Safety of Interoperable Systems

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Safety of Interoperable (Medical) Systems

- We want safe, interoperable systems of medical devices.
- Interoperability = The ability of two or more medical devices and other equipment, which are intended by their manufacturers to exchange information via an electronic data interface (EDI), to safely perform a clinical function with a specific intended use, and in a assembled configuration not necessarily foreseen by the manufacturers.
- This presentation represents our initial experiments and first pass applying STAMP to this domain, not necessarily correct
- Medical devices are designed and regulated as stand-alone devices, not as system components
- But they are being used in very complex systems.

Disclaimer: None of this is in any way official commentary from FDA

Safety of Interoperable (Medical) Systems

- Medical devices are different from other communities
  - Many stakeholders: hospitals, regulators, patients, clinicians
  - No single system integrator
  - No process model
- Every integration effort is an individual, one-off exercise
- Every day, clinicians have ideas about how to implement safer systems, but these can't be implemented
- Medical devices are already part of the patient care system, whether or not they're good players. Clinicians manually coordinate device usage.
- A standardized approach with defined, reusable components across the industry will lead to easier integration
- The system can be safer than the device (e.g., PCA) if we can address the known significant system hazards and common PCA failure modes. Need contextual info + sensor info + supervisory system to enhance safety.
- The system may detect/compensate for device safety shortcomings (e.g., PCA fails in free flow or drug library has error)

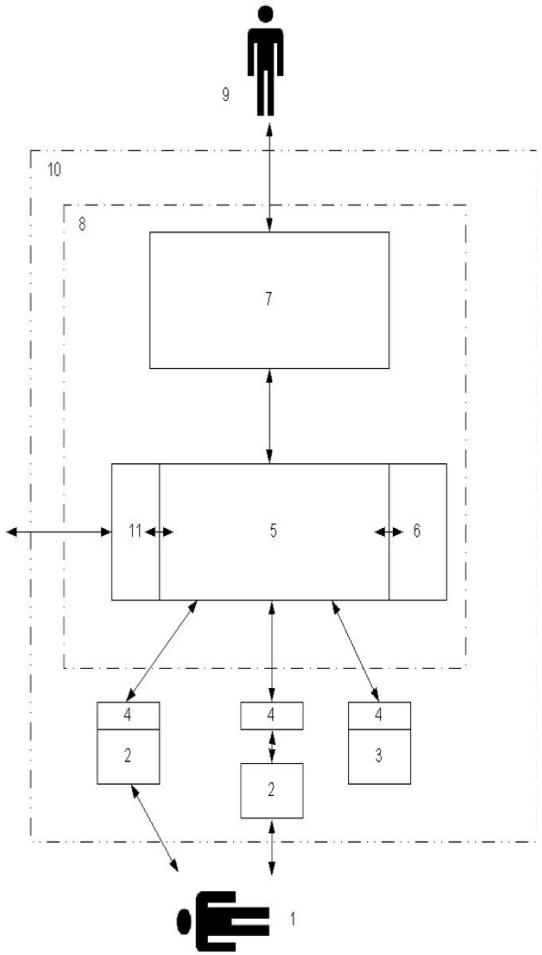
RESOLVED, That our American Medical Association (AMA) believes that intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. Our AMA also recognizes that, as in all technological advances, interoperability poses safety and medico-legal challenges as well … ”

as of July 2009:

Anesthesia Patient Safety Foundation
Society for Technology in Anesthesia
Society of American Gastrointestinal Endoscopic Surgeons

American Medical Association
World Federation of Societies of Anesthesiologists
American Society of Anesthesiologists
Massachusetts Medical Society

