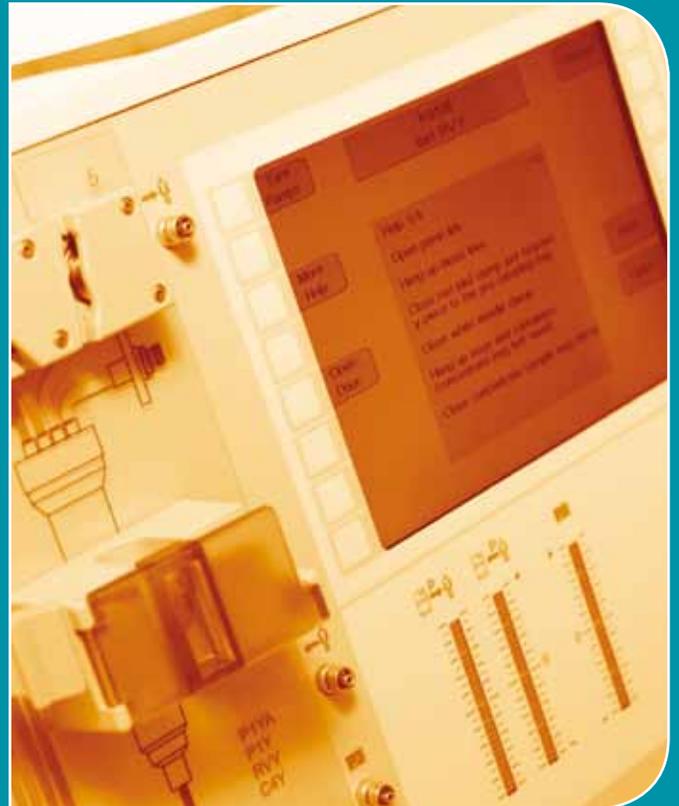




Medical Device Interoperability

A Safer Path Forward



*Priority Issues from the 2012
AAMI–FDA Interoperability Summit*

Interoperability Summit Conveners

AAMI

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a diverse alliance of nearly 7,000 members from around the world united by one critical mission—supporting the healthcare community in the development, management, and use of safe and effective medical technology.

AAMI serves as a convener of diverse groups of committed professionals with one common goal—improving patient outcomes. AAMI also produces high-quality and objective information on medical technology and related processes and issues. AAMI is not an advocacy organization and prides itself on the objectivity of its work.

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Medical Device Interoperability

PRIORITY ISSUES FROM THE
AAMI–FDA INTEROPERABILITY SUMMIT

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A Call to Action



Dear Colleagues,

AAMI and the FDA have had another very successful summit—convening an issues-oriented, multidisciplinary “continuous learning” event.

Two hundred sixty-six people from across healthcare attended this two-day event on Oct. 2–3, 2012. The mix of disciplines was excellent, with strong participation by clinicians. The lineup of speakers was overall the best ever.

The desired outcomes were to:

- Develop a list of device interoperability and integration challenges
- Agree on which of those challenges have the highest priority
- Suggest who in healthcare should follow up

The summit accomplished these objectives:

- Coalesced stakeholders around a common goal
- Energized users to challenge the norm
- Encouraged the entire community to get past barriers
- Challenged government to engage and enable
- Gave the healthcare community input it can use

The summit was a community event, and this publication belongs to the community. It does not present what AAMI or the FDA thinks or believes. It presents what we heard from the community. We all have a responsibility to support continuous learning in healthcare. Please read, highlight, mark up, and share this publication with your colleagues. The dialogue needs to continue for progress to be made. Please share your lessons learned with us!

We are grateful to these 14 supporting organizations: American College of Clinical Engineering (ACCE), American Society for Healthcare Engineering (ASHE), Anesthesia Patient Safety Foundation (APSF), Center for Integration of Medicine and Innovative Technology (CIMIT), Continua Health Alliance, ECRI Institute, Healthcare Information and Management Systems Society (HIMSS), Healthcare Technology Foundation (HTF), Integrating the Healthcare Enterprise (IHE), International Council on Systems Engineering (INCOSE), The Joint Commission, National Institute of Standards and Technology (NIST), UL (Underwriters Laboratories), and West Health.

Thank you again. We look forward to continuing the dialogue with you in the coming months. More important, we look forward to looking back in a few years to see how far we have come.

Sincerely,

Mary Logan
AAMI President

Bakul Patel
Policy Advisor
Office of the Center Director
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Executive Summary



“First, people need to talk. Then, organizations need to talk. Finally, medical technology will talk.”

— Pat Baird, systems engineering specialist,
Baxter Healthcare

Ostensibly, the more than 260 people at the 2012 AAMI–FDA Interoperability Summit gathered to make headway on a technical challenge: how to improve the safety and effectiveness of connectivity for the diverse array of medical and information technology that proliferates in healthcare environments today.

Why interoperability? Why now? The advancement and availability of new technologies, coupled with a growing number of serious public health concerns and adverse patient events in which interoperability issues have been a root cause, spurred AAMI and the FDA to convene the summit. Many events, publications, and conversations have focused on the information side of what technology can do. Little attention to date has been focused on the device side of that connectivity, especially as it relates to patient safety.

By the end of the October event in Herndon, VA, summit participants had come to consensus that human and organizational challenges are actually more significant than any technical obstacles. Challenges impeding progress include uneven leadership; limited cooperation, collaboration, and expertise; and inconsistent clinical workflow. However, while the challenges are becoming more acute, many of them are not new or exotic. In fact, standards, strategies, and tools for making progress are within sight, if they do not already exist.

What is unprecedented is that AAMI, the FDA, and 14 supporting organizations came

together to put all of the issues with interoperable healthcare systems on the table, all in one bracing two-day forum. Joining them were patient safety advocates, clinicians, healthcare technology managers, and other professionals in leading healthcare delivery organizations; systems safety experts; and representatives of manufacturers, standards-setting organizations, regulatory bodies, research and academic institutions, and professional groups.

Applying their intellectual capital to every aspect of device interoperability, summit participants prioritized long and detailed lists of issues they are encountering in the field. AAMI then grouped the issues into seven clarion themes after the summit. The clarion themes synthesize the issues into a succinct call to action.



What does interoperability mean for patient safety? That's one area worthy of more scrutiny.

Seven Clarion Themes

- 1. Standardize to achieve success.** Shared goals and standards for interoperability—and widespread use of standards and tools—will improve the safety, effectiveness, and efficiency of medical technology and unleash innovation.
- 2. Align incentives, expectations, roles, and responsibilities.** Multiple incentives, leadership in healthcare delivery organizations, and the expertise of systems integrators—all focused on patient safety and clinical need—will empower healthcare to use interoperable medical technology to improve quality and safety, benefit from decreased costs and risks, and better technology offerings.
- 3. Drive patient safety with a systems approach to design and implementation.** Harnessing salient disciplinary expertise in systems engineering will enable healthcare to better design and manage interoperable medical technology.
- 4. Focus on human behavior first.** Understanding interoperability as a sociotechnical system will reduce risk, improve clinical efficacy, and optimize the value of medical technology investments.
- 5. Improve regulatory clarity.** Answering questions about the lines of authority will reduce patient safety risks and improve the development, design, approval process, and implementation of interoperable medical technology.
- 6. Streamline clinical workflow to improve return on investment.** A standardized, coordinated, and comprehensive clinical workflow will improve the efficiency and effectiveness of clinical processes and patient care and make it possible to scale interoperable medical technology.
- 7. Remove barriers with shared, continuous learning.** Transparency about successes and failures, and better use of data from robust, interoperable medical technology, will create a platform for wisdom and knowledge that supports clinical practice and patient care.

Key Messages for Healthcare Leaders

Steeped in the seven themes are several key messages at the 30,000-foot level for leaders in the healthcare community. First, **interoperability matters first and foremost because it impacts patient safety.** Getting it right protects patients, contributes to clinical decisions and positive patient outcomes, and improves efficiency. Getting it wrong introduces significant risk and the likelihood of adverse patient events. Worse, getting it wrong doesn't mean returning to the baseline risks of an unconnected world—it will lead to more serious situations than exist now. *Safe* interoperability is central, not peripheral, to the core mission of healthcare.

Second, **the twin goals of healthcare—first, doing no harm, and second, doing good for patients—require not just information, but knowledge and wisdom.** By definition, information technology (IT) captures data; interoperable systems capture even more. Despite the information flow, the healthcare community's ability to share and learn from the data to make better decisions and investments remains sketchy. Ultimately, the holy grail is to use interoperable technology as a foundation for a learning system that contributes to patient safety and the efficacy and efficiency of healthcare. As such, interoperable technology can serve as a powerful tool that supports clinical and business decision making—but only if the healthcare community makes a commitment to learn to use these tools to improve.

Moreover, interoperable technology also can support the business side of healthcare, such as record keeping and billing; facilities; asset, and inventory management; and the management of technology throughout its lifecycle.

Third, **interoperability is not the exclusive domain of technical wizards.** The challenges of interoperability are primarily sociotechnical—with the emphasis on the *socio-* syllables in healthcare practice. This means that the solutions lie in the interaction between people and technology, in the context of healthcare processes, environments, and organizations. People who know technology—and people who know patients, clinicians, environments of care, organizational behavior, and more—must work together to optimize that interaction. Otherwise, information from tech-

nology remains just information—or worse, noise in already noisy workplaces suffering from information overload.

Fourth, **healthcare is by no means singular in the quest for safe, efficient interoperable systems.** Other highly complex, safety-is-paramount industries, notably the aviation, automation, banking, military, nuclear, and petrochemical enterprises, have been there and done that. Typically, a crisis spurred them to action. Healthcare is behind on this front—perhaps decades behind, in the estimation of some summit participants. Yet there are lessons to be learned from pioneering industries, and from best practices in healthcare, which could help the community leapfrog ahead. Healthcare should not wait for a crisis to spur action.

Fifth, and perhaps most important, **leadership in healthcare delivery organizations is an essential missing ingredient in past false starts to overcome interoperability challenges.** While there are ways to make progress, there has not been the will. The vital and increasing significance of interoperability in healthcare is not well understood by the C-Suite, which faces numerous compet-

“There are interdependencies in these systems and their ecosystems and we’re only beginning to understand those interdependencies. We need different rules of the road than we have had in the past.”

— Elliott Sloane, president, Center for Healthcare Information Research and Policy

Next Steps

Maximizing the effectiveness of connected medical technology and information systems thus requires an understanding of potential patient safety hazards; standardization of the clinical workflow; strong, multidisciplinary collaboration; adaptation of innovations from leaders in the healthcare community and from other industries; the right incentives; better examples of the return on investment; and deeper commitment from healthcare leaders.

An easy, straightforward path it is not. Healthcare organizations are focused on getting electronic health records (EHRs) up and running. Very few are stepping into the even more complex space of device interoperability. For example, beyond the integration of

“Interoperable systems capture metrics that can add to or improve human knowledge and wisdom around healthcare. Knowledge and wisdom also can constrain medical devices and improve patient safety—if this intelligence is built into system controls and rules that allow devices to self-monitor and operate within safe limits.”

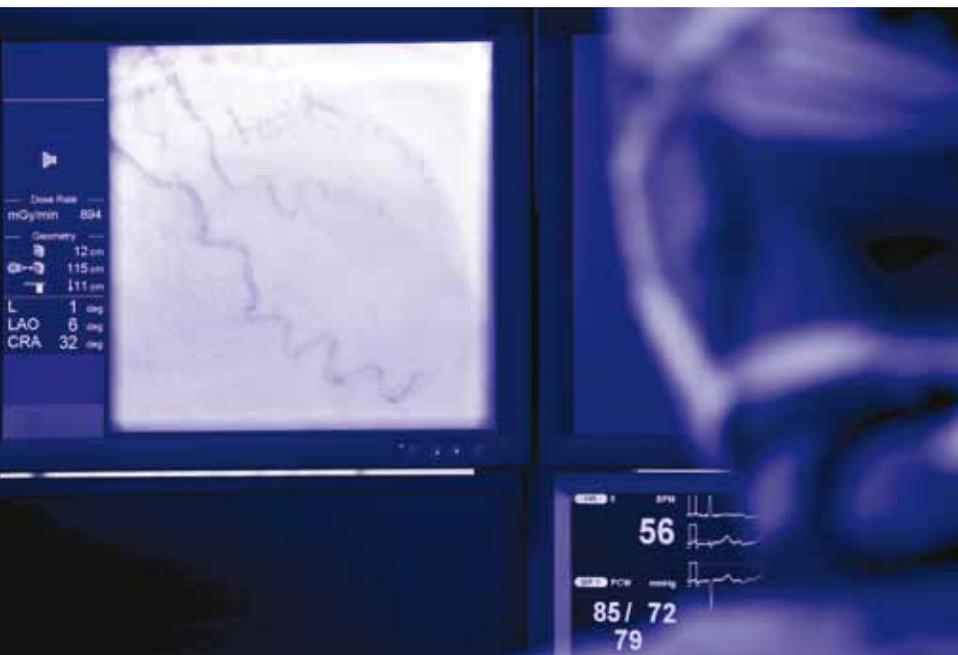
— John Thomas, president, International Council on Systems Engineering (INCOSE)

ing and more immediate challenges and priorities. Those who have been working for years to improve interoperability believe visionary leadership and strong direction are critical for achieving success. That leadership and direction will be achieved only if leaders surround themselves with “multilingual” counselors who can help them synthesize complex, multifaceted issues into a comprehensive and coherent framework for action.

To be fair, healthcare delivery organizations that are trail blazers would say they would readily jump on device interoperability if industry players would work together to create open architectures. These leaders are frustrated that greater progress has not been made by industry.

patient telemetry monitoring, only a handful of healthcare organizations are taking steps to fully integrate their most widely used medical device—infusion pumps. The path for significant device integration is so complex and multifaceted that most organizations across healthcare remain in a wait-and-see or prove-it-first mode.

The capital purchases and currently required customization for this single-device integration remain cost-prohibitive for most organizations. Indeed, current and projected financial conditions are a primary focus for all healthcare organizations. Financial considerations relative to interoperability are not well understood beyond the technical components. With competing worthy



initiatives, it's not easy to commit hundreds of thousands, if not millions, of dollars to connectivity and interoperability. But the cause of patient safety demands that healthcare organizations address these issues.

That's why the talented and committed group of healthcare professionals at the summit contributed to a vision for what can be. By raising awareness for what's needed for success, participants went home hopeful that their contributions will increase the commitment of the entire healthcare community to work together to achieve success.

About This Report

This publication reports on the clarion themes, challenges, and priority actions developed by consensus at the summit. The report summarizes summit presentations and provides additional perspectives from experts. The clarion themes, challenges, and priority actions have not been endorsed by AAMI, the FDA, or any of the summit supporting organizations. The views expressed by individuals do not necessarily represent these organizations' views.

More Summit Information on AAMI Website

The summit agenda, PowerPoint® presentations of summit speakers, reference materials, and updates are posted on the AAMI website.

www.aami.org/interoperability

Clarion Themes, Challenges, and Priority Actions



“I would argue that if we don’t know where we are in patient safety, then it’s hard to use IT to improve patient safety. We have an opportunity to use interoperability to improve our measures of safety.”

— David Classen, associate professor of medicine at the University of Utah and chief medical information officer, Pascal Metrics

A Top 10 Health Technology Hazard

The early years of the 21st century have been called “the lost decade” in terms of progress on huge challenges in advancing the American experiment. In the realm of interoperability in healthcare, that phrase seems apt.

In 2004, the Institute of Medicine (IOM) published *Patient Safety: Achieving A New Standard for Care*, a report offering a “road map” for improving healthcare quality with a sound information infrastructure, healthcare data standards, and improved information exchange, reporting, and analysis. That report built on a seminal report published in 2000, *To Err Is Human: Building a Safer Health System*, which laid out a comprehensive strategy for reducing preventable medical errors.

