PROGRESS REPORT:
MEDICAL DEVICE INTEROPERABILITY
SAFETY WORKING GROUP

3rd Annual Medical Device Connectivity Conference & Exhibition
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Disclaimers

• The opinions and conclusions stated in this presentation are those of the presenter and do not represent the official position of the FDA, NIH, HHS, ONC, MGH, CIMIT, the Continua Health Alliance, or Anakena Solutions.

• The topic and content of this presentation is only on the Science and Engineering of Interoperable Medical Devices.
MD PnP Quantum Grant

Development of a Prototype Healthcare Intranet for Improved Health Outcomes

Translation: The creation of an eco-system for interoperability of medical device and CISs in high-acuity environments to support innovation in patient safety and healthcare quality

Award: 5 Years: $10M
Collaborating Organizations:
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An HHS ONC Health IT
SHARP affiliated program
Progress Report

• Background: Conference and MDISWG Committee
• Problem Space
• Solution Space
• Results
The FDA (CDRH) Workshop on Medical Device Interoperability: achieving safety and effectiveness

Co-sponsored by CIMIT and the Continua Health Alliance

3 days of slides, audio, and video available on www.mdpnp.org
Overview

• The workshop led to creation of a working group to develop specifications for a prototype/mock regulatory submission of an integrated medical device system
  – Medical Device Interoperability Safety Working Group (MDISWG)
  – Formerly Prototype Regulatory Submission (PRS)
  – Working group comprised of companies, standards organizations, clinical and legal participants, and the FDA.
• The results of this work have been taken in-house by the FDA for further internal work on a regulatory pathway.
• The working group is continuing to explore safety and reliability aspects of interoperable devices.
MDI WSG Membership

Terenzio Facchinetti (UL)
Anura Fernando (UL)
Alasdair MacDonald (TMS)
George Samaras (Samaras Associates)
Dave Osborn (Philips)
Insup Lee (Penn)
Oleg Sokolsky (Penn)
Andrew King (Penn)
John Zaleski (Nuvon)
Ken Fuchs (Mindray)
Julian Goldman (MDPNP/Partners)
Susan Whitehead (MDPNP/Partners)

Rick Schrenker (MDPNP/Partners)
Tim Gee (Medical Connectivity Consulting)
John Hatcliff (KSU)
Eugene Vasserman (KSU)
John Murray (FDA)
Sandy Weininger (FDA)
Russ Gray (Epstein Becker Green)
Peter Kelley (Capsule)
Scott Thiel (Anson Group)
Michael Robkin (Anakena)
PROBLEM STATEMENT

- The current regulatory approach for integrated medical systems (such as central station monitors) is that a system is cleared with respect to a specific set of medical devices.
- Thus, adding a new pairing of a medical device with the system's communication infrastructure requires the system to be re-cleared: "pair-wise clearance".
- Pair-wise clearance is applied because the proprietary architectures and non-standardized interfacing used in these systems do not allow system safety issues to be clearly exposed and evaluated from an external POV.
- System components cannot be examined in isolation without the context of the specific system configuration in which they will be deployed.
MISSION

• The mission of the MDIS Working Group is to describe and illustrate (with mock regulatory submissions) a "component-wise" regulatory approach for ICE-compliant systems that avoids the need to rely on pair-wise clearance.

• The component-wise approach allows each ICE component to be cleared individually without having to enumerate a priori all the possible ways in which it might be combined and used within a system.

• The component-wise approach is enabled by standardized interfacing between components
  – Clear enumeration of the safety responsibilities and risks associated with each component, and by
  – Evidence-based processes by which a component is shown to be safe and compliant with ICE interoperability standards
End State

- Individual components are approved for use with other approved components AND
- Assembling a system using approved components is not a regulated activity.
To fully explore these issues, the MDISWG methodology involves working through a progression of mock regulatory submissions for components with increasing levels of functionality/utility.

Various elements of these mock submissions will be "stubbed out.“

Clearly identify intended use, hazards/risk, verification/validation goals.

Safety and effective to be assessed.
Solution - Foundation

- **Interoperability Architecture** – identifies the components of the framework at the level of granularity at which interoperability will be applied.
  - An interoperability architecture may differ from a traditional functional architecture of the same framework in that it may not expose all the important functional components of the system.
  - Only exposes components at a granularity at which interoperability will be applied.