ASTM 2761 Integrated Clinical Environment



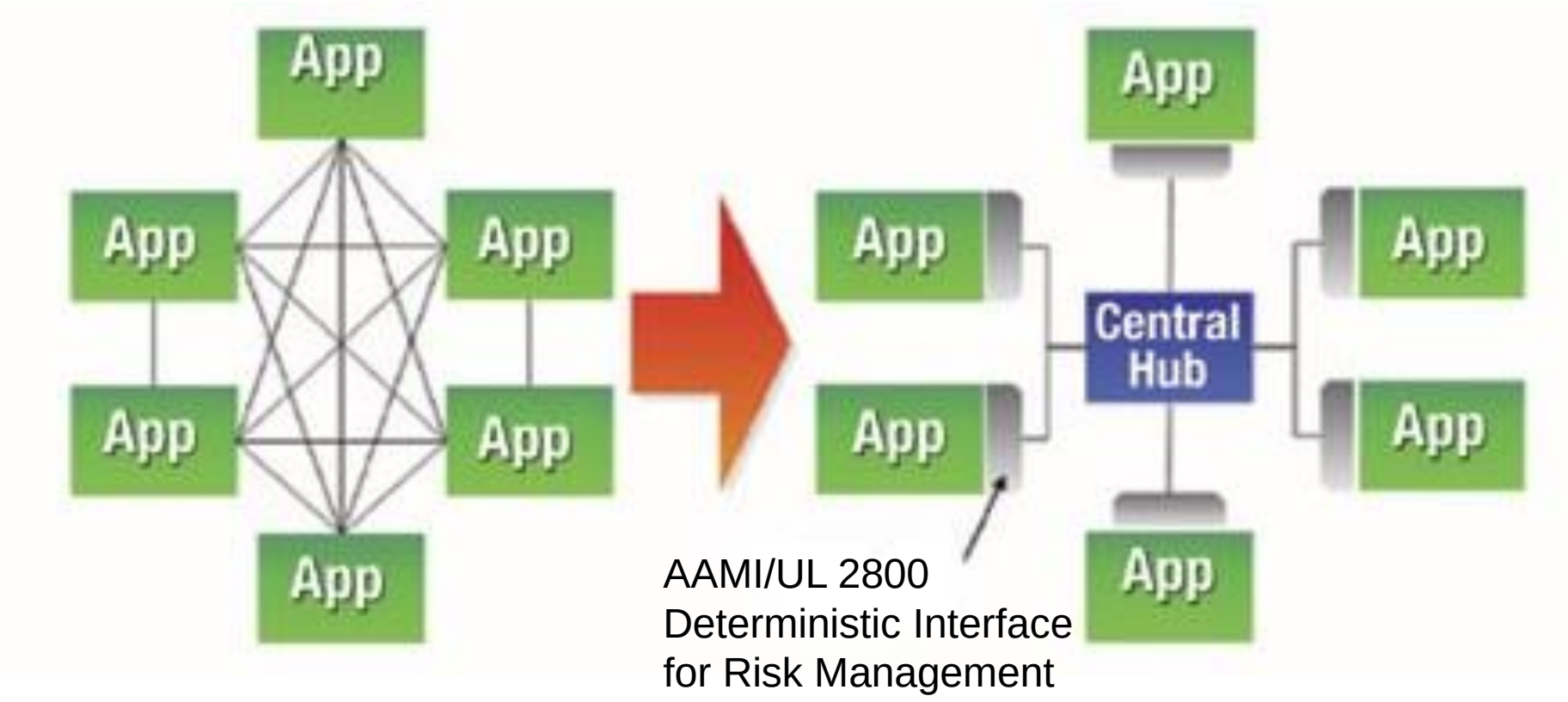
Conceptual functional model from ASTM F2761 showing the elements of the **INTEGRATED CLINICAL ENVIRONMENT**

Key
1 PATIENT
7 ICE SUPERVISOR
2 MEDICAL DEVICE
8 ICE Manager
3 Equipment
9 OPERATOR
4 ICE EQUIPMENT INTERFACE
10 ICE
5 ICE NETWORK CONTROLLER
11 External Interface
6 Data logger

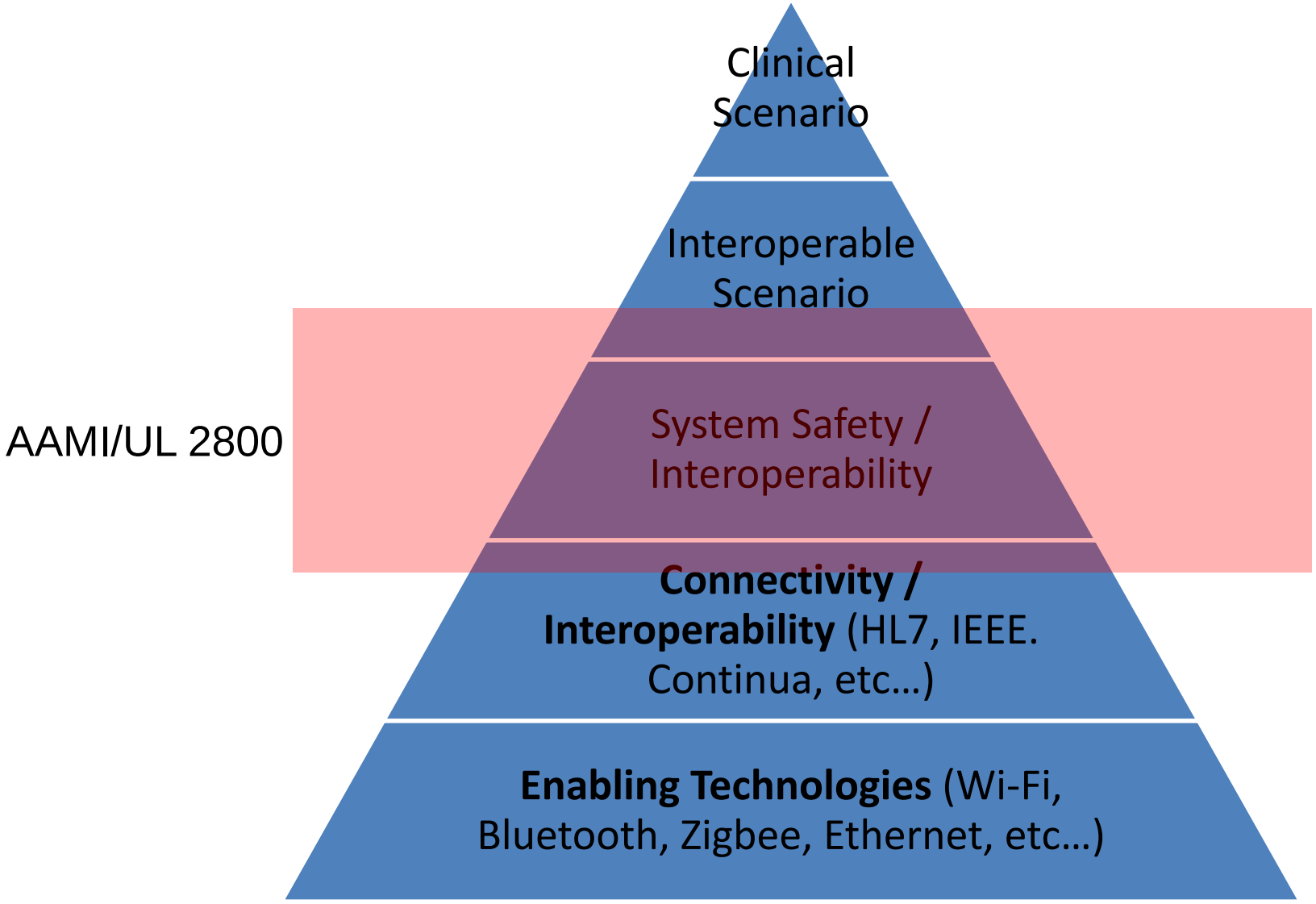
Each box is a system component.
Apps are components with intended uses

