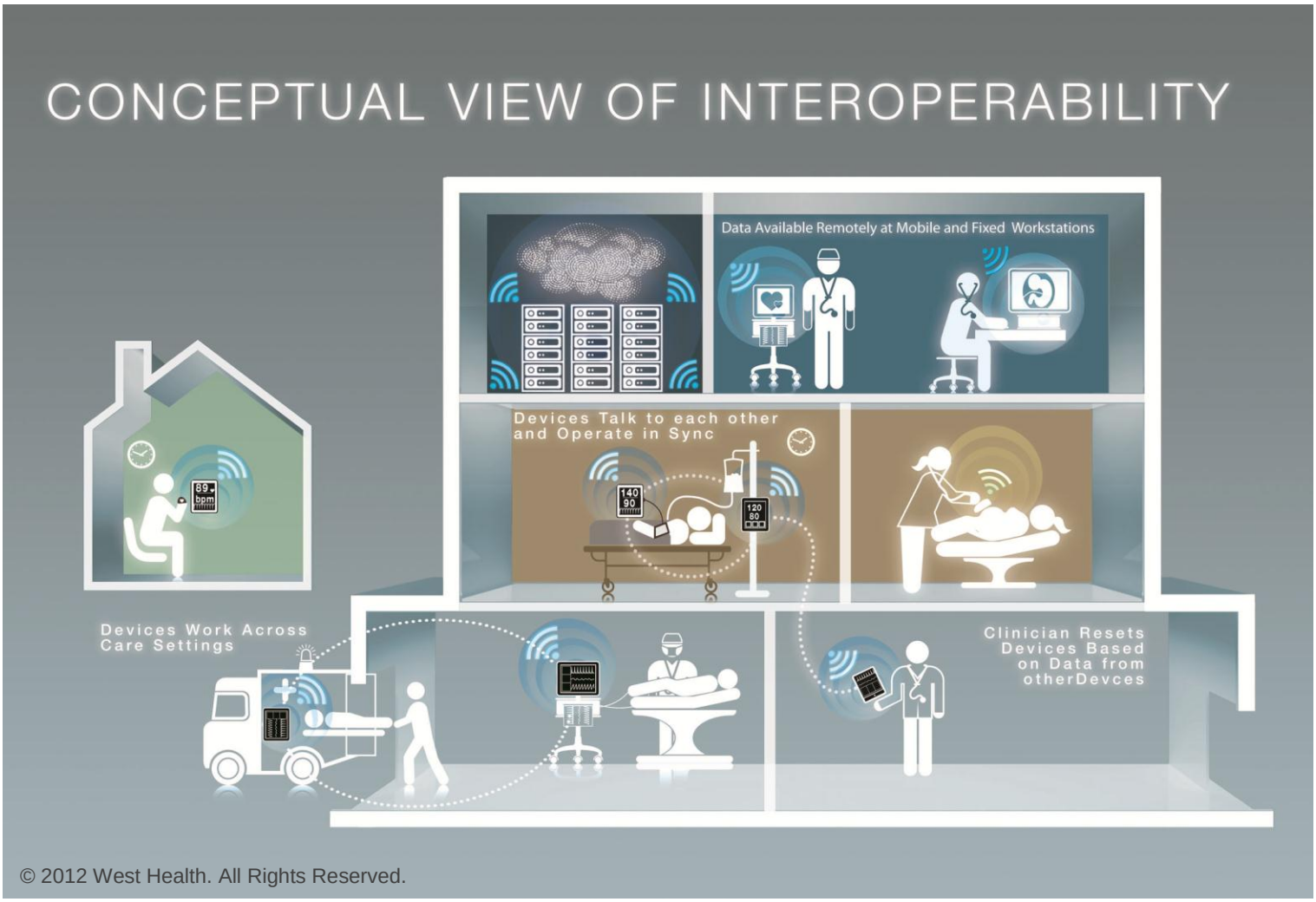
Advancing Wireless Medical Device Interoperability: Overview of Current Efforts

Introduction

Interoperability is one of the more daunting challenges facing the integration of advanced technologies in health care. Interoperability involves many complicated layers of functional and technical requirements, and has many practical, technical, and commercial implications that influence implementation and adoption. However, interoperability is **a key enabler of improved health care delivery**, and has become an imperative that numerous entities are now dedicated to making a reality. The objective of this paper is to overview efforts to advance interoperability within the context of **wireless medical device technology**.

What Is Interoperability?

Carefully considered, the definition of interoperability is contextual – and might appear to preclude a single definition. This paper takes as a working definition that wireless medical device interoperability can be said to exist when all relevant information is available whenever needed regardless of setting, and all desired interactions between disparate agents (devices, systems, individuals) are enabled by effective (timely, safe, secure) communication.



Why Interoperability?

