Introduction

The healthcare industry has always been a changing and developing field. From the advances in medical expertise to the introduction of cutting-edge technology, no hospital facility has avoided the impact. The past decade though has brought changes that have affected how healthcare is delivered more than ever before. Computers and information technology have intertwined into nearly every aspect of healthcare.

Background

The forerunner of these changes is the introduction and government mandate of the Health Information Technology for Economic and Clinical Health (HITECH) Act, which includes implementation of Electronic Medical Records (EMRs). The use of an EMR allows access to patient data anywhere in a hospital enterprise with automated data entry. This benefit is easy to understand, but what is not apparent to people outside of the healthcare profession is how the EMRs have required adaptations and changes to how every other component of healthcare is delivered. The Integrating the Healthcare Enterprise (IHE) is the initiative focused on improving the area of healthcare most important to both medical device manufactures and biomedical engineering departments, device integration.

The requirement for medical devices to transition from stand-alone devices to components of an integrated system providing patient data to the EMR, has become important. With a majority of the older technologies (legacy equipment) not being able to communicate with other devices or systems, need for standardization has arisen. The primary focus of the IHE standards is to foster development and further improvement of ways for medical computer systems in healthcare, information.

Currently there are established data communication standards, such as DICOM and HL7, which aid in a more seamless transfer of healthcare information. With the continuous development of medical technology it is important to ensure devices are “speaking in the same language” and providing data in an expected format. For example, to have a vital signs monitor send a patient’s data directly to the patient’s EMR the vital signs monitor needs to have both networking capabilities and ability to transmit the data over that network in a form compatible with the EMR. IHE strives to guide developers to use standardization because it helps make implementation of systems and devices easier and more effective. This initiative publishes tools, specifications, and services to help develop, test, and implement medical device communication standard-based solutions.

The IHE initiative is worldwide, with committees in 17 countries, which originated in 1997. The IHE committee in the USA was founded in 2010 and focuses on the interoperability of health IT systems. Within IHE there are 12 clinical and operational domains. The most relevant domain to professionals in biomedical and clinical engineering is Patient Care Devices (PCD). This particular domain focuses purely on the integration of medical devices into the healthcare enterprise. Information regarding this domain, and associated integration profiles, is available at http://wiki.ihe.net/index.php?title=PCD_Profiles.

Interoperability Initiatives

One of the most well-known initiatives of IHE is the Connectathons, which have been held in America since 1999. Connectathons are weeklong events where vendors, engineers, and IT architects work together to test products’ interoperability. These products are tested in simulated clinical scenarios, in guidance with IHE’s development integration profiles, to determine compatibility with multiple vendors. If and when problems with interoperability arise, participants work together to trouble shoot. Nearly all major medical device companies participated in the last IHE North America Connectathon held in 2014, with over one hundred
vendors in attendance\(^2\). A database of products which passed testing are available at [http://product-registry.ihe.net/PR/home.seam](http://product-registry.ihe.net/PR/home.seam). The success of these events is based on the profiles developed by IHE to create a standards-based framework for information sharing. Companies are drawn to this event because if products pass testing they are eligible for certification of interoperability by ICSA Labs, an ISO accredited lab. This past year the first fourteen products were IHE USA certified\(^3\).

**Meaningful Use and the IHE**

The push for interoperability has not only been fueled by the desire to streamline workflow and simplify workload, but by Meaningful Use certification, needed for Medicare and Medicaid reimbursement. In order for hospitals to continue to receive government support for patients with Medicare and Medicaid health insurance, compliance with Meaningful Use is required. The use of an EMR is one of the main requirements of Meaningful Use, and fully functional communication with medical devices is necessary.