ASTM F2761 (ICE) architecture and AAMI/UL 2800 – interoperable medical device interface safety

Reducing Interface Complexity is Key



AAMI/UL 2800 in the “big picture”

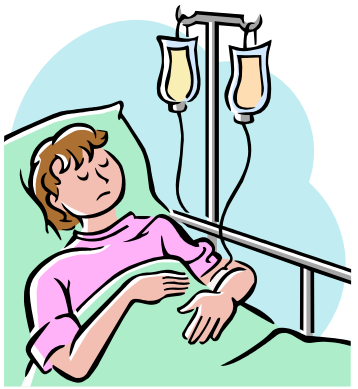


Environment for which medical devices are designed and regulated

program

Infusion Pump

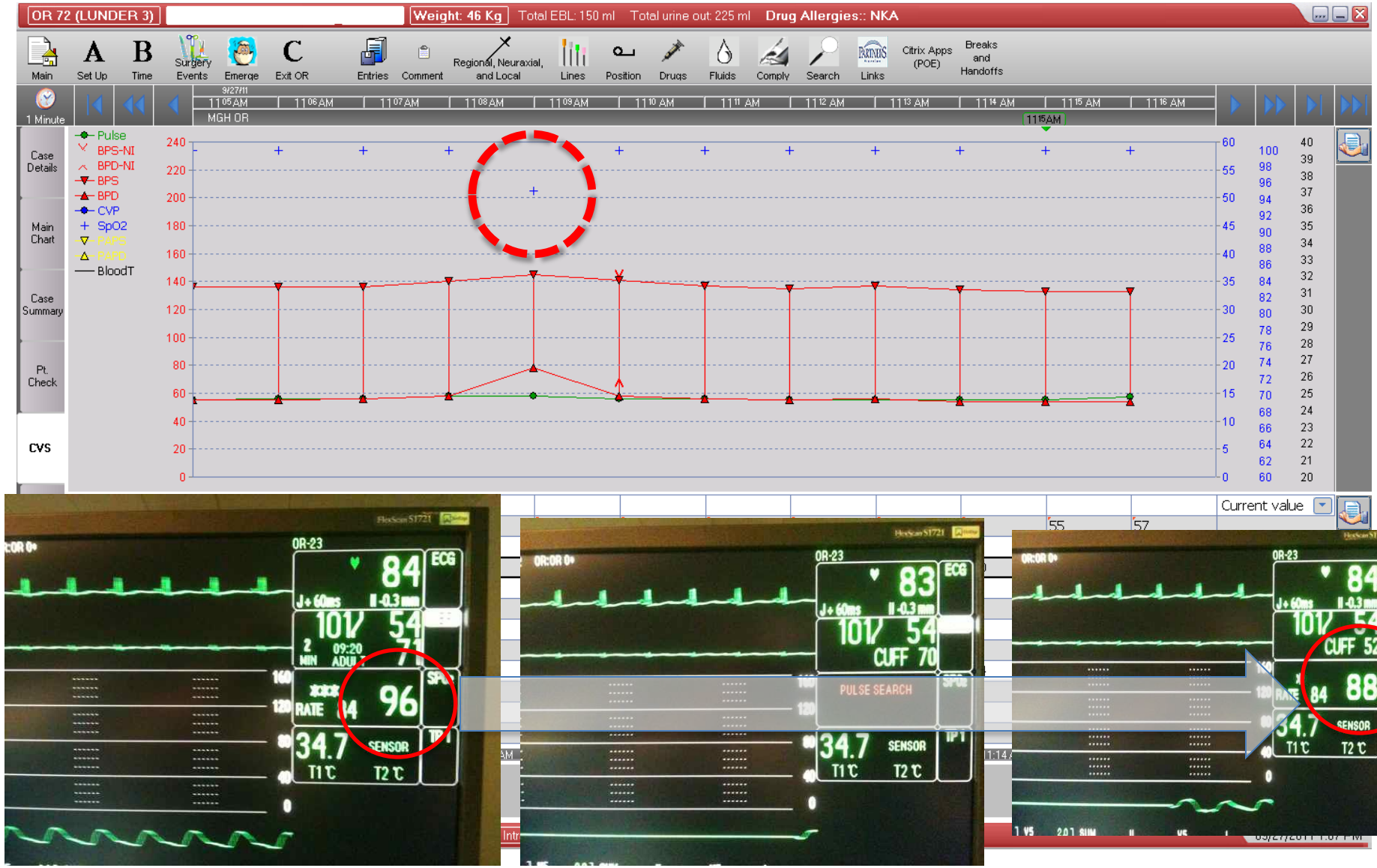
Flow of fluid



Stand-alone device development

- System-level Accidents, Hazards, Safety Constraints are minimally considered in current development and regulatory practice.
- Intended use may include sending data to an EMR
- Very few devices allow control inputs through their network connection
- So of course we see unintended interactions all the time.

NIBP-SpO_2 Interaction

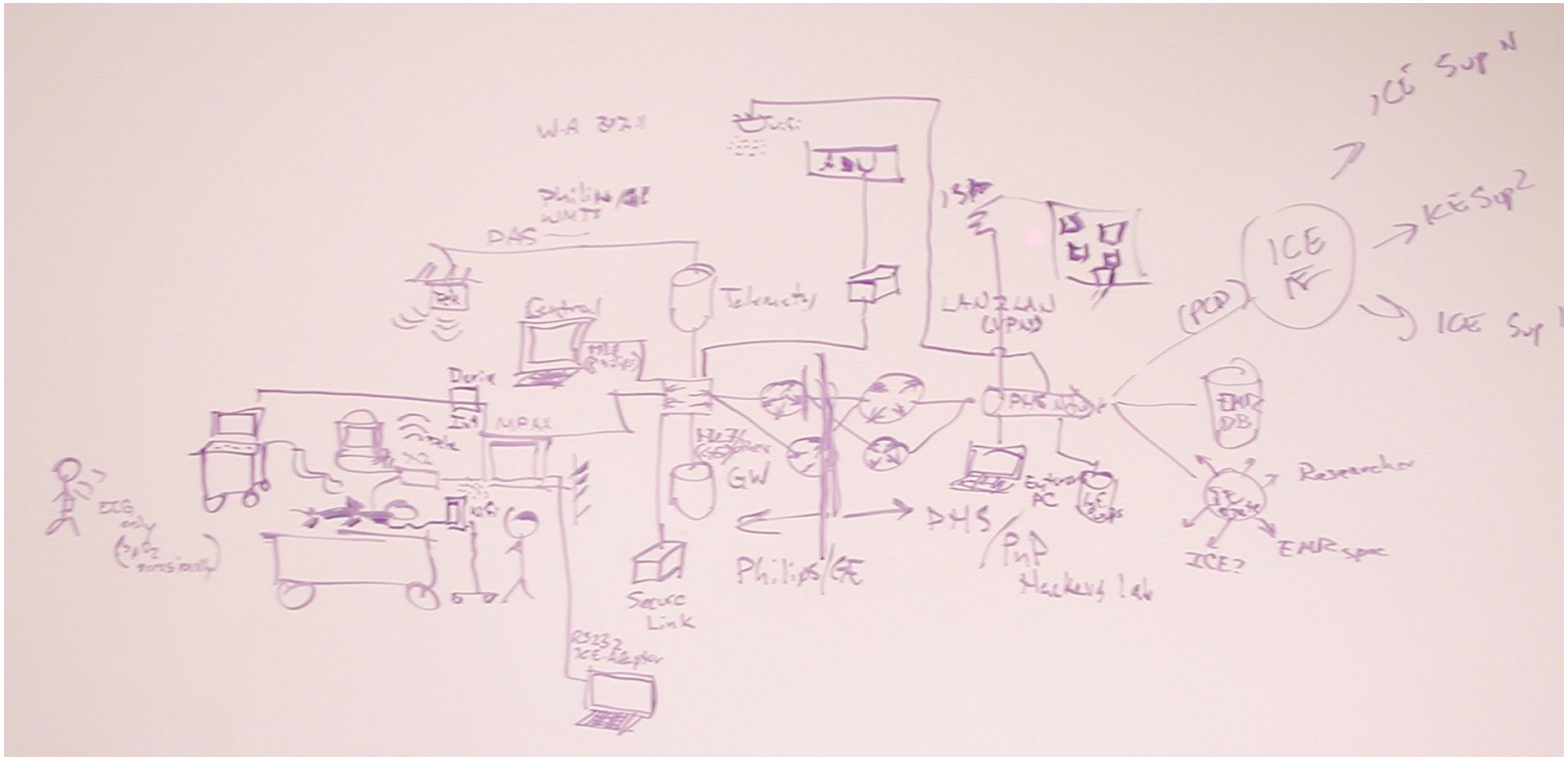


Real use environment for medical devices

Clinical care:
Is not neat and tidy.
Poor access to data, only manual coordination of devices.

Hospital IT system

- Hospital IT is highly balkanized
- Typically, each manufacturer has a VPN and gateway server
- Integration is up to each hospital