In 2011, IOM released another report, *Health IT and Patient Safety: Building Safer Systems for Better Care*. This report questions whether any real progress has been made since the earlier reports were issued, and highlights the increase in serious patient safety risks with an increase in connectivity—risks that seem largely ignored to date.

And, weeks after the AAMI–FDA Interoperability Summit, interoperability challenges earned the dubious distinction of securing two spots on ECRI Institute’s Top 10 Health Technology Hazards for 2013:

- The specific issue of patient/data mismatches in EHRs and other health IT systems

- The broader issue of interoperability failures with medical devices and health IT systems

In addition, based on a 2012 AAMI survey of healthcare technology management professionals in 1,900 different U.S. hospitals, interoperability issues placed first and second on AAMI’s list of Top 10 Medical Device Challenges:

- Medical devices and systems on the IT network (cited by 72 percent of respondents)
- Integrating device data into electronic health records (EHRs) (cited by 65 percent of respondents)

“If you’re doing something the same way for 10 years, the chances are you are doing it wrong.”

— Charles Kettering, American inventor, engineer, and businessman



AAMI and the FDA convened the summit, with the backing of 14 supporting organizations, to renew the focus on the challenges of interoperability in healthcare and put that lost decade to rest.

Interoperability as a Patient Safety Issue

Keynote presenter David Classen, associate professor of medicine at the University of Utah and chief medical information officer at Pascal Metrics, framed the summit by positioning interoperability squarely as a patient safety issue.

What's Driving Health IT?

- Economic pressures
- Rapidly evolving technology
- Expanding private and public infrastructure
- Exploding expectations
- Stimulus plan incentives
- Global participation

— David Muntz, principal deputy national coordinator, Office of the National Coordinator for Health IT, U.S. Department of Health and Human Services

He began by sharing this patient case: A decade ago, a 69-year-old woman suffered a “very rocky course” when the interface between a bedside monitor and an EHR malfunctioned. She had developed pneumonia two days after surgery, prompting a transfer to the intensive care unit (ICU). There, she endured a prolonged period of unrecognized low blood pressure, and ultimately was diagnosed with sepsis. The technical glitch delayed her diagnosis, treatment, and recovery. Even though nurses at a central station were monitoring her vital signs, inaccurate blood pressure readings in the EHR handicapped their ability to care for a gravely ill patient.

“Nobody ever heard about the case I just reported because we never reported it,” said Classen, who is a member of the IOM Committee on Patient Data Safety Standards that developed the 2004 report and the Committee on Patient Safety and Health Information Technology that developed the 2011 report on health IT safety. “We couldn’t learn much about it. We’re not being very transparent or sharing learning about these cases.”

Classen pointed to a broader event a decade later, which illustrates that those who fail to learn history are doomed to repeat it. In 2011, the FDA issued a Class I recall of a medical monitor with similar interoperability problems as the one that failed the septic

patient. A Class I recall, the most serious, is defined as a situation with a reasonable probability of causing serious adverse health consequences or death. The recalled device, part of a system connected to a central station via a hospital network, is used to help clinicians monitor patient vital signs and therapy, control alarm parameters and signals, review web-based diagnostic images, and access patient records.

Classen challenged the status quo, noting that the healthcare community cannot learn and thus improve if mistakes are not shared.

“It is a horrible pervasive characteristic of American healthcare that information about errors causing patient harm are concealed,” adds John Rhoads, interoperability and standards architect at Philips Healthcare.

Learning from and with Interoperable Systems—and from Other Industries

If there is any silver lining in events like these, it is this: “We’re not alone in our struggle for interoperability,” Classen said. “This is an issue that crosses many, many industries.”

IOM brings the perspective of other industries, and of healthcare systems outside of the United States, into its 2011 report, which focuses on two areas:

- Preventing adverse patient events from health IT
- Leveraging IT to improve patient safety

“If the goal is to improve patient safety, we have a very big problem,” he said. “I would argue that if we don’t know where we are in patient safety, then it’s hard to use IT to improve patient safety,” he said.

A place to start learning is in measuring harm and recognizing its scope. Classen offered three data points as indications that there are enormous opportunities for improvement:

- A 2010 report by the U.S. Department of Health and Human Services found that every month, as many as 13.5 percent of Medicare beneficiaries experience adverse events during their hospital stays, and as many as 15,000, or 1.5 percent, experience adverse events contributing to their deaths. “That’s just Medicare,” he said. “In the whole healthcare system, the problem is probably much bigger.”

“Of patient safety issues, how many are related to a lack of interoperability? We don’t have a good measurement system. Ambulatory care is even more foggy. We have terrible measurements on patient safety.”

— Summit participant Ken Fuchs, senior principal architect for enterprise systems at Mindray North America and co-chair of the Integrating the Health Enterprise (IHE) Patient Care Device Domain (PCD) Planning Committee



- A five-year study of 10 hospitals in North Carolina—a state with organized patient safety initiatives—detected patient harm from medical care in 25 percent of hospital admissions (Landrigan et al., 2010). Moreover, there was no improvement in the trend of the number of incidents over the period studied (2002 to 2007).
- The Institute for Healthcare Improvement’s “Global Trigger Tool” estimated in 2011 that adverse events in hospitals might be 10 times greater than is known, due to shortcomings in voluntary reporting and patient safety indicators (Classen et al., 2011).

Robust, effective interoperable systems could be part of the solution in early detection and prevention of adverse events, such as medication errors, lack of patient monitoring or assessment, and patient deterioration. In the future, these systems could play a bigger role in treatment, and in enabling objective, voluntary reporting of successes and failures as well. That said, the current path with interoperability will not be part of the solution and will only contribute further to the problem unless the serious shortcomings that are preventing healthcare from making progress with patient safety are addressed.

With patient safety in the foreground, the clarion themes, challenges, and priority actions developed by summit participants follow, with additional highlights from Classen and other summit presenters and experts.

Features of Safer Health IT

“Safely functioning health IT should provide easy entry and retrieval of data, have simple and intuitive displays, and allow data to be easily transferred among health professionals. Many features of software contribute to its safe use, including usability and interoperability. Although definitive evidence is hard to produce, the committee believes poor user-interface design, **poor workflow, and complex data interfaces are threats to patient safety.**”

“Similarly, **lack of system interoperability is a barrier to improving clinical decisions and patient safety,** as it can limit data available for clinical decision making. Laboratory data have been relatively easy to exchange because good standards exist such as Logical Observation Identifiers Names and Codes (LOINC) and are widely accepted. However, important information such as problem lists and medication lists are not easily transmitted and understood by the receiving health IT product because existing standards have not been uniformly adopted. Interoperability must extend throughout the continuum of care; standards need to be developed and implemented to support interaction between health IT products that contain disparate data.”

— Institute of Medicine, *Health IT and Patient Safety: Building Safer Systems for Better Care*

“Poor user-interface design, poor workflow, and complex data interfaces are examples of poor interoperability—even though they don’t necessarily have to do with the flow of electrons through a technical system,” said Carol Davis-Smith, vice president, clinical technology, at Kaiser Permanente. “When people—pharmacists, physicians, nurses—do not agree on standards (interoperability), it’s another example of nontechnical interoperability gone wrong.”

Clarion Theme 1: Standardize to achieve success.



“Interoperability is all about communication. It isn’t just the message—it’s the way the message is translated. Most people, when they think about interoperability, are thinking about devices, connectors, hardware, software, connecting devices to health information technology, and health information technology to more health information technology. More important, interoperability means connecting technology to *people*.”

— Matthew B. Weinger, Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, medical informatics, and medical education at Vanderbilt University School of Medicine

Challenge	Priority Action	Accountability
A lack of a common definition of interoperability	Develop a consensus definition that includes all dimensions of interoperability: data, communication, semantic, workflow, and user interoperability.	ONC, FDA, NIH, DoD, HHS, HVA, Standards Development Organizations (SDOs)
Uneven use of existing standards	Promote use of the same Health Level Seven International (HL7) interface for many use cases, especially for communicating data to the EMR and other hospital ancillary systems. For imaging devices, promote the use of Digital Imaging and Communications in Medicine (DICOM). For use cases requiring real-time communication between devices at the bedside, consider Institute of Electrical and Electronics Engineers (IEEE) 11073.	FDA, ONC, Industry, HL7, IEEE, Other SDOs
Limited use of existing, standardized tools	Use Integrating the Health Enterprise (IHE) Profiles for acquiring or upgrading systems to specify a level of compliance to standards sufficient to achieve efficient interoperability.	Industry
	Use International Electrotechnical Commission (IEC) 80001 to manage risk, along with other standardized tools	Healthcare delivery organizations (HDOs)
A need for new standards where none exist	Standardize the design and implementation of safe, interoperable products.	AAMI/UL, IEEE, HL7, IHE, HITSP, Other SDOs
	Standardize device and system security.	AAMI/UL, NIST, Other SDOs
	Develop global harmonization standards.	SDOs

What Is Interoperability?

The struggle to achieve safe, effective interoperable medical technology begins with a fundamental question: What is interoperability? Summit presenters and participants agreed that a common definition is lacking—and much needed for stakeholders to know what the goals are and to work to achieve them.

Summit presenter John F. Murray Jr., software compliance expert at the FDA’s Center for Devices and Radiological Health (CDRH), admitted that there is “no consensus meaning or definition” for interoperability in healthcare. In fact, the FDA has been working for more than three years to develop a definition, he said.

The challenge is complex because of the broad landscape, in terms of fast-changing, abundant, and variable technology; unlimited numbers of scenarios for connecting different technologies; and many stakeholders, Murray said.

In a presentation titled “Medical Technology Interoperability: A View from the Trenches,” summit presenter Matthew B. Weinger cast interoperability in terms of clinical practice. “Interoperability is all about communication,” said Weinger, Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, medical informatics, and medical education at Vanderbilt University School of Medicine.

“It isn’t just the message—it’s the way the message is translated,” he said. “Most people, when they think about interoperability, are thinking about devices, connectors, hardware, software, connecting devices to health information technology, and health information technology to more health information technology. More important, interoperability means connecting technology to *people*.”

In the operating room, for example, many clinicians with different roles and expertise interact with multiple wired and wireless devices, which are connected to an EHR system on its own network. “Many of our systems don’t ‘talk’ to each other and, if they do, there are high costs to do so and the full benefits have not been realized,” Weinger said. Those technology-to-technology and technology-to-people disconnects result in a number of interoperability concerns in the clinical arena, which are summarized in the sidebar in the next column.

“The term ‘interoperability’ can mean anything from connecting one thing to another through the expenditure of considerable time and effort—most current interoperability is in this category—to spontaneous or plug-and-play interoperability where things just work out of the box,” said summit presenter Ken Fuchs of Mindray North America.

“Because interoperability is a continuum,” he said, “the definition usually covers the lowest level on the spectrum. There is no discussion of the degree of effort, the reliability, the security, the completeness, and so on of a given interoperability implementation.

“What we have today is ‘ad hoc’ device and system integration. If devices are not designed, tested, and regulated for interoperability, we will still have ad hoc integration. We need safe interoperability, where we know a device’s limits and don’t exceed those limits.”

— Julian Goldman, anesthesiologist at Massachusetts General Hospital and medical director, biomedical engineering, Partners HealthCare System

We sometimes talk about basic interoperability, seamless interoperability, functional interoperability, spontaneous interoperability, plug-and-play interoperability.”

Summit presenter Meghan Dierks, assistant professor of medicine at Harvard Medical School in the Division of Clinical Informatics at Beth Israel Deaconess Medical Center, framed the definitional issues more formally. She offered four concepts for understanding interoperability as continuum; four dimensions for defining interoperability (data, communication, semantic, and workflow); and the four biggest challenges for achieving interoperability, detailed in the sidebar on the next page.

Many summit participants added that user interoperability is another important dimension to recognize explicitly in defining the term.

Interoperability Concerns in Clinical Practice

- Safety (e.g., lack of or incomplete data integration)
- Poor prioritization (e.g., alarmed devices)
- Lost and missing data
- Inefficiency (e.g., double entry of data)
- Reluctance to standardize processes
- Inability to measure care and use metrics to improve care
- Failure to transfer/disseminate successes

FOUR CONCEPTS, FOUR DIMENSIONS, AND FOUR CHALLENGES OF INTEROPERABILITY

Meghan Dierks

Assistant professor of medicine at Harvard Medical School in the Division of Clinical Informatics at Beth Israel Deaconess Medical Center

FOUR CONCEPTS

1. Interoperability should always be measured or assessed with respect to a specific function or task.
2. Interoperability should be thought of as falling along a continuum.
3. On a function-by-function, task-by-task basis, two or more systems can be anywhere from “incompatible” to “fully integrated.”
4. Because of the diversity of data, functions, and uses, systems can simultaneously exist in both states, leading to hidden vulnerabilities.

FOUR DIMENSIONS

1. Data interoperability

Definition: Agreement/consistency in formatting, storage, querying, and synchronization of data

Examples: Do two systems mutually understand what characters cause terminations or truncations? Do they share the same formatting of dates and times? Do they format medical record numbers as a string or as a numeric and, within a single system, is there consistency in the length of these numbers? Do two systems or applications apply the same default and/or permitted values for individual field elements?

Patient safety scenario: A (new) automated microbiology system performs and sends results on 30 lab tests to the laboratory information system (LIS). The (old) LIS is configured to expect/accept only 20 results. Data on items 21–30 are stored to unallocated memory, which cannot be retrieved and reported out to the clinician or patient’s EHR.

2. Communication interoperability

Definition: Consistency in transmission and reception of messages between nodes

Examples: Does a hospital information system’s computerized physician order entry (CPOE) module share the same format for addresses with its radiology information system (RIS) so that the CPOE knows where to send a message for an order? Do these systems have the same rules for acknowledging that a message has been received completely? Do the systems have the same rules for timeouts and retransmission if a receipt has not been detected? At the message structure level, do the systems share an understanding of when the message begins and ends? Do the systems have a mutually accepted understanding of when a message has errors and when it should be rejected?

Patient safety scenario: A clinician sends an order message over the CPOE to the pharmacy requesting a “STAT” dose of medication for a patient. The pharmacy information system (Rx system) does not receive the message due to a transient network issue.

The standard calls for the CPOE system to wait for an acknowledgment (an HL7 ACK message), and display a message to the user that the order transaction was not completed, but this does not happen. The clinician is not aware that the order has never been received, and there is a delay in treating the patient.

3. Semantic interoperability

Definition: Agreement/consistency between systems on the meaning of communicated information

Examples:

- RxNorm (National Library of Medicine's normalized names for drugs)
- CPT® (American Medical Association's current procedural terminology)
- ICD-9-CM (International Classification of Diseases, Ninth Revision, Clinical Modification)
- SNOMED®CT (Systemized Nomenclature of Medicine of the International Health Terminology Standards Development Organization, or IHTSDO)
- LOINC® (Laboratory Observations Identifiers Names and Codes)
- MedDRA® (Medical Dictionary for Regulatory Activities, developed by the International Conference on Harmonization), a medical terminology used by the regulated biopharmaceutical industry to code and classify adverse event information for pre- and post-market reporting

Patient safety scenario: A clinical decision support application is designed to screen a patient's active medication list for concurrent nephrotoxin exposure risk when a clinician orders a contrast-enhanced imaging study. The system screens using a conventional drug dictionary, which does not have a mapping to NKTR- 061, an investigational formulation of the aminoglycoside amikacin. Without an explicit "understanding" that NKTR-061 is a member of the aminoglycoside category, the decision support application does not detect the concurrent use of a potentially nephrotoxic medication and the alert is not triggered.

4. Workflow interoperability

Definition: Agreement/consistency on how technology supports/shapes the workflow:

- Processing or sequencing tasks between participants according to a set of procedural rules
- Formatting or displaying information
- User interfaces
- Penetration of decision support

Examples:

- Semi-automation of workflow involving Indium-labeled leukocyte scintigraphy—Processes and information need to be coordinated and passed across CPOE, RIS for scheduling and Modality Work List generation, LIS phlebotomy scheduling, isotope inventory management, ordering, and so on.
- Semi-automation of workflow around antimicrobial approval—All systems/subsystems (CPOE, LIS, telecom/pager) must have a shared model of the work process and the rules/conditions necessary before passing information/status to the next system and step in the process.

