

Federal Vision

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- Distinguish the types of interoperability
- That safety is a systems engineering problem that has been addressed in other industries
- That much effort has gone into this already (standards, guidance docs, conferences)

- Yet ...

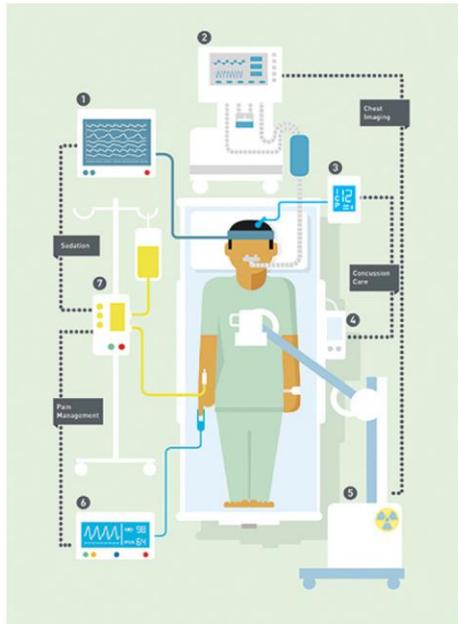
The Problem

This scenario has not changed in the last 20 years...

Technologies and standards to reduce medical errors and improve efficiency have not been implemented — in theater or at home.



- Contextually rich data is difficult to acquire – there is no clinical blackbox recorder
- Medical devices do not interact with each other autonomously (monitors, ventilator, IV pumps, etc.)



PUBLISHED ON FEB 12, 2016

TECHNOLOGY

Babel in the ICU

Machines in an ICU can't speak to one another—but what if they could?

Preventable medical errors may account for more than 100,000 deaths per year. These errors are primarily caused by failures of communication—a chart misread, or the wrong data passed along to a machine or a colleague.

Part of the problem could be solved if the machines could just speak to one another. Devices in hospital wards, which monitor everything from oxygen intake to the tilt of the hospital bed, are made by many manufacturers, which have little incentive to make their proprietary code—the language that makes the machines run—easy to process by their competitors' machines. So that task of middleman falls to harried hospital staff.

<http://protomag.com/articles/babel-in-the-ICU>

What can we do about it?

- What kind of system would we imagine to address this patient safety issue?
- A little background first

2007

2007 Joint Workshop on High Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability

Medical Device Interoperability – Assessing the Environment

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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**

Jan 2010 – FDA/CIMIT/Continua Workshop

- What are the types of clinical scenarios that would make use of medical device interoperability?
- What are the issues associated with premarket and postmarket studies for interoperable medical devices?
- What tools (e.g. standards, guidances) are in place or need to be developed to assure safety and effectiveness of interoperable medical device systems; what issues should they address?
- What organizations are in place to assure safety and effectiveness of interoperable medical device systems and what are their roles?
- What are the risks associated with medical device interoperability and “system of systems” composing medical devices?
- What are other issues relevant to assuring the safety and effectiveness of interoperable medical devices?
- An important outcome of the workshop was the shared recognition that improved, interoperable product designs are the key to reducing adverse events (e.g. via automated safety interlocks) and enabling new clinical treatments that are greater than the sum of their components. FDA clearly understands the value proposition of these technologies.

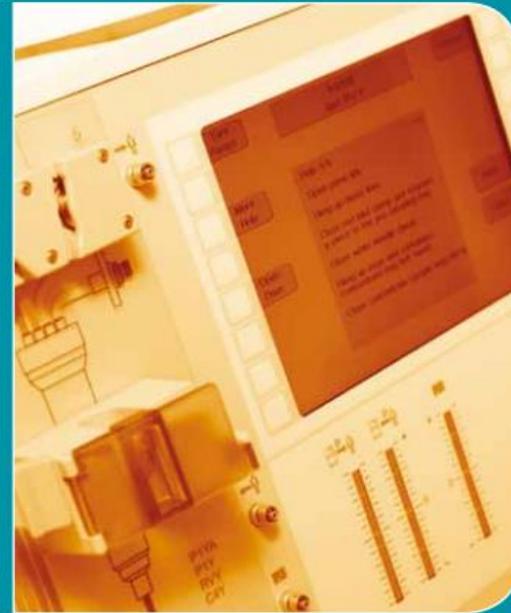
2012

FDA



Medical Device Interoperability

A Safer Path Forward



*Priority Issues from the 2012
AAMI-FDA Interoperability Summit*

http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/Summits/2012_Interoperability_Summit_Report.pdf

