Syllabus

0830-1000. Medical Device Connectivity Market, Standards, Strategic Direction
- How do medical device data interact with electronic health records as part of episodes of care?
- What does it mean to "integrate" data from medical devices into electronic medical record and healthcare information systems vs “interoperability” and what are the perils?
- HIPAA/Privacy implications and solutions.
- What are the patient safety aspects and concerns of transmitting and using medical device data?
- What are some of the system of systems challenges, such as validation & verification and multi-vendor systems integration?

1000-1030. Break
Syllabus

1030-1215. Standards in healthcare surrounding medical device data integration
- Health Level Seven (HL7)
- Integrating the Healthcare Environment (IHE)
- Integrating the Clinical Environment (ICE)
- Continua
- Technical/technology risk management, and ISO 80001

1215-1315. Lunch
Syllabus

1315-1500. Technical Aspects of Medical Device Interoperability
- Raw data vs meta data vs filtered data vs episodic/batched data
- Specific examples of connectivity from the medical device landscape (ED, OR, ICU, MED/SURG, HOME)
- Device Driver Development
- Alarms, real-time alerting & waveforms
- Worked Problems in Implementation

1500-1530. Break
1530-1700. Medical device data integration, Regulatory Considerations, Lessons Learned, and the Future

- Regulatory challenges
- MDDS
- Lessons learned from the field (e.g.: implementation, troubleshooting, network management, project lifecycle)
- Future of medical device data integration vis a vis clinical decision making and migration towards standards.
Related Textbooks

Integrating Device Data into the Electronic Medical Record [Paperback]

John Zaleski (Author)

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Priced: $65.00 & this item ships for FREE with Super Saver Shipping. Details

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Medical Device Data and Modeling for Clinical Decision Making (Artech House Bioinformatics & Biomedical Imaging) [Hardcover]

John R. Zaleski (Author)

Price: $139.00 & this item ships for FREE with Super Saver Shipping. Details

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Related Textbooks (concluded)
MEDICAL DEVICE CONNECTIVITY DEFINITION,

PATIENT IDENTIFICATION AND ASSOCIATION,

SYSTEMS OF SYSTEMS INTEGRATION
What is Medical Device Connectivity?

- The retrieval by electronic means of data and information gathered by devices used in the therapy, treatment, intervention and general care of patients...

- The data gathered from these devices is often used as a supplement to or replacement for manual charting and provides a more complete, stable, accurate and reliable means of communicating information measured from or on the patient to systems that make use of this information in support of bedside clinical decision making...

- Medical Device Connectivity is particularly useful in situations in which patients are technologically dependent or for which a reliable means of capture of this information would assist the clinical decision making process...
Medical Devices Supporting Acute Care Setting

Highly Technologically-Dependent Patients

- Mechanical Ventilation
- Infusion
- Monitors
- Intra-Aortic Balloon Pumps
- Anesthesia
- Bed
Who are stakeholders and what are their needs?

- Clinicians: Need data for decision making, charting
  - Anesthesiologists, surgeons, intensivists, pulmonologists, CRNAs, nurses, respiratory therapists, phlebotomists, etc.
Who are stakeholders and what are their needs?

- IT Staff: support application and IT needs of Clinicians
  - Software support, interoperability support, internal and external (vendor) EMR implementation staff
Who are stakeholders and what are their needs?

- Clinical Engineering: in support of biomedical devices implemented at point of care
  
  - Management & Maintenance of h/w, devices that support patient care and the clinicians that employ them for patient care management
Summary of Key Stakeholder Needs

- Rich, timely data for patient care management
- Temporally and semantically synchronized data to ensure accuracy for patient care management
- Secure, ubiquitous access for availability to data for patient care management
- Clinically sensitive IT solutions that support data needs as well as support clinical workflow
Medical Devices (OR & Surgical Services)
Medical Devices (ICU)
Medical Devices (General Wards)
Medical Devices (Remote / Home)
Management of the Technologically-Dependent patient
Management of the Technologically-Dependent patient

- Each Medical Device has its own autonomous and independent timing
- Each Medical Device employs its own syntax and method of communication (many proprietary)
- Each medical device must be validated with end point receptor systems (e.g.: AIMS, CIS, EMRs)
## Typical Frequencies of Data Collection—Various Departments

<table>
<thead>
<tr>
<th>Unit / Ward</th>
<th>What Functions Measured</th>
<th>Frequency of measurement</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Emergency Department</strong></td>
<td>Heart (e.g.: pulse, ST segments); Perfusion (e.g.: O2 saturation); Temperature</td>
<td>Continuous</td>
<td>Hours</td>
</tr>
<tr>
<td><strong>Surgery</strong></td>
<td>Heart (e.g.: pulse, ST segments); Perfusion (e.g.: O2 saturation, end tidal CO2); Pulmonary (e.g.: breath rate, tidal volume); Temperature; Drug administration</td>
<td>Continuous</td>
<td>Hours</td>
</tr>
<tr>
<td><strong>Cardiac Catheterization</strong></td>
<td>Heart (e.g.: pulse, ST segments); Perfusion (e.g.: O2 saturation)</td>
<td>Ad hoc</td>
<td>Hours</td>
</tr>
<tr>
<td><strong>Intensive Care</strong></td>
<td>Heart (e.g.: pulse, ST segments, cardiac output, ejection fraction); Perfusion (e.g.: O2 saturation, end tidal CO2); Pulmonary (e.g.: breath rate, tidal volume); Temperature; laboratory measurements; drug administration; outputs</td>
<td>Continuous</td>
<td>Hours – days – weeks</td>
</tr>
<tr>
<td><strong>Medical / Surgical</strong></td>
<td>Heart (e.g.: pulse); Perfusion (e.g.: O2 saturation); Temperature</td>
<td>Ad hoc</td>
<td>Days-weeks</td>
</tr>
<tr>
<td><strong>Radiology</strong></td>
<td>Heart (e.g.: pulse); Perfusion (e.g.: O2 saturation)</td>
<td>Ad hoc</td>
<td>Hours</td>
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### Meaningful Use Matrix

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<td>Improve quality, safety, efficiency, and reduce health disparities</td>
<td>• Provide access to comprehensive patient health data for patient’s health care team</td>
<td>Goal is to electronically capture in coded format and to report health information and to use that information to track key clinical conditions</td>
<td>• Use CPOE for all order types including medications [OP, IP]</td>
<td>• Use evidence-based ordering lists [OP, IP]</td>
<td>• Use evidence-based order sets [OP, IP]</td>
<td>• Achieve minimal levels of performance on quality, safety, and efficiency measures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Use evidence-based order sets and CPOE</td>
<td></td>
<td>• Implement drug-drug, drug-allergy, drug-formulary checks [OP, IP]</td>
<td>• Generate and transmit permissible prescriptions electronically (eRx) [OP]</td>
<td>• Record clinical documentation in EHR [IP]</td>
<td>• Medical device interoperability [OP, IP]</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Apply clinical decision support at the point of care</td>
<td></td>
<td>• Maintain an up-to-date problem list [OP, IP]</td>
<td>• Maintain active medication list [OP, IP]</td>
<td>• Generate and transmit permissible prescriptions electronically [IP]</td>
<td>• Multimedia support (e.g., x-rays) [OP, IP]</td>
<td></td>
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<td></td>
<td>• Generate lists of patients who need care and use them to reach out to patients (e.g., reminders, care instructions, etc)</td>
<td></td>
<td>• Use CPOE for all order types including medications</td>
<td>• Maintain active medication list [OP, IP]</td>
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<td>• Report to patient registries for quality improvement, public reporting, etc</td>
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<td>• Generate and transmit permissible prescriptions electronically</td>
<td></td>
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</tbody>
</table>

