

Developing a Healthcare IIoT Application

Ideas are Easy. Execution is Hard.

Boston Connex Conference 2018

May 16, 2018

Speakers



David Niewolny

Director, Healthcare Market
Real Time Innovations (RTI)
United States, Austin TX



Dr. Julian Goldman

Medical Director of Biomedical
Engineering at Partners Health
Anesthesiologist at Mass General
Director of the MD PnP Program
United States, Boston, MA



Tracy Rausch

CEO
Doc Box
United States, Boston, MA

Agenda

- The Current State of Healthcare
- The IIoT as Potential Solution
- Challenges to Implementation
- The Case for an Open Standard Architecture in Healthcare
- From Concept to Reality - The Development of a Commercial Offering
- Q & A



Agenda

- The Current State of Healthcare
- The IIoT as Potential Solution
- Challenges to Implementation
- The Case for an Open Standard Architecture in Healthcare
- From Concept to Reality - The Development of a Commercial Offering
- Summary
- Q & A



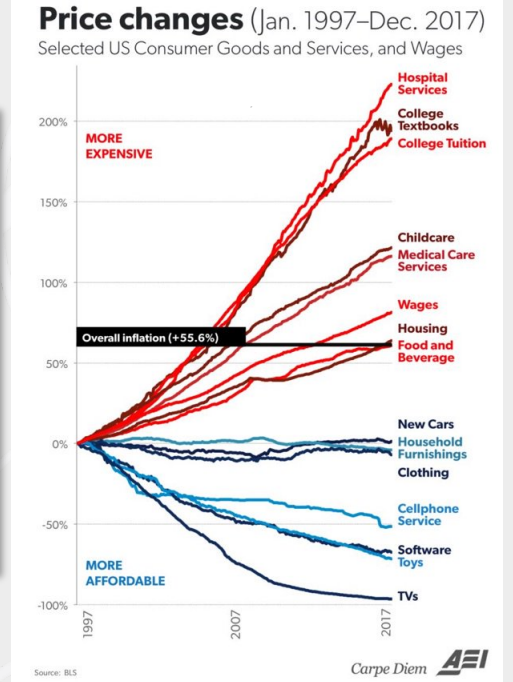
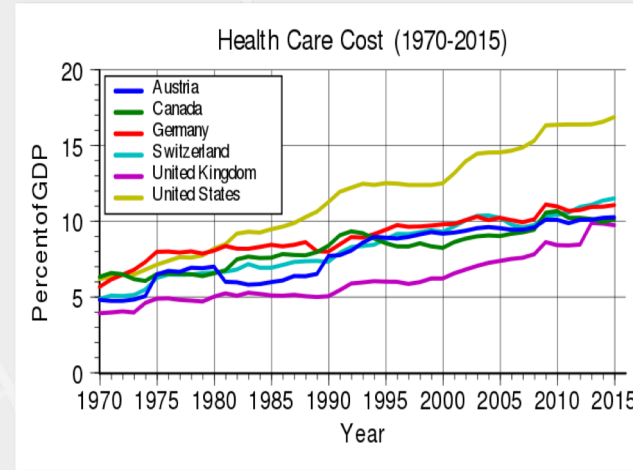
David Niewolny

Director, Healthcare Market
Real Time Innovations (RTI)
United States, Austin TX

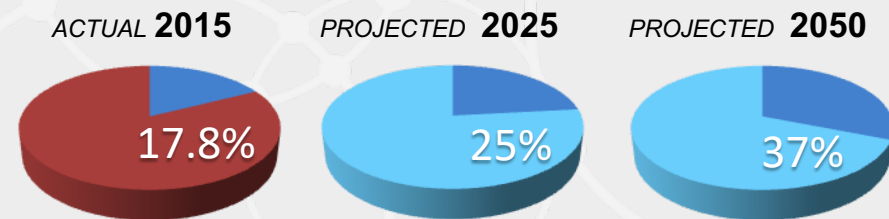
The Current State of Healthcare

Worldwide today:

- Medical error is the **third highest cause of death** behind cancer and cardiac disease.
 - Errors in medical care may lead to **>200k** in preventable deaths
- Lack of medical device interoperability **cost >\$30B** to the healthcare system.
- **900 million** elders age 60 or older
 - 1.2 billion by 2025
- Estimated physician shortage of **>50k** by 2025



US HEALTHCARE SPENDING AS SHARE OF GDP



The Internet Transforms Industries

Music

Physical Records -> Subscription streaming



Television

Cable -> TV-on-Demand



Retail

Brick-and-mortar -> Digital marketplaces



Transportation

Personal cars -> ride-share -> self-driving ride-share



Publishing

Printed newspapers -> Online news feeds



Has the Internet Changed Healthcare?

