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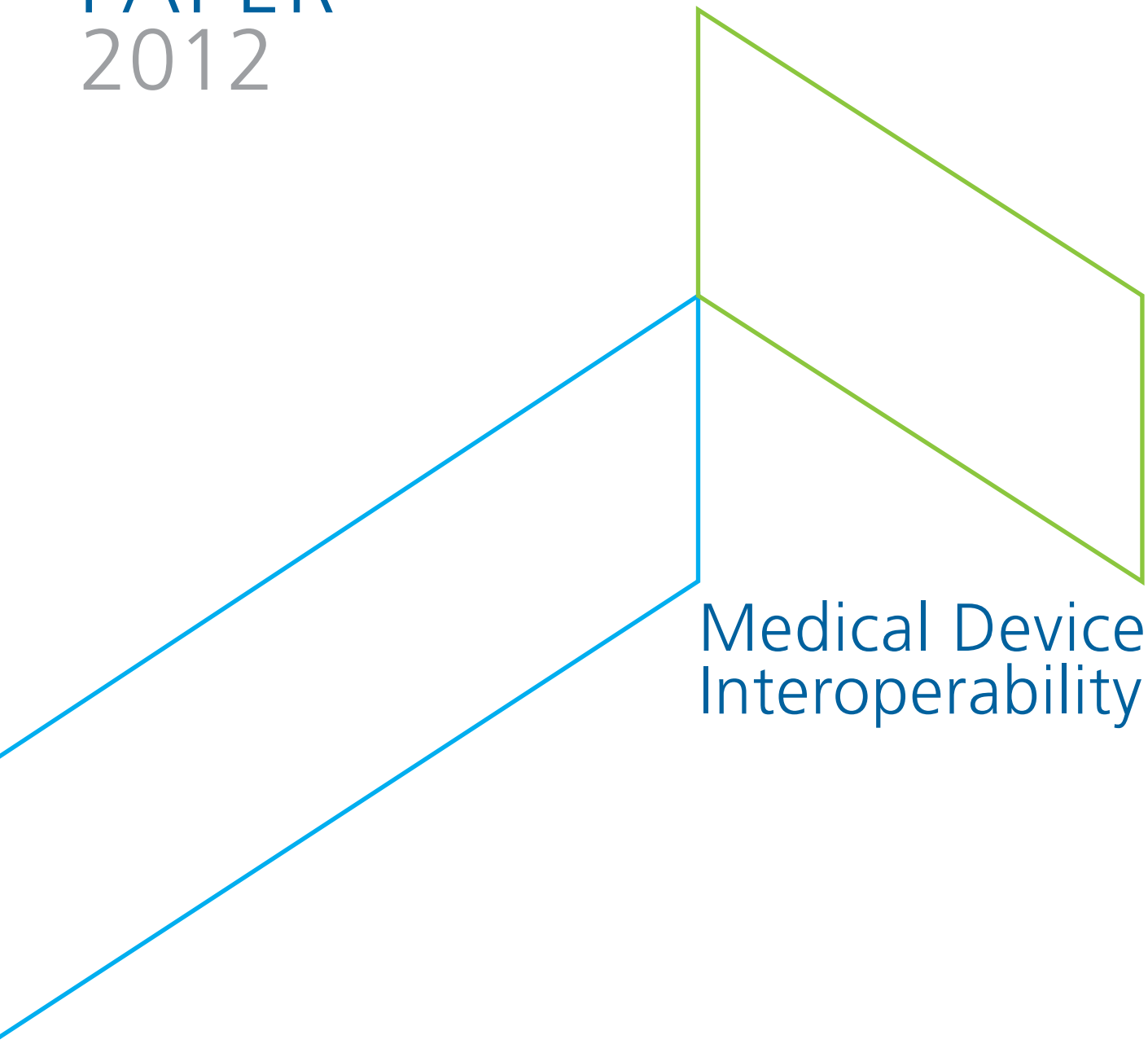

Medical Device Interoperability

AAMI
Advancing Safety in Medical Technology

AAMI White Paper **AAMI MDI/2012-03-30**

Medical device interoperability

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Executive summary

This White Paper was developed by the AAMI Ad Hoc Group on Health Information Technology and Interoperability (HITI). The purpose of the White Paper is two-fold: First, and most importantly, it provides recommendations on how AAMI can make contributions to the field of medical device interoperability; second, it includes an overview of medical device interoperability standards and related efforts that will make the White Paper useful to a wider audience. After reviewing numerous definitions of "interoperability," HITI defines it here as “the ability of medical devices, clinical systems, or their components to communicate in order to safely fulfill an intended purpose."

In making recommendations, HITI has surveyed medical interoperability concepts; market factors; applicable standards from HL7, IEEE, ASTM, and others; and related efforts such as profiling, testing, and certification available from such bodies as IHE, Continua, and the Medical Device "Plug-and-Play" Interoperability Program. We have identified gaps and considered how AAMI's unique strengths can be applied to this increasingly important field of endeavor. Our conclusion is that AAMI should develop standards for individual clinical scenarios that define specific clinical functional requirements and non-functional requirements, such as QoS, quality of measurement (precision and accuracy), and, most importantly safety. These standards would describe the essential performance requirements for such a composite system.

Clinically-based interoperability standards would be based on a complete systems-level approach, follow systems engineering best practice, and incorporate standards for user interaction, patient interface, and device-to-device interoperability. The primary emphasis would be on ensuring that the resulting composite devices can operate safely and effectively for a specific intended use, by describing the essential performance requirements for composite systems intended for those clinical scenarios. These standards may then be recognized by regulatory bodies. Along with appropriate AAMI-developed process standards for validating multi-vendor composite systems, these standards would enable a regulatory pathway for the approval of such solutions, creating the necessary conditions for vendor investment in developing and marketing devices that can be used in interoperable composite systems.

HITI envisions an entire family of clinically-based, systems-level standards, each targeted at specific important clinical scenarios. These standards would draw on the same, or substantially similar, technically oriented interoperability standards—standards that are orthogonal to the AAMI-developed, clinically-based standards. AAMI should cooperate with other organizations to leverage existing interoperability standards, profiles, testing, certification, and verification and validation (V&V) infrastructure.

AAMI should not focus on the development of technology, engineering, or communication standards. If a situation arises in which such a standard is needed but does not exist, AAMI should engage the appropriate technology, engineering, or communications standards developer to create and deliver the required standard.

If this approach is adopted, AAMI will need to undertake the following:

- In collaboration with other standards-development organizations (SDOs), AAMI will need to recommend appropriate standards and profiles for specific clinical scenarios. In situations where no standards exist, or existing standards are inadequate, AAMI will need to work with other SDOs to develop, supplement, or modify underlying interoperability standards.

- AAMI should identify the best practices, standards, SDO’s, or organizations that have expertise or products in development processes, verification, and validation that are applicable to assuring the safe operation of composite devices. This informs SDOs, medical device manufacturers, healthcare providers, and regulatory and quality bodies to ensure that processes exist for the verification and validation of composite devices.

- Because clinically-based, multi-vendor, systems-level standards will apply to a wide variety of devices, AAMI will need to draw on multiple technical committees and groups for expertise, perhaps through a joint working group structure. AAMI will also have to develop internal processes for collaborating with other organizations for selecting, refining, and profiling interoperability standards and interfaces to health information systems to

support the creation of multi-vendor, composite devices. Systems engineering expertise should also be sought from groups like International Council on Systems Engineering (INCOSE).

- AAMI may need to collaborate with regulatory bodies and other efforts to ensure that regulatory pathways exist for the approval of interoperating composite devices.

Close involvement from regulatory authorities with jurisdiction, including the U.S. FDA, is required. Ideally, AAMI would like to see the U.S. FDA become more active in medical device interoperability. The interoperability arena is a complex environment that requires the contribution, collaboration, and participation from many groups and stakeholders. The FDA with its mission to promote and protect public health in the United States is well positioned to facilitate the communication across these groups and stakeholders.

These recommendations and the advantages of this approach are elaborated in the White Paper, which also provides extensive background information on the clinical need that better medical device interoperability addresses, levels of interoperability, the conceptual underpinnings of interoperability, current standards, and profiling efforts for clinical point-of-care devices.

Medical device interoperability

1 Introduction

1.1 Overview

The concept of medical device interoperability has been defined in many different ways by different stakeholders. This White Paper represents a collaborative effort of stakeholders to advance the adoption of medical device interoperability with the goal of improving patient safety and healthcare efficiency. It is important that interoperability be carefully defined for this purpose in terms of needs, functions, benefits, and challenges. Broadly speaking, interoperability will enable clinicians to improve patient care by working with integrated systems of diagnostic and therapeutic devices and sharing data with electronic health records (EHRs), thus providing enhanced clinical-decision support, safely and effectively.

Interoperability can be achieved by several different parties: the medical device manufacturer, the middleware vendor, the system integrator, the healthcare delivery organization (HDO), or the physician. Preferably, however, the original medical device manufacturer should design and build the product with interoperable capabilities.

Varying levels of functions, features, and data can be exchanged in different implementations of interoperability—even between identical components integrated by different parties for different purposes. The safety, reliability, and capabilities of the interfaces between and integration of multiple systems (whether or not they are regulated) depend on the implementation and type of interoperability. The type of interoperability desired and its relevant attributes or properties must be specified before one can determine what to develop and how to maintain the system.

1.2 Background of the White Paper

The AAMI Ad Hoc Group on Health Information Technology and Interoperability (HITI) was formed early in 2010 to explore how AAMI could expand its work beyond its traditional role of medical device safety to explore important areas in HIT and interoperability.

In February 2011, the FDA submitted to AAMI a new work item proposal, “Interoperable Medical Devices Interface Standards (IMDIS),” to further advance standards for medical device interoperability. The proposal was discussed in meetings of the AAMI Information Technology Committee and the AAMI Ad Hoc Group on HITI at the AAMI 2011 Annual Conference, 25–27 June, in San Antonio, TX. At both meetings, an approach was discussed and elaborated that the committee members believed would best leverage AAMI’s strengths, avoid duplicate effort in medical device interoperability standards, and advance the applicability, scope, and implementation of standards in the marketplace, thereby leading to better patient care. FDA strongly supports medical device interoperability as a means of improving patient safety and fostering innovation, and sees AAMI’s efforts to understand the process, roles, and tools as essential to achieving these goals (Tillman and Kessler, 2007; FDA, 2010).