6/15/2009

Source: healthit.hhs.gov
Medical Device Interfacing to Electronic Medical Record Systems

- Infusion
- Respiratory
- Critical Care Vital Signs
- Glucose
- Ad Hoc Vital Signs
- Beds/Scales

EMR

Results, Findings, Notifications (e.g.: to event queues)

Source: DVHIMSS 2008
Medical Device Interfacing to Electronic Medical Record Systems

- Infusion
- Respiratory
- Critical Care Vital Signs
- Beds/Scales
- Admission, Discharge, Transfer (where applicable/possible)
- Glucose

Source: DVHIMSS 2008
Medical Device Connectivity Spectrum

Self-contained Workstations
(e.g.: Nursing station monitors, MRI & CT Scan monitors)

Multiple measurement
(e.g.: Med/Surg & ICU Monitors, Ventilators)

Single measurement
(e.g.: glucometers, thermometers, stethoscopes, probes)

- Point-to-point serial
- Point-to-point wireless (e.g.: blue tooth, IR)
- Fixed IP Network enabled (e.g.: TCP/IP & Multicast over Ethernet)
- DHCP IP Network enabled (e.g.: TCP/IP & Multicast over Ethernet)
- Wireless Network enabled (e.g.: TCP/IP & Multicast over Ethernet)
- Secure Wireless Network compliant (e.g.: WPA, WPA2)

Source: Zaleski, Integrating Device Data Into the Electronic Medical Record. February 2009
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  (e.g.: glucometers, thermometers, stethoscopes, probes)

**Connectivity Technology**
- Point-to-point serial
- Point-to-point wireless (e.g.: blue tooth, IR)
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- DHCP IP Network enabled (e.g.: TCP/IP & Multicast over Ethernet)
- Wireless Network enabled (e.g.: TCP/IP & Multicast over Ethernet)
- Secure Wireless Network compliant (e.g.: WPA, WPA2)

**Data**
- Measurements (e.g.: Temp=37C, SpO2=98%)
- Settings (e.g.: SIMV/12, PEEP=5cmH2O)
- Alarms (e.g.: ASYSTOLE)
- RTCP & Waveforms (e.g.: ECG trace)
- Video & Audio (e.g.: Camera)
- Remote Control (e.g.: Pacemakers, ventilators)

Source: Zaleski, Integrating Device Data Into the Electronic Medical Record. February 2009
Cross Enterprise Medical Device Connectivity: Essential

- Architectures that provide access from bedside to provider, anywhere
  - Spontaneous breathing trials,
  - Holter monitoring
  - Glucose, blood pressure, O2 saturation

- Achieving trusted, reliable, available connectivity is necessary first step to ensure seamless access
  - At home, all departments, wards,
  - assisted living and long-term nursing environments

- Challenge becomes one of systems of systems integration
Some medical device manufacturers have developed more standardized interfaces to medical devices.

Many medical devices communicate using vendor-proprietary messaging syntax & semantics.

As a result, the need for medical device intermediaries has arisen that provides the proprietary link between medical device and standardized communication to end-point receptor systems.
Medical Device Communication from Surgical Areas

ANESTHESIA SYSTEMS

SPECIALTY MONITORS (ETCO2, BISPECTRAL INDEX, CARDIOPULMONARY BYPASS, ETC.)

Communicate through existing anesthesia machines or device intermediaries
Medical Device Communication from Intensive Care

INFUSION SYSTEMS

- Formularies, Identifiers
- Volume delivery, dosing

Gateway or Concentrator

Interface Server

EMR, Rx, Departmental CIS

ICU MONITORING SYSTEMS

- Identifiers, Labs
- Measurements, Observations

Gateway or Concentrator

Interface Server

EMR, Departmental CIS

MECHANICAL VENTILATION, SPECIALTY MONITORING

- Queries, Identifiers, etc.
- Observations

Device Intermediary

ADT, etc.

HL7 R01

Interface Server

EMR, Departmental CIS
Medical Device Communication from Post-Surgical Wards, some EDs

INFUSION SYSTEMS

- Formularies, Identifiers
- Volume delivery, dosing

SPOT VITAL SIGNS MONITORING, BEDS

- Queries, Identifiers, etc.
- Observations

Device Intermediary

- Gateway or Concentrator
- ADT, Rx
- HL7 R01
- Interface Server

EMR, Rx, Departmental CIS

ADT, etc.

EMR, Departmental CIS
Home Health, Assisted Living

- Blood Pressure
- Weight Scales
- Blood Glucose
- Spirometers
- Holter Monitoring

...and many more devices to come
The essence of the challenge: Communication

- Medical Device communication, for most part, is non-standardized.
- Many manufacturers provide proprietary interfaces that follow the EIA232 (i.e., RS232) interface requirements, but no informational formatting requirements. Especially true of smaller, handheld devices (glucometers, flow meters, home blood pressure equipment, pulse oximeters, etc.)
- Larger manufacturers—especially those producing vital signs monitors, and some in the infusion pump market—provide gateways. Systems within systems that provide both an internal proprietary mechanism for communication and a gateway for establishing a more ubiquitous interface via an HL7 messaging approach.

What we have here is a failure to communicate.

Source: Zaleski, DVHIMSS 2008
Methods and approaches to interfacing are maturing

- Many organizations, IEEE, IHE, AHIMA, AAMI, HL7, ACCE, are actively engaged in promoting standards and their development.
- However, even with standards there is no consensus on best methods for device integration.
  - For example: IEEE 11073, Medical Interface Bus communication
- Thus, device-level interface standards are still not universally adhered to by device manufacturers.
- Yet, IHE & HL7 standards (v2.x and beyond) does provide a framework for data communication among disparate systems (focused more on interfacing of IT systems than medical devices)
Examples of Top Commercial Device Integration Products – Medical Device Intermediaries

- DataCaptor by Capsule Technologie
- iSirona
- Nuvon
- Cerner
- Cardiopulmonary Corp.
- Etc.
The use of barcoding and radio frequency identification for patient identification have been shown to have a real impact on patient safety. The Food and Drug Administration (FDA) estimated that 25,000 medical errors amounting to $4.5 billion dollars could be prevented each year using an ID band.