Patient safety scenario: A clinician requests that hard copies of a digital mammogram be printed for use in the operating room to guide a biopsy. The default behavior for most printers is "scale to fit" (i.e., fitting the image as well as can be achieved into the space available on the film) vs. producing a "true-size" copy. The image is printed without explicit labeling of "scale to fit." The clinician does not realize that the distance between nipple and lesion measured using the "scale-to-fit" image is less than the actual anatomic distance. This results in uncertainty and multiple failed passes as the surgeon tries to gauge the appropriate depth of penetration for the needle and under-sampling of the target lesion.

FOUR CHALLENGES

1. Latent (hidden) interoperability failures—failures within specific functions—that may not be obvious to the user
2. Assumptions that users make about the "integrity" (the completeness of the integration) of the components
3. Asynchronous evolution of interfaced or interdependent components—legacy components
4. Balancing need for standardization and innovation/customization

Working Definitions of Interoperability in Healthcare

Medical device interoperability is the ability of medical devices, clinical systems, or their components to communicate with each other in order to safely fulfill an intended purpose.

— AAMI

Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities.

— HIMSS

Uneven Use of Existing Standards and Tools

Many summit participants urged the development of new standards and tools to pave the way to safe, secure, and effective connected medical technology. At the same time, others pointed out that some comprehensive standards and tools already exist, but are not being widely used in the field, including but not limited to:

- Health Level Seven International (HL7), a global authority on standards for interoperability of health IT in more than 55 countries, which develops standards accredited by the American National Standards Institute (ANSI). HL7 provides a framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services. At the summit, participants applauded the announcement by Charles Jaffe, chief executive officer of HL7, that the organization will license its standards and profiles free of charge.
- Integrating the Health Enterprise (IHE) Profiles, which are not standards but provide a common language for purchasers and vendors to use when acquiring or upgrading systems to specify a level of compliance to standards sufficient to achieve efficient interoperability.

- International Electrotechnical Commission (IEC) 80001: *Application of risk management for IT networks incorporating medical devices*, which defines the roles, responsibilities, and activities necessary for risk management for IT networks incorporating medical devices to address safety, effectiveness, and data and system security.
- American Society for Testing and Materials (ASTM) F2761, *Medical Devices and Medical Systems—Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE), Part 1: General Requirements and Conceptual Model* describes a platform and an architecture for heterogeneous systems composed of devices from multiple vendors.

An Expressed Need for New Standards

Summit presenters and participants identified huge variability in clinical, health IT, and organizational practices, which makes it difficult to develop technical standards that would be universally applicable. And there are gaps in existing standards that need to be addressed.

“What is needed is to build standards that are accurately targeted at a particular gap or need,” said Bakul Patel of the FDA’s CDRH. “As of yet, there have been no activities to assess these needs in sufficient detail, nor where there are common needs. As an example, even a new work item proposal in AAMI for patient-controlled analgesia is unspecific about what it should include.”

On another front, summit participant Erin Sparnon, senior project engineer at ECRl Institute, said she is concerned that consumer technology which is increasingly used in healthcare, such as off-the-shelf software and medical “apps” for tablets and smartphones, is currently beyond the reach of standards—or, at this point, regulation. She worries that these unregulated apps are potentially dangerous.

To address some of these challenges, AAMI and UL joined forces in September 2012 to develop a suite of consensus-based standards on medical device interoperability, with a focus on risk analysis and testing. These standards will help manufacturers design safer, interoperable products and aid healthcare facilities in implementation. The

standards will complement, not replace or supplant, existing implementation standards or profiles. Instead, they will map existing implementation practices into a risk management framework and, where applicable, address further safety issues.

The tension between standardization and innovation that exists throughout the medical technology industry surfaced at the summit. Some summit presenters and participants worried that too much standardization will suppress innovative interoperability solutions.

Summit presenter David Muntz, principal deputy national coordinator, Office of the National Coordinator (ONC) for Health IT, U.S. Department of Health and Human Services, argued that interoperability standards could enable innovation.

“You can be really innovative, but you can’t do the innovation that will serve the populace without interoperability standards,” he said. “Think of it as the ‘transitive property of interoperability’: If product A can talk to B and B can talk to C, A should be able to talk to C.”

“A proper connectivity standard,” for example, “allows the things that are connecting to innovate independently, which can help, rather than hinder, innovation,” said John Rhoads of Philips Healthcare.

John Thomas of INCOSE puts this another way: “Interoperability standards are critical to ensure safe medical devices while simultaneously enabling innovation from the configurability of those devices to meet unique problems.”

‘Cybersecurity of Cyberphysical Systems’

One area that is ripe for new standards is device and system security, summit participants agreed. Interoperability introduces greater potential for devices and systems—and confidential patient data they store, transmit, or share—to be breached or compromised. These and other failures in devices or systems could result in patient harm as well.

Potential risks will only increase as the volumes of information shared, and the use of “big data analytics,” increases, according to summit presenter Kevin Stine, group leader for security outreach and integration group at the National Institute of Standards and

Expert Perspectives on Version Control

“HL7 is like ice cream. You never know what flavor you are going to get.”

— Matthew B. Weinger, Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, medical informatics, and medical education at Vanderbilt University School of Medicine

“I think HL7 is widely used, but HL7 alone doesn’t get us there. Also HL7 is open to interpretation. Two HL7 devices don’t necessarily understand each other—think of language dialects, or think about British vs. American English. That’s why we need the IHE Profiles to come up with commonalities built on top of HL7.”

— Pat Baird, systems engineering specialist, Baxter HealthCare

“Isn’t this similar to the challenges with DICOM [Digital Imaging and Communications in Medicine] standards? That is, the interoperability of medical imaging devices—radiology—with PACS [picture archiving and communications systems] and RIS [radiology information systems]. Are there lessons to be learned and/or parallels to be drawn?”

— Carol Davis-Smith, vice president, clinical technology, Kaiser Permanente

“The issue with HL7 is that it can be interpreted widely by the implementer so that two systems using the same version of HL7 can express the same thing in very different ways. This is why the IHE was formed, to create profiles of standards (not just HL7) that try to squeeze out all the variability of interpretations for a specific use case. They also test implementations for consistency and interoperability with partners and test tools.”

— Ken Fuchs, senior principal architect for enterprise systems at Mindray North America and co-chair of the Integrating the Health Enterprise (IHE) Patient Care Device Domain (PCD) Planning Committee

Summit participants recommended that all vendors use the same version of HL7 standards, because it confusing to have many versions in use.

Technology (NIST). NIST's Information Technology Laboratory is investigating the "cybersecurity of cyberphysical systems." Stine explained that implantable medical devices, for example, could be considered cyberphysical systems, in that they are physical devices controlled or monitored by IT systems.



"We need 'intelligent standardization.' You cannot standardize everything when you work with chaos."

— Julie Vilardi, executive director, strategic projects and clinical informatics, Kaiser Permanente, Information Technology



Summit participants agreed that one area that is ripe for new standards is device and system security.

NIST convened a multi-sector conference on cybersecurity issues in 2012, and now plans to focus on medical device security by applying lessons learned from other industry sectors. "We're working with industry and academic partners," Stine said. "It's not new concepts; it's really back to basics: Design security from the beginning to increase resiliency of the system. If a system fails, you want it to work like a firewall in the IT space—you don't want it to fail open, you want it to fail shut. You want to assume that no other system is secure or that every other system is insecure, so there are boundaries on the perimeters of the device as well as internally to protect the data."

"Failing shut doesn't mean closing down and isolating yourself from the world," Thomas adds. "It means the device goes into a safe mode where the outside system still knows what it is doing—but the device won't take commands from an untrusted outside system. Isolating itself from the outside system where nothing is known about its operation in 'safe mode' is as dangerous as continuing to operate in an untrusted environment. The space industry has proven this point time and time again."

In healthcare, as in other industries, it's important to express security requirements in a common way—and to design security to allow for the adoption of new technology and adaptation for security threats that are constantly changing. An additional complexity in healthcare is the patient at the other end of the device. If that person's life depends on the technology, a "shutdown" has very different implications that in other industries.

Clarion Theme 2: Align incentives, expectations, roles, and responsibilities.



“To be successful, we must define and align goals. Economic incentives, user needs and challenges, clinical practices, and decisions are completely at odds with one another.”

— Charles Jaffe, chief executive officer, HL7

Challenge	Priority Action	Accountability
Misaligned incentives across the board for improving interoperability	Align all incentives to patient safety and clinical need. Develop multiple, diverse incentives (e.g., regulatory, standards-based, economic, technical, participatory) to improve interoperability.	All stakeholders; federal government needs to address this as a priority
	Align interoperability requirements with Stage 3 of the Medicare and Medicaid EHR Incentive Programs of the U.S. Department of Health and Human Services. Require that interoperable systems that provide safety assurances are eligible for reimbursement by the Centers for Medicare & Medicaid Services (CMS).	ONC CMS HIMSS Professional societies
	Align the standards of The Joint Commission (TJC) and other accreditation and certification bodies for healthcare delivery organizations to interoperability requirements.	TJC, DNV, HFAP CMS State regulators
Confusion about who “owns” the system, who is the systems integrator, and who is responsible for interoperability testing, safety, maintenance, and liability enhances risk. Unless an obvious systems integrator emerges, healthcare delivery organizations are systems integrators by default—whether or not they know it.	Clarify who is responsible for interoperable systems throughout their lifecycles.	AAMI, NIST, UL, IEEE, IEC/SC 62A, HIMSS, DICOM, HL7, HITSP, West Health, ASTM, Continua, FDA, ONC, TJC, DNV, HFAP, CMS, State regulators
Lack of leadership for interoperability solutions and risk mitigation	Create an executive-level document (or series of documents) that makes the business case for managing interoperability in terms of patient safety and care and medical system risks, costs, and value.	AAMI, ACCE, ECRI Institute, HIMSS, CHIME
	Fully engage the C-Suite in setting the vision and direction for interoperability—with the emphasis on patient safety and improved outcomes—and overseeing its execution.	All stakeholders

A Call for Incentives

Summit presenters and participants repeatedly asserted that interoperability progress is hindered by misaligned incentives, or a lack of incentives. Multiple, diverse incentives are needed for healthcare to achieve fully functional, interoperable systems. Further, they urged aligning all incentives for all stakeholders—including patients, clinicians, healthcare facilities, payers (including government), manufacturers, regulators, standards development organizations, insurers, and lawyers—to patient safety and clinical need.

“Collaboration is the first step in overcoming interoperability challenges not only for EHRs but for system and device integration,” summit presenter Charles Jaffe of HL7 said. “Too often, the stakeholders in this process fail to recognize that interoperability challenges are not at a technical level but at a policy and process level. Economic incentives, user needs and challenges, clinical practices, and decisions are completely at odds with one another.”



“We don’t have alignment across stakeholders, between the public and private sectors, different models of care, or the diversity of healthcare IT.”

— Elliott Sloane, president, Center for Healthcare Information Research and Policy

What’s needed, he said, is alignment of goals, incentives, priorities, technologies, and governance. “To be successful, we must define and align goals,” he said. Jaffe offered this food for thought:

- **Align goals**—Where do the domains of efficacy, safety, and privacy intersect ... if at all? ... Why are our priorities so different—different business requirements, developer requirements, end user requirements, regulatory requirements? All of the priorities have a different focus.
- **Align incentives**—The U.S. market will not continue to pay for the world’s R&D indefinitely.
- **Align priorities**—You cannot have more services and lower cost. You can have higher quality and lower cost.

- **Align technologies**—“Pharma” cannot expect to benefit from healthcare data if the industry (and regulators) insists upon their own information models, their own vocabulary, and their own data standards.
- **Align governance**—Coordinate policies, funding, and regulation. The entire healthcare community needs federal agencies to talk to one another to effect this coordination.

Money Talks

The dearth of economic incentives to improve patient safety and address clinical needs is of particular concern. “If we don’t start putting an economic incentive to these issues, they won’t be addressed,” said Ken Fuchs of Mindray North America and IHE.

“There are real, short-term costs to manufacturers,” explained Vanderbilt University School of Medicine’s Matthew Weinger.

Potentially, those costs include:

- Increased development costs for redesigning existing technology
- Loss of value of existing intellectual property
- Loss of proprietary market advantages and increased competition
- Reduced return on investment from research, development, implementation, service, and management of technology
- Increased risk due to interconnectivity with technology from other vendors

Likewise, summit participants say, there are potential costs to healthcare delivery organizations, including:

- Increased cost for replacing legacy systems and for testing, installing, and integrating new technology
- Increased cost to integrate distributed technology in satellite and outpatient facilities and in home healthcare
- Process improvement and standardization costs (including huge cultural change efforts)

Summit participants also pointed out that interoperability should play a bigger role in The Joint Commission’s accreditation and certification standards for healthcare delivery organizations, and those of other accrediting bodies as well. For example, there is no compelling incentive for healthcare delivery organizations to use tools such as IEC 80001

as a mechanism to manage health IT risk and improve system safety. Some summit participants, in fact, said there are strong disincentives for all but elite systems to use this tool, including the time, effort, and cost of undertaking a risk management assessment of medical IT networks.

Yet fully interoperable medical technology and information systems could deliver real value to every stakeholder, such as:

- Improved healthcare quality and safety
- Improved technology offerings and innovation
- Decreased cost of development and deployment
- Decreased cost of implementation and ongoing support
- Decreased cost of care
- Decreased liability risk

Incentives for Meaningful Use of EHRs

Looming large in the incentive equation is the Medicare and Medicaid EHR Incentive Programs, which provide a financial incentive to eligible providers, eligible hospitals, and critical access hospitals for achieving “meaningful use” of certified EHR technology to achieve five broad health and efficiency goals:

- Improve quality, safety, and efficiency
- Engage patients and their families
- Improve care coordination
- Improve population and public health and reduce disparities in care
- Ensure privacy and security protections

ONC is supporting platforms to develop interoperability standards and innovative solutions in the interest of promoting these goals, according to the ONC’s David Muntz. “Why is government involved? Because industry didn’t do the kind of interoperability that was necessary,” he said. “Profit motives don’t encourage interoperability.”

The EHR Incentive Programs are staged in three steps toward meaningful use of EHRs, with increasing requirements for participation:

- Stage 1, which began in 2011, focuses on capturing and sharing data from EHRs.
- Stage 2, which will begin in 2014, focuses on using EHRs to advance clinical processes.
- Stage 3, which is scheduled to begin in 2016, is expected to focus on improving health outcomes.

“If we do this right, everyone is going to win.”

— Matthew B. Weinger, Norman Ty Smith chair in patient safety and medical simulation and professor of anesthesiology, medical informatics, and medical education at Vanderbilt University School of Medicine



Right now, ONC and most providers are planning for Stage 2 certification, which requires the EHR to share information, including patient care summaries and relevant documentation, with the ability to view, download, and transmit this information. Summit participants urged incentives that encourage healthcare delivery organizations to meet the more ambitious requirements for Stage 3. Specifically, they want interoperability requirements to be aligned to Stage 3 requirements, once these are finalized—and they want to make sure that systems that meet safety assurances are eligible for Medicare and Medicaid reimbursement.

In its role as a standards and solutions broker, ONC offers these guiding principles for standards and interoperability:

- Interoperability is a *journey*, not a destination.
- *Leverage government as a platform* for innovation to create conditions of interoperability.
- Health information exchange is *not one-size-fits-all*.
- Build in *incremental steps*—“don’t let the perfect be the enemy of the good.”

