

# Use Case Presentation Summaries:

FDA Workshop on Medical Device Interoperability: Achieving Safety and Effectiveness

1:10 – 1:50 (Monday)

## Session 1: Lessons Learned from Existing Regulatory Practices

<b>NHS</b>	Dr Maureen Baker CBE	Clinical Director of Patient Safety	NHS Connecting for Health, England
<p>NHS systems are used, or being developed for, all care settings in England (acute, community, mental health, ambulance etc) and are used by clinical professionals (physicians, nurses, pharmacists etc) and by managers and administrators. These include Patient Administration Systems; Picture Archiving and Communication Systems; electronic booking systems; electronic transfer of prescriptions; and e-prescribing. Tele-health products may need to be inter-operable with health IT systems within a care setting, e.g. an acute hospital, but also across care settings, e.g. from primary and community care across to acute hospitals.</p>			
<b>Diabetes and Home Management</b>	Linda Ricci	Acting Chief	FDA/CDRH/ODE Cardiac Electrophysiology and Monitoring Branch
<p>Diabetes management goes on mainly in the home environment. In addition to using an insulin pump, a diabetes patient can also use (subcutaneous) blood glucose sensors to monitor glucose levels continuously and save the trouble of regular finger stick tests. Currently, glucose sensors have the ability to talk directly to the insulin pump to transmit blood glucose readings. It remains the responsibility of the patient to confirm that readings received from glucose sensors are correct. Most insulin pumps not only provide a low, continuous infusion of insulin for background insulin replacement, but also administer correction boluses, when blood glucose readings are too high such that blood glucose levels are brought back to normal. A newer technology is implantable glucose sensors, which can send insulin pumps blood glucose readings every few seconds, and compare previous readings to project what blood glucose levels will be in next 5-15 minutes. These readings and projections provided by glucose sensors can help insulin pumps calculate correction boluses with appropriate dosage.</p>			
<b>FDA</b>	Mary Brady	Associate Office Director	FDA/CDRH/OSB Home Care Initiatives
<p>A patient was given a heart monitor by her physician and was told to wear it 24/7 for the next few days. The monitor would constantly transmit data wirelessly from her home in MD to a site in TX and the physician would receive the information from the site in TX. She received an expired device from her physician; the device started to alarm when she got home. She called the 800 number provided; they said they would send her a new device (this took 8 days). When she received her new device, she had another alarm issue. She was given different information from different people at the 800 number, one being "I don't know what that alarm is". Another time, she was called by the site in TX and they asked her if she had disconnected her monitor because they weren't getting any readings and she said hadn't. She verified that the electrodes were connected to the leads. Another time, the device disconnected and she wasn't aware that it had disconnected; they did not call her.</p>			

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Salient Points:

Issues:

Solutions:

1:50 – 2:30 (Monday)

## Session 2: Enterprise Issues

<b>Digital Operating Room</b>	Tom Judd Tom McGrane Doug Grey, MD	National Project Director, Clinical Technology Principal Solution Consultant Chair, KP Biomedical Device Integration Council Vice-Chair, KP National Product Council	Kaiser Foundation Hospitals Kaiser Foundation Hospitals The Permanente Medical Group
<p>The Case Study will address what particular interoperability aspects add value in terms of workflow and patient safety, and then what aspects/connections/components of this solution should and/or should not be regulated by the FDA.</p> <p>Care Delivery Systems</p> <ul style="list-style-type: none"> <li>§ Connected to our EMR through “middleware” or direct mechanisms as appropriate</li> <li>§ Including remote monitoring and wireless transmission of data where appropriate</li> <li>§ Supporting safety controls and alerts, and</li> <li>§ Enabling other clinical workflow and decision support systems.</li> </ul> <p>Middleware functionality may include:</p> <ul style="list-style-type: none"> <li>§ Connecting devices to an IT network</li> <li>§ Translating proprietary messages into standard HL7 format</li> <li>§ Monitoring and integrating patient data and contextual data from multiple sources, and</li> <li>§ Executing algorithms to reduce medical errors and improve clinical outcomes.</li> </ul>			
<b>Converged Medical Device and Enterprise Network</b>	Tim Gee	Principal	Medical Connectivity Consulting

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Scenario: The convergence of networked medical devices and the enterprise network. This approach puts medical device networks on the enterprise network with other hospital applications, without resorting to anything beyond the standard features of the network (support for various protocols, VLANs, routing tables, etc.).