Examples of Unique Patient Identifying Information

<table>
<thead>
<tr>
<th>Identifier</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Patient last, first, middle initial</td>
</tr>
<tr>
<td>MRN</td>
<td>Medical record number</td>
</tr>
<tr>
<td>PTN/ACN</td>
<td>Patient number / Account number</td>
</tr>
<tr>
<td>DOB</td>
<td>Date of birth</td>
</tr>
<tr>
<td>Gender</td>
<td>M/F/variant</td>
</tr>
<tr>
<td>Blood Type</td>
<td>Self-explanatory</td>
</tr>
<tr>
<td>Height</td>
<td>Measured in cm</td>
</tr>
<tr>
<td>Weight</td>
<td>Measured in kg</td>
</tr>
<tr>
<td>Location</td>
<td>Patient room and bed information</td>
</tr>
</tbody>
</table>
Example of HL7 Transaction with Patient Identifying Information

MSH|^~\&|Source_System||Destination_EMR||YYYYMMDDhhmm||ORU^R01|
YYYYMMDDhhmmss|P|2.3|YYYYMMDDhhmmss|

PID|1||123456^^^MRN~123456789^^^ACN||Last_Name^First_Name|||||

OBR|1||^Vitals||200403130304|
OBX|1|ST|^Resp||20|min||R||
OBX|3|ST|^Pulse||65|min||R||

OBX|4|ST|^Pulse Location|Monitor|R||
OBX|5|ST|^Temp|29.3°C||R||

OBX|6|ST|^Temp Site|Oral||R||
OBX|7|ST|^NIBP Systolic|122|mmHg||R||
OBX|8|ST|^NIBP Diastolic|80|mmHg||R||

OBX|9|ST|^NIBP Location|Left Arm||R||OBX|10|ST|^NIBP Source|Monitor||R||
OBX|11|ST|^NIBP Position|Sitting||R||

OBX|12|ST|^Weight|52|kg||R||
OBX|13|ST|^Scale Type|Bed||R||

OBX|14|ST|^Height|120|cm||R||
OBX|15|ST|^O2 device|Mask||R||

OBX|16|ST|^lpm|5|L/M||R||
OBX|17|ST|^O2Sat|98||R||

OBX|18|ST|^Pain Scale|2||R|
EXAMPLE WORKFLOW FOR ASSOCIATING MEDICAL DEVICES WITH PATIENTS
Log in to Health Information System
Select Patient from Census List
Pass patient identifying information
Launch External Application to Communicate with Medical Device
Retrieve Findings from Medical Device
Create Message Containing Patient Identifying Information With Findings
Transmit Findings to EMR
Update HIS Record to Show Findings for Patient
OR, ICU, Sub-Acute

- Staffing & Resource shortages top list of unmet needs associated with high-acuity environments
- Others:
  - Faster/More accurate diagnoses
  - Faster/unimpeded access to patient information
  - Improved care protocols
  - Better alerting and notification of patient status
  - Treatment maps and pathways
  - Risk-scoring and acuity prioritization support

Clinical Decision Support (CDS):
(1) Enables early prediction and identification of ICU patients at risk,
(2) Allows ICU clinicians to focus their attention on critical cases, preventing complications, reducing length of stay, and improving outcomes.
State of Acute Care

- American College of Physicians estimates 500,000 deaths annually in ICUs (U.S.)
- Larger amounts of hemodynamic, respiratory, I&O information will be automated
  - Motivates enterprise integration
  - Reduces charting workload
  - Improves completeness, accuracy
- Key Drivers
  - Patient safety
  - Longitudinal EMR deployment
  - Increase efficiency
  - Staffing shortages
  - Increasing numbers of CC beds
## Types of Data Most Used in ICU Clinical Decision Making

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Value</th>
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Section Summary

- Today, many medical devices are standalone and do not conform to specific messaging interface standards:
  - Rely on proprietary, vendor-specific interface communication
  - Support direct serial connectivity and require network-enablement through medical device data systems
  - Reliance on medical device intermediaries to translate from vendor-proprietary formats to more standardized (HL7)
- Associating medical devices with patients is important to minimize data alignment errors and misassociating data from one patient with another:
  - Workflows involving barcodes, radiofrequency identification (RFID) and picklists must be woven into clinical workflow to ensure application and compliance
  - Many standalone medical devices provide no means of direct patient association. Hence, associating data with specific patients must be carried out through separate applications and prior to transmitting to end-user receptor systems (EMRs).
- Medical Device Data are increasingly becoming part of the fabric of information required for clinical decision making at the point of care.
STANDARDS IN HEALTHCARE IT SURROUNDING MEDICAL DEVICE DATA INTEGRATION
Health Level Seven (HL7)

- From [http://www.hl7.org](http://www.hl7.org):
  - “Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. HL7's 2,300+ members include approximately 500 corporate members who represent more than 90% of the information systems vendors serving healthcare.”

- “Health Level Seven“
  - refers to the seventh level of the International Organization for Standardization (ISO) seven-layer communications model for Open Systems Interconnection (OSI) - the application level. The application level interfaces directly to and performs common application services for the application processes. Although other protocols have largely superseded it, the OSI model remains valuable as a place to begin the study of network architecture.
Health Level Seven is one of several American National Standards Institute (ANSI)-accredited Standards Developing Organizations (SDOs) operating in the healthcare arena.

Most SDOs produce standards (sometimes called specifications or protocols) for a particular healthcare domain such as pharmacy, medical devices, imaging or insurance (claims processing) transactions. Health Level Seven's domain is clinical and administrative data.
Vision & Mission

- Vision
  - To create the best and most widely used standards in healthcare

- Mission
  - HL7 provides standards for interoperability that improve care delivery, optimize workflow, reduce ambiguity and enhance knowledge transfer among all of our stakeholders, including healthcare providers, government agencies, the vendor community, fellow SDOs and patients. In all of our processes we exhibit timeliness, scientific rigor and technical expertise without compromising transparency, accountability, practicality, or our willingness to put the needs of our stakeholders first.
Approved standards that apply to medical device connectivity

- **Health Level Seven Standard Version 2.2** - An application Protocol for Electronic Data Exchange in Healthcare Environments
  Designation: ANSI/HL7 V2.2-1996 Date Approved: 2/8/1996

- **Health Level Seven Standard Version 2.3** - An application Protocol for Electronic Data Exchange in Healthcare Environments
  Designation: ANSI/HL7 V2.3-1997 Date Approved: 5/13/1997
  Information: This is a revision of ANSI/HL7 V2.2-1996

- **Health Level Seven Standard Version 2.3.1** - An application Protocol for Electronic Data Exchange in Healthcare Environments
  Designation: ANSI/HL7 V2.3.1-1999 Date Approved: 4/14/1999
  Information: This is a revision of ANSI/HL7 V2.3-1997

- **Health Level Seven Standard Version 2.4** - An application Protocol for Electronic Data Exchange in Healthcare Environments
  Designation: ANSI/HL7 V2.4-2000 Date Approved: 10/16/2000
  Information: This is a revision of ANSI/HL7 V2.3.1-1999
Approved standards that apply to medical device connectivity

• **HL7 Version 3 Standard**: Clinical Document Architecture, Release 1  
  Designation: ANSI/HL7 CDA, R1-2000  
  Date Approved: 10/24/2000

• **Health Level Seven Standard Version 2.5** - An application Protocol for Electronic Data Exchange in Healthcare Environments  
  Designation: ANSI/HL7 V2.5-2003  
  Date Approved: 6/26/2003  
  Information: This is a revision of ANSI/HL7 V2.4-2000

• **Health Level Seven Standard Version 2.6** - An Application Protocol for Electronic Data Exchange in Healthcare Environments  
  Designation: ANSI/HL7 V2.6-2007  
  Date Approved: 10/12/2007  
  Information: This is a revision of ANSI/HL7 V2.5.1-2007

• **Health Level Seven Standard Version 2.7** - An Application Protocol for Electronic Data Exchange in Healthcare Environments  
  Designation: ANSI/HL7 V2.7-2011  
  Date Approved: 1/28/2011  
  Information: This is a revision of ANSI/HL7 V2.6-2007

• **Health Level Seven Standard Version 2.7.1** - An Application Protocol for Electronic Data Exchange in Healthcare Environments  
  Designation: ANSI/HL7 V2.7.1-2012  
  Date Approved: 7/9/2012  
  Information: (revision of ANSI/HL7 V2.7-2011)
Integrating the Healthcare Enterprise: http://www.ihe.net
IHE.NET Patient Care Device Domain

IHE PCD Profiles

IHE Patient Care Device

The IHE Patient Care Device (PCD) domain was formed in 2005 to address the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR, potentially resulting in significant improvements in patient safety and quality of care. In 2008/2009 the first profile was successfully developed, tested in a Connectathon and demonstrated at HIMSS10, exchanging information from vital signs, physiologic monitors, ventilators, infusion pumps, and anesthesia workstations with enterprise applications such as clinical information systems. This enterprise-level integration is actively being extended to point-of-care integration, as well as to new workflow integration needs, such as alarm communication management.