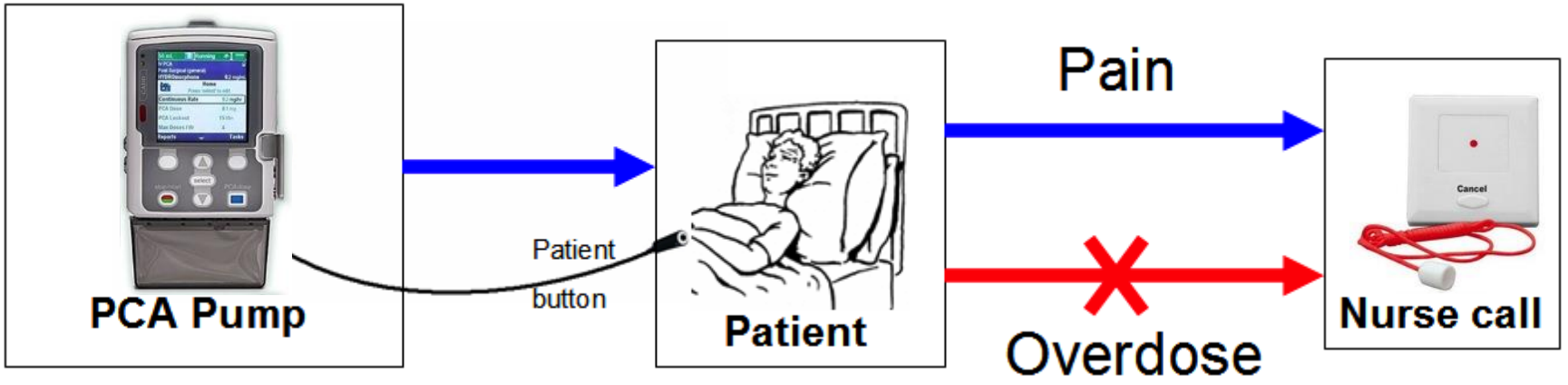


PCA Clinical Scenario

- **Clinical Scenario Narrative Description**
- **Scenario Current State**
- A 49--year--old woman underwent an uneventful 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) infusion pump. A few hours after leaving the post--anesthesia care unit (PACU) and arriving on the floor, 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 by providers implicated a PCA overdose (1)

- **Scenario Proposed State**
- While on the PCA infusion pump, the patient is monitored with a respiration rate monitor and a pulse oximeter. If physiological parameters move outside the pre--determined range, the infusion can be stopped and alarms sent to notify the clinical staff and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart monitor to optimize sensitivity to detecting respiratory compromise while reducing false alarms.
- One Clinical Scenario of NIH "Quantum Medical Device Interoperability" [www.mdpnp.org/quantum.html] research project

Patient-Controlled Analgesia (PCA)
system safety concerns



- *Patient presses button to receive intravenous pain medication*
- *Patients can call to request more analgesia, but, cannot call for help when over-medicated.*
- *Over-medication can cause respiratory and cardiac arrest*
- *Comprehensive monitoring is not typically used due to high false/nuisance alarm rate*
- *How can we improve safety of this system?*

Why is optimizing the safety and effectiveness of PCA difficult? I/III

Assumption	Challenge
A. PCA is safe because patient must be alert to "request" each dose	1. Patients may have marked variation in sensitivity. Requirements vary across patients and over time, co-morbidities (OSA, ARF), and use of other medications. In some patients one dose may cause overdose. 2. Use of basal infusion rate is controversial 3. PCA by proxy (especially in pediatrics, also adults) 4. Device and delivery problems can overestimate dosage requirements
B. PCA is effective because patients can dose on demand	1. PCA protocols are optimized for "average" patient 2. Fear of iatrogenic respiratory arrest delays aggressive, effective pain management especially in opioid-tolerant patients
C. Q 4-hour recommended reassessment is appropriate to achieve analgesic efficacy	Pain scoring requires awakening/disturbing patient and possibly their family members. Automated continuous analgesic assessment may be possible.

Why is optimizing the safety and effectiveness of PCA difficult? II/III

Assumption	Challenge
D. Current monitoring is adequate to provide detection of respiratory compromise	1. Current detection of respiratory compromise is not sufficiently sensitive and specific to prevent harm. Earlier detection of respiratory distress may avoid harm. Algorithm development is challenging due to lack of historical, comprehensive, baseline data. 2. Use of supplemental O2, placement of monitors, and monitor response time must be considered 3. Comprehensive monitoring has been shown to reduce/prevent "dead in bed" events, but not early detection of respiratory compromise and associated morbidity. In addition iatrogenic response is to undertreat pain in these settings. optimization of analgesic therapy.
E. Stopping PCA pump after detection of respiratory distress will be a sufficient intervention	1. Cessation of therapy is a poor and painful solution. Adaptive dose titration may be a better response. 2. Adaptive system requires reliable Integration of monitors and clinical data, deployment of personalized alarms, AND ability to adjust rate of IV opioid delivery

Why is optimizing the safety and effectiveness of PCA difficult? III/III

Assumption	Challenge
F. Current vital signs monitors provide accurate, complete, and timely data for real-time decision support. Information about nursing interventions, patient activity, time-of-day, co-morbidities, and concurrent medications can be easily documented and used to create optimum monitoring algorithms	1. Comprehensive PCA observational data set is not available. Useful data set may require customized electronic data interfaces and expert observation. 2. Performance (accuracy, sensitivity, specificity) of conventional non-invasive monitors may be inadequate. Specialized monitoring strategies may be required.
G. Relevant Co-morbidities are known	Obstructive sleep apnea is under-diagnosed and may be an important factor in PCA safety. PCA Safety System may also be able to screen for OSA.

