ICE Motivation

http://mdcf.santos.cis.ksu.edu/

Part of the tutorial series for the Medical Device Coordination Framework (MDCF) developed by Kansas State University and the University of Pennsylvania

Acknowledgements:
Funding provided by US National Science Foundation awards 0734204, 0930647, 0932289 and the NIH/NIBIB Quantum
Overview

- Clinical motivation for the “Integrated Clinical Environment”
  - Development led by Dr. Julian Goldman at CIMIT
  - ASTM Standard F2761-2009 for ICE defines a high-level architecture and functional concept
  - Subsequent standards are intended to provide specific functional and interfacing requirements for components
- The “Medical Device Coordination Framework” developed jointly at KSU and UPenn provides a prototype implementation of ICE
Network enabled devices...

Many modern medical devices are network-enabled...

How is this connectivity being leveraged in emerging commercial products?
Cerner SmartRoom

Integrated displays with views customized for caregiver

Care Giver B

Care Giver A

Electronic Patient Medical Record

Networked Devices

Enterprise Service Bus
Emergin System ESB product graphic
Current FDA regulations do not allow any automated control of devices/settings or significant reformatting of data.
From *Integration* to *Systems*

Looking ahead...

- Delivering modern medical care involves complex cyber-physical systems...
  - many medical devices, electronic medical records, clinicians/care-givers...all working together to achieve a goal

- Although most modern medical devices have some form of connectivity, they are not integrated so that they can work together as a system
  - devices are “unaware of their context”, e.g., details of patient parameters, history, current procedures they may impact/distort readings
  - data from multiple devices is not combined to produce more meaningful information to clinicians
  - actions of multiple devices cannot be automatically coordinated to achieve greater safety and efficiency

*How might health care delivery benefit if devices and EHR databases could function as components of automated systems?*
At present, in MDDS, data only flows from producers to consumers and data must be faithfully represented.
Main Idea

Fully leverage device data streams and the ability to control devices

**Moving forward:** aggregating data streams to create "smart alarms" that reduce nuisance alarms by triggering alarms only when multiple physiological parameters are in agreement, e.g., agreement in trends on ET CO2 as well as pulse ox SpO2

"Medical Device Integration Platform application (app)"

Data Consumers

- iAware Gadgets
- Nurse Station

Devices

- Data Stream 1
- Data Stream 2

Smart Alarm Logic

Alarm Info
Safety Interlocks

Moving forward: aggregating data streams to solve systems problems by making devices context aware.

Tracheal tube fire hazard -- caused by failure to reduce \( O_2 \) concentration during tracheal laser surgery.

Proposed and published by Sem Lampotang, PhD, Univ. of Florida -- not commercially available. Device coordination systems can provide a solution. From Dr. Julian Goldman -- MDPnP.
Problematic Clinical Workflows

Example Use-Case: X-Ray / Ventilator Interaction

- Constant movement of a patient on ventilator makes it difficult to acquire x-ray image.
- Clinicians often manually disable ventilators -- sometimes with very bad consequences

A 32-year-old woman had a laparoscopic cholecystectomy [gall bladder removal] performed under general anesthesia. At the surgeons request, a plane film x-ray was shot during a cholangiogram [bile duct image]. The anesthesiologist stopped the ventilator for the film. The x-ray technician was unable to remove the film because of its position beneath the table. The anesthesiologist attempted to help her, but found it difficult because the gears on the table had jammed. Finally, the x-ray was removed, and the surgical procedure recommenced. At some point, the anesthesiologist glanced at the EKG and noticed severe bradycardia. He realized he had never restarted the ventilator. **This patient ultimately expired.**
Device Coordination

**Moving forward:** live detection of patterns in monitoring data, automation of sequences of tasks in a clinical workflow

Fully leverage device data streams and the ability to control devices

From Dr. Julian Goldman -- MDPnP.
Closed Loop Control

Example Use-Case: PCA Monitoring

- Patients are commonly given patient-controlled analgesics after surgery
  - ...better outcomes than nurse administered opioids
- Administers analgesics such as morphine, fentanyl, and hydromorphone
  - constant basal rate of infusion
  - bolus doses delivered when patient pushes button

Opioid Side-Effects -- Respiratory Depression

- decreased respiratory rate, decreased oxygen saturation, increased end tidal carbon dioxide
- detect by monitoring
  - heart rate, respiration rate, blood pressure
  - pulse oximeter (oxygen saturation)
  - capnography (CO2 exhalation)

PCA Hazards

- operator error (wrong drug, wrong dosage)
- PCA by proxy
  - e.g., relative pushes button for patient
- monitoring device alarms tends to lag time of overdose
Closed Loop Control

Example Use-Case: PCA Monitoring

- Patients are commonly given patient-controlled analgesics after surgery
- There have been occurrences of patients overdosing

