide unique and limited capabilities.
- Infusion pump programming will begin with image recognition that assigns a pump to an individual patient using bar code drug labels or radio frequency identification, which will help ensure that the right medication, concentration and dosing units are selected for that particular patient.
- Infusion parameters will be sent wirelessly to the pump and automatically program the infusion, with a clinician confirming the programming. Or a clinician's manual programming will be automatically compared to the medication order. Clinical alerts, recent laboratory values and other up-to-the-minute patient information will be immediately communicated to the clinician, either through the pump or through other avenues currently being developed. In addition, all infusion programming will automatically be documented

in the patient record electronically, eliminating the need for nurses to manually record copious amounts of infusion data and freeing them to spend more time with patients.

- Any infusion programming outside the DERS limits will automatically be sent to clinical experts for evaluation and possible action. Patients requiring extraordinary amounts of medications will be identified as “high risk” and closely monitored for drug-induced adverse events.
- Infusion pump alarms, which today sound at the bedside, will be automatically directed to an assigned clinician. Clinicians will be able to view alarms remotely and be fully prepared to respond as soon as they reach the bedside. Clinicians will likely be able to reset alarms remotely, since the necessary information will be available to assess corrective action and delay visiting the bedside just to cancel an alarm. This will also help spare patients the too-frequent alarms that disrupt patient care.
- As smart infusion pumps become part of a much larger system, many other issues can also be addressed in close to real time. These include detecting infusions that have no physician’s order, that are continuing despite orders to be discontinued or that are resulting in physiologic or laboratory abnormalities, and identifying the current status of infusions to help optimize pharmacy workload scheduling.

Summary

In the past decade the infusion pump industry has provided many safety and performance benefits by reinventing IV infusion technology and enabling each hospital to customize their pumps’ performance attributes and drug-specific safety limits. Continuing challenges with the current pumps include ensuring compliance with safety software use, eliminating unnecessary drug-library variation and using the CQI data to aggressively manage drug libraries. Without individual patient information, the technology has for the most part reached its safety potential. The next decade will focus on interoperability and system integration, as smart infusion pumps seamlessly become a fully functioning component of each hospital’s IT systems.

PROCEEDINGS

Medication Administration from a Nurse's Perspective: Prioritizing Making a Safety/Productivity Difference

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Key Points

- Nurses are the primary hospital caregivers, and efficient use of their time and energy is critical to hospitals' future.
- A growing body of evidence links more nursing time per patient day with better patient outcomes.^{1,2}
- Medication administration is a high-risk activity that consumes a large portion of a nurse's time.
- Consideration of nursing workflow and staffing is critical to the successful integration of technology into the healthcare bedside environment.

Nurses play an integral role in caring for hospitalized patients. Rapid advances in healthcare and technology have changed how hospitalized patients are cared for and the roles nurses play in facilitating this complex care. Nurses' ability to keep pace with the latest technology and to apply advances to their bedside practice directly affects patient safety and outcomes.

Recent studies focused on nurse staffing in hospitals have linked quality of care, outcomes, job dissatisfaction, and patient mortality to patient-nurse ratios. More nursing time per patient day is associated with better patient outcomes.^{1,2} These findings have serious implications for patient safety and quality of care, since the increased nursing workload and the growing workforce shortage may reduce the amount of nursing time available for patient care activities. It is imperative to prioritize efforts that can help optimize

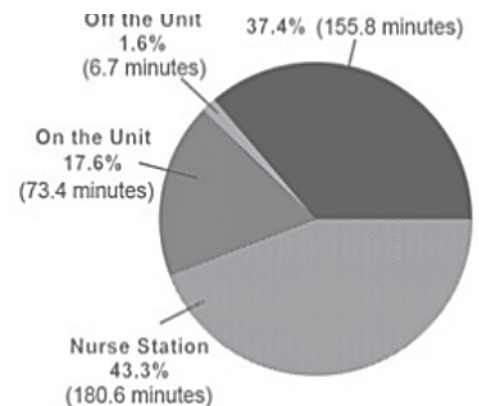
the essential elements of nursing practice time yet also improve efficiency. Such efforts need to start by looking at how hospital nurses spend their time.

In a recent study by Hendrich et al,³ nurses from 36 medical-surgical units participated in a time and motion study to identify drivers of inefficiency in nursing work processes. Analyzing nursing practice time by location revealed that the largest proportion of nursing practice was done at the nursing station and patient room (Figure 1). Further analysis showed that the majority of that time was consumed by documentation, medication administration, and care coordination (Figure 2). Documentation alone accounted for 35.3% of nursing time. Can new technology and software to associate electronic medical records with medication administration devices make documentation more efficient while also improving safety?

Does adding new technology add to the nursing workload by requiring double documentation? Follow-up studies are needed to answer these questions.

Medication administration is a high-risk activity that consumes a large portion of nursing time. Keohane et al⁴ recently studied the impact of bedside technologies on nursing workflow and nursing practice with regard to medication administration in a large university hospital involving 23 medical/surgical units and six intensive care units (ICUs). The average percent of nursing time spent on medication-related activities ranged from 22.8% in the ICU to 29.1% in combined medical/surgical units (Figure 3). Of note, the time spent on medication administration was consistent throughout the 24-hr day.

Figure 1. (4A. Location)



The authors indicate that because such a large proportion of nursing time is spent on medication administration and because it is such a high-risk activity, advances in technology should be aimed at opportunities to streamline the process and improve efficiency.

Conclusion

Complex technology systems and software have changed the way nurses care for patients at the bedside. The importance of developing efficient tools to help optimize the critical thinking of bedside staff cannot be overemphasized. From the nursing perspective, priorities to be considered include integrating technology into hospital documentation systems (device-to-device); avoiding duplicate documentation; improving data functionality for multidisciplinary communication; and emphasizing patient safety along with increasing the efficiency and productivity of bedside staff.

Figure 2. (4B. Subcategory)

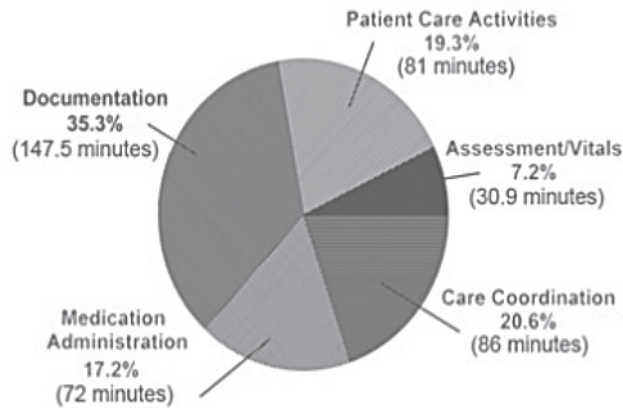
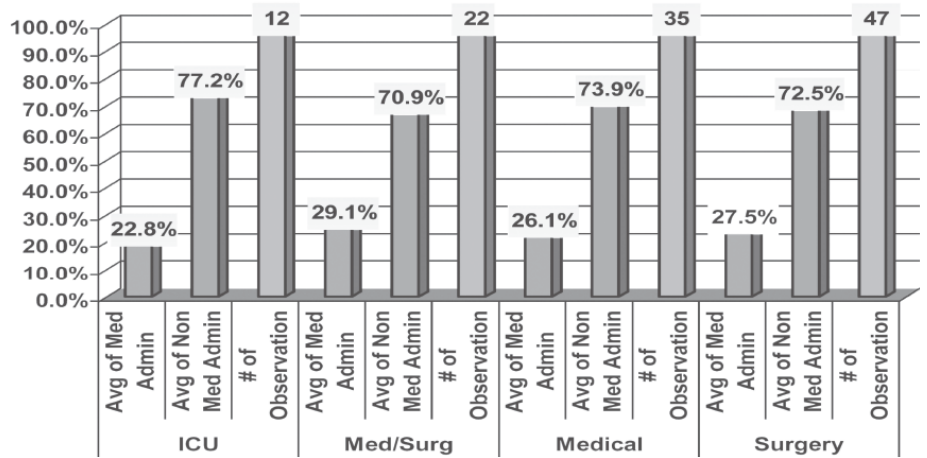


Figure 3.



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PROCEEDINGS

Intravenous (IV) Medication Infusion Device Integration: Readiness Assessment

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Key Points

- *The adoption rate of interoperable medication-management supporting technologies, including intravenous (IV) medication infusion devices (“smart pumps”), remains low.*
- *Current health system information technology (IT) priorities are focused on meeting meaningful use measures, optimizing existing clinical systems and building core medication-use process supporting systems.*
- *The indifference towards adopting IV medication infusion device integration is most likely due to competing IT priorities and the apparent risk and complexity of implementing this technology.*

Medication management comprises a highly complex group of processes and sub-processes with multiple points for potential breakdown. It involves several professional disciplines, requires multiple methods of documentation and communication across a variety of health care settings, and demands precision at every point of preparation, entry, handoff and transition in care. In this context, the use of information technology (IT) has been widely promoted as a strategy to reduce the human contribution to medication errors by effectively organizing information, linking discrete pieces of information, and performing repetitive tasks, including the assessment for medication-related problems. For example, computerized physician order entry (CPOE) and bar code-enabled medication administration (BCMA) systems have been shown to reduce errors

associated with medication ordering and administration, and pharmacy dispensing, preparation and clinical information systems have been shown to be valuable tools for reducing mistakes related to medication preparation and distribution.¹

The introduction of “smart” (computerized) IV medication infusion pump technologies has also shown great promise in reducing programming errors that CPOE and bar coding miss, by comparing information entered during programming to hospital-defined best practices.² The national trend toward adopting smart pump technology remains strong, with nearly 65% of all hospitals reporting smart pump use and 63% of those without smart pumps planning on implementing them within the next three years.³

Despite the documented benefits of smart pump use, researchers believe their full potential has yet to be realized,

arguing that, in order to achieve maximum protection against all IV administration-related errors, seamless, multi-directional communication and integration among smart pumps and electronic medical record (EMR) systems need to occur.⁴ Because of its perceived and studied benefits, such integration remains the “holy grail” for medication administration safety; however, for a number of reasons the majority of health care organizations have yet to adopt the technology.

In this article, a readiness assessment including organizational and departmental capacity, vision and benefits realization, financial and human resources required for IV medication infusion device integration within the current state of EMR, and hospital IT-enabled, closed-loop medication management, are discussed.

Current State of Medication Management Supporting Technologies

Over the last three to five years the trend toward implementing core and ancillary medication management supporting technologies and EMRs has continued to rise steadily, as depicted in Figure 1.³ The most “wired” medication use processes include pharmacy order transcription and dispensing, with nearly 90% of all hospitals using automation for dispensing and nearly 95% using a pharmacy information and order management system for medication order fulfillment and review.

Figure 1. Current State of Medication Management Supporting Technologies³

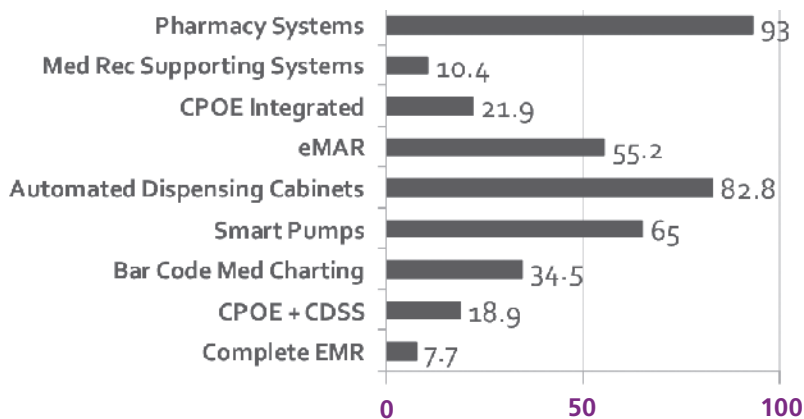
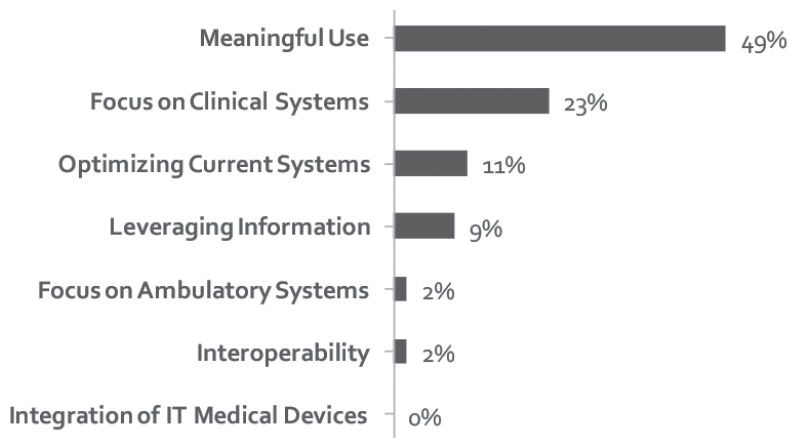


Figure 2. 2011 Top IT Priorities: Next 2 Years¹¹



Although the trend for adopting automation and technology to support medication ordering and prescribing continues to rise overall, in 2010, except in federal facilities, the deployment rates of fully integrated CPOE and pharmacy information management systems were less than 25%.³ While implementation of medication administration systems has increased significantly over the past three to five years, the integration of these systems remains low, with only 3% of all hospitals reporting significant integration of smart pumps with their EMR.^{5,6} Approximately 8% of all hospitals regardless of size have implemented complete EMRs, with only 2% of them having a system that meets the federal government’s “meaningful use” criteria.⁷

The integration of medical devices onto hospital IT networks offers enormous promise for reducing medication-related adverse events; however, most health care organizations have struggled to fully leverage and integrate these technologies and fully address the growing number of operational, regulatory, safety, continuity of care and quality issues. In addition, as hospital IT departments shift their focus from adoption and deployment to system connectivity and applied informatics, finding personnel who possess the necessary skill mix to meet the growing demand for IT-device integration remains challenging.^{8,9}

Other barriers to device-IT integration include:¹⁰

- Uncertainty about vendor systems
- Lack of standards
- Competing non-IT priorities
- Difficulty choosing among various HIT solutions
- Need to make essential processes more reliable and predictable
- Need to optimize existing systems
- Regulatory incentives and penalties

Competing IT Priorities

The 2011 Healthcare Information Management and Systems Society (HIMSS) leadership survey showed that for roughly 80% of health care organizations, their top priorities are meeting the meaningful use objectives, optimizing applications, and maintaining existing clinical systems (Figure 2).¹¹ These initiatives have increased the demand for financial and human resources and have caused more-targeted IT solutions such as smart pump integration to fall off the growing list of priorities. Many organizations are also finding it hard to choose among all the potential IT-related solutions, knowing that the larger ones take time, many involve significant infrastructure costs, and the risk of failure is much higher than with non-IT capital expenditures.