Some summit participants urged careful planning and caution with this timing. “One of the issues of shooting for Meaningful Use 3 is the time it takes for the standards to be fully released and the medical device vendors to turn around and implement,” Fuchs said. “For medical devices, the typical cycle time is one year—unless the FDA gets involved, in which case it is longer.”

ONC is putting these guidelines into practice by working to:

- **Enable** stakeholders to come up with simple, shared solutions to common information exchange challenges.
- **Collaborate** with other federal agencies to

- coordinate federal health IT priorities as manager of the federal health architecture.
- **Curate** a portfolio of standards, services, and policies that accelerate information exchange.
 - **Support innovation** through its Strategic Health IT Advanced Research Projects (SHARP) program, Innovation/Challenge grants, and interfacing with the international standards community.

ONC in 2011 launched a Standards and Interoperability (S&I) Framework to orchestrate input from the public and private sectors to create harmonized health IT specifications. The S&I Framework supports an open community of implementers and experts who are collaborating to solve real-world interoperability challenges, including emerging challenges of “big data” and massively parallel processing.

A Call for Clearer Accountability

Confusion over who “owns” interoperable systems and is accountable for safety is another challenge to healthcare stakeholders.

When medical technology was in its infancy, healthcare delivery organizations clearly owned the stand-alone “boxes” in their inventories. They purchased the technology, deployed it, serviced it, maintained it, documented it, decommissioned it—or they hired vendors or third-party providers to support the technology lifecycle.

Regulation of devices was clear as well. The FDA’s CDRH developed regulations for stand-alone devices. Manufacturers were accountable for the regulatory aspects of the “box” and its safe implementation for its intended use. More recently, vendors started to extend this concept by integrating devices into their systems. For example, patient monitoring vendors would interface to carefully selected medical devices, such as ventilators. They remained responsible for the regulatory and safety aspects of the composite system.

Today, the lines of accountability are less clear. Most medical devices don’t function as stand-alone boxes anymore; they are becoming components of a larger system. Healthcare delivery organizations build their own systems. Information systems are integrated into medical technology systems.

Systems are connected to other systems and networks. Healthcare delivery organizations deploy and connect proprietary and off-the-shelf products from many vendors, all of which might have different designs, specifications, compatibilities, and lifecycles. Manufacturers push out software updates, which can affect system and network performance, remotely. There is no integrator of all of these divergent component parts, and no real consideration for system-wide safety, from a patient safety lens.

To add to the complexity, all of this health IT is configured to meet inconsistent institutional needs, sometimes internally and sometimes in partnership with one or more vendors. In the name of clinical care need, configurations often differ among units in the same healthcare organization, or among healthcare organizations in a large health system. Teams of internal and external professionals—including clinical staff and experts in purchasing, healthcare technology management, clinical engineering, IT, facilities, finance, and risk management—might be more or less involved in decisions, specifications, configurations, testing, implementation, use, and care.

In this complex environment, who is responsible for system and patient safety?

CDRH still regulates stand-alone medical devices and vendor-integrated composite systems. The Joint Commission and others accredit healthcare organizations, with different requirements and standards for various areas in a healthcare organization. No one is currently responsible for looking at or regulating the entire system. There is no air traffic control; no National Transportation Safety Board; and no single manufacturer like Boeing integrating the thousands of components that constitute an airplane.

Right now, whether they know it or not, healthcare delivery organizations own it all, by default—the health IT, the responsibility, the accountability, and the liability if something goes wrong. This remains the case, even though multiple organizations might have a hand in designing, configuring, and testing interoperable systems.

Given that any number of things can go wrong, summit participants advocated for an explicit role in healthcare, that of the systems

integrator. “It’s not really a new role,” said John Rhoads of Philips Healthcare. “Organizations fill it, but it sometimes comes without recognition of what they are doing and the responsibilities it entails.” Systems integrators might be organizations or individuals who can analyze the big picture, manage risk, and facilitate safe connectivity. *(For more on a systems approach to interoperability, see Clarion Theme 3.)*

Looking for Leadership

Again and again, summit participants pushed for leadership and direction at the C-Suite level in healthcare delivery organizations. Part of the problem with gaining C-Suite attention could be that those who are immersed in the challenges have not done a good job communicating with organizational leaders.

“We’re focused on the technical aspects of interoperability so much so that the clinical drivers are often forgotten or overlooked,” said Carol Davis-Smith of Kaiser Permanente. “Similarly, the clinical drivers often imply ‘soft’ benefits—cost avoidances, such as reduced adverse events. Additionally, a lack of focus on or commitment to implement the ‘hard’ costs, such as staff reductions, diminishes the value and subsequently the credibility of the interoperability team.”

“Normally, the systems integrator acts as the translator between the mission and the business impact vis-à-vis the technology implementation issues,” John Thomas of INCOSE added. But because this role rarely exists formally in healthcare, the links between interoperability, mission, and business considerations aren’t clear to C-Suite leaders.

Summit participants proposed rectifying these shortcomings by creating an executive-level document (or series of documents) that makes the business case for managing interoperability. They want to fully engage the C-Suite in setting the vision and direction for interoperability and overseeing its execution.

“These documents must be clinically focused,” Davis-Smith said. “It is very easy to slide into a focus on the technical aspects. If there is not a commitment to the clinical drivers—patient safety, quality of care at an affordable cost—then there really is no reason to implement interoperability.”

Indeed, leading practitioners whose work was highlighted during the summit pointed to C-Suite leadership as the driver and enabler for groundbreaking progress. Some of these presenters, in fact, are members of the C-Suite.

“Barely half of healthcare executives have begun to address interoperability.”

— James Keller, vice president, healthcare technology evaluation and safety, ECRI Institute



The Changing Landscape in Healthcare

- **69 percent** of physicians have EHR systems
— Capsite (2012)
- **61 percent** of consumers are interested in using a medical device that would enable them to check their conditions and send that information to their doctors electronically
— Deloitte Center for Health Solutions (2011)
- **15 percent** of consumers have renewed a prescription online
- **10 percent** of consumers have a personal health record
- **8 percent** of consumers have emailed their healthcare provider
— Pew Research Center’s Internet and American Life Project (2011)

“We still have a lack of clarity about what the future of healthcare could be with interoperability. A lot more nurturing and direction is needed to have a clear, unified vision of the desired end state so that this becomes more than just a cool thing.”

— Julian Goldman, anesthesiologist at Massachusetts General Hospital and medical director, biomedical engineering, Partners HealthCare System



Clarion Theme 3: Drive patient safety with a systems approach to design and implementation.



“Safety is a system-level property. A real challenge is that people in hospitals don’t have systems engineering knowledge.”

— Nancy Leveson, professor of aeronautics and astronautics and engineering systems, Massachusetts Institute of Technology

Challenge	Priority Action	Accountability
Rapid proliferation of connected medical devices and systems that operate in silos—and an “incredible appetite” for integration	Bring systems engineering rigor to interoperability challenges. Analyze the V-model for the systems development lifecycle (including system requirements, design, engineering, integration, testing, verification, validation, operation, and maintenance) and refine it for medical devices and systems, using FDA-approved safety and quality methodologies. Use real, exemplary cases to provide practical guidance to the healthcare community.	ONC and FDA, CHIME, HIMSS, HDOs, AAMI, IEEE, INCOSE, and other SDOs
Inconsistent expectations among healthcare delivery organizations and medical device and system providers	Develop a technical information report (TIR) on the design control process for device interoperability.	AAMI INCOSE
	Define the dimensions of use of existing products. Establish common use criteria, labels, and interface specifications in standards and/or a TIR.	AAMI/UL, ASTM, CIMIT, IEEE, ISO TC 215, other SDOs
	Encourage medical device and system providers to converge around consistent communication and implementation standards and deployment models. Start by reviewing Integrating the Healthcare Enterprise (IHE) International Profiles, which provide a common language for healthcare organizations and vendors to discuss integration needs and product capabilities. Evaluate the Information Technology Infrastructure Library (ITIL), a set of practices for IT service management, as a model for aligning and staging of interoperability requirements. Prototype examples for the healthcare community to assess and discover the dimensions for interoperability.	CHIME, HIMSS, HL7, IHE, IEEE, NIST, ISO TC 215, other SDOs
	Empower healthcare delivery organizations (HDOs) with a list of questions to ask medical device and systems providers about the evidence of the interoperability of their products. Develop “drop-in” purchase contracting language for various types of devices and systems by polling the healthcare community for best practices—or use recommended language from respected consultants. Attendees encouraged HDOs to hold the line and not back down from interoperability requests.	AAMI, ACCE, ECRI Institute, CHIME, other professional societies HDOs

Who's Engineering the System?

Healthcare has become a complex, sprawling enterprise that is failing to take advantage of the salient disciplinary expertise to design and manage it: systems engineering.

This expertise is critical in an era dominated by the industry-wide push to integrate health IT and make meaningful use of EHRs. The goals of meaningful use go beyond capturing and sharing data—the most basic capacities of connectivity—from EHRs. The ultimate goals focus on patient safety, in terms of advancing clinical processes and improving health outcomes.

Achieving those goals requires designing, connecting, configuring, and managing health IT systems for patient safety.

“Safety is a system-level property,” said summit presenter Nancy Leveson, professor of aeronautics and astronautics and engineering systems, Massachusetts Institute of Technology (MIT), and author of *Engineering in a Safer World: Systems Thinking Applied to Safety*. “It must be designed top-down and include the entire sociotechnical system”—meaning the people who interact with the connected health IT. “A device or network of devices that is safe in one system may not be safe in another.”

If safety is a system-level property, who's engineering the system?

“A real challenge is that people in hospitals don't have systems engineering knowledge,” said Leveson, who has been a safety consultant to the National Aeronautics and Space Administration and on blue-ribbon panels investigating safety issues in the nuclear power, transportation, aerospace, defense, and air traffic management industries.

John Thomas of INCOSE asserted that health IT “systems” intended to support patient safety might not, in fact, be systems at this point. They're merely collections of (very expensive) parts. As Leveson pointed out, “The compilation of safe components doesn't necessarily add up to a safe system.”

“This is exemplified when healthcare technology management and/or IT teams implement interoperability (integration) without incorporating the clinical perspective,” said Carol Davis-Smith of Kaiser Permanente. “The resulting systems may be ideal from the technical perspective, but are not reliable or

useable from the clinical perspective.”

Summit participants advocated for “systems integrators” charged with improving the capacity of health IT to contribute to patient safety. That role is important, Thomas said, but healthcare organizations can't outsource it. While they may work with vendors and outside experts, healthcare organizations need to understand their systems and own the decision making.

To help summit participants envision what the systems integrator role might entail, Thomas offered a primer on systems, interoperability, and systems engineering from a safety perspective, “Expert Perspective: Systems Engineering for Healthcare,” on the next page.

“We will need to determine how we shift our models of care delivery to ensure that we have the right roles in place to manage the ‘work’ of interoperability, both on the business and technical sides of the equation.”

— Julie Vilardi, Kaiser Foundation Health Plan and Hospitals

Safety Is a Control Problem

Leveson's presentation focused on systems engineering approaches to designing safety into interoperable healthcare technology.

“Interoperability is more than simply standardizing interfaces,” she said. She made a distinction between reliability and safety. “Highly reliable components are not necessarily safe.”

“The physical components are only a small part of the whole system,” she said. “To deal with safety we have to deal with the whole thing.”

“Interoperability is more than simply standardizing interfaces.”

— Nancy Leveson, professor of aeronautics and astronautics and engineering systems, Massachusetts Institute of Technology

Leveson characterized safety as a control problem that requires a “safety control structure” to mitigate. That control problem refers to the proper configuration, along with the feed forward and feedback of information. As more technology is connected, healthcare organizations need to consider

“The compilation of safe components doesn't necessarily add up to a safe system.”

— Nancy Leveson, Massachusetts Institute of Technology

EXPERT PERSPECTIVE

SYSTEMS ENGINEERING FOR HEALTHCARE

John Thomas

President, International Council of Systems Engineering

ENGINEERING 101: UNDERSTANDING A SYSTEM

To an engineer, a system is a *behavior* that comes from a set of parts interacting with one another properly. Here are two examples of that abstract concept:

- Think of the common activity of driving a car. A car has an engine, chassis, body, and many other parts (some of which are self-contained systems). Not one of these parts, operating alone, can produce the desired behavior of a car—the ability to transport people safely from point A to point B. That behavior only comes from the interaction of the parts.
- Or consider a more sophisticated example—getting directions and traffic conditions using a GPS app on a smartphone. A built-in computing processor, memory chips, battery, and software work together to power the smartphone and display information on a screen. Smartphone components provide wireless connectivity to a remote telecommunications network, where data and signals are transmitted, processed, and stored in a remote cloud infrastructure.

Location software on the smartphone pinpoints the physical location of the device. A GPS app sends that location to a data center in the cloud—which aggregates it with turn-by-turn directions from that location to the destination, and with information transmitted from traffic sensors along the route. This aggregated information is sent to the smartphone, where it can be displayed on the screen. The system behavior of delivering directions and traffic conditions only happens because of the interaction between the smartphone hardware and software and the remote wireless network, data processing center, and traffic sensors.

INTEROPERABILITY 101: DESIGNING FOR DESIRED BEHAVIORS

The sum of the parts and the interactions among them produce a behavior that is greater than, and

different from, the collection of individual parts.

Cars and smartphones only work as a system if they are designed with the desired behavior in mind. “If the system isn’t designed to do the behavior you are interested in, all you’ve got is parts,” Thomas said. “The reason this is important is that the healthcare community still thinks of components as a system.”

Summit presenters Meghan Dierks and David Muntz characterized interoperability is a continuum or a journey. Healthcare is still in the early stages of the work, as shown below.

STARTING POINT: CONNECTING DIFFERENT PRODUCTS THAT HAVE DIFFERENT FUNCTIONS



Most products that healthcare delivery organizations want to connect have common features—hardware, software, and packaging—that are implemented with different technologies. But the products are fundamentally different as well, in that they perform different functions. For example, one function of a respiratory ventilator is to provide mechanical, positive pressure support to help a patient breathe, which happens mostly at the hardware level. One function of an EMR could be logic programming, which happens mostly at the software level.

FOUR TYPES OF INTEROPERABILITY

There are four distinct types of interoperability: connect, transport, translate, and interpret. “People want to blur or combine these four,” Thomas said. “But each one has different systems issues.” And each one builds upon the previous one.

1. Connect



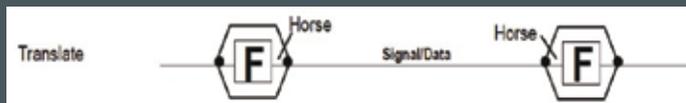
At a basic level, connectivity is simply plugging two devices or systems together—although things can go wrong if the “plugs” are not compatible. Still, “not a lot of interesting things are generated with just two nodes connected together,” Thomas said.

2. Transport



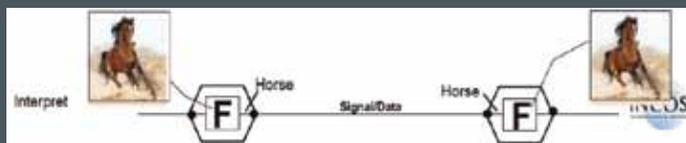
Once devices or systems are physically connected, the next step is sending information between them. Ethernet standards and TCP/IP (Transmission Control Protocol and Internet Protocol), for example, provide communications protocols and rules that allow signals and data to move back and forth over computers, routers, and networks.

3. Translate



Connected devices or systems become more useful when they can understand the signals and data that they are transmitting to one another. This means that the signal and data have to be translated, or formatted, in ways that each can understand. In this illustration, each device or system understands that the information they are sharing is about a horse.