The interoperability value proposition includes improved clinical safety and health outcomes, and more efficient care delivery at lower cost. Much of the dysfunctionality in contemporary health care delivery is marked by balkanization of information into non- or poorly interacting silos. Electronic medical records (EMRs) were initially touted as the vehicle by which broad and seamless exchange of health care information would be achieved. However, they have evidenced the same sort of dysfunctionality that inspired their creation, and have automated the process of confining information within proprietary networks, thus falling short of early expectations to create an interoperable network. This has resulted in needless, costly and time-consuming repetition of different elements within the clinical care paradigm; sub-optimal individual patient care; compromised clinical safety; and, ineffective population health management. Furthermore, the absence of fully integrated and timely data has frustrated the ability to use advanced analytics on

aggregated data sets to test and validate existing models of care, or develop learning systems of care.

There is growing need for predictable, reproducible and dependable ways to drive effective functional interaction between agents across the system. The growing acceptance (and soon ubiquitous use) of wireless medical devices provides a second chance to create an interoperability solution that has thus far eluded EMRs. Individual device manufacturers may create vertical integration within their product lines, but horizontal interoperability is required to break the stranglehold of silos and create a safer, functionally interactive and more efficient macro environment. This imperative increases in urgency as our current health care delivery model shows signs of financial and logistical unsustainability, with an undeniable need for us to 1) exploit the efficiencies of automatic, integrated and learning system architectures that have effectively revolutionized many other industries; and, 2) integrate remote diagnostics and titratable therapies into the management of chronic disease in non-traditional settings (home, office, etc.) – a model of "Infrastructure Independent" care[1].

This new model of infrastructure-independent care is enabled by the ubiquitous availability of low-cost wireless communication and can be contrasted with the prevailing approach to care as follows:

Current Model	*Infrastructure Independent Model*
Low frequency visits	High touch
Acute-care focused	Right treatment
Appointment driven	When patients need it
Location centric	Where patients are
High cost	Low cost

The infrastructure-independent model of care is one in which health care delivery is extended on a foundation of wireless health technologies to become preventive, continuous, supportive and ubiquitous. This model enables providers to more efficiently and effectively care for patients, leading to improved health outcomes and lower costs. The vision of infrastructure independence includes the following scenarios:

- An individual uses a smartphone application for a medically validated weight-loss and fitness program specifically aimed at preventing diabetes.
- A heart-failure patient is discharged from the hospital and is monitored and supported by wireless technologies to prevent being readmitted.

[1] *http://www.westwirelesshealth.org/index.php/wireless-health/infrastructure-independence*

- An individual in a hospital is able to have the settings of an infusion pump adjusted automatically in response to a change in a biometric value (such as blood pressure) without having to wait for a human to directly intervene.
- A frail elder is monitored in her home to ensure she is eating properly, taking her medications, and that she is not at risk of a fall, all as a means of enabling her to remain at home and away from institutional long-term care.

The building blocks of infrastructure-independent care are:

Ubiquitous telecommunications
Communications infrastructure for all, regardless of location, is imperative. To support future data transmission needs, it must continue to rapidly increase bandwidth and coverage. Recognition of this is reflected in the growing pervasiveness of fourth-generation cellular and data services between settings, and maturing technologies such as Wi-Fi and Bluetooth within settings.

Sensors
Safe, reliable, wireless sensors can assess biometrics such as weight, blood pressure, blood glucose, blood oxygenation and blood coagulation. Sensors offer further value in their ability to provide other actionable diagnostics for common ailments whose management can be greatly improved by more frequent monitoring of disease activity and more accurate tailoring (course correcting) of potent therapeutics (e.g., malignancies, auto-immune diseases, neurodegenerative diseases). Even an individual's environment and behavior can provide useful and actionable insights, particularly in the case of asthmatics and the frail elderly.

Advanced Analytics
Rapidly evolving analytics technologies can transform data from sensors and subjective assessment of patient risk factors into actionable knowledge and provide superior decision support not only for clinicians, but also for patients and their informal caregivers. These technologies can facilitate interactions between medical devices that ultimately could lead, for instance, to dynamic adjustment of medication dosing based on a measured change in a biometric value such as weight or blood pressure. They may also provide valuable input to clinical trials, and tertiary drug interaction and adverse reaction networks.

Data Sets
Large and growing data sets at both the individual and population levels that are mined to continually enhance the detection, assessment and management of a wide array of medical conditions.