Even larger healthcare organizations are experiencing difficulties in meeting the demand for high-priority IT-related projects and are looking to implement more process-related solutions, including:¹

- Standardization and process reliability
- Checklist utilization
- System and procedural redundancy

Understanding that layering new technologies onto bad processes does not necessarily lead to better outcomes, many healthcare leaders have chosen to maintain the safety gains attained from stand-alone smart pumps and to shore up existing processes and procedures, including the use of standardized infusion medication concentrations. A 2010 ASHP practice survey indicated that more than 70% of all hospitals implemented the use of one or two standardized IV infusion concentrations included on the Institute for Safe Medication Practices' list of high-alert medications.³

Risk/Value/Complexity Assessments

In order to more effectively assess the potential impact of a given technology, many healthcare organizations are using business problem-solving methodologies such as matrix modeling to guide them in determining the relative complexity, risk and value of an emerging technology. Realizing that the speed of technology adoption is a business problem, not an IT problem, they are stepping outside the IT realm and considering a technology's value from a purely business perspective before adopting it. If a technology is tied to any regulatory, legal or customer requirements, and if it significantly reduces costs and increases revenues, then its use is regarded as inevitable, making early adoption advisable. But they tend to start small, allocating enough time and resources to make revisions or reverse direction, if necessary. If a technology does not pass the inevitability test, late adoption is usually considered a better approach.¹²

For smart infusion systems, the financial and safety benefits, as well as the complexity, risk, value and comparative payback profiles, have led the use of this technology to be considered inevitable. Nearly 65% of all hospitals have adopted this technology, and 63% of hospitals without smart pumps are

planning on implementing them within the next three years.³

IV medication infusion device-IT integration, however, has yet to pass the inevitability test.¹² Despite recognizing the future value of real-time interaction among monitors, pumps, a patient's EMR and decision-support tools, most health care organizations have been comfortable remaining on the sidelines when it comes to device-IT integration. The complexity, risk, value and comparative payback profiles are not as favorable as for stand-alone smart infusion systems. This is causing health systems to take a more wait and see strategy, preferring to use the lessons learned from the early adopters and observe how the technology will impact the competition and the marketplace.^{12,13}

IV medication infusion safety systems are evolving into an integrated component of an ideal IT-enabled medication management strategy. Technical barriers are beginning to fall, allowing such devices to share data reliably, securely and quickly from the point of care to the EMR and decision support systems. As a result, many healthcare systems no longer view device-IT integration as an unnecessary distraction but as an important piece to close the loop on the medication-use cycle and further reduce medication errors. However, despite the progress in overcoming the many barriers and challenges of device-IT integration, the vast majority of health care institutions have chosen a wait and see strategy when it comes to adopting this technology due to competing IT priorities, limited financial and human resources, the persistence of legacy medication management supporting systems, relative risk, complexity and value.

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PROCEEDINGS

CNIOs and IV Pump Interoperability: Is this a Must Have or a Nice to Have?

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Aurora Health Care, Milwaukee, WI
June 2011*

Key Points

- *Aurora Health Care is a nationally recognized, 15-hospital, integrated delivery network headquartered in Milwaukee, WI, with an information technology (IT) department of 550 employees and an annual IT capital budget of about \$35 million.*
- *IT governance structures help keep a strategic focus on how a particular IT project will support the higher-level goal.*
- *In the prioritization of possible IT projects, IV pump interoperability comes up against meaningful use and governmentally required changes in electronic data interchange (EDI) standards and ICD-10 coding and billing.*
- *Data for the US EMR Adoption ModelSM show that only about 19% of US hospitals have reached the higher stages where IV pump interoperability would be implemented.¹*
- *For the majority of US hospitals, building core infrastructure will have to come before more complex undertakings such as IV pump interoperability.*

Aurora Health Care is an integrated, not-for-profit health care provider serving communities throughout eastern Wisconsin and northern Illinois. Its extensive experience with hospital information technology (HIT) can help shed light on whether chief nursing information officers' (CNIOs) consider intravenous (IV) pump interoperability a "must have" or a "nice to have." This experience is also relevant to smaller hospitals and health systems, which face equally challenging issues with few resources.

A national leader in developing and implementing best practices in clinical improvement and disease management, the Aurora Health Care network includes 15 hospitals (60 to 850 beds), 3,400 staff physicians, 1,500 employed physicians, 500,000 inpatient days/year and \$3.2 billion annual revenue. Aurora began its electronic health record implementation journey in 1995, and today has mature functionality such as CPOE and bar coded medication administration and over 17,000 user logins.

IT Department

The average annual IT capital budget is about \$35 million, with an average annual operating budget of \$56 million (3% of revenue). Demands on those resources are equally large. Even spending about 50% on infrastructure, the refresh cycle on laptops is seven years and about the same on desktop computers. With approximately 20,000 devices, including printers, personal computers and about 8,000 mobile devices, expenditures for network and desktop upgrades, etc, quickly consume the department's resources.

The IT department typically manages nine to 12 strategic projects each year, along with 100 to 200 "departmental" projects, which come up as requests, and 50 to 100 "infrastructure" projects. These can range from upgrading the uninterruptible power supply (UPS), which took \$7 million and two years, to upgrading closets in the different facilities, which took much less time. Having to spend money on infrastructure can be frustrating, when more is needed for the EHR; however, it is important to appreciate the need for expenditures such as disaster recovery. Having an EHR would serve no purpose, if it could not be recovered quickly. Determining how precious dollars will be spent on requires balancing many important, conflicting priorities.

IT governance

Good IT project governance is essential. Within the Aurora IT department, a “modified” project management office (PMO) comprised of project managers and supervisors is responsible for intake, portfolio management, project planning, time recording, project monitoring and controlling. Having a more formal structure in place (Table 1, Figure 1) ensures that when an idea becomes an actual project, it has staffing, a budget, a defined beginning and end, outcomes, evaluation criteria and return on investment (ROI), so that it can be fully executed and completed.

Table 1. Governance for IT

- Allocate capital and operating budgets for IT (determine allocations for new projects vs. maintenance and support)
- Prioritize incoming IT requests
- Create IT roadmap and set strategic direction for IT projects based on organizational goals, mission and vision

About six years ago the staff realized that the best IT-project is probably not an IT best-project; it is probably a clinically oriented project that has clear goals, investment criteria and ROI. Then IT becomes the enabler for the clinical project, rather than being the project itself.

For example, in considering implementation of computerized prescriber order entry (CPOE), the focus has to be on changing the way care is delivered, rather than on the technology and how it will be implemented. Governance structures help keep the focus on the strategy the organization is trying to execute and how a particular IT project will support that higher-level goal.

Prioritizing incoming potential projects is essential. In a given year only about 10% to 15% of suggested projects can be accomplished. Considering what can actually be done is extremely important. For strategic projects, IT governance creates an overall roadmap to determine where they will fit in with the many project suggestions coming up from staff.

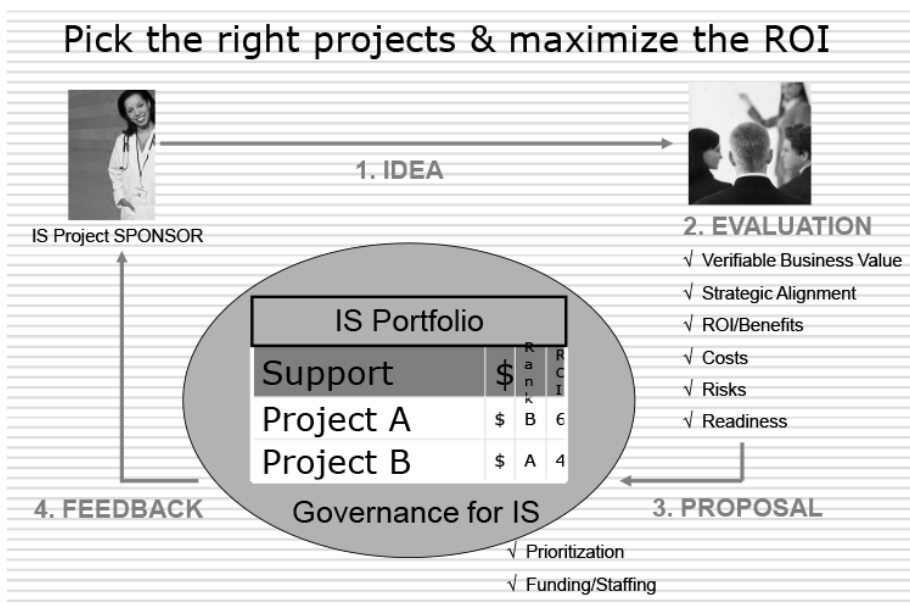
The IT governance council recently reviewed their current roadmap and performed a gap analysis with the Health Information Technology for Economic and Clinical Health (HITECH) Act (part of the American Recovery and Reinvestment Act) that revealed two areas that were not being considered: patient involvement and health information exchange. As a result, the roadmap was revised, so that all possible government incentives for EHR implementation could be obtained as early as possible.

Intravenous (IV) Pump Interoperability - Considerations

If a nursing or pharmacy group suggested that IV pump interoperability should be considered, that suggestion would go through the governance process and be evaluated. Some of the questions that would be asked include: What is the business value? Is it verifiable? What is the objective? How does the idea rank in terms of strategy? Are the benefits quantifiable? What is it going to cost, what are the risks? How difficult will it be to implement? What is the ROI? That information is then used to create a proposal to see how it fits in the portfolio. Is it going to require five new interfaces? Will it require new expertise? Will additional staff need to be hired? After the proposal has been thoroughly vetted, it goes back to the governance council for prioritization and then, of course, possible approval and funding.

By following this process, people feel that their ideas are thoroughly vetted and brought forward. Clinician involvement is crucial, because that will be required for success. When the final candidates for projects are identified, the sponsors come to present their thoughts on their project’s value, cost, and importance. Some bottom-up requests end up

Figure 1. Governance for IT



becoming integrated into the overall strategic roadmap. Having some transparency around project tracking and dashboards on the organization's internet sites also makes sense, so that everyone understands what projects are being implemented, or not.

IV Pump Interoperability - Status?

"Smart" IV pumps have been installed at Aurora, but are not integrated with the EHR. That has not been brought forward as a project request but is something that the staff wants to do. However, as possible IT projects are prioritized, IV

pump interoperability comes up against meaningful use, which represents about a \$110 million revenue opportunity for Aurora. Other high-level, conflicting needs are the changes in electronic data interchange (EDI) standards and ICD-10 coding and billing. Governmental regulatory changes are requirements that must be put on the roadmap. Another pressure is to provide clinicians with mobile devices to be able to access the EHR anytime, anywhere. As a result, medical device interface will probably end up low on the list.

Nation-wide, data for the US EMR Adoption

ModelSM (Table 2¹) show that only about 19% of US hospitals are in the higher stages where projects such as IV pump interoperability would be implemented. Eighty-one percent of hospitals are in lower stages or just beginning.¹ Thus, for the majority of US hospitals, building core infrastructure will have to come before more complex undertakings such as smart pump integration.

¹ HIMSS Analytics (2012). EMR Adoption ModelSM. Retrieved April 24, 2012 from http://www.himssanalytics.org/hc_providers/emr_adoption.asp

Table 2. US EMR Adoption ModelSM

US EMR Adoption Model SM			
Stage	Cumulative Capabilities	2011 Final	2012 Q1
Stage 7	Complete EMR; CCD transactions to share data; Data warehousing; Data continuity with ED, ambulatory, OP	1.2%	1.2%
Stage 6	Physician documentation (<i>structured templates</i>), full CDSS (<i>variance and compliance</i>), full R-PACS	5.2%	6.2%
Stage 5	Closed loop medication administration	8.4%	9.4%
Stage 4	CPOE, Clinical Decision Support (<i>clinical protocols</i>)	13.2%	13.2%
Stage 3	Nursing/clinical documentation (<i>flow sheets</i>), CDSS (<i>error checking</i>), PACS available outside Radiology	44.9%	43.9%
Stage 2	CDR, Controlled Medical Vocabulary, CDS, may have Document Imaging; HIE capable	12.4%	12.1%
Stage 1	Ancillaries - Lab, Rad, Pharmacy - All Installed	5.7%	5.5%
Stage 0	All Three Ancillaries Not Installed	9.0%	8.4%
Data from HIMSS Analytics SM Database ©2012 ¹		N = 5,337	N = 5,318

PROCEEDINGS

Between Now and the “Big Bang”: Interim Technology Applications to Help Achieve IV-IT Interoperability

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Key Points

- *The “Big Bang” refers to a future state when full integration between intravenous (IV) infusion systems and hospitals’ enterprise clinical information technology (IT) systems functions optimally, permitting a seamless intelligent digital pathway between provider order entry and the patient vein. It has been generally accepted that “Big Bang” meant “automated programming of infusion pumps from the pharmacy information system”; here we articulate and examine a broader interpretation of the term.*
- *Desirable characteristics of the “Big Bang” include: (a) elimination of manual order entry and of transcription of the same information into a succession of different, loosely-coupled systems; (b) robust, patient-aware clinical decision support; (c) some form of assisted caregiver programming of drug infusion pumps; (d) auto-documentation of each infusion pump’s status into electronic acute care documentation and anesthesia information systems, and (e) enhanced alerts and second-checks. Since this future state does not yet exist, several provocative implementations and ‘practical roadmaps to the future’ are discussed.*
- *Academic medical centers and other institutions have advanced toward their own unique visions of the “Big Bang”: examples include Intermountain Healthcare and the Partners Healthcare System.*
- *In the future, as more and more clinical information is maintained electronically and becomes immediately available to front-line caregivers, the role of computerized intravenous (IV) infusion systems (“smart pumps”) may dramatically change.*

The “Big Bang”

The notion of a “Big Bang” refers to a future state where continuous, electronic, two-way communication between intravenous (IV) infusion systems, enterprise clinical information technology

(IT) and electronic health records (EHR) systems becomes the norm and functions optimally. It is widely anticipated that achievement of the “Big Bang” will reduce the incidence of device failures and medication administration errors and

increase caregiver productivity, patient safety, and patient satisfaction.

Such interconnectivity can “close the loop” in IV medication administration, sending physician’s orders from computerized provider order entry (CPOE) systems to automatically program the infusion pumps, and then sending infusion data from the pumps back to the EHR to close the loop in real or near-real time. Essential elements of the “Big Bang” are shown in Table 1.

In this article, the current state of IV-IT interoperability, device information acquisition (DIA), enhanced notification of errors, a crawl-walk-run roadmap to the future, and an emerging ‘mobile-computing-centric’ approach to medical device connectivity are discussed.

The question of how the design and functionality of smart pumps should logically evolve over time, as more and more clinical information is available, is also posed for consideration.