This White Paper is the result of the deliberations of the AAMI Ad Hoc Group on HITI and subsequent peer review. It provides information on device interoperability and existing standards, as well as recommendations on how AAMI can expand its mission.

1.3 Benefits of interoperability

Interoperability is currently a vaguely defined concept about which almost everyone involved has some idea as to function and need. It is an important concept that must be defined carefully and then pursued with equal care. In most broad visions, interoperability enables clinicians to apply both diagnostic and therapeutic equipment and systems in

which individual components interact, maintaining records of appropriate data and initiating appropriate actions safely and effectively.

Adopting standards-compliant interoperable devices and associated systems will have numerous benefits, including the following:

- facilitating the development of innovative approaches to the improvement of patient safety, healthcare quality, and provider efficiency for patient care;
- improving the quality of medical devices;
- accelerating adoption of new clinical technology;
- reducing HDO resources now used to maintain customized interfaces; and
- acquiring and analyzing more complete and more accurate patient and device data, which will support improved healthcare quality and outcomes.

These benefits are elaborated in Goldman and Robkin (2008), which also describes the clinical context of interoperability and provides examples of Requests for Proposals (RFPs), Requests for Information (RFIs), and contracting language that can be used in the purchase and maintenance of fully interoperable medical devices and systems. See also (ECRI, 2011) and (IHE, 2011).

1.4 Challenges in interoperability

There have been successful medical device integration implementations, however, there are still challenges (

- Each new device integration is a custom installation requiring significant effort by implementers, even with widely accepted and widely used standards, such as HL7.
- Clinicians desiring to use a set of interoperable devices to fulfill a clinical need must wait for application vendors to develop new “drivers”.
- The complexity of device interfacing hinders research that could lead to improved patient care.
- The software development effort and on-site customization required to integrate devices can create quality and performance issues that might lead to unsafe conditions.
- System integration services are very costly to HDOs.
- There is reduced assurance that all data are accurate and complete.
- All of the data required to address a clinical scenario might not be available, regardless of the integration effort expended.
- Attempts to solve problems lead to finger-pointing rather than solutions.
- There is too much complexity in maintaining each link in the communication chain.

It is commonplace to decry the poor state of the “device interoperability problem,” but it actually impedes progress to describe it as a unitary “problem” rather than a diverse set of problems, each generated by a sphere within the wide domain of particular clinical or enterprise uses of medical devices. Interoperability is not a ladder that the community is climbing together by filling in a single series of interoperability requirements.

The various taxonomies and ordered scales of interoperability measures of merit that have been developed are interesting and analytically useful, but to be applied concretely they must be broken down into elements and applied in a specific way to particular problems; the measure of a device’s interoperability is always relative to a particular purpose. That said, there are indeed capabilities that are quite general-purpose, such as:

- identifying some observed values and control capabilities of a device in a standardized way;

- communicating a device's capabilities with standardized messages; and
- specifying syntax for transmitting observations and control actions.

These are problems for which there are demonstrated partial solutions based on current standards. But, the mere existence of standards does not bring about interoperability, nor does a demonstration ensure safety and reliability.

It is a misconception that gaps in existing technical/networking infrastructure standards are the sole impediment to interoperability, especially because those standards tend to be general multi-purpose standards not created to address specific verifiable clinical scenarios. Had they been defined to a level of interoperability so that two independent implementations were interoperable, and had they been implemented across a larger share of the healthcare market, the landscape would be very different.

Another cause of the lack of implementation is the view of some vendors that there is insufficient return on investment for contributing to standards-development work, for fully implementing genuine interoperability in products, and—perhaps just as importantly—for supporting development of material for implementation, such as open-source reference implementations and accompanying design guidelines. Widely available reference implementations of interoperability in its various forms, contexts, scenarios, and levels would accelerate the development of interoperability, but by themselves are not sufficient.

Assuring the safety and reliability of complex systems of interoperable components relies on multiple parties that have specific roles and responsibilities and that depend on each other for performing pieces of the process. It also requires additional detailed information on device settings currently considered "internal" by manufacturers, such as averaging time, device alarm limits, software revisions, hardware revisions, calibration date/time, last date of maintenance, and more. Other interfaces, such as USB and Bluetooth, have independent certification bodies and accreditation systems that support regulatory requirements. What process will be used to assure the safety and reliability of systems of interoperable medical devices, who will fulfill those roles, and what tools (e.g., standards, accredited parties) will be used?

1.5 Composite systems

When multiple devices are brought together and interoperate to accomplish a purpose or a set of purposes, these devices form what might be thought of as a "composite device"—a larger system composed of multiple devices. Though the individual devices might have some very specific uses to accomplish specific clinical tasks, the composite device also has its own clinical functionality or "intended use." Indeed, individual vendors commonly design and manufacture devices to interoperate with other devices from that same vendor. This can be done using standards or proprietary interfaces, but they nevertheless interoperate. A vendor that markets a composite device is required to employ a quality system and to perform verification and validation (V&V) to ensure that the composite device can be operated safely and effectively. It is recognized that interoperability within a single vendor's product line is insufficient to meet the needs of HDOs and their clinicians.

1.6 Multi-vendor systems

It is easy to see why hospitals might wish to use single-vendor composite systems but also, just as importantly, composite systems composed of devices from different vendors. It should be noted that single-vendor solutions are not always possible. Multi-vendor systems have been implemented successfully, but as expensive projects in which, for example, a monitor vendor implements interoperability with a particular ventilator from another vendor using the other vendor's proprietary interface, taking full responsibility for the integration, verification, and validation of the composite system. More generally, without the availability of such custom combinations of devices, clinical uses are limited to composite systems that are supported by one vendor's product line and that were foreseen in the design of the devices (even in a single vendor's products, device intercommunication is frequently a problem), and institutions are limited in their ability to make "best of breed" choices. Third-party integration vendors offer expedient solutions and additional functionality, but they cannot compensate for information and capabilities not exposed by the medical device interfaces.

This joining of individual device systems from multiple vendors into a larger composite system is new in the standards arena, but not because of technical challenges or because vendors do not know how to do it technically. Although

there have been internal and cross-vendor integration failures, there are many examples of successful interoperability within a single vendor's product line and even in particular cross-vendor solutions. However, market business conditions present a far greater challenge than the implementation of a composite system in a general, standards-based way. It is these factors, rather than the technical requirements, that set a high bar for vendor participation. It is a fallacy that, with regard to standards, "if we build it they will come"; the existence of workable standards is but one of many practical preconditions for a decision to support multi-vendor systems.

ASTM 2761, one example of an integrated clinical environment (ICE) standard, describes a platform and an architecture for heterogeneous systems composed of devices from multiple vendors; the exposed, standardized, certified interfaces of the components enable additional capability like that found in third-party "apps."

1.7 Specific market considerations

Medical device manufacturers and HIT vendors might be reluctant to publish interface specifications or to implement fully standardized interfaces, because of concerns about liability, regulation, product support, proprietary capabilities, and enabling the competition to enter their market niche. The market (the return on investment to manufacturers) must be sufficient to overcome these concerns and justify the development and support of interoperable products. A number of factors contribute to this outcome:

- There is a demand for medical device data to be more complete, nonproprietary, interoperable, detailed, and accurate. This would support greater availability of innovative clinical capabilities to improve clinical outcomes and patient safety. Clinicians and HDOs have conveyed the need for these capabilities, but they are not often articulated specifically as a request for medical device interoperability. In the United States, the Department of Health and Human Services' "meaningful use" requirements, the implementation of accountable care organizations (ACOs), and other recent changes in federal healthcare law and regulations, such as Medicare and Medicaid financial incentives and penalties, have contributed significantly to this goal. See also ONCHIT (2009).

- The medical and nursing professions should be made more aware of the clinical and business value facilitated by interoperability and should communicate their expectations for those capabilities to both vendors and HDOs. HIT and medical device vendors and standards organizations should educate the clinical community about the value of interoperability.

- Healthcare delivery organizations should be more aware of the clinical and business value of capabilities supported by interoperability, including improving the quality and safety of patient care, reducing the total cost of ownership of integrated devices and HIT, facilitating compliance with government reimbursement regulations, and meeting various non-governmental quality and performance standards.

- There must be a regulatory and certification pathway for vendors and customers that does not impede either the value proposition or the use of interoperable products. This pathway includes provably correct standards and trusted independent testing of those standards' implementations by vendors or HDOs. For several years, the FDA has said that the existing medical device law is sufficient to handle heterogeneous interoperability.

  > *CDRH has the tools to resolve the issues that will inevitably arise. Our principal tool is the medical device law, which embraces fundamental principles rather than prescriptive practices. Our regulatory tools are based on a systems engineering approach, focusing on how well a given system satisfies a medical intended use. This systems approach, which works well for complex systems provided by one manufacturer, can be extended to systems of interconnected devices from multiple manufacturers* (Tillman and Kessler, 2007).

- Non-technical professionals (the vast majority of clinical and healthcare professionals) are not—and need not be—aware of interoperability, per se. They should be educated by the HIT and medical device communities on the value of capabilities and functions that are enabled partially or completely through interoperability in acquired products, such as safety, efficiency, improved outcomes, and enhanced quality of patient care.

- Standards must specify how to interoperate. In addition, profiles must exist to constrain open-ended standards sufficiently to achieve interoperability.

- Implementer-friendly guideline documents should be available to explain the standards clearly enough for practical implementation. (To serve their purpose, standards are by necessity written with a high degree of formality and abstraction, not for readability. It has been aptly said that "a standards author is someone who makes you an offer you cannot understand." Even for a skilled engineer, it can be extremely difficult to translate standards language into a real implementation.) Tutorial material and reference implementations can improve the lot of the implementer immensely and lead many more to try and succeed much more quickly.

- Relentless and well-resourced promotion is important, because customer demand depends on widespread knowledge of, and confidence in, standards-based composite system solutions.

- It must be provable under quality and regulatory regimes that the system is safe and effective. Therefore, new V&V standard methods and entirely new procedures and rules from regulatory agencies are needed. Is it sufficient to test to a standard and trust that such testing can assure the safety and effectiveness of all combinations of systems, or must each combination of device models and versions be verified and validated?