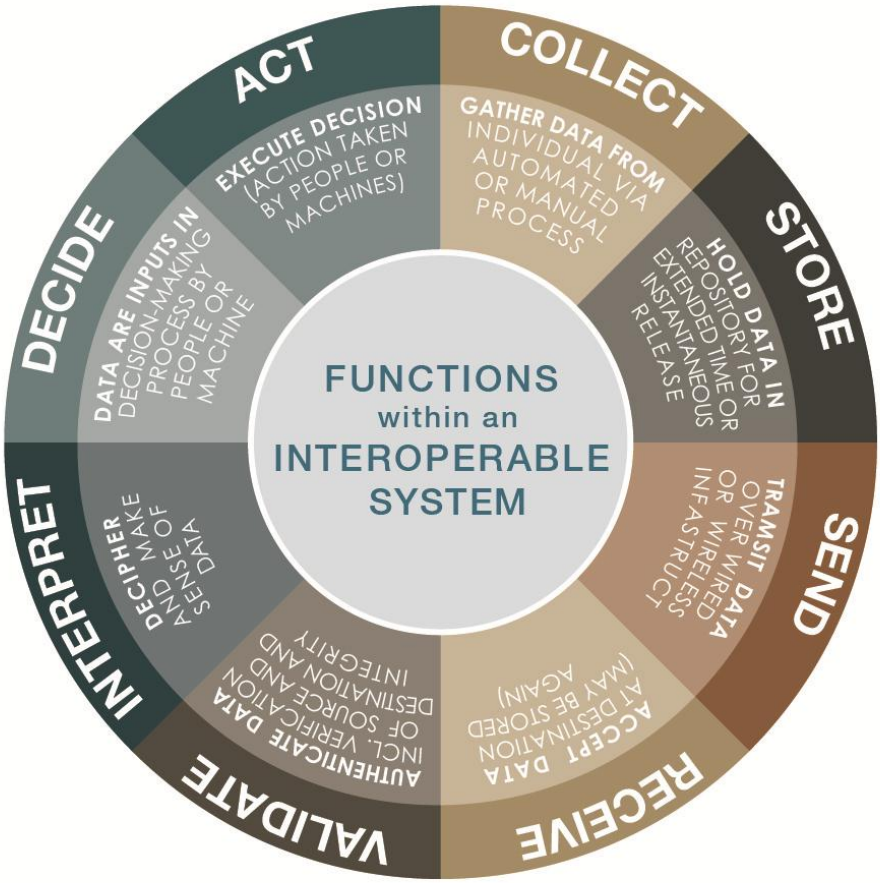
Interoperability – ensuring relevant information is readily available to all agents regardless of setting – is necessary to realize the full benefits of infrastructure-

independent care. A first tangible and addressable step in the path to overall interoperability is the relatively narrow case of wireless medical device interoperability, which has the greatest near-term potential to create the "Infrastructure Independent" environment.

What Is Wireless Medical Device Interoperability?

Wireless medical device interoperability is a critical enabler of infrastructure-independent care. Independently operating medical devices are typically designed for specific and narrowly defined outcomes. They do not consider the larger context that often includes information from other medical devices that, if available and appropriately integrated, would enable improved outcomes. With increasing availability and adoption of independent (stand-alone) devices, not only has the opportunity for improved outcomes via effective interoperability grown, so too has concern regarding the potential perils of multiple independent systems inadvertently 'conspiring' to cause harm. Ubiquitous wireless communication affords a low-cost communication channel through which interoperability of otherwise independent medical devices could be achieved. **It is clear, however, that the large and growing opportunity to improve effectiveness via interoperability and decrease the safety concerns associated with a growing plurality of independently acting and potentially confounding devices *will not come about spontaneously – it requires positive, proactive effort.***

To facilitate ease of understanding, wireless medical device interoperability can be considered by focusing on the functions involved. In basic terms, the functions that comprise an interoperable system include the following: collect, store, send, receive, validate, interpret, decide and act. Within each of these functions are multiple layers of sub-functions, which are often nuanced depending on the context in which they operate.



In addition to considering the basic functions that are necessary to achieve interoperability, it is important to contemplate degrees of interoperability. A prominent framework for this is the Levels of Conceptual Interoperability Model (LCIM), in which each level progresses toward a fully interoperable state. This model describes the need for communication infrastructure and protocols; common data structures and formats; shared meaning of data and word definition; shared understanding of the context in which data are applied; systems to take advantage of changes in state, including effects on data interchange, that occur over time; and, alignment of assumptions and constraints related to data exchange. Other models address organizational and social issues, which are equally important contributors to the success or failure of interoperability efforts.

With the foregoing acknowledgement of the detailed technical considerations required for technical interoperability, for purposes of this paper, we identify five ***functional*** levels of interoperability of wireless medical devices.

1. Device **transmits** details of its functions and available data.

2. Device **receives** details of other device functions and data.

3. Device **integrates** information from another to alter its behavior.

4. Device **allows for control** by another device.

5. Device **assumes control** of another device.

It is worth noting that the number and nature of actors involved in the direction of information exchange associated with each functional level of interoperability may vary. For example, there could be a consolidated display of transmitted data from multiple devices, or a single device could transmit to several other devices. Similarly, it is contemplated that the levels of interoperability may not be static, but instead vary with use case or in response to clinical/professional interaction.

