Physician's Perspective on Past, Present and Future CE/HTM Impact
from vision to implementation

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Not atypical Operating Rooms …

We have come a long way …

"OR of the Future"
At MGH

The OR of the Future at MGHwould not have been possible without

- "new" technologies
- Thoughtful technology assessment and selection
- Extensive collaboration with vendors
- Full-time availability of expert CEs to adjust, reconfigure, optimize, maintain ...
- Technology innovation is a team sport
- It begins with a vision

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How do you get from

A ⟶ B

Many paths and outcomes
a vision helps keep you on target

A

B
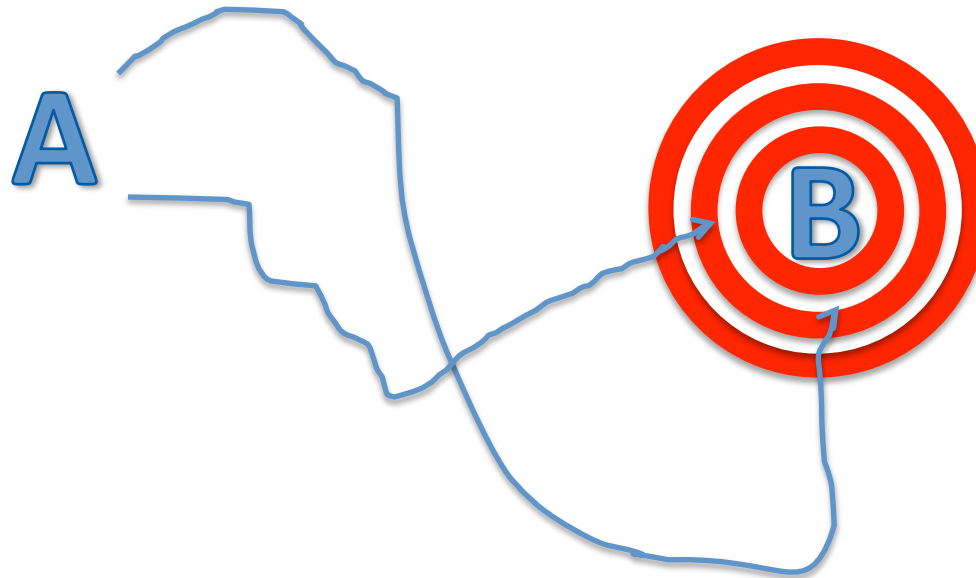
What do you want?

- What do you need?
- The future is in your hands.
- Be clear about the "what" and "why", and be open to a new "how"

- Or, don't complain when nothing improves

FDA recently initiated a "MDICC"
Medical Device Interoperability Coordinating Council

- To share information about activities and resources in support achieving medical device interoperability

- Several groups with different focus areas

- WG on Clinical Needs and Clinical Landscape – identifying clinical scenarios and use cases where md interop could have healthcare benefits – including technology management

MDICC – CN&CL
excerpt from scope and charter 5/7/12

"The Clinical Needs & Clinical Landscape team is compiling clinical examples that demonstrate clinical benefits that could be realized from interoperable medical devices.

Identifying currently available capabilities as well as future needs (or gaps) are within scope of this project.

Given the nascent state of medical device interoperability, articulation of future (desired) states is especially important to ensure that proposed technical solutions and standards will yield useful clinical capabilities.

The "to be" (future) clinical scenarios will include interoperability among medical devices, among components of integrated medical device systems, among medical devices and EHRs, among medical devices and hospital IT / CIS systems, and among (personal) medical devices and telehealth data hubs.

Data exchange among EHRs and entirely within a single medical device are out of scope."

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A method to transform clinical needs into systems engineering requirements in order to improve efficiency, patient safety, and the quality of care.

CLINICAL SCENARIO

Description of the current clinical situation and related problems identified from clinical stories, adverse event reports, etc.
Includes proposed workflow/technology enhancement to prevent unwanted outcomes.
Value statement (impact on patient safety, quality of care, or the cause of adverse events).

CLINICAL WORKFLOW

A paragraph or diagram describing the sequential events that occur during a specific patient/clinician interaction including:

- Human interactions with equipment and each other
- Equipment used
- Supplies used
- Movement of clinicians and patients through clinical environment
- Sequential timeline of events

Adverse event reports
Clinical experiences
Clinical and engineering focus groups

TECHNICAL SOLUTION AND CLINICAL IMPLEMENTATION

A device or system which improves the quality, safety, efficiency, of a clinical scenario.

Clinicians
- Clinical Scenario
- Clinical Workflow

Clinical Engineers
- Use Cases
- Logic Map/Key

Design Engineers
- State Diagram
- Technical Solution and Clinical Implementation

USE CASES

Use cases are a detailed look at a specific part of the clinical workflow. A work flow may not be required for a use case, but is helpful for examining human interaction.

