Achieving Successful Healthcare Enterprise Interoperability Using IHE Profiles and Standards
2007 ACCE Clinical Engineering Forum Keynote
February 25, 2007 HIMSS New Orleans

Elliot B. Sloane, Ph.D. Villanova School of Business
IHE Strategic Development Committee co-chair
IHE Patient Care Device Domain co-chair

My Bio-Brief:
Just A CE/IT Kind of Guy!

- Vice President, ECRI - 1975-1990, CIO & CTO
  - Medical technology research, testing, and education; medical device nomenclature; standards directories; product evaluations; forensic/accident investigations
- Vice President, MEDIQ/PRN - 1990-2000, COO, CTO, & CRO
  - Medical device & drug distribution, service, rental, and manufacturing
  - Registered medical device manufacturer, drug distributor, and repair company
  - 500,000 life-support devices rented to hospitals nationwide, 24x7
- Faculty, Department of Decision and Information Technologies, Villanova University, since 2000 (In 12-step CE and MIS Recovery Program...)
  - Teaching, research and publishing in databases, decision support, healthcare technology assessment and management, telecommunications, and health informatics
  - Co-Chair of the HIMSS/RSNA/ACC IHE Strategic Development Committee
  - Board of Directors, IEEE Engineering in Medicine and Biology Society
  - Past President, ACCE; Board of Directors, ACCE Healthcare Technology Foundation
  - Advisor to WHO/PAHO in Healthcare Technology Management since 1985

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My Presentation Goals:

• Understand the “Integrating the Healthcare Enterprise” (IHE) initiative, and how it works as a cost effective model for interoperability
• Review the various levels of interoperability from physical connectivity through use case semantics
• Learn the impact of-and-on standards for the networking of medical devices
• Investigate the systemic implications for CE and IT of placing clinical data on the network

IHE - Connecting STANDARDS to CARE

• What is Integrating the Healthcare Enterprise (IHE)?
  – Care providers and clinical and computer engineers working with vendors to coordinate the implementation of standards for patient care

  • Care providers identify key interoperability problems
  • Drives industry to develop and make available standards-based solutions
  • Implementers follow common guidelines in purchasing and integrating systems that deliver these solutions
What Is IHE?

- IHE is a collaborative response to healthcare IT market requirements for system integration.
  - Develop standards-based implementation specifications called profiles.
    - Useful subsets of one or more standards
    - Tested at Connectathons
    - Demonstrated at HIMSS, RSNA, and ACC shows
  - Correct known integration problems.
    - Intra-enterprise and multi-enterprise scope
    - Constrain optionality
  - Build trust, collegiality, effectiveness among vendors, providers, and other stakeholders.

IHE Contributors & Participants

Sponsored by:
- Professional Societies Representing Healthcare Segments
  - RSNA, HIMSS, ACC, ACP, ACCE, AAO, others…

Participants are:
- Users - Clinicians, Medical Staff, Administrators, CIOs
- Information Systems & Equipment (e.g. imaging) Vendors
- Consultants
- In addition, active liaison with Standards Development Organizations (SDOs)
  - HL7, DICOM, NCCLS, ASTM, ISO, others
And the result? The 2007 IHE Showcase!

Featuring “A Heartfelt Patient” at the 2007 IHE Showcase
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Featuring IHE interoperability demonstrations by leading COMPETING companies:

Leadership

Implementer

Supporter

Organizational Participants

And Our 2007 IHE Interoperability Breakthrough: Patient Care Devices
The "Heartfelt Patient" Critical Care Scenarios
Emergency Care ➔ Intensive Care ➔ Perioperative Care

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IHE PCD 2007 Showcase Premiere:

• This will be the first IHE Showcase to feature multi-vendor interoperability demonstrations between:
  – Anesthesia systems
  – Clinician information and display systems
  – Infusion pumps
  – Physiologic monitors
  – Ventilators

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IT Infrastructure Domain (ITI)

• Supports profiles which supply necessary infrastructure for sharing healthcare information.