IHE PCD is sponsored by the American College of Clinical Engineering (ACCE) and the Health Information Management Systems Society (HIMSS).

IHE PCD Profiles

IHE Patient Care Device integration profiles include:

- [ACM] Alarm Communication Management enables the remote communication of point-of-care medical device alarm conditions ensuring the right alarm with the right priority to the right individuals with the right content (e.g., evidentiary data). It also supports alarm escalation or confirmation based on dissemination status, such as whether the intended clinician has received and acknowledged the condition.
- [DEC] Device Enterprise Communication supports publication of information acquired from point-of-care medical devices to applications such as clinical information systems and electronic health record systems, using a consistent messaging format and device semantic content.
- [DEC-PID] Patient Identity Binding provides an optional extension to the DEC profile that supports a means of binding authenticated patient identity information to device data communication transactions.
- [DEC-SPD] Subscribe to Patient Data provides an optional extension to the DEC profile that supports a filtering mechanism using a publish/subscribe mechanism for applications to negotiate what device data they receive based on a set of client-specified predicates.
- [P4V] Point-of-care Infusion Verification supports communication of a 5-Rights validated medication delivery/intubation order from a BCMA system to an infusion pump or pump management system, thus “closing the loop.” Optionally, the [DEC] profile may be used to selectively monitor the status of the devices that have been programmed.
- [RTM] Rosetta Terminology Mapping establishes a set of tools (Excel spreadsheets & XML files) that map the proprietary semantics communicated by medical devices today to a standard representation using ISO/IEEE 11073 semantics and UCMC units of measurement. Additionally, the Rosetta tables capture parameter co-constants, specifying the set of units of measurement, body sites, and enumerated values that may be associated with a given parameter, thus enabling even more rigorous validation of exchanged medical device semantic content.
"The IHE Patient Care Device (PCD) domain was formed in 2005 to address the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR, potentially resulting in significant improvements in patient safety and quality of care. In 2006/2007 the first profile was successfully developed, tested in a Connectathon and demonstrated at HIMSS '07, exchanging information from vital signs, physiological monitors, ventilators, infusion pumps, and anesthesia workstations with enterprise applications such as clinical information systems. This enterprise-level integration is actively being extended to point-of-care integration, as well as to new workflow integration needs, such as alarm communication management."
Integrating the Healthcare Enterprise (IHE) (from the Web site)

- **IHE** is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. In 1997, a consortium of radiologists and information technology experts formed IHE, or "Integrating the Healthcare Enterprise."
- IHE created and operates a process through which interoperability of health care IT systems can be improved.
- The group gathers case requirements, identifies available standards, and develops technical guidelines that manufacturers can implement.
- IHE also stages "connectathons" and "interoperability showcases" in which vendors assemble to demonstrate the interoperability of their products.
- IHE is an international organization that focuses on the development of open and global IHE Integration Profiles and on the regional deployment of interoperable IT systems. Because of its limited resources, IHE concentrates on specific projects. It solicits proposals; and after surveying its members to better understand their priorities, it chooses areas to focus on.
Welcome to Integrating the Healthcare Enterprise

IHE is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively.

Learn More:

Developers of Healthcare IT Systems
- Process
- Profiles
- Technical Frameworks
- Participate
- Connectathon

Users of Healthcare IT Systems
- Process
- Profiles
- Integration Statements
- User Handbooks
- Presentations

What's New in IHE?
- IHE Europe Connectathon breaks new ground >>
- Register for Connectathon preview sessions, June 20 and 21 >>
- IHE International gains ISO Liaison A status >>
- More news...
IHE Connectathon

IHE North America Connectathon 2011

January 17-21
Hyatt Regency
Chicago

Developers of healthcare IT systems will take part in testing more than 150 healthcare IT systems at the industry’s only large-scale interoperability testing event. The Connectathon tests HIT systems to foster compliance with standards, electronic health record system connectivity and interoperable exchange of patient health information. Many of the capabilities tested at the Connectathon are closely aligned with the criteria for achieving "meaningful use" of electronic health records recently published by the U.S. Department of Health and Human Services.

- Details for Participants: Registration, rules, timelines, logistics and technical issues
- Connectathon Results Database

To receive communications about the Connectathon enter your email address in the blank below:
Integrating the Clinical Environment (ICE) ASTM F2761

F2761-09
Medical Devices and Medical Systems —
Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model
ICE Framework for plug-and-play connectivity

Introduction

MEDICAL DEVICES are essential for the practice of modern medicine. Some MEDICAL DEVICES utilize open networking standards for communication to provide data for the electronic health record. However, unlike the interoperable “plug-and-play” environment of modern computers and consumer electronics, most acute care MEDICAL DEVICES are not designed to interoperate. MEDICAL DEVICES typically utilize proprietary protocols for system integration. These approaches do not provide the comprehensive integration capabilities necessary for safe, cross-MANUFACTURER MEDICAL DEVICE integration for data communication and MEDICAL DEVICE control for the care of a single high acuity PATIENT. This standard series establishes the general principles for the design, verification, and validation of a model-based integration system that enables the creation of an INTEGRATED CLINICAL ENVIRONMENT intended to facilitate cross-MANUFACTURER MEDICAL DEVICE interoperability. This series of standards focuses especially on communication of PATIENT data and on equipment command and control, as well as on the functionality necessary for the seamless creation of an INTEGRATED CLINICAL ENVIRONMENT. The approach defined and described by this series of standards for the INTEGRATED CLINICAL ENVIRONMENT (ICE) includes provisions for error resistance, and continual improvements in PATIENT safety, treatment efficacy and workflow efficiency based on device interoperability. [30]
ICE Network Controller:
• ensures functional capabilities, in accordance with non-functional requirements in DEVICE MODEL of ICE-COMPATIBLE EQUIPMENT, can be reliably delivered to ICE SUPERVISOR; or
• generates a TECHNICAL ALARM CONDITION that indicates that required performance cannot be delivered.

ICE Supervisor:
• ensure functional capabilities and non-functional requirements, as indicated by the ICE NETWORK CONTROLLER, are suitable for INTENDED USE of ICE SUPERVISOR; or
• Generates a TECHNICAL ALARM CONDITION that indicates required capabilities cannot be delivered.
IEC 80001-1:2010

Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities
An increasing number of MEDICAL DEVICEs are designed to exchange information electronically with other equipment in the user environment, including other MEDICAL DEVICES. Such information is frequently exchanged through an information technology network (IT-NETWORK) that also transfers data of a more general nature.