Analyzing Interoperable Medical Devices with STAMP

- We need a defined, controlled development process
- Manufacturers must build in safety as opposed to testing at end
- We’re here to figure out what that means from practical perspective

Component-level

- Component only introduced into system if it meets conditions of acceptability
- Components are (typically) FDA cleared devices that can maintain basic safety and essential performance while functioning in a heterogeneous networked environment
- Interface standard is intended to be applied early in the product development process to help establish a baseline set of safety constraints to be implemented during the design phase, and which we hope to determine as a function of system hazards (clinical workflow driven) with the aid of STPA/STAMP.
- Many system level hazards are mitigated by the controller app component

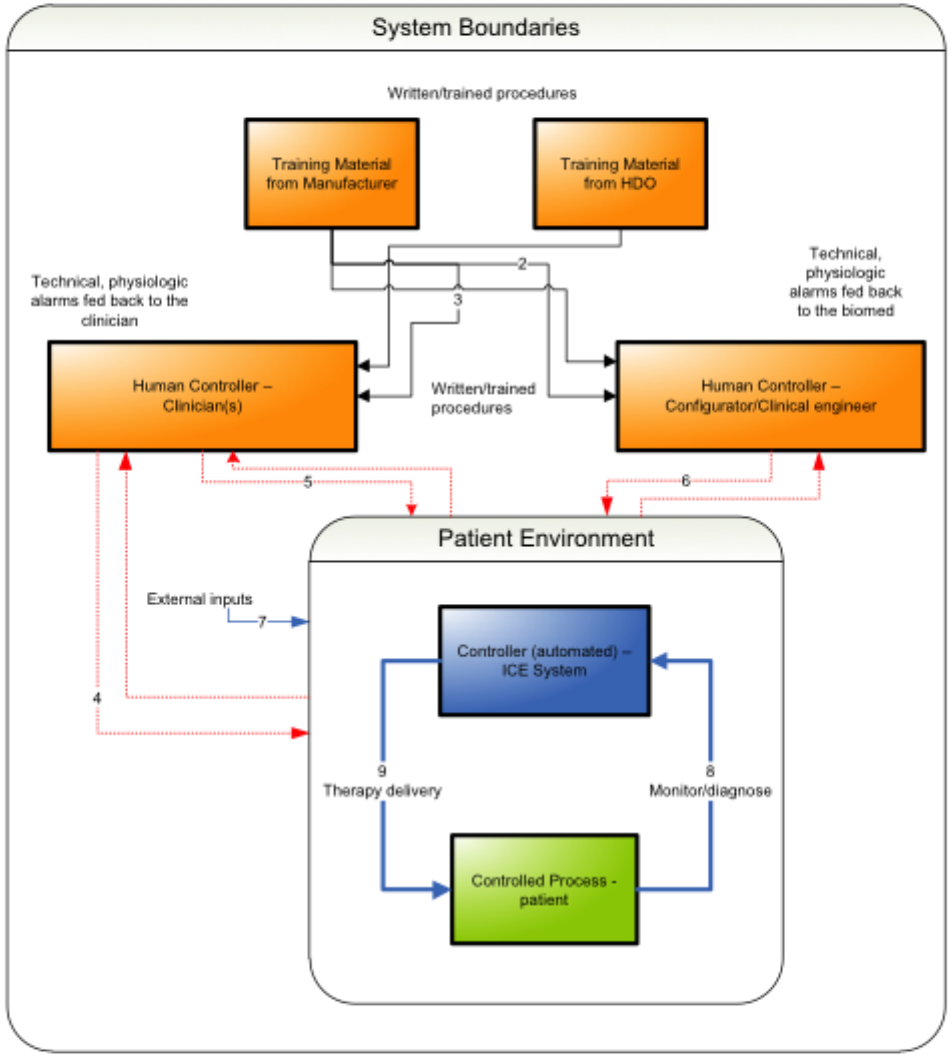
System-level

System goal: Identify entities (and boundaries) that have a responsibility in assuring the safety of the patient, determine the monitoring or control action, and provide a means of assessing what happens if …

1. required action not provided or followed
2. incorrect or unsafe control action is provided
3. potentially safe control action is provided too early or too late
4. correct control action is stopped too soon

- And what happens if one of the entities doesn't do its job.
- Hope to provide template as starting point for instantiations designs that are compatible with this control loop notion