• IT Infrastructure domain began in 2003 and now has 18 profiles that it supports.

• Key ITI profiles demonstrated today:
  – Information Exchange: XDS, XDM, XDR, XDS-SD, RFD
  – Security: ATNA, CT
  – Identity Management: PIX, PDQ (HL7 V2 & V3)

Types, or Dimensions, of Interoperability

• Electrical or physical Interoperability
• General Infrastructure or Enterprise Interoperability
• Domain-Specific Semantic Interoperability
Electrical or physical interoperability

- Generally becoming “ubiquitous,” relying on common IEEE and related standards
  - IEEE 802.x Wi-Fi, Bluetooth

EXAMPLE: Using widely-adopted wireless and wired interfaces to replace most wires and proprietary data link communications for the CIMIT “Operating Room of the Future” project.

IHE leverages electrical and physical interoperability trends, using existing standards:

- Untethered access to information when possible
- Affords Mobility
- Affords Electrical and Physical Interoperability
- Standards-Based, Reduces cost and complexity

Courtesy of NIST, CIMIT, and ORF

IEEE 802.11b WiFi™
IEEE 802.3 Ethernet
IEEE 802.15.1 Bluetooth™
IEEE 802.15.4 Zigbee™

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IHE does not try to “re-invent the wheel,” but uses existing, proven, commercially electrical and physical interfaces to enable interoperability.

But, the “devil’s in the details…”

• As we’ve all learned with cell phones and laptops, reliable wireless interoperability is not a trivial challenge to ensure.
  – There’s plenty of work under way to make those technologies more appropriate for life-critical uses, and more work is still needed…
Types, or Dimensions, of Interoperability

- Electrical or physical Interoperability
- General Semantic Infrastructure or Enterprise Interoperability
- Domain-Specific Semantic Interoperability

Semantic Interoperability for the Enterprise: IT Infrastructure (ITI) Technical Framework

  - General enterprise-wide tools, such as Universal Clock, Find Personnel, Authenticate Users and Nodes, Add/Retrieve/Update Document or Pictures

- Supplements:
  - Cross-enterprise Document Media Interchange (XDM)
  - Cross-enterprise Document Reliable Interchange (XDR)
  - Cross-enterprise Sharing of Scanned Documents (XDS-SD)
  - Patient Identifier Cross-Reference and Patient Demographic Query HL7 V3 (PIX/PDQ V3)
  - Registry Stored Query Transaction for Cross-Enterprise Document Sharing Profile
  - Retrieve Form for Data Capture (RFD)
Example 1: Ensuring Enterprise-Wide Consistent Time for Semantic Interoperability

3.1 Maintain Time
This section corresponds to Transaction ITI-1 of the IHE IT Infrastructure Technical Framework. Transaction ITI-1 is used by the Time Server and Time Client actors.

3.1.1 Scope
This transaction is used to synchronize time among multiple systems.

3.1.2 Use Case Roles

Actor: Time Server
Role: Responds to NTP time service queries.

Actor: Time Client
Role: Uses NTP or SNTP time service responses to maintain synchronization with Time Servers and maintain the local system clock.

Consistent Time is maintained in accordance with Standards described at ntp.org

The NTP transactions are described in detail in RFC1305. There is also extensive documentation on the transactions and recommendations on configurations and setup provided at http://www.ntp.org. Rather than reproduce all of that material as part of this Framework, readers are strongly encouraged to explore that site. The most common mode is the query-response mode that is described below. For other forms, see RFC1305 and the material on http://www.ntp.org.
Examples of Other ITI Enterprise Interoperability “Profiles:”

1. Find Staff: Person’s identity, pager/phone/office numbers, licenses and permissions, patient assignments
2. Authenticate User: permit/deny access to various features, functions, or information
3. Authenticate Node: Allow a particular laptop, printer, communication line, or storage device onto the network

As always, “The devil’s in the details…”

- Consider Gender (“Administrative Sex”),
  - In the Admission, Discharge, and Transfer (ADT) and billing systems information that field is likely Male, Female, or Unknown.
  - IHE may use the FIVE (5) Gender codes from HL7: Male, Female, Other, Ambiguous, and N/A!
  - This may not really matter to the billing system, but some Metabolic Carts, Cardiac Output, and Drug Formulary systems, for example, use Gender in their calculations and record-keeping!
    - A mistake could prove deadly…
  - Eventually, all of the Enterprise systems need to be able to handle all six codes properly…
“Devil’s in the details” example 2: IHE has to match patient records between multiple systems!