Standards efforts & FDA recognition

- AAMI/UL 2800-1 - Standard for Medical Device Interoperability
 - For general interoperability
 - For specific architectures
 - For specific applications
- ISO/IEC particular standards
- IHE, IEEE, ISO 11073 - Health informatics - Medical / health device communication standards
- IEC 80001 - Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities
- AAMI 2700 (formerly ASTM F2761) - 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
- AAMI HIT1000 - Safety and effectiveness of health IT software and systems-Part 1: Fundamental concepts, principles, and requirements

2017

GUIDANCE DOCUMENT

Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

Guidance for Industry and Food and Drug Administration Staff

SEPTEMBER 2017

[Download the Final Guidance Document](#)

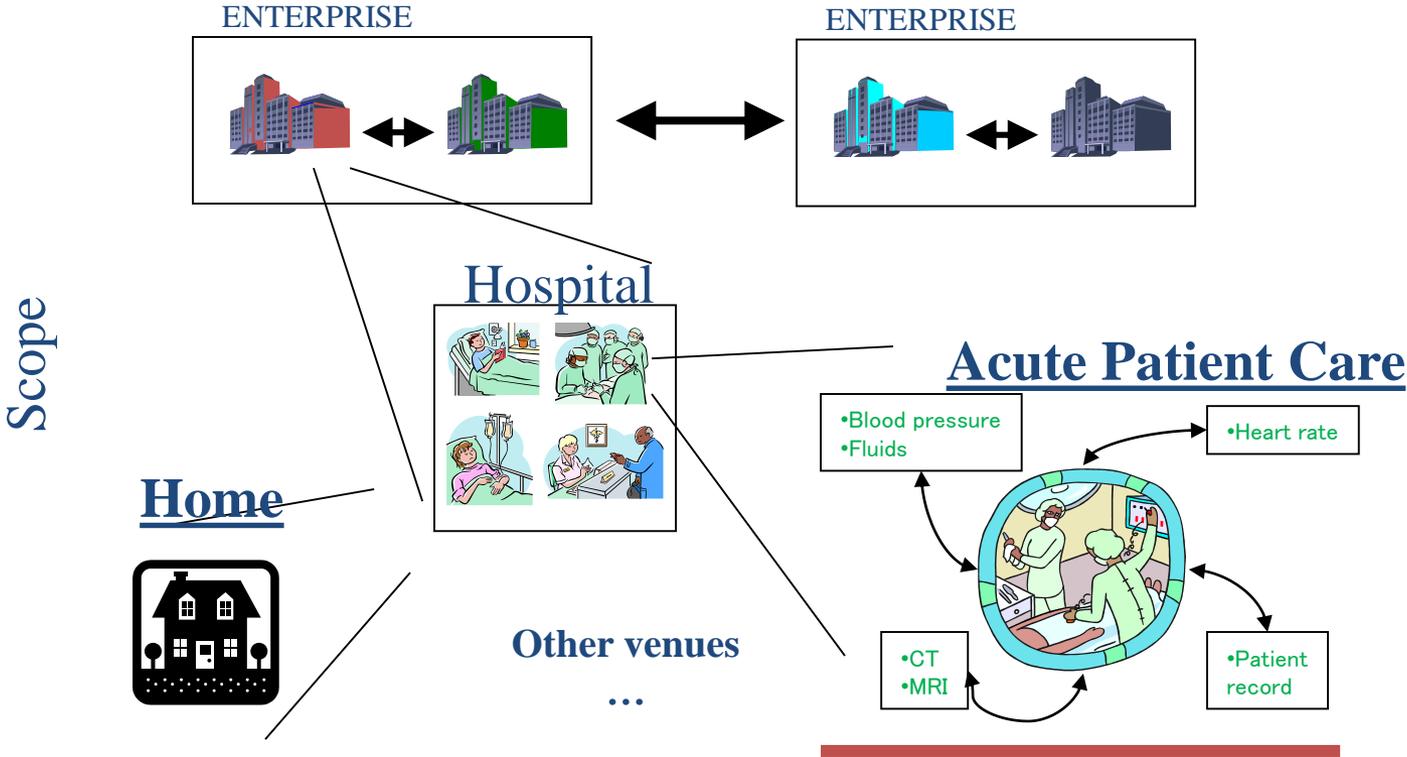
Final



FDA Guidance Document

- Definitions
- **Electronic Data Interface:**
- For purposes of this guidance, electronic data interface is the medium by which independent systems interact and/or communicate with each other thereby allowing the automated exchange of information between systems. It includes both the physical connection (i.e. USB port, wireless connection, etc.) and the data schema which defines the information content. An electronic data interface (EDI) is a medium by which a medical device exchanges and uses info.
- **Interoperable medical devices:**
- For purposes of this guidance, interoperable medical devices are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act that have the ability to exchange and use information through an electronic data interface with another medical device, product, technology, or system. Interoperable medical devices can be involved in simple unidirectional transmission of data to another device or product or in more complex interactions, such as exerting command and control over one or more medical devices.