4. Interpret

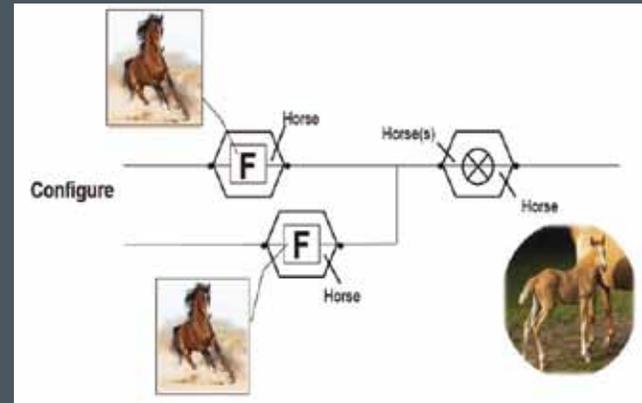


For data and signals to become more useful, information has to be coded for interpretation, so each device or system gets the same “image,” or meaning, from it. HL7 standards, for example, support translation and interpretation of data.

THE OFTEN-FORGOTTEN CONCEPT: CONFIGURE

Just like the parts in a car or smartphone, connected medical technologies have to be

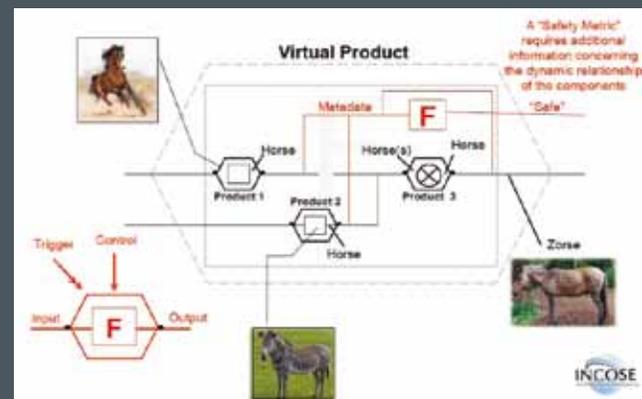
configured purposefully so that the translation and interpretation of signals and data is consistent and produces the desired system behavior. If even one connected device or system doesn't interpret the information correctly, it could distort the message transported through the system. Any time a new device or system is added, the system needs to be reconfigured.



ENGINEERING THE SYSTEM FOR PATIENT SAFETY

If patient safety is truly a desired behavior of the system, configuration becomes a design effort with the objective of producing patient safety. Safety needs to be engineered into the system to create a “virtual product.” That requires a systems approach to safety, with safety metrics that can be evaluated to ensure that the configuration of interoperable devices will detect and control any interactions that would put patient safety at risk.

Virtual products, which are made up of different technologies with different functions, can produce “emergent,” or unanticipated, behavior. Safety metrics recognize emergent or rogue behavior and, if necessary, stop any interactions that would jeopardize patient safety.



Expert Perspectives: Adapting Systems Solutions to Healthcare

Tailoring systems approaches to healthcare is important, summit participants stressed, because healthcare is different than other industries. Here are two expert perspectives:

Pat Baird

Systems Engineering Specialist, Baxter Healthcare

"I argue that not enough is known about these systems. Since we have no owners—systems integrators—we have no experience. Our governance model is not the same as for the aerospace industry. Either we need a governance model people are willing to submit to, or we need a different model. Perhaps the same systems engineering principles still apply, but if no one is in charge, no one has the depth of knowledge to do these steps.

"Stated another way, how do we crowdsource safety? These devices are being connected together either with no one in charge or with someone who doesn't have the depth of knowledge to understand how this all works. I know there are success stories, but they are rare. I think we need a different way to think about things because there is no owner—and without incentives, there won't be an owner. Just like crowdsourcing—no one is in charge. So perhaps we need new tools and concepts. They can still be based on these principles, but they need to be customized for a crowdsourced world."

Ken Fuchs

Senior principal architect for enterprise systems at Mindray North America and co-chair of the Integrating the Health Enterprise (IHE) Patient Care Device Domain (PCD) Planning Committee

"The vendor community and probably many of the hospital community know about systems engineering and use it in their daily

lives for formal projects that take months and years. The problem is applying this to medical device interoperability where the expectation is that we can easily substitute one device for another based on clinical need, device availability, and so on.

"When Boeing puts together an aircraft it very carefully evaluates every component that is used, even if it was designed against specs provided by Boeing. If Boeing decides to use a new altimeter module, it probably takes a year-plus and \$1,000,000-plus in testing to get to the point where it can replace the old one, even if it was designed to be 'interoperable.' This is not possible in the hospital environment and highlights the challenge when clinicians want to swap one plug-and-play ventilator with another plug-and-play ventilator in the middle of the case.

"... Hospitals cannot be expected to go through a formal systems engineering process every time they assemble some devices. The burden needs to be placed on the level of interoperability these devices need to comply with so that hospitals can more easily assemble these systems. So, this means that the standards and profiles must be developed using systems engineering with a detailed understanding of the use cases that need to be supported and any restrictions that come out of the analysis. Hospitals can then reuse these solutions rather than invent totally new approaches that would require them to do the systems engineering."

that they are migrating toward states of higher risk. Accidents are often caused by unsafe interactions among system components. System design and operations need to enforce constraints to ensure safe interactions. “Controls must be maintained not just at the device level,” she said. “We need a top-down system safety analysis, for each system in which devices are embedded.”

She offered this advice about system hazard analysis and design for safety:

- Start with system hazards and behavioral safety constraints.
- It is necessary to carefully specify devices’ external behavior to integrate them safely.
- It also can help to specify minimum requirements for safety and assumptions about the larger system in which it will be embedded during design.
- Human factors is critical—design to reduce human error (includes integration of devices).

System design is an art and a process, which ensures design activity that drives the configuration of the parts to be as safe as possible. Following a prescribed journey results in safe designs. This cannot be done by the manufacturer of a single device that in essence becomes a component part in the system.

Learning from Systems Engineering Processes

Jamie Bishop, chief engineer, ICE STORM™ (Integrated Clinical Environment: Systems, Training, Operations, Research, Methods) at Lockheed Martin, introduced some interoperability and systems integration concepts and processes from the aerospace industry that resonated with summit participants.

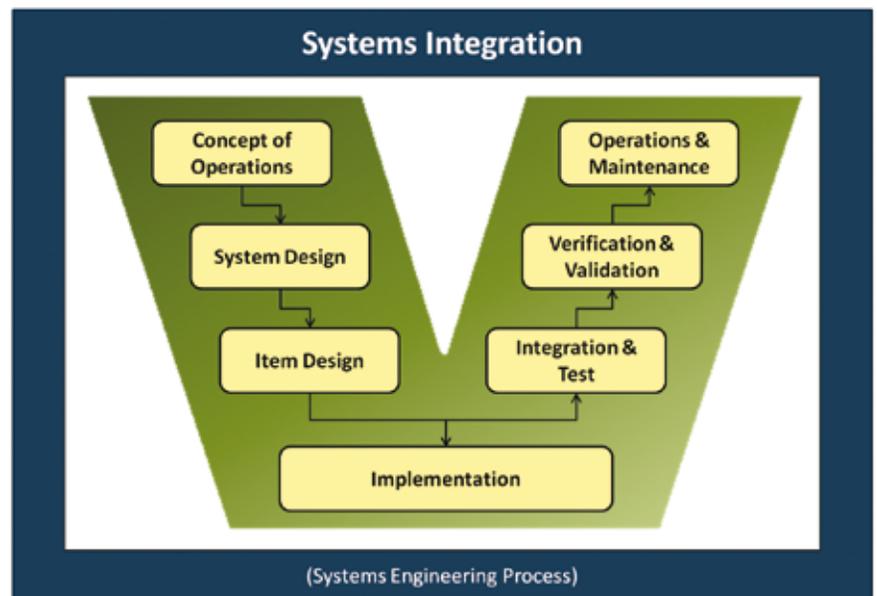
The healthcare community knows that safety of the system, patient safety, and clinical decision support are the desired new system behaviors of interoperable sets of medical devices, which Bishop termed the “mission objectives.” And the healthcare community knows that medical technology options are, or will be, available to support that behavior. What is as yet unknown is the platforms that will connect the technology safely and effectively to support the mission objectives.

That’s the space where systems integration processes could help. He shared the V-model

of systems integration, which includes the concepts of operations, system design, item design, implementation, integration and testing, verification and validation, and operation and maintenance, as shown in Figure 1. The V-model appealed to summit participants, who want to analyze and refine it for medical devices and systems, using FDA-approved safety and quality methodologies and a real, exemplary case to provide practical guidance to the healthcare community. (See the INCOSE Systems Engineering Handbook for more detail on the V-model.)

The aerospace and other industries develop “integration-ready” products to facilitate systems integration, in terms of devices that can be integrated, common interfaces, and functional qualifications, include robust, built-in testing, standard behavioral compliance, reliability, and testing. Health IT isn’t at this stage yet. The summit Clarion Themes and priority actions suggest that this is the direction in which healthcare needs to move.

In that vein, Bishop offered recommendations for healthcare interoperability, detailed in the sidebar on page 29. Bishop reiterated the advice of other summit presenters that interoperability can be accomplished with “building blocks,” moving from incremental technology advancement to technology innovation to custom solutions.



©2012 Lockheed Martin Corporation. Source: Jamie Bishop. “Learning from the Aerospace Industry Interoperability and Systems Integration,” presented at the AAMI–FDA Interoperability Summit, Oct. 2–3, 2012.

Figure 1. V-Model of Systems Integration

Challenges of System-Level Design in Practice

Summit presenter James Keller, vice president, healthcare technology evaluation and safety at ECRI Institute, discussed some of the practical challenges of implementing system-level design. He began by sharing two visuals, at left and below. The first shows a “nice and clean” design for system-level connectivity. The second shows a “back-of-the-envelope” schematic that illustrates how messy and complicated such systems can be.

That messiness surfaced when ECRI, independent, nonprofit healthcare research organization, conducted an evaluation of the performance of seven vital signs monitors connected to two intensive care ventilators, with a focus on EMR connectivity.

The major performance goals of physiologic monitor and ventilator connectivity were to centralize alarm signals for ventilators at a central station and the exchange of ventilator data to EMR systems. A key question for the evaluation: Does the alarm signal on the ventilator display the same on the central station monitor? Sample findings from the evaluation include:

- Hard-wire connections are too easily misconnected—with no indication of a lost connection

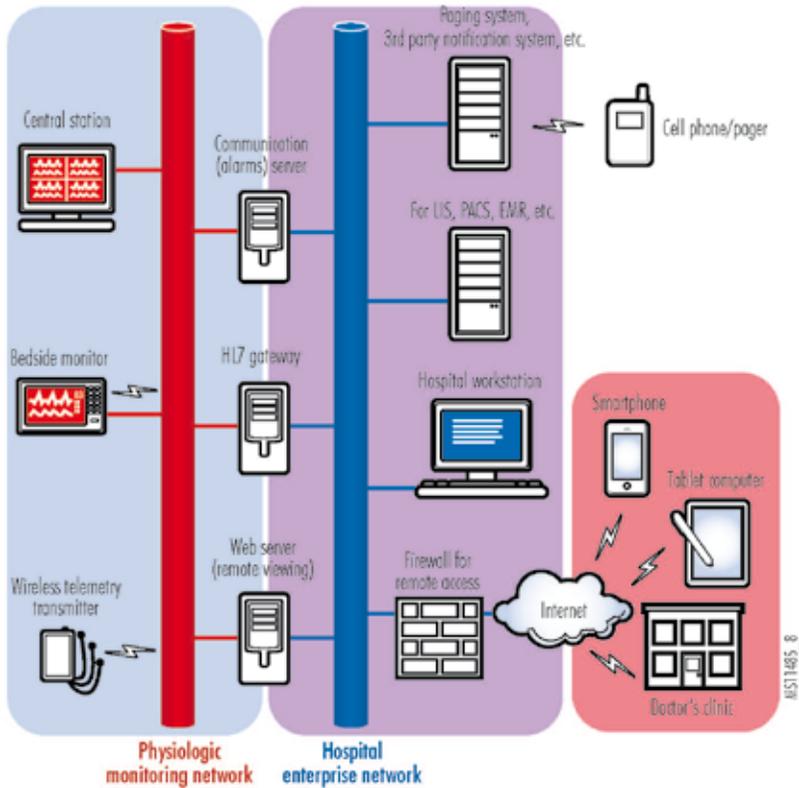


Figure 2. Connectivity System-Level Design ... Nice and Clean

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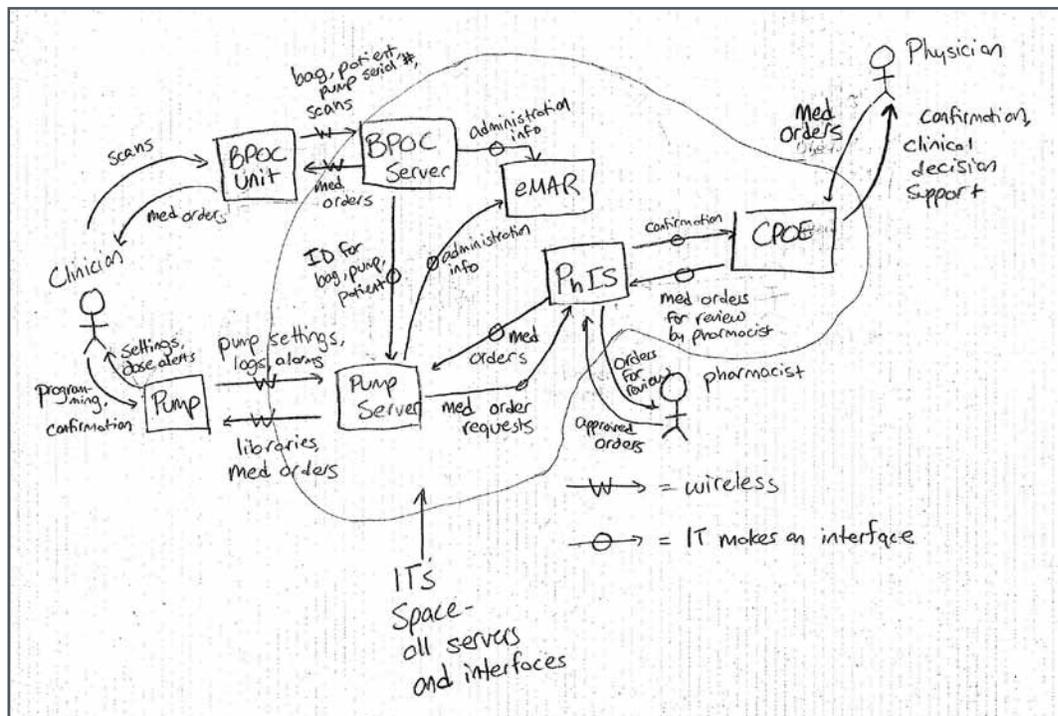


Figure 3. Connectivity System-Level Design ... Not Really So Clean—or Easy

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- No audible or visual indicator on the monitor of a critical disconnection of the ventilator patient circuit
- Critical priority ventilator alarm conditions displayed on the monitor as medium priority
- Inability to display ventilator waveforms on the monitor

ECRI Institute has been discussing integration-related issues like these with hospitals—all of which are in the early phases of adoption. “The cost, complexity, lack of standardization, legacy use, longer-term meaningful use timelines, and other priorities are impediments,” Keller said. “The range of options can be daunting. Testing is a great idea—but it is complex, very costly, and time consuming.” The good news is that progress is beginning to happen, on a small scale, he said.

Typical efforts focus on patient monitors, starting with basic functionality, such as numerical data. Common challenges that hospitals face in this systems integration include:

- Unplanned downtime, including troubleshooting causes of interruptions and dealing with vendor “fingerpointing”
- Need for routine data validation by clinicians
- Disruption and changes to traditional workflow (a topic discussed in Clarion Theme 6)
- Need for multiple custom interfaces
- “The experience of this organization may not necessarily be experienced by other organizations”
- Controlling/defining costs

The advent of telemedicine is introducing new system-level complexities, including:

- Real-time information exchange across many health systems
- Timeliness, accuracy, reliability, security and fidelity of systems are “life critical.”

The system-level and practical challenges of interoperability are resulting in inconsistent expectations among healthcare delivery organizations and health IT providers. To overcome these challenges, summit participants agreed that they need specific tools and actions and that could put the healthcare community on the same page, including:

- Information on the design control process
- Definitions of the dimensions of existing products and common use criteria, labels, and interface specifications
- Consistent implementation and deployment models
- Tools for purchasing decisions.

RECOMMENDATIONS FOR HEALTHCARE INTEROPERABILITY

Jamie Bishop, chief engineer, ICE STORM™ (Integrated Clinical Environment: Systems, Training, Operations, Research, Methods), Lockheed Martin

HEALTHCARE ORGANIZATIONS FOCUS ON OPERATIONAL REQUIREMENTS

- Define common interfaces and protocols (e.g., RS-232, Ethernet, HTTP, SSL)
- Consider device interoperability use cases: 1) data push; 2) data query; 3) remote control
- Define a set of security measures for bus technologies
- Avoid specifying implementation details

DEVICE INDUSTRY FOCUS ON STAND-ALONE, INTEROPERABLE PRODUCTS

- Role-specific, stand-alone, modular, and service-oriented (with or without the need for server software)
- Rugged, human factors design for usability
- Networked-enabled interface with identical features and controls as human interface

LEAVE SYSTEM DECISIONS TO SYSTEMS INTEGRATION

- Wired vs. wireless
- Redundancy in communications network
- Enterprise security and impacts of network outages
- Architectural growth and system roadmaps

USE MODULAR INTEGRATION TECHNIQUES

- Follow systems engineering and systems integration design processes
- Recognize that “need is the mother of invention” and modular integration techniques help meet the “need”

TEST IMPLICATIONS FOR SYSTEMS

In the 1890s, as fires began plaguing American cities, safety experts who investigated the “mysterious causes” of these events eventually realized that electricity was a source of energy that can cause harm if not treated properly, according to summit presenter Anura Fernando, principal engineer, eHealth, medical systems interoperability and mHealth at UL (Underwriters Laboratories).

Today, healthcare safety experts are wrestling with a similar problem. “Do we fully understand all of the safety issues associated with the distribution and utility of data?” he asked.

Like medical IT networks, the smart electrical grid is a network of networks, with many use cases to be considered—in central power plants, industrial plants, generators, offices, homes, and more—and many layers of complexity to be tested, from wiring to cords and plugs, outlets and receptacles, switches and power lines, circuit breakers and fuses, and all the equipment that is powered by these components.

“The point is that every ‘component’ could be a ‘system,’ and every ‘system’ could be a ‘component,’” Fernando said. “So, ‘component’ testing has to meet ‘system’ safety objectives. And ‘component’ capabilities must satisfy ‘system’ requirements.”
Realizing safe interoperability

requires layers of technical interoperability—physical, protocol, data/object model, and information interoperability—and organizational interoperability—knowledge/awareness, aligned procedures, aligned operations, harmonized strategy/doctrines, and political objectives.

Regulations, codes, specifications, and standards are the drivers for alignment of safety thinking to achieve technical and organizational interoperability, Fernando said. In healthcare, Hazard Based Safety Engineering (HSBE)—testing and certifying energy sources or data, their transfer mechanisms to the human body, and people or processes susceptible to hazard—drives standards development, testing, and certification.

Regardless of the application domain, system testing and certification should strive to address:

- Responsibility/accountability (ownership of the system)
- The potential for miscommunication (requirements)
- Incomplete understanding of technology (failure modes)
- Inadequate risk controls for random faults (including common cause failure, or CCF)
- Ineffective project management metrics (safety detractors)

Lead User Profile: Kaiser Permanente

“We want to think of this work as workflow solutions, not as technical solutions.”

— Julie Vilardi, executive director, strategic projects and clinical informatics,
Kaiser Permanente, Information Technology

Summit presenters from Kaiser Permanente highlighted their “interoperability” projects that they framed as patient safety, workflow, and clinical solutions.

Kaiser, the largest U.S. integrated healthcare delivery system, operates 37 hospitals and more than 500 medical office buildings in eight regions of the country. Managing the complexities of a large organization is daunting, according to Kaiser’s Julie Vilardi. “Quite honestly, it keeps us from being facile—and making an error at this size is costly.”

Kaiser is trying to avert errors and transform its healthcare system by focusing on the challenges clinicians face in patient care settings, including simplifying and supporting the nursing role. Kaiser’s “SmartCARE strategy” now guides this work with these operating principles:

Patient Centered Design

- Facilities
- Workflow
- Technology

Integrated Technology

- Automate—where possible and reasonable
- Standardize—intelligently and where it makes sense to do so
- Integrate—ensure compatibility and consistency with existing systems
- Validate—ensure solutions are tested prior to introduction to clinical settings

Seamless Workplace Environment

- Foster innovation/technology adoption
- Workflow alignment for every technology decision and initiative – think of the solutions as workflow solutions, not just technical solutions

Vendor Partnerships

- Collaborate with and influence medical technology vendors

- Leverage relationship with EMR vendor to influence functionality design and development

Using these principles for a smart infusion pump integration project, Kaiser is aiming for:

- **Rapid sign-on** to ease the burden and repetition of logging in to the EHR every few minutes
- **Clinical intelligence** to provide cognitive support and real-time contextual information
- **Workflow automation** to manage tasks, schedules, and events
- **Mobility** to untether clinicians from workstations

Clinical engineers, IT professionals, and nurses worked together—a paradigm shift for Kaiser—to standardize nursing workflow and drug libraries to improve infusion safety, according to summit presenter Desiree Gandrup-Dupre, executive director, facilities strategic solutions and application delivery at Kaiser. The standardized workflow then informed the design and configuration of more than 16,000 new smart pumps enterprise-wide.

Among the challenges to this project, and other implementations of new technology, is comprehensive testing before go-live events. Kaiser puts technology through its paces at the Sidney R. Garfield Health Care Innovation Center, a laboratory for brainstorming, testing, prototyping, evaluating, enacting, and demonstrating new practices. The center is a simulated care environment that enables testing of interoperability among multiple sources. End-to-end testing of the infusion pumps involved multiple stakeholders, including nursing, clinical technology, IT, compliance, and security.

“Everyone has to understand their role,” said Marlene Davis, senior clinical systems engineer at Kaiser. “It used to be that we would do our part and walk away and be done. Now, we do these steps in conjunction with everyone else. I think it’s going to take a team effort to solve these interoperability issues.”

Clarion Theme 4: Focus on human behavior first.



“There’s a human component to every system. If you’re not managing the human aspect, you’re not managing half of the system. You may be getting results, but you’re driving only half the car; the other half goes wild in any direction.”

— Fred Kofman, former MIT faculty member and part of Peter Senge’s original Center for Organizational Learning at MIT

Challenge	Priority Action	Accountability
A tendency to view interoperability as a technical issue only	Communicate interoperability risks and the value of interoperability solutions in terms of clinical need and patient safety first.	All stakeholders
The complexity and abundance of many different devices and systems in use in diverse healthcare environments make it difficult for clinicians to use them safely, effectively, and to their full potential for decision support.	Ensure the usability of interoperable systems for their intended use in their intended use environments by their intended users.	HDOs, Industry, ECRI, CIMIT, FDA, ONC, and other regulators
	Train clinicians and other users to use interoperable systems safely.	HDOs, Industry, Professional Societies

Understanding Interoperability as a Sociotechnical System

The scurry to meet meaningful use requirements and other healthcare goals is focused largely on connectivity of devices and systems and data. All but forgotten in the push for technical standards and solutions are the people who will actually use—and, if national aspirations are achieved, benefit from—this technology.

Again and again, summit presenters and participants emphasized that people are an integral part of every aspect of interoperability.

The tendency to view interoperability as a purely technical challenge is misguided. “If we don’t do the socio-interoperability, we will probably fail,” keynote presenter David Classen of the University of Utah and Pascal Metrics said.

He illustrated this point with an example from the electrical industry, in which information from many interoperable systems was displayed on an enormous, highly interactive screen that spanned an entire wall in a large room. The display featured a color-coded electricity grid; parts of the grid flashed red to indicate problems.

“It’s fascinating,” Classen said. “They got the technical part right, with multiple systems displayed on one screen. But they didn’t get the socio part right. People prefer to use small screens. Many millions of dollars were spent creating a galactic interoperability display that no one used.”



“Incompatibilities between the way things are designed and the way people perceive, think, and act can result in human error, or, more accurately, design-induced error.”

— Steven Casey, *The Atomic Chef*

Interoperable health IT systems will not achieve full value, and will introduce greater risk, without a sociotechnical approach to design, hazard analysis, implementation and the entire technology lifecycle. A sociotechnical approach factors in people, technology, environment, process, and organization, a recommendation of the IOM. In addition, a sociotechnical approach aims for learning systems—ones that learn as devices, systems, data, and people change.

“Systems are not static, especially social systems,” said summit presenter Leveson of MIT. “People are acting differently than they were before we put the devices in.” As she pointed out, human factors expertise is critical in designing for system safety. In healthcare and in other industries, this discipline is underused, she said.

Governing and Managing a Sociotechnical System

Summit presenter Lane Desborough, product strategist, Medtronic, offered perspectives on interoperability from facilities in an industry with attributes that the healthcare community would recognize:

- It cost billions of dollars to build, operate, and maintain.
- It is in some way unique and has no identical twin.
- It is one of the most complex systems in the world.
- It’s but one part of a larger system.
- It deals with incredibly hazardous situations, 24x7.
- It provides something which society must have to survive.
- It employs hundreds of professionals from many disciplines.
- Its ongoing operation involves thousands of complex tasks.
- It’s subject to ever-changing conditions in the environment.
- It adapts and changes over a multi-decade life.
- It is incredibly safe, reliable, secure, and efficient.

These attributes pertain not to hospitals, however, but to oil refineries and petrochemical plants. As an engineer, Desborough implemented automation systems in such

Principles for Safe Interoperability

Lane Desborough

Product strategist, Medtronic

“We design for dependability.” Before, during, and after implementation, think about emergent properties, such as safety, reliability, security, and usability. Consider the application of approaches such as:

- Model-based development
- Agile, robust, proactive architectures
- Safety-driven design

“We design for simplicity.”

- If you’re not the simplest solution, you’re the target of one.
- A system can be so simple there are obviously no errors, or so complex there are no obvious errors.
- Complexity is like a weed; once it’s in your system it will be difficult to remove.
- Complexity creates an ever-increasing technical debt; a debt upon which you pay interest. If you’re not careful, you’ll go bankrupt from complexity.
- Use interface standards, user-centered design, lean, and system architecting.

“We manage change.”

- If we don’t manage change, it will manage us.
- Impose constraints on who, what, where, when, why, and how change enters the system.
- Provide effective governance during design, procurement, implementation, and operation.

“We design for human behavior.”

- Perhaps most important, never forget that the human is part of the system.
- Safety and resilience are not achieved by technology alone—understanding and accommodating human behaviors is critical.

facilities all over the world, with the aim of driving improvements in cost effectiveness, reliability, and, above all, safety. In the past, individual devices in these systems were largely independent, expensive, and inflexible.

Automating processes introduced multiple systems and new complexities—multiple vendors, devices, software, and stakeholders.

Eight years ago, he was called in to a large Gulf Coast oil refinery to address a dangerous condition, known as “loss of view.”

Control room operators supervise the facility’s operation; the automation system provides a view into a complex, dangerous process

that might be up to a half mile away. At this refinery, they were experiencing slow refreshing of the numbers and graphs on their displays. Instead of updating every four seconds, they were updating every eight, or 20, or freezing altogether. “Completely unacceptable, extremely dangerous, an accident waiting to happen,” he said.

“The ultimate resolution to this situation was, as is often the case, not a technical one,” Desborough said. “Instead it depended on governance, on changing the various stakeholders’ approaches to the management of the technology. It is here that we may be able to gain some insights for safe interoperability in healthcare.”

“If we don’t manage change, change will manage us.”

— Lane Desborough, product strategist, Medtronic

When it comes to safe interoperability, experts say it’s important to design for human behavior, simplicity, and dependability.



Clarion Theme 5: Improve regulatory clarity.



“The box is a sum of boxes. We need to be clear about where the regulatory aspect stops and what needs to be done with the virtual box. We need a definition of what should be privately regulated, government-regulated, and self-regulated.”

— James Welch, vice president, quality systems, regulatory affairs, and clinical affairs, Sotera Wireless

Challenge	Priority Action	Accountability
Uncertainty about regulatory requirements	Create a regulatory pathway that permits clearance of FDA-regulated medical devices or systems to an interface specification, rather than the current pair-wise verification and validation submission.	FDA
	Determine whether there are different regulatory requirements for integrated systems than for components of systems. Determine whether the FDA should regulate data flow.	FDA Other Regulatory Bodies

The Wild, Wild West? Not Quite

With the rapid evolution, development, and implementation of interoperable medical technologies, the line of who is responsible for these technologies, as well who regulates them, is blurring.

Comparisons to the Wild, Wild West, however, are greatly exaggerated, according to summit presenter Michael Robkin, president, Anakena Solutions. Unregulated behavior—crime, theft, and violence—was lower in frontier times than in modern times, Robkin pointed out.

“Property rights were almost universally and perfectly respected in the frontier,” he said. “The West had effective self-governance based on information: reputation. Every wagon train, mining camp, and settlement had its own constitution to settle disputes.” From this perspective, he offered these lessons for interoperability:

- Self-governance is better than poor governance.

- Reputation and disclosure are effective civilizing mechanisms when regulation is absent.
- But only if reputational information is complete, relevant, and accurate.
- With full disclosure—of interfaces, effectiveness, data, quality, errors, and adverse events—the commercial landscape would be safer and better managed.
- The same information is needed for both self-regulation and government regulation.

Summit presenter James Welch, vice president, quality systems, regulatory affairs, and clinical affairs, Sotera Wireless, built on this theme of a “frontier justice culture.” Like a wagon heading across the prairie, Sotera Wireless, a young company, is trying to find its way amidst a confusion of regulations, standards, and technologies.

Sotera Wireless navigated these challenges through a combination of self-regulated and government-regulated actions as it went

through the regulatory approval process for a mobile system that monitors patient vital signs—and generates enormous amounts of data. The FDA cleared the system as a Class II device in March 2012. In August 2012, the FDA separately cleared the system’s wireless connectivity and cleared the solution to operate with other systems on a hospital wireless infrastructure, enabling clinicians to use computers, tablets, or other mobile devices as secondary notification devices.

The FDA clearance process worked well, Welch said. “We submitted four four-inch binders for the device approval,” he said. “The FDA came back with 52 questions. A wonderful reviewer helped us make the device even better.” The submissions were successful, Welch said, because the company adopted every applicable standard, created each interface to represent different use models and stakeholders, and used an open application programming interface (API), to its wireless monitoring system.



“Is it possible to establish a list of consensus questions that could be expected to be asked and answered for every interoperable medical device?”

— John F. Murray Jr., software compliance expert at the FDA’s CDRH

Still, questions remain for Welch and other summit participants:

- Where does the regulatory authority lie when clinicians and patients use such systems in home care or other remote settings, where the “walled garden” of the hospital network is not in use?
- When building a system that will run on unknown systems, how much validation and assurance are needed to satisfy safety requirements?
- Where does the continuum of integration cross the line between what is regulated and what is not, when you have several products, “a system of systems,” a product of products, a virtual box?
- When is a number—a piece of data—a medical device? (By FDA definition, data is not a medical device.) Should the FDA regulate the data flow for its intended use?

The influx of wireless technology compounds the complexity, according to summit presenter Rick Hampton, wireless communications manager for Partners HealthCare System. “People who know wireless are in the minority,” he said. “Some vendors can’t spell Wi-Fi, let alone wireless. ‘Medical-grade’ wireless systems aren’t. Most planning is now being done for BYOD (bring your own device) with little regard for how that might affect the medical system.”