Current State of IV-IT Interoperability

The significant problems associated with the absence of full integration have been well documented in numerous studies, notably the landmark ethnographic study by Husch et al.¹ Many institutions here and abroad have worked diligently to reduce the gaps in interconnectivity. The status and evolution of IV medication safety systems at two integrated health

delivery networks (IHDN)—Intermountain Healthcare (Utah) and Partners Healthcare System (Massachusetts)—provide noteworthy examples.

Intermountain Healthcare

Intermountain Healthcare (IHC) has long exhibited strong leadership in the use of computers in the practice of medicine. The pioneering work by Homer Warner, MD, at LDS Hospital in Salt Lake City from 1950 to 1980 in developing clinical decision support for cardiology set the stage for the emergence of the field of medical informatics.² An early electronic medical record (EMR) was implemented at LDS in the 1970s. Their “informatics-centric perspective” to healthcare computing led to early recognition that data being sent to and from medical

devices are important elements in clinical information repositories. These data repositories could provide the basis for clinical management, sophisticated quality management systems, and analysis of variation and the effectiveness of process improvement initiatives.

IHC initiatives around medical-device data flows included outstanding achievements involving IV medication administration safety. These achievements have been published in several venues and are summarized in video presentations available online. The following achievements are arguably the most significant.^{3,4}

Barcode “license plate” for pump.

Clinical engineers and the informatics team created a hybrid bar code/pump identifier label that is put on the front

of each drug infusion pump, allowing the user to link a specific infusion pump to an individual patient. This association between pump and patient is a critical step to advance IV medication safety at IHC and beyond.

Displaying a patient-specific infusion order on the infusion pump. Once a bedside caregiver associates a particular pump with a patient’s medication order, the pump receives the order information over the wireless network and displays the information as a scrolling text message across the top of the screen. This scrolling message assists the caregiver in navigating the pump’s menu prompts by repeating the key specifics of the medication order, such as “Nitroglycerine 250mg in 250 ccs; 50 ug/kg/min” or “Heparin 500U/ml; 800 U/hr”. This could be described as “auto-programming” or a “clinician-programming-assist function.”

Device information acquisition (DIA). IHC has implemented auto-documentation from patient-connected medical devices such as drug infusion pumps into the electronic flow sheets that serve as the basis for the moment-to-moment care of critically ill patients. DIA provides sophisticated software that filters device-status changes to capture only clinically significant data such as drug-dose rates, dose-rate changes, and alerts. This reduces the manual documentation burden and permits a highly granular remote view of patient status.

Enhanced alert notification. IHC has enhanced the vendor-supplied smart-pump features by connecting the smart system with the EMR and providing “enhanced notification of infusion pump programming errors.”^{3,4} A sophisticated surveillance system tracks the patient’s drug-dose rate and associated laboratory values over time, recognizes when a clinician has programmed a “step-change,”

Table 1. The “Big Bang”: Elements of Ideal IV-IT Interoperability

- *Software versioning:* The onboard software and safety features for every device are always fully up-to-date.
- *Perfect connectivity:* Wirelessly connected patient-care devices can rely on perfect connectivity 100% of the time.
- *No latency:* There is no clinically significant delay between the time patient-care information is generated and its availability to all hospital systems and devices.
- *Seamless digital pathway:* There is perfect information fidelity between the provider’s order and any device’s need for order elements.
 - *Standardized terminology:* All providers, clinicians, devices and systems use the same vocabulary and syntax—units of measure, rates/time, default dose rates, etc.
 - *Computerized prescriber order entry (CPOE):* Except in emergent situations, CPOE is the only way to an order can be placed.
 - *CPOE personalized clinical decision support:* Every order is electronically checked for safety—drug interactions, dosing limits, allergies, etc.—as it is created, and the provider makes all corrections.
 - *Automatic identification:* Patient-care devices use electronic recognition to identify drug, dose, concentration, etc. of all doses. Tags point to information that resides elsewhere.
 - *Auto-programming:* Patient-care devices receive all initial dosing instructions directly from the verified provider order via the network.
 - *Auto-documentation:* Smart-pump infusion data are automatically sent from the pump to electronic acute care documentation (ACD or “eChart”).

and promptly alerts a second expert (eg, a unit-based pharmacist or another clinician) to check the infusion and validate whether the new programmed dose rate is correct and safe for the patient. Such enhanced notification of infusion pump programming errors appears to be a significant advance in IV medication safety surveillance, and seems promising for validation at other provider organizations, which could lead to wider adoption.

These DIA-enabled achievements represent noteworthy success that is directly aligned with the strategic perspective of IHC’s leadership. As Brent James, MD, IHC’s chief quality officer, has said, “The complexity of modern medicine exceeds the capacity of the unaided expert mind. Good practice means good focus. Good focus means the right information and the right format at the right time. That requires carefully-designed systems, a context in which physicians and nurses can work.”^{2,6}

Partners HealthCare System (PHS)/Massachusetts General Hospital (MGH)

Recognizing the importance of information connectivity, PHS convened a multidisciplinary Connectivity Task Force to develop a roadmap for the transition of IV drug administration systems from stand-alone smart pumps to networked intelligent infusion devices (IIDs). The connectivity/integration vision is robust, correct and of strategic importance. However, far from being obvious or easy, the transition from interoperability to full integration is expected to require significant design planning, prototyping and validation, as well as advocacy and collaboration with pump vendors. A systematic roadmap was defined and metrics articulated to measure success along the way.

History of medication safety initiatives at PHS/IMGH

The first priority of High Performance Medicine at Partners HealthCare was to implement CPOE, new pharmacy information systems, bar coding, bar code medication administration (BCMA) systems, and smart pumps at every patient care bedside at PHS. These efforts extended from 2004 to 2009 and were facilitated by pay-for-performance incentives structured collaboratively by PHS, its insurers and the Center for Medicare and Medicaid Services (CMS). The second priority (still in process) is to effectively link every smart pump to the hospital’s secure wireless network, adopting and implementing the most rigorous standards for security and authentication of the medical devices on the PHS wireless network. After implementing mechanisms to associate each pump with a patient’s medication order, as at IHC, the next priority likely will be to automatically document infusion data in electronic acute care documentation (ACD or “eChart”).^{5,7-11} A further step will be to create “middle-ware” that can check whether a patient’s medication order (as entered into the pharmacy profile) is

correctly implemented by the infusion pump and, if not, provide necessary alerts. This provides a second safety check of the pump’s programming against an actual medication order, augmenting the vision of “making the right thing easier to do.” For selected high-risk medications, a second-nurse pump-programming check (with electronic signature) will be required, not as a functionality that resides within the infusion pump but as a prompt within the hospital’s BCMA system.

PHS design considerations to achieve full integration of infusion devices

Currently all IV infusion pumps at PHS are smart pumps. The future vision is to proceed as shown in Table 2, starting with the easier tasks shown at the top of the table and working down to the ultimate goal of infusion pump auto-programming. Each task may evolve into a strategic adoption metric that can be tracked across the many cooperating PHS provider organizations. Determining which tasks are harder, easier, highest and lower priority is inevitably a moving target. Some of these nuanced issues are discussed more fully in the Report (available upon request to Dr. Sims at PHS).

Table 2. PHS’ Connectivity Task Force for Wireless Infusion Pumps: PHS’ Current State

Smart Pump Wireless Integration with Clinical Systems

- Association of pump to patient
- Pump status data to pump server
- Back office safety check—pump settings vs. med order—*Not likely to be subject to FDA regulation; non-real time*
- Auto-documentation—pump settings auto-filled into EMAR—*Likely FDA Class 1 device; non-real time*
- Auto-programming pumps—*Likely FDA Class 2 or 3 device; real-time*



* No PHS infusion pumps are here yet. Pre-pilot considerations: buy-in, resources, scale-up, regulatory/PHS IS network issues.

Design considerations that were viewed by PHS as “nuanced, but critical to quality” include the following four key issues.

- The first PHS consideration for clinically desirable design is a hazard analysis requirement. Hazard analyses are designed to avoid the introduction of new products or services that initially seem useful but may have unintended negative consequences. Potential hazards are typically screened for severity, detectability, and ease of design mitigation.
- The second PHS consideration is to consider designs which included data flows that would not require eye-blink-speed network latency in order not to interfere with clinician workflow. For example, until perfect wireless network performance can be guaranteed, it may not be advisable to auto-program infusion pumps but rather to concentrate on auto-documentation, where network delays of seconds or minutes would not likely be noticeable or bothersome to front-line clinicians.
- The third PHS design consideration has to do with allocation of liability. It is widely assumed that customized drug libraries and drug-dosing algorithms enhance patient safety while improving efficiency of care. The library framework is designed by the manufacturer, while the content of the drug libraries (often containing off-label drug administration practices) is the responsibility of the provider organization. This approach places the burden of responsibility on the provider and allows for a customization of practice presumably based on sound clinical decision making. A “back-office safety check” (middleware that checks whether an infusion pump’s programming corresponds with the unique medication order) may have a

more defensible safety assurance case. The content of the clinical decision support is implemented by the provider organization itself, rather than by a device manufacturer. The provider organization appropriately would have to take responsibility for writing the back-office safety check, aspects of which relate to codification of medical practice within a medical device.

- The fourth PHS design consideration is ease of implementation: how to design an added feature or capability that improves safety or productivity for front-line caregivers, while minimizing impact on current clinical practice or workflow. The approach recommended to facilitate IV-IT communication was to leverage recently installed BCMA infrastructure, which included wall-mounted bedside computers; portable, wireless, bar-code-scanners; and an intense program of caregiver training. Leveraging existing infrastructure and routine workflow are necessities.

Alternative Approaches

Provider organizations such as IHC and PHS are proceeding in a systematic fashion towards the “Big Bang” of full IV infusion pump integration with clinical information systems. The implementation rates among institutions are not homogenous, however, and institutional resources and commitment are two important rate-limiting factors. As a result, alternative approaches have emerged that take advantage of local resource availability and reflect the crawl-walk-run approach.

Future Directions

Given the variety of methods that can be used to achieve true connectivity, multiple approaches likely will evolve. It is reasonable to assume that many of the approaches will take advantage of

existing infrastructure (smart pumps, BCMA systems and the like) and many will strike out onto uncharted waters. An ongoing discussion is the future need for smart pumps. Will device intelligence increase, or will future developments lead to a simpler device with increasing system connectivity? Regardless of the path chosen, opportunities abound for structural improvements to what most would argue is a still imperfect system.

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PROCEEDINGS

Intravenous (IV) Infusion Pump Device Wireless Connectivity: Development, Current Status and Requirements for Success

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Key Points

- *In the early 21st Century the sudden surge in demand for wireless connectivity required the market to quickly accept 802.11 “WiFi” technology that is not a perfect match for mission-critical or roaming wireless clients applications and devices.*
- *Matching the demands of various wireless functions with the required wireless infrastructure demands (Table 3) is of primary importance.*
- *The development of real-time, mission-critical functions goes beyond what either infusion vendors or hospital IT can accomplish alone; wireless infrastructure vendors and hospital IT departments must work collaboratively for these efforts to succeed.*
- *The increasing convergence of biomedical/clinical engineering and hospital IT roles and responsibilities will mandate new ways of thinking and acting, which that can make a huge difference in the successful deployment of wireless infusion pumps on hospital IT networks.*

From Smart Pumps to Smart Integrated Systems

“Smart” intravenous (IV) infusion pumps with sophisticated dose-error-reduction software (DERS) help avert high-risk medication errors and, just as importantly, provide previously unavailable data that can help hospitals with continuous quality improvement (CQI). Now wireless connectivity greatly increases the value and utility of these devices by making it possible to integrate smart pumps on a hospital’s information technology (IT) infrastructure.

With wireless connectivity, hospital staff can easily upload software updates and

download CQI data, without having to manually interact with individual pumps. Easier access to the data allows staff to more easily analyze usage, assess variations in practice and identify opportunities to improve patient safety and quality of care. Connectivity also provides the necessary foundation for advanced applications such as automatic smart pump programming and automatic documentation of infusion data in the electronic medical record (EMR), closing the loop for complex IV order management.

The road to achieving scalable infusion pump connectivity was long and complex, and debate continues as to whether hospitals have the necessary technology

and resources to fully integrate IV infusion pumps into the complex IT ecosystem.

In this article, the development of IV infusion pump wireless connectivity, real-world requirements, an ideal wireless smart pump system, successful integration, future needs, and recommendations for hospitals considering deployment of smart pump integration are discussed.

Development

In the mid-1980s several different technologies were being evaluated as potential solutions to infusion pump connectivity (Table 1). At the same time, several competing technologies were being evaluated for hospital IT connectivity (Table 2).

Medical device companies and hospital IT departments had the same goal: to make it possible for smart pump data to be easily shared and analyzed, and for smart pumps to remain connected to the IT infrastructure regardless of their location in the hospital. Unfortunately, for the most part the companies’ and hospital IT connectivity solutions were evolving independently. Most hospitals were run as a collection of departments such as biomedical/clinical engineering and IT that shared certain strategies but not much else. Not surprisingly, medical device companies rarely considered what hospital IT was doing and vice-versa. But ultimately the demand for device mobility

and data sharing forced a convergence of medical devices with hospital IT and the development of wireless connectivity.

The demand for hospital-wide data mobility exploded in the early part 21st century with the implementation of hospital IT applications such as computerized prescriber order entry (CPOE) and barcode medication administration (BCMA). Unfortunately, the sudden surge in demand for wireless connectivity required the market to quickly accept 802.11 “WiFi” technology that is not a perfect match for mission-critical or roaming wireless clients applications and devices.

In 2001 CareFusion (then ALARIS Medical Systems, Inc.) introduced the first smart pump,⁹ which included a serial RS 232 interface, and was the only company to offer the option of IEEE 1073 Medical Information Bus connectivity. As early as 2002, the company began work to develop technology that would enable connectivity through the emerging IEEE 802.11 wireless standards, which have become the de facto standards for hospital IT networks. Although this set of standards is not the best for integrating commercial medical devices, so long as client and server software are developed appropriately, a medical device can exist nicely on these networks. Today CareFusion has implemented well over 300,000 such IEEE 802.11 wireless infusion channels running in over 600 hospitals, delivering more than 200 million infusion data messages every day.

Real-World Demands

The journey to widespread use of smart pump wireless connectivity has provided many “lessons learned.” These start with a vendor’s commitment to real-world connectivity. In the real world, as soon as the data leave the pump on a hospital wireless network, they are no

Table 1. Infusion pump connectivity: potential technology solutions

Infusion Pump Connectivity	Comments
RS232 Serial	Traditional “PC” type of serial interface with attached cable. A single point-to-point interface.
RS449 Serial	High-speed serial interface allowing greater distance using an attached cable. A single point-to-point interface.
Current-Loop	A low-powered, long-distance interface with attached cable.
IEEE 488	Traditional “bench lab” type of serial interface with several control elements allowing pumps to be “daisy chained” using an attached cable. More than one pump on a single cable. Cables are large multi-conductor type and not appropriate for multi-room connections.
IEEE 1073	First attempt to provide a standard that could connect all medical devices, including infusion pumps. A complex infrastructure of device connections and hubs allowed multiple device integration and time sequencing. Sometimes referred as the Medical Information Bus or MIB.
IEEE 802.11	IEEE 802.11 is a set of standards for implementing wireless local area network (WLAN) computer communication in the 2.4, 3.6 and 5 GHz frequency bands. The standards are created and maintained by the IEEE LAN/MAN Standards Committee (IEEE 802) and provide the basis for wireless network products using the Wi-Fi brand. The original version of the standard—IEEE 802.11-2007—has had subsequent amendments. The current version is IEEE 802.11-2012.