Interoperability roles/responsibilities



Interoperability: Two perspectives

In the domain of EHR systems:

the ability to seamlessly share patient information among health care providers and payers.

At the patient point of care:

the ability of medical devices to share information and autonomously coordinate aspects of patient care in an open (non-proprietary) manner.

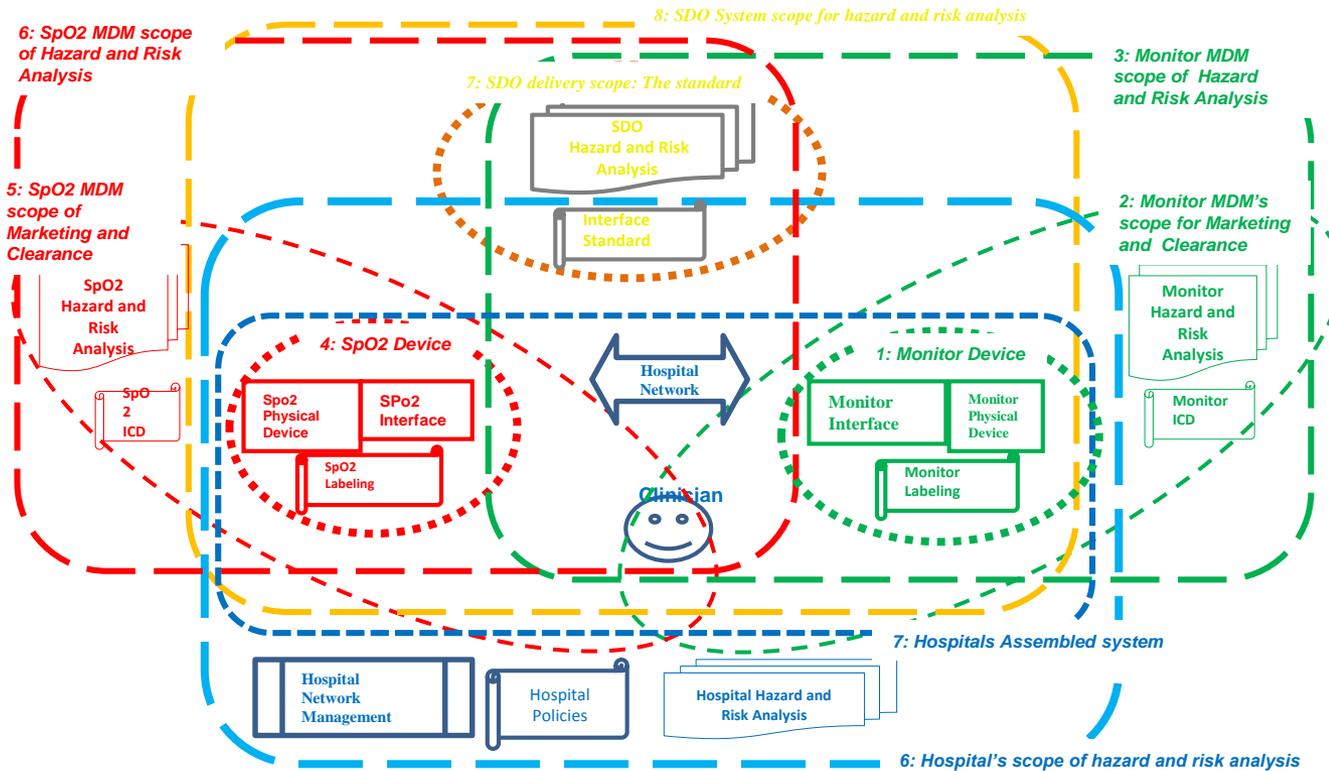
Dual nature

- Devices can be “stand-alone”
- Device can be a component in a larger system

- At the same time!
- What is the role of the device and who bears responsibility?

What is the System?