At Partners HealthCare, Hampton is also dealing with congestion on the wireless infrastructure. “We have tens of thousands of devices on our wireless network concurrently, at a minimum, at 3 a.m. on a Saturday. On Wednesday at noon, that number quadruples. We’re getting slammed on the wireless side.”

Beyond congestion, wireless technology can introduce interference, constrain other systems, and compromise system security.

For Carilion Clinic Health System, a seven-hospital system in southwestern Virginia, managing more wireless technology and the data it generates are other challenges, according to summit presenter Chris Riha, senior director, technology services group. The healthcare system has more than 23,000 wireless medical devices, including EMRs and physiological monitors interfaced to the EMRs; infusion pumps; and a laboratory information system (LIS) interfaced to a point-of-care lab system. The deployed wireless infrastructure includes 802.11 public and private networks, wireless medical telemetry services (WMTS), cellular, one-way pagers, an FM signal for clock synchronization, 900 Mhz portable phones, and a Vocera communication system.

“IT and IS [information systems], manufacturers, and hospitals need to recognize and share responsibility and work together,” Hampton said. “If you don’t like regulation, we need to do this. If we don’t, we’re going to cause harm and the FDA is going to regulate us.”

(Following the Interoperability Summit, AAMI held a Wireless Workshop to investigate wireless issues in healthcare. For more on that workshop, see the workshop report, *Healthcare Technology in a Wireless World*, on the AAMI website at www.aami.org/wireless/2012_Wireless_Workshop_publication.pdf.)

“Information technology generally owns the network,” said summit presenter Shaun Neal, consultant at Burwood Group. “Biomedical engineering owns the device. Clinical staff own the patient care experience. All are responsible for providing quality care.”

From the FDA: ‘This Problem Is Actually Solvable’

Summit presenter John F. Murray Jr., software compliance expert at the FDA’s CDRH, acknowledged the regulatory concerns in light of today’s broad landscape of interoperable technology, unlimited number of scenarios in which it is implemented, and many stakeholders. “The scenarios may change but the questions remain the same,” he said.

He challenged the healthcare community to work with the FDA to develop a list of consensus questions that would be useful to users. “Having that information available would be one small step,” Murray said. “I think this problem is actually solvable.”

“This may not necessarily be only a government effort,” said summit presenter Bakul Patel, policy advisor, Office of the Center Director at the FDA’s CDRH. The Centers for Medicare and Medicaid, ONC, The Joint Commission, and others may need to work together to provide regulatory clarity.

Murray posed the questions that the FDA is already asking—most of which should be familiar to the healthcare community:

What is Your Intention or Goal?

- Who or what do you intend your device to connect to or communicate with?
- Is this device designed to remotely control or operate another device?
- Is this device designed to be remotely controlled or operated by another device?
- What specific controls and operations are allowed?
- What clinical applications have you planned for?

Are You Achieving the Intention or Goal?

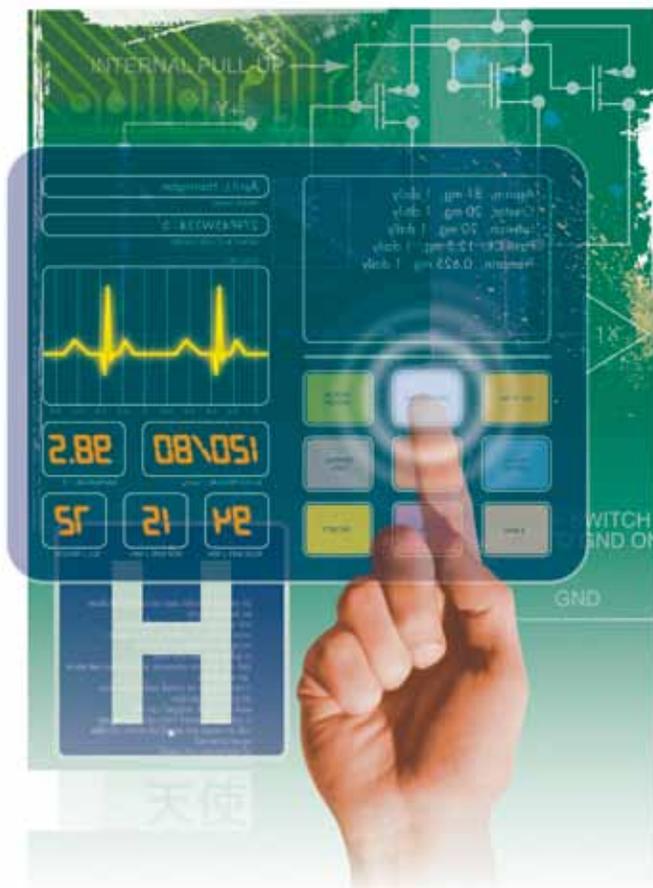
- Have you clearly established functional and performance metrics or goals?
- How have you verified that you meet your functional requirements?

- Have you measured your performance?
- How have you assured your clinical performance?

Is Your Box Safe?

- What failure modes of the device have you considered?
- What hazards have you considered in your design?
- What hazardous situations have you considered?
- Have you defined risk and system boundaries?
- Have you established risk controls?
- Have you validated your risk controls?

Summit participant Erin Sparnon of ECRI Institute likes this list of questions, but she added: “My problem is, ‘Who answers the questions about an integrated system—the hospital, à la MDDS [Medical Device Data Systems]?’ The main challenge identified by this summit is that there is no one person or group who is in charge of answering for the safety of the integrated system.”



Clarion Theme 6: Streamline clinical workflow to improve return on investment.



“All four aspects of interoperability are equally important: technical; semantic; usability; workflow. If we only get one right, we will fail.”

— David Classen, associate professor of medicine at the University of Utah and chief medical information officer, Pascal Metrics

Challenge	Priority Action	Accountability
Complex and idiosyncratic clinical practices make it difficult to achieve interoperability solutions	• Standardize the clinical workflow.	All Stakeholders
	• Let the clinical workflow drive technical solutions and innovations.	Clinically focused professional organizations (e.g., AORN, ACCN, ASA, SCCM); IHI has published some clinical protocols (e.g. perinatal – L&D)
	• Use interoperability to facilitate improvements in the clinical workflow.	

A Call for a Standardized, Coordinated, and Comprehensive Overhaul of Clinical Workflow

Efforts to improve interoperability are exposing a significant barrier: adapting to the enormous variability in the clinical workflow within and across healthcare organizations. This variability is holding back progress not just in interoperability solutions, but in improving the efficiency and effectiveness of clinical processes and patient care.

“It seems like when we put medical devices into healthcare, everybody’s trying to build their own systems from scratch—every time,” said Bakul Patel of the FDA’s CDRH. “We

don’t need to do that anymore. It’s been done.”

“What is clear is that everyone is trying to solve a different problem and, therefore, no synergy is extracted from understanding the common infrastructure needs,” Patel said.

Summit participants called for a standardized, coordinated, and comprehensive overhaul of the clinical workflow. This is the only way to achieve affordability that will make interoperability scalable. Consistent clinical practices will reduce inefficiencies and errors that result from multiple complex (and often unnecessary) steps to complete a task, duplication of effort, and inaccurate manual entry of data (see, e.g., Hendrich,

“Standardizing clinical workflow will allow vendors to optimize installation configuration to reduce complexity and potential impacts on safety. They can also optimize the user interface to work best for the workflow. This can reduce costs and allow better comparison of best practices across hospitals.”

— Summit participant Ken Fuchs, Mindray North America

Chow, Skierczynski, & Lu, 2008). Streamlined clinical workflow also could drive technical solutions and unleash innovation.

Standardizing clinical workflow will empower clinicians to focus on patient care rather than technology. The incentive for making progress on this front is improved clinical outcomes, efficiency, and return on healthcare and technology investments.

A Chicken-and-Egg Dilemma?

Not all summit participants are convinced that a sweeping standardization of the clinical workflow is possible at this point. “Interoperability will facilitate improving clinical workflow, not the other way around,” the FDA’s Patel said.

Thomas cautioned that while important, it will be challenging to standardize every aspect of the workflow. “I have never seen it happen in a distributed, self-empowered group of tribes,” he said. “I have seen, however, hundreds of millions of dollars spent on trying to make it happen—only to be thrown away. There are a lot of examples of this in the Department of Defense.”

That said, he acknowledged, “there is a lot of gain in standardizing sections of workflow, like infusion. There is a balance to be achieved.” He believes a dialogue in the healthcare community to pinpoint specific areas of the clinical workflow that are ripe for standardization is a good place to start.

Lead User Profile Oklahoma Heart Hospital

Implementing an All-Digital Infusion Device System

Oklahoma Heart Hospital, which sees 1,600 patients daily, became the first all-digital hospital in the United States about 11 years ago, with a fully integrated EMR system across two hospital facilities and 60 clinics. The hospital recently implemented an all-digital, interoperable infusion device system, including wireless and EMR, which went live in February 2012.

The hospital’s Chief Information Officer Steve Miller noted that “staggering statistics” on IV medication errors and other adverse drug events were a driving factor in going all digital. “We wanted to automate IV pump programming,” he said. “It used to take 20 steps for a nurse to program and administer an IV. Now it’s down to five steps—an 86 percent reduction.”

The new pump programming system involves scanning the patient’s wristband, medication, and pump; and feeds infusion data into the EMR in real time. The result? Nurses see alerts as they happen, adverse drug events are prevented, and patient safety is improved. Miller noted that clinical quality at the hospital went up significantly between 2011 (pre-project) and 2012 (post-project).

Implementing the new system was not all smooth sailing: There were a few bumps along the way, according to Miller, such as ensuring that the weights were accurate and that the pump firmware for the 400 pumps was upgraded, requiring the pumps to be taken out of service one at a time. The process brought home the importance of training, testing, and understanding current processes.

“As we found problems, it was very difficult to troubleshoot the source of the problem,” said Miller. However, collaboration with critical players including analysts, clinical educators, and vendors, as well as biomedical, nursing, pharmaceutical, and network engineering staff, enabled the team to gain access to data and find the sources of errors. The key to ensuring interoperability and the successful implementation of the system was cooperation between the multiple players.

Clarion Theme 7: Remove barriers with shared, continuous learning.



“Knowledge is knowing a tomato is a fruit. Wisdom is knowing not to put tomatoes in a fruit salad.”

— Peter Kay, British comedian

Challenge	Priority Action	Accountability
A lack of transparency, and a lack of accurate and complete data	Create a forum for sharing up-to-date information (e.g., adverse events, “near misses,” success stories, works in progress, lessons learned) to improve both connectivity and clinical care. Benchmark the Federal Aviation Administration’s incident self-reporting system—a protected, non-attributable, trusted, crowdsourcing approach—as a success in this area.	ONC, FDA, CMS, AAMI, ECRI, CHIME, CIMIT, and other interested organizations Healthcare Technology Safety Institute’s consortium of patient safety organizations
	Ban confidentiality clauses in EHR and other vendor contracts so that data can be used to improve patient safety.	ONC and CMS, EHR vendors, CHIME, and HDOs
Meeting the requirements of the Centers for Medicaid & Medicare Services (CMS) incentive program, which promotes better use of data for clinical decision making and patient engagement	Engage all stakeholders, including manufacturers, clinicians, human factors engineers, healthcare technology management specialists, IT and IS specialists, risk managers, pharmacists, patient safety specialists, and patients in multidisciplinary collaboration to design and create interoperable systems that function as true “learning systems.”	All stakeholders
	Create a Meaningful Use Community of Practice (COP) to aggregate and share best practices. Consider a meaningful use conference. Consider building on the “connect-a-thon” at the HIMSS Annual Conference with “hack-a-thons” and “disaster-a-thons” to showcase on-the-fly solutions to cybersecurity and disaster preparedness challenges.	ONC

From ‘Plug and Pray’ to ‘Plug and Play’

Summit participants expressed a strong appetite for seamless interoperability because of its bright promise: the ability to turn data and information into knowledge and wisdom to improve clinical practices, patient safety, and patient care.

According to summit presenter Bakul Patel of the FDA’s CDRH, healthcare is somewhere in the middle of the journey from “plug and

pray” to “plug and play.” “Where do we need to be? We need an infrastructure that supports a learning healthcare system,” he said.

Healthcare is already drowning in data, but lacking in the ability to learn from and use this data for clinical decision support and patient engagement. Summit participants called for a safe forum for sharing information about failures and successes about integrated medical devices and systems.

“Government agencies must take a leader-

ship role and ensure that healthcare providers are not penalized for reporting,” said Kaiser Permanente’s Carol Davis-Smith. “Healthcare continues to struggle with implementing safe zones for reporting. The reality is that it is still a fairly punitive world.”

One significant barrier is locked data and information. As summit presenter Michael Robkin of Anakena Solutions pointed out, “The patient’s data is the property of the patient. If you don’t believe this, read HIPAA [the Health Insurance Portability and Accountability Act],” which includes a privacy rule that provides federal protections for personal health information. Confidentiality clauses in EHR and other vendor contracts also prohibit access to patient records that could be used to improve interoperability and patient safety.

Summit presenter Steven Baker, senior principal engineer at Welch Allyn, cited additional data challenges. The healthcare community has to specify a full list of data it is interested in—and at what times it is and is not critical. For example, “lab results are usually not life critical,” he said. “If electrolyte levels are way off, it is life critical.” It’s also important to quantify and qualify data. For example, not all blood pressure readings are reliable. And healthcare still hasn’t achieved a basic dimension of interoperability—confirmation that data are successfully received, end-to-end.

“False, misleading, and protected information” also inhibits learning, Baker said. For example, the healthcare community doesn’t know how to provide a testable solution for multiple manufacturers’ devices to run on the same wireless network. This information is often protected as proprietary information.

Crowdsourcing to Build Knowledge

Healthcare generates more data than people know how to handle—and therein lies the problem. People need systems that help them look at the data in ways that help them transform it, together, into knowledge.

“If we can start to capture, transfer, and substantiate knowledge with crowdsourcing, we can close the clinical care workflow, provide real-time safety, make it harder to make a mistake, and unleash innovation in patient care and safety,” said Julian Goldman,

anesthesiologist at Massachusetts General Hospital and medical director, biomedical engineering, Partners HealthCare System.

But current EMR/EHR systems simply archive and display, said Davis-Smith. “They don’t provide context-based displays, nor do they generally provide decision support tools,” she said.

Summit presenter John Zaleski, chief technology officer and vice president of clinical applications at Nuvon, Inc., outlined these data needs to support clinical decision making, patient safety, and patient care:

- Rich, timely data for patient care management
- Temporally and semantically synchronized data to ensure accuracy in patient management
- Secure, ubiquitous access to ensure availability to data for patient care management
- Clinically sensitive IT solutions that support data needs and clinical workflow

“If you make sure you’re connected, the writing’s on the wall. But if your mind’s neglected, stumble you might fall.”

— Lyrics to “Connected,” a song by Stereo MCs



Clinicians aren’t the only ones who would benefit from better data. Engaging patients with better data will help them become more involved in their own care and decisions. Engaged patients have better health outcomes than those who are not engaged, including less likelihood to experience a hospital readmission or medical error, according to summit presenter David Muntz of ONC.

“Enabled for advanced medical purposes, interoperable medical devices and health IT could take healthcare to the next level,” Patel said.

Lead User Profile

The Johns Hopkins School of Medicine

The intensive care unit (ICU) offers a microcosm of the challenges in medicine and a laboratory for addressing these challenges, according to summit presenter Adam Sapirstein, associate professor, Department of Anesthesiology/Critical Care Medicine at The Johns Hopkins School of Medicine.