Devices are most useful when they act in concert to positively change care. For example, attainment of a specific clinical end point can be optimally reached by modulating the device providing therapy based on knowing that end point. An infusion pump that dispenses blood pressure control medication would be far more effective (in both timing and dose) if it knew the patient's blood pressure, which it could directly obtain from a blood pressure cuff. In order for devices to operate differently by virtue of data learned from another agent, they would have to know the source providing that data. For this example, not all devices measure blood pressure the same way, so the infusion pump would need to be able to recognize the source device.

Who is Addressing Interoperability?

Several entities ranging from government to industry to traditional standards bodies are involved in the effort to advance medical device interoperability. The following chart offers a high-level snapshot of their activities:

	Organization	Objectives Relative to Medical Devices	Focus	Creates Standards
AAMI	Association for the Advancement of Medical Instrumentation	Develop Interoperable Medical Devices Interface Standards (IMDIS)	• Clinical use cases • Safety • Quality	X
AdvaMed	Advanced Medical Technology Association	Further standards efforts	• Touches multiple aspects	
AHIMA	American Health Information Management Association	Promote standards for EHRs and HIEs	• Health ICT	X
ANSI	American National Standards Institute	Promote voluntary consensus standards	• Touches every sector	X
ASTM International (ASTM ICE) ***Integrated Clinical Environment***	Formerly American Society for Testing and Materials	Integrate devices and other equipment in clinical environment	• Patient safety in high-acuity clinical care	X
Continua	Continua Health Alliance	Certify that personal health devices are interoperable	• Personal Connected Healthcare	
HITSP	Healthcare Information Technology Standards Panel	Develop interoperability specs for EHRs, including transfer of remote monitoring data	• EHR data exchange	X
HL7	Health Level Seven International	Integrate health care device information at enterprise level	• Message exchange • Terminology	X
IEEE	Institute of Electrical and Electronics Engineers	Develop communications standards for LANs and MANs; promote automatic exchange of data between devices	• Personal health care • Acute care • Wi-Fi networks	X
IHE (IHE PCD) ***Patient Care Device Domain***	Integrating the Healthcare Enterprise	Support clinical needs thru integration profiles	• Point-of-care medical devices • Specific clinical and operational domains	
MD PnP (Medical Device "Plug-and-Play" Interoperability Program)	Center for Integration of Medicine & Innovative Technology (CIMIT) and Massachusetts General Hospital	Provide interoperability building blocks and change clinical and market expectations of what can be achieved	• Use cases • Neutral lab environment • Open research tools • Regulatory pathway	
MITA (DICOM) ***Digital Imaging & Communications in Medicine***	Medical Imaging & Technology Alliance	Oversee DICOM standard for medical images	• Medical image sharing	X
NIST	National Institute of Standards and Technology	Facilitate development and adoption of standards for medical device communications	• Testing tools • Personal health care	X
UL	Underwriters Laboratories	Develop safety standard for Interoperable Medical Devices Interface Standards (IMDIS)	• Safety specs for interoperability	X

AAMI (Association for the Advancement of Medical Instrumentation)
AAMI, a nonprofit organization with more than 6,800 multidisciplinary members from around the world, focuses on increasing the understanding and beneficial use of medical technology primarily through effective standards, educational programs and publications. In early 2010, AAMI formed an ad hoc group ("AAMI/HITI") on health information technology and interoperability. This group concluded that AAMI should play a leading role in developing Interoperable Medical Devices Interface Standards (IMDIS), at the behest of the FDA. In this capacity, AAMI would focus on standards development for specific clinical functional (use cases) and non-functional (e.g., safety and quality) requirements, while avoiding duplication of existing device interoperability standards efforts. AAMI/HITI is close to publishing a white paper on medical device interoperability that includes a useful overview of medical device interoperability standards and related efforts.

AdvaMed (Advanced Medical Technology Association)
AdvaMed consists of companies that produce medical devices, diagnostic products and health information systems. Its members account for nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent globally. AdvaMed members range from the largest to the smallest medical technology innovators and companies. AdvaMed represents its members' interests in various standards and interoperability efforts.

AHIMA (American Health Information Management Association)
AHIMA is an association of health information management (HIM) professionals, originally founded in 1928 to improve the quality of medical records. Its more than 63,000 members are dedicated to the effective management of personal health information required to deliver quality health care to the public. AHIMA is involved in standards and interoperability initiatives for electronic health records and health information exchanges. In July 2011, it became the new Secretariat and U.S. Technical Advisory Group Administrator for ISO's Technical Committee on health informatics (ISO/TC 215). TC 215 works on the standardization of health information and communications technology (ICT) to allow for compatibility and interoperability between independent systems.