- 1: Monitor Instantiation in the hospital
- 2: Monitor MDMs Scope of Labeling, Marketing Claims, User Manuals, and Intended Use
- 3: Monitor MDM's system for the scope of hazard and risk analysis:
- 4: SpO2 Device instantiation in the hospital
- 5: SpO2 MDM's scope for Labeling, Marketing Claims, User Manuals, and Intended Use
- 6: SpO2 MDM's scope for hazard and risk analysis
- 7: SDO scope of delivered standard
- 8: SDO's scope for hazard and risk analysis for the standard
- 9: Hospital's scope of the assembled system
- 10: Hospital's cope of hazard and risk analysis, quality assurance, and non-FDA regulatory compliance



Emergent properties

- Can be intended (adding new use to system)
- Can be un-intended (sensor or actuator used incorrectly)
- Mismatch between needs of the system as specified by its developers and the capabilities of the components
 - How is this information communicated?

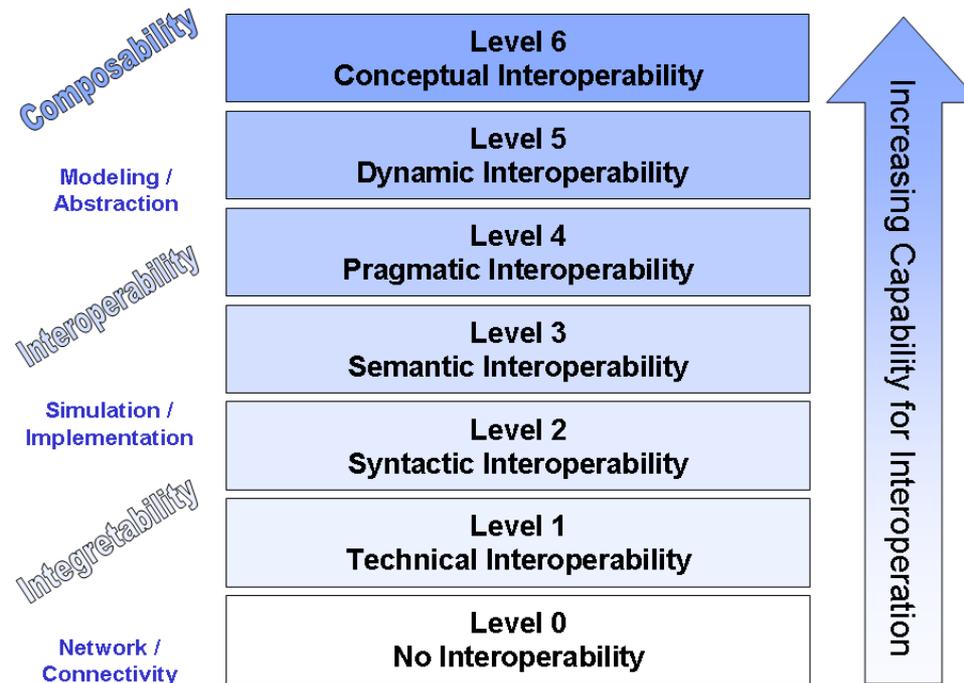
Engineering a Safer World

Systems Thinking Applied to Safety

(This is a draft. It's complete but still is undergoing professional editing. Expected publication date by MIT Press is Fall, 2011.)