**Middleware and the IHE**

Placing priority on EMRs has led to the development of technology that can “translate” from medical devices to the health records. This is known as middleware and provides an immediate, and interim solution for communication. Middleware works by extracting data from medical devices in whichever form the device produces data and translates the data into a form EMRs can use. The current standard format for transferring data into EMRs is Health Language 7 (HL7). Frameworks provided by HL7 dictate how information is packaged, including the language, structure, and data types. Middleware is necessary for all equipment that cannot “communicate” in HL7, which currently is the majority of medical devices used in hospitals. Until recently when Meaningful Use became a requirement medical device manufactures had no motivational factor to comply with standardization. It was only important to have devices be compatible with the companies’ other products because communication to other vendor’s product was not necessary. Now that medical devices need to be compatible with EMRs, manufactures are being encouraged to develop products that can communicate with all EMRs. For the companies to be competitive they have to apply IHE standards.

**Benefits**

Outside of EMRs there are several other needs for device interoperability. Three of the founding organizations of IHE USA are the Healthcare Information and Management Systems Society (HIMSS) and the American College of Clinical Engineering (ACCE). These organizations support the goals of IHE from the perspective of biomedical and clinical engineers. HIMSS holds an annual conference and exhibition with a showcase focused specifically on interoperability. These events allow healthcare developers to demonstrate the benefits of using standards based health IT solutions. In addition, these demonstrations show the impact of successful collaboration of the various stakeholders, particularly the developing partnerships between medical device manufacturers, computerized maintenance management systems (CMMS) developers, real time location systems (RTLS) developers, and medical device testing/calibration companies.

**RTLS**

This year at the HIMSS interoperability showcase, a demonstration of how the future of medical device interoperability expands much farther than EMRs was shown. Several companies from various disciplines have recently been working together to integrate technologies to not only have ability to communicate with each other but to enhance functionalities, including alarms and event notification. While RTLS is still a new technology, yet to be implemented in most healthcare facilities, its advantages are already evident. The benefit of locating medical devices without physically searching for them is invaluable to easing frustrations of biomedical technicians. Additionally, lost, broken, or stolen devices can be identified. In a state of the art facility RTLS can pinpoint device locations, and provide locations in real time on computers and handheld devices. What RTLS systems available on the market are currently unable to provide is status of the medical devices. For example, if the device is in use. Technician’s time is often wasted locating devices that are in use and not available for scheduled maintenance, affecting overall productivity. A recent IHE development is
that devices can now transmit data regarding status, communicating from a transmitter on the device to the RTLS software.

CMMS

A limitation of most RTLS systems has been the inability to communicate with most CMMS systems. While a select few companies have collaborated to allow use of the benefits of RTLS to be accessed within the CMMS systems, interoperability between the majority of systems is currently unavailable. From a clinical engineering department’s perspective ability to view work orders and upcoming scheduled maintenance in conjunction with devices’ location and use status is invaluable. Communicating directly from devices to CMMS systems allows for elimination of many time consuming processes required for device maintenance. The IHE PCD white paper regarding Medical Equipment Management (MEM) illustrates how IHE technical frameworks could be used to aid in management activities.

Many medical devices are now incorporating automatic self-checks upon power up, or when prompted to do so. Devices are also increasingly being provided with capability to store logs of failures, issues, or malfunctions. These tools provide vital information regarding device health, but are often not utilized. An up-to-date record of device health would allow for more accurate and sound decision making regarding equipment. Utilizing the ability of the devices’ self-check function would allow for real time confirmation of device safety.

Integration Profiles

The IHE envisions a healthcare industry where all devices and systems are able to communicate in order to provide the best and safest care in the most streamline and effective manner. In order to aid in this vision, IHE participants have diligently worked to provide Integration Profiles which use already established standards to integrate systems. These profiles define clinical requirements for systems that need to become integrated, as well as solutions to meet said requirements. All transactions or “communications” of components within the system are completed in accordance to standards, including IEE 11073, DICOM, and HL7. While integration of all systems in guidance with IHE standards is not possible, any integration that can be done following the profiles is recommended for future ease of incorporating new acquisitions. Each of the twelve defined IHE domains has a User Handbook designed to help users understand the importance of device integration as well as how to begin planning, purchasing, and implementing related systems and devices.