Included in the converged network: Networked medical devices, medical device system servers and client computers, legacy medical devices attached to the network through a Medical Device Data System, a wired local area network (LAN), a wireless LAN, and optionally extending the network across metropolitan and/or wide area networks (MANs and WANs).

Users/operators: Hospital IT department and Biomed share network configuration and management responsibilities, medical device and network manufacturers share responsibility for disclosing product and system operating specifications and capabilities, and resellers/systems integrators are responsible for network engineering, design and initial installation.

Actions performed: Besides the operation of both regulated medical device systems and health care enterprise information systems converged on the same network, additional actions include system and network monitoring and management, repair and upgrade of the network.

Salient Points:

Issues:

Solutions:

2:50 – 3:30 (Monday)

## Session 3: Systems-of-Systems Issues

<b><i>Systems of Systems Issues: Clinical Vignette</i></b>	Frank E. Block, Jr., M.D.	Professor of Anesthesiology	VCU
Burn patient in ICU Room connected to Multi-Parameter Monitor (MPM). Patient is “Admitted” to the MPM. MPM operates correctly for a time, then failure occurs that cannot be corrected on the device. Similar MPM device is available, but how to swap out and maintain the continuity of care and data, including trend history. Matching patient information and data with hospital medical record and merging data from both MPM devices.			
<b><i>Using Standard Communications Protocols to Implement Medical Device Plug-and-Play</i></b>	Dick Moberg	President	Moberg Research, Inc.
Device interoperability requires plug-and-play of devices in order to be widely used. This entails the use of a common data communications protocol such that the receiving system learns about the device at the time of connection, without any prior information about the device. The users are those that deal with patient monitoring: anesthesiologists, critical care personnel, nurses, and technical personnel. The user needs to be able to connect new devices to the information system without worrying about compatibility. Likewise, users need to quickly swap out malfunctioning equipment with a functionally equivalent replacement that may or may not be the same brand. Biomed needs to be able to track devices and know software update status. Data needs to be tagged with a specific “source device” for quality purposes.			

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<p><b><i>Wrangling the human element of interoperability: Defending against Reason's latent flaws and Dekker's drift</i></b></p>	<p>GM Samaras, CEO PhD, DSc, PE, CPE, CQE</p>	<p>Samaras &amp; Associates, Inc</p>
<p><u>Scenario:</u> Volume management of fluid in burn patients using a set of interoperable medical devices functions well, until suddenly it does not, and the cause is NOT readily identifiable (unlike someone forgetting to turn on the ventilator).  <u>Devices:</u> Sensor(s) [e.g., mass &amp; flow sensors], Integrator(s) [parameter programmed intelligence], Effector(s) [e.g., infusion pumps]  <u>Humans:</u> Operator(s) [clinicians &amp; technicians], Maintainer(s) [engineers &amp; technicians], Regulator(s) [D inspectors, headquarters staff]  <u>Activities:</u></p> <ul style="list-style-type: none"> <li>• Operators: interconnection (assembly/disassembly), program selection (starting, stopping, modifying), program modification (creation, "development")</li> <li>• Maintainers: routine (diagnosis, repair, preventive maintenance), upgrades (scheduled, unscheduled, covert)</li> </ul> <p><u>Regulators:</u> device clearances &amp; establishment inspections  <u>Failure Loci:</u> Human operators, human maintainers, &amp; human regulators  <u>Failure Cause:</u> Incomplete, incorrect, and/or missing device requirements (Design Inputs)  <u>Root Cause:</u> Incorrect management &amp; regulation of device manufacturers and user facilities  <u>Conundrum:</u> Everybody did his or her individual job as they understood it, but there was still a system failure!</p>		
<p>Salient Points:</p> <p>Issues:</p> <p>Solutions:</p>		

**3:30 – 4:10 (Monday) Session 4: Mass Interoperability**

<p><b><i>Mobile Health</i></b></p>	<p>Praduman Jain</p>	<p>CEO</p>	<p>Vignet Inc.</p>
<p>The future of healthcare is remote monitoring, mHealth, Wireless connectivity, Interoperability, HIT. Connected care is vital to meeting the world's need for quality and affordable healthcare for all and for each individual.          Mobile Devices are considered to be most effective to deliver Connected health and "Personalized medicine".          We can use Mobile devices for collecting clinical data, remote monitoring, merging of sensor data along with a person's lifestyle.</p>			
<p><b><i>"Tooling" Communities to advance Community Resilience</i></b></p>	<p>Dr. Brigitte Pinewski</p>	<p>CMO</p>	<p>PeaceHealth Labs</p>

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Scenario: H1N1 is moving through the community, Problem: it remains difficult to separate out individual who may be experiencing un-complicated flu versus those that might progress to complicated flu and irreversible pulmonary compromise and death.  
Devices: Disposable Patch integrating Heart rate, temperature and pulse oximeter linked to a cell phone app to central data base.  
Actions: Flu experience across an n=many is being tracked to understand if integrating the clinical parameters of Hr, T and O2 can sufficiently distinguish in a clinically relevant way those who might be at risk for deteriorating pulmonary function.

<b><i>The Do's and Don'ts of creating an ULP Wireless Network</i></b>	Mike Paradis	Wireless Sales Manager	Dynastream Innovations Inc.
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The presentation will outline the traps system architects often fall into when defining an Ultra Low Power consumer price point wireless personal area network.  
 The typical scenario is the worried well middle age individual with a need to keep their active lifestyle to which they have become accustomed to while adhering to dietary and health related doctor/insurance providers' advice.  
 The individual is not well to do and requires a group of 4-6 biometric parameters to be monitored for extended periods of time. Heart rate, blood pressure, weight and body mass, activity and blood sugar levels.  
 The company the individual works for has a vested interest in their employees health and have offered to subsidize the cost of the program as long as they see solid evidence of conformance to rules of the program. This compliance will need to be automatically collected daily once the individual enters their office.

Salient Points:

Issues:

Solutions:

4:10 – 4:50 (Monday)

## Session 5: System Level Risk Analysis

<b><i>Multi-parameter data integration to support clinical decision making</i></b>	John Zaleski, PhD, CPHIMS	Department Head, Biomedical Informatics	Philips Research North America
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<p>Integrating multi-parameter data simultaneously from several point-of-care devices for use in assessing patient state to support real-time clinical decision making requires access to simultaneous feeds of medical device data and observations propagated to specific common time frames and in formats that are useable by clinical decision support functions within clinical information systems and electronic medical records. Access to accurate and timely data is necessary to ensure clinical decision support algorithms have the latest information, thereby ensuring accurate assessment—a patient safety concern. Examples include post-operative weaning from mechanical ventilation and management of spontaneous breathing trials: respiratory, cardiovascular (e.g., cardiac output, pulse, pulse oximetry), blood gas (e.g., partial pressures of oxygen and carbon dioxide, base excess, pH), and fluid intake and output information is required for assessing and managing patients during the critical process of discontinuation from mechanical ventilation and for assessing patient condition and co-morbidities (e.g., acute lung injury brought on by trauma, cardiac instabilities or septic shock). These data need to be drawn at common time points and a useful device would be a transaction that could support specific clinical data based on a specific protocol or need would greatly assist in supporting clinical decision making.</p>			
<p><b><i>FiO2 Control in Preterm Infants – A Case for Device Interoperability</i></b></p>	<p>Dale Wiggins</p>	<p>Vice President and CTO Healthcare Informatics and Patient Monitoring</p>	<p>Philips Healthcare</p>
<p>Preterm infants on ventilator support may experience both hyper and hypoxemia events when insufficient attention is given to the adjustment of the inspired oxygen fraction (FiO2) to maintain the pulse oxygenation (SpO2) within a target range. Devices involved are a neonatal ventilator and a pulse oximeter patient monitor. The users/operators are clinicians (nurses, respiratory therapists, neonatologists). Actions are to adjust the FiO2 settings based upon the measured SpO2 readings for the infant.</p>			
<p><b><i>The Building Blocks of Clinical Systems</i></b></p>	<p>Tracy Rausch</p>	<p>Founder and CTO</p>	<p>DocBox Inc</p>
<p>Research work that has been completed at DocBox and through various standards committees has been focused around the analyzing of clinical workflow in order to derive clinical requirements. These requirements are from not only how workflow at the point of care occurs now, but also what will be required in the future when advanced systems are in place, which allow for device-to-device communication as well as nondeterministic heterogeneous systems. This scenario will focus around clinical situations related to infusion therapy and ventilator support to understand the general blocks that make up these workflows and the risk analysis associated with these scenarios.</p>			
<p><b><i>Managing Risk in Systems of Systems</i></b></p>	<p>Peter Kelley</p>	<p>Director of QA/RA</p>	<p>Capsule Technology Inc</p>
<p><u>Scenario:</u> Integration by Hospital/Professional users of regulated medical devices and PHRs or EMRs. Multiple interoperable systems working in tandem.  <u>Involves:</u> Medical devices, EHR, MDDS, Hospital Network Infrastructure.  <u>Actors:</u> Clinicians, Biomed Engineers, IT  <u>Actions:</u> Connecting, replacing, configuring medical devices. Connecting, replacing, configuring network components. Configuring EHR. Remotely controlling medical devices.</p>			
<p><u>Salient Points:</u></p>			
<p><u>Issues:</u></p>			
<p><u>Solutions:</u></p>			

10:20 – 11:00 (Tuesday)

## Sessions 6: Software Issues

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<b>Safety and Effectiveness Issues in Electronic Medical Records</b>	John Denning	Consultant	Independent
<p><b>Scenario:</b> Integration by Hospital/Professional users of regulated medical devices and PHRs or EMRs Multiple interoperable systems working in tandem.  <b>Involves:</b> Medical devices, EHR, MDDS, Hospital Network Infrastructure.  <b>Actors:</b> Clinicians, Biomed Engineers, IT  <b>Actions:</b> Connecting, replacing, configuring medical devices. Connecting, replacing, configuring network components. Configuring EHR. Remotely controlling medical devices.</p>			
<b>Medical Device Data Patient Context Challenges</b>	Luis Melendez	Assistant Director, Partners HealthCare Biomedical Engineering, Medical Device Integration and Informatics	Massachusetts General Hospital
<p>Personally (patient) identifiable information (PII) is not systematically entered into most modern medical devices. However, each medical device connected to a corresponding information system, needs a mechanism to reliably bind device data to the person or patient associated to the measurement or therapy delivered.  To date, the widest use of PII is limited to networked physiological monitors through an ADT feed. Since healthcare providers' medical device inventories generally constitute a diverse range of equipment of varying age, providers, device connectivity and electronic medical record vendors are left to implement their own application (or system) specific, and occasionally diverging, solutions to a modern healthcare challenge. Electronic medical records, and future connectivity applications, require a simple (from the users' perspective), consistent and reliable mechanism to associate patients to the medical device they are connected to, and the data the device generates.  Because there is no industry consensus or regulatory guidance regarding how to associate medical device data to the patient, various devices may require different means of data binding and user interfaces with greater complexity and likelihood of error. This could prove particularly challenging for healthcare providers if they need to learn multiple means to bind data from different devices to one patient. Compounding this complexity, user requirements may change at varying stages of care (e.g. emergency department, transport, radiology, OR, ICU) and with different devices (e.g. physiological monitors, ventilators, infusion pumps).</p>			
Salient Points:			
Issues:			
Solutions:			

# Use Case Presentation Summaries:

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11:00 – 11:40 (Tuesday)

## Session 7: Integration and Interoperability Issues in a Regulated Environment

<b>Interoperability through integration</b>	Renate A. MacLaren, Ph.D.	Director, Regulatory Affairs	Integrated Medical Systems, Inc.
<p>The delivery of care can often involve an unmanageable clutter of medical devices, data systems, and utilities (such as power and oxygen). Though critical care patients are approximately 10-20% of the patient population, they can require/consume 70-80% of the resources. For example, such patients require multiple caregivers, multiple transports, multiple devices (ventilator, monitor, infusion pumps, suction, blood chemistry analyzer, defibrillator and all related disposables); extensive data generation, storage and communication; and significant and sustained electrical power and oxygen. Operator's of these devices include physicians, nurses, Emergency Medical Technicians, and Physician's Assistants.</p>			
<b>Universal interface between medical devices and IT / Communications systems</b>	Alasdair MacDonald	CEO	TeleMedic Systems Ltd
<p>A composite medical system, comprising an assortment of electronic medical devices from different manufacturers are connected via a medically approved 'host' system that may, optionally comprise additional software components to offer improved functionality. The host communicates and controls the devices to which it is connected while also providing a composite stream of the physiological and other associated data elements to local viewing stations as well as a secure data server. The data server will allow authenticated access to a real-time data stream or will allow it to be replayed at some later date. The data is identified only by the unique software certificate of the 'host' and the date &amp; time of the data session. Individual elements of a session can be used to populate the specific elements of a patient record or can be provided as an 'attachment' to the file for viewing as a composite chart. Alternatively a dynamic link to the data session can be embedded in the patient record to allow full replay at any time.</p> <p>The users and operators of any number of variants of this composite system cover almost every conceivable healthcare environment such as;</p> <ul style="list-style-type: none"> <li>a) In a hospital where automatic collection and synchronization of medical device data with clinical observations enables an RRT assessment to be completed automatically. Decision support software can determine whether a patient is deteriorating and to automatically notify the clinical staff.</li> <li>b) In a diver's hyperbaric chamber at great depth to transmit real-time physiological data to a remote, surface based, doctor for diagnosis.</li> <li>c) A patient can be discharged early from hospital for care at home as the monitoring equipment is of hospital grade and allows full remote access. Furthermore, automatic alarms alert a local care giver and the remote clinicians in the event of an 'out of scope' condition across multiple simultaneous physiological parameters. The care giver, when changing a drip, scans the new pack for confirmation of correct drug and concentration, thus providing a safety check and audit trail.</li> </ul>			
<b>Toward a plug-and-play system for medical devices: lessons from case studies.</b>	Dave Arney	Student	University of Pennsylvania
<p>Our team at Penn worked with the MD PnP group to implement two use cases involving medical device interoperability. I will discuss the lessons we learned by building these systems and the challenges we uncovered. These challenges included characterizing the performance of the devices, building a network to support real-time closed-loop control, and using formal methods to verify the implementations.</p>			
<b>Title Pending</b>	Bonnie Norman	Director, Quality Assurance & Regulatory Affairs	Intel



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Class II regulated telehealth device for use in the home, interacting with both regulated Class II devices and non-regulated devices.

Users: May be first-time user of technology, dealing with either a hospital discharge, on-going disease states, etc.

Actions: Clinicians are able to supply custom protocols to each patient, asking health-related questions and prompting for vital signs measurements. Patients are able to respond via a touch-screen based UI and connected peripherals (wireless and/or tethered).

Salient Points:

Issues:

Solutions:

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11:40 – 12:20 (Tuesday)

Session 8: Standards, Interfaces and Interoperability Issues

<p><b><i>Impact of ARRA/HITECH on Device Connectivity: Safe? Effective? Say what?!</i></b></p>	<p>Todd Cooper</p>	<p>President</p>	<p>Breakthrough Solutions Foundry, Inc.</p>
<p>With the passing of the ARRA / HITECH legislation coupled with the assignment of the “Common Device Connectivity” (CDC) use case to the Health Information Technology Standards Panel (HITSP) for harmonization, significant focus – including CMS financial incentives – are being brought to bear on breaking the decades-old impasse in achieving true standards-based heterogenic device interoperability across all care contexts. This legislation and use case were so broad and in many cases incomplete or inconsistent, that the HITSP working group assigned to work on the CDC use case quickly determined that a document needed to be created that presented a more comprehensive treatment of device connectivity considerations and establish a roadmap for developing the necessary technologies and capabilities necessary to achieve the stated objectives and timeline.</p>			
<p><b><i>Connectivity? Integration? Plug and Play? What is the Interoperability end game?</i></b></p>	<p>Ken Fuchs</p>	<p>Principal Engineer</p>	<p>Draeger Medical Systems, Inc.</p>
<p>Infusion devices are among the most widely used medical devices in the hospital setting. This presentation will discuss some of the scenarios that arise when considering integrating these devices into the overall clinical documentation workflow including:</p> <ul style="list-style-type: none"> <li>• Data flowing to the EHR</li> <li>• Settings flowing from the EHR to the device</li> <li>• Alarm notifications</li> </ul>			
<p><b><i>Helping the Cause of Medical Device Interoperability Through Standards-based Test Tools</i></b></p>	<p>John J. Garguilo</p>	<p>Computer Scientist</p>	<p>DoC/NIST</p>
<p>The lack of interoperability between bedside devices in an ICU can lead to preventable medical errors and greater efficiencies. Due to the lack of standards for these medical devices: (a) manually captured data is labor intensive, recorded infrequently and prone to human error, (b) expensive custom connectivity equipment may only be used for patients with the highest acuity, (c) detection of patient problems, (e.g., adverse drug events) is hindered due to the inability to collect real-time data from multiple devices, and (d) vendors intending to communicate data between devices must develop specialized interfaces for each device to which it interacts.</p> <p>In the absence of a communications standard, every interface between a medical device and any device or system to which it is to communicate must at a minimum be examined to determine what physical and logical interfaces must be developed to effect communication. To address the need for intercommunication among medical devices and clinical information, the IEEE 11073 Working Group has developed a set of standards for Medical Device Communications which is being adopted as a base standard within the Integrated Health Enterprise (IHE) Patient Care Devices (PCD) Domain and the IEEE 11073 Personal Health Devices (PHD) and HL7 Healthcare Devices Working Groups. Additionally, HL7 message transactions are being defined and used by IHE-PCD and IEEE PHD working groups.</p>			
<p><b><i>Semantic Interoperability for Medical Device Data Interchange</i></b></p>	<p>Paul Schluter, Ph.D.</p>	<p>Principal Engineer</p>	<p>GE Healthcare - Monitoring Solutions</p>

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The principal scenario is to translate and convey near real-time medical device data to the EMR or other data recipients (possibly including devices and workstations used at the point-of-care) using a standardized nomenclature and semantic model that can be rigorously defined and enforced to facilitate safe and effective plug-and-play interoperability.

This action can be performed on behalf of multiple devices made by multiple vendors, typically using a gateway or other translation engine, and sending the standardized representation to one or more data recipients.

For example, an in-hospital gateway could use the IHE PCD-01 Technical Framework that uses HL7 V2 messaging and standard ISO/IEEE 11073-10101 nomenclature. Alternatively, a home hub or cell phone could use the same IHE PCD-01 Technical Framework and the ISO/IEEE 11073-20601 and nomenclature extensions for personal health devices.

## ***ICE-PAC Approach to Understanding Clinical Requirements***

Tracy Rausch

Founder  
and CTO

DocBox Inc

In October of 2008 during a joint meeting of the writing group of ASTM F2961-2009 "ICE" Standard and the Integrated Healthcare Enterprise Patient Care Domain meeting it was determined that a joint work group would analyze existing medical device communication standards (IEEE 11073, ASTM F2961, IHE PCD profiles). This scenario reviews the process of analyzing the clinical scenarios and the outcomes of this analysis. This presentation will focus around the systems level risk analysis completed within this process.

Salient Points:

Issues:

Solutions: