GHTF 11 Oct 2007, Washington, DC

Update on Medical Device Interoperability and recommendations from GHTF 10

Julian M. Goldman, MD
Harvard Medical School /
Massachusetts General Hospital, Boston, Mass., USA
Director, CIMIT Program on Interoperability and the
Medical Device Plug-and-Play (MD PnP) Program
User Vice Chair, ASTM F29
Chair ISO/TC 121/SC2

GHTF 10, 28 June 2006
Workshop on Emerging Technology I: Clinical expert and control systems, and plug and play

Workshop panel members:

- Julian Goldman (Chair)
- Larry Kessler
- Oliver Christ
- Peter Mildenberger
- Ralf Dittmann
- Jörg-Uwe Meyer
- Michael Meyerhoff
- Ted Murphy
- Chris Eckman

Seven Recommendations:

1. Ecosystem for safe clinical use
2. Risk Assessment
3. PnP may create new medical devices
4. “ICE” - an Integrated Clinical Environment
5. Hospital’s perspective
6. Medical device control/safety interlocks
7. “Virtual” devices and object models

Recommendations from GHTF 10, Lubeck Workshop on Emerging Technology I

1. Ad-hoc networked medical device systems must support the formation of a complete ecosystem of devices and policies to support safe clinical use
   - Conform to appropriate communication and interoperability standards
   - Incorporate network monitoring ("black box recorder") to
     - Allocate risk and responsibility
     - Support forensic analysis and rapid correction of system problems
     - Undergo interoperability validation testing ("plug fest" or "connect-a-thon") with representative devices to reduce risk of device incompatibility
     - Regulatory agencies need to develop criteria to accept data on such testing
   - Incorporate technology to prevent non-complaint devices from interoperating with network (e.g. digital device authentication, unique device ID)
   - Protect data privacy and security
   - Wireless devices invoke unique requirements. Unintended interaction with active implanted devices must be avoided.

Recommendations from Workshop on Emerging Technology I

2. The medical device system must be assessed using a Risk Management approach.

   - While ISO 14971 may provide a useful foundation, it is not the only system and with respect to networked systems may need modification or recalibration. This should include assessment of hospital network interactions, and methods to trigger re-assessment when necessary.

Recommendations from Workshop on Emerging Technology I

3. Interoperability standards can support safe innovation by facilitating the inclusion of new networked medical devices to an existing system.
   - Integration may generate new functionality. Will this fall under the rules of “practice of medicine”?
   - We may need a new definition of “medical device”. We need definitions for medical device systems and their components.

Recommendations from Workshop on Emerging Technology I

4. An "Integrated Clinical Environment", including a ICE Manager, which is a device to manage local networks of medical devices, could be used to:
   - Manage the discovery of devices on the network
   - Support the input, interpretation, and validation of clinical scripts (business rules),
   - Implement context-dependant clinical scripts
   - Provide "black box" recording functionality
   - Provide security and authentication and device authorization

Recommendations from Workshop on Emerging Technology I

5. Networked medical device systems, assembled by hospitals from interoperable components, will require performance assessment/testing by hospital BME or system integrators to evaluate system integrity.
- Evaluation under simulated use conditions may be necessary. Where possible, testing under unusual or stressful situations should be performed in order to increase confidence in the systems.
- Hospitals should demand proof that devices conform to relevant standards and have undergone interoperability testing.

Recommendations from Workshop on Emerging Technology I

6. External control of medical device function is required to implement safety interlocks and distributed closed-loop control systems. In order to prevent external devices from setting unsafe conditions, devices may only expose limited functions for external control.

Recommendations from Workshop on Emerging Technology I

7. “Virtual devices” with object models are necessary to represent and model device behavior in networked medical device systems.

Updates …

- IEC 80001
- ICE
- External “control” via network interface
- PCLC IEC 60601-1-10
- APSF (Anesthesia Patient Safety Foundation)
- Implications

Application of RISK MANAGEMENT for IT-Networks incorporating Medical Devices

- IEC 62A/ISO 215 JWG7 (IEC 80001)
- Two plenary meetings since GHTF 10
- Co-conveners: Sherman Eagles and Todd Cooper
- Next plenary conference 29-31 May, Sweden

“ICE” - Integrated Clinical Environment

- US TAG to ISO/TC 121 authorized writing group to prepare draft standard to be used for New Work Item Proposal
- NWIP submitted by US to ISO/TC 121/SC3 and IEC 62A in September 2007; closing date for NWIP ballot is 21 December 2007.
- Proposed liaison with ISO/TC 215/WG7 and ISO/TC 121/SC1
- Included draft of “ICE Part I, Network Control” proposed as CD.
- Proposed meeting: 25-28 March 2008, Lubeck, DE