ANSI (American National Standards Institute)
ANSI is a not-for-profit organization whose mission is to enhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems, and safeguarding their integrity. It represents the interests of more than 125,000 companies and 3.5 million professionals. ANSI oversees the creation, promulgation and use of thousands of norms and guidelines that directly impact businesses in nearly every sector: from acoustical devices to construction equipment, from dairy and livestock production to energy distribution, and many more. ANSI is also actively engaged in accrediting programs that assess conformance to standards.

ASTM International
ASTM International, formerly known as the American Society for Testing and Materials, is a developer of international voluntary consensus standards. It has more than 30,000 members representing 135 countries. There are approximately 12,000 ASTM standards in use around the world.

ASTM ICE (Integrated Clinical Environment)
Part one of the ASTM F2761–09 standard provides general requirements, a model and framework for integrating equipment to create an Integrated Clinical Environment (ICE). This standard specifies the characteristics necessary for the safe integration of medical devices and other equipment, via an electronic interface, from different manufacturers into a single medical system for the care of a single high-acuity patient. Its purpose is to promote a medical system that has greater error resistance and improved patient safety, treatment efficacy and workflow efficiency than can be achieved with independently used medical devices. Proposed future parts of the standard include:

Part 2 – Requirements for network control and equipment interface
Part 3 – Requirements for device models
Part 4 – Requirements for supervision (the "ICE Supervisor" to host clinical decision support algorithms)

The technical work for ASTM ICE is led by the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program based at CIMIT (Center for Integration of Medicine and Innovative Technology) and Massachusetts General Hospital.

Current MD PnP projects include evaluating gaps in existing standards that would affect safe function of devices in four clinical scenarios. The selected scenarios represent common acute care devices and key device interoperability functionality:

1) Patient-controlled analgesia (PCA) infusion pump safety interlock
2) Prepare intensive care unit (ICU) to receive post-op patient after cardiac surgery (e.g., coronary artery bypass graft (CABG))
3) Use of home tele-health devices in the hospital (i.e., maintain patient monitoring through the transition from home via ambulance to the hospital emergency department)
4) Increasing levels of interoperability of medical devices in the hospital

Scenario four is the implementation of a "levels of interoperability" analysis produced by the FDA Prototype Regulatory Submission (PRS) Working Group., which was formed as a follow-on to the January 2010 FDA Workshop on Medical Device Interoperability: achieving safety and effectiveness, co-sponsored by the Continua Health Alliance and CIMIT. The purpose of the PRS is to identify scientific, engineering and organizational principles that will enable ICE systems to be built with adequate safeguards so that interoperability is safe and effective. This effort describes and illustrates – through mock regulatory submissions - a "component-

wise" regulatory approach for ICE-compliant systems that avoids the need to rely on pair-wise clearance. The component-wise approach allows each ICE component to be cleared individually without having to enumerate a priori all the possible ways in which it might be combined and used within a system. The component-wise approach is enabled by standardized interfacing between components, a clear enumeration of the safety responsibilities and risks associated with each component, and evidence-based processes by which a component is shown to be safe and compliant with ICE interoperability standards.

Continua Health Alliance

Continua Health Alliance is a non-profit, open industry organization of health care and technology companies joining together in collaboration to improve the quality of personal health care. With more than 240 member companies around the world, Continua is dedicated to establishing a system of interoperable personal connected health solutions. Its focus on the personal telehealth arena encompasses disease management, health and wellness, and aging independently.

The Continua logo signals that a device is certified to be interoperable with any other Continua-branded product. Continua acts as a certifying body for personal connected health devices, software, and services. There are currently more than 50 Continua-certified products. These products tend to be small and portable, and generally rely upon personal area network (PAN) wireless protocols. Continua's Design Guidelines contain references to the standards and specifications selected for ensuring interoperability of devices. The Guidelines are utilized to describe a complete end-to-end connection model that integrates several sets of standards into an interoperability paradigm. They also contain additional design guidelines for interoperability that further clarify standards and specifications by reducing options or adding missing features in the underlying standard or specification. These guidelines focus on interfaces to personal area network health devices, and between disease management services WAN devices (senders) and electronic health record devices (receivers). Existing standards such as IEEE 11073-20601 (plus device specialization standards), HL7, IHE Patient Care Devices, web security and wireless transport technology are used to fulfill use cases.

HITSP (Healthcare Information Technology Standards Panel)

HITSP was chartered by HHS to provide standards harmonization in the health information technology arena to meet the federal mandate for a universal electronic health record. It concluded its contract April 30, 2010. HITSP devised interoperability specifications (IS) based on use cases promulgated by the National e-Health Collaborative (NeHC). The interoperability specifications are meant to be compulsory on any health care players that contribute to an electronic medical record.