In 2009, the U.S. medical instrumentation and supply manufacturing industry had revenues of $86.1 billion and profits of $6.9 billion. Revenue growth has been steady, averaging 3.6 % annually from 2004 to 2009. Future growth is predicted to remain steady at a slightly reduced 3.3 % annual growth rate (Kidson, 2009). The average profit margin for the entire industry is 8 %. As a whole, healthcare did not experience the recent recession; employment and revenue have grown every quarter. It can be expected that such a successful industry would be adverse to changes in their operating and business environment. The U.S. Army Telemedicine and Advanced Technology Research Center (TATRC) report on the hospital of the future concluded the following:

> *What will be the driver to establish interoperability? Some combination of healthcare delivery organizations and government agencies will probably become the force that creates impetus for companies to accept a standard, to allow interface or "plug and play." DOD with its huge procurement power can force this issue—although it may be politically difficult given the lobbying power of industry* (Schimpff, 2008).

1.8 An example of a clinical scenario

Some causes of adverse events and medical errors are well studied. The number of sepsis cases, MRSA infections, allergic reactions, and significant device failures, for example, are known with precision. Clinicians are trained to detect some adverse events, and HDOs are motivated to gather relevant statistics and report them to the appropriate authorities. FDA regulations require that certain kinds of adverse events be reported to the FDA. Thus, the FDA has good data on the prevalence and relative harm of a variety of known medical device failures.

One clinical area that has been well studied can serve as an edifying example of patient safety areas ripe for improvement through interoperability:

Patient-controlled analgesia (PCA) infusion has been recognized as an important patient safety issue by AAMI (AAMI, 2010), the ECRI Institute (ECRI, 2010), and the Anesthesia Patient Safety Foundation (APSF) (Calkins, et al., 2010; Weinger, 2006). ECRI includes PCA hazards directly as one of its top ten health technology hazards for 2011; the list also includes alarm hazards and HIT complications, two other areas that overlap with efforts to reduce PCA over-infusions. A meeting hosted by the APSF in October 2006 focused on the patient safety issues associated with PCA; at a follow-up summit in 2011, it was concluded that there had not been any significant improvements in patient safety during the last five years (Weinger and Lee, 2011), largely because of the lack of pump connectivity, which includes a means for a patient-monitoring-based decision-support system to pause the PCA infusion when monitors detect changes consistent with significant respiratory depression.

There are multiple causes of over-sedation from PCA. Syed, et al. (2006), enumerates 17 potential errors that can occur in PCA administration and relates a case in which six of these errors occurred during one patient's PCA use. An analysis of reports made from 1984 to 1989 to the MAUDE database maintained by the FDA's Center for Devices

and Radiological Health (CDRH) found that 67 % of problems associated with PCA pumps were caused by operator error (Callan, 1990). This early study took place before the 1990 promulgation of the FDA's Medical Device Reporting (MDR) regulation, which requires the reporting of incidents involving "device malfunctions and serious injuries or deaths" to FDA. A later study found that nearly 80 % of the 2,009 incidents reported to FDA in 2002 and 2003 were blamed on device malfunctions, and that nearly 65 % of these suspected device malfunctions were confirmed by the device manufacturers (Hankin, et al., 2007). The human factors of pump interface design are an important means of reducing use errors (Lin, et al., 1998; Lin, et al., 2001). A study of MAUDE data from 2007 to 2009 conducted by Pat Baird of Baxter found that about a third of reported infusion-related adverse events involved PCA and attributed 55 % of PCA adverse events to "use error" and 42 % to "unknown" causes (AAMI, 2010). Better interoperability of pumps should help to reduce medication delivery errors by allowing more automated verification of pumps and the systems to which the pumps connect.

The incidence of respiratory depression associated with PCA varies between 0.3 % and 6 %, depending on the patient population and on how respiratory depression is defined (Paul, et al., 2004). Even though most cases of respiratory depression do not lead to permanent harm to the patient, these are serious incidents with the potential to harm or kill patients. Meta-analysis of the PCA adverse-event literature by researchers at the MGH/CIMIT MD PnP research program shows that there is approximately one PCA-related patient death per day in the United States.

The Institute for Safe Medicine maintains a voluntary database of medication errors. The MedMarx database contains 9,500 PCA-related errors reported from 2000 to 2004 (Hicks, et al., 2008). These account for only 1 % of the medication errors submitted to the database, but this 1 % accounts for 6.5 % of harmful outcomes. The actual number of occurrences of PCA-related errors is almost certainly under-reported, because the voluntary database can only track the rate of reporting, not the rates of errors or adverse events (Leape, 2002).

2 Definitions and abbreviations

2.1 Definitions

accreditation: Specific organization's process of proving and demonstrating certification.

certification: The documented confirmation of certain characteristics of a component or system. For medical device interoperability Certification means an objective and repeatable verification through tests that a product meets a verified specific set of specifications and functions as expected for the intended use.

clinical scenario: Brief description of a clinical situation or event (ASTM, 2009).

compliance: In the IT sense, compliance is the state of being in accordance with established guidelines, specifications, or legislation. In a legal sense, it usually refers to organizational behavior in accordance with legislation such as HIPAA.

conformance: State or acts of adherence to a certain specification, standard, or guideline. Conformance does not necessarily imply the target specification, and desired functionality may work as expected until the system has been validated or that conformance has been independently verified.

device model: Abstract model that represents those capabilities and characteristics of a device that can be accessed and operated on externally in a particular context of use, typically including data types, relationships, and nomenclature used for input and output of observations and controls.

functional vs. non-functional capabilities: Terms describing the desired behavior, features, and capabilities of a system that are intended to address one or more use cases. Functional capabilities are expressed in the form “the system must do . . .” Non-functional capabilities are more closely associated with “how” the functions perform: “A system shall be . . .”

interoperability: Ability of medical devices, clinical systems, or their components to communicate in order to safely fulfill an intended purpose.

plug-and-play: Ability of medical devices, clinical systems, or their components to communicate in order to safely fulfill a-manufacturer’s intended purpose without custom integration or development.

profile: Specification showing in detail how to apply existing standards by restricting or constraining requirements in the referenced standards.

quality of service: Set of non-functional properties of a system that define quantitative constraints on how well a service is delivered.

standard: Document established by consensus and approved by a recognized body that provides for common and repeated use, rules, guidelines, or characteristics for activities or their results. A standard is aimed at achieving the optimum degree of order in a given context. Standards are

- shaped by consensus;
- typically developed in an open and transparent process, with representation of all interested and engaged parties; and
- primarily market-driven (industry-sponsored).

use case: Description of a set of sequences of actions, including variants, that a system performs that yields an observable result of value to achieve a clinical or technical goal. Use cases are characterized by human interaction and workflow considerations.

validation: Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled (CFR, 2011).

verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled (CFR, 2011).

2.2 Abbreviations

AAMI: Association for the Advancement of Medical Instrumentation.

ACO: Accountable Care Organization.

AHIC: American Health Information Community.

APSF: Anesthesia Patient Safety Foundation.

BSR: Board of Standards Review.

CDA: Clinical Document Architecture.

DICOM: Digital Imaging and Communications in Medicine.

DIM: Domain Information Model.

EHR: Electronic Health Record.

ER: Entity Relationship.

FDA: U.S. Food and Drug Administration.

HDO: Healthcare Delivery Organization.

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.

ICE: Integrated Clinical Environment.

IEEE: Institute of Electrical and Electronics Engineers.

IHE: Integrating the Healthcare Enterprise.

IHTSDO: International Health Terminology Standards Development.

IS: Interoperable Scenario.

ITI: Information Technology (IT) Infrastructure.

ISO: International Organization for Standardization.

LOINC: Logical Observation Identifiers Names and Codes.

MD PnP: Medical Device “Plug-and-Play” Interoperability Program.

MRSA: Methicillin-Resistant Staphylococccus Aureus.

NIST: National Institute of Standards and Technology

OASIS: Organization for the Advancement of Structured Information Standards.

ONC: Office of the National Coordinator for Health Information Technology.

PCA: Patient-Controlled Anesthesia.

PCD: Patient Care Device.

PnP: Plug-and-Play.

RIM: Reference Information Model.

RTM: Rosetta Terminology Mapping.

QoS: Quality of Service.

SDO: Standards Development Organization.

SNOMED CT: Systematized Nomenclature of Medicine—Clinical Terms.

UL: Underwriters Laboratories.

UML: Unified Modeling Language.

V&V: Verification and Validation.

3 What is interoperability?

3.1 Overview

The term *interoperability* has become extremely popular over the last few years, especially in the context of healthcare IT systems. Everyone recognizes that the concept of interoperability is extremely important when trying to connect different devices or systems together to create an integrated solution. Everyone seems to know what interoperability is (they know it when they see it), but the expectations of what an interoperable system is can be very different from one person to another.

Over the past few years, "interoperability" has received a bad reputation. Many of the ills of IT integration or device interfacing are blamed on the "lack of interoperability." Claims are being made that certain applications cannot be built because of a "lack of interoperability" or that the EHR is not displaying certain parameters from a device because of a "lack of Interoperability." One can liken this situation to the phrase, "the network is down," which can mean anything from a specific application not working to a true general failure of the networking infrastructure.

What is clear is that errors made in connecting systems together, resources expended in order to integrate systems, money spent on integration products, and so on, are symptoms of the impact of poor interoperability. Through substantial effort by designers, devices do manage to talk to other devices and to IT systems, however, at great cost and with significant complexity. Bridget Moorman of BMoorman Consulting LLC says that it can cost between $6,750 and $10,000 per bed to integrate the devices, including ventilators, in a typical intensive care unit (Moorman, 2010).

The fact of the matter is that "interoperability" can refer to a continuum of technical solutions that might or might not solve the problem at hand for a specific clinician.

3.2 The AAMI definition of interoperability

The AAMI Ad Hoc Group on Health Information Technology and Interoperability (HITI) reviewed many different descriptions of interoperability (e.g., Broder, 2005; Continua Health Alliance, 2011b; Heubusch, 2006; HIMSS, 2005, 2006) and converged on the following definition:

> **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.**

This definition is different from most others, because it encompasses two very specific concepts relevant to the medical device/system community: safety and intended purpose.

- ***Safety:*** The concept of safety is extremely important when patients' lives are at stake. It is also tied closely to AAMI's mission. If one system communicates a concept that is misinterpreted by a second system, the misinterpreted communication can result in an unsafe condition. Therefore, safety and accuracy of communication must be extended to include the concepts of "semantic interoperability" and "dynamic interoperability" (see Section 3.3). Safety might also relate to issues such as error detection and fault handling when error conditions are encountered.