IHE PCD Example

Healthcare facilities transitioning from paper charting and manual data entry to automated data entry EMRs are charged with the difficult task of integrating electronic medical device data into the EMR. Monitoring equipment was not designed or configured to transfer data physiological data generated from monitoring equipment to Patient healthcare records because the need had not previously arisen.

The IHE provides tools and standards, which are intended to help simplify the integration process. One of the first examples of integration is elimination of the need for vital signs documentation. In order for this to occur patient physiological data must be sent from the medical device to the EMR. Benefits of automated data entry are numerous, including prevention of incorrect data due to manual entry, reduction of staffs’ time entering data, and increase in patient data collection without additional staff.

Stating systems requirements to medical device vendors in an articulate manner can be a daunting task. Features the end users assumes would come standard may not be of the same priority level to the system developers. In order to help with this task IHE has created IHE Integration Profiles designed to aid in proper communication.
When making decisions regarding integration projects it is important that the entire facility is in agreement with requirements/capabilities. The IHE Integration Profiles can then be identified to reach corresponding goals, because the profiles are designed to describe a clinical requirement for systems integration.

In this example of patient monitors and an EMR, selection of the *Device Enterprise Communication* (DEC) profile would be necessary. This profile is related to transmission of data from any PCD device, in this case the patient monitor, to an enterprise application, in this case the EMR. The profile dictates the requirements of the system including:

- Consistent (uninterrupted) communication of the patient monitor to the EMR
- Reduction (or elimination) of manual data entry patient monitor data into the EMR

A more in-depth description of the DEC profile can be found at http://wiki.ihe.net/index.php?title=PCD_Profile_DEC_Overview#References

The IHE PCD User Handbook is an invaluable tool for all participants involved in selecting, purchasing, installing, configuring, and maintaining systems with integrated medical devices. The IHE PCD User handbook is a public resource available at http://www.ihe.net/technical_framework/upload/ihe_pcd_user_handbook_2011_edition.pdf. This resource provides step by step guidance and examples of how to incorporate integration profiles into purchasing requirements. Vendors are becoming increasingly familiar with providing proof of compliance with IHE standards. In order to guarantee the company is capable of meeting the facility’s requirements, inclusion of the Integration Profile(s) in the Request for Purchase (RFP) is necessary.

There are also instructions and tips on how to read and understand Integrations Statements provided by vendors in response to the RFP. The database for statements is maintained at http://product-registry.ihe.net/PR/pr/search.seam?date=ANY|1406169799098|1406169799098. An example of an Integration Statement for Philips patient monitor can be found in the Appendix. Making Integration Statements and IHE Integration Profiles standard for both consumers and vendors would allow for vendors to receive the needs of the healthcare providers in a manner where they could design systems to a meet these requirements.

**Integration: Where it is and where it is going**

Even with guidelines, handbooks, and other tools, resources, and examples; ease of integration in the healthcare environment is not where it needs to be. Currently many devices and systems have been integrated, but the majority have been done on an as needed basis with solutions developed for specific scenarios. Plug-n-Play, a term coined referring to simply plugging one device into another and have them seamlessly communicate, is not possible. The ultimate goal of integration is to have medical information readily available for any person who needs it, at any given location, regardless of distance or time. More importantly though, is for the data to be complete, accurate, and up to date. Eliminating human errors in transcription or data entry, and increasing ability for real time decision making.

To decrease the use of piece-meal integration solutions standardization in both how devices are developed and how systems acquire information is necessary. IHE is the organization driving this initiative forward and standards committee are working continuously to provide guidance and solutions. It is within the next ten years where integration will become a full-fledged reality and no longer a far off goal of the future.
References


Appendix

IHE Integration Statement

Philips IntelliVue Information Center Rev. L, M, N.0 with IntelliBridge Enterprise Rev A.03
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1. **INTRODUCTION**

1.1. **Overview**

The Integrating the Healthcare Enterprise (IHE) Integration Statement specifies the Integration Profiles, its Actors, and Options Philips Healthcare has chosen for implementing in this product. This document helps the reader to investigate whether and to what extent interoperability with other products might be supported.