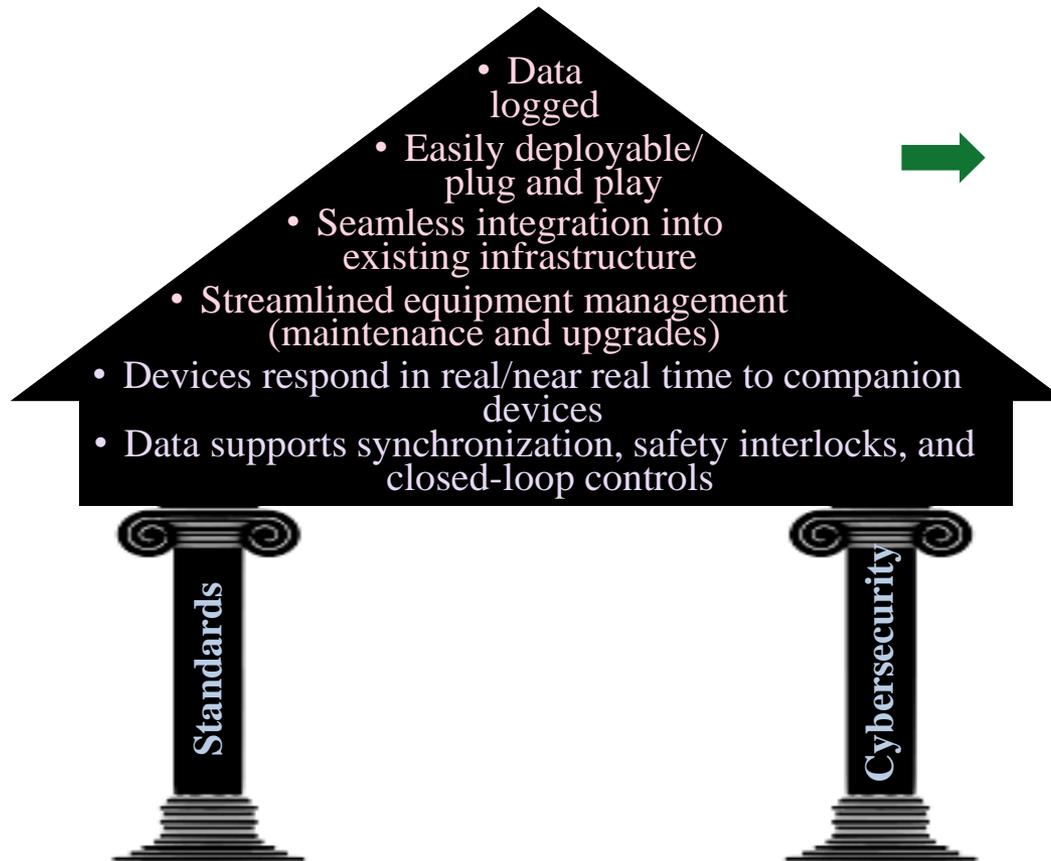
Nancy G. Leveson

Levels of Interoperability



M. Robkin, S. Weininger, B. Preciado and J. Goldman, "Levels of conceptual interoperability model for healthcare framework for safe medical device interoperability," *Product Compliance Engineering (ISPCE)*, 2015 IEEE Symposium on, Chicago, IL, 2015, pp. 1-8.

Desired Future Features of MDI



- Improved patient safety, including fail-safes and data checks
- Reduced transcription errors
- Better adaptability to changed conditions
- Richer high quality data for clinicians' decisions
- More sophisticated learning health system

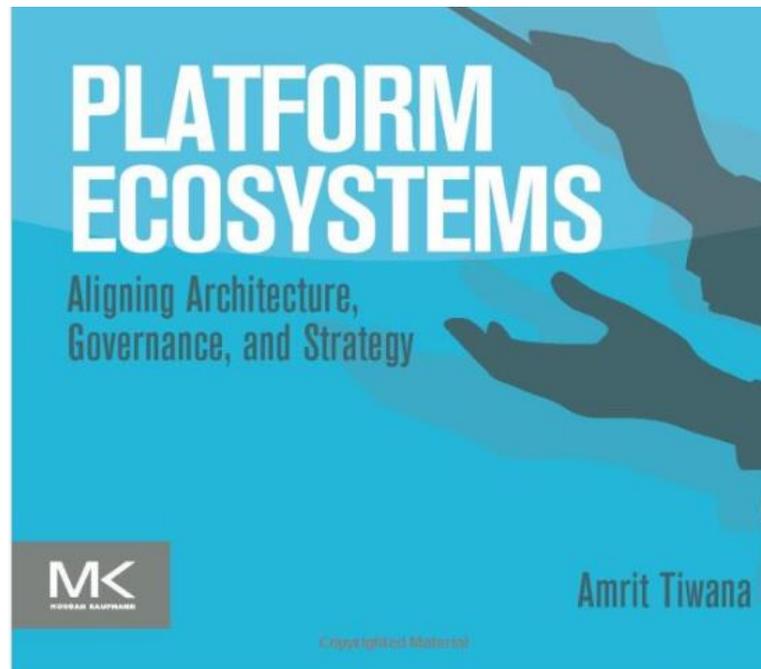
Platform-based medical systems

- Standardize:
 - sensors, actuators,
 - apps that run on platforms;
 - plug-n-play
 - Evaluate Apps independently of platform: composability

