




Business Cases and “Warp Speed Ahead” to Patient Care Device Interoperability!

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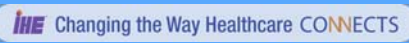



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IHE Patient Care Devices (PCD)

Helping to fulfill the general IHE Vision:

“Providers and vendors working together to deliver interoperable health information systems within and between enterprises and settings”



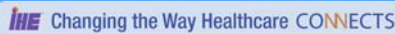
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In June, 2005, The American College of Clinical Engineering (ACCE) was appointed the *Domain Sponsor* for Patient Care Devices by IHE's principal sponsors, ACC, HIMSS, and RSNA.

A *Clinical Engineer* is a professional who supports and advances patient care by applying engineering and managerial skills to healthcare technology. Founded in 1991, ACCE is the professional college of Clinical Engineers throughout the US.

(www.ACCEnet.org)

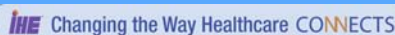


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Why Patient Care Devices?

- For every connected IT Device in the hospital, there are 4 Patient Care Devices that are *not* connected
- There are over 1500 Patient Care Device manufacturers and over 3500 Make-Model combinations
- The typical 200 bed hospital contains 1,000's of Patient Care Devices
...that are constantly changing with updated/upgraded technology ... and interoperability too?!



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One Patient – Many Devices

Legend:
● Intra-department
⊖ Inter-department
⊕ Enterprise

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“REALITY CHECK” – Patient Care Devices are quite unique ...

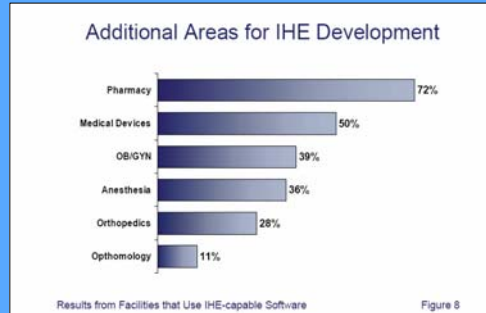
- **Many devices** are used in multiple clinical contexts, with acquired data having **different implications** depending upon the clinical setting.
- **Many devices** provide signals or **critical alarms** that have direct significance to **patient safety** and well being in **real-time**, and should be accorded appropriate priority in the system.
- **Many devices** are **portable**, meaning that connectivity must include **wireless** portions, direct network connections, and Internet links, all with “hacker and virus” **risks**, too.
- **Many devices** provide data that should be **automatically** and **accurately incorporated** directly into the information stream that feeds the emerging Electronic Health Record (**EHR**).

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HIMSS Survey IHE pre-2005 Annual Conference results:

- Survey of all IHE Users
- Over 50% of those surveyed said patient care devices should be the next area developed for IHE *



- Further, 56% said they'd pay more for IHE-compliant products!
- So, in Summer 2005, HIMSS conducted a supplemental Patient Care Devices survey, which allowed us to "drill down" to the detailed issues and priorities...

* IHE-Europe survey placed Medical Devices behind Pharmacy & Pathology



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2005 Summer Survey Results:

- Highest priority devices for integration are Vital Signs Monitors, Blood Gas Analyzers (POC), and Infusion Pumps
- Highest priority departments are ICU, Emergency, OR/Anesthesia, and Lab (POC)
- Highest technology priority is Enterprise Wide Sharing
- Highest priority for clinical application is EHR or CIS integration followed by Improved Management and Decision Support
- Highest *perceived* barrier is "Lack of Standards." – Fear of Litigation not a concern
- Users are willing, on average, to pay a premium to achieve IHE compliance ... but expect lower total cost!



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Key Benefits of PCD Interoperability:

- **Heterogeneity** – Multiple manufacturers + multiple device modalities coexisting over a shared infrastructure
- **Semantic Interoperability** (comparability) – shared terminology and data models, interpret data based on the clinical context, compare information from different healthcare facilities, and interrogate systems across enterprises and regions.
- **Real-Time Availability** – ability to provide data in a time frame appropriate to the physiologic function being measured, displayed or affected (controlled).



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SO, WHAT IS HAPPENING IN THIS DOMAIN?

*In September, 2005, the PCD gathered **60 vendors, purchasers, providers, and regulators** in Washington D.C. for 2 days to explore the value propositions, explore the scope and mission of the domain, and begin the process of use case development.*



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The PCD Business Case

What outcomes of IHE-PCD Domain will create real, tangible value for the participants (i.e., What is the “**Value Proposition**” or, “Why should we do this, and why now?”)