Table 2. IT connectivity: potential technology solutions

IT Connectivity	Comments
Token-Ring	Devices connected in a loop where a data “token” is generated and passed from one client to another until an address match is made. Promoted heavily by IBM as the best standard for computer connectivity
Linear-Bus	First large-scale implementation of “collision detection – collision avoidance,” now considered a protocol standard. All devices listen and transmit on a single coax cable bus with tap feeds for each client. This is the basis of today’s “Ethernet”
Star	Ethernet protocol using a hub or switch in a star pattern connecting to each client individually. The star topology is emerging as the most common network layout used today.

longer under the control of the pump vendor. This was a foreign concept many years ago, particularly for most medical device vendors. It is critically important to recognize that the wireless throughway is a shared highway. In-depth knowledge of bandwidth utilization, roaming, and security are fundamental requirements for a vendor to be able to design an ideal wireless device that shares the wireless highway as a “good neighbor.”

Ideal System

An ideal IV infusion safety system would have a single wireless communication link that is independent of the number or type of infusion modules attached to a point-of-care unit’s computer “brain.” With a common technology platform, any combination of large-volume, syringe, patient-controlled analgesia (PCA), capnography (EtCO₂), and pulse oximetry (SpO₂) modules could be supported by a single wireless link, a single database and single server administration. Having all devices on a common platform with a common wireless protocol greatly reduces variability and greatly enhances wireless security and bandwidth utilization. This cannot be easily achieved with multiple infusion platforms from the same or different vendors, all running different wireless protocols with different security, administration, and database behaviors.

Requirements for Successful Integration

Even with an ideal device, integration remains a challenge because of the enormous variability of hospital IT networks. It has been said that “If you’ve seen one hospital network... you’ve seen one hospital network.” Successful implementation of wireless connectivity requires in-depth knowledge of hospital IT and what is needed for success.

A successful approach has been for a vendor to establish a dedicated field IT-support team and deploy all server-based applications within the hospital IT data center. Using subject experts with a keen understanding of the hospital’s strategic IT goals allows the installation team to partner with the hospital’s IT department, while setting performance expectations based on real needs. Matching the demands of various wireless functions with the required wireless infrastructure demands (Table 3) is of primary importance.

Even though the performance and security of these hospital wireless systems have continued to evolve, it remains uncertain whether the 802.11 “WiFi” wireless infrastructures can sustain continuous medical device connectivity with the HIT network, much less the interconnectivity among multiple devices necessary for the future.

Need for Industry-Healthcare Collaboration

The demand for faster, more secure wireless infrastructures in hospital IT will continue to grow. Only by using wireless connectivity to close the loop with IV orders management will it be possible to move safely from a single human interface (a nurse programming a pump) to complex, integrated functions such as CPOE and auto-programming. As shown in Table 3, the development of real-time, mission-critical functions goes beyond what either infusion vendors or hospital IT can accomplish alone; wireless infrastructure vendors and hospital IT departments must work collaboratively for these efforts to succeed.

Current wireless design can be “tweaked” to accomplish fully functional, closed-looped, infusion pump-connectivity integration. However, as the industry evolves, there are amazing opportunities for companies such as CISCO to step in with a true medical-grade, wireless network based on the needs of these connected infusion pumps.

In the future, medical device integration may take a new turn with the availability for hospital use of capabilities such as the metropolitan area network currently used in cell phone technology. For now the burden is on the medical-device

Table 3. Wireless Functions and Required Infrastructure

Wireless Function	What’s Needed	Comments
Infusion pump drug library update	Batch data push	Real-time not required. Batch updates can be optimized in software
Infusion pump status (Flowsheet and status board population)	Semi Real-time	A few minutes between updates acceptable
Infusion pump alarms push	Almost real-time. High QoS mission critical	Less than one minute end-to-end. Validate and display connectivity status
Infusion pump auto programming	Near Real-time. High QoS mission critical	Within seconds end-to-end. Validate and display connectivity status

developer to take the necessary steps to ensure that its wireless software and hardware are designed to meet the demanding needs of a mobile medical device in the hospital setting.

Continuing Convergence of Clinical Engineering and IT

Hospitals will also be faced with challenges and opportunities of the continuing convergence of what were once considered separate domains. The roles of biomedical/clinical engineering and hospital IT are merging and responsibilities becoming blurred. This convergence— or collision— of disciplines will mandate new ways of thinking and acting, which can make a huge difference in the successful deployment of wireless infusion pumps on hospital IT networks.

Recommendations

Drawn from the real-world experience of more than 300,000 wireless infusion channels in use, the recommendations listed in Table 4 should help any organization thinking of deploying wireless infusion technology.

Footnotes

Alaris® (formerly Medley™) System from CareFusion Corporation (at that time ALARIS Medical Systems, Inc.)

Table 4. Recommendations for Hospitals Considering Deployment of Wireless Infusion Technology

- Develop a long-term strategy for medical device wireless integration
 - Ask: Will what I'm doing today enhance or block the future value of a connected strategy?
- Promote the convergence of clinical engineering and IT domains
 - This takes unique skills and may require new job descriptions/titles.
- Validate security and performance
 - Ask: Has there been qualified validation of wireless security and performance?
- Be flexible – be ready
 - Value of wireless connectivity is high for greater safety and efficiency.

PROCEEDINGS

Medical Device Data Systems, IEC 80001 and Managing Networked Medical Technology

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Co-chair, ISO/IEC “80001” Joint Working Group 7

Key Points

- *Networked medical technology is increasingly used in day-to-day health care, promising not only improved safety, care and efficiency but also new regulatory oversight and risk management requirements.*
- *The Food and Drug Administration (FDA) final rule for Medical Device Data Systems (MDDS) provides for regulatory oversight of information technology (IT) network components and software applications used to handle medical-device information.*
- *The MDDS rule clearly states that health care delivery organizations (HDO) are considered medical device manufacturers (MDM) if they create an MDDS system, even if it is made available only for “internal” use.*
- *MDDS and IEC 80001: Implementing IEC 80001 can support key requirements of the FDA MDDS rule’s Quality System Regulation provisions.*
- *The IEC 80001-1 standard for risk management of IT-networks that incorporate medical devices provides a framework for addressing the safety, effectiveness and security aspects of networked medical technology.*
- *IEC 80001 provides for:*
 - *Multi-stakeholder collaboration—both within the HDO and with external technology suppliers—to manage the risk of medical IT-networks;*
 - *Information sharing—disclosure and dialog—that is fundamental to the risk management of networked medical technology;*
 - *HDO roles and responsibilities— including executive management responsibilities and a new medical IT-network (MITNet) risk manager role—that are necessary to support risk management activities; and*
 - *Full network life cycle management—from initial creation to change management, live network monitoring and eventual decommissioning.*

The ever-increasing role of networked medical technologies in day-to-day healthcare activities promises improved

patient safety, quality of care and efficiency. However, the use of these integrated systems often has unintended

consequences when their operation does not go according to plan. Examples include not having access to information when needed, having an entire enterprise-wide wireless network become inoperable for days, and having information mixed between patients result in misdiagnoses and medication errors. In most cases, the resulting harm to the patient and care organization is minor, but there are increasing reports of permanent patient harm and even death.

As Jeffrey Shuren, MD, JD, Director, FDA Center for Devices and Radiological Health, noted in his testimony to the Office of the National Coordinator for Health Information Technology (ONC HIT) Policy Committee, “In the past two years, we have received 260 reports of HIT-related malfunctions with the potential for patient harm—including 44 reported injuries and 6 reported deaths. Because these reports are purely voluntary, they may represent only the tip of the iceberg in terms of the HIT-related problems that exist.”¹ A recent TJC Sentinel Alert also noted the increase in technology-related adverse events and stated, “Not only must the technology or device be designed to be safe, it must also be operated safely within a safe workflow process.”²

One of the Priority Issues from the 2010 Association for the Advancement of Medical Instrumentation (AAMI)/FDA Infusion Device Summit was the need

to “Improve the integration of infusion devices with information systems and drug libraries,”³ including bridging differences in wireless networking, HIT systems, formulary and drug library standards, etc. This is a challenge for any organization and raises important questions: In the push to get networked solutions deployed, what organization is performing an overall risk assessment of the networked components and deploying risk control measures that mitigate the potential harm that could result from unexpected hazards?

Two key developments provide help in addressing these problems: the FDA’s reclassification of MDDS as Class I regulated systems,⁴ and the publication of ICE 80001-1, a new international standard for the risk management of medical IT-networks.⁵

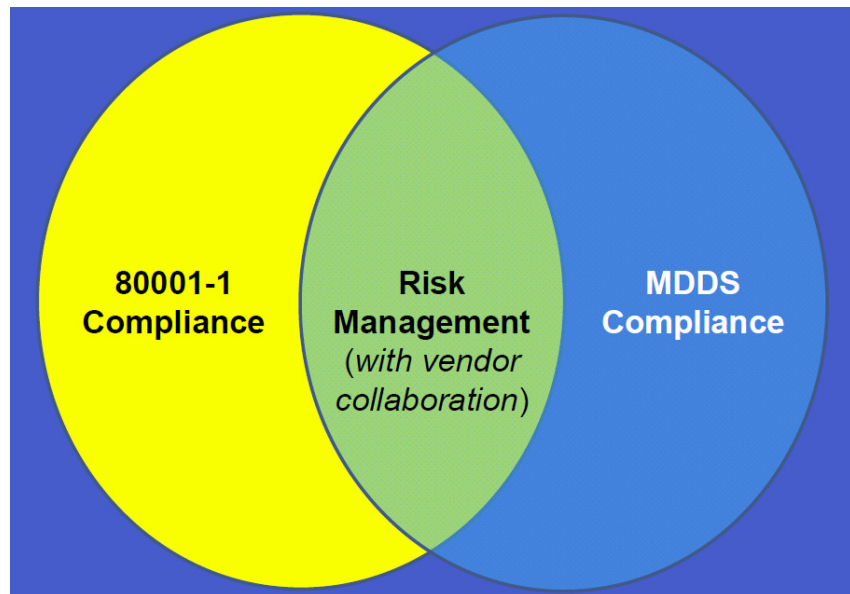
FDA MDDS Rule

MDDS components previously were thought to be generic HIT-networking components, but play a role in the transfer, storage, conversion and display of data that are acquired from medical devices.⁴ If an MDDS does not function properly, the resulting unintended consequences may be significant; thus, the quality and continued reliable performance of MDDS are essential for the safety and effectiveness of health care delivery.

The FDA final rule announced on February 14, 2001,⁴ clearly states that if a hospital creates an MDDS, it becomes an MDM and has to comply with Class I regulatory requirements. This is the case, for example, when a health care provider takes off-the-shelf IT components and adds software “glue” specifically to provide the MDDS functions listed above, a practice that today is used extensively in the healthcare industry.

Class I requirements for both companies and hospitals include registration of the developer as an MDM, adverse event

Figure 1. Risk Management, 80001-1 and MDDS Compliance



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reporting, and good manufacturing practice (eg, quality system requirements).⁴ As shown in Figure 1, many of the risk management requirements for an MDDS are also addressed by the quality system design controls of the IEC 80001 standard.

IEC 80001

IEC 80001-1 applies to systems after they have been made available for use and targets unintended consequences and adverse events resulting from networked medical technology. It provides the basis for communicating potential hazards and risk controls to end users from developers so that networked-technology risk management may be properly performed during integration/deployment and after “go live.”

This requires that all stakeholders, both HDO internal and external technology suppliers, cooperate around a shared vision of safe, effective and secure networked medical technology. The standard addresses all these entities, not only HDOs. The IEC 80001-1 standard applies to any medical IT-network, defined as a general-purpose network to which one or more regulated

medical devices is attached. This includes physical equipment and stand-alone software applications that perform functions meeting the legal definition of a medical device. IEC 80001-1 does not apply to networks where a single vendor assumes control of the entire network, including when the network is defined as a medical device. Instead, it focuses on the most prevalent case, in which an HDO brings together different technologies to create a network that best meets its organizational needs.

IEC 80001: The Basics

IEC 80001 focuses on three main aspects of networked medical technology management:

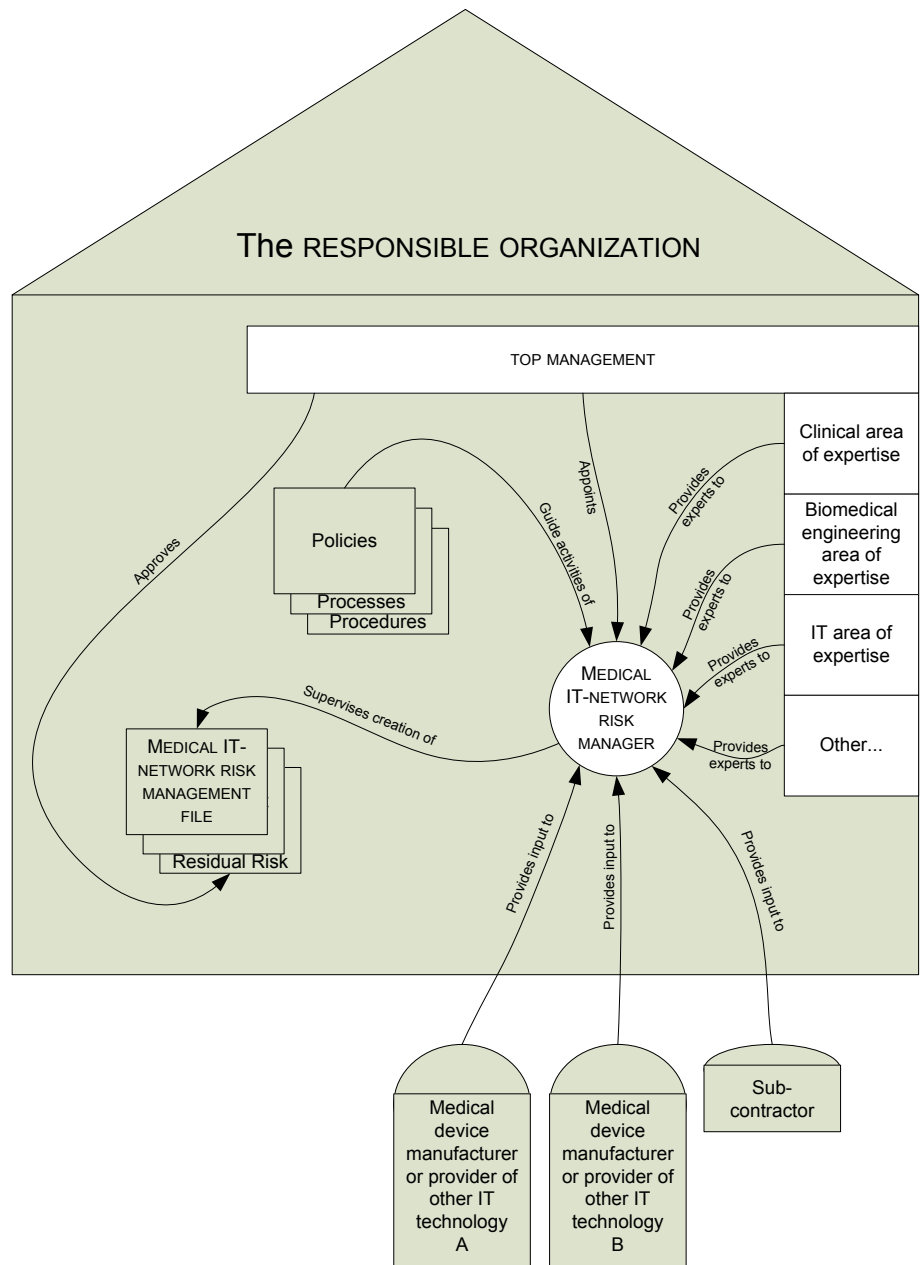
1. Roles and Responsibilities—both of the HDO that owns and operates the network and of its technology suppliers
2. Activities—the process of risk managing medical IT-networks
3. Documentation—all information collected as part of 80001-based risk management activities