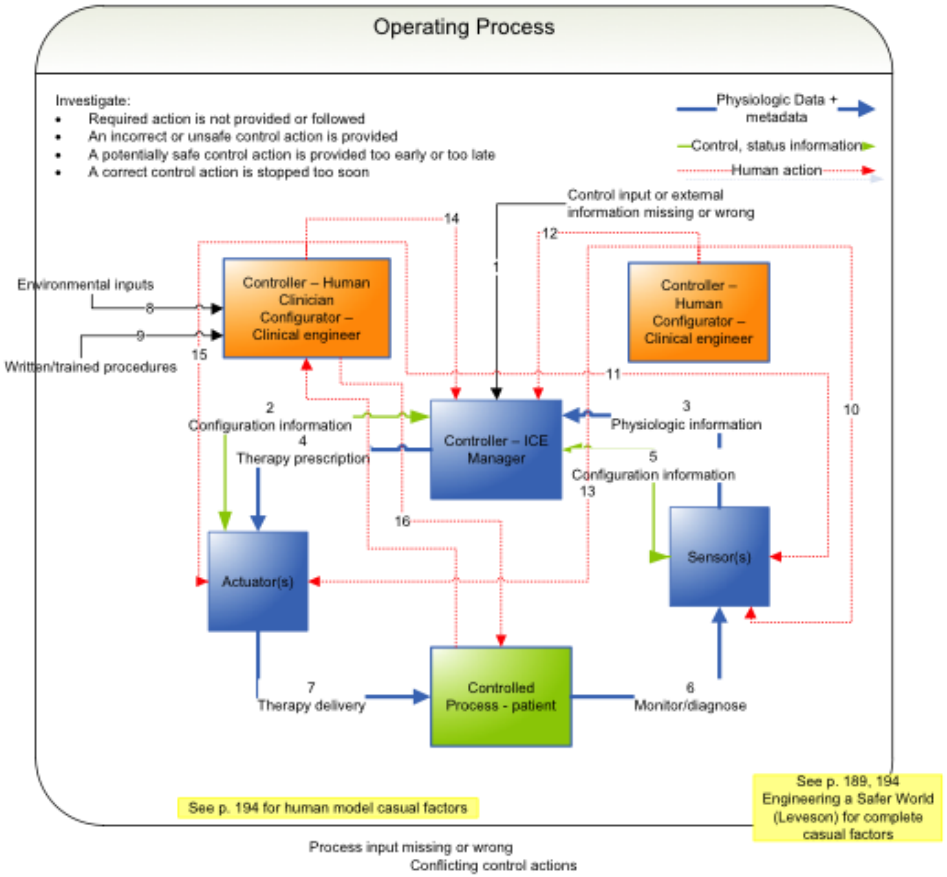
Black Box Level Process Model



Only a very few elements are captured here to illustrate that influence can go in both ways from each box, and that there are interactions that need to be made explicit for both entities and devices.

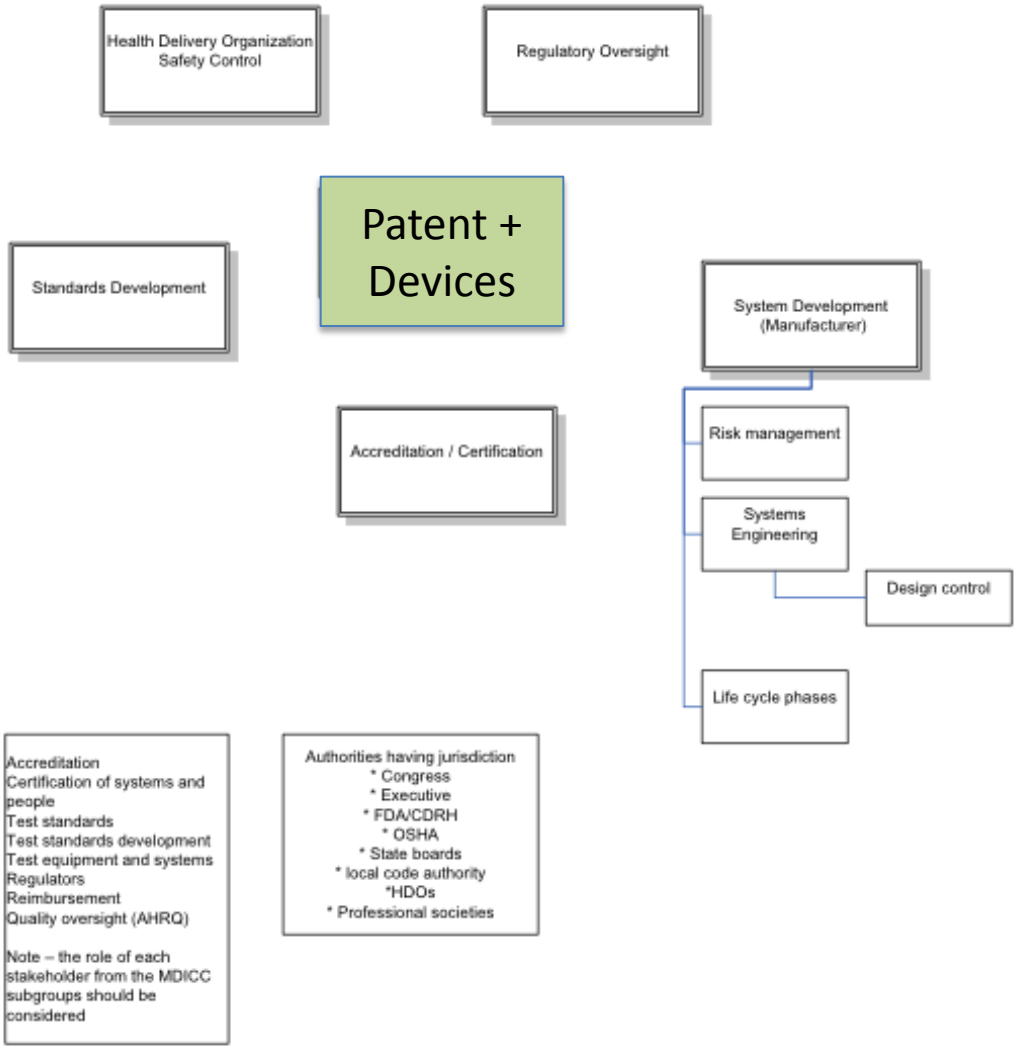
For example, the training material for the HDO and from the manufacturer are related. Problems found in one need to be communicated to the other.