- ***Intended purpose:*** This concept recognizes that interoperability cannot be achieved in the abstract, but is always relative to a particular intended purpose. One example is the exchange of .pdf files. If the clinical scenario requires patient allergy information or vital sign data, the exchange of .pdf files will not meet the intended purpose because the required information is not extractable.

  Another example of an "intended purpose" from the medical device interoperability field involves a ventilator. A ventilator might be connected with a patient monitor, for example, to export information on the ventilation of a patient for monitoring purposes or for retrospective review by a clinician; thus, the ventilator interoperates. However, such a ventilator might not be capable of interoperating with an imaging device to pause or synchronize ventilation in order to obtain a clear image; in this case, the ventilator does not interoperate. Therefore, it is not a question of whether, in general, the ventilator interoperates or does not interoperate, but whether it interoperates to accomplish some intended purpose.

An additional key concept associated with the AAMI definition of interoperability is common to all forms of interoperability: communication. In order for systems to communicate, it is necessary that they share a common basis for that communication, either a common adherence to a static standard or a dynamic shared model. In this definition, the term “communicate” should be interpreted in the broadest possible sense—not just transmission of information but also communication of intent and desire, as when one party of the communication requests another party to take action.

3.3 Levels of interoperability

When we say that two systems must be interoperable, does this mean that as long as there is some way of getting data from one system to another, we are happy? Or, do we expect that one only needs to point two or more systems at each other and stand back, satisfied that the job is done? It becomes clear that there are different levels of interoperability.

We have adopted an interoperability hierarchy model proposed by Turnitsa (2005) and adapted it (Table 1) in order to better describe the concept of interoperability for medical devices. In Turnitsa’s model, Level 0 interoperability describes a situation in which two systems have no need to, or cannot, interoperate. Technical interoperability (Level 1) is achieved when two systems have the means to communicate, but neither has a shared understanding of the structure or meaning of the data communicated. Turnitsa gives an example of technical interoperability: a receiving system simply records what is received, not understanding structure or meaning. Syntactic interoperability (Level 2) occurs when information is communicated with structure but without any meaning. Semantic interoperability (Level 3) in the Turnitsa taxonomy is achieved when the data have meaning, but a full understanding of the relationships between elements of data and the context of the data is missing. Pragmatic interoperability (Level 4) encompasses a shared understanding of data, the relationships between elements of the data, and the context of the data; however, pragmatic interoperability cannot accommodate changing relationships or context. Dynamic interoperability (Level 5) is more flexible, allowing for changing contexts and relationships over time or within the scope of specific transactions. Turnitsa defines an even more advanced level of interoperability (not shown in Table 1): Level 6 or “conceptual interoperability.” According to Turnitsa, “true conceptual interoperability, or communication, is only available when complete understanding of the concepts inherent within the target and source data models is shared, or shareable.” In a conceptual model, assumptions of relationships between the data and functions performed on the data are incorporated.

Although the model implies a strict hierarchy of interoperability, solutions do not necessarily have to implement one level before moving to the next. For example, it is possible to have semantic interoperability, but not technical interoperability. This situation is rarely the case, but could occur. The ordering is based on the typical implementation of and historical approaches to interoperability.

It should be clear from these descriptions that the sort of interoperability needed to support sophisticated clinical scenarios (see Section 1.8 for an example) requires, at a minimum, semantic interoperability. However, the more challenging the clinical need and the more demanding the requirements for interoperability, the higher the level of common understanding needed, as embodied by pragmatic and dynamic interoperability. This is particularly true for the proper mitigation of safety risks associated with sophisticated, life-critical composite systems.

Table 1—Levels of interoperability

	Level	Turnista name	Short description	Standard or effort working to that goal	Interoperability achieved in market or in practice in market or in practice	Ecosystem components			
						Resources	Testing	Verification	Certification
Interoperability	5	Dynamic	Components internal states and capabilities understood	None					
	4	Pragmatic	Context understood	Continua	Multiple vendor PnP products on market	Design guidelines, reference implementations, testing tools, certification process	Continua	Continua	Continua, 3rd party
				IHE PCD	Multiple vendor products on market	Profiles, implementations guide, user handbook	Connecta-thons, demon-strations	None	None
				ASTM F2761 (ICE)	Multiple vendor interoperable products in development	System architecture standard	Planned	Planned	Planned
Integratability	3	Semantic	Meaning understood	SNOMED	Numerous products on market				
				Continua/ 11073 Nomencla-ture	Multiple vendor products on market	Continua/ Rosetta database	Continua	Continua	Continua, 3rd party
				IHE-PCD/ 11073 Nomencla-ture	Multiple vendor products on market	IHE-PCD/ Rosetta database	Connecta-thons, demon-strations	None	None
	2	Syntactic	Common format	HL7	Multiple vendor products on market. Not interoperable off-the-shelf	HL7 SDO published standards documents			
				11073 series	In use by all Continua products	SDO published standards documents (ISO, IEEE)			
Connectivity	1	Technical	Common physical and transport	Ethernet, WiFi, USB	Numerous PnP interoperable products on market	Design guidelines, reference implementation, development tools, mature supply chain	3rd party or SDO/ consortium	3rd party or SDO/ consortium	3rd party or SDO/ Consortium
	0	None	None						

3.4 Additional interoperability concepts

In addition to the levels of interoperability, other attributes need to be considered, as required, as part of the solution. It should be noted that interoperability levels and risk levels are not equivalent; clinical context and risk levels are not equivalent. Medical devices can be part of many systems simultaneously, and those systems function at different levels of risk.

3.4.1 Plug-and-play

The phrase "plug-and-play" describes an advanced interoperability capability. Plug-and-play would enable clinical, technical, and business capabilities—many of which are currently lacking in healthcare—and often not described by clinical professionals in terms of interoperability per se, but in terms of a means to improve safety, efficacy, and workflow. Plug-and-play is also potentially the most challenging level of interoperability performance for product developers and standards organizations. Although plug-and-play capability could significantly reduce the burden of end-users such as physicians, hospitals, and patients, the infrastructure and interfaces needed to achieve plug-and-play are the most complete and may be difficult to achieve. In the Turnitsa (2005) interoperability model (see Section 3.3), plug-and-play is Level 5, "dynamic interoperability," the penultimate level of interoperability where the ontology is situationally dependent and interfaces include not only data and commands, but also relevant data on the state and intentions of the components. Plug-and-play requires high levels of cooperation and consistency among manufacturers, customers, users, SDOs, and regulatory bodies.

It is important to distinguish the strict technical view of plug-and-play, described above, from a misinformed vision of plug-and-play. Too often, the vision of plug-and-play has two medical devices plugged together doing everything medically valuable that one might imagine two devices of these types doing. Such a view, however, is a gross oversimplification of what plug-and-play can achieve. It does not incorporate the significant systems engineering, process, and planning that must be applied to specific clinical workflows and uses, and it does not recognize that interoperability and implementations in every domain require forethought and planning to enable specific purposes. It is important to define the clinical contexts within which a set of devices can interoperate and for what purpose, both individually and in concert. Open-ended plug-and-play, where any device could plug into any other device for any imagined clinical purpose, is not realistic; within carefully defined context, scope, and device requirements, however, real plug-and-play medical device interoperability is both achievable and valuable.

Plug-and-play interoperability will provide significant value for safety, efficiency, and reduction of healthcare costs. Former Secretary of Health and Human Services Mike Leavitt stated in 2005, as part of his remarks on the conclusion of the Commission on Systemic Interoperability, *Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology:* "We will move our healthcare system to the plug-and-play world. As a result of this move, we will see fewer medical mistakes, lower costs, better care, and less hassle" (Commission on Systemic Interoperability, 2005).

The experience of the consumer electronics industry in plug-and-play can be instructive. The core components of consumer electronics industry implementation of plug-and-play interoperability are well known. In some cases, a single vendor with market dominance creates and enforces a de-facto standard. IBM was able to do this with the first PC architecture standards, and this is still a popular business strategy with Apple and other companies. In other cases, a non-profit industry consortium or trade association is created (e.g. Bluetooth SIG, Wi-Fi Alliance). These organizations help to create the standards, but also other useful components such as testing, validation, and certification tools for interoperability. Consortia use member dues to create sharable implementation resources, such as design guidelines, and reusable software; they also own and manage trademarks that give consumers confidence that products will work together.

Unfortunately, a comparison of health care to consumer electronics can be misleading. It is not unusual for consumers to purchase devices and then experience significant problems in connecting devices that they expect to work together, but do not, or that require additional set-up effort and knowledge that most consumers do not possess. Some incompatibility problems are well known to both professionals and consumers (e.g., the HDMI incompatibility problems described in AV Forums [2011]). Finally, the cost of failure in consumer electronics is mainly in inconvenience, wasted time, and sometimes money spent on devices that will never achieve their promise. The cost in health care is potentially more severe, and includes patient injury and death. It is not that health care cannot learn

from consumer electronics, but such experience needs to be carefully applied within the requirements and expectations of the healthcare ecosystem.

Some of the benefits of interoperability are mentioned in a resolution by the American Medical Association (see below).

> *RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve optimum patient safety, efficiency, and outcome benefit while preserving incentives to ensure continuing innovation* (American Medical Association, 2011).

It should be noted that other industries, such as transportation, computer hardware, industrial controls, aviation, rail, and automotive, have safety and reliability concerns that in some cases equal or exceed that of healthcare. These industries have successfully applied systems, safety, and quality engineering principles to achieve plug-and-play interoperability of safety-critical components. The Continua Health Alliance has successfully applied the best practices of consumer electronics and other industries for plug-and-play interoperability in the health and fitness and personal healthcare market.

The challenges of plug-and-play interoperability in health care were recently described in the Networking and Information Technology Research and Development (NITRD) report, *High-Confidence Medical Devices: Cyber-Physical Systems for 21st Century Health Care: A Research and Development Needs Report*:

> *Another enabling technology … is the development of plug-and-play networking technology for medical devices. Plug-and-play capability is needed to ease the setup of integrated point-of-care and extramural arrays of medical devices that communicate with a patient's electronic health record.*
>
> *Devising the technology would require addressing concerns about privacy, security, safety, regulations, and technology. In hospital settings, for example, networks would form and reform frequently, as patients are admitted and discharged. Technology for the rapid formation of ad hoc networks needs developing. At the same time, authentication mechanisms would be needed to ensure that a device is on the correct network—and not, say, incorrectly attached to the one next door. Communication among devices would need to be made more secure than current wireless technology supports, and the problem of incorporating legacy devices must be addressed. Regulatory approaches ensuring the safety of open networks would need to be developed* (NITRD, 2009).