Of particular interest to the medical device community is IS 77- Remote Monitoring. The Remote Monitoring Interoperability Specification addresses the information exchange requirements for the transfer of remote monitoring information from a

device physically attached to or used by a patient in a location that is remote to the clinician to an EHR system and/or a personal health record system. Moreover, HITSP's "Device Connectivity Technical Note" (TN905) attempts to provide a roadmap for addressing more complex medical device connectivity situations. Specific requirements under consideration are only those arising from the Harmonization Requests assigned to HITSP that include device connectivity elements, especially the Common Device Connectivity (CDC) AHIC Extension/Gap (December, 2008), which includes generic types of devices such as ventilators and infusion pumps.

HL7 (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. Its 2,300+ global members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving health care. Level Seven refers to the seventh level – the application level - of the ISO seven-layer communications model for Open Systems Interconnection (OSI). HL7 standards pertaining to electronic lab reporting to public health agencies, patient summary clinical document architecture and continuity of care documents, and messaging for public health surveillance and immunization submissions are included in HHS' final rule for electronic health records.

HL7 established a Health Care Devices Working Group whose mission is to facilitate the integration of health care device information at the enterprise level. It proposes to establish standardized version 2.x and version 3 content; harmonize device data models between HL7 and other organizations (including ISO/IEEE 11073); coordinate device terminology usage within HL7 components; support revision of the Clinical and Laboratory Standards Institute (CLSI) Point of Care Test (POCT) and laboratory automation standards; and, work with other national and international organizations involved in health care device informatics and interoperability.

IEEE (Institute of Electrical and Electronics Engineers)

The IEEE Standards Association (IEEE-SA) is a globally recognized standards-setting body within IEEE. It develops consensus standards through engagement of a broad stakeholder community spanning more than 160 countries. The IEEE-SA has a portfolio of over 900 active standards and more than 500 standards under development. Two standards families of particular relevance to medical devices are IEEE 802 and IEEE 11073.

IEEE 802.11

IEEE 802 standards deal with local area networks (LAN) and metropolitan area networks (MAN) that carry variable-size packets. The IEEE 802.11 standards provide the basis for Wi-Fi-branded wireless network products. Wi-Fi has become increasingly relied upon for wireless health care devices. Despite the attractiveness

of low-cost, broad-based connectivity, Wi-Fi may not be well suited to safely support the proliferation of wireless medical devices.

IEEE 11073
IEEE 11073 standards pertain to medical, health and wellness device communications, and reflect joint efforts of the International Organization for Standardization (ISO) and the European Committee for Standardization (CEN). Recent activity has targeted personal use of health and fitness devices (e.g., glucose monitors and weight scales), while continuing to focus on acute care devices (e.g., pulse oximeters, ventilators and infusion pumps). The 11073 standards promote automatic exchange and evaluation of vital signs between different medical devices, as well as remote control of those devices.

IHE (Integrating the Healthcare Enterprise)
IHE is a non-profit organization that was created in 1998 by health care professionals and industry to improve the way computer systems and other clinical technologies like medical devices share and use information. It is composed of more than 400 vendor, provider and government agency member organizations globally. It promotes the safe, secure and well-coordinated use of established technical standards (e.g., DICOM and HL7) to address specific clinical needs in support of optimal patient care. IHE is organized by clinical and operational domains (e.g., cardiology, eye care, radiology, and patient care coordination) and creates integration profiles.

IHE is patient-, clinician- and process-centric. Therefore, by design, the IHE toolset integrates clinical and operational events using the context of clinical data (e.g., time, department and clinical and administrative process sequencing information) to trigger best practice alignment. IHE-compliant systems use best practice standards to generate health care quality notifications, data and reports. Because the internal architecture is designed for secure cross-enterprise, information exchange, there are product, institution, region, national, and trans-national implementations of IHE on several continents.

In 2005, IHE formed the Patient Care Device Domain (IHE PCD) to address issues related to integration of point-of-care medical devices both with each other and with enterprise systems. IHE PCD is based on use cases (e.g., reporting of implantable device data to EHRs) in which at least one actor is a patient-centric point-of-care medical device. An integration profile that describes actors, transaction(s), interface(s), and existing standard(s) is developed for each use case. This effort is co-sponsored by ACCE (American College of Clinical Engineering) and HIMSS (Healthcare Information and Management Systems Society). Each profile is designed to automate data transfer to EHRs and other medical devices to enhance clinical decision support and patient safety.

IHE PCD is addressing semantic interoperability thru its Rosetta Terminology Mapping (RTM) project. This profile maps proprietary medical device terminologies

to standardized ISO/IEEE 11073 concepts (including co-constraints that specify valid units of measurement and value enumerations). RTM supports harmonization activities within IHE, HL7, ISO TC215, IEEE 11073 and the International Health Terminology Standards Development Organisation (IHTSDO) to advance semantic interoperability.