ICE Draft Writing Group

(Participants from industry, healthcare, regulatory)

Convener: Julian Goldman

Seven meetings:

- Aug 1, 2006 CIMIT, Cambridge, MA
- Sept 7-8, 2006 Meeting, hosted by Draper Laboratory, Cambridge, MA
- Oct 30-Nov 1, 2006 Meeting, CIMIT
- Jan 8-10, 2007 Meeting, FDA/CDRH
- Mar 12-14, 2007 Meeting, CIMIT
- May 21-25, 2007 Document review at ASTM F29, Norfolk, VA
- Aug 27-29, 2007 ICE I completion

MD PnP™

Getting connected for patient safety™

Scope of ICE Part I

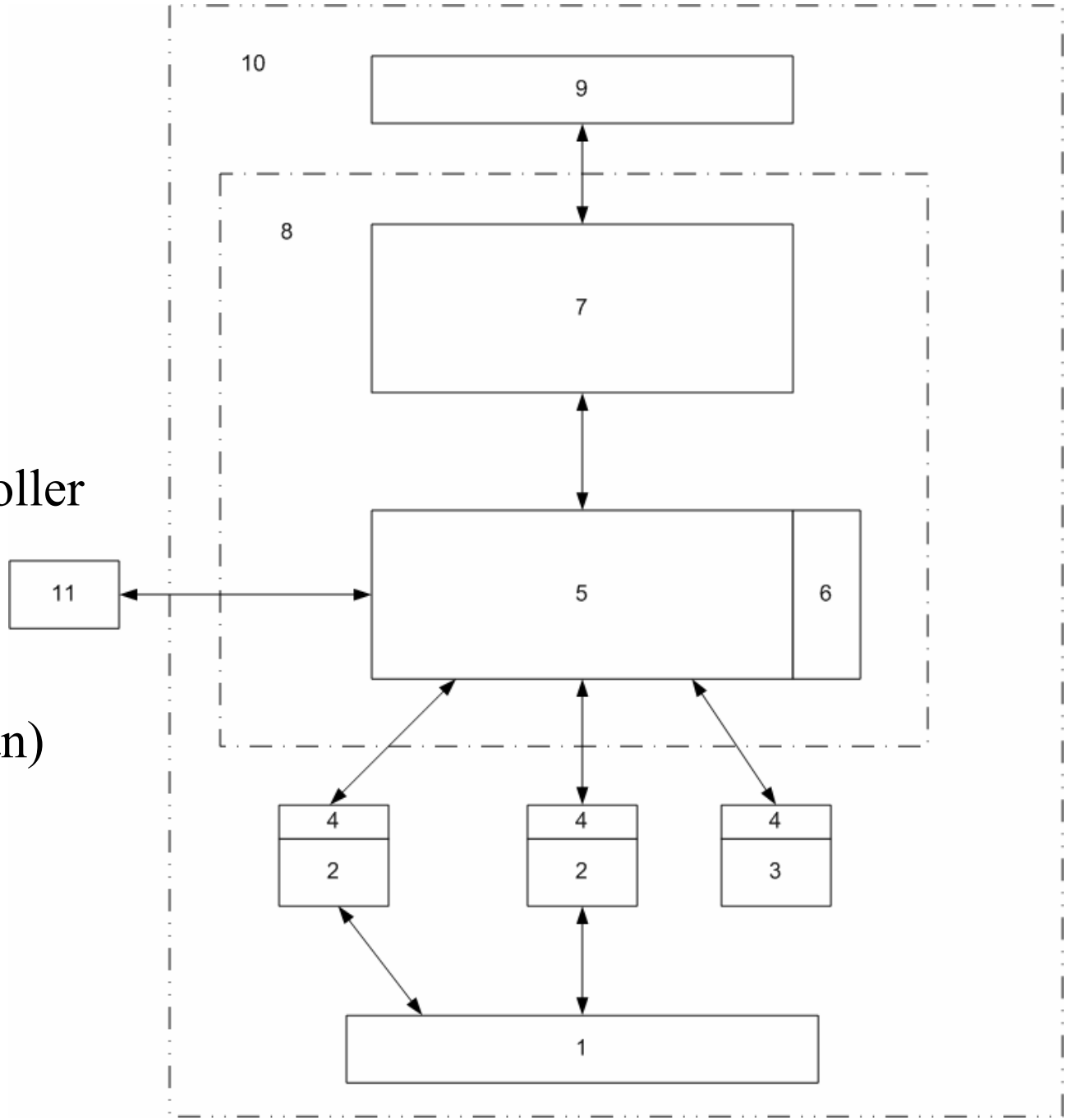
- “This International Standard is applicable to the basic safety and essential performance of an ice network controller .. and ice equipment interface … for managing a network of medical devices in a medical system in support of a single patient in the integrated clinical environment, (ice)...
- This standard series establishes the general principles for the design, verification, and validation of a model- based integration system that enables the creation of an integrated clinical environment intended to facilitate cross-manufacturer medical device integration...”