Achieving higher levels of interoperability (such as plug-and-play) in healthcare requires addressing the numerous device- and use-case-specific requirements around functions, safety, workflow, security, and regulation. These are exactly the same sort of requirements addressed by stand-alone medical devices. The effort required by a single manufacturer to enable safe end-user integration or connection of two of their own proprietary products is not substantially different from the effort that would be required by two different manufacturers to create plug-and-play interoperable devices, but it does require the cooperation and some level of consistency between medical device manufacturers, SDOs, clinician SMEs, regulatory bodies, and HDO customers. However, this can only be achieved with complete standards and within the well-defined workflows and carefully described uses of specific clinical scenarios

Plug-and-play does not imply that there would be no configuration effort, sometimes implemented by sophisticated or trained clinical or engineering end-users. This would be analogous to the configuration required by network printers or other network appliances in the IT industry.

Plug-and-play interoperability has significant challenges that will not be achieved in the short-term for all systems, but that does not reduce the importance of implementing open, interoperable interfaces with well-defined requirements and clinical purposes that are easy to configure and troubleshoot to enable the ecosystem to transition from closed, proprietary interfaces to plug-and-play.

3.4.2 Device models

The major challenge of getting devices to interoperate is not simply getting the devices to communicate, but getting them to communicate in a meaningful way. An analogy with oral human communication is instructive. Assuming that two people have functioning vocal and hearing apparatus, it is not difficult to see that one could talk and the other could hear. However, if they speak different languages, the communication cannot be meaningful. Just as importantly, some degree of shared experience and culture is necessary for one person to communicate effectively with another. In addition, the specific environment or context of the communication, as well as a specific representation or model of the parties participating in a conversation, is indispensable not only to meaningful communication but also to confidence that meaningful communication has occurred. Although devices do not have cultures or the richness or expressiveness of human natural language, there are analogs in device communication—what is commonly referred to as "device models," which have several facets:

- ***Information models:*** The creation of information models in informatics is a common technique used to facilitate a shared understanding of a domain of information. Information models are abstract representations of concepts or things, their semantics, attributes, relationships, and constraints. These models are often represented using a graphical language such as Entity-Relationship (ER) diagrams or, more commonly in the modern era, the Unified Modeling Language (UML). Information models help to ensure that when two or more entities are communicating, whether they are people or machines, there is a common understanding of the concepts being communicated. Examples of information models from healthcare informatics include the Health Level Seven (HL7) reference information model (RIM) (ANSI/HL7 V3 RIM, R1 [2003]) and the IEEE domain information model (DIM) (IEEE 11073-10201 [2004b). Common information models are necessary to achieving pragmatic interoperability.

- ***Dynamic models:*** Typically, information models are models of static concepts. Static models are often adequate when there is no need to characterize the behavior of the entities communicating. However, when it is important to understand not only specific protocol behavior but also how specific entities behave when communicating, a model of the dynamic behavior of the communicating devices is critical. Unlike ER diagrams, UML is well equipped for modeling dynamic behavior in the form of sequence diagrams, event flows, timing diagrams, activity diagrams, and state machines. Dynamic models are particularly important when communication involves not only the transfer of information, but also control when the behavior of the communicating parties will be directly influenced. Dynamic models help achieve dynamic interoperability.

- ***Run-time models:*** Unlike an information model or a dynamic model, a run-time model is not a different class of model but a derivative of the information and dynamic models. Rather than being a generic, abstract model of concepts, things, communicating parties, and their dynamic behavior, a run-time model is an internal representation of the specific entities involved in a communication. The run-time model is generated and updated dynamically as the devices operate, representing not only the behavior of peers in a communication but also the behavior of the device itself. A run-time model represents not how the devices should behave, but how they are behaving. Run-time models are important for allowing devices to adapt to actual conditions, and they facilitate graceful behavior in the face of the unexpected. An IEEE 11073 context scanner is an example of a run-time model.

3.4.3 Profiling

As important as standards like the HL7 (messaging) and IEEE 11073 (2004a; 2004b) series are in enabling meaningful communication, alone they are insufficient to achieve effective interoperability without extensive site- or device-specific work by skilled integration professionals and, sometimes, vendors. Standards are often the representation of a mutually acceptable intersection of capabilities of standards-development organization (SDO) member companies; the result is broad standards with very wide applicability and enormous amounts of flexibility, but insufficient specificity to achieve immediate interoperability for most, if not all, combinations of standards-compliant products. To address these challenges, "profiling" was developed.

Profiling is a technique by which a base standard, or a set of standards, is further restricted in flexibility or optionality in order to reduce the variability in implementation. This is possible because the profile is specified for a restricted use or set of uses. For example, there might be multiple profiles for HL7 messaging that use the same messages, but

restrict the messages in different ways to accomplish different tasks. The Andover Working Group (AWG), formed in the 1990s, profiled HL7 messages (Harrington, et al., 1998). Its successor, Integrating the Healthcare Enterprise (IHE), did the same thing for the Digital Imaging and Communications in Medicine (DICOM) standard and later expanded to other standards. IHE also effectively leverages multiple standards, drawing not only on healthcare-related standards but also on other, wider interoperability standards, like those of the Internet Engineering Task Force (IETF) and the Organization for the Advancement of Structured Information Standards (OASIS), among others. The Healthcare Information Technology Standards Panel (HITSP) used a similar approach to IHE, drawing on multiple standards in support of American Health Information Community (AHIC) clinical use cases. (The AHIC was a federal advisory body that made recommendations on health information technology.)

The profiles developed by IHE ultimately do not achieve the highest levels of interoperability for the same reasons standards groups do not: IHE takes what vendors support and build up from existing capabilities; it is difficult to match clinical user integration needs with technology suppliers that are able to work on standards and standards-based profile solutions; the profiles tend to rapidly evolve and are focused on the capabilities that vendors are interested in implementing. Also, because IHE standards are based on the availability of foundational standards, if there is a gap a profile cannot provide that missing capability. Often, profile development must be suspended to engage the appropriate standards group(s) to fill the gap before re-engaging the profiling process.

3.4.4 Design guidelines

Design guidelines are somewhat similar to profiling, in that they are narrow and have precise implementation rules, often built on existing standards. However, there are significant differences. Design guidelines are used in the clinical engineering industry and the Continua Health Alliance for PnP interoperability. In best industry practice, they are created using systems engineering concepts. The work begins with a complete scenario, use cases, user interactions, and workflows. Design guidelines include both functional and non-functional requirements. This is a top-down approach that can result in assured non-functional capabilities such as safety and reliability.

3.4.5 Architecture, process control, and safety

The required, *de facto,* or implied functional architecture (not product architecture) of HIT has implications for interoperability.

Component-to-component (pair-wise) interoperability (the interaction of two components of a system) can lead to complexity. Each new component increases the number of potential interactions exponentially. Even when interfaces are verified and validated, a large number of interactions makes assuring safe and effective interoperability a challenge—even defining safe operation is a challenge.

In hub-and-spoke functional architecture, medical device components interoperate only with the hub component (sometimes called a manager or aggregator). Consequently, as new components are added, complexity increases linearly rather than exponentially. Assurance of safe and effective interoperability is then a more manageable task.

Functional architecture is addressed in ASTM F2761 (see Section 4.3.4).

An integration methodology by which interface, integration, software, safety, functionality, and any implementation issues are collected in a single point responsible for documenting and ultimately improving all parties' implementation of interoperability might work over time to improve the safety and effectiveness of interoperability. Third-party consortia (e.g., the Continua Health Alliance) are able to implement this sort of continuous process improvement. Medical device manufacturers could also implement such a process, but are usually hindered by liability concerns that make them reluctant to publicly document interface errors.

3.4.6 Emergent, latent, and unintended properties

Functional properties are a product of system design. Non-functional properties are a product of the system architecture and the development process. Examples of non-functional properties include availability, performance, quality of service (QoS), reliability, safety, and usability.

Latent properties are capabilities that exist in a component. They might be unused, dormant, and undocumented, but were nevertheless intentionally created. A medical device with interface capabilities known only to the service and support employees would have, from an HDO perspective, latent capabilities.

Emergent properties are properties of a system arising from the interaction of the system's constituent components—properties that are not embodied by any of its components and not specifically accounted for in their design. Emergent properties are inherent in any complex system and, indeed, many non-functional properties of a complex system are naturally emergent. However, emergent properties can be unpredicted and unpredictable, and unpredicted properties cannot be assured to be safe or effective.

One of the major goals of systems engineering is to understand, characterize, and control emergent properties. This is particularly important for safety-critical systems, because an unintended and unanticipated system property could represent a safety risk. Without understanding the property, it is not possible to mitigate these risks. Systems engineering best practices develop requirements from the top down (i.e., starting from the clinical scenario and use cases) to eliminate unanticipated properties and control non-functional system properties. This approach also supports the development of safety and risk analyses and mitigations.

It should be noted that the boundaries of a system can be defined at different levels. Often it is necessary to consider a system to be composed not only of technological components but also of the people that interact with those components. In medicine, such people include the patient, clinicians, and, potentially, biomedical engineers and IT professionals; they can produce emergent system characteristics when interacting with medical devices. Predicting the responses of patients and others who interact with the system is sometimes more challenging than assessing the response of the hardware and software components and can limit the validation that can be achieved. Human factors engineering plays an important role in systems composed of both people and technology.

4 Current standards for point-of-care

4.1 Overview

This section presents a necessarily high-level overview of some of the more prominent medical device interoperability standards and standards-development organizations. These standards fall into several common patterns.

- ***Enterprise and departmental systems:*** Examples of these systems include EMR systems and clinical information systems, such as nursing flow-sheet systems, which treat point-of-care device data as material to be joined together with information from other sources for such purposes as clinical surveillance, archiving, and clinical-decision support. Communication from medical devices to such systems is usually indirect, through an intermediary or gateway, because few devices are capable of sending a widely understood, standards-based communications format without translation by an intermediary system.