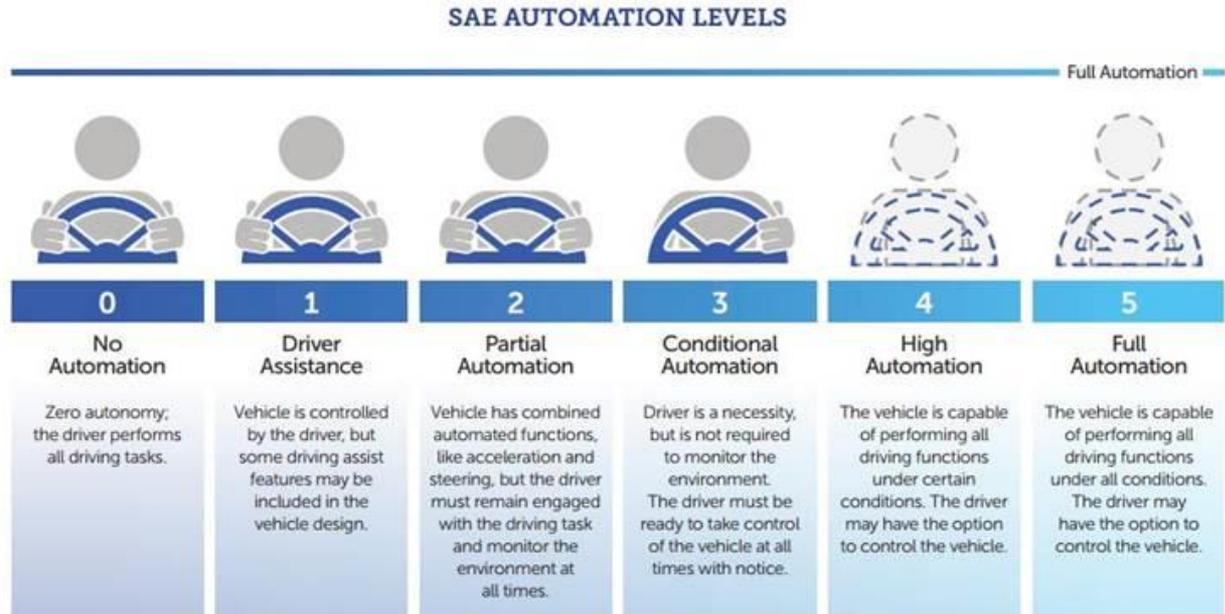
= Integrated Clinical Environment

Platforms are not new

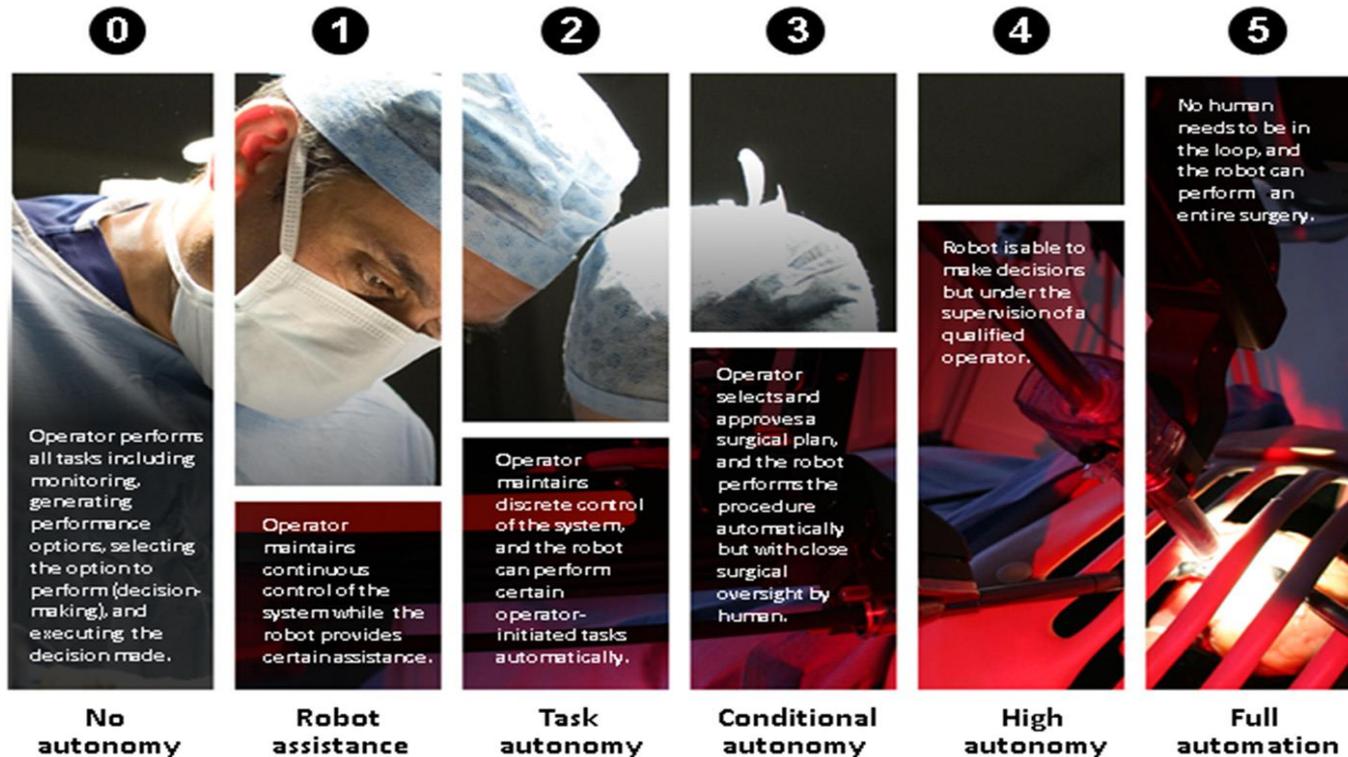
(1 edition (December 16, 2013))