Next slides -> draft functional architecture

Figure 1: Functional Elements of the Integrated Clinical Environment

Key

1 **patient**
2 medical device
3 Equipment
4 ice interface
5 ice network controller
6 data logger
7 ice supervisor
8 ice manager
9 **operator** (clinician)
10 ICE
11 external port



From proposed draft standard "ICE Part I"

The ICE supervisor supports the following patient-centric capabilities of the integrated clinical environment

- Provide safety interlocks
- Distribute integrated alarm conditions to relevant operators
- Provide context-aware clinical decision support
- Set command input variables of other medical devices, per operator-defined, context-appropriate rules in order to manage their operation
- Assess the readiness of medical devices in a clinical environment to support specified functions or clinical workflow
- Perform integration of alarm conditions from multiple medical devices
- Perform automated record keeping
- Support remote access and control of medical devices

From proposed draft standard "ICE Part I"

The ICE network controller supports the following patient-centric capabilities of the integrated clinical environment

- Provide and retrieve relevant clinical data to a healthcare information system/electronic medical record/electronic health record (HIS/EMR/EHR)
- Provide relevant information to support a healthcare equipment management system
- Provide data logs for forensic analysis (flight recorder)
- Provide “Plug and Play” (PnP) connectivity with medical devices and other devices
- Provide a common time base and binding of data to patient identity
- Interface with equipment that contains an ice equipment interface
- Perform network control functions independently of the underlying data communication mechanization

From proposed draft standard “ICE Part I”

Medical electrical equipment –

Part 1-10: General requirements for basic safety and essential performance – Collateral Standard:
Requirements for the development of physiologic closed-loop controllers

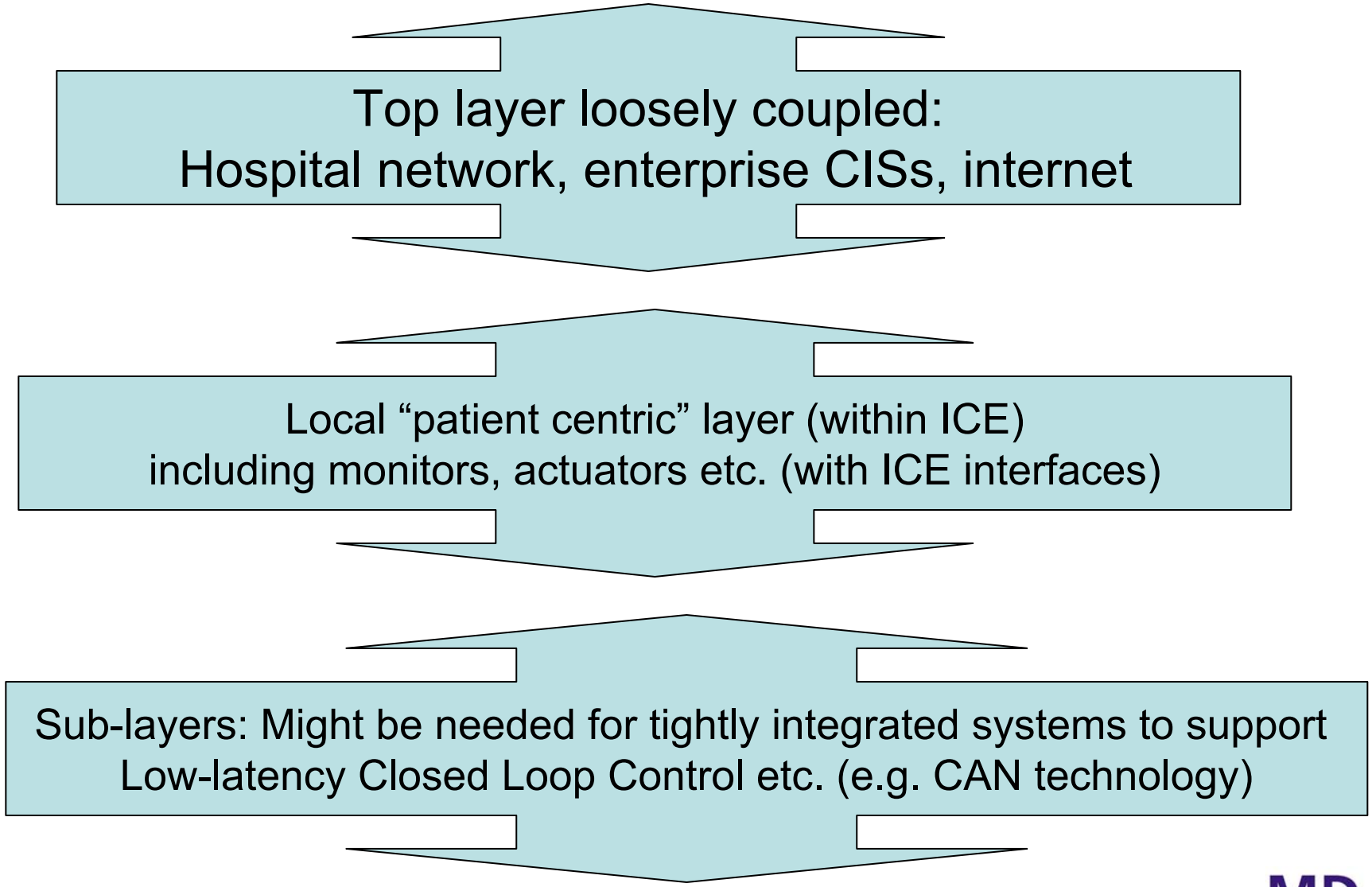
"Physiologic" implies controlling a patient variable