Figure 2, often called the “House of 80001,” shows how these main aspects are related.⁵ An HDO—called “responsible organization” in the standard—has ultimate responsibility for the defined use and operation of networked medical technology. IEC 80001 recognizes this key role and provides the tools needed to manage these networks. “Top Management” refers to the executive, C-level functions of an organization that have to establish the risk management policy and processes, ensure that sufficient resources are available to perform the policy, and designate key roles such as the MITNet risk manager, define the probability and severity scales that are used to determine acceptable risk within the organization, and approve all changes to the medical IT-network before it is allowed to “go live.”⁵

An “MITNet Risk Manager” is an individual who acts as the central coordinator for all 80001-based risk management activities for a given network. Depending on its size and need, an organization may have one or more MITNet risk managers, who ensure that the policy and procedures are properly followed and fully performed, and coordinate with Top Management, clinical management, purchasing, biomedical engineering, IT and others. The MITNet risk manager also interfaces with technology suppliers and third-party service providers to ensure that required information is provided to support the risk management process, and that communication lines are in place to ensure that when problems arise, the suppliers will respond in a timely manner to resolve the issues.⁵

Required documentation includes the defined policies, processes and procedures that are followed by the organization to manage the risk of their medical IT-networks. The MITNet risk management file (RMF) is the central

**Figure 2. The “House of 80001”:
Roles, Responsibilities, Activities and Documentation⁵**



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repository for all information consumed and created by risk management activities. This does not need to be a single file cabinet (physical or virtual) that contains all information; however, all information should be referenced using a single RMF repository for each medical IT-network. Throughout the 80001 standard, compliance statements refer the auditor to review the RMF for evidence that required activities have been performed.⁵

A simplified version of the basic 80001 risk management process and key terms used during the process are shown in Figure 3. For example, real-time physiologic monitoring information may be delayed (hazard) due to wireless network dropouts or overloading (root causes) that could occur when a patient experiences asystole (hazardous situation), potentially resulting in (probability) delayed treatment or even patient death (severity). (Risk = a combination of probability and severity.) To reduce the risk of harm or “unintended consequence” an organization might deploy network monitoring tools (risk control measures) that would notify appropriate personnel when a potential source of harm (hazard) is present, allowing appropriate action to be taken before a hazardous situation develops.

Coordination with best HIT service activities is factored into the IEC 80001 full life cycle process, including change/release management, network configuration management and issue/problem resolution management. Finally, IEC 80001 is a high-level process standard—it does not provide all the answers for a given type of network, medical device or organization personnel. It establishes an overall framework that must be applied to address the specific needs and limitations of any specific HDO.

Collaboration: Disclosure & Dialog

IEC 80001 is founded on collaboration among all stakeholders involved in networked medical technology development and deployment, including external technology suppliers, both medical and IT. Disclosure of the information needed for risk management of a supplier’s system(s) when used with those from other suppliers is mandatory. Without that, the entire risk management process is crippled from the beginning.

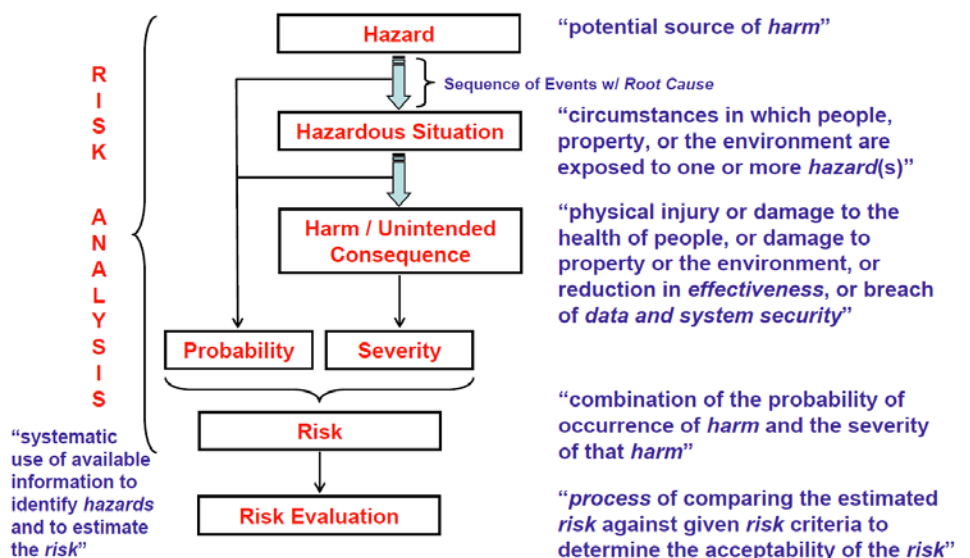
There must also be dialog between supplier and user about the unique requirements of the deployment environment and what is and is not feasible, for example, with regard to the security requirements of a given system. Each vendor provides what it sees as the best way to secure its system. Often this conflicts with the policies and tools already deployed in a specific organization and IT-network. For this reason, the supplier has to disclose its system’s security needs and risks, along with the associated controls. The end-user must

then evaluate how these controls may or may not support its own security needs, risks and capabilities, and dialog with the supplier to achieve an acceptable level of overall security risk for those systems.²

The end goal of all 80001-based risk management is to manage networked medical technology to achieve acceptable levels of risk with regard to safety, effectiveness and security, in order to improve outcomes for both the patient and the organization. Unless 80001 becomes business-as-usual within the healthcare industry, unintended harm to patients and care providers will only increase as technology is integrated more and more into clinical practice.

Copies of the IEC 80001 standard⁵ and publications with practical guidance for “Getting Stared with IEC 80001”⁶ are available from AAMI. The ISO/IEC Joint Working Group 7 (JWG7) continues to develop follow-on standards and technical reports.⁷ AAMI also can provide information on how to follow and engage in these efforts.

Figure 3. 80001: Basic Risk Management Process and Key Terms⁷



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PROCEEDINGS

Considerations in Multi-Hospital Wireless Integration

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Sharp HealthCare, San Diego, CA

Key Points

- *As part of its patient safety improvement efforts, in 2004 Sharp HealthCare implemented more than 1400 intravenous (IV) infusion “smart pumps” and wireless connectivity, first in one unit, then throughout that hospital and finally enterprise-wide.*
- *Wireless connectivity made it possible to upload smart pump safety software changes and download continuous quality improvement (CQI) data without having to physically touch every pump, greatly improving safety and efficiency.*
- *Even without being able to attach the infusion data to specific patients, the use of advanced analytics with the general CQI data has helped identify high-risk-of-harm medications and practices and address significant issues.*
- *Sharp is now moving towards bi-directional connectivity, which will lay the necessary foundation for auto-programming of the smart pumps and auto-documentation of infusion data.*
- *To realize the full potential of these new technologies, vendors need to work together to optimize the wireless integration of their various devices and systems onto hospital IT networks.*

Sharp HealthCare, the largest health care system in San Diego, CA, with 2060 licensed beds, is one of the leading hospitals in the United States. Selected as a “100 Most Wired” health care system for 11 years, Sharp is ranked by Modern Healthcare in 2010 as the most integrated health care network in California and sixth in the nation. Sharp Memorial and Sharp Grossmont Hospitals have received MAGNET® recognition from the American Nurses Credentialing Center (ANCC).

In 2003, as part of its patient safety improvement efforts, Sharp purchased

1407 intravenous (IV) infusion “smart pumps.”^a The following year Sharp implemented the smart pumps in its five acute care hospitals and installed wireless connectivity to integrate them onto the health system's information technology (IT) network. In 2007 the improvements achieved through these efforts played a major role in Sharp's receiving the prestigious Malcolm Baldrige National Quality Award, the nation's highest presidential honor for quality and organizational performance excellence.

In this article, the enterprise-wide implementation of the smart pump safety systems and wireless connectivity, continuing technology improvements, representative results of smart pump use, current state and future vision are reviewed.

Technology to Improve Patient Safety

The smart pumps' dose-error-reduction software (DERS) provides alerts whenever a programmed IV infusion exceeds hospital-established parameters. In addition, the software logs previously unavailable data on “good catches,” when a clinician reprograms or cancels an infusion in response to an alert. Analyzing these data helps staff identify continuous quality improvement (CQI) opportunities to further refine the software or clinical practice.

Adding wireless connectivity helps optimize the smart pumps' use and maximize their safety benefit. Connecting the smart pump safety systems to a wireless server make it possible for staff to download CQI data and upload software changes without having to physically touch every pump.

Step-Wise Integration

Implementation of wireless connectivity at Sharp proceeded in stages. The smart pump systems were installed first in a 25-bed unit in one hospital, then throughout that hospital and finally, enterprise-wide. At that time adult and infant devices needed to be separated. Initial plans called for the

implementation of a single server to feed the entire organization; however, security and encryption issues prevented that approach and a server was installed in each hospital. Patient-controlled analgesia (PCA) pumps were added to the system in 2006.

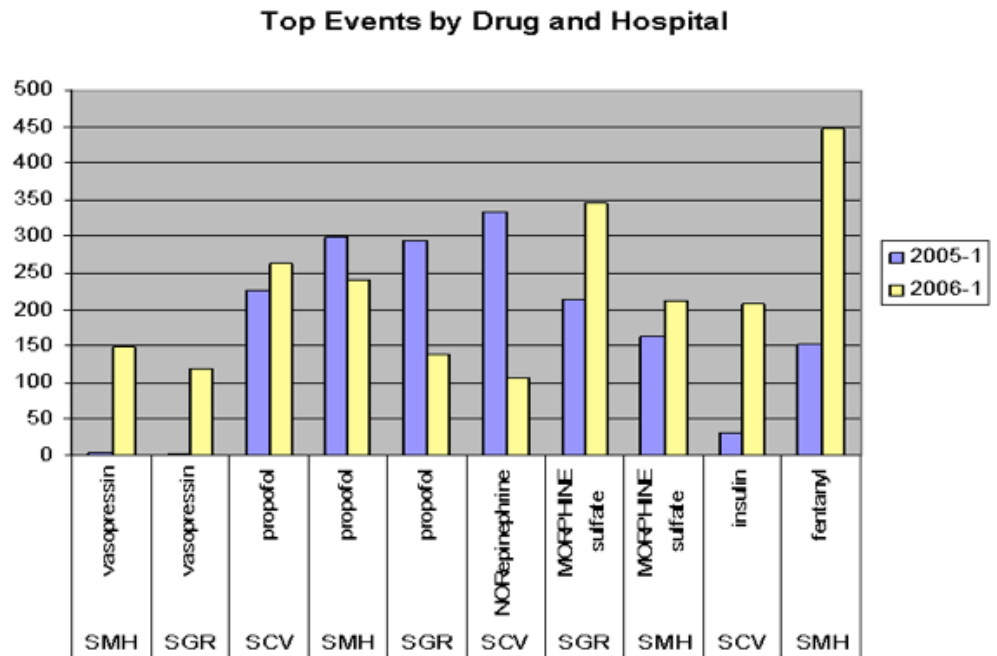
Sharp staff continued to refine the software drug libraries based on the CQI data from the pumps, and the company continued to upgrade the system. The number of entries in the drug libraries was greatly increased and the software architecture changed so that adult and infant drug libraries no longer needed to be separated. Smart pump security improved to where Sharp was very comfortable with the encryption. This allowed Sharp to install a single server in the data center to support the whole organization to manage the system more effectively and efficiently.

It still was not possible to associate a smart pump device with a particular patient; nonetheless, the use of advanced analytics with the general CQI data provided valuable insights (Figures 1 and 2). Various reports generated by the upgraded system helped staff identify high-risk-of-harm medications and practices and address issues such as: Were the drug limits set properly? What types of alerts were being generated? The smart pump reporting capabilities allowed staff to refine the drug limits, soft stops (can be overridden), hard stops (cannot be overridden), etc. As a result, Sharp was able to make significant safety improvements, even without being able to attach the information to specific patients.

Current State

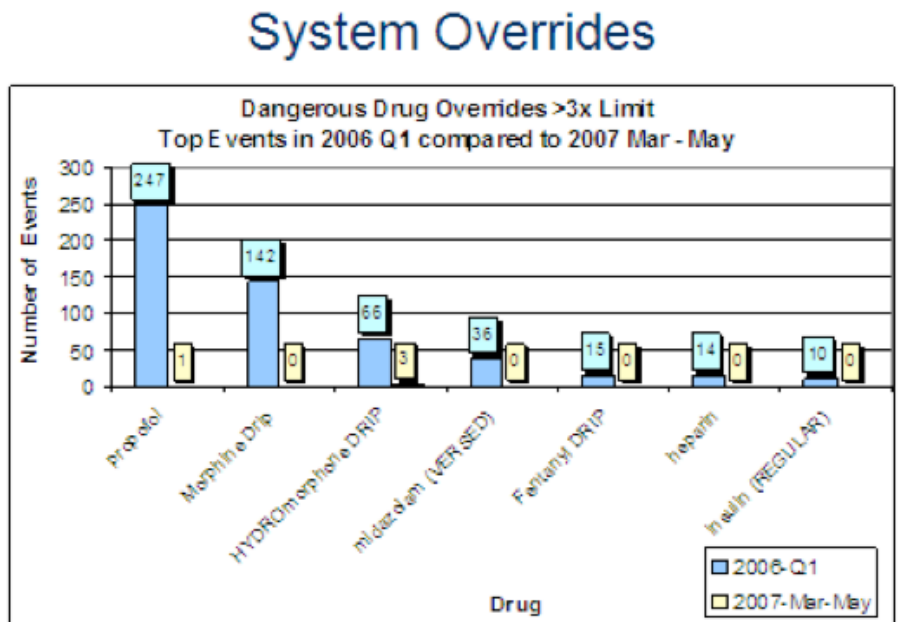
In 2011 next version of the safety software will expand the drug libraries from 1500 to 2500 items. Instead of relying on their own, independent server, Sharp is

Figure 1. Smart Pump CQI Data: Sample Report



“Event” = when clinician cancels or reprograms an infusion in response to a smart pump alert.