There remain a number of potential problems associated with the incorporation of MEDICAL DEVICES into IT-NETWORKS, including:

- lack of consideration for risk from use of IT-networks during evaluation of clinical risk
- lack of support from manufacturers of MEDICAL DEVICES for incorporation of their products into IT-NETWORKS, (e.g. unavailability or inadequacy of information provided by manufacturer to OPERATOR of IT-NETWORK
- incorrect operation or degraded performance (e.g. incompatibility or improper configuration) resulting from combining MEDICAL DEVICES and other equipment on same IT-NETWORK
- incorrect operation resulting from combining MEDICAL DEVICE SOFTWARE and other software applications (e.g. open email systems or computer games) in same IT-NETWORK, and
- conflict between need for strict change control of MEDICAL DEVICES and need for rapid response to an attack by malware.
Incorporation or removal of a MEDICAL DEVICE or other components in an IT-NETWORK is a task which requires design of action; this might be out of control of manufacturer of MEDICAL DEVICE.

RISK MANAGEMENT should be used before incorporation of a MEDICAL DEVICE into an IT NETWORK takes place, and during entire life cycle of IT-NETWORK incorporating MEDICAL DEVICE, to avoid unacceptable RISKS, including possible HARM to PATIENTS, resulting from incorporation of MEDICAL DEVICE into IT-NETWORK.

Aspects of removal, change or modification of equipment, items or components should be addressed adequately in addition to incorporation of MEDICAL DEVICES.

Manufacturer of MEDICAL DEVICE intended to be incorporated into an IT-NETWORK might need to provide information about MEDICAL DEVICE that is necessary to allow RESPONSIBLE ORGANIZATION to manage RISK according to this standard. This information includes, as part of the ACCOMPANYING DOCUMENTS, instructions specifically addressed to person who incorporates a MEDICAL DEVICE into an IT-NETWORK.
Aspects of removal, change or modification of equipment, items or components should be addressed adequately in addition to incorporation of MEDICAL DEVICES.

Manufacturer of MEDICAL DEVICE intended to be incorporated into an IT-NETWORK might need to provide information about MEDICAL DEVICE that is necessary to allow RESPONSIBLE ORGANIZATION to manage RISK according to this standard. This information includes, as part of the ACCOMPANYING DOCUMENTS, instructions specifically addressed to person who incorporates a MEDICAL DEVICE into an IT-NETWORK.
HL7 Unsolicited Observation Result: R01 Transaction

Source: Zaleski, DVHIMSS 2008
Example HL7 Record from Device Intermediary System (Nuvon) (anesthesia machine part 1)
Example HL7 Record Device Intermediary System (Nuvon)
anesthesia machine part 2

HL7 MESSAGE #77234:
MSH|~\4|VEGA|^1|VEGA00000538|NUVON|20120803070845|ORU|R01|0538:01:00031EA4|P|2.3
PV1||EV-DM3K-AN008
OBR|1|11111112012803070842
OBX|1|NM|148-2448^HAL-CONC||0|mL
OBX|2|NM|148-2449^ENF-CONC||0|mL
OBX|3|NM|148-2450^ISO-CONC||0|mL
OBX|4|NM|148-2451^DES-CONC||0|mL
OBX|5|NM|148-2452^SEV-CONC||35|mL
OBX|6|NM|148-2447^SEV-P-IN||0|kPa
OBX|7|NM|148-2445^SEV-P-EX||0|kPa
OBX|8|NM|148-2094^BARO-MBAR||1980|mbar
OBX|9|NM|148-2447^SEV-IN||10|%
OBX|10|NM|148-2445^SEV-EX||10|%
OBX|11|NM|148-2090^LEAKAGE||19|mL/min
OBX|12|NM|148-2004^APN-T||0|s
OBX|13|NM|148-2092^FGF-N20||0|L/min
OBX|14|NM|148-2093^FGF-AIR||0|L/min
OBX|15|NM|148-2091^FGF-O2||0|L/min
OBX|16|NM|148-0131^SET-AGE||18|
OBX|17|NM|148-01A1^SET-WEIGHT||146|kg
OBX|18|ST|148-5024^DEV-MODEL||Apollo|
OBX|19|ST|148-5022^DEV-CODE||0057|
OBX|20|ST|148-5023^DEV-PROT||MEDIBUS|
OBX|21|ST|148-5025^DEV-PROT-VER||04.03|
OBX|22|ST|148-5025^DEV-VER||04.30|
OBX|23|ST|148-5026^DEV-TXT-TS||07:09:5503-AUG-12|
OBX|24|TS|148-5011^DEV-TS||20120803070955|
OBX|25|NM|148-5021^IDM-SRC||6|
OBX|26|ST|148-5027^DEV-MODE||Carrier Gas AIR\No 2nd anesthesia gas\Mode STANDBY|
OBX|27|ST|IDM-SN||13E3VEGA0000998|
OBX|28|ST|IDM-IP||10.132.14.254|
OBX|29|ST|IDM-NAME||EV-DM3K-AN008|
OBX|30|ST|IDM-LOC||EV-DM3K-AN008|
OBX|31|NM|IDC-SLOT||1|
OBX|32|NM|IDC-CB||148|
NTE|1||Msgs: 1, Wnd:1/1, PriQ: 0/0, SecQ: 0/0|GR
NTE|2||source: I3E3VEGA0000998, EV-DM3K-AN008, 10.132.14.254|GR

HL7 ACK:
MSH|~\4|VEGA|^1|VEGA00000538|NUVON|20120803070845|ACK|0538:01:00031EA4|P|2.3|1111
3 Device Enterprise Communication (DEC)

The Device Enterprise Communication Integration Profile supports consistent communication of vendor independent, multi-modality Patient Care Device data to Enterprise Applications using consistent semantics. It accomplishes this by mapping of PCD data from proprietary legacy syntax and semantics into a single syntactic and semantic representation for communication to the enterprise. The PCD data is time stamped with a consistent enterprise time. Options are provided to allow applications to filter particular PCD data of interest.

Depending on the use case, the PCD data includes identification of the patient either by location or by means of one or more authoritative enterprise patient identifiers, and is time-stamped with a consistent enterprise time.

3.1 Actors/Transactions

Figure 3 DEC Integration Profile: Actors and Transactions diagrams the actors involved with this profile and the transactions between actors.
3.1 Actors/Transactions

Figure 3 DEC Integration Profile: Actors and Transactions diagrams the actors involved with this profile and the transactions between actors.

Table 4 DEC - Actors and Transactions lists the transactions for each actor directly involved in the DEC Integration Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O”
Continua Health Alliance unites smart technology and medical devices with health care industry leaders to empower patients to not only exchange vital information but to change the way they manage health and wellness. Because when patients, loved ones and caregivers connect for greater health, everyone thrives.
Continua Health Alliance Mission

Manage Chronic Conditions
860 million individuals with chronic conditions worldwide

Continua member companies help individuals with chronic conditions live healthier lives by connecting them to their care team through a more efficient exchange of personal health information.
Section Summary

- Standardized messaging in healthcare usually employs Health Level Seven (HL7)
  - Some Medical devices and virtually all intermediaries strive to communicate outbound messaging in HL7 formats – as results transactions
  - HL7 implementations can vary greatly and can be dependent on the requirements of the receiving EMR
  - Integrating the Health Environment (IHE) has sponsored the development of a number of recommended medical device communications formats
    - All based on HL7
    - Patient Care Device (PCD) Domain
    - Transactions tailored for specific medical device communication

- Architectural standards for medical device communication, such as IEEE, can be augmented using these messaging standards
- Recommendations on architectural implementations also exist (e.g.: ASTM F2761) to provide a data communication framework whereby medical devices can interact with one another
TECHNICAL ASPECTS OF MEDICAL DEVICE INTEROPERABILITY
Medical Devices can have serial ports that provide communication access
Example: Foresight CASMED – Cerebral Oximeter used in Operating Rooms
Example: Datascope (Mindray) Passport V Monitor (GI/Endo Unit)
Example: Fabius GS Anesthesia Machines & Bispectral Index Monitor Used in OR
Example: Fabius Tiro Anesthesia & Solar 8000 Used in OR
Example: Passport 2 Monitor Used in Step-Down Units
Device Level Communications interfaces can be complex

- Can be developed using standard programming languages
  - E.g.: Java supports mature serial communication libraries
- Devices can operate in Transmit-only or Query-Response mode
  - Asynchronous
  - Proprietary command language
- Examples
  - Mechanical ventilators
  - Medical / Surgical Monitors
  - Glucometers
  - Scales
  - ...