1991



2016



Monitor

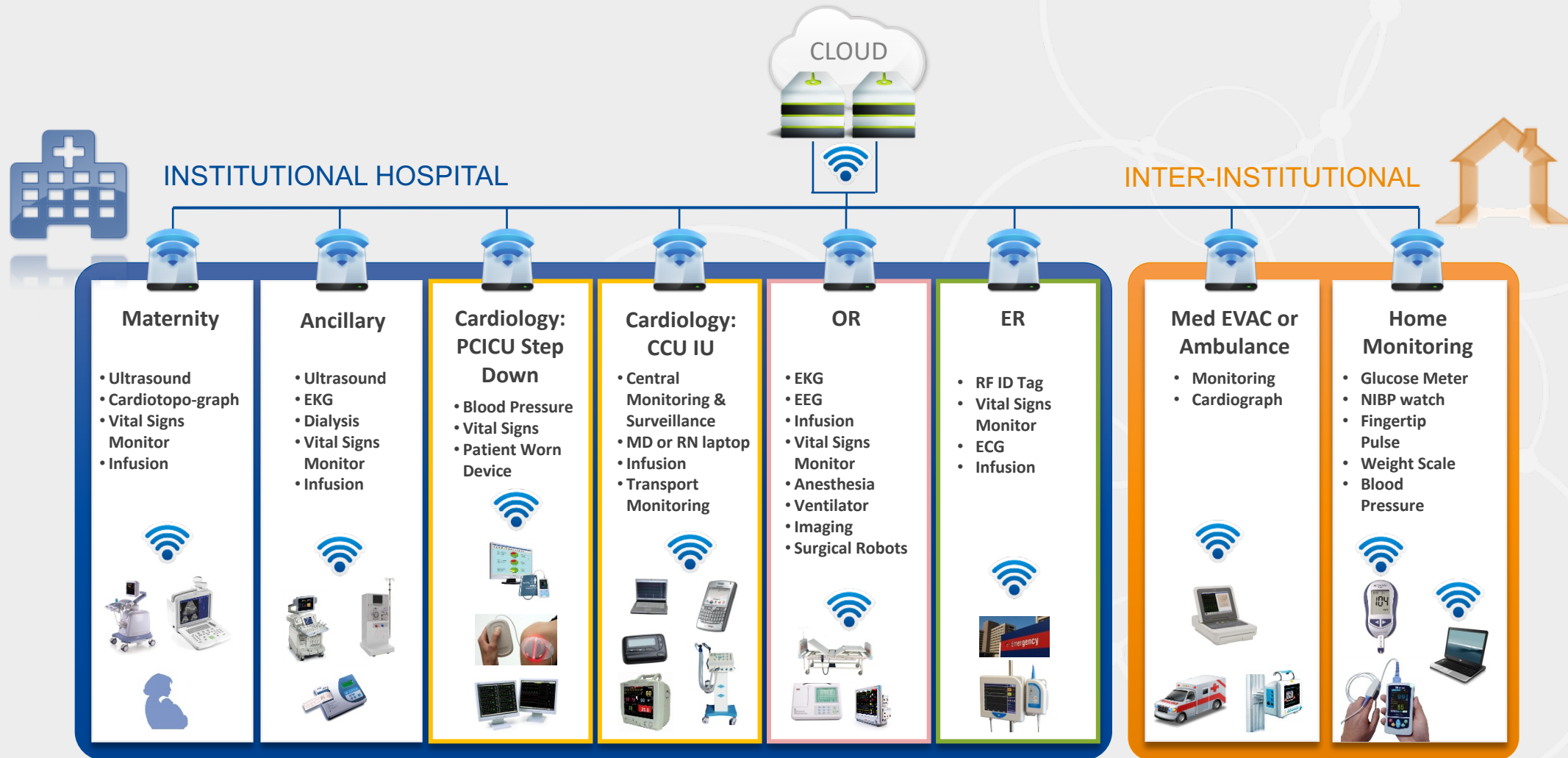
Data Storage

Keyboard

Movable Stand

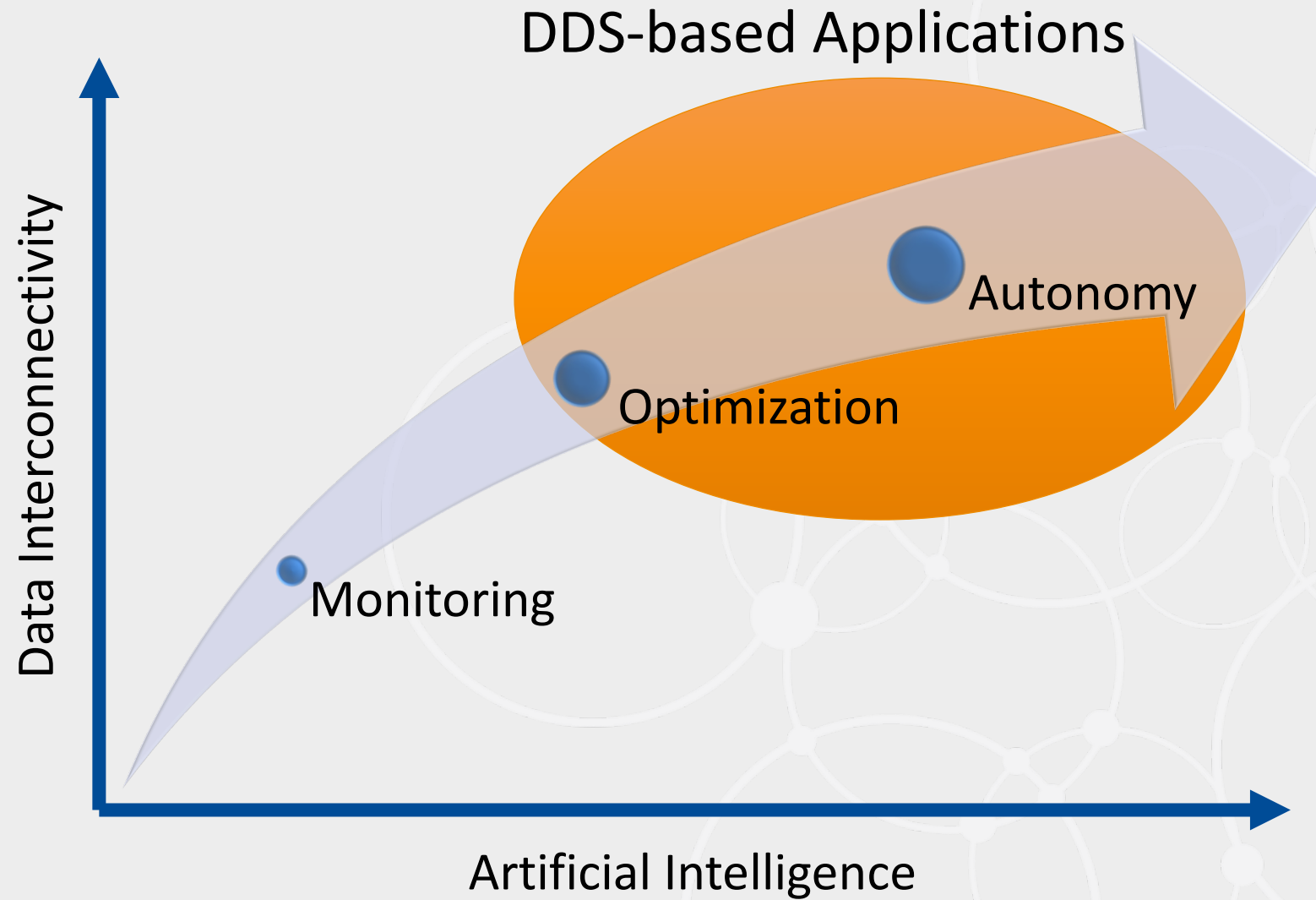


Is the IIoT a Solution for Healthcare?



Simplifying a Complex Problem With **EMBEDDED** Medical Devices

Evolution of IIoT

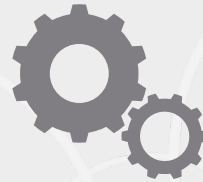


Why is this so HARD to implement?



Connectivity