“Devil’s in the details” Ex. 3: IHE also deals with reconciling “John/Jane Doe” records

3.4.1 Case C1: Patient Registered at ADT and Procedure Ordered at the Order Placer
3.4.2 Case C2: Patient Registered at ADT and Procedure Ordered at DSS/OF
3.4.3 Case C3: Patient Registered at ADT and Procedure Not Ordered
3.4.4 Case C4: Patient Registered at DSS/OF and Procedure Ordered
3.4.5 Case C5: Patient Not Registered
3.4.6 Case C6: Patient Updated During Procedure
3.4.7 Case C7: Change Rooms During Procedure
3.4.8 Case C8: Cancel Procedure

Figure 3.3-1. Scheduled Workflow: Administrative Process Flow
In general…

• If you need a semantic interoperability profile to accomplish a common enterprise-wide a task, it likely exists – or is under development – in the ITI Technical Committee…

• If not, join the ITI-TC and help get it in motion!
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NOTE: The IHE ENTERPRISE profiles include Clinical/Technical AND Workflow!
Types, or Dimensions, of Interoperability

- Electrical or physical Interoperability
- General Infrastructure or Enterprise Interoperability
- Domain-Specific Semantic Interoperability

E.g., PCD Domain Semantics: Describing the device/system...

Medical Device System

Top level object that establishes the overall context for all device data. In addition to a basic device name (e.g., Ventilator), this object includes attributes for a unique identifier (e.g., EUI-64), manufacturer and model, subcomponent serial numbers, device date and time, A/C power status, battery charge level, locale, etc. Note that an MDS may contain additional MDS objects. This would be the case when, for example, a physiological monitor integrates additional devices such as external infusion pumps and ventilators.
e.g. Domain-specific semantics: Units of measure

ISO/IEEE 11073 Alternative Units Mapping

<table>
<thead>
<tr>
<th>ISO/IEEE 11073</th>
<th>UCUM</th>
<th>LOINC</th>
<th>SNOMED-CT</th>
<th>Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDC_DIM_CM_H20 (4-1994)</td>
<td>cmH2O</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_MCGROG_PER_HR (3379)</td>
<td>μG/hr</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_MICROG_PER_MIN (3377)</td>
<td>μG/min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_MI1LI_G_PER_HR (3378)</td>
<td>mG/hr</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_MI1LI_G_PER_MIN (3374)</td>
<td>mG/min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_MI1LI_L (4-1618)</td>
<td>mL</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_MIN (4-2706)</td>
<td>min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_PERCENT (4-544)</td>
<td>%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_RESP_PER_MIN (412784)</td>
<td>rpm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_SEC (4-2175)</td>
<td>sec</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_X_INTLOTUNIT_PER_HR (5095)</td>
<td>l.u./hr</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDC_DIM_X_L_PER_MIN (4-3072)</td>
<td>l/min</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