Example: Servo-i ventilator

Sending: RB Query
Received: 196224862094248920703066229021502317222521462048

Sending: RT Response
Received: 031204144241

nResults: 12
sf = 5000.0
data = 1962

::: -0.0839876

OBX|1|NM|mib Flow^local^8462-4^LAB| -0.0839876|l/s|||C||20031204144241

sf = 5000.0
data = 1962

::: 0.4277508

OBX|1|NM|mib Tvi^local^8462-4^LAB| 0.4277508|l|||C||20031204144241

sf = 50.0
data = 2094

::: 4.49236

OBX|1|NM|mib IAP^local^8462-4^LAB| 4.49236|cm H2O|||C||20031204144241
Device Level Communication Interfaces... (continued)

- Not all devices of same class even produce same data feeds
  - Different nomenclature/semantics
  - Uncertain parameter mappings

- Example: Servo versus Puritan Bennett Ventilators
  - Expiratory & Inspiratory Minute, Tidal Volumes (Servo) versus Minute, Tidal Volume (7200ae)

- Example: Vital Sign definitions require some mapping between ad hoc monitors—a posteriori calculation required to equate parameter streams
  - Spot Vitals Signs Monitor temperature data
    - Kelvin, Celsius, Fahrenheit
  - Dinamap temperature data
    - Celsius, Fahrenheit

Source: Zaleski, 1996
Device Level Communication Interfaces... (continued)

Sending: RB

Received: 19622486209424892070306622902150231722521462048

Sending: RT

Received: 031204144241

nResults: 12

sf = 5000.0
data = 1962

--- -0.0839876

OBX|1|NM|mib Flow\^local^8462-4\^LAB||-0.0839876\|l/s|||C|||20031204144241

sf = 5000.0
data = 2486

--- :0.4277508

OBX|1|NM|mib Tvi\^local^8462-4\^LAB||0.4277508\|l/s|||C|||20031204144241

---

Maquet Servo-I Ventilator

---

Inspiratory Tidal Volume vs Tidal Volume

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Puritan Bennett 7200 Ventilator

---

Maquet Servo-I Ventilator

---

Inspiratory Tidal Volume vs Tidal Volume

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Puritan Bennett 7200 Ventilator

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Maquet Servo-I Ventilator

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Inspiratory Tidal Volume vs Tidal Volume

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Puritan Bennett 7200 Ventilator

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Maquet Servo-I Ventilator

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Inspiratory Tidal Volume vs Tidal Volume

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Maquet Servo-I Ventilator

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Inspiratory Tidal Volume vs Tidal Volume

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Puritan Bennett 7200 Ventilator

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Maquet Servo-I Ventilator

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Inspiratory Tidal Volume vs Tidal Volume

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Puritan Bennett 7200 Ventilator

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Maquet Servo-I Ventilator

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Inspiratory Tidal Volume vs Tidal Volume

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Puritan Bennett 7200 Ventilator
Device Level Communication Interfaces... (continued)

- Some devices support synchronous communication
  - Transmit all the time
  - Either write to file or transmit over network

Volume Delivered (ml)
Some devices communicate normally in Hexadecimal
Some medical devices support networked communication

- Many critical care monitors & other devices communicate via Ethernet to Gateways—central points of communication within a proprietary network.
Example of Networked Medical Devices

- Some can communicate wirelessly with an access point via 802.1x networking
- Others require hard-wiring
Section Summary

- Medical device communication requires an understanding of vendor-specific protocols
  - Proprietary syntax for query-response
  - Different medical devices have unique communication protocols
  - Intermediaries are often used to perform the physical and semantic transformation / translation from the proprietary to the standardized formats
MEDICAL DEVICE DATA SYSTEMS, REGULATORY CONSIDERATIONS, IMPLEMENTATION LESSONS LEARNED, AND THE FUTURE
Medical Device Data Systems (MDDS)

“Medical Device Data Systems (MDDS) are hardware or software products that transfer, store, convert formats, and display medical device data. An MDDS does not modify the data or modify the display of the data, and it does not by itself control the functions or parameters of any other medical device. MDDS are not intended to be used for active patient monitoring.”
Identifying an MDDS

- The Federal Register notice provides the following definition of a medical device data system:

  " § 880.6310 Medical device data system. -- (a) Identification.

  A medical device data system (MDDS) is a device that:
  - is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:
    - The electronic transfer of medical device data;
    - The electronic storage of medical device data;
    - The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or
    - The electronic display of medical device data.

  An MDDS may include:
  - software,
  - electronic or electrical hardware such as a physical communications medium (including wireless hardware),
  - modems, interfaces, and communications protocols."
Functions of an MDDS

- The electronic transfer or exchange of medical device data from a medical device, without altering the function or parameters of any connected devices. For example, this would include software that collects output from a ventilator about a patient's CO2 level and transmits the information to a central patient data repository.

- The electronic storage and retrieval of medical device data, without altering the function or parameters of connected devices. For example, software that stores historical blood pressure information for later review by a healthcare provider.

- The electronic conversion of medical device data from one format to another in accordance with a preset specification. For example, software that converts digital data generated by a pulse oximeter into a digital format that can be printed.

- The electronic display of medical device data, without altering the function or parameters of connected devices. For example, software that displays the previously stored electrocardiogram for a particular patient.
Components with the following functions by themselves are NOT considered MDDS if they are used as part of general IT infrastructure even though they may transfer, store, display or convert medical device data, in addition to other information:

- The electronic transfer of medical device data;
  - Network Router, Network Hub, Wireless access point
- The electronic storage of medical device data;
  - Network Attached Storage (NAS), Storage area network (SAN)
- The electronic conversion of medical device data from one format to another in accordance with a preset specification
  - Virtualization System (ex: VM Ware), PDF software
- The electronic display of medical device data.
  - Computer Monitor, Big screen display
- Networks used to maintain medical devices to see which systems are running or malfunctioning, or other similar uses that do not meet the definition of medical device under 201(h) of the FD&C Act.
- Standard IT software that is not specifically sold by the manufacturer as a MDDS, which may have MDDS functionality such as reading serial numbers, barcodes, UDI or other data from a medical device, but is not used in providing patient care.
Pre-Market Notification

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9).

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm
Submitting 510(k) Applications

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm

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### 510(k) Submission Process

**Introduction**

Premarket Notification 510(k) submissions for medical devices are reviewed and processed by the Center for Devices and Radiological Health (CDRH) within the Food and Drug Administration (FDA). The Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostic Device Evaluation and Safety (OVDS) within CDRH are responsible for the processing and review of 510(k)s for marketing clearance in the U.S. Branches within these offices are organized according to medical scientific disciplines. ODE and OVDS staff includes biomedical engineers, physicians, microbiologists, chemists, etc., that performs scientific reviews of 510(k)s and other research (Investigational Device Exemption) and marketing applications (Premarket Approval). These individuals are commonly referred to as reviewers. It is their recommendation that determines whether a new device is substantially equivalent (SE) or not substantially equivalent (NSE).