- Example: administer fluid boluses to achieve/maintain target Blood Pressure

JWG5 between IEC 62A and ISO/TC 121/SC1 and SC3
Convener: Julian Goldman
Initiated July 2004. Publication anticipated by Dec 2007.

How might the functional layers “fit together”?

(from MD PnP architecture working group)



The Anesthesia Patient Safety Foundation endorsement of interoperability March 2007

"APSF believes that intercommunication and interoperability of devices could lead to important advances in patient safety, and that the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind.

APSF also recognizes that as in all technologies for patient safety, interoperability poses safety and medicolegal challenges as well. Development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety and outcome benefit."

Proposed language to be included in update to “anesthesia workstation” standard

- “If an anaesthetic ventilator is equipped with an operator-controlled means to pause automatic ventilation:
- e) Means may be provided to initiate the ventilatory pause from a network/data coupling.

- *Comment: this is to support synchronization with an imaging device, or remote pause activation from, for example, an Interventional Radiology control room.*

Interoperability = Empowerment

- Cross-vendor standards-based interoperable Consumer Electronics -> Consumer Empowerment
  - Digital photography
  - Personal computer peripherals
  - USB memory

- Medical System Interoperability -> Healthcare Provider Empowerment
  - **Allow clinicians and biomedical engineers to leverage medical devices and IT systems to solve clinical problems, improve patient safety, and improve efficiency … provide an infrastructure for innovation**

End

MD PnP™
Getting connected for patient safety™

Standards <> Interoperability

- **Standards create the opportunity for interoperability … but they are just an ingredient**

- **True interoperability requires…**

1. Market viable use cases (a real need for interoperability)
2. A Standard or collection of Standards to enable the use cases
3. Business conditions that support interoperability
4. Interoperability Guidelines that describe how to use the Standards to achieve interoperability
5. Interoperability compliance testing (formal and/or informal)
6. Enabling technology
7. Promotion (marketing, education, conferences, evangelists)

Acknowledgement: David Whitlinger, Intel

Kaiser Contract Language
(24 new hospitals planned in USA)
(in use now)

- **Medical Device Plug and Play.** Supplier agrees to participate with Kaiser in the development of a medical device plug and play integration standard (the "Integration Standard"), and … will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved, Supplier intends to continue … to provide open interfacing protocols …

(sample text)

Conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software"

- June 25-27, 2007
- Cambridge, Mass. USA
- 145 attendees: Federal agencies, clinical researchers, engineers, manufacturers
- Proceedings to be published January 2008

MD PnP™
Getting connected for patient safety™

June 2007


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