- ✓ Nothing durable can be accomplished with a project like this **UNLESS** there are **clear rewards for all stakeholders** (economic, safety, quality, etc.).



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Key Stakeholders with Business Cases that are driving the PCD

- Stakeholders presently fall into four general categories
 - ✓ **Vendors** who sell devices or services
 - ✓ **Purchasers** who buy devices - Providers (Clinicians) who use devices
 - ✓ **Regulators** and **Government** who represent the public good



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Business Case for the Vendor as a stakeholder

- Value lies in the ability to attract, retain, or deepen a customer relationship
- For example “IHE PCD will enable new market development” would be a value proposition



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Vendor Value Propositions (e.g., ROI and other motivations):

- **Simplify** product development process
- Spend time **innovating** rather than doing infrastructure work
- Facilitate clinical decision support - innovation - **added functionality**
- **Reduce regulatory** impact/work
- Improve patient safety - **reduce liability** - make operations easier - device aware



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Business Case for the Purchaser/Provider Stakeholders

Purchaser Stakeholders

- Value lies in simplifying “quality” buying decision criteria
- For example “IHE PCDD will reduce the complexity of the purchase” would be a value proposition

Provider Stakeholders

- Value lies in the benefit you derive
- For example “IHE PCDD will simplify workflow” would be a value proposition

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Value Propositions for Purchaser and Provider:

- **Integrity of data** – automatic population of all information systems – reducing medical errors
- Automated systems **saves time for clinicians**
- Improves **agility** of enterprises to meet varied patient loads
- Improved **life-cycle cost** of ownership
- Automates clinical **data capture** for EHR
- Access to patient data across devices and systems so custom communication interfaces can be eliminated. **Allows for best of breed**

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Value Proposition for Government and Regulatory Stakeholders

- Value lies in easing regulators' tasks by industry adoption and implementation of **uniform specifications**.
 - ✓ For example one Business Case statement for government and regulatory stakeholders is: "IHE PCDD can **simplify the approval process** for medical devices and related clinical information systems."
- *IHE-PCD accelerates the fulfillment of key clinical requirements for **Efficacy, Efficiency, and Safety** in the emerging Electronic Health Record programs that have been mandated by President Bush and Health and Human Services leadership.*



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IHE-PCD Charter

The Patient Care Devices Domain is concerned with Use Cases in which at least one actor is a regulated patient care device. The PCD coordinates with other IHE clinical specialty based domains such as medical imaging.



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IHE-PCD Domain Vision Statement

The IHE Patient Care Devices Domain (IHE PCD) is the nexus for vendors and providers to jointly define and demonstrate unambiguous interoperability specifications, called profiles, which are based on industry standards, and which can be brought to market.

IHE-PCD profiles:

1. **improve patient safety** and clinical efficacy,
2. **optimize healthcare delivery cost** by improving efficiency, reliability, and operational flexibility for healthcare providers,
3. **enable innovative patient care capabilities**, and
4. **expand the international marketplace** for patient care device vendors.



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IHE-PCD Mission

➤ The IHE Patient Care Devices Domain will apply the proven, Use Case driven IHE processes to:

- ✓ **Deliver** the technical framework for the IHE-PCD domain profiles;
- ✓ **Validate** IHE-PCD profile implementations via Connectathons; and
- ✓ **Demonstrate** marketable solutions at public trade shows.





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Examples of emerging IHE-PCD Work flows:

- ✓ *Enterprise sharing of Patient Care Data* *
- ✓ *Patient & Device ID Binding to Device* *
- ✓ Real-time data archiving and communication
- ✓ PCD Alarm Management
- ✓ Drug Administration
- ✓ Hospital Bed–Blood Pressure Coordination
- ✓ Mobile, enterprise-wide, reliable vital signs monitoring
- ✓ ... many more!

Initial device classes – vital sign monitors, infusion pumps and ventilators



* Key Objectives for 2006/2007

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➤ **2006 Development Schedule:**

✓ Planning Committee decision:	mid-January
✓ Issue Public Comment version:	June 2006
✓ Public Comment Due:	July 2006
✓ Issue Trial Implementation version:	August 2006
✓ IHE Connectathon:	January 2007
✓ HIMSS Demo:	February 2007

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Come and join the IHE-PCD Domain Team - see or email any of the following PCD leaders:

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- Elliot Sloane (ebsloane@villanova.edu)
- Ray Zambuto (rzambuto@techmed.com)

- ... or visit us at www.ACCEnet.org/IHE



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