IHE-compliant products are tested at five to seven annual "IHE Connectathon" events around the globe. IHE uses open-source testing software to coordinate the event, and integrates open source technical quality testing software written by NIST and similar national standards bodies from other countries to assure reliable test results. IHE is vender-neutral, and membership is free of charge to any vendor, health care organization, or government agency. All IHE profiles are balloted publically in the same manner as formal standards bodies. All IHE publications, software and Connectathon test results are publically available for examination or download worldwide at no charge.

MD PnP (Medical Device "Plug-and-Play" Interoperability Program)
The MD PnP program, established in 2004, has become a recognized leader in the development of the concepts and capabilities for integrated clinical environments of the future. MD PnP has been working to accelerate the adoption of medical device interoperability by providing interoperability building blocks (use cases, standards, a neutral lab environment, and open research tools) and by changing clinical and market expectations of what can be achieved.

MD PnP is an interdisciplinary, multi-institutional medical device informatics research program that seeks to improve patient safety and clinical efficiency by enabling standards-based integration of medical devices, and is developing a framework and capabilities for integrated clinical environments of the future. CIMIT is a non-profit consortium of Boston's leading teaching hospitals and universities that fosters interdisciplinary collaboration among world-class experts in translational research, medicine, science and engineering, in concert with industry, foundations and government, to rapidly improve patient care.

The MD PnP program has many collaborators, including the FDA, DoD, NIST, NSF, Veterans Health Administration, Anakena Solutions, DocBox Inc., Draeger, Draper Labs, Geisinger, Johns Hopkins Medicine, Kaiser Permanente, Kansas State University, LiveData, Massachusetts General Hospital, Mitre, Moberg Research Inc., Partners HealthCare System, Philips, the University of Illinois at Urbana-Champaign, and the University of Pennsylvania. It is funded in part by DoD/TATRC, NSF, NIST, CIMIT, and most recently a five-year Quantum Grant from NIH's National Institute of Biomedical Imaging and Bioengineering toward overcoming technical, development, safety, clinical, regulatory, and certification adoption barriers to medical device interoperability through the creation of verified and validated interface software, development environments, and clinical environments. The project has been adopted as an affiliate of the SHARP (Strategic Health IT Advanced Research

Projects) program administered by HHS' Office of the National Coordinator for Health Information Technology (ONC).

The MD PnP program deliverables provided the foundation for the ASTM ICE standard, and the "MD FIRE" open source procurement language used by providers to specify interoperable medical devices and HIT through RFIs, RFPs, SOWs, and SLAs. The 1.0 version of this contract language was approved by Kaiser Permanente, Partners Healthcare, and Johns Hopkins. Version 2.0 is currently in development and will be released in February 2012.

MITA (Medical Imaging & Technology Alliance)
MITA, a division of the National Electrical Manufacturers Association (NEMA), is the leading organization for medical imaging equipment manufacturers, innovators, and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include medical X-ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, magnetic resonance imaging (MRI), and imaging information systems. MITA is responsible for overall management and administration of the DICOM Standard, and its committees and work groups.

DICOM (Digital Imaging and Communications in Medicine)
DICOM is a global standard that is used in virtually all hospitals worldwide. It is designed to ensure the interoperability of systems used to produce, store, display, process, send, retrieve, query or print medical images and derived structured documents, as well as to manage related workflow. DICOM establishes a set of communication protocols; specifies syntax and semantics of commands and associated information exchanged using these protocols; specifies media storage (file formats and medical directory structure); specifies format for devices to claim conformance to components of DICOM, and a protocol to negotiate which components of the standard are supported and will be used for any given communication.

NIST (National Institute of Standards and Technology)
Founded in 1901, NIST is a non-regulatory federal agency within the U.S. Department of Commerce. NIST's mission is to promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life.

Medical Device Communications Testing Project
NIST researchers are collaborating with medical device experts to facilitate the development and adoption of standards for medical device communications throughout the health care enterprise as well as integrating it into electronic health records. They are developing point-of-care medical device communication standards that address plug-and-play medical device interoperability.

NIST researchers have developed test tools and corresponding electronic representation of an international standard's information model that provides several important capabilities leading toward device interoperability. Test tools include the following:

> *ICSGenerator* – Implementation Conformance Statement (ICS) generator that facilitates creation of vendor conformance statements that would be applicable to testing a particular ISO/IEEE 11073 (X73) device.
>
> *ValidatePDU* – Provides basic syntax and structure check, and low-level semantic checks for one or more captured messages.

NIST's Information Technology Laboratory (ITL) is collaborating with ISO/IEEE 11073 (X73) Medical Device Communications, IHE PCD domain working groups, and the Personal Health Devices working group. They are developing conceptual information-based frameworks and test tools that ensure device implementations are conformant to medical device standards. This effort ultimately contributes to high priority needs to reduce medical errors, promote patient safety and provide accurate information into electronic health record systems.