Levels of Autonomy for Driving a Car



Autonomy Scoring for a Surgery Context



Ref Guang-Zhong Yang et al. Sci. Robotics 2017;2:eaam86388 <http://robotics.sciencemag.org/content/2/4/eaam86388.full>
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That's where we've been and where we
want to go –
Now let's talk about how to get there

Extra material

The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems

Sandy Weininger, PhD,* Michael B. Jaffe, PhD,† and Julian M. Goldman, MD‡§||

Medical device and health information technology systems are increasingly interdependent with users demanding increased interoperability. Related safety standards must be developed taking into account these systems' perspective. In this article, we describe the current development of medical device standards and the need for these standards to address medical device informatics. Medical device information should be gathered from a broad range of clinical scenarios to lay the foundation for safe medical device interoperability. Five clinical examples show how medical device informatics principles, if applied in the development of medical device standards, could help facilitate the development of safe interoperable medical device systems. These examples illustrate the clinical implications of the failure to capture important signals and device attributes. We provide recommendations relating to the coordination between historically separate standards development groups, some of which focus on safety and effectiveness and others focus on health informatics. We identify the need for a shared understanding among stakeholders and describe organizational structures to promote cooperation such that device-to-device interactions and related safety information are considered during standards development. (Anesth Analg 2016;XXX:00-00)

Anesthesia & Analgesia – August 2016

What information to capture

POINT-OF-CARE TECHNOLOGIES



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date of current version 24 August 2016.

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The Importance of State and Context in Safe Interoperable Medical Systems

SANDY WEININGER¹, (Senior Member, IEEE), MICHAEL B. JAFFE², (Senior Member, IEEE),
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Sandy Weininger, Michael B. Jaffe, Michael Robkin, Tracy Rausch, David Arney and Julian M. Goldman,
"The Importance of State and Context in Safe Interoperable Medical Systems", Translational Engineering in
Health and Medicine IEEE Journal of, vol. 4, pp. 1-10, 2016, ISSN 2168-2372.

From ISO 80601-2-61 Pulse Oximeters

TABLE 1. Selected information in an exemplary pulse oximeter device model.

Category	Examples
Parameters and units of measurement	SpO ₂ Pulse rate, Pulse Plethysmographic Waveform, Signal Quality Metric
Equipment identification	Manufacturer, model, serial number, software version and firmware version, unique device identifier (UDI), operating system version, anti-virus software version
Equipment configuration	Sensor Type Connected (reusable/single patient use; adult/pediatric; finger/ear), Sensor Model Connected
Equipment specifications	SpO ₂ accuracy, declared ranges of SpO ₂ , Accuracy under motion and low perfusion, pulse rate accuracy, declared ranges of pulse rate
Equipment settings	Data Update Period, Averaging Time, Gain
Service monitoring	Remaining sensor life; next periodic maintenance date, time that real-time clock was last set

Getting the data to where its useful

The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems

Sandy Weininger, PhD,* Michael B. Jaffe, PhD,† and Julian M. Goldman, MD†‡§||

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Applications

Table 1. Examples of Opportunities for Medical Device Informatics

Examples	Observed General Problem	Information Needed for Safety
1 Loss of pulse oximeter data during cuff inflation due to ipsilateral placement of blood pressure cuff and the pulse oximeter finger sensor	Unintended documentation in EMR of artifactual data change	Blood pressure device—transmits changes in blood pressure cuff status (eg, off, inflation start, and deflation completed)
2 Failure to record lowest saturation of a transient event	Failure to record lowest value of a transient event due to data sampling methodology and time resolution of data recorded of EMR	Pulse oximeter—receives information regarding blood pressure status and location on patient (eg, ipsilateral arm) to be used in data screening algorithm
3 Transient desaturation improperly or not recorded in EMR	Failure to record clinically significant event in the EMR due to mismatched data-time resolution	Pulse oximeter—receives contextual information on patient type to be used in data algorithm
4 Erroneous pulse rate value recorded in EMR	Absence of the waveform in the EMR inhibits signal validation	Pulse oximeter transmits averaging algorithm's filter settings (meta-data) to EMR
5 Spurious inverted T wave	Filter setting spuriously inverted the T wave	Pulse oximeter plethysmographic waveform stored and time synchronized with ECG heart rate values ECG device transmits filter settings

Abbreviations: ECG, electrocardiogram; EMR, electronic medical record.