Figure 2. Smart Pump CQI Data: Sample Report



San Diego's Health Care Leader



Override – when a clinician receives an alert and proceeds anyway.

moving to the use of virtual servers. Most significantly, the organization is moving toward bi-directional connectivity, which will allow for two-way communication between the smart pumps and the electronic medical record (EMR). This lays the necessary foundation for both auto-programming (orders transmitted from the EMR to the pump) and auto-documentation (infusion data transmitted from the pump to the EMR).

Future

Major issues will need to be resolved as infusion safety and wireless connectivity continue to evolve. Finding a way to associate a device with a patient is necessary for auto-programming and auto-documentation. Debate continues with regard to the type and amount of data that are needed for analytics and how medication data can be integrated in the EMR, so they can be associated with other data, such as a patient's vital signs.

Another challenge is the need to integrate different models of data networks (eg, Cisco Systems or Brocade) and different wireless devices, especially with regard to security. Vendors need to develop a more "generic" model that can be easily integrated with other systems. To meet these and other challenges, it is essential that vendors work together to optimize the wireless integration of their various devices and systems. For example, resolving differences among competing gateways is critical to making the traffic the most efficient and the most fall tolerant. Finally, of course, a major consideration in multi-hospital wireless integration is cost.

Conclusion

Wireless integration of medical devices, EMR and a hospital IT network presents major technology and process challenges. However, meeting these challenges holds the promise of greatly improving patient safety, quality of care, financial performance and clinician satisfaction.

Footnote:

- a. The Alaris[®] System with the Guardrails[®] Suite, CareFusion Corporation, San Diego, CA.

PROCEEDINGS

What is IHE Doing About Pump Integration?

Erin Sparnon, MEng

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ECRI Institute, Plymouth Meeting, PA

Key Points

- *Standards-based approaches to integration can reduce the time and costs involved with planning, building and maintaining interfaces between and among devices and information systems.*
- *Integrating the Healthcare Enterprise (IHE) Profiles define standardized messages and standardized roles and responsibilities for the systems that send and receive these messages.*
- *IHE-Patient Care Devices (PCD) has written Profiles that cover the programming and documenting information sent between infusion pump servers and other systems like pharmacy information system (PhIS) and electronic medication administration record (eMAR) to allow for closed-loop infusion management.*
- *Hospitals can purchase pump servers and information systems that support these infusion management profiles by using drop-in request for proposal (RFP) language from IHE.*

Integrating the Healthcare Enterprise (IHE) is a global nonprofit organization with active arms in North America, Europe and Asia-Oceania. IHE North America is organized into several application-specific "domains" from Cardiology to Radiology. Infusion pumps, along with other bedside devices such as patient monitors and ventilators, fall under the Patient Care Devices (PCD) domain, sponsored by the Healthcare Information Management Systems Society and the American College of Clinical Engineering. The PCD planning and technical committees are staffed by volunteers, including clinical engineers, software experts from device and electronic health record (EHR) and electronic medical record (EMR) suppliers, and integration experts with experience

with standards like HL7 and IEEE 11073. One group within PCD, the Point-of-care Infusion Verification (PIV) workgroup, is specifically tasked with supporting the integration of infusion pump servers and EHR/EMR systems.

IHE supports integration of medical devices and systems through the development of Integration Profiles that spell out the rules of engagement to solve a particular integration problem. To start the process, a clinical integration problem is submitted to a relevant domain by a supplier, an end-user or another interested party. The domain then drafts an Integration Profile, sends it out for internal and external review and then tests it in a Connectathon event to see if revisions are

necessary. This review-test-refine process is repeated in a yearly cycle until the Profile reaches 'final text' status and remains relatively stable (and, therefore, ready for inclusion in supplier systems).

Whenever possible, IHE domains use existing standards like HL7 for language structure and IEEE 11073 nomenclature for medical device information transfer. For example, both HL7 and IEEE 11073 allow a wide range of implementation options, which means that two systems that conform to both standards may not be able to interface with each-other. However, if two systems both conform to the structure and nomenclature spelled out in a specific IHE integration profile, a facility can expect a certain level of interoperability.

Each Integration Profile has a descriptive name and includes specific transactions that spell out messages that are sent between *actors* (Table 1).

- A single profile may include several different transactions, and new profiles try to use existing transactions whenever possible, adding new transactions only when a new type of message is needed.
- The transaction name includes an identification number and a brief description. For example, the transaction "PCD-01 Communicate PCD Data" is a periodic message that can handle numerical device information (eg, "I'm monitor 5 in the ICU and I'm monitoring Mr. Smith, whose heart rate is 110 BPM"), and shows up in several PCD Profiles.

- The message specifies the exact order (structure) and language (nomenclature) of the information sent by a transaction. For example, the message of the PCD-01 transaction will tell the supplier, “Fill out a standard HL7 message as follows: put the device ID in field W, the patient ID in field X, and the heart rate (which must be a whole positive number) in field Y, being sure to state the unit of measure (which must be BPM) in field Z”.
- The actor specifies which type of activity a particular system will perform with respect to the transaction. Actors fall into three general categories: provider or reporter (sends information), consumer (receives information), or filter (receives, modifies, and then transmits information); and a single device or system can support more than one actor. For example, consider a computerized prescriber order entry (CPOE) system. It may receive patient data from an admit/discharge/transfer (A/D/T) system (fulfilling the role of the ‘consumer’ actor), and send medication orders to a pharmacy information system for review (fulfilling the role of the ‘provider’ actor).

Communicate Infusion Order, as the Infusion Order Consumer actor”, it means that a facility can reasonably expect this pump server to be able to receive medication order information (patient name, order number, drug, rate, etc.) coming in from an external source like a pharmacy information system (provided, of course, that this pharmacy system supports PCD-03 as the Infusion Order Provider actor).

Healthcare facilities can use Integration Profiles in Request for Proposal (RFP) language to specify connectivity by requiring suppliers to specify whether (and how well) their proposed product supports a particular Actor in a profile. PCD is currently developing RFP guidance to help facilities (1) identify which profiles, actors, and transactions apply to a specific clinical application and (2) require support of these transactions and actors in language that is meaningful to the suppliers and allows for a minimum of wiggle room in compliance.

Table 1. What’s in an IHE Profile?

- ▶ **Profile name**
 - Point-of-care Infusion Verification™ (PIV) supports 5-rights messages from clinical systems like PhIS to pump servers
- ▶ **Transactions: descriptive name and an identification number**
 - “PCD-01 Communicate PCD Data” is a general aperiodic message type
- ▶ **Messages: the content and format of information transferred**
 - Using HL7, put the patient name in field x, and the heart rate in field y...
- ▶ **Actors: labels with defined roles and responsibilities**
 - A system may send, receive, or filter (receive, modify, then send) data

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Table 2. Integration Statements

How can I tell if a system supports IHE profiles?

- ▶ Ask to see an Integration Statement for the profile you’re interested in
- ▶ If an integration statement is unavailable, request conformance in an RFP- guidance is coming soon!

I want this vendor system (Sender)	To send this information (Requirements)	To another vendor system (Receiver)	What is my RFP language for the sending system?	What is my RFP language for the receiving system?	What is the related IHE-PCD transaction?
BPOC or Pharmacy	Drug ID and dosing/programming information	Pump server	Shall Support PIV as the IOR	Shall Support PIV as the IOC	PCD-03 as specified by both IOC and IOR
CPOE, BPOC or Pharmacy	Start Order Infusion	Medication Administration Record (eMAR)	Shall Support the PIV as the IOR	Shall Support PIV as the IOC	PCD-03 as specified by both IOC and IOR
Pump server	Infusion documentation	Medication Administration Record (eMAR)	Shall Support the PIV as the DOR	Shall Support PIV as the DOC	PCD-03 as specified by both IOC and IOR

The PIV Profile Now

The Point-of-care Infusion Verification profile (PIV) has been revised yearly since 2008 and is heading into final text this year. The PIV committee includes volunteers from most infusion pump suppliers and several EHR suppliers, and last year's Healthcare Information and Management Systems Society (HIMSS) Showcase included auto-programming and auto-documentation with demonstration platforms (not available for commercial purchase). The current version of PIV supports two-way communication of infusion order (for auto-programming) and pump status (for documentation) information between a pump server and an enterprise system such as pharmacy, EMR, or EHR. As of right now, the transactions can support continuous infusion (including secondary or piggyback and keep vein open [KVO]), clinician-programmed boluses (eg, loading doses), and single-admixture solutions (eg, dopamine in normal saline).

Because PIV is heading into final text, hospitals should start asking suppliers for PIV-conforming systems in their RFPs this year and look for updates in the years to come.

The PIV Profile Later

PIV's next steps are to tackle more complex orders such as patient-controlled analgesia (with patient-administered boluses and lockout intervals), total parenteral nutrition (with ramping and tapering), and intermittent administration. PIV will also need to tackle multiple-admixture solutions, such as those used for epidural (eg, bupivacaine plus ropivacaine) or nutrition (eg, lipids plus carbohydrates) administration.

To Get Involved

Contact efurst@ieee.org or sign up for the PCD Planning or Technical Committees at <http://www.ihe.net/pcd>.

PROCEEDINGS

The Role of Middleware in Medical Device Interoperability

Brian McAlpine

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Key Points

- *Hospitals today are leveraging device connectivity middleware as part of a hospital-wide strategy to connect all medical devices, including intravenous (IV) pumps.*
- *Middleware not only facilitates the integration of the medical device's data but also helps meet the increasing requirements for the integration of alarms and waveforms.*
- *Designing an optimized clinical workflow is a key factor to consider when implementing device connectivity and ultimately enabling device interoperability.*
- *Designing a workflow for managing patient-to-device association for all wireless and mobile devices remains a key focus and challenge.*

Middleware is often referred to as the “glue” that ties together systems and/or applications; it is essentially software that can take on many different forms and can be implemented to address many types of information technology (IT) issues. In the specific case of device connectivity, middleware is used to “glue” or integrate medical device data onto enterprise information systems such as electronic medical records (EMRs), alarm-management systems and other types of Medical Device Data Systems (MDDS). This type of middleware is not new; in fact, device connectivity middleware has been successfully deployed in hospitals for more than 12 to 15 years.

Most of the currently implemented connectivity middleware solutions connect and integrate data from the diverse mix of devices that hospitals

currently use, traditionally starting with patient monitors. These solutions also integrate a mix of older legacy medical devices such as ventilators. However, connectivity needs are evolving. Newer and more advanced devices such as smart intravenous (IV) infusion pumps and infusion management systems now require integration. Interoperability of smart IV pumps with enterprise systems such as pharmacy IT and EMRs is also rapidly evolving as a hospital requirement. In US hospitals the initial deployments of smart pump-EMR integration has generally been accomplished with direct interfaces; however, going forward this approach will not address some important usability and workflow requirements.

Connectivity middleware is recognized by the industry as a solution for addressing the complex requirements of

interoperability and the need to optimize clinical workflow and address patient safety requirements. Challenges such as these mean that the industry will need to come together to collectively analyze and address the issues and create solutions that meet the short- and long-term needs of hospitals.

Connectivity Requirements Should Support a Broad Integration Strategy

In developing their IV pump connectivity strategy and evaluating options for connectivity, most hospitals think more broadly than a single class of devices. Most focus on requirements for their entire healthcare enterprise, which includes a broad range of medical devices. The following list includes some of the detailed requirements that hospitals submit to connectivity vendors in their requests for proposals (RFPs) and that should be considered by any hospital considering a broad-range integration strategy:

- Connect all legacy and current medical devices across all care areas—including intensive care units (ICUs), emergency department, operating room, medical-surgical and specialty care areas—to handle both continuous and periodic data from various devices.
- Connect, manage and integrate data and alarms to existing and future planned EMR and alarm management systems.
- Provide a method to manage positive

patient identification (PPID) and an ability to manage patient-to-device (P2D) association at the bedside.

- Provide a means for clinicians to have real-time access to information on the status of devices and their state of connectivity.
- Provide a means for the hospital to design the optimized clinical workflows required for clinicians to safely and effectively manage PPID, P2D association and various aspects of device connectivity.

This list might suggest that managing IV pump connectivity is simply one part of a broader strategy to integrate all medical devices; however, this is not the case. While many components of a broader integration strategy remain the same, IV pump integration has a number of unique requirements that need to be considered.

This is important to understand, because determining early on how IV pumps fit into a broader strategy will save hospitals a lot of time and money in not having to undo a solution because it does not meet their longer-term needs. In this article,

the requirement for basic connectivity versus wireless smart pump connectivity will be explored, in order to understand what is necessary to meet hospitals' long-term needs.

The Role of Device Connectivity Middleware for Basic Connectivity (One-Way)

Once planning shifts from tactical to strategic, it becomes more evident that connectivity middleware is necessary to meet all the diverse requirements. Figure 1 shows the general flow of data from devices to enterprise applications such as an EMR. It also shows the main functions of a middleware solution with regard to the clinical workflow and technical features required.

It is important to note that even though connectivity middleware is generally thought of as a software platform, typically hardware and cabling are also required to implement a basic connectivity solution. Table 1 shows the key functions and value provided by connectivity middleware.

Why Smart IV Pumps are Different

from Other Medical Devices

Smart IV pump safety systems are part of a unique class of device that poses some interesting challenges. From an integration perspective, the following characteristics must be considered:

- Multiple IV pumps are often deployed per patient. In some ICUs a patient can have up to 20 or more separate IV lines driven by many pumps. Often the pumps are identical, except for the medications or fluids being dispensed.
- Most smart pumps are wireless and lack a way for clinicians to easily capture the room ID, patient ID or the ID of the clinician programming the pump. These missing data elements are critical to making integration work seamlessly and assisting with documentation in the EMR.
- Some IV pumps are modular units that can be combined on a single software platform. Individual modules can be added or removed dynamically and can include different types of pumps (large-volume, syringe, and patient-controlled analgesia [PCA]).
- Smart pump integration is at the intersection of several different workflows, including medication administration (of infused drugs), positive patient ID (PPID) and the 5-rights of medication administration, and clinicians' management of the physical devices (setup, programming, monitoring status, etc.).
- Smart pumps are at the forefront of bidirectional device communications. For example, integrated smart pumps can receive a medication programming order (a set of auto-programming instructions) to further optimize the process of medication administration.