e.g. Domain-specific semantics: Alarm Event Codes

Device Alert Event Semantics

<table>
<thead>
<tr>
<th>General Events</th>
<th>Term Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alarm</td>
<td>MDC_EVT_ALARM (3-48)</td>
</tr>
<tr>
<td>Disconnected</td>
<td>MDC_EVT_DISCONNECT (3-22)</td>
</tr>
<tr>
<td>Empty</td>
<td>MDC_EVT_EMPTY (3-26)</td>
</tr>
<tr>
<td>Error</td>
<td>MDC_EVT_ERR (3-30)</td>
</tr>
<tr>
<td>Failure</td>
<td>MDC_EVT_FAIL (3-38)</td>
</tr>
<tr>
<td>High</td>
<td>MDC_EVT_H (3-40)</td>
</tr>
<tr>
<td>High – Greater than set limit</td>
<td>MDC_EVT_HT_ST_LIM (3-42)</td>
</tr>
<tr>
<td>INOP (device is inoperative)</td>
<td>MDC_EVT_INOP (3-52)</td>
</tr>
<tr>
<td>Low</td>
<td>MDC_EVT_LO (3-62)</td>
</tr>
<tr>
<td>Low – Less than set limit</td>
<td>MDC_EVT_LT_ST_LIM (3-64)</td>
</tr>
<tr>
<td>Occlusion</td>
<td>MDC_EVT_OCCL (3-80)</td>
</tr>
<tr>
<td>Range Error</td>
<td>MDC_EVT_RANGE_ERR (3-164)</td>
</tr>
<tr>
<td>Door/Handle Position Problem</td>
<td>MDC_EVT_DORHANDLE_POSN_PROB (3-234)</td>
</tr>
<tr>
<td>Fluid Line Problem</td>
<td>MDC_EVT_FLUID_LINE_PROB (3-252)</td>
</tr>
<tr>
<td>Gas is contaminated</td>
<td>MDC_EVT_GAS_CONTAM (3-256)</td>
</tr>
<tr>
<td>Lead is off/disconnected</td>
<td>MDC_EVT_LEAD_OFF (3-272)</td>
</tr>
<tr>
<td>Sensor problem</td>
<td>MDC_EVT_SENSOR_PROB (3-312)</td>
</tr>
<tr>
<td>Low signal level</td>
<td>MDC_EVT_SIG_LO (3-380)</td>
</tr>
<tr>
<td>Timeout</td>
<td>MDC_EVT_TIMEOUT (3-384)</td>
</tr>
</tbody>
</table>

Physiological/Medical Events

<table>
<thead>
<tr>
<th>Term Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apnea</td>
</tr>
</tbody>
</table>
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ANSI Considers IHE to be a “Composite Standard”

• i.e., IHE is a Standard made up of other Standards
  – In general, IHE does not create the original standards, but selectively adopts proven ones, and/or suggests extensions to the SDOs

• e.g., the IHE PCD Technical Frameworks include references to IEEE 11073, HL7, LOINC, SNOMED, ISO, ANSI, AAMI, and other relevant standards
Cross-Enterprise Document Sharing (XDS) Standards Used

- Healthcare Content Standards
  - HL7 CDA, CEN EHRcom
  - HL7, ASTM CCR
  - DICOM

- Electronic Business Standards
  - ebXML Registry, SOAP, Web Services...

- Internet Standards
  - HTML, HTTP, ISO, PDF, JPEG...

- Implemented world-wide by more than 30 vendors/open source. Final text published December 2006.
- Adopted in several national & regional projects (Italy, France, Canada, Austria, USA, etc.)
- IHE XDS: 42,300 “Google” references (Feb’07)

Another IHE standard: XML is used to assure data transparency and structure.

```xml
<patient>
  <id> Patient Identifier (a.k.a. Medical Record Number) </id>
  "root" is UID scoping the local ID, usually identifying the Organization that assigned it
  "extension" is ID assigned by the Organization.
  <id root="1.3.6.1.4.1.20029.10.2332.23" extension="324414"/>
  <patientPatient>
    <name>
      <family>Smith</family>
      <given>John</given>
    </name>
    <administrativeGenderCode code="M" codeSystem="2.16.840.1.113883.5.1"/>
    <birthTime value="19650423"/>
  </patientPatient>
  <providerOrganization>
    <id root="1.3.6.1.4.1.20029.10.2332.23"/>
    <name>XYZ Memorial Hospital</name>
  </providerOrganization>
</patient>
```

Fairly easy to read and troubleshoot!
Although IHE does not formally write “standards” per se:

- IHE conducts its activities with open dialog and transparent processes that are consistent with most SDOs procedures.