Please note that the submitter should consider the Quality Systems (QS) regulation before and during the 510(k) process. Class II, Class III, and certain Class I devices are subject to design control requirements of the quality system regulation during the design phase of product development. For more information on the QS regulation, please refer to Quality Systems.

**Log in Procedures**

Upon receipt in the CDRH Document Mail Center (DMC) located within ODE, 510(k) submissions are date stamped and logged into the DMC computer database where a unique control number is assigned to the document. This
Key Lessons and Questions to ask for Physical Device Connectivity

- How are medical devices being connected?
- Is a physical adapter being used?
- Is this developed in-house or an OEM OTS product?
- Are there device drivers present to communicate with the device?
- Who manages the device driver software?
- Is the device communicating with the enterprise network? If so, how?
- Has the enterprise network been provisioned to receive the data?
- Where is target receptor system (a.k.a. CIS) and how is the connection made?
Network Considerations

- Medical devices which are configured to transmit data across the enterprise must be given consideration on the enterprise network.
- Implication: higher quality of service requirement, linkage between network team, IT and clinical team.
- Policies that support high availability and port access by medical devices across entire enterprise (i.e., policies that ride across multiple hospitals).
- Network team becomes part of triage team when issues arise.
Benefits of Medical Device Connectivity
Clinically quantifiable benefits of medical device connectivity

Where data from medical devices are necessary for status and management of patients in large measure:
- Emergency Department
- Surgery
- Cardiac-Catheterization Labs
- Intensive Care
- Medical/Surgical Units
- Radiology
Clinically quantifiable benefits of medical device connectivity

Within the listed environments, medical device data on patients are used for assessing status of patients—primarily cardiovascular and pulmonary/respiratory state: the bodily functions most associated with maintaining existence. In terms of the manner of which specific types of measurements are taken in these environments, a typical allocation of the key functions is typically as follows:

<table>
<thead>
<tr>
<th>Unit / Ward</th>
<th>What Function Measured</th>
<th>Frequency of measurement</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency Department</td>
<td>Heart (e.g.: pulse, ST segments); Perfusion (e.g.: O2 saturation); Temperature</td>
<td>Continuous</td>
<td>hours</td>
</tr>
<tr>
<td>Surgery</td>
<td>Heart (e.g.: pulse, ST segments); Perfusion (e.g.: O2 saturation, end tidal CO2); Pulmonary (e.g.: breath rate, tidal volume); Temperature; Drug administration</td>
<td>Continuous</td>
<td>hours</td>
</tr>
<tr>
<td>Cardiac Catheterization</td>
<td>Heart (e.g.: pulse, ST segments); Perfusion (e.g.: O2 saturation)</td>
<td>Ad hoc</td>
<td>hours</td>
</tr>
<tr>
<td>Intensive Care</td>
<td>Heart (e.g.: pulse, ST segments, cardiac output, ejection fraction); Perfusion (e.g.: O2 saturation, end tidal CO2); Pulmonary (e.g.: breath rate, tidal volume); Temperature; laboratory measurements; drug administration; outputs</td>
<td>Continuous</td>
<td>Hours – days – weeks</td>
</tr>
<tr>
<td>Medical / Surgical Radiology</td>
<td>Heart (e.g.: pulse); Perfusion (e.g.: O2 saturation); Temperature</td>
<td>Ad hoc</td>
<td>Days-weeks</td>
</tr>
<tr>
<td></td>
<td>Heart (e.g.: pulse); Perfusion (e.g.: O2 saturation)</td>
<td>Ad hoc</td>
<td>hours</td>
</tr>
</tbody>
</table>
Clinically quantifiable benefits of medical device connectivity

- Information needs from patients are based upon what clinical end user (e.g., physician) requires to treat and manage patient through standard practice of medicine.

- In reviewing all of environments shown in previous table, there are two (typically) in which patient is not either unconscious or sedated for extended periods of time. These include surgery services and intensive care.
Clinically quantifiable benefits of medical device connectivity

- In surgery and intensive care, patients communicate to clinician through status of their bodily systems.
- These measurements “speak” for patients and communicate how cardiovascular and pulmonary systems are responding to treatment, sedation, or both.
- In terms of clinical decision-making, both of environments usually involve integration of multi-source information to provide necessary information to communicate and project how patient is evolving over time.
Clinically quantifiable benefits of medical device connectivity

- Intensive care settings can be different. It is not unusual for critically ill patients to spend many weeks to months in these units.
- Because of acuity and duration, much focus in hospital settings is devoted to caring for most ill of patients.
- Sources vary to a degree, but billing data tend to indicate that > 20% of hospital costs are associated with intensive care environments, accounting for fewer than 10% of patient population.
Patients in intensive care are either admitted in association with a post-surgical event or directly through an ailment already diagnosed.

- E.G.: coronary bypass surgery is a major “feeder” for intensive care units, as well as head trauma, cancer, or ailments acquired at home that require treatment in the acute setting.
- Patients in intensive care often require pulmonary assistance in the form of mechanical ventilation. This not only increases the complications and cost of their treatment, it exposes them to the likelihood of infection.

Because patients tend to be elderly having several co-morbidities, also prone to ailments that can exacerbate their reasons for being in unit as well as decline over time.

Hospital acquired infections (HAI) as well as ventilator associated pneumonia (VAP) are killers and become real threats the longer the stay in intensive.
Clinically quantifiable benefits of medical device connectivity

- One study on duration and costs of patients in intensive care related to mechanical ventilation made the follow finding:
  - “Days of intensive care and mechanical ventilation were identified using billing data, and daily costs were calculated as the sum of daily charges multiplied by hospital-specific cost-to-charge ratios. Approximately 36% of identified patients were mechanically ventilated at some point during their intensive care unit stay. Mechanically ventilated patients were older (63.5 yrs vs. 61.7 yrs, p < .0001) and more likely to be male (56.1% vs. 51.8%, p < 0.0001), compared with patients who were not mechanically ventilated, and required mechanical ventilation for a mean duration of 5.6 days... Mean intensive care unit cost and length of stay were $31,574 ...14.4 days ... for patients requiring mechanical ventilation and $12,931 ... 8.5 days for those not requiring mechanical ventilation ... Adjusting for patient and hospital characteristics, the mean incremental cost of mechanical ventilation in intensive care unit patients was $1,522 dollars per day (p < .001)”

As patients remain in intensive care for longer durations they become targets for HAIs, and particularly VAPs:

- "Ventilator-associated pneumonia (VAP) is common in the intensive care unit (ICU), affecting 8 to 20% of ICU patients and up to 27% of mechanically ventilated patients. Several risk factors have been reported to be associated with VAP, including the duration of mechanical ventilation, and the presence of chronic pulmonary disease, sepsis, acute respiratory distress syndrome (ARDS), neurological disease, trauma, prior use of antibiotics, and red cell transfusions. Mortality rates in patients with VAP range from 20 to 50% and may reach more than 70% when the infection is caused by multi-resistant and invasive pathogens."