- ***"First-hop" communication between individual devices and an intermediate point:*** An example of such a pattern is a gateway between the enterprise network and medical devices. Currently, almost all "first-hop" communications are transmitted by means of non-standardized vendor and device-model-specific legacy communications methods. Taming the wild heterogeneity of these systems by standards adherence could simplify life for healthcare facilities. "First-hop" communications form an element of all the enterprise-level communications of the previous category, as well as all more ambitious forms of interoperability. A sizeable business segment specializes in providing hardware concentrators and software drivers for these hundreds of one-off protocols. Additionally, most of these legacy protocols do not provide a documented way of getting information to, or influencing the operation of, the device. This is very understandable from the point of view of the manufacturer; however, the user can potentially harm a patient by making a mistake in programming. Outputs of parameters and controls are unfulfilled preconditions for many more ambitious interoperability use cases.

- ***Point-of-care integration:*** In this pattern, multiple devices collaborate intimately in the care of a particular patient, rather than being relatively simple, send-only data sources. These are the sorts of clinical scenarios that the ASTM F29.21 committee has advocated (see Section 4.3.4).

4.2 Basic top-level communication requirements

A good starting point for understanding basic top-level communications requirements is "Common Device Connectivity AHIC Extension/Gap," published December 31, 2008, by the Office of the National Coordinator for Health Information Technology (ONCHIT, 2008). These are high-level requirements. As discussed elsewhere, assured safe and reliable implementation of any capability requires a complete systems engineering approach not yet achieved by a healthcare SDO. The ONCHIT requirements are listed below.

A. The ability to configure and register a device to communicate with an EHR or other system.

B. The ability to associate patient identification and device information within an EHR.

C. The ability to communicate detailed measurement information to the EHR for effective patient monitoring and management.

D. The ability to support point-of-care integration to uniquely identify a device and related components and communicate device setting and detailed device information, associated with each measurement value, to the EHR.

E. The ability to communicate measurement intervals and device setting information within the EHR.

F. The ability to query the device or device intermediary for additional information captured by the device that may not have been communicated to the EHR.

G. The ability to communicate device and measurement information to the EHR when there is a lapse in EHR connectivity.

H. The ability to communicate standardized alarm types and alarm violation types to the EHR in near real-time.

I. The ability to set and communicate limits and safeguards for device settings from the EHR to a device.

J. The ability to wirelessly communicate point-of-care device information from the device to a device intermediary or EHR.

4.3 The players: standards-development organizations and others

4.3.1 IEEE Engineering in Biology and Medicine Society

The IEEE Engineering in Biology and Medicine Society has a long history of standards development in medical device communications, most notably as the developer of the IEEE 11073 series of standards. There are numerous standards in the IEEE 11073 suite, but the most important for purposes of this white paper are the medical device semantics standards, including the nomenclature standard ISO/IEEE 11073-10101, the domain information model standard ISO/IEEE 11073-10201,and the ISO/IEEE 11073-20101 Application Profile Base (format) standard. These standards are central to profiling efforts in other groups (e.g., the IHE Patient Care Device [PCD] Committee). The IEEE 11073 standards suite is also the foundation for home health communications standards, such as those developed by the IEEE 11073 Personal Health Devices (PHD) group and by the Continua Health Alliance. These include the ISO/IEEE 11073-20601a Optimized Exchange Protocol and IEEE 11073-104xx PHD specialization standards. It should be noted that, in general, all IEEE 11073 standards have also been officially approved within ISO and CEN, so that IEEE 11073 standards are harmonized within all three standards bodies.

Areas well covered by the IEEE 11073 suite of standards are medical device semantics (terminology/nomenclature + information model), operational setting and measurement reporting, device state reporting, alarm and waveform reporting, outbound data to devices, and outbound controls to devices. Areas that could usefully be extended include discovery and service enumeration over a common Internet Protocol (IP) infrastructure, as well as support of additional transports (e.g., web-based transports).

In the acute-care domain, the IEEE 11073 standards are frequently described as not widely implemented, but that is true only because relatively few vendors are currently using the standards, not because there are few implementations or few units delivered. Hundreds of thousands of such devices are operating in hospitals all over the world; user experience and appropriate regulatory approvals attest to their safety. As noted previously, however, the implementation—even the wide implementation—of a standard or section of a standard is not the same as interoperability.

The IEEE 11073 standards are sometimes also described as “too complicated”; however, this is a direct result of supporting full plug-and-play interoperability support for the complex and safety-critical medical networking context. Although some unfamiliar older standards are referenced in the construction of certain network packets, they are demonstrably not beyond the capabilities of programmers of ordinary abilities. Moreover, some quite small development organizations have proved that they can implement an IEEE 11073 interface for receiving medical device data reports in a few weeks. Nevertheless, because of the power, and the concomitant hazards, of multi-vendor interactions using these protocols, development, verification and validation, and release of fully standards-based implementations represent a very major engineering and economic commitment for a manufacturer, even one already familiar with the protocols.

4.3.2 Health Level Seven (HL7)

Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive 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. HL7's 2,300+ members include approximately 500 corporate members who represent more than 90 % of the information systems vendors serving healthcare.

HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of its stakeholders, including healthcare providers, government agencies, the vendor community, other SDOs and patients. HL7 and its members provide a framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information. These standards define how information is packaged and communicated from one party to another, setting the language, structure and data types required for seamless integration between systems. HL7 standards support clinical practice and the management, delivery, and evaluation of health services, and are recognized as the most commonly used in the world.

4.3.3 Integrating the Healthcare Enterprise (IHE)

4.3.3.1 IHE interoperability profiles

The HL7 standard aims at comprehensiveness in order to provide a method for the interchange of a wide variety of clinical data through messaging. That is in some ways a worthy goal, but it leaves considerable variation between applications that allow for a nearly infinite number of possible mismatches between messages that are compliant but cannot be processed by another system without an interface customization project.

One of the main reasons for the existence of IHE is to "profile" HL7 messages, that is, to narrow or constrain the wide range of implementation possibilities and options allowed by HL7 so that IHE-compliant systems have much more predictable content and form, with the goal of making them immediately and consistently interpretable by collaborating systems that are also IHE-compliant.

The IHE interoperability profiles are divided into subject areas (domains), which in many cases correspond to clinical and ancillary departments in healthcare institutions (e.g., radiology, cardiology, anatomic pathology, and so on).

IHE has a testing program in which the National Institute of Standards and Technology (NIST) is a key contributor. Chiefly for political, legal, and liability reasons, IHE has avoided upgrading this program to the level of a certification program.

4.3.3.2 IHE information technology infrastructure (ITI) domain

The broadest in scope of IHE domains, the one on which all others depend, is the information technology infrastructure (ITI) domain. ITI creates profiles of baseline information technology, like time synchronization, which is a precondition to the proper operation of all healthcare information systems and is particularly critical in relation to PCD data. The ITI domain further specifies the communication of patient identity data (admission, discharge, transfer, patient index, and the like), general-purpose document transfer and indexing, security and privacy data, and many other types of information.

4.3.3.3 IHE patient care device (PCD) domain

The IHE PCD domain deals primarily with profiling standards for communication of data from regulated acute-care medical devices. Up to the present, it has primarily dealt with communication of device data from devices or gateway information systems to departmental or enterprise-wide information systems accepting device data. Its key profile in this area, Device Enterprise Communications, covers the transmission of device data to EMRs, clinical decision support, and other hospital systems. Part of the key value of this PCD profile and others comes from the standardization of nomenclature for device measurements, alarms, events, and device attributes in Rosetta Terminology Mapping (RTM), which is based on the IEEE 11073-10101 nomenclature. In collaboration with IEEE and NIST, the Rosetta team is engaged in a long-term program for terminology maintenance and for harmonization with other terminology standardization efforts, such as the Regenstrief Institute's Logical Observation Identifiers Names and Codes (LOINC) and the International Health Terminology Standards Development Organisation's (IHTSDO's) Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT).

There is a PCD subgroup that works on safe communications for use cases involving infusion pumps (Point-of-Care Infusion Verification).

For transactions to support the association of patient identity and demographic information, the IHE PCD relies mainly on the relevant ITI profiles, but there is also a profile activity in progress dealing with specifically device-related aspects of the patient identity problem.

A large part of standards-development efforts associated with the PCD domain is connected with conformance testing for its profiles. This conformance testing is conducted in collaboration with NIST (see Section 4.3.7).

Table 2 shows the implementation status of the various IHE PCD profiles and technical frameworks relative to the original ONCHIT requirements and other device connectivity requirements. Figure 1 shows the IHE profiles and the underlying connectivity standards that were demonstrated at HIMSS11 as trial implementations for clinical device connectivity. Figure 2 shows the available Continua Health Alliance guidelines (see Section 4.3.8) related to personal health device connectivity.

Table 2—Implementation status of IHE PCD profiles and technical frameworks relative to ONCHIT and other device connectivity requirements

Requirement	IHE PCD[3)]
ONCHIT Requirements[1)]	
A. The ability to configure and register a device to communicate with an EHR or other system.	[ADQ]
B. The ability to associate patient identification and device information within an EHR.	PAM/PDQ [PCIM]
C. The ability to communicate detailed measurement information to the EHR for effective patient monitoring and management.	PCD-01
D. The ability to support point-of-care integration to uniquely identify a device and related components, communicate device setting and detailed device information, associated with each measurement value, to the EHR.	PCD-01
E. The ability to communicate measurement intervals and device setting information within the EHR.	PCD-01
F. The ability to query the device or device intermediary for additional information captured by the device that may not have been communicated to the EHR.	[ADQ]
G. The ability to communicate device and measurement information to the EHR when there is a lapse in EHR connectivity.	option
H. The ability to communicate standardized alarm types and alarm violation types to the EHR in near real-time.	ACM
I. The ability to set and communicate limits and safeguards for device settings from the EHR to a device.	
J. The ability to wirelessly communicate point of care device information from the device to a device intermediary or EHR.	option
Additional Requirements Not Cited by ONCHIT	
The ability of a device to report its entire set of capabilities and configuration to another device or information system (ISO/IEEE 11073).	
The ability of another device or information system to provide measurement or device state information to a point-of-care device (ISO 11073 and HL7).	
The ability for therapeutic actions to be controlled from another device or information system.[2)]	PIV

1) Other capabilities specified in the ONCHIT (2008) device connectivity requirements, such as bidirectional EHR–medical device communication for patient safety, have not yet been demonstrated by the IHE standard or the ISO/IEEE 11073 series.