A 49-year old woman underwent an uneventful operation (total abdominal hysterectomy and bilateral salpingo-oophorectomy). Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. She began receiving a continuous infusion of morphine via a patient controlled analgesia (PCA) pump. A few hours after leaving the PACU [post anethesia care unit] and arriving on the flow, she was found pale with shallow breathing, a faint pulse, and pinpoint pupils. The nursing staff called a "code", and the patient was resuscitated and transferred to the intensive care unit on a respirator. Based on family wishes, life support was withdrawn and the patient died. Review of the case implicated a PCA overdose. Delayed detection of respiratory compromise in patients undergoing PCA therapy is not uncommon because monitoring of respiratory status has been confounded by excessive nuisance alarms.
“A particularly attractive feature may be the ability to automatically terminate or reduce PCA (or PCEA) infusions when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, we strongly endorse the efforts to develop international standards for device interoperability and device-device communication.

It is critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner.”
Closed Loop Control

Fully leverage device data streams and the ability to control devices

Devices

- **PCA Pump**
  - Pump Settings
  - Disable Pump

- **Respiratory Rate Monitor**
  - Monitoring Data + Alarm Information

- **Pulse Oximeter**
  - Monitoring Data + Alarm Information

- **Combined PCA Vitals Monitoring**

- **Device Task controller**
  - Enable bolus dose only when ticket present

- **Dosage Calculator**

- **EMR Database**
  - Patient Parameters
  - Pain & Sedation Scores
  - PCA Bolus "Enable" Ticket
  - Aggregated Monitoring Status

- **Clinician / Monitoring**

- **Status Display for PCA Monitoring Application**

**Application**

- **Dosage Calculator**
- **Clinician / Monitoring**
- **Status Display for PCA Monitoring Application**

- **Pain & Sedation Scores**
- **Aggregated Monitoring Status**

**Devices**

- **PCA Pump**
  - Pump Settings
  - Disable Pump

- **Respiratory Rate Monitor**
  - Monitoring Data + Alarm Information

- **Pulse Oximeter**
  - Monitoring Data + Alarm Information
Develop a bus-based app for implementing a safety interlock by coordinating monitoring of vitals with pump control...

Pulse ox, respiratory rate monitor, infusion pump with hand-held control are connected to the patient.
Develop a bus-based app for implementing a safety interlock by coordinating monitoring of vital signs with pump control...

An app library holds apps that automate a variety of workflows including “closed loop” scenarios.

A Coordination Supervisor module calls the app launcher to create an instance of app classes and make pub/sub connections to the bus.

An app may acquire exclusive access to relevant devices and sends/receives information to those devices during execution.

Device Attachment

Bus

App Launcher

Acquired Devices

Coordination App Library

Active Apps

Coordination Supervisor

Respiratory Rate Monitor

Pulse Ox

PCA Pump
Develop a bus-based app for implementing a safety interlock by coordinating monitoring of vitals with pump control...

"Begin monitored PCA infusion"

Clinician uses ICE Clinician console to interact with the app supervisor, select apps, and to respond when human input is requested.
ICE Architecture Goals/Concepts

- Partition desired ICE functionality into components that may be implemented by different vendors and composed to form a functioning system
  - The determination of components within the architecture will define the granularity at which one chunk of an ICE implementation can be swapped out and replaced by another
- Component boundaries are characterized by precise standardized interfaces for which it is possible to determine/certify compliance
- Open-ended wrt devices and apps
- Enable the development of a commodity market of component implementations
- Regulation of ICE systems occurs component-wise
  - Individual components are submitted for regulatory approval
- The ICE architecture provides sufficient safety and security guarantees such that composing components to form an instantiation of the ICE architecture at the point of care is not a regulated activity
  - Composing components should never result in a system failure
Interoperability Points

- ASTM Standard F2761-2009 for ICE defines a high-level architecture and functional concept
- Green dashed lines represent interoperability (interfacing) points between ICE architecture component
- Each interoperability point must (eventually) have a standardized interface against which compliance can be judged and certified
ICE Standard

- ASTM Standard F2761-2009 for ICE defines a high-level architecture and functional concept
- Subsequent standards are intended to provide specific functional and interfacing requirements for components
- The ICE architecture standard is the focal point for FDA’s evaluation of bus-based app concepts in future medical systems
  - A key element of this evaluation is moving from regulation of “systems as a whole” to component-wise regulation
ICE and the MDCF

- The Medical Device Coordination Framework, jointly developed by KSU and U Penn provides a prototype implementation of ICE
- MDCF is designed to serve as a test-bed to illustrate issues related to...
  - Functional concepts
  - Safety
  - Security
  - Verification and Certification technology
- Subsequent lectures will present the details of the MDCF