Figure 1. Integration of Medical Devices: Overview

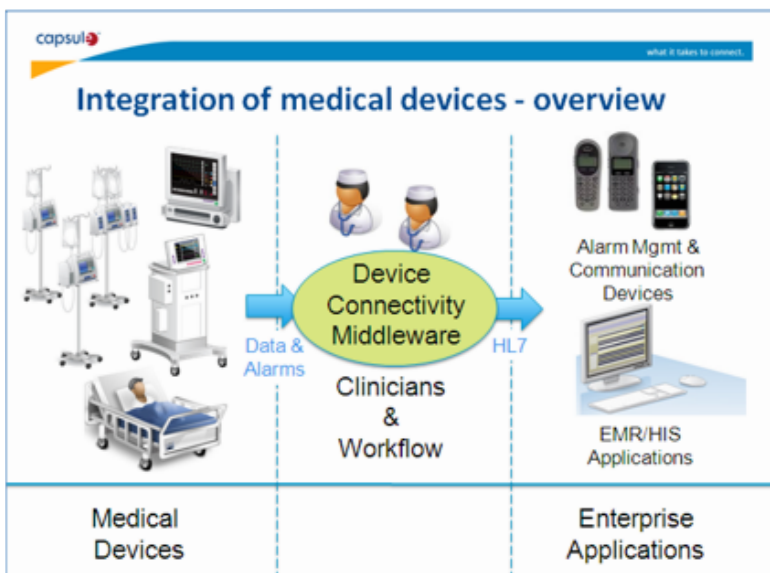


Table 1. Key Functions and Value Provided by Connectivity Middleware

- **Physical connectivity in patient room.** There will almost always be a requirement to connect a “legacy” or older device with a serial connector (RS-232). These devices are connected to something in the room, typically a personal computer (PC) or dedicated serial concentrator box with multiple serial ports.
- **Networked or logical connectivity.** In addition to serial devices, often there are requirements to connect a networked device such as a patient monitor that is connected to a patient monitoring network. A monitoring gateway is often the most effective means to collect the data from this class of devices.
- **Data aggregation and single HL7 feed.** One of hospitals’ key requirements is to simplify the management of all of the discrete data feeds and interfaces. This can be accomplished by directing all of the collected device data to a centralized aggregation server. The data can then be centrally managed and a single data feed configured to feed the receiving enterprise system (EMR).
- **Data management and filtering.** Data often are collected from medical devices in raw, unfiltered format. Especially for continuous data collection, the data always require some form of filtering, conversion of units of measure, normalization, etc. Middleware can provide such data-management capabilities, thereby simplifying the configuration and integration requirements for systems such as EMRs.
- **Data protection and high reliability.** In designing a device-connectivity solution, vendors need to address how data will be protected in the case of a fault or outage in either the hardware (server or bedside concentrator) or the network. Middleware and related hardware components need to be configured to provide data caching in the event of an outage.
- **Bedside/point of care status.** Clinicians need to always be in control of the patient care environment. They can be much more efficient at the bedside when they have access to real-time information on the status of various devices. One way to provide this information is to have the middleware provide a real-time status indication of device connectivity.
- **Manage P2D association.** Clinicians need to be able to efficiently establish the association between stand-alone medical devices and a patient by confirming the right patient ID and the devices that should be associated to that patient. Middleware can provide the necessary capabilities for hospitals to establish optimal workflows for managing devices and the required association to the patient.

Standards Help but are Not a Panacea for Solving Device Integration

In considering medical device integration, often the question of standards comes up. Standards certainly address some important issues, and will ultimately help drive down costs and make connectivity easier. Many industry efforts are currently underway to improve standardization. But it is important to remember that hospitals have legacy devices that will not be able to incorporate standards for some time to come; therefore, hospitals cannot base their device connectivity strategy solely on standards. In addition, standards efforts today do not address most of the issues outlined above regarding the necessary functions of a complete connectivity middleware solution. (See the January 2011 article by Bikram Day¹ for more information on standards.)

IV Pump Interoperability Requires Advanced Middleware Features

More than just one-way data transfer from an IV pump system to an EMR for clinical documentation purposes, it is generally understood that interoperability refers to two-way or bidirectional communication between the IV pump system and other enterprise systems. A key bidirectional feature is the transfer of a pump programming order from the EMR to the IV pump system. This sends a set of specific instructions that automatically programs the pump with a patient-specific order.

As shown in Figure 2, middleware can provide key features for both the nurse at the bedside and the pharmacy technician.

- At the bedside, nurses need to have real-time information about the status of each pump. Middleware can provide this information, whereas the pumps cannot. Is the pump currently connected? A clinician cannot easily tell by looking at a wireless pump whether it is communicating its data via the WiFi network. Is every pump properly associated to the right patient? Again, a clinician cannot tell by looking at the pump. Without a confirmed association to the right patient, errors are likely to occur. Middleware can also help manage P2D association using a variety of methods, including barcoding and radio frequency identification (RFID).

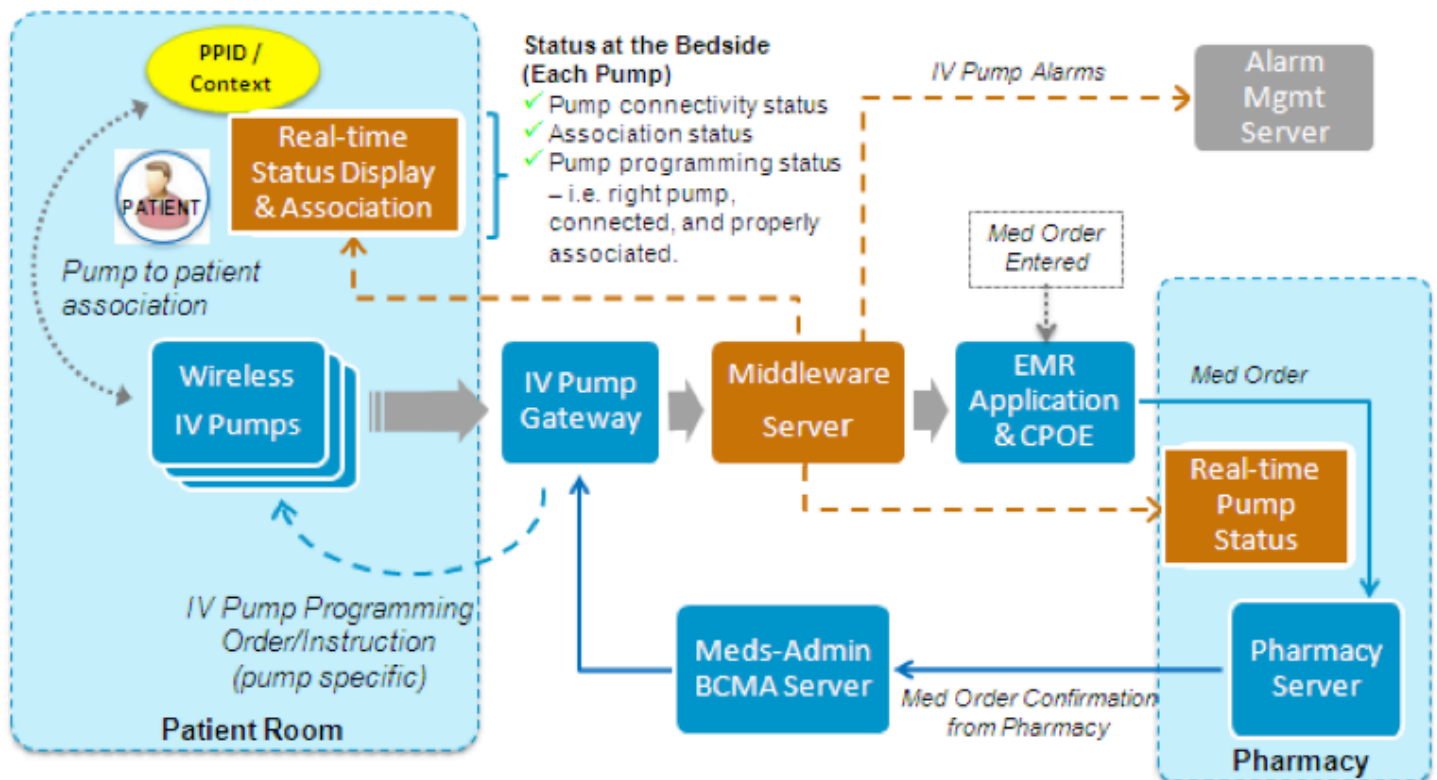
- Middleware can also display real-time status of each infusion for the pharmacy technician. Pharmacy can be alerted when a critical infusion is about to run out. Or, if there are issues with any currently running infusions, pharmacy can intervene accordingly.
- IV pumps generate many different types of alerts or alarms, and managing these alarms is critical. Middleware can provide a way to feed these alarms to other enterprise systems such as an alarm management system.

Conclusion - What Should Hospitals Do Now?

Hospitals must realize that IV pump connectivity and interoperability are in the very early stages of development. Even one-way communication of pump data to EMRs is still in the pilot stages for most EMR vendors. Hospitals planning for pump connectivity and interoperability (closed-loop auto-programming) should consider taking the following actions:

- Map out and plan a complete strategy that includes an evaluation of all medical devices. Without a comprehensive middleware solution, a lot of extra or custom work will be required to make an end-to-end solution that is usable for all clinicians in the workflow.
- Start with a plan for basic one-way connectivity. First get the data from the pump gateway into the EMR. Bi-directional functions can be added later.
- Include nursing in the decision-making process and examine what the desired workflows should be.
- Examine the requirements for managing P2D association and the role of PPID at the bedside.
- Evaluate what real-time status information the nurse will require at the bedside and how middleware can help provide that information.

Figure 2. Role of Middleware in Closed-loop IV Pump Programming



Note: Using the BCMA appl, the order getting to the right individual pump is dependant on the clinician deciding which pump to use based on availability and status of each pump.

PROCEEDINGS

Making Sure Critical Alarms are Heard: Promoting Critical Alarms from Bedside to Caregiver and Central Station

Ann Holmes, MS, RN

Nurse Manager, Munson Medical Center

Traverse City, MI

Key Points

- *The Anesthesia Patient Safety Foundation (APSF) has noted a significant, under-appreciated risk of serious injury from patient-controlled analgesia (PCA) in the post-operative period.¹*
- *The APSF has urged health care professionals to consider the potential safety value of continuous respiratory monitoring in patients receiving PCA or neuraxial opioids in the postoperative period, with any monitoring system linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner.¹*
- *In 2010, Munson Medical Center (MMC), a nationally recognized Top 100 Hospital in Traverse City, MI, implemented a PCA safety system with "smart" (computerized) PCA infusion, capnography and pulse oximetry modules on a single platform wirelessly integrated with central surveillance and alarm management.*
- *Capnography was found to be much more effective than pulse oximetry in identifying patients with opioid-related respiratory distress.*
- *Implementation of the continuous respiratory monitoring system allows patients at risk of opioid-related respiratory depression to be cared for safely and effectively in the medical-surgical unit, reducing the intensive care unit (ICU) and step-down ICU census by approximately 2 patients per day, leading to an annual savings of \$1.28 million per year.*

In October 2006, the Anesthesia Patient Safety Foundation (APSF) hosted a workshop on patient-controlled analgesia (PCA) and opioid administration for post-operative patients. As noted in the workshop report,¹ there is a significant, under-appreciated risk of serious injury from PCA in the post-operative period, including a low, unpredictable incidence of life-threatening respiratory depression even in young, healthy patients. Rates of

respiratory depression are higher among patients receiving continuous opioid infusions. In light of these findings, the APSF urged health care professionals to consider the potential safety value of continuous monitoring of oxygenation (pulse oximetry) and ventilation in patients receiving PCA or neuraxial opioids in the postoperative period. The report further noted that it is critical that any monitoring system be linked to a reliable process

to summon a competent health care professional to the patient's bedside in a timely manner.¹

Munson Medical Center (MMC) in Traverse City, MI, part of an eight-hospital system, is known for its culture of patient safety and high-quality care and has received national recognition such as the 2008 American Hospital Association-McKesson Quest for Quality Prize®, inclusion on the Top 100 Hospitals® list 11 times, and designation as a Magnet hospital for nursing excellence and a Bariatric Surgery Center of Excellence.

In 2010 MMC launched a Munson Patient Safety Initiative to improve the medication safety for the many patients who required opioid therapy in the post-operative setting. In keeping with its culture of safety, the initiative enabled MMC to follow the APSF recommendations and to improve the safety, quality and cost-effectiveness of post-operative pain management. In this article, the need for continuous respiratory monitoring of post-operative patients receiving opioid therapy, the Munson Patient Safety Initiative, the technologies selected and results achieved are briefly reviewed.

Munson Patient Safety Initiative

Patients receiving opioid analgesics in the post-operative setting included those with sleep apnea, healthy post-operative patients receiving opioids through patient-controlled-analgesia (PCA) or epidural

analgesia (PCEA), the opioid-naïve, the elderly and patients receiving concomitant central-nervous-system depressants.

At that time, patients with untreated, diagnosed sleep apnea were sent to the intensive care unit (ICU) post-operatively just to be monitored for the first 12 hours. The challenge was to keep patients out of the ICU and to provide optimal care to patients receiving high doses of narcotics.