The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise and specifies their interactions in terms of a set of coordinated transactions. The actors and transactions described in the IHE Technical Framework are abstractions of the real-world healthcare information system environment. While some of the transactions are traditionally performed by specific product categories (e.g. HIS, RIS, PACS, or modalities), the IHE Technical Framework intentionally avoids associating functions or actors with such product categories. For each actor, the IHE Technical Framework defines only those functions associated with integrating information systems. The IHE definition of an actor should therefore not be taken as the complete definition of any product that might implement it, nor should the framework itself be taken as the complete definition of a healthcare information system architecture.

This IHE Integration Statement provides the reader with a high-level view of supported IHE Integration profiles. For further investigations, additional information can be found in the DICOM Conformance Statement of this product and in the IHE Technical Framework.

1.2. **Important Note to the Reader**

This IHE Integration Statement by itself does not guarantee successful interoperability of this Philips product with other products. The user (or user’s agent) should be aware of the following issues:

**Interoperability**

Interoperability refers to the ability of application functions, distributed over two or more systems, to work successfully together. It is the user's responsibility to analyze thoroughly the application requirements and to specify a solution that integrates Philips equipment with non-Philips equipment.

**Validation**

Philips equipment has been carefully tested to assure that the actual implementation of the IHE Integration Profiles corresponds with this Integration Statement.

Where Philips equipment is linked to non-Philips equipment, the first step is to compare the relevant Integration Statement. If the Integration Statement indicates that successful information exchange should be possible, additional validation tests will be necessary to ensure the functionality, performance, accuracy and stability of image and image related data. It is the responsibility of the user (or user’s agent) to specify the appropriate test suite and to carry out the additional validation tests.

**New versions of the IHE Technical Framework**

The IHE Technical Framework will evolve in future to meet the user’s growing requirements and to incorporate new features and technologies. Philips is actively involved in this evolution and plans to adapt its equipment to future versions of the IHE Technical Framework. In order to do so, Philips reserves the right to make changes to its products or to discontinue its delivery.

The user should ensure that any non-Philips provider linking to Philips equipment also adapts to future versions of the IHE Technical Framework. If not, the incorporation of IHE enhancements into Philips equipment may lead to loss of connectivity (in case of networking).
1.3. General Acronyms and Abbreviations

The following acronyms and abbreviations are used in the document.

- **Actor**  
  An entity within a use case that performs an action

- **DICOM**  
  Digital Imaging and Communication in Medicine

- **HIS**  
  Hospital Information System

- **HL7**  
  Health Level 7

- **IHE**  
  Integrating the Healthcare Enterprise

- **PACS**  
  Picture Archiving and Communication System

- **RIS**  
  Radiology Information System

- **RSNA**  
  Radiological Society of North America
## 2. IHE INTEGRATION STATEMENT

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<td>Philips IntelliVue Information Center Rev. L, M, N.0 with IntelliBridge Enterprise Rev A.03</td>
<td>Rev. L, M, N.0</td>
<td>2012-10-15</td>
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This product implements all the transactions required in the IHE Technical Framework to support the IHE Integration Profiles, Actors and Options listed below.

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<tr>
<td>Alarm Communication Management</td>
<td>Alarm Reporter</td>
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</tr>
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</table>

**IHE statements**

- Philips IHE
  [http://www.philips.com/ihe](http://www.philips.com/ihe)

**DICOM Conformance Statements**

- Philips DICOM
  [http://www.philips.com/dicom](http://www.philips.com/dicom)

**More about products from Philips Healthcare**

- [http://www.healthcare.philips.com](http://www.healthcare.philips.com)

**General information on IHE**

- [www.ihe.net](http://www.ihe.net) (general and North America)
- [www.ihe-europe.org](http://www.ihe-europe.org) (Europe)
- [http://www.ihe-japan.org](http://www.ihe-japan.org) (Japan)