Textual Use Case
- Clinical alarms required
- Proposed process or technological improvement
- Event sources of required data and sources of potential error
- Proposed solution to correct the problem statement and enhanced alarm requirements
- Description of the required data to solve the problem
- Required feedback to the clinician

Graphical Use Case
- Graphical layout of the textual use case
- Diagram of new process
- Clarifies input and output of data between related systems
- Shows interdependencies between devices/systems
- Focuses on systems interactions (states) vs clinical work flow

STATE DIAGRAM (PRE-CODE)

A methodological approach utilized by programmers and engineers to script the behavior of a system in all possible states. This is utilized for technical development and analysis of a system.

LOGIC MAP

Breakdown of each step of graphical use case in order to analyze and define behavior of the system.

- Provide accurate and detailed data
- List of variables for each graphical step and the expected interactions (logic map variable key) including units, range, data type, system output, input, and derived variables.
- Form of data (discrete, waveform, setting)
- Failure analysis done at each location
- Terminology defined utilizing standard terms
- Graphical pre-code of technological enhancement

Eliciting Clinical Requirements for Medical Device Interoperability

From ASTM F2761-09, Annex B

"Assume that the integrated medical system provides seamless connectivity of medical devices to allow communication (e.g. remote data display, population of the electronic medical record, etc.) and integration of medical devices with control functions …

Assume that there are no technical, economic, legal or regulatory obstacles to deploying a comprehensive system. Define the high-level clinical needs without specifying the details of the technical specifications.

a) Which clinical challenges exist today that could be solved by the proposed system?

b) Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?

c) How would this approach affect the practice environment, both clinically and from a business/process perspective?

d) What risks can be introduced by an integrated medical system, and how could they be mitigated?

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Medical Device Connectivity
for Improving Safety and Efficiency

Julian M. Goldman, M.D.
Committee on Electronic Media and Information Technology

"Use wireless technologies to eliminate the 'malignant spaghetti' of cable clutter that interferes with patient care, creates hazards for the clinical staff and delays positioning and transport."

"Synchronize the respiratory cycle of the anesthesia machine ventilator with portable X-ray exposure so that an X-ray will be triggered at end-expiration, thus avoiding the need to turn-off the ventilator for an intraoperative cholangiogram."

"Trigger the portable X-ray at end-inspiration by synchronizing with the ICU ventilator."

"Why can't a pulse oximeter be connected to a PCA infusion and automatically interrupt the infusion and activate an alarm when a patient is hypoxemic?"

"Support the recording of infusion pump data in the electronic anesthesia information system and permit control of the infusion rate at the anesthesia machine."

Clinical Scenario Panel Discussion and Audience Participation
Clinical Scenarios from prior interactions at AAMI 2005 and other conferences and meetings

Req #	Clinical Scenario	Current Hazards	Desired State	Future Hazards
CLN-006	Scheduled procedure may not be possible due to availability of resources: equipment, supplies, room, clinicians; probability of procedure success may be lower than desired due to resource issues: need documentation/ verification/audit trail of resource availability and proper functioning for specific procedure	Delayed or prolonged procedures and/or not the best procedural outcomes; human environment becomes overly stressful, increasing probability of negative outcomes	Need to track and verify what is in clinical environment prior to and during clinical procedure: equipment, infrastructure, devices, connectivity, people; devices need to confirm at outset that they are working; enable prospective analysis for future resource needs for procedure success	Overdependence on automation: need override and/or backup procedures; would make customization/ personalization of interface difficult
CLN-015	Network failure causes loss of medical device availability	Inability to deliver therapy or patient care	Device must be able to function/be controlled independently as well as within the integrated control interface, and/or operate in a failsafe mode; maintain ability for manual operation and override	Inability to define a failsafe mode

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Clinical Scenario Panel Discussion and Audience Participation
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Req #	Clinical Scenario	Current Hazards	Desired State	Future Hazards
CLN-019, CLN-024	Display of information is in many physical places; Information display is limited to specific geography within the clinical environment	Surgeon must look in different places/ directions to access information, Barrier to comprehensive situational awareness	Integrated display of hemodynamic information on minimally invasive surgical display; comprehensive data capture and display to enhance vigilance; Ability to display information and control interface where easily accessible by clinician	Cluttered screen causing cognitive overload and/or confusion; Introduction of cognitive overload; possible physical barriers to envisoning; complex control mechanism; could take clinician focus off of patient

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Req #	Clinical Scenario	Current Hazards	Desired State	Future Hazards
CLN-031	Decision support currently depends on disparate device alarms	Alarms are ineffective, not integrated; appropriate response to clinical situation is limited	Capability to have decision support (multivariate parameters from disparate devices) and smart alarms, as well as ability for data mining/ analysis; data centralization to create derived parameters	Difficulty of data validation in real-time
CLN-033	Clinicians don't have adequate situational awareness via existing data flows		Context-specific information needs to be available to clinician	Not enough/too much information available, causing overload