In 2009, a multidisciplinary team developed a Munson Patient Safety Initiative with the following objectives:

- Identify safety risks related to respiratory depression and opioid administration
- Improve patient safety related to pain management while standardizing clinical practice and dosing
- Decrease the risk for respiratory depression by continuously monitoring end-tidal carbon dioxide (EtCO₂) or

oxygenation (SpO₂) and having the ability to automatically stop opioid infusions if pre-established respiratory parameters were exceeded

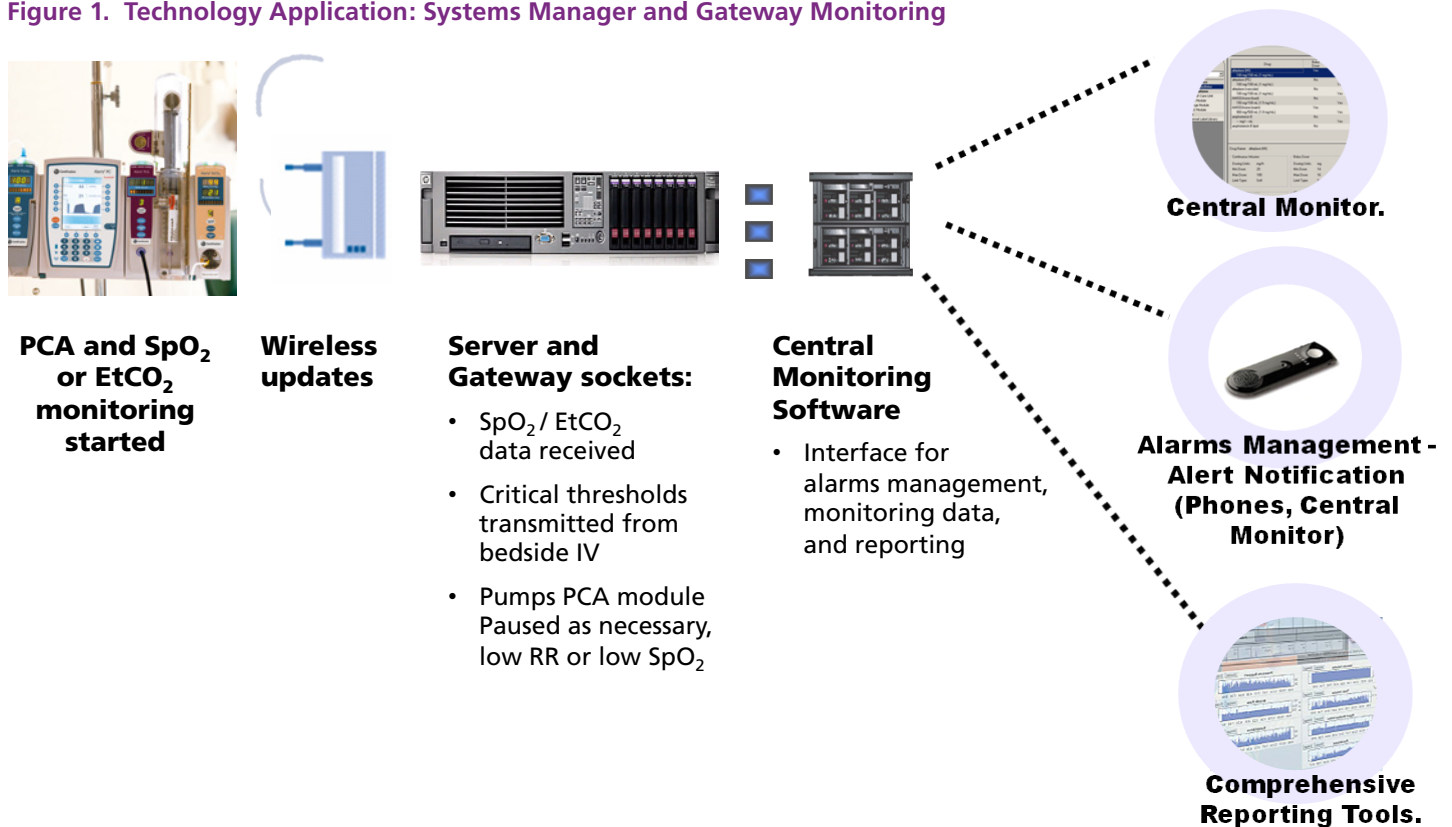
- Invest in technology that supports clinical decision-making (a monitoring system with an integrated platform for opioid infusion and respiratory monitoring with trend data)

In selecting a respiratory monitoring system, it was very important to MMC nursing management that the system would alarm not only at the bedside but also at a central monitor and the nurse's pager, cell phone or some other device. If an alarm were sounding from behind a door or the patient's nurse were out of the room, no one would know the patient was going into respiratory distress. Thus, remote surveillance with a central monitor and alarm management were critical selection requirements.

Technology

Following extensive evaluations, a "smart" (computerized), modular PCA safety system was selected (Figure 1). At the bedside the system comprises a point-of-care unit (PCU, "brain") with PCA, capnography and pulse oximetry modules on a single platform.^a A gateway server wirelessly transmits data to and from the PCU.^b A central surveillance server with a rules engine sends remote alarm notifications in real time via wireless communication to the central station and the clinician's pager, allowing quick response to respiratory alerts.^c If a patient's respiratory values fall below hospital-defined limits, the system generates an alert and the unique "pause protocol" automatically pauses the PCA infusion and deactivates the dose-request cord. The system provides up to 24 hours of PCA dosing history with corresponding time-based values from capnography and/or pulse oximetry monitoring.

Figure 1. Technology Application: Systems Manager and Gateway Monitoring



Central Surveillance

Wireless connectivity allows nurses at the central station to monitor up to 12 patients in real time (Figure 2). If a patient sets off an alarm with the EtCO₂ or SpO₂ monitor, the alarm sounds at the station and the box on the touch-screen monitor with patient’s information turns red. The alarm also goes to the nurse’s pocket pager. The PCA infusion is automatically paused. Trend data (Figure 3) can be printed and put into the patient’s medical chart, so staff can review instances of low respiratory rates or SpO₂.

Patient Selection

Capnography was found to be much more effective than pulse oximetry in identifying patients with opioid-related respiratory distress. Pulse oximetry values may be misleading if a patient is receiving supplemental oxygen. Moreover, pulse oximetry does not detect critical markers of respiratory depression: respiratory rate, pauses in the respiration cycle, increased exhaled CO₂ and inadequate respirations; capnography does. For these reasons, all patients receiving opioid analgesics are monitored with capnography, except for patients who are on continuous or bi-level positive airway pressure (CPAP or Bi-PAP) or who have had nasopharyngeal surgery (Table 1).

Results

Clinical experience, safety-system continuous quality improvement (CQI) and alarm management data confirm that patients at risk of opioid-related respiratory depression can be cared for safely and effectively in the medical-surgical unit and do not need to be sent to an ICU. Because of this, the implementation of the monitoring system has reduced the ICU and step-down ICU census by

Figure 2.

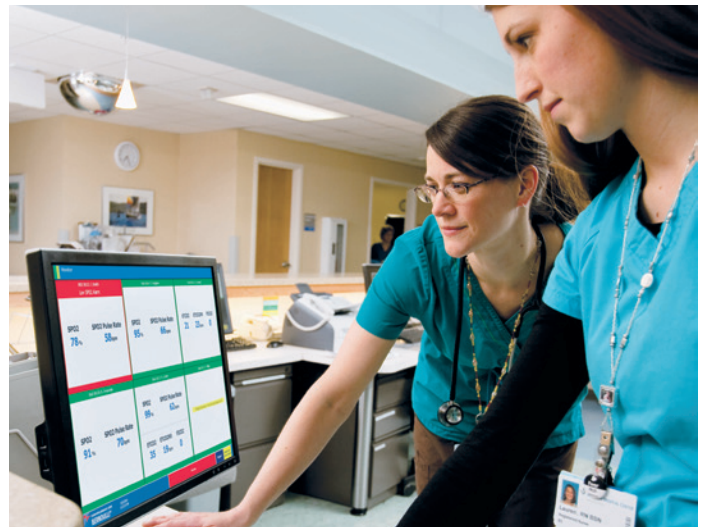


Table 1. Continuous respiratory monitoring: patient selection

- Postoperative patients receiving PCA or PCEA therapy
- Sleep apnea confirmed by a sleep study not treated with a CPAP or Bi-PAP
- OSA screening score ≥ 5
- Risk of de-oxygenation observed by nurse or respiratory therapist as evidenced by loud snoring, periods of apnea, decreased level of consciousness or seizures
- All patients are monitored with capnography (EtCO₂ and respiratory rate) unless on CPAP or Bi-PAP or following nasal/oral surgery; oximetry (SpO₂ and heart rate) are used to monitor these patients.

Figure 3. Printed Patient-specific Respiratory Reports

Filter: 'Alarms', 'Events' Date: 11/5/2010 1:51am to 11/5/2010 1:51:59pm Page: 1, descending order		Filter: 'Alarms', 'Events' Date: 11/5/2010 2:29am to 11/5/2010 2:29:59pm Page: 1, descending order	
Time	Event	Time	Event
Friday, November 05, 2010			
1:51:03 PM	[Pulse Oximeter] SPO2 Low at 86	2:29:21 PM	[EtCO2] RR Low at 5
10:19:51 AM	[Pulse Oximeter] SPO2 Low at 87	2:14:57 PM	[EtCO2] RR Low at 5
10:19:33 AM	[Pulse Oximeter] SPO2 Low at 87	2:14:07 PM	[EtCO2] RR Low at 5
10:18:21 AM	[Pulse Oximeter] SPO2 Low at 86	2:11:54 PM	[EtCO2] RR Low at 5
10:17:43 AM	[Pulse Oximeter] SPO2 Low at 84	2:07:09 PM	[EtCO2] RR Low at 5
10:16:57 AM	[Pulse Oximeter] SPO2 Low at 87	2:03:37 PM	[EtCO2] RR Low at 5

approximately 2 patients per day. Given the lower cost of caring for patients in non-intensive care, at MMC this change in practice has resulted in an annual savings of \$1.28 million per year (Table 2).

A before-and-after research study (250 patients before implementation; 500, after) showed decreased use of Narcan, medical response team, fewer patient transfers to ICU for treatment of respiratory depression, an increase in nursing intervention to

stimulate patients, and decreased use of supplemental oxygen. Nurses can make appropriate, patient-specific adjustments to opioid dosing safely, based on the patient's ability to breathe correctly and maintain a good respiratory rate.

Discussion

Implementation of PCA safety system with continuous respiratory monitoring integrated with central surveillance has allowed MMC

to follow the APSF recommendations to improve the safety of post-operative opioid therapy. Patients also seem to experience much better pain control.

The system supports nurses' clinical decision-making in several ways. Nurses use clinical assessment data along with the technology data to better assess a patient's response to PCA therapy. The trend data are used to review opioid dosing and patient response during nursing rounds, for end-of-shift reports and as needed. The comprehensive reporting tool allows nurses to review how many times a patient's respiratory rate decreased to 4 or 5 breaths per minute (bpm). This has also been useful when patients do not believe they have sleep apnea and nurses can show them that they stopped breathing 12 times in the last hour.

Narcan is no longer needed as frequently, because a patient's PCA infusion can be

Table 2. Continuous respiratory monitoring: economic impact

- Prior to implementation of continuous respiratory monitoring with central surveillance, postoperative patients with suspected or known sleep disordered breathing were admitted to ICU or ICU step-down unit
- Patient cost on a post-operative unit is 56% less than on an ICU unit
- The implementation of the monitoring system has reduced the ICU and step-down ICU census by approximately 2 patients per day
- At MMC this represents an annual savings of \$1.28 million per year

adjusted long before the patient begins to experience respiratory problems. Now, if a patient's respiratory rate suddenly drops to 4 bpm, a nurse will stop the continuous infusion and stimulate them to resume normal breathing. Automatic deactivation of the dose-request cord has proved to be very beneficial, especially with patients who have been given "PCA by proxy," whereby a family member or friend is pushing the button without assessing the patient's condition.

Conclusion

The use of using continuous respiratory monitoring, especially capnography, allows clinicians obtain a more accurate evaluation of the patient's respiratory status in response to opioid therapy, leading to more cost-effective post-operative care on a medical/surgical unit, without any increase in adverse events as compared to post-operative care in an ICU. Clinicians can use nursing assessment and safety-system trend data, leading to more appropriate nursing interventions.

Promoting critical alarms from the bedside to the central station and the nurse's pager helps ensure that critical alarms are heard and appropriate interventions made in a timely manner, thus avoiding the need for more intensive care. The system's unique "pause protocol" also helps improve the safety of PCA opioid delivery. Safety system CQI data are beneficial to measure improvements in practice and compliance. Most importantly, continuous respiratory monitoring with a PCA "pause protocol," central surveillance and alarm management leads to safer patient care during PCA opioid delivery in the post-operative setting.

Footnotes

- a. The Alaris[®] System with the Guardrails[®] Suite of safety software, CareFusion Corporation, San Diego, CA, with Nellcor OxiMax[™] pulse oximetry technology and Oridion's Microstream[®] capnography technology.
- b. Alaris[®] Gateway from CareFusion
- c. Bernoulli[®] Enterprise, Cardiopulmonary Corp., Milford, CT [CORRECT?]

References

- 1 Weinger, M.B. APSF Newsletter, Winter 2006-2007; 21(4):63-7.

Center for Safety and Clinical Excellence
Infusion Therapy and Information Technology:
Taking IV Therapy to New Levels of Safety with IT Integration
San Diego, CA June 2-3, 2011

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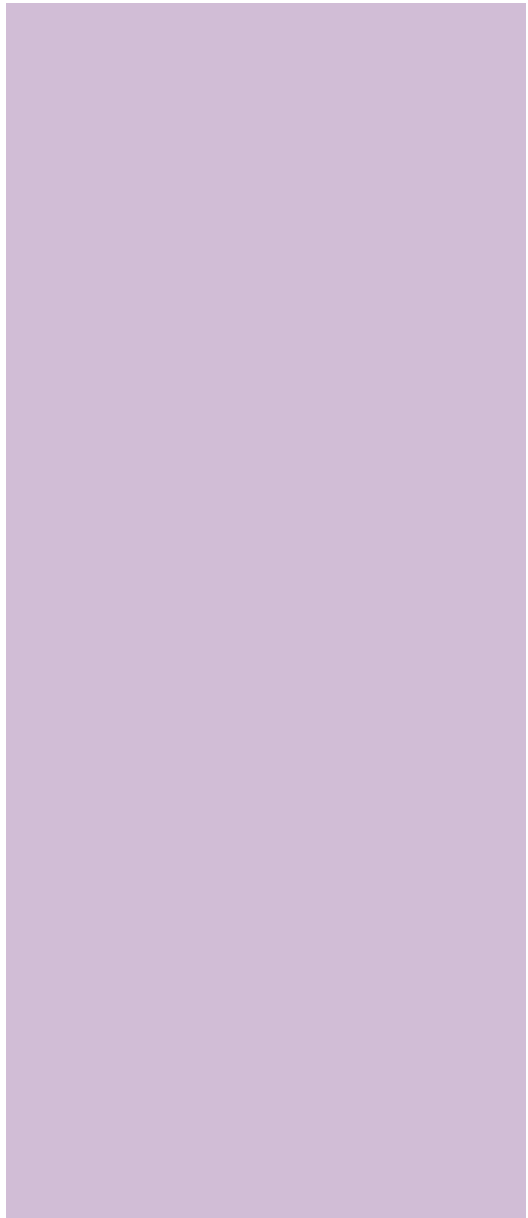
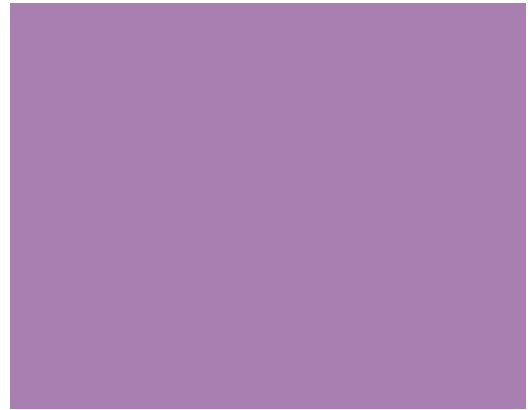
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