Synchronizing Medical Devices to Common Reporting Timelines:
Can vary by department, reporting requirements, device capabilities

Device 1 Reporting Time

Device 2 Reporting Time

Device M Reporting Time

Common Reporting Timeline
Example: Common time synchronization

- Benefit of time-aligning data is to ensure that information collected from separate sources is associated with same time bin. Why does this matter?
  - Because data may have a causal relationship with drug orders or events and understanding the temporal sequence of these events can be informative or crucial to establishing what actually is happening to a patient.
  - Yet, is the need for synchronized data embellished or over-played? After all, so what if data are, say, 5 minutes off.
One clinically quantifiable benefit of time synchronization

To answer this question:

- Measurement of blood pressure is a process that can require up to 2 minutes. Oftentimes during surgery a physician will require blood pressure measurements to be taken continuously (where possible) from two independent sources so they can be corroborated.

- If one source indicates no pressure and no pulse, second source can be used to verify finding or to determine if there is artifact.

- If indeed blood pressure is not found it can require approximately two minutes to re-ascertain finding. In that amount of time brain death can occur.
Another example: sepsis

Sepsis, or septicemia, is a blood infection that has the potential to impact all patients, particularly in the intensive care unit (ICU). However, two classes of patients—the old and the very young—are most susceptible:

- “Sepsis is the 10th most common cause of death in the United States and its management has been estimated to cost 17 billion dollars annually. Seventeen percent of all patients who develop sepsis have a malignancy as an underlying co-morbidity.”
- “...as many as 10% of all cancer deaths (46,729 annual deaths) are attributable to sepsis...”


Late Onset Neonatal Sepsis (LONS)

“Earlier detection and treatment of LONS offers the best opportunity to improve outcomes. To date, the approach has been to use biomarker screening or empiric antibiotic therapy for every patient with subtle non-specific symptoms. Neither of these strategies is satisfactory due to insufficient diagnostic accuracy of biomarkers and complications associated with overuse of antibiotics. A new technology, continuous monitoring of neonatal heart rate characteristics, has been developed for earlier diagnosis and treatment of LONS in NICU patients.”


"Heart rate and respiratory rate variability, when measured continuously, provide non-invasive metrics for detecting the early onset of sepsis. The first study identified that the presence of at least two of four clinical signs, including abnormalities in heart rate, temperature, respiratory rate and white blood cell count or its differential count, herald the onset of sepsis and that these conditions manifest many hours before the actual diagnosis:"

- Heart rate >90 beats per minute
- Respiratory rate >20 breaths per minute or PaCO2 <32 mmHg
- Temperature >38.0° C or <36.0° C
- White blood cell count >12,000 cells/mL, <4,000 cells/mL, or >10% bands

What’s next?
The Evolving Face of IT & Healthcare

- WHAT WILL WE SEE IN 2... 5... 10 YEARS?

- Do-it-yourself Genome Kits from the local drugstore for <$10?

- CHEMOTHERAPY...AT HOME?

- TUMOR BOARDS STAFFED...FROM AROUND THE GLOBE?

- SURGERIES ASSISTED FROM...ACROSS THE GLOBE

- PATIENT CARE DEVICES THAT COMMUNICATE WITH ONE ANOTHER TO SUPPORT REAL-TIME DECISION MAKING?
Can Widespread Remote Monitoring Cut Chronic Care Costs by ~$200B\(^1\)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Estimated 25-Yr Cost Saving</th>
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<tbody>
<tr>
<td>Congestive Heart Failure (CHF)</td>
<td>$102.5B</td>
</tr>
<tr>
<td>Diabetes</td>
<td>$54.4B</td>
</tr>
<tr>
<td>Chronic Obstructive Pulmonary Disease (COPD)</td>
<td>$24.1B</td>
</tr>
<tr>
<td>Chronic Skin Ulcers</td>
<td>$16B</td>
</tr>
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</table>

“Savings largely attributable to better management… because widespread implementation … means key vital signs can be transmitted to a caregiver or data center in real-time and trigger instant alerts when readings change in a medically different way.”

--Robert Litan, Page 2.

Patients with chronic illness account for ~80% of increases in Medicare costs


\(^1\)Tim Rowan reporting on AT&T Study, and conducted by Brookings Institution economist Robert Litan. Study presented by Better Health Care Together Coalition.
Chronic diseases whose management is aided by patient care device integration

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<th>Condition</th>
<th>Parameters Typically Measured</th>
<th>Benefit</th>
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<td>Congestive Heart Failure (CHF) and Coronary Artery Disease (CAD)</td>
<td>Regular measurement of weight, blood pressure, pulse, blood oxygenation, Holter monitors</td>
<td>Regular measurement &amp; evaluation provides holistic view of dangerous trends, including weight gain due to fluid retention</td>
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<td>Chronic Obstructive Pulmonary Disease (COPD)</td>
<td>Decreased lung function, principally due to bronchitis, emphysema. Regular measurement of forced expiratory volume in one second (FEV1) and vital capacity (FVC)</td>
<td>Regular trending and evaluation by home health nursing can enable intervention prior to exacerbations (hospitalizations)</td>
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<td>Diabetes Mellitus</td>
<td>Blood sugar measurement and management, along with secondary calculations such as A1c, weight, blood pressure</td>
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<td>Skin &amp; Pressure Ulcers</td>
<td>Remote video, blood pressure, weight, wound photography</td>
<td>Remote evaluation mitigates need for patient to make uncomfortable trips to offices and allows for more regular assessment and, if necessary, intervention</td>
</tr>
</tbody>
</table>
Sepsis and Relationship to Heart Rate Variability

- Sepsis w/ acute organ dysfunction is leading cause of death in non-coronary ICU; accounting for more than 750,000 diagnosed cases in US annually.

- Sepsis-induced organ dysfunction due to several sources, including induced hypotension and diffuse intravascular coagulation.

- HRV governed through sympathetic & parasympathetic branches of autonomic nervous system.

- Regulation of beat-to-beat frequency is accomplished through primary pacemaker: sinoatrial node.

- Clinical studies have shown relationships between changes in HRV as heralding onset of sepsis blood borne infections in adults.

http://biology.about.com/library/organs/heart/blsinoatrialnode.htm

Significance: Sepsis Onset Correlated to HRV in Continuously Monitored Adults (Ahmad et al)

- 24 HOUR HOLTER MONITOR OF PATIENTS UNDERGOING BONE MARROW TRANSPLANTS (BMT),
  - HIGH-RISK GROUP OF PATIENTS, Owing to high risk of infection (80%) & mortality (5%)
  - START 1 DAY PRIOR TO BMT, CONTINUING THROUGH RECOVERY OR WITHDRAWAL
  - HOLTER MONITORING: ZYMED DIGITRACK-PLUS
Key Study Findings

- Baseline HRV as mean variability for first 24H
- Onset of sepsis: systemic inflammatory response syndrome (SIRS) w/ clinically suspected infection requiring treatment
- 17 patients of 21 Completed Study.
  - 14 patients developed sepsis, requiring antibiotic therapy
  - 12 of 14 infected patients (86%) showed 25% drop in HRV 35 hours (ave) prior to sepsis onset
  - Infected population showed drop in HRV from 24-120 hours
  - No significant drop represented in non-infected population
- Promising: onset correlation determination made using simple measurements typically available w/o expensive lab tests
Clinical benefits of access to real-time and complete medical device data are legion

- Data are readily available from devices
- Provide accurate, timely and complete representation of the state of the technologically-managed patient
- Studies show that use of these data can play pivotal roles in diagnoses and bedside clinical decision making.
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THANK YOU