So many choices....



Interoperability

Is it even possible?



Security

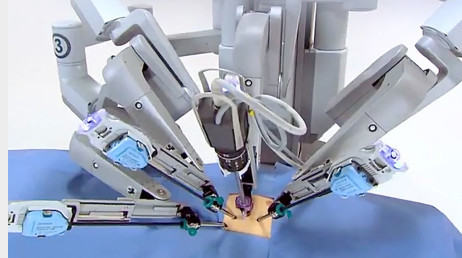
What does this even mean?



Real-Time Analytics

Are we even ready for this?

DDS: A Databus for Intelligent Medical Devices



Streaming Analytics
& Control

HMI/UI

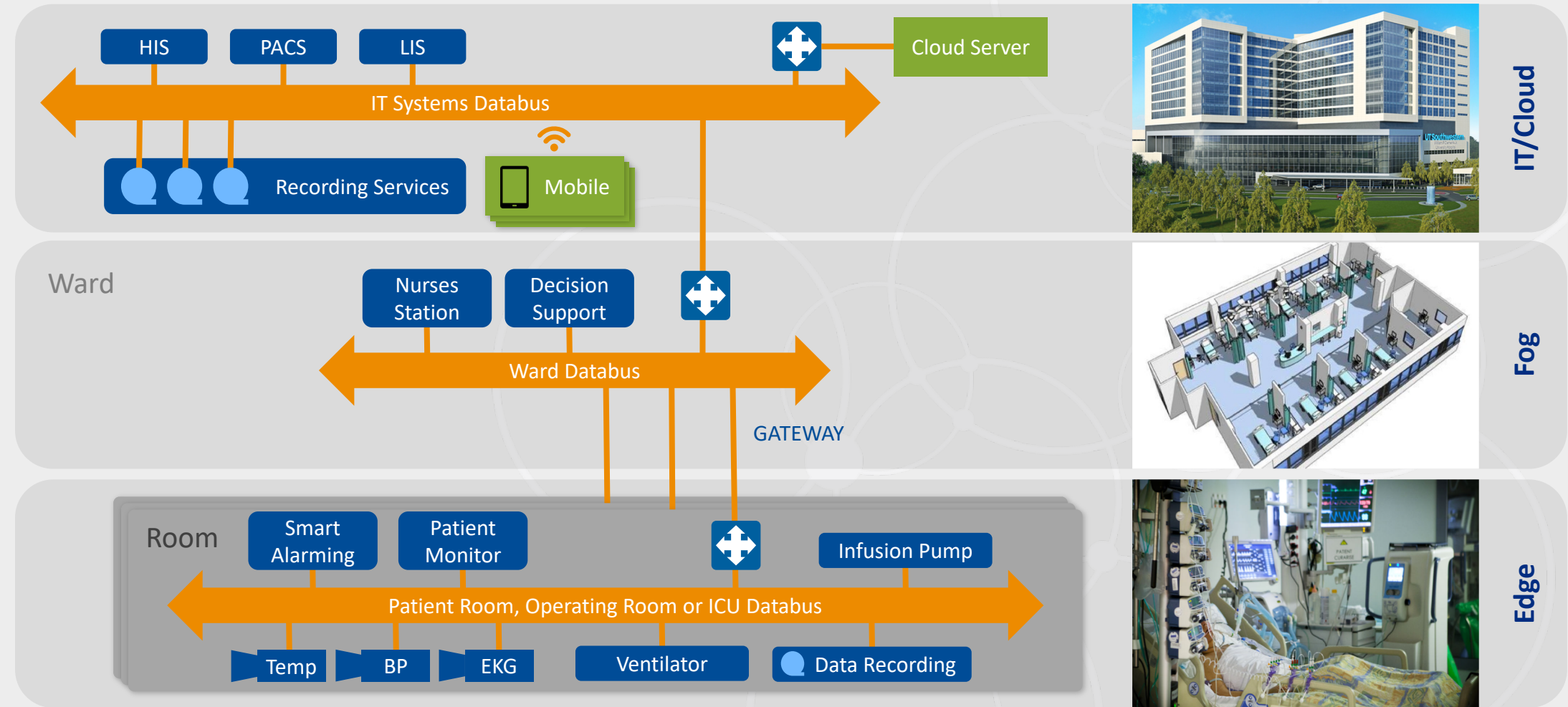
IT, Cloud &
System of Systems
Connectivity

RTI Connexx Databus

Sensors

Actuators

RTI Connex DDS Solution for Healthcare IIoT



Agenda

- The Current State of Healthcare
- The IIoT as Potential Solution
- Challenges to Implementation
- **The Case for an Open Standard Architecture in Healthcare**
- From Concept to Reality - The Development of a Commercial Offering
- Summary
- Q & A



Dr. Julian Goldman

Medical Director of Biomedical
Engineering at Partners Health
Anesthesiologist at Mass General
Director of the MD PnP Program
United States, Boston, MA



RTI Boston Conference
May 16 2018
Waltham, MA

Enabling Digital Healthcare Transformation

Julian M. Goldman, MD
Anesthesiologist, Mass General Hospital / Harvard Medical School
Director, Program on Medical Device Interoperability & Cybersecurity (MD PnP)
Medical Director, Partners HealthCare Biomedical Engineering

Contact and bio: www.jgoldman.info

Smart and Secure Medical Device Systems can Enable Healthcare Transformation

- Future health environments need integrated apps, sensors, actuators, and rich data to improve patient safety and enable new care delivery models.
- Medical devices must function as modular “Legos” to easily implement medical device systems to enable innovation . (“Configure, not program”)
- The “to be” environment is the “Medical IoT” - will enable secure, smart and automated medical device systems

The “good old days”?

ANESTHESIA RECORD

DATE: 10/10/10 TIME: 10:00 AM

PATIENT: J. Smith

OPERATION: Laparoscopic cholecystectomy

ANESTHESIA: General

PRE-OP: NPO 8 hours

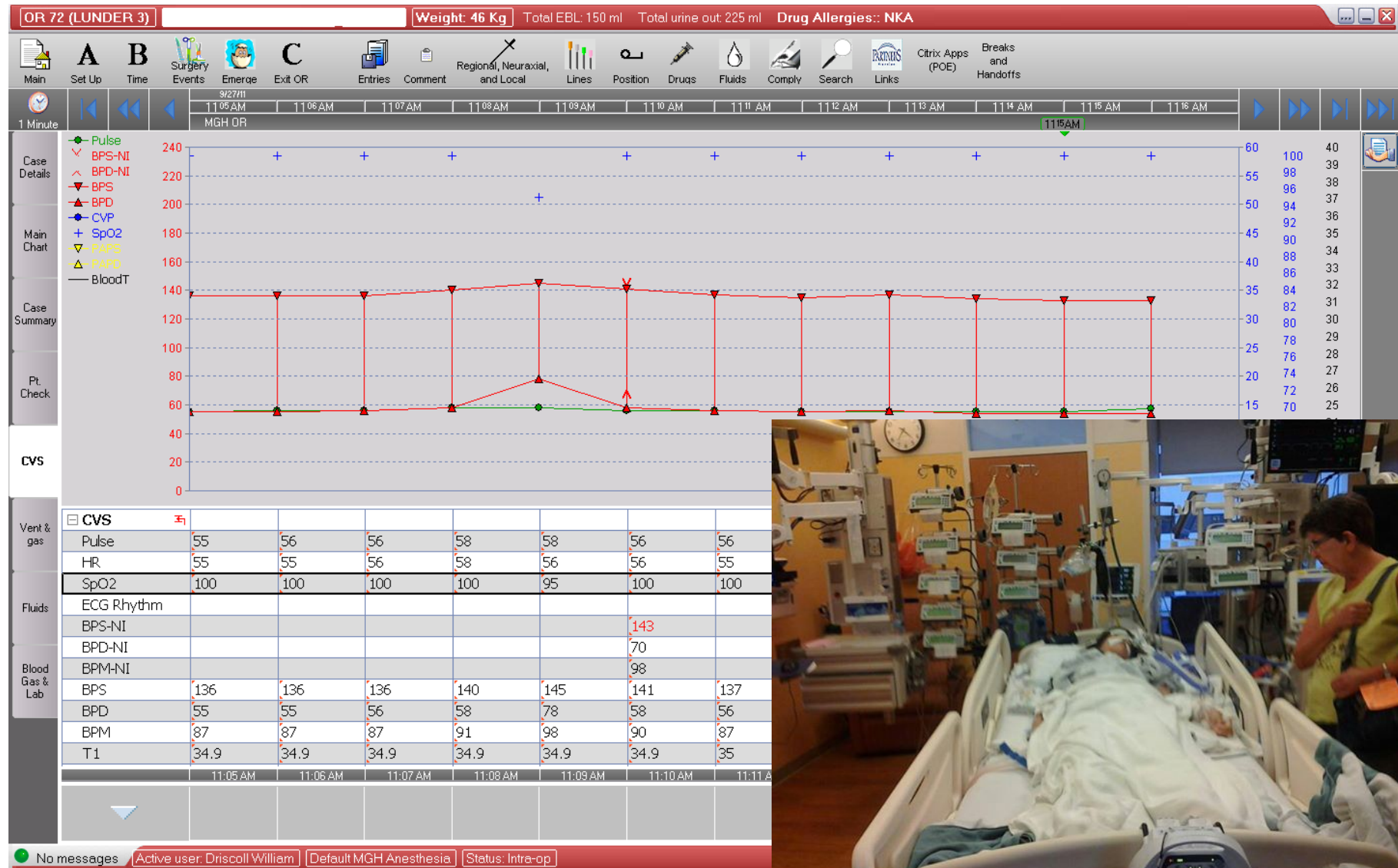
INTRA-OP: 100% O2, 100% N2O, 100% Fentanyl

POST-OP: 100% O2, 100% N2O, 100% Fentanyl

ANESTHESIA RECORD



Electronic Medical Records

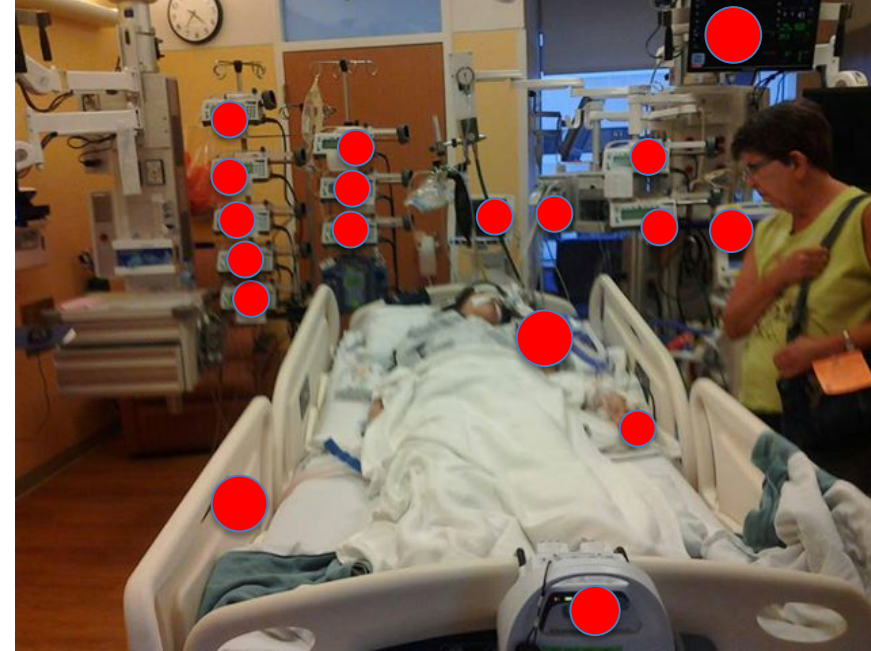


Medical devices proliferate, complexity increases



Caregivers must maintain vigilance, integrate data ...

● Medical Device (Electronic)



Has this scenario changed in the last 20 years?

Technologies to reduce error and improve efficiency are difficult to implement

Good ideas to improve the system are not adopted(able)

Contextually rich data, time-aligned data is NOT available (no black box recorder)



**These infusion pumps are
for use on ONE patient**



Medical Devices provide the “First Mile” of Data from the patient , and part of the “Last Mile” (data back to devices)

Examples of “last mile”:

1. “Artificial pancreas”
Capabilities (closed loop)
2. Prevent contra-indicated infusion
3. Acquire time-synchronized data for adverse event analysis
4. Stop pumps before harm from drug overdose



How Many Die From Medical Mistakes in U.S. Hospitals?



<http://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm>

Leading Causes of Death (2015):

1. 633,842 Heart Disease
2. 595,930 Cancer
3. *210,000-440,000 Deaths Due to Preventable Medical Errors (not listed on CDC web site)*
4. 155,041 Chronic lower respiratory diseases
5. 146,571 Accidents
6. 140,323 Stroke
7. 110,561 Alzheimer's disease
8. 79,535 Diabetes
9. 57,062 Influenza & Pneumonia
10. 47,112 Kidney diseases
11. 41,149 Intentional self-harm (suicide)

http://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A_New,_Evidence_based_Estimate_of_Patient_Harms.2.aspx

“Legacy” Devices: hard to integrate hard to secure

- Not manufactured with awareness of modern cybersecurity threats, modern software and networking environments, or pathway to safely & easily patch software components of deployed equipment
- Not necessarily intended by medical device manufacturers to be integrated with other devices/systems. Not intended or designed to be interoperable

* - working definition

PCA Current State and Future State with Data Fusion



PCA safety-interlock is an Archetypal Use Case
~ 6 patient are severely injured or die every day



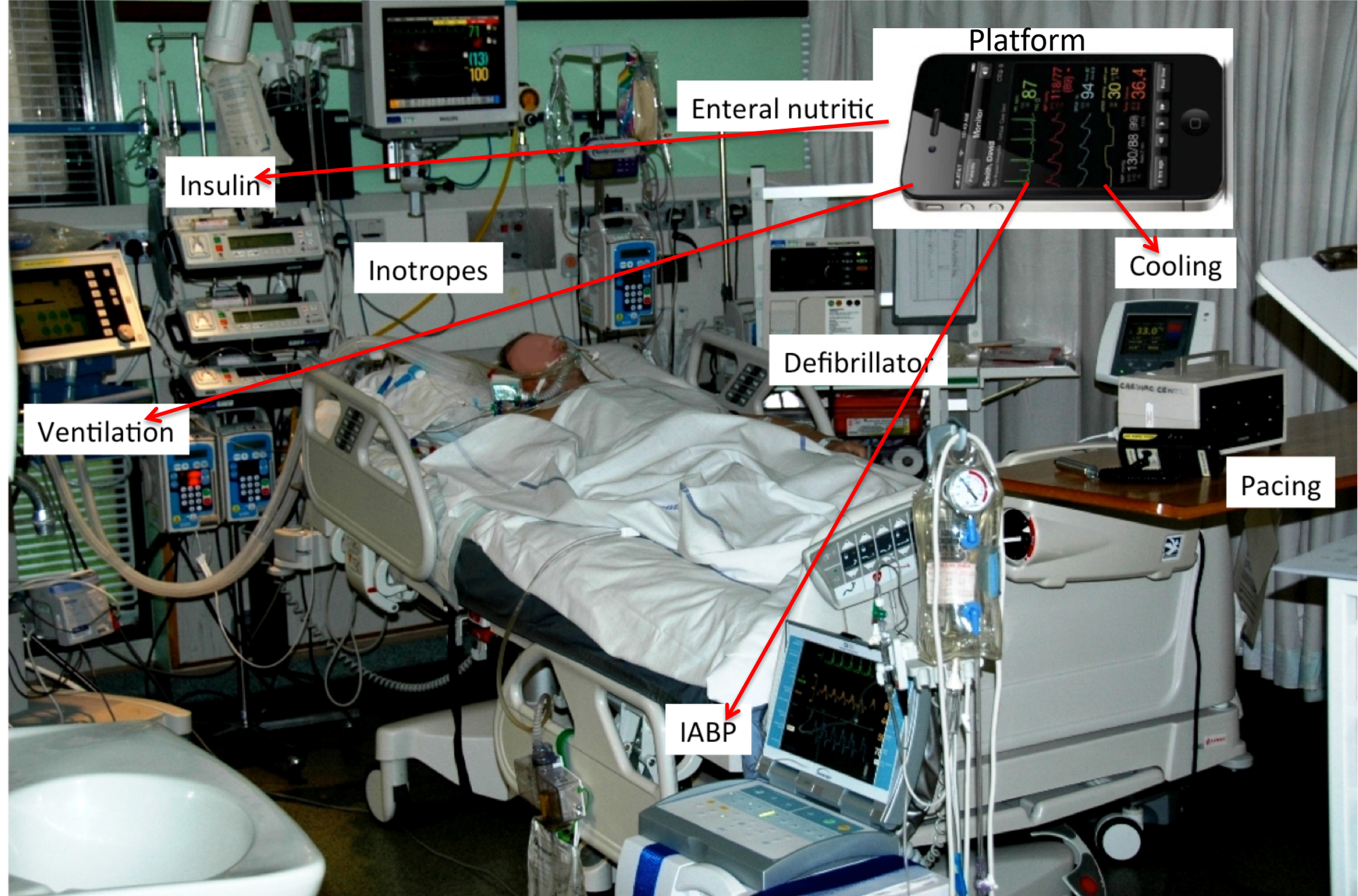
What is required:²

1. Apps to integrate data for early detection of respiratory depression prior to patient harm, minimize false alarms, stop the pump, and summon help
2. Devices that can provide necessary data interfaces and be controlled
3. Open platforms, to allow safe integration of interoperable components from different manufacturers to enable the community to develop, evaluate, and improve PCA safety algorithms to optimize analgesia and safety
4. “Safe Interoperability”³– safe systems to improve patient safety

1. http://patientsafetyauthority.org/PATIENTSCONSUMERS/PatientConsumerTips/Pages/PCA_Pump_Consumer_Tips.aspx

2. <http://mdpnp.mgh.harvard.edu/projects/clinical-scenarios/qmdi-clinical-scenarios/>

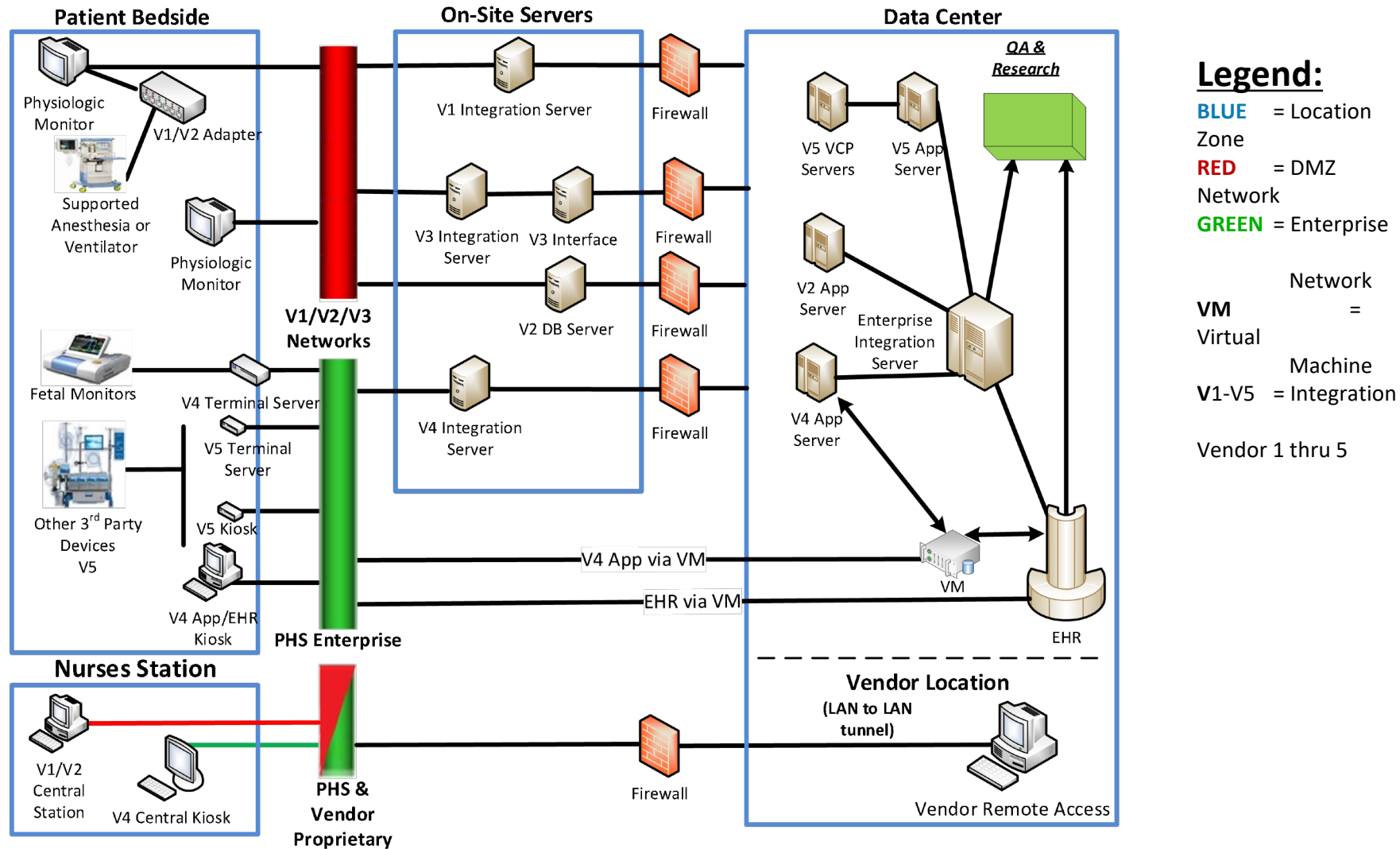
3. [Solving the interoperability challenge: safe and reliable information exchange requires more from product designers.IEEE Pulse. 2014 Nov-Dec;5\(6\):37-9. doi: 10.1109/MPUL.2014.2355307](#)



What if... Integrating Clinical Environments can enable Apps to rapidly and safely implement solutions?

HealthCare System

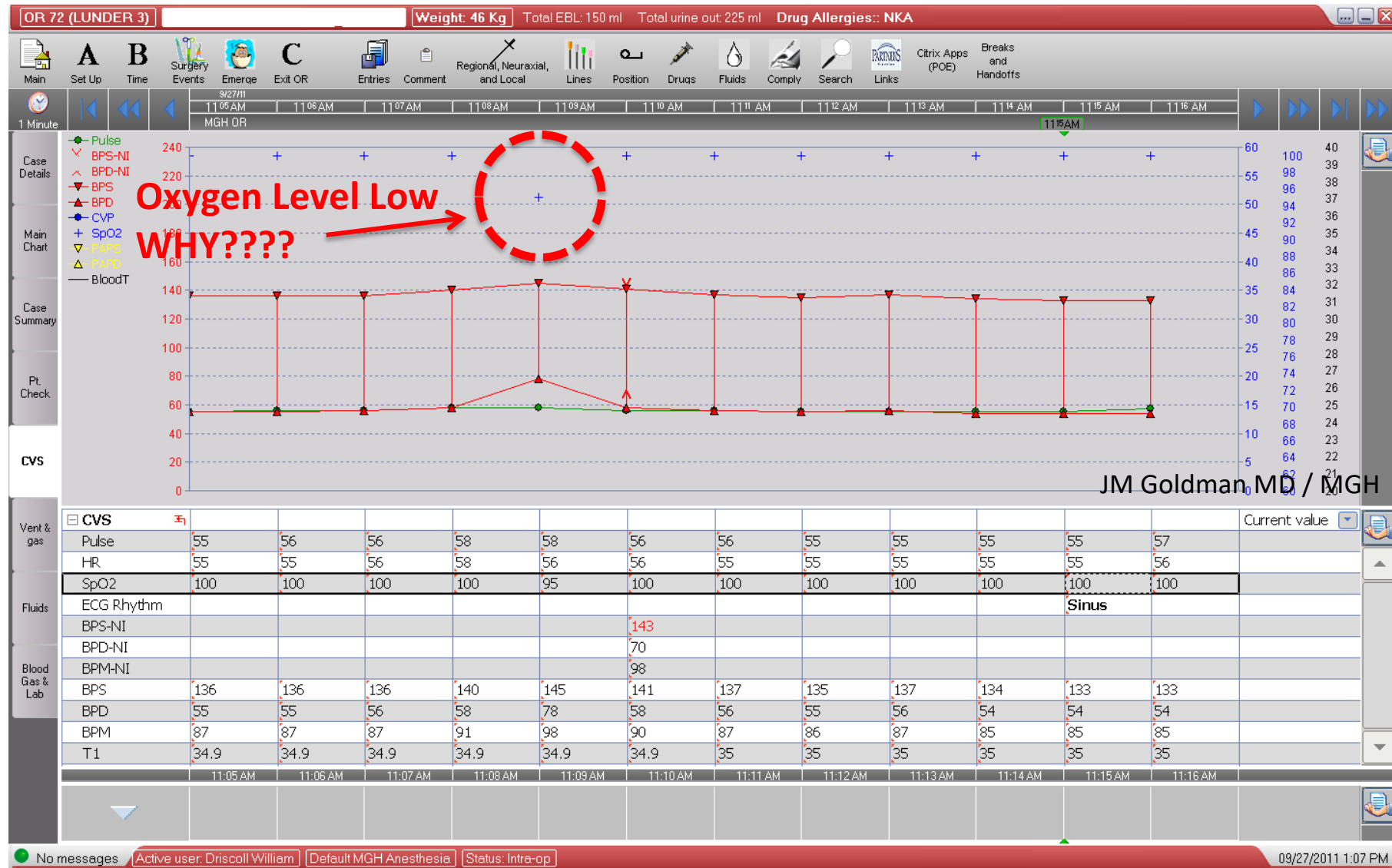
Example Medical Device Integration High-Level Architecture



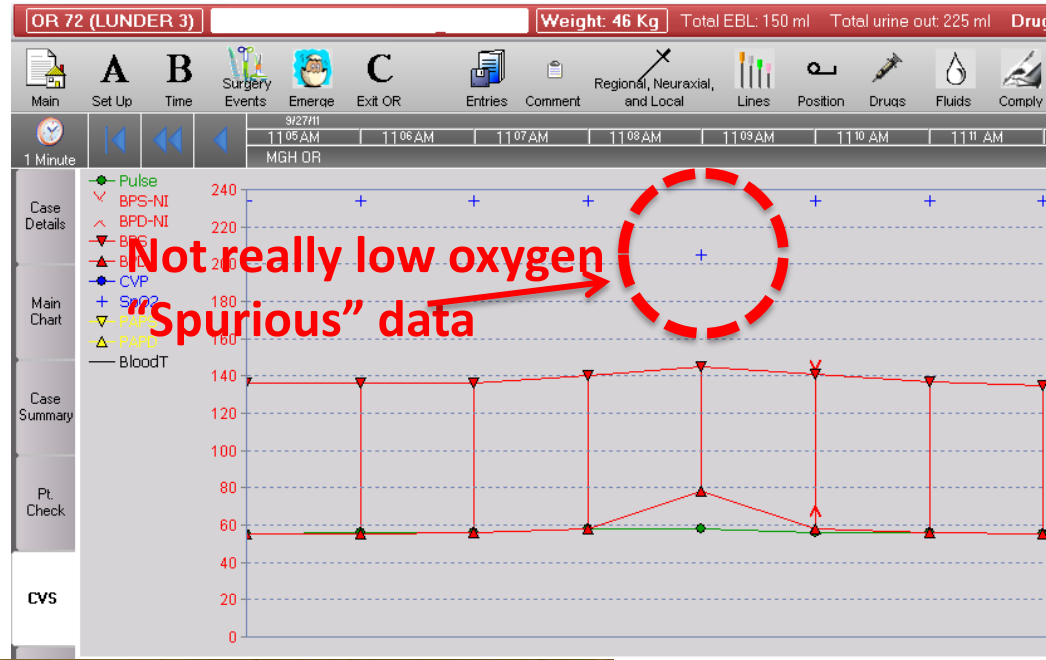
Rationale for MORE (and smarter) medical device/system integration

- Improve safety
- Improve documentation
- Build smarter systems (e.g. smart alarms, dashboards, AI applications)
- Monitor and protect medical device systems like IT systems!
- Don't we already have a complete medical device data set?
Indirect result of EHR integration?

Pulse oximeter data example



Blood Pressure cuff Inflates -> interferes with blood flow to finger -> erroneously low SpO₂



Baseline



Cuff inflates – loss of SpO₂ signal