- **Interfaces** – the specific interoperability points within the interoperability architecture where components interact.
  - All component interaction must be limited to these explicitly declared interoperability points.
  - The components that interact at that particular interfacing point can be interchanged without adversely affecting the correct operation of the system.

- **Compliance** – processes, verification and validation techniques, existing standards, and other methods that will be applied to ensure that components conform interface and architecture requirements.
Architecture
Standard for the “Integrated Clinical Environment”
ASTM F2761-09

“Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model”

Provides a standards-based system architecture intended to support safe medical system composition
MDISWG- ICE Architecture

• The MDISWG group will work to identify scientific, engineering, and organizational principles that will enable ICE systems to be built with adequate safeguards so that interoperability works (is safe and effective).
• While ICE demands uniformity for certain aspects of component capabilities, it also allows certain degrees of freedom.
• ICE components produced by different manufacturers may provide different levels of functionality and performance as allowed by ICE.
• Therefore, an important overarching principle of ICE interoperability is that components are "self-aware" with respect to their capabilities.
  – When components are connected in a clinical context
  – before they are fully associated and available for use,
  – each ICE component compares its capabilities to the functional and performance requirements of system context, and
  – can reject or accept association based on requirements
ICE ENABLES:

• Acquisition of comprehensive healthcare data
• Support for distributed healthcare workers in managing high-acuity patients
• Error-resistance in patient care
• Compliance with data security, integrity, and privacy requirements
• Management of connected devices
• Apps for high-acuity healthcare

These needs are present across continuum of high-acuity healthcare: hospital, home, transport, etc.
Enterprise Integration Topologies

Adding new components affects all components.

Adding new components ONLY affects the Hub and the new component.
ICE MANAGER consists of:
- ICE NETWORK CONTROLLER
- ICE SUPERVISOR

ICE INTERFACE permits a medical device or IT system to communicate with the ICE Network Controller.

ICE NETWORK CONTROLLER handles all aspects of communication to and from the ICE Manager to all other attached components be they medical devices or IT systems.

INTERFACE provides the ICE NETWORK CONTROLLER with all the information about device type, classification, identification, capability, performance and control through metadata.

ICE MANAGER contains the required data, processes, actions for implementing a Use Case.

Integrated Clinical Environment
ASTM standard F2761-09
ICE Architecture Enables Certification

Data Logger

ICE NETWORK CONTROLLER

ICE SUPERVISOR

EHR

5 Devices
14 Interactions

Scope of Certification
ICE Architecture Enables 3rd Party Apps

5 Devices
14 Interactions
Simple ICE Architecture

Un-regulated IT system: Data storage, CIS, EMR, etc..

- Medical Device(s) & Sensor(s)
  - Wired or wireless connection
  - USB

- Medical Device(s) & Sensor(s) & Effectors
  - Wired or wireless connection
  - 802.11

- ICE NETWORK CONTROLLER
- ICE INTERFACE
- ICE SUPERVISOR

Regulated IT system for medical use
ICE Architecture Applied to Continua

- Glucometer with Radio
- Cell Phone running Regulated Application
ICE Architecture Applied to Continua

- Sensor
- Health Manager with Radio
- Cell Phone running Unregulated Application
Clinical Scenario
Key Interaction Consideration

• Limit the scope (and therefore the time) of the project by carefully selecting a use case that is:
  – Sufficiently complex to exercise interoperable components
  – Not so complex as to require a PMA filing
Key Interactions

- Built upon a mock use case with the initial focus on high acuity clinical environment
  - Ventilator weaning based on an ICE compatible architecture
    - Many sensors and actuators
    - Significant risk involved but not a new intended use
    - “ICE” system chosen as a documented infrastructure with focus on safety.
- Crafted the use case to highlight system needs to ensure that adjustments to the system do not change functions (e.g. swapping out equivalent actuators)
Mock 510(k)
Hazard Analysis

• Understand the roles of the devices and people within the environment bounded by the use case described.
• Understand how the systems will be constructed so as to predict failure modes.

• Main focus factors that are a result of interoperability:
  – Message delivery
  – Use/human factors

• Assume compliance with basic safety aspects of standards (e.g. IEC 60601-1) handled by individual devices
Interoperability
Functional Levels
<table>
<thead>
<tr>
<th>Level</th>
<th>Implementation - functionality</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td><strong>Disconnected, stand-alone device</strong>&lt;br&gt;The analog outputs from the monitors are captured on a strip chart for later review by the clinician.</td>
</tr>
<tr>
<td>1</td>
<td><strong>Virtual Device Display</strong>&lt;br&gt;Send device configuration (filter settings), saturation data and alarm conditions to EHR for later review.&lt;br&gt;Send data to remote display and polysomnography application.</td>
</tr>
<tr>
<td>2</td>
<td><strong>Synthesis of Derived Notices/Alarms</strong>&lt;br&gt;Combine SpO2, CO2, ecg, BP, inductance plethysmography, into smart alarm combination to detect dangerous events during sleep session.</td>
</tr>
<tr>
<td>3</td>
<td><strong>Virtual Front Panel Control Person in the loop</strong>&lt;br&gt;Connecting sensor devices to a sleep lab system to configure the devices for appropriate filter settings and silences alarms.</td>
</tr>
<tr>
<td>4</td>
<td><strong>Control of devices via conditional statements No person in loop</strong>&lt;br&gt;Supervisory APP detects motion in SpO2 and confirms with inductance plethysmograph and updates SpO2 filter times to improve signal quality.</td>
</tr>
<tr>
<td>5</td>
<td><strong>Scripting engine = Practice of Medicine</strong>&lt;br&gt;Clinician selects and configures devices on an as needed basis to alarm on a particular pattern of interest.</td>
</tr>
</tbody>
</table>
Mock 510(k) Overview

- For each component:
  - For each interoperable Functional Level:
    - Intended Use
    - New issues for safety and effectiveness
    - New technological characteristics
    - Performance data
Supporting Work
MDPNP NIH Clinical Scenarios

1. PCA Safety Interlock, example of component-level medical device interoperability
2. ICU preparedness, example of in-hospital patient transfer and rich clinical context
3. Tele-health devices in hospital, example of transferring care from home to hospital and TH devices for high-acuity care
4. FDA PRS – implementation of framework for levels of interoperability and associated levels of hazards and their mitigation
Problem Statement:
System integration of multi-vendor (heterogeneous) devices is inherently difficult. When hospitals perform the integration at the point of care, there are concerns about the safety and performance of the resultant systems. This has relevance to addressing clinical performance requirements, FDA regulatory requirements, and medico-legal liability concerns. If we hope to use “apps” that interact with interoperable medical devices in real time to deliver innovative patient safety solutions, a safe, reliable approach to ad-hoc point-of-care system composition is required. We will implement a layered approach developed by the FDA Prototype Regulatory Submission WG (on medical device interoperability).
Scenario #4 - Levels of Interoperability

- **Virtual Display**: Pulse Ox, ETCO$_2$, and BIS data are remotely displayed (possibly on mobile device). Monitoring devices are exchanged to demonstrate interoperability.

- **Derived Alarms**: SpO$_2$ and ETCO$_2$ and BIS signals are combined to create smart alarm (to detect overdose/respiratory depression during colonoscopy).

- **Virtual front panel**: manually control multi-parameter monitor and IV infusion pump through single integrated control panel.

- **Autonomous control**: use SpO$_2$, ETCO$_2$, BIS data for:
  - Safety interlock - Stop IV propofol pump if respiratory or BP problem, or
  - PCLC - Titrate infusion rate of IV propofol pump to target BIS value
  - And, create smart alarm and activate innovative alarm signal

ETCO$_2$ – end tidal CO$_2$ monitor; BIS – EEG depth of sedation/anesthesia monitor
PCLC – Physiologic Closed Loop Control
UL 2751

• Interoperable Medical Device Interface Safety (for testing and certification only).

• Initiated under ANSI standards process (still in very early phases of development)

• A standard that offers a Third Party certification process to facilitate interoperability and demonstrate safety.

• Not intended to replace existing device interface standards or protocols, but rather to leverage them as part of the certification process
  – to provide oversight of safety aspects of interoperability of disparate components and subsystems
  – to support regulatory processes (e.g. 510k)

• Will support architectures including ICE
Questions?