2) Further elaboration is likely to be desired. Safety and V&V aspects will challenge multiple SDOs and, of course, the regulatory agencies.

3) Brackets [ ] are used here to indicate a draft PCD profile or standard, rather than a mature and implemented profile or standard.

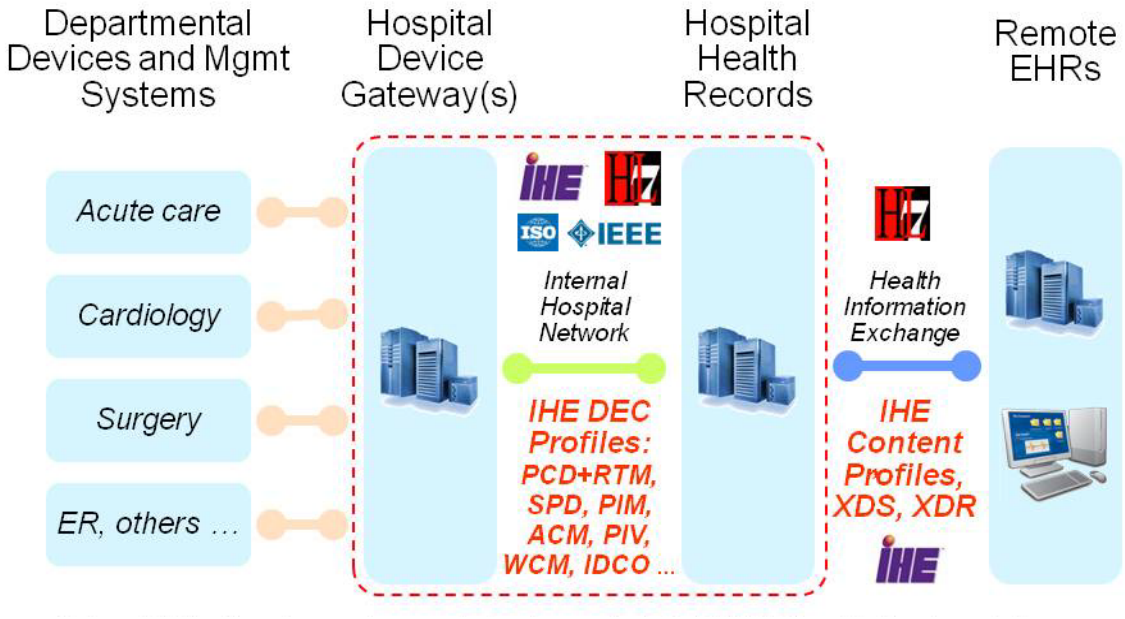

Figure 1—Clinical device connectivity: IHE profiles being demonstrated at HIMSS11 and underlying standards (Schluter and Sloane, 2010)

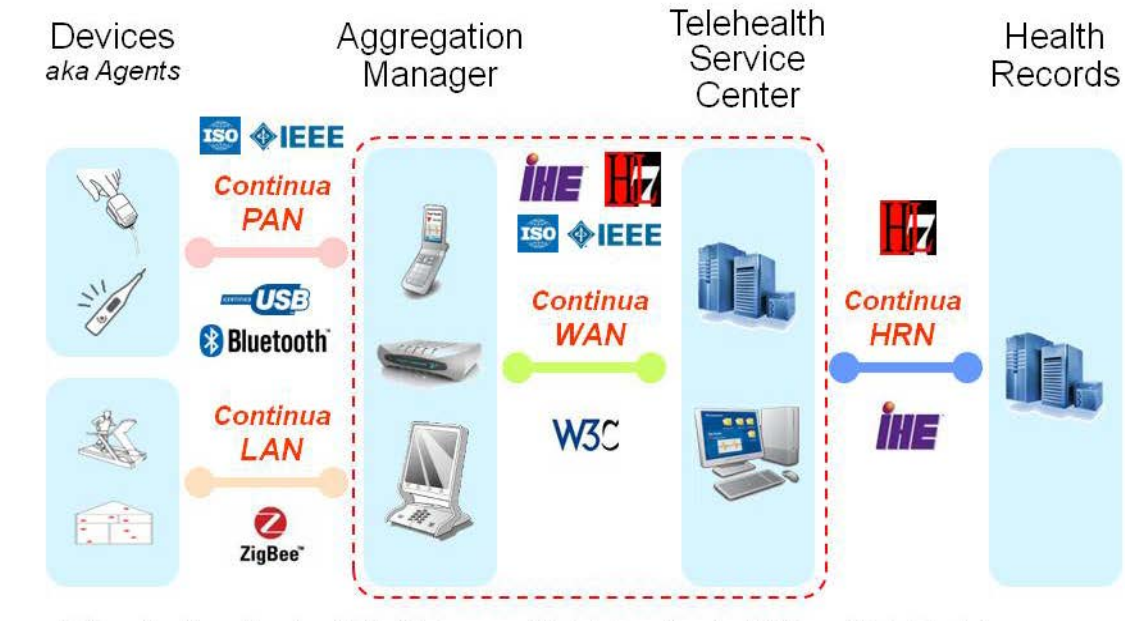

Figure 2—Personal health device connectivity: Continua Health Alliance guidelines (see Section 4.3.8) (Schluter and Sloane, 2010)

4.3.4 ASTM Subcommittee F29.21

ASTM Subcommittee F29.21, “Devices in the Integrated Clinical Environment,” under the auspices of the MD PnP program, developed 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.* Published in 2009, this standard provides a high-level system architecture for medical device interoperability and references specific clinical scenarios. The ICE functional architecture involves a network controller interacting with devices (potentially using multiple communications protocols), a higher-level supervisory subsystem interacting with the clinical user, and control and safety features. This functional infrastructure is intended to support clinical “apps” such as safety interlocks, real-time decision support, and closed-loop control, as well as comprehensive data acquisition for adverse event analysis and equipment management. Additional parts of the standard are planned to further specify details.

It is important to note that the ASTM F2761 architecture is not a product architecture, but a functional architecture that provides a framework for describing the functions necessary to safely support medical device interoperability in patient-centric applications. The standard covers data logging, which is necessary for forensic analysis of adverse events and for the resolution of quality, safety, technical integration, and support issues across the spectrum of care.

The development of the technical content of the standard was supported in part by Massachusetts General Hospital’s MD PnP (Medical Device "Plug-and-Play" Interoperability Program) and by Partners Healthcare and the Center for Integration of Medicine & Innovative Technology (CIMIT) in Boston. It was federally funded through research projects. The research program is also supported by a 5-year National Institutes of Health/Strategic Health IT Advanced Research Projects (SHARP) grant to develop high-acuity medical device interoperability solutions to improve clinical care and to advance related standards and technology. Additional funding at all levels—basic research, implementations, technology development—is currently being provided by NIST, the National Science Foundation, and the Department of Defense in order to advance development of ICE-compliant technologies.

4.3.5 ISO Technical Committee 215

The ISO/TC 215, Health informatics is the central venue for international standards relevant to HIT. Working Group 7 specifically addresses standards for medical device interoperability. To date, at least 93 standards have been published under the purview of ISO/TC 215, including the ISO/IEEE 11073 series. ISO/TC 215 supervises the work of nine Working Groups, which develop standards in the following areas:

- Data structure
- Data interchange
- Semantic content
- Security
- Pharmacy and medicines business
- Devices
- Business requirements for EHRs
- SDO harmonization

4.3.6 (UL) Underwriters Laboratories

UL has recently initiated a new standards activity in medical device interoperability: BSR UL 2800, *Standard for safety of interoperable medical devices interface standards (IMDIS) and guidelines.* This standard would define the safety and related specifications of medical device interfaces required when a device is declared an interoperable medical device. The standard will address the available medical device interface characteristics needed to operate under safe interoperable conditions. The standard will focus on the safety and risks mitigation associated with the interoperability of the medical device interface within an ICE implementation.

UL has extensive experience in providing services and creating standards in many areas, most relevantly including medical device manufacturer quality system education and consulting, embedded software development methodology, and infusion pump safety.

4.3.7 DICOM ISO 12052:2006

Within the field of health informatics this ISO 12052:2006 addresses the exchange of digital images, and information related to the production and management of those images, between both medical imaging equipment and systems concerned with the management and communication of that information.

ISO 12052:2006 is intended to facilitate interoperability of medical imaging equipment and information systems by specifying the following:

- a set of protocols to be followed by systems claiming conformance to this International Standard;
- the syntax and semantics of commands and associated information data models that ensure effective communication between implementations of this International Standard; and
- information that shall be supplied with an implementation for which conformance to this International Standard is claimed.

4.3.8 National Institute of Standards and Technology (NIST)

U.S. National Institute of Standards and Technology projects for advancing medical device communications include:

- collaboration with IHE on test tooling for conformance of HL7 messages to IHE PCD domain profiles; and
- collaboration with IEEE 11073 committees, the IHE PCD Device Point-of-Care Integration Work Group, and the Continua Health Alliance on software tools for constructing models of device capabilities and on conformance test tooling.

See (NIST, 2011).

4.3.9 Continua Health Alliance

The Continua Health Alliance is a non-profit industry consortium that takes a systems-level approach to home health interoperability. The Alliance does the following:

- gathers clinically relevant use cases;
- selects base standards;
- develops detailed implementation guidelines (see Figure 2, earlier in this chapter);
- conducts a testing and certification program;
- collaborates with regulatory authorities to clarify regulatory requirements; and
- markets and promotes a Continua logo that has wide recognition in the industry.

The Alliance has adopted the successful consumer electronics plug-and-play interoperability business model to use member dues to help create shareable resources and a self-sustaining business ecosystem. Although still relying heavily on volunteer effort, the Alliance's membership of more than 260 companies is sufficient to allow for use of consultants and vendors when appropriate.

The result of this effort is that there are now 28 certified Continua products representing 10 different device types. Eight products were approved in 2009, eleven in 2010, and nine in the first 6 months of 2011 (Continua, 2011).

4.3.10 IEC Technical Committee 62

IEC TC 62, Electrical equipment in medical practice, was established in 1968. It has four SCs (Subcommittees) that deal with very distinct domains and issue all its publications.

The preparation of International Standards for the design and production of electrical medical equipment requires the participation of many experts from the medical professions, industry, health-care establishments, the IT (information technology) and software worlds, and regulatory bodies. All take part or are represented in TC 62 and its SCs.

IEC/SC 62A is involved in a joint working group with ISO/TC 215 that develops standards information technology (IT) networks incorporating medical devices.

4.3.11 West Wireless Health Institute

The Institute's mission is to lower health care costs through technology and innovation. Founded in March 2009 by the Gary and Mary West Foundation, the independent nonprofit medical research organization is dedicated to innovating, validating, and advocating for the use of technologies including wireless medical devices to transform medicine.

The West Wireless Health Institute is committed to addressing the most pressing need in health care today—affordability. To accomplish its mission of lowering health care costs, the Institute aims to catalyze a whole new ecosystem for low-cost health care innovation. The Institute is one of the only organizations in the world leading this charge. Interoperability is a critical component to lowering the cost of health care. Innovation at the Institute is focused on and is being translated into end-to-end solutions to meet the needs of patients, doctors and health care organizations—and with the rigor to ensure that these solutions are safe, secure, reliable and cost-effective.

5 Recommendations to AAMI

5.1 Overview

HITI believes that AAMI can make significant contributions to medical device interoperability by focusing on its strengths:

- A strong clinical focus
- A long history in safety-based process and product standards
- Excellent working relationships with healthcare providers, medical device manufacturers, and other SDOs
- Knowledge of best practices for verification and validation
- Multi-disciplinary expertise

There are a large number of important and successful medical device interoperability, technology, engineering, and communication standards, and other work products. AAMI should not duplicate the work of IEEE, ASTM, IHE, DICOM / ISO 12052, or other ISO work, but should instead develop standards focused on specific clinical scenarios, leveraging existing technical interoperability standards when appropriate. Component and communication standards are not enough to attain the level of interoperability needed for the future of patient care. Newly developed system level standards, certification and independent accreditation could pave the way to the level of interoperability required to enable clinical decision support and other advanced care models involving interconnected medical devices. AAMI standards would be based on specific clinical functional requirements (use cases) and on non-functional requirements such as QoS, quality of measurement (precision and accuracy), and, most importantly, safety. Moreover, they would be based on a complete systems-level approach, follow systems engineering best practice, and incorporate standards for user interaction, patient interface, and device-to-device interoperability. The primary emphasis would be on ensuring that the resulting composite device can operate safely and effectively for a specific intended use. For example, if AAMI were to develop a standard to address the PCA clinical scenario (see Section 1.8), such a standard would describe the essential performance requirements for such a composite system: performance, QoS, and interoperability for each part of a composite solution. Standards like these might be recognized by regulatory bodies (e.g., the U.S. FDA), creating a uniform approach for ensuring the safety of composite systems.

HITI envisions an entire family of AAMI standards, each targeted at specific important clinical uses. These standards would draw on the same, or substantially similar, technically oriented interoperability standards—standards that are orthogonal to the AAMI-developed, clinically-based standards.

For such standards to be successful, there must be efficient and efficacious regulatory pathways for the approval of composite devices developed using these systems-level standards. Device manufacturers are already capable of creating composite devices using proprietary or standards-based interoperability standards, amongst their own devices or in close collaboration with business partners. However, such composite devices do not provide for the creation of open, multi-vendor composite devices, and they follow the same regulatory pathways as any medical device. Indeed, the current approach allows for no distinction between “medical device” and “composite medical device.”

There is nothing wrong with such an approach, and device manufacturers do avail themselves of it. Unfortunately, this approach is not conducive to promoting the creation of innovative composite devices that meet urgent clinical needs, facilitated by the creation of rapid and affordable new clinical applications. A regulatory pathway that permits the creation and use of after-market composite devices is needed. Otherwise, manufacturers will not commit to building devices adhering to systems-level standards for composite devices, because there would be no market for such capability. Close involvement and commitment from regulatory agencies, particularly the U.S. FDA, is required. Fortunately, The Continua Health Alliance and The Center for Integration of Medicine & Innovative Technology (CIMIT) have convened two committees to address the regulatory pathway for interoperable medical devices: a group

formed to develop prototype regulatory submission and the follow-on Medical Device Interoperability Safety Working group. AAMI should cooperate with these efforts.

Finally, standards and appropriate regulatory pathways are required but not sufficient to ensure success. There is a need to establish certification and accreditation processes and bodies, as well as educational programs. AAMI should rely on existing standards, profiles, design guidelines, systems level essential performance standards, best practices, and certification processes for composite devices. AAMI will identify gaps and develop clinical deliverables as necessary. While making contributions to systems-level, essential performance standards for composite devices, AAMI should cooperate with other groups to leverage their expertise. It is not in AAMI's best interest to compete with other organizations. Much more can be achieved through collaborative relationships.

5.2 Standards collaboration

In collaboration with other SDOs, AAMI will need to recommend appropriate standards for specific clinical uses. In situations where no standards exist, or existing standards are inadequate, AAMI will need to work with other SDOs to develop, supplement, or modify underlying standards; duplication should be avoided. AAMI and other SDOs could play the following roles:

- **AAMI:** systems-level standards, use cases, patient safety, V&V methodology, and technical education. AAMI could provide guidance to other SDOs on important clinical scenarios and promote the testing and improvement of clinical performance in composite devices.
- **ASTM:** high-acuity clinical use case development; requirements and architectural development for systems to serve safety interlock, closed-loop control, and related needs. ASTM F2761 architecture provides for the application of systems engineering best practices, compartmentalizes functions that enable key regulatory pathways, and provides a framework and technical environment for third-party clinical "app" development.
- **HL7:** enterprise integration, messaging and clinical documents.
- **IEEE:** device communication, nomenclature, and device models.
- **IHE:** profiling, enterprise connectivity, demonstration, and testing frameworks and tools.
- **ISO TC 215:** support of selection, continued development, and international propagation of ISO/IEEE 11073 standards.
- **UL:** testing and certification.
- **DICOM/ISO 12052 and NEMA/MITA:** image and clinical information interchange for image and radiotherapy. Interoperability for medical imaging and radiotherapy.
- **West Wireless:** Validation of new technologies using clinical and economic methods demonstrating safety, effectiveness and cost savings, advocacy, and promotion of innovation—particularly for wireless applications.

5.3 Verification and validation

Although it is tempting to think that any set of devices conforming to standards could be assembled to achieve a clinical purpose, ensuring that the resulting composite device is safe requires additional V&V effort. Normally, V&V is performed by a manufacturer when assembling a composite device, but in this case there is no manufacturer. HITI recommends that AAMI also develop process standards to ensure that specific combinations of conforming devices can be operated safely. Other organizations, including healthcare providers, can then implement the process and publish the results so that providers can be assured that specific combinations of assembled devices are safe.

5.4 Process and organizational structure

Because clinically based standards will apply to a wide variety of devices, AAMI will need to draw on multiple committees for expertise. It is likely that most of these standards will be developed through a joint working group

structure and will require formal liaison relationships with other SDOs. AAMI can provide broad and deep coordination of these efforts so that the resulting standards are part of a complete systems solution.

AAMI will also have to develop internal processes for collaborating with other SDOS, for selecting and profiling interoperability standards, and for coordinating committees in the development of systems-level standards for composite devices.

5.5 Advantages

The HITI recommended approach has many advantages and solves several problems:

- ***It solves real clinical needs:*** There are clinical uses that are currently not well supported by individual vendors or by medical device interoperability standards.
- ***It ensures safety:*** Although individual vendors can safely develop and support composite devices for clinical uses, it will be necessary to use systems engineering best practices to validate multi-vendor composite devices.
- ***It leverages existing work in medical device interoperability while avoiding duplication of effort:*** By focusing on clinically-based standards and safety, AAMI is free to rely on and leverage existing, well developed technical interoperability standards.
- ***It encourages uptake of existing interoperability standards:*** If standards address specific and real clinical needs, providers will request interoperability functionality, thereby creating economic incentives for vendors to leverage interoperability standards.

This approach also addresses the challenges identified in section 1.4:

- **Each new device integration is a custom installation requiring significant effort by implementers, even with widely accepted and widely used standards like HL7.**

  Custom integration effort will be minimized by the development of essential performance standards to which medical device vendors build; accreditation bodies validate and certify specific combinations of devices. HDOs can have confidence that these composite systems will be safe and effective.

  By developing essential performance standards to which medical device vendors build and that certification and accreditation bodies use for validating specific combinations of devices, custom integration effort will be minimized. HDOs can have confidence that these composite devices will be safe and effective.

- **Clinicians desiring to use a set of interoperable devices to fulfill a clinical need must wait for application vendors to develop new "drivers".**

  Clinicians can rely on a common set of essential performance standards and devices compliant to them. No individual vendor is required to develop the entire suite of capabilities for urgent clinical requirements.

- **The complexity of device interfacing hinders research that could lead to improved patient care.**

  While existing essential performance standards are unlikely to meet the needs of researchers exploring new applications, the existence of essential performance standards and certification and accreditation processes and organizations will encourage the development of medical devices designed for interoperability. A culture of medical device interoperability in the medical device marketplace will help accelerate research into new clinical applications.

- **The software-development effort and on-site customization required to integrate devices can create quality and performance issues that might lead to unsafe conditions.**

  Essential performance, systems-level standards will describe not only the requirements for individual devices, but also requirements for the entire composite device. Systems engineering discipline in the

development of standards will enhance quality and safety; effective certification and accreditation infrastructure will help enforce it.

- **System integration services are very costly to HDOs.**

  Alone, medical devices designed for interoperability would reduce integration costs. However, standards describing the essential performance requirements of composite devices that meet the requirements for specific clinical scenarios enable any third party to integrate standards-compliant devices.

- **There is reduced assurance that all data are accurate and complete.**

  Essential performance standards would describe the necessary conditions and context for accurate and complete operation.

- **All of the data required to address a clinical scenario might not be available, regardless of the integration effort expended.**

  Essential performance standards would describe the preconditions for data availability.

- **Attempts to solve problems lead to finger pointing rather than solutions.**

  While the impulse to assign blame for integration problems cannot be completely eliminated, well-defined standards that describe the required operation of individual devices, as well as the composite, will greatly reduce uncertainty as to which device may be causing a problem in integration.

- **There is too much complexity in maintaining each link in the communication chain.**

  A standard would describe not just the underlying interoperability standards, but also constraints on how those standards are used. The performance entire composite device would be described and tested.

Finally, this approach fully utilizes AAMI's unique strengths. AAMI is uniquely qualified to develop standards requiring clinical, safety, and device expertise.

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