- Unlike most SDOs, though, participation in the IHE composite standards development is FREE to HIMSS members!

- IHE Composite Standards are written so they do NOT replace other standards.
  - You still have to buy specific HL7, IEEE, AAMI, etc. standards to get the full details on all optional features and functions.

Final words about regulatory standards:

- Information systems that affect the diagnosis or treatment of a patient ARE considered medical devices too.

- FDA, JCAHO, CMS, Insurers, and other oversight is inevitable, though their explicit standards, recommendations, or requirements may lag this field.
Executive Order: “Promoting Quality and Efficient Health Care in Federal Government Administered or Sponsored Health Care Programs”

Sec. 3. Directives for Agencies. Agencies shall perform the following functions:

(a) Health Information Technology.
   (1) For Federal Agencies. As each agency implements, acquires, or upgrades health information technology systems used for the direct exchange of health information between agencies and with non-Federal entities, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.
   (2) For Contracting Purposes. Each agency shall require in contracts or agreements with health care providers, health plans, or health insurance issuers that as each provider, plan, or issuer implements, acquires, or upgrades health information technology systems, it shall utilize, where available, health information technology systems and products that meet recognized interoperability standards.

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Health Information Exchanges create Interoperability using IHE Profiles like Cross-enterprise Document Sharing

- Cross-Enterprise Information Sharing simplifies clinical data management by defining interoperable infrastructure. *Transparency = Ease of Evolution*
- Patients have guaranteed portability and providers may share information without concerns of aggregation errors. *Digital Documents = Patients and providers empowerment*
- Supports both centralized and decentralized repository architectures. *Ease of federation nationally. Flexible privacy, Flexibility of configurations*
- Addresses the need for longitudinal healthcare data and its intend is for support of archival data. It does not address workflow or dynamic data access.
- Workflows addressed in a second step in a much simpler manner. *Point-to-Point messages best suited for workflows mgmt*

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**XDS Scenario + use of Audit Trail & Consistent Time**

- Physician Office
- Community Clinic
- Lab Info. System
- Pacs
- ED Application
- Teaching Hospital
- EHR System
- PMS
- ATNA Audit record repository
- CT Time server
- Secured Messaging

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Cross Enterprise Data and Document Sharing Scenario + use of PIX & PDQ

Hierarchical Exchange
From Cross Community Information Exchange White Paper

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Portions of IHE have already been approved for the US National Healthcare Information Network

- Under President Bush’s Presidential Order, the Secretary of Health began work on the NHIN in 2004.

HHS Health IT Strategy

- The Community serves as the hub for identifying breakthrough opportunities
- CCHIT is developing a mechanism for certification of health care IT products
- HITSP brings together all relevant stakeholders to identify appropriate IT standards
- HISPC is addressing variations in business policy and state law that affect privacy and security
- NHIN is focusing on interoperability pilots starting in 2007
IHE is part of the US NHIN solution...

- In 2005, HHS contracted with ANSI to host the Healthcare Information Standards Panel (HITSP)
- After a full year of work by 220 independent organizations, in 2006, HITSP recommended using several IHE profiles for the first year designs
  - e.g., using the IHE Laboratory Technical Frameworks
- In 2007, the Secretary of Health accepted the HITSP recommendations as drafts, and HITSP is working on the second year’s designs now.

Lateral Exchange and non-IHE Domains

From Cross Community Information Exchange White Paper

What communities have specific attributes?

- National or Regional Network B
  - Cross Community Bridge
  - IHE Transactions (future)
  - Cross Community Bridge

- National or Regional Network C
  - IHE based Sub-Networks
  - Community Locator service
  - Non-IHE Sub-Network
  - Integrated Delivery Network

- National Network A
  - Non-IHE National EHR

- National Network A
  - National or Regional Networks not required to be IHE-based
  - Mapping to & from IHE Transactions performed by X-Community bridges
  - Mapping practical as most European projects use variants of structured document creation
So what? What will IHE for Patient Care Devices do for ME?