ICUs have it all—high technology that drives high costs; increasing complexity and burden of illness; high rates of errors and complications; care provider and

to integrate technology, will be a self-sustaining model for continuous improvement. In addition to the school of medicine, the project partners include the Armstrong Institute for Patient Safety and Quality at The Johns Hopkins School of Medicine; the Applied Physics Laboratory, Berman Institute of Bioethics, and Systems Institute at The Johns Hopkins University; and the G.B. Moore Foundation. The project hypothesis is that a systems engineering approach can improve the quality, safety, and efficiency of patient care in the ICU. The primary outcome of the project is to establish an integrated clinical system. The secondary outcome is to improve care through targeted reduction in harms to patients.

For the primary technology-related outcome, the project aims to shift away from today's model—the tight coupling of devices, user displays and controls, and electromechanical subsystems that require error-prone manual data entry.

Instead, the project team is taking a more holistic look at the ICU environment and developing a concept for a model, interoperable system. Data inputs from medical technology, such as patient vital signs and device data elements, will be supplemented with patient and family information. Integration middleware will aggregate this information and deliver it to clinicians, using graphical user



“The point of this system is to enable information rather than data to be displayed.”

— Adam Sapirstein, associate professor, Department of Anesthesiology/Critical Care Medicine at The Johns Hopkins School of Medicine.

family stress; and alarm fatigue. Yet ICUs are designed as if people are like “Star Trek’s hyper-rational Mr. Spock” rather than for people who are “limited in the way we use and understand information ... more like the fallible, myopic, vindictive, emotional, biased Homer Simpson,” Sapirstein said, quoting Dan Areily’s book, *The Upside of Irrationality*.

Never one to sidestep a challenge, The Johns Hopkins School of Medicine has taken on a collaborative project to demonstrate that a systems approach to the ICU, using an open architecture platform

interfaces on display screens in each patient room and at a central station—and accessible on mobile devices.

The display screens will provide clinicians with an at-a-glance view of what's happening in the ICU—to support a situational awareness that's often missing on these units—and comprehensive information about each patient. This will help clinicians manage multiple patients, tasks, and communications. In addition, patients and families will be able to access information about their care and communicate with one another and with their clinical teams. The model system also will deliver greater automation and analytics that can improve clinical care, outcomes, accountability, and satisfaction.

In addition, the project team is building the Armstrong Institute's Model to Improve Care into the technology and safety programs. Already, clinicians at Johns Hopkins are addressing such evidence-based contributors to patient harm in ICUs as delirium, weakness, injuries associated with mechanical ventilation, blood clots from deep vein thrombosis and pulmonary embolism, central line-associated bloodstream infection, poor lighting associated with falls, and loss of respect and dignity—"a lightning rod for us," said Sapirstein.

To address even a limited number of potential harms, all of the systems

that factor into them must be brought together into the interoperable ICU system. Beyond infusion pumps, vital signs monitors, and ventilators, the Johns Hopkins team is planning for information from HVAC and lighting systems, patient position control sensors, and information about patients' psychological and cognitive states, to be integrated into the ICU system so it can be used for decision support.

"Clinical care is the benchmark for all performance," Sapirstein said. "Technology only works if it improves the system. Continuous improvement is a benchmark. Ethical and respectful care is a 'systems' requirement."

Conclusion



“We will have achieved interoperability when we stop talking about it.”

— Anura Fernando, UL (Underwriters Laboratories)

Imagine if the vast quantities of sophisticated medical technology could work together—reliably and securely—to support critical healthcare goals, including improved patient safety and care, clinical decision making, and business objectives.

The 266 participants at the AAMI–FDA Interoperability Summit do imagine this. More important, they share a vision of what it will take to get there. Indeed, some are already blazing a safer path forward for others to follow.

6. Streamline clinical workflow to improve return on investment.
7. Remove barriers with shared, continuous learning.

In the words of the FDA’s John Murray, “This problem is actually solvable.” Summit participants with all manner of expertise in the many facets of interoperability agree.

What’s urgently needed now is coordinated, collaborative and multidisciplinary leadership: by C-Suite executives in healthcare delivery organizations; clinicians; healthcare technology management professionals; systems engineers; industry; regulators; standards development organizations; and professional associations, all working together toward common goals. Guided by forward-thinking leaders, the entire healthcare community stands to benefit from multidisciplinary collaboration to address the issues identified at the summit as top priorities.

“Interoperability is a means to system integration. Really what we’re trying to do is improve patient safety through system safety.”

— Julian Goldman, anesthesiologist at Massachusetts General Hospital and medical director, biomedical engineering, Partners HealthCare System

Summit participants are cognizant of the challenges to achieving seamless interoperability of different devices, networks, and systems:

1. Standardize to achieve success.
2. Align incentives, expectations, roles, and responsibilities.
3. Drive patient safety with a systems approach to design and implementation.
4. Focus on human behavior first.
5. Improve regulatory clarity.

Next Steps

The follow-up work identified at the summit is not an AAMI project. It’s not even a series of projects that AAMI can ‘drive.’ AAMI convened the right people to get the priority issues up on the table and out in front of the healthcare community. It’s now up to the community to take up the charge and drive this work forward. AAMI has a role to play,



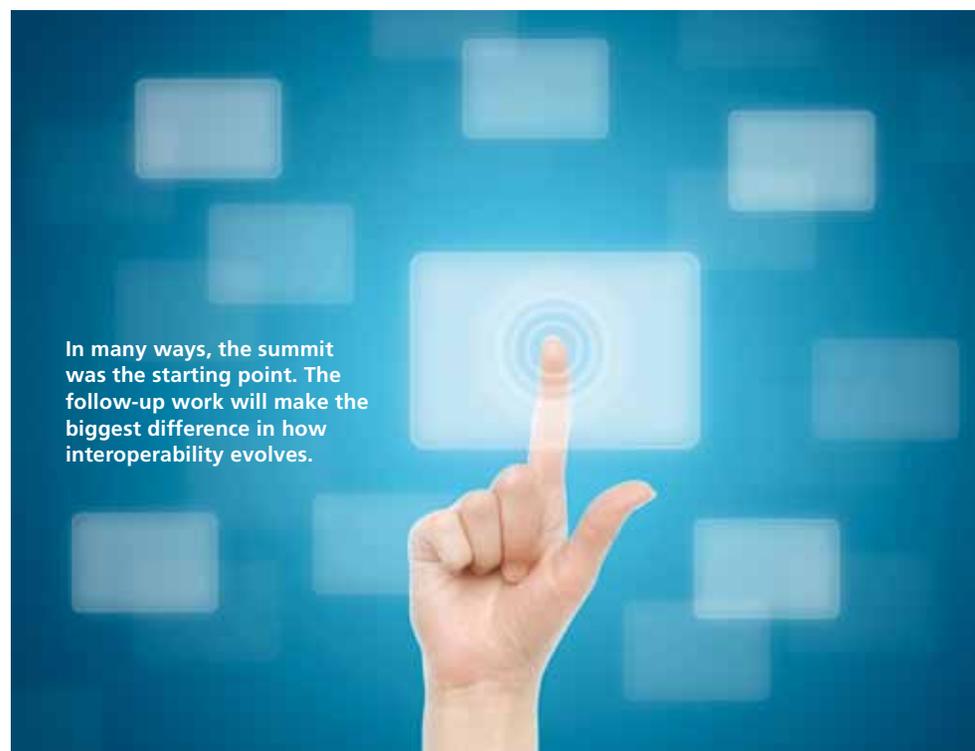
especially around standards development and education. It is AAMI's hope that all stakeholders will see clear roles they can play on one or more of the priority issues outlined in this report. Some of the issues are so big that they need close attention and coordinated regulatory collaboration from the ONC, FDA, CMS, and healthcare accrediting organizations such as The Joint Commission.

While readers may focus on a single 'aha' point in this synthesis of the summit, none of those points standing alone will be enough to drive the changes that are needed. It took voices from across all parts of the healthcare community to develop the content for this publication, and it is going to take similar voices from across all parts of the community to develop and implement the solutions. Healthcare delivery organizations cannot put all of the burden on industry; industry cannot put all of the burden on healthcare delivery organizations or consultants; and regulators from one regulatory organization cannot assume that the market will figure it all out, or that another agency has the responsibility. Perhaps the two most powerful examples to illustrate this point are the lack of a system integrator and the need for a much stronger system safety approach.

As Henry Ford's words remind us, "Coming together is a beginning. Keeping together is progress. Working together is success." AAMI looks forward to being part of the next steps of 'keeping together' and 'working

together' to achieve success. And what is success? It's an integrated healthcare system that improves patient outcomes through increased human knowledge and wisdom, fewer adverse incidents, streamlined workflow, and reduced stress and technology fatigue for clinicians.

www.aami.org/interoperability 



APPENDIX

A Look Back: Milestones on the Road to Interoperability

Interoperability is not a new topic, nor is this the first time healthcare interoperability issues have been raised and discussed. Since at least the 1980s, the concept has been used in a variety of fields, including business, law, engineering, medicine, sciences, and social sciences.

A quick glance at The Medical Device Plug-and-Play Program (MD PnP) plenary meetings page shows a list of meetings on the topic going back 10 years or more. However, the term “interoperability” is becoming an increasingly well-known buzzword, given the surge in technological advances in medical devices and IT.

Included below is a snapshot selection from the history of interoperability:

- **1893**—According to a presentation by Michael Robkin at the 2010 FDA-Continuum-CIMIT Workshop, the first U.S. government “interoperability” standard, the Safe Appliances Act, defines compressed airbrakes as standard on railcars and aims for worldwide compatibility, with an industry association setting standards.
- **1982–1984**—The MD PnP notes that although not adopted by medical device manufacturers, the medical information bus (MIB)—focused on intravenous infusion devices and RS-232 hardware—is the first well-known effort to develop a medical device-specific communication standard and supporting hardware.
- **1987**—HL7 (Health Layer 7), a nonprofit organization, is launched to develop international healthcare informatics interoperability standards. It is best known for standards that are used to communicate patient data between clinical information systems at the application level.
- **1991 onwards**—The IEEE 1073 series of standards are released, building on MIB concepts; as well as the ISO/IEEE 11073, an international standard focusing on communication between healthcare devices and external computer systems.
- **1999**—Integrating the Healthcare Enterprise initiative (IHE), an international organization of radiologists and IT experts, set up to improve how healthcare computer systems share information, holds first IHE Connectathon—a face-to-face interoperability testing event to foster the adoption of standards-based solutions in products.
- **2004**—The Office of the National Coordinator for Health Information Technology (ONC) is created to promote the development of a nationwide health IT infrastructure that allows for electronic use and exchange of information.
- **2004**—The MD PnP program is launched: a multi-disciplinary, multi-institutional program that aims to “support the development and adoption of clinically grounded solutions for medical device interoperability,” according to its website.

- **2004**—The FDA hosts “Operating Room of the Future: Developing a Plug-and-Play Open Networking Standard,” a kickoff plenary meeting, and the first of yearly FDA meetings on interoperability.
- **2005**—IHE starts work on data transmission and point-of-care devices to EMR connectivity.
- **2006**—The International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) propose the standard IEC 80001 to define how to address new problems in connecting medical devices to a network. The standard was published by AAMI in 2010 and two companion additions were published by AAMI in 2012.
- **2009**—The ASTM F2761 standard is published, “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE),” providing a high-level system architecture for medical device interoperability.
- **2012**—AAMI Ad Hoc Group on Health Information Technology and Interoperability (HITI) releases white paper on interoperability envisioning “an entire family of clinically-based, systems-level standards, each targeted at specific important clinical scenarios.”
- **2012**—AAMI and UL sign a memorandum of understanding to develop a suite of medical device-related interoperability standards with a focus on patient safety.

Many other notable organizations, including HIMSS, NIST, Continua Health Alliance, and the West Wireless Health Institute, have been instrumental in defining roadblocks to interoperability and devising innovative solutions.

However, despite the fact that the health-care industry has been exploring this issue for years, there is still a long way to go for full healthcare interoperability to become a reality. Fortunately, research efforts continue to focus on both the challenges and benefits of interconnected medical devices, and how to implement the paradigm shift needed to achieve full interoperability.

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ABBREVIATIONS

AAMI: Association for the Advancement of Medical Instrumentation

ACCE: American College of Clinical Engineering

ACCN: American Association of Critical-Care Nurses

ACO: Accountable Care Organization

AHIC: American Health Information Community

AHRQ: Agency for Healthcare Research and Quality

ANSI: American National Standards Institute

AORN: Association of Perioperative Registered Nurses

API: Application Programming Interface

APSF: Anesthesia Patient Safety Foundation

ASA: American Society of Anesthesiologists

ASHE: American Society for Healthcare Engineering

ASTM: American Society for Testing and Materials

BSR: Board of Standards Review

BYOD: Bring Your Own Device

CDA: Clinical Document Architecture

CDRH: Center for Devices and Radiological Health

CIMIT: Center for Integration of Medicine and Innovative Technology

CMS: Centers for Medicare & Medicaid Services

COP: Community of Practice (COP)

CPOE: Computerized Physician Order Entry

CPT: Current Procedural Terminology

DICOM: Digital Imaging and Communications in Medicine

DIM: Domain Information Model

DNV: DNV Healthcare, Inc.

DOD: U.S. Department of Defense

EHR: Electronic Health Record

EMR: Electronic Medical Record

ER: Entity Relationship

FDA: U.S. Food and Drug Administration

GPS: Global Positioning System

HDO: Healthcare Delivery Organization

HFAP: Healthcare Facilities Accreditation Program

HHS: U.S. Department of Health and Human Services

HIMSS: Healthcare Information and Management Systems Society

HIPAA: Health Insurance Portability and Accountability Act

HIT: Health information Technology

HITI: AAMI Ad Hoc Group on Health Information Technology and Interoperability

HITSP: Healthcare Information Technology Standards Panel

HL7: Health Level Seven

HL7 ACK: Health Level Seven Acknowledgement

HTTP: Hypertext Transfer Protocol

HVA: Hazard Vulnerability Assessment

ICD-9-CM: International Classification of Diseases, Ninth Revision, Clinical Modification

ICE: Integrated Clinical Environment

ICE STORM: ICE Systems, Training, Operations, Research, Methods

ICU: Intensive Care Unit

- IEC:** International Electrotechnical Commission
- IEEE:** Institute of Electrical and Electronics Engineers
- IHE:** Integrating the Healthcare Enterprise
- IHI:** Institute for Healthcare Improvement
- IHTSDO:** International Health Terminology Standards Development
- INCOSE:** International Council on Systems Engineering
- IOM:** Institute of Medicine
- IS:** Interoperable Scenario
- ISO:** International Organization for Standardization
- ITIL:** Information Technology (IT) Infrastructure Library
- IV:** Intravenous
- L&D:** Labor and Delivery
- LIS:** Laboratory Information System
- LOINC:** Logical Observation Identifiers Names and Codes
- MD PnP:** Medical Device “Plug-and-Play” Interoperability Program
- MedDRA:** Medical Dictionary for Regulatory Activities
- MIB:** Medical Information Bus
- MIT:** Massachusetts Institute of Technology
- NIH:** National Institutes of Health
- NIST:** National Institute of Standards and Technology
- NKTR:** Nektar Therapeutics
- ONC:** Office of the National Coordinator for Health Information Technology
- PACS:** Picture Archiving and Communications System
- PCA:** Patient-Controlled Anesthesia
- PCD:** Patient Care Device
- PnP:** Plug-and-Play
- RIM:** Reference Information Model
- RIS:** Radiology Information System
- RS-232:** Recommended Standard 232
- S&I:** Standards and Interoperability
- SCCM:** Society of Critical Care Medicine
- SDO:** Standards Development Organization
- SNOMED CT:** Systematized Nomenclature of Medicine—Clinical Terms
- SSL:** Secure Sockets Layer
- TCP/IP:** Transmission Control Protocol and Internet Protocol
- TJC:** The Joint Commission
- UL:** Underwriters Laboratories

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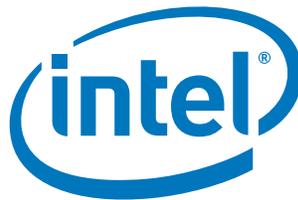
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