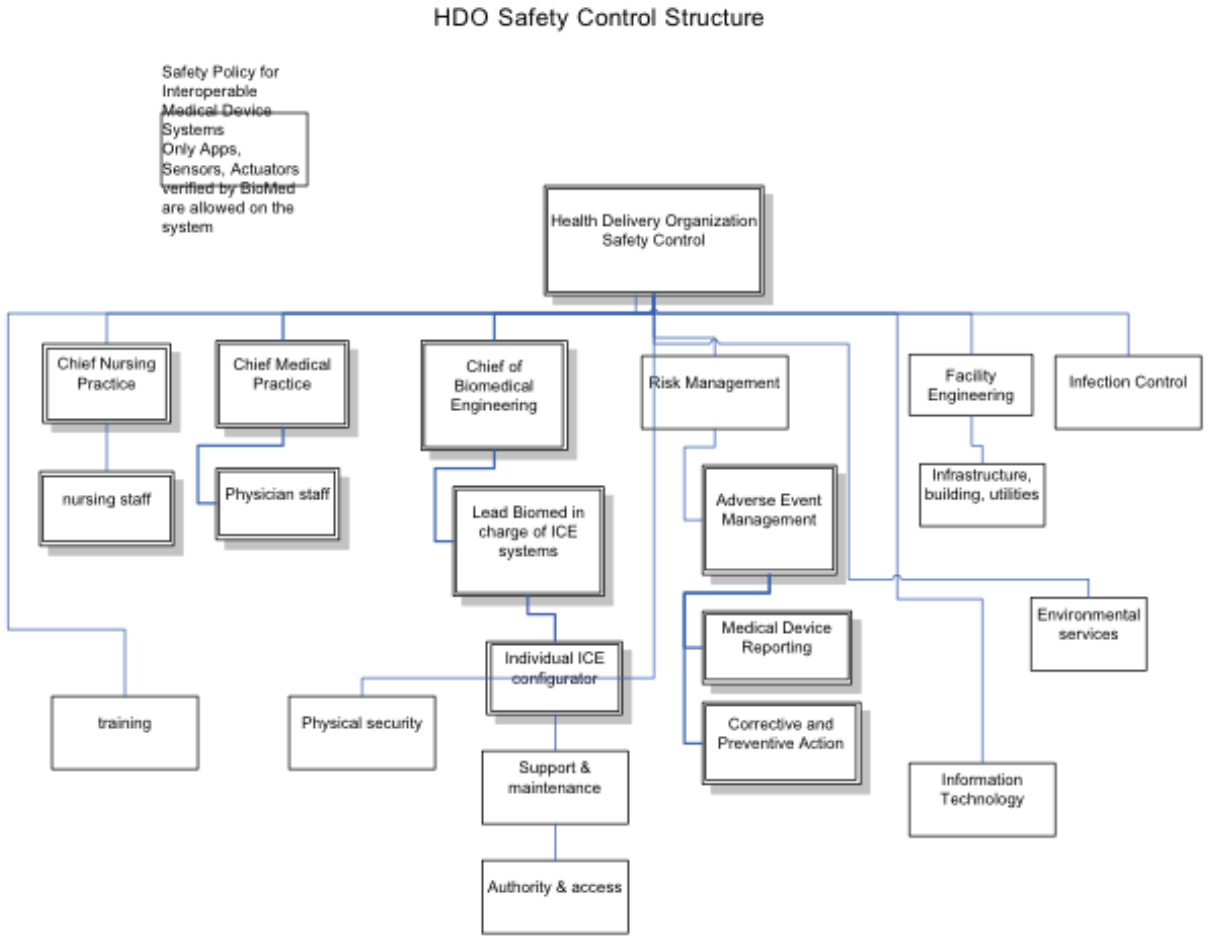
White Box Level Process Model



arrow #	directivity	explanation
1	uni	inputs affecting the ICE manager from external sources such as EHR and clinician
2	bi	status and configuration information such as technical or physiological alarms or device status (e.g. heart beat)
3	uni	physiologic data from patients as acquired by sensors
4	uni	delivery of therapy or energy to patient via actuator
5	bi	acquiring physiologic information from patient and setting sensor configuration (e.g. filter characteristics)
6	uni	connection to patient (example hazards include electrical safety and biocompatibility)
7	uni	delivery of therapy or energy to patient via actuator
8	uni	environmental inputs, such as w orkload or lighting conditions, affect clinician
9	uni	clinician needs to be properly trained to operate complex equipment and understand hazardous situations that they are responsible for controlling the risk of
10	uni	configurator needs to verify sensor operation and maintain performance
11	bi	clinician can interact w ith front panel of sensor to effect a setting or gather information
12	bi	configurator needs to verify ICE manager operation and maintain performance
13	uni	configurator needs to verify actuator operation and maintain performance
14	bi	clinician selects App and receives device and patient status information to update their internal mental models
15	uni	clinician can interact w ith front panel of actuator to effect a setting or gather information

High Level Safety Control Structure





Medical Device Interoperability

Medical Device Interoperability includes the total device perspective including all related aspects and management of the device(s) and systems.

Project Management: installation of device(s) & systems, infrastructure (facility/structural renovations)

Maintenance: preventative & corrective. Cleaning of the device and its environment (Environmental Services/House keeping)

Training: clinical & technical

Software: compatibility to other device(s) & systems (include software updates to any single device or system)

Infection Control: handling & cleaning of the devices

Adverse event reporting: Risk management, local government, state, FDA, other (ECRI)

Device Environment (Facility Engineering): temperature and relative humidity of device location

First attempt at understanding the functions in a health delivery organization; note that no interactions have been drawn in yet.

Conclusions

- STAMP is a tool for identifying and thinking through the safety and regulatory issues for plug and play interoperable medical devices.
- The current STAMP exercise is only a first attempt at getting experience using the STAMP process.
- STAMP process looks useful, particularly for identifying roles and responsibilities and interactions - we are trying to apply it to our issues.
- We will be analyzing the outcomes looking to see how it can guide our work.
- Several standards activities are underway; would like a means for understanding how their work products fit into the broader environment to assure safe and effective devices, and safe delivery of health care (promote and protect public health)