- PROVIDERS finally have a reliable, seamless, and consistent interfacing between multiple competing vendors, and between ongoing evolutionary product generations – throughout the hospital.
  - Direct data transfer to the Electronic Health Records
    - Reduce errors, labor costs, delays; improve patient safety
  - Significantly better device deployment and configuration flexibility
    - Reduce hospital operating costs, improve revenue capability
  - Easier and more consistent device and system diagnostics and troubleshooting
    - Faster installation, lower MTTR

**Improved Clinical Care, Total Cost of Ownership and Return on Investment!**

IHE value proposition is Win-Win for ALL!

- Vendors
  - Align product interoperability with industry consensus
  - Decreased cost and complexity of interface installation and management, especially in multi-vendor and multi-modal systems
  - Focus competition on functionality/service space not information transport space
- Standards Development Organizations
  - Rapid feedback to adjust standards to real-world
  - Establishment of critical mass and widespread adoption

Again: Improved Clinical Care, Total Cost of Ownership and Return on Investment!
How can YOU participate?

As a Provider or Vendor Contributor
• Offer Clinical Use Case Input to Drive IHE Profile Development
• Become a member of relevant domain’s Planning or Technical Committees
• Become a member of relevant Regional/National Committees
• Help to shape IHE’s future direction

As a Vendor Participant
• Respond to Public Comments of Domain Supplements
• Attend the yearly September Educational Workshops
• Participate in Connect-a-thons and Demonstrations

As a Provider/Consultant Participant
• Respond to Public Comments of Domain Supplements
• Attend the yearly September Educational Workshops
• Attend Demonstrations and include IHE Integration Profiles in your RFPs and Integration Projects.

HOW?

• Learn about more IHE frameworks at IHE.net

• Insist on IHE compliance in your RFPs and contract documents:
  – Select Integration Profiles, and Appropriate Actor(s)
  – Ask vendor’s for their products “IHE Integration Statements”.

• Ask for more dimensions of interoperability.
  – Join and contribute to the IHE Committees!
Special credit and thanks to:

• The IHE PCD Domain leaders
  – Co-chair: Todd Cooper, Breakthrough Solutions
  – Co-chair: Jack Harrington, Philips Medical
  – Co-chair: Ray Zambuto, Technology in Medicine
  – Technical Project Director: Manny Furst, Imp-Tech

• Dozens of volunteers (companies, hospitals, individuals) who’ve planned and written the 2006 frameworks

• All our partnering companies in the IHE PCD Connectathon and IHE Showcase
  – B. Braun, Draeger, GE, Live Data, Philips, Welch Allyn

• ACCE and HIMSS for their sponsorship

The IHE Connectathon, just held in January, 2007, shows the HUGE amount of work, money, and dedication it takes! For this year, each company paid a $10,000+ entrance fee, plus many thousands more to supply 430 engineers from 80+ organizations representing 160+ systems and applications.

All this just to become qualified to enter this week’s IHE Showcase!
What we covered:

- The “Integrating the Healthcare Enterprise” (IHE) initiative, and how it works as a cost effective model for interoperability
- Reviewed the various levels of interoperability from physical connectivity through use case semantics
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Come see our 2007 IHE Interoperability Breakthrough: Multi-vendor Patient Care Devices performing The “Heartfelt Patient,” a series of Critical Care Scenarios Emergency Care → Intensive Care → Perioperative Care
Always, we must remind ourselves to do good, but, too, first do no harm. Beware the unintended consequences!

Technology will be used in ways we never expected; we must do our best to expect the unexpected.
Teach your teams to ask:
“What could go wrong, and who could be hurt?”

Stay tuned for the next Episode, coming March 1: 'IHE International:' Global Health Connections...
Thank you!
Questions?
Comments!