Medical Device Interface Data Sheets (2019) – publication pending in A&A

Applying Medical Device Informatics to Enable Safe & Secure Interoperable Systems – Medical Device Interface Data Sheets (MDIDS)

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Conflicts: Julian M. Goldman reported no conflicts of interest

Attestation: Julian M. Goldman approved the final manuscript.

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Conflicts: Sandy Weininger reported no conflicts of interest

Attestation: Sandy Weininger approved the final manuscript

3. Michael B. Jaffe, PhD

MDIDS: The general framework states:

- 1. All data displayed to the medical device operator must be made available through the electronic data interface. (Note— This requirement excludes proprietary manufacturer data that are not displayed to the operator/clinician.)
- 2. The state and change in state of any operator-adjustable setting must be made available through the electronic data interface (eg, alarm settings, signal averaging time, and computation constants).
- 3. Important device attributes, such as mode, software and firmware revisions, time of last clock update, and equipment maintenance–related data.

What is safety?

Capturing Essential Information to Achieve Safe Interoperability

Sandy Weininger, PhD,* Michael B. Jaffe, PhD,† Tracy Rausch, CCE,‡ and Julian M. Goldman, MD§||

In this article, we describe the role of “clinical scenario” information to assure the safety of interoperable systems, as well as the system’s ability to deliver the requisite clinical functionality to improve clinical care. Described are methods and rationale for capturing the clinical needs, workflow, hazards, and device interactions in the clinical environment. Key user (clinician and clinical engineer) needs and system requirements can be derived from this information, therefore, improving the communication from clinicians to medical device and information technology system developers. This methodology is intended to assist the health care community, including researchers, standards developers, regulators, and manufacturers, by providing clinical definition to support requirements in the systems engineering process, particularly those focusing on development of Integrated Clinical Environments described in standard ASTM F2761. Our focus is on identifying and documenting relevant interactions and medical device capabilities within the system using a documentation tool called medical device interface data sheets^a and mitigating hazardous situations related to workflow, product usability, data integration, and the lack of effective medical device-health information technology system integration to achieve safe interoperability. Portions of the analysis of a clinical scenario for a “patient-controlled analgesia safety interlock” are provided to illustrate the method. Collecting better clinical adverse event information and proposed solutions can help identify opportunities to improve current device capabilities and interoperability and support a learning health system to improve health care delivery. Developing and analyzing clinical scenarios are the first steps in creating solutions to address vexing patient safety problems and enable clinical innovation. A Web-based research tool for implementing a means of acquiring and managing this information, the Clinical Scenario Repository™, is described. (Anesth Analg 2016;XXX:00–00)

Anesthesia & Analgesia – in press

What to look for PostMarket

- Mismatch of interface specifications
 - “plug compatible” but not “data compatible”
- Wrong devices talking to each other
 - Updates for Ventilator A sent to Ventilator B
- Mismatch in semantics
 - Weight in lbs vs. kg
- Claims/labeling – what did the manufacturer intend to expose over the EDI? How was this conveyed?

Standards and other



UL 2800-1

STANDARD FOR SAFETY

Medical Device Interoperability

UL 2800

- **Scope**
- This Standard is applicable to INTEROPERABLE MEDICAL PRODUCTS, including assembled systems of INTEROPERABLE MEDICAL PRODUCTS that comprise or are intended to be incorporated into INTEROPERABLE MEDICAL SYSTEMS within an INTEROPERABLE ENVIRONMENT.
- This Standard specifies a baseline set of requirements for assuring safe and secure interoperability for INTEROPERABLE MEDICAL SYSTEMS.

AAMI TIR 75 (2019)

Factors to consider when multi-vendor devices interact via an electronic interface; Practical applications and examples

Approved d mmm yyy by
Association for the Advancement of Medical Instrumentation

Abstract: Guidance on factors that manufacturers should consider when designing, testing, and monitoring interoperable medical devices.

Keywords: interoperability, connectivity, risk management

"Any opinions, findings, conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the views of the Networking and Information Technology Research and Development Program."

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