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Req #	Clinical Scenario	Current Hazards	Desired State	Future Hazards
CLN-034	Inability to do comprehensive root-cause analysis, including all resource interactions, of events in the clinical environment	Inappropriate "blame" assigned to causes of events; inability to diagnose and improve system performance; inability to obtain insurance and/or FDA clearance for a system	Ability to have a comprehensive PnP audit trail	Disclosure of proprietary information; perception/concern about increased exposure to liability

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Clinical Scenarios and CConops

Clinical Scenario

- A Clinical Scenario is a brief description of a clinical situation or event. The purpose of the Clinical Scenario is to provide background and illustrate the need for the development of technical solutions. Two States are described for each situation:
    1. **The Current State** typically describes an adverse event, a barrier to providing clinical care, or a barrier to improving workflow. Which clinical challenges exist today that could be solved by the proposed system?
    2. **The Proposed State** is a brief illustration of the improvement in safety and effectiveness obtained by applying an integrated solution.
- *Assume that the integrated medical system provides seamless connectivity of medical devices to allow communication (e.g. remote data display, population of the electronic medical record, etc.) and integration of medical devices with control functions (e.g. control of infusion pumps from the anesthesia workstation, implementation of "safety interlocks" at the bedside).*
- *Assume that there are no technical, economic, legal or regulatory obstacles to deploying a comprehensive system. Define the high-level clinical needs without specifying the details of the technical specifications.*

Clinical Concept of Operations (CConOps)

A Clinical Concept of Operations (CConOps) is a more detailed description of how devices and clinical staff could interoperate in a clinical environment. Each CConOps permits an improvement in safety and effectiveness via a specific solution implementing the Proposed State. It provides details for the following sections:

1. **The type of equipment, software, and HIS systems utilized.** Major devices, their outputs or sensors and any interaction they have with other biomedical devices or systems. Major software systems, such as PACS, HIS, EMR, eMAR could be detailed. (If you want to provide more detail, include Communications Flow and Potential Connectivity between these devices and systems.)
2. **The clinical processes required**. How would this approach affect the practice environment, both clinically and from a business/ process perspective?
3. **The type or category of clinical staff.** EXAMPLES: Surgeon, intensivist, anesthesia provider, chief nurse, nursing assistant, respiratory therapist.
4. **Potential changes or new/novel equipment or workflow** that does not exist today but that could improve the process (optional).
5. **Benefits of the proposed process**. Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?
6. **Risk analysis of the proposed process:** What risks can be introduced by an integrated medical system, and how could they be mitigated?

Template for Clinical Scenario Collection
Version: April 2012

Template for Collection of Clinical Scenarios
Version: April 9, 2012
Available at www.mdpnp.org

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This document is designed for use as a template for collecting and documenting information about Clinical Scenarios in order to understand the clinical landscape for interoperability – current state and proposed state for addressing issues or barriers to providing safe and cost-effective healthcare. The Clinical Scenario with both Current and Proposed States is described first, followed by the Clinical Concept of Operations, which provides a more detailed description of the equipment and personnel involved, the clinical processes, and the potential benefits and risks of the proposed system.

1. **Clinical Scenario**
   A Clinical Scenario is a brief description of a clinical situation or event. The purpose of the Clinical Scenario is to provide background and illustrate the need for the development of technical solutions. Two States are described for each situation:
   1.1. **The Current State** typically describes an adverse event, a barrier to providing clinical care, or a barrier to improving workflow. Which clinical challenges exist today that could be solved by the proposed system?
   1.2. **The Proposed State** is a brief illustration of the improvement in safety and effectiveness obtained by applying an integrated solution.
      ▪ *Assume that the integrated medical system provides seamless connectivity of medical devices to allow communication (e.g. remote data display, population of the electronic medical record, etc.) and integration of medical devices with control functions (e.g. control of infusion pumps from the anesthesia workstation, implementation of "safety interlocks" at the bedside).*
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2. **Clinical Concept of Operations (CConOps)**
   A Clinical Concept of Operations (CConOps) is a more detailed description of how devices and clinical staff could interoperate in a clinical environment. Each CConOps permits an improvement in safety and effectiveness via a specific solution implementing the Proposed State. It provides details for the following sections:
   2.1. **The type of equipment, software, and HIS systems utilized.** Major devices, their outputs or sensors and any interaction they have with other biomedical devices or systems. Major software systems, such as PACS, HIS, EMR, eMAR could be detailed. (If you want to provide more detail, include Communications Flow and Potential Connectivity between these devices and systems.)
   2.2. **The clinical processes required.** How would this approach affect the practice environment, both clinically and from a business/process perspective?
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   2.4. **Potential changes or new/novel equipment or workflow** that does not exist today but that could improve the process (optional).
   2.5. **Benefits of the proposed process.** Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?
   2.6. **Risk analysis of the proposed process:** What risks can be introduced by an integrated medical system, and how could they be mitigated?

This template is based on work that was also used for clinical scenarios published in Annex B of ASTM standard F2761-09 "Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model"

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MD PnP Website Project Section: Clinical Scenarios Page

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