UL (Underwriters Laboratories)

UL is a global independent safety science company with more than 116 years of history. It employs more than 6,900 professionals in over 100 countries, and has five distinct business units -- Product Safety, Environment, Life and Health, University, and Verification Services.

UL filed a project initiation notification with ANSI (American National Standards Institute) to develop a standard for safety for interoperable medical devices interface standards (IMDIS). According to the May 13, 2011 ANSI Standard Action, BSR UL 2751-201x defines the safety and related specifications of medical device interface(s) required when it 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 to the interoperability of the medical device interface within an integrated clinical environment and interoperable scenario.

How Can FDA Advance Wireless Medical Device Interoperability?

The importance of wireless medical device interoperability to improving health care delivery is generally accepted. Furthermore, the efforts of many groups, particularly those highlighted above, suggest that interoperability is technically achievable. **Importantly, experience has shown that overarching system value and technical feasibility alone are insufficient to incentivize an interoperability solution**. Rather, market-based innovation will, as it did in the case of EMRs, perversely incentivize a series of 'walled-garden' proprietary solutions, each limited to a segment of the overall health care ecosystem.

In order to accelerate the imperative of wireless medical device interoperability, we believe there is a key role for the FDA to play. The agency can enhance interoperability by advocating for it, assuring a rational and uniform set of requirements, enabling testing against those requirements by certified bodies, and granting specific labeling related to interoperability. The market has yet to produce interoperable devices, despite their acknowledged benefits – enabling the safety and efficacy of health care – and end users' requests. The FDA can fill this void by using its leadership position to assert that interoperability is vital and appoint certifying bodies to test interoperable solutions. The agency already has several mechanisms at its disposal to encourage interoperability, including establishing requirements for labeling claims for wireless medical device interoperability, modifying device review processes, helping standards development efforts, updating policies, leveraging and coordinating interoperability efforts with the Office of the National Coordinator for HIT, etc. Three primary actions include:

1. The agency, in concert with the above listed organizations and other critical stakeholders (hospital system CIOs and CTOs, medical device manufacturers, etc.), needs to establish a regulatory pathway for specific levels of functional interoperability claims.

2. The agency needs then to recognize external certifying bodies that test and validate candidate devices against the requirements for those claims.

3. The agency should encourage demonstration of the benefits of deploying interoperable-certified wireless medical devices through affirmative actions with model hospitals and other setting-oriented constructs.

Creation of a mechanism to assert, certify, and demonstrate interoperability claims would enable regulators to more quickly evaluate devices; device manufacturers to more effectively innovate; end users to better assess the tools they wish to employ; and, patients to be assured that their care is being optimized.

Next Steps

A common understanding of the challenges associated with wireless medical device interoperability and close coordination of remediation efforts are necessary to develop solutions that will be broadly adopted and implemented. Solution efforts must begin with the end in mind – **solving unmet clinical needs as espoused by the health care delivery system**. Action across several fronts will be necessary to advance interoperability efforts. We offer the following suggestions:

- **Engage Implementers.** Those entities and individuals (e.g., CIOs and CTOs) that bear responsibility for delivering care and integrating interoperable solutions lend a critical voice. They are a resource for the FDA, manufacturers and industry to understand clinical needs and functional requirements, and can best assess the feasibility of solutions. Broad representation of the voice of health care delivery is inadequate in efforts to derive concrete, implementable solutions, and should be included in a greater, structured capacity.

- **Leverage Procurement Power.** A key hurdle to breaking vertically integrated silos is the lack of a business model for manufacturers to do so. If customers (ie, health care delivery) were to demand interoperability and specify functional requirements in RFPs, there would be greater "pull" from the demand side.

- **Include Interoperability in Meaningful Use.** Adoption of interoperable solutions (and thereby development) could be advanced by incorporating interoperability requirements into meaningful use criteria. These requirements should be grounded in open standards-based medical device interoperability solutions that are informed by clinical needs.

Summary

Advancing wireless medical device interoperability is critical to improving health care delivery and health outcomes, improving the costs and speed of innovation, lowering the cost of care, and enabling a sustainable and affordable health care system. Despite these recognized benefits and the requests of end users, the market understandably has failed to deliver broad interoperability. To alleviate this market failure, the government has a responsibility to act.

The FDA is uniquely positioned to enhance interoperability by requiring it. A pathway to interoperability should be construed in consultation with the health care delivery system and other parties that have long been engaged in this complex effort. Key facets will include understanding the clinical needs to be met and establishing a testing and certification mechanism that is open to all manufacturers.

The health care delivery system, established manufacturers, innovation community, standards development bodies and regulatory agencies must come together to forge interoperability solutions. These solutions should ensure that devices work together (by learning patient information from each other) to change care for the better. We must arm our health care system with the tools to prevent the onset of illness while supporting a population that is aging with a greater burden of chronic disease.

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