Quantum Clinical Scenarios
Version: October 27 2011,
For NIH research group

Clinical Scenarios and Clinical ConOps for "Quantum Interoperability" NIH UO1 – "Development of a Prototype Healthcare Intranet for Improved Health Outcomes"

P.I. Julian M. Goldman, MD
Massachusetts General Hospital / Harvard Medical School
www.jgoldman.info

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Summary of Quantum 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 (TH) devices in hospital, example of transferring care from home to hospital and use of TH devices for high-acuity care
4. FDA regulatory – staged implementation of framework for levels of interoperability and associated levels of hazards and their mitigation

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Clinical Scenario #1

PCA Infusion Pump Safety Interlock

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PCA INFUSION PUMP SAFETY INTERLOCK

Clinical Summary: Hospitalized patient is receiving intravenous (IV) opioid medication by PCA. Patient is monitored with a pulse oximeter and respiratory CO_2 (capnography). An automated system monitors clinical data and IV pump status. If the medication depresses the patient's respiration to an unsafe level, the supervisory system "app" detects the problem, stops the medication, and calls the nurse.

Clinical Innovation: Heterogeneous (multi-vendor) integration of monitors and actuators to improve PCA safety will be developed. Apps to improve the quality of real-time monitoring will be developed.

Scenario based on ASTM F2761-2009, Annex B PCA = Patient Controlled Analgesia

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PCA INFUSION PUMP SAFETY INTERLOCK

Technical Innovations:

"Component level" heterogeneous medical device plug-and-play interoperability, including rapid development of Clinical Apps that interact with devices in real-time

Scenario Extension: Use clinical data for real-time control of other medication infusions and devices

Smart PCA monitoring system

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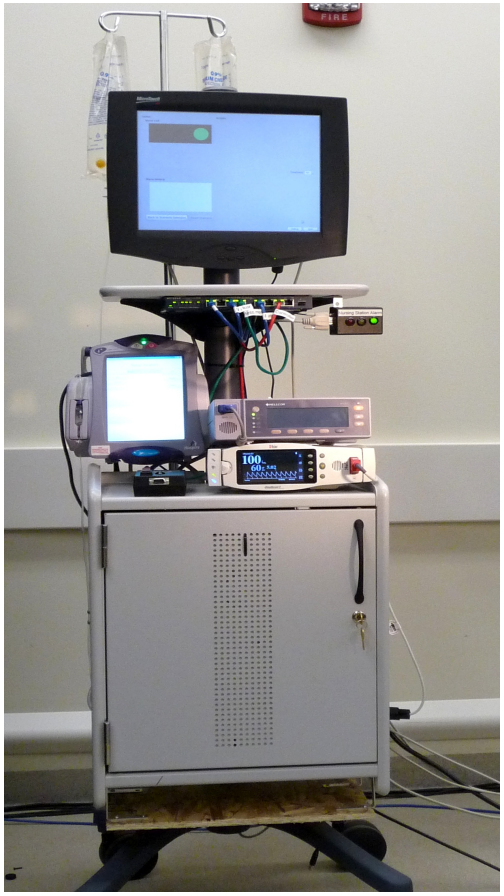
- *Plug-and-play integration of monitors/pump connected to patient.*
- *Hosts "apps" to detect respiratory problems -> stop IV pump*
- *Permits selection of "best" monitor and alarm algorithm at point of care*

American Society of Anesthesiologists
Scientific Exhibit October 2007



2011
version

Exhibit recognized with First Place award

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Clinical Scenario #2

Prepare ICU to Receive Post-OP Cardiac Patient

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Quantum Clinical Scenario #2

PREPARE ICU TO RECEIVE POST-OP CARDIAC PATIENT

Clinical Summary: While patient undergoes CABG surgery in the OR, a decision support system reads, via medical device interfaces, medication infusions, lung ventilator settings, and medical devices/therapies being used.
This information will guide ICU staff to prepare equipment and medication for the patient. ICU medical device settings are set automatically to OR settings (with clinician confirmation). Hospital protocol "checklists" will also be presented to the ICU team, and missing steps/data/devices will be automatically identified when possible.

Clinical Innovation: Intelligent device-related data transfer and setup, dynamic smart checklists, and reduction of nursing workload and errors related to complex patient transfers.

ICU: Intensive Care Unit; CABG: Coronary Artery Bypass Graft, or "bypass"

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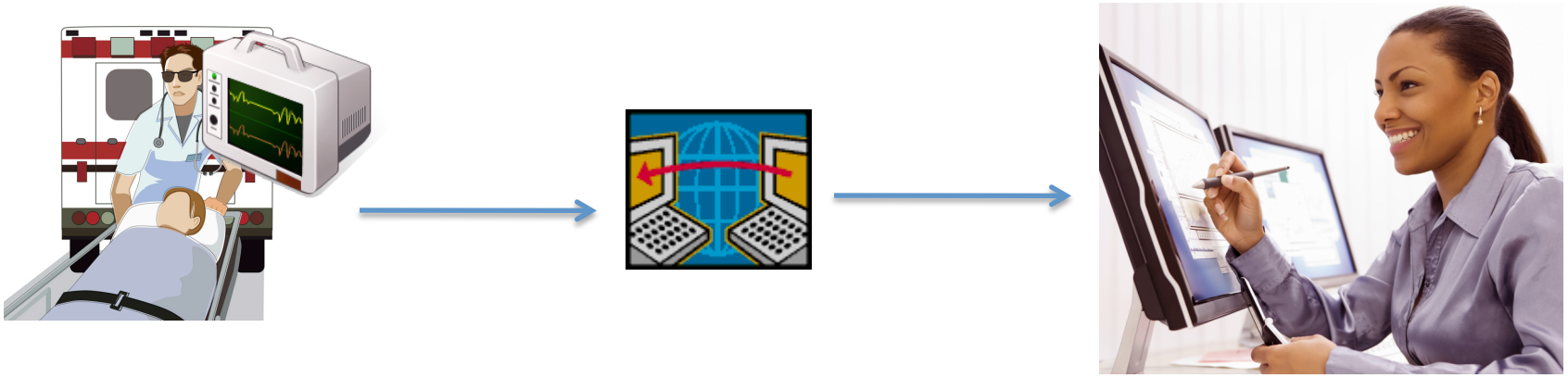
Quantum Clinical Scenario #2

PREPARE ICU TO RECEIVE POST-OP CARDIAC PATIENT

Technical Innovations:

- Querying complete status of medical devices in use (just as is routinely done with networked computers and printers)
- Configure medical devices. For example, read ventilator settings from OR brand X vent, translate to ICU brand Y ventilator terminology, and apply settings.
- "System readiness assessment" of clinical environment, prior to initiating care.
- Dynamic checklists for ICU staff: Alert to missing steps and devices, allergies
    - Example: Do not setup routine post-op medication or product (e.g. latex) if allergy (read remote allergy via NHIN)

Clinical Scenario #3



Use of Tele-health Devices in Hospital

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Quantum Clinical Scenario #3

USE OF TELE-HEALTH DEVICES IN HOSPITAL

Clinical Problem:

Data from home tele-health (TH) devices are typically monitored by a remote monitoring service.

TH devices and their use paradigms are specialized. For example, patient identity is typically bound to data by a "home health hub". Also, TH medical devices may not have clinical alarms, and even if they do, their standards/ interfaces may not transmit alarms

When a patient wearing TH devices arrives in the Emergency Department (ED), how would the clinical data be accepted in the EMR? Will it be tagged as TH-sourced? How could the absence of device alarms be addressed?

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Quantum Clinical Scenario #3

USE OF TELE-HEALTH DEVICES IN HOSPITAL

Clinical Summary:

Patient with chronic medical condition is wearing an array of tele-health (TH) sensors at home, and is monitored by a commercial remote disease monitoring service. The patient's condition worsens, and in consultation with the medical team, the patient – still wearing the TH sensors – is transported by ambulance to the hospital Emergency Dept. On arrival in the ED, the TH devices are linked to the hospital IT network/EMR, enabling continuous monitoring of the patient on the hospital network.

Clinical alarms are implemented with ICE Supervisor "apps"

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Quantum Clinical Scenario #3

USE OF TELE-HEALTH DEVICES IN HOSPITAL

Technical Innovations:

- Hospital “grade” connectivity to TH devices
- Implementation of clinical alarms from TH devices (devices function as “thin sensors”)
- Use of hospital-located TH monitor data for real-time patient management:
    - TH device data provenance management
    - Patient ID-TH monitor data association in hospital environment
    - Time syncing of data from TH monitors

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Clinical Scenario #4

Increasing Levels of Interoperability of Medical Devices in Hospital (FDA Regulatory Scenario)

Quantum Clinical Scenario #4

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INCREASING LEVELS OF INTEROPERABILITY OF MEDICAL DEVICES IN HOSPITAL

Regulatory Background:

Following the FDA workshop on medical device interoperability in January 2010, an interdisciplinary team formed the FDA Prototype Regulatory Submission Working Group ("PRS") to analyze the hazards of, and risk mitigation strategies for, interoperable medical device systems, in order to inform future regulatory approaches.

The PRS WG produced a "levels of interoperability" analysis which aligns risk with the complexity and clinical function of the system. This scenario is an implementation of the analysis developed by the PRS WG Jan 2010 – May 2011

News & Events (Medical Devices)

Workshops & Conferences (Medical Devices)

Past Workshop & Conference

Medical Device Interoperability, January 25, 2010

The public workshop was held on January 25 and 26, 2010, from 9 a.m. to 5 p.m. and on January 27, 2010, from 9 a.m. to 12 noon.

Location: The public workshop was held at the FDA White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993.

FR Doc E9-30871

Related Document

- Transcript: Medical Device Interoperability, January 25, 2010 (PDF - 574KB)
- Transcript: Medical Device Interoperability, January 26, 2010 (PDF - 320KB)
- Transcript: Medical Device Interoperability, January 27, 2010 (PDF - 244KB)

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Scenario #4 - Levels of Interoperability

- 1. Virtual Display: Pulse Oximeter, $ETCO_2$ (end-tidal CO_2),and BIS (depth of anesthesia monitor) data are remotely displayed to monitor a patient during colonoscopy. Monitoring devices are exchanged to demonstrate interoperability.
- 2. Derived Alarms: SpO_2 from pulse oximeter, and $ETCO_2$ and BIS signals are combined to create smart alarms (to detect medication-induced respiratory depression during procedure)
- 3. Virtual front panel: manually control multi-parameter monitor and IV infusion pump through single integrated control panel to assist with patient management from outside of procedure room
- 4. Autonomous control: use SpO_2, $ETCO_2$, BIS data for:
  - Safety interlock – e.g. Stop IV propofol pump if resp or BP low, or
  - Physiologic Closed Loop Control - Titrate infusion rate of IV propofol pump to target BIS value
  - And, create smart alarm and activate innovative alarm signal


Contact info:
www.jgoldman.info
MD PnP Program:
www.mdpnp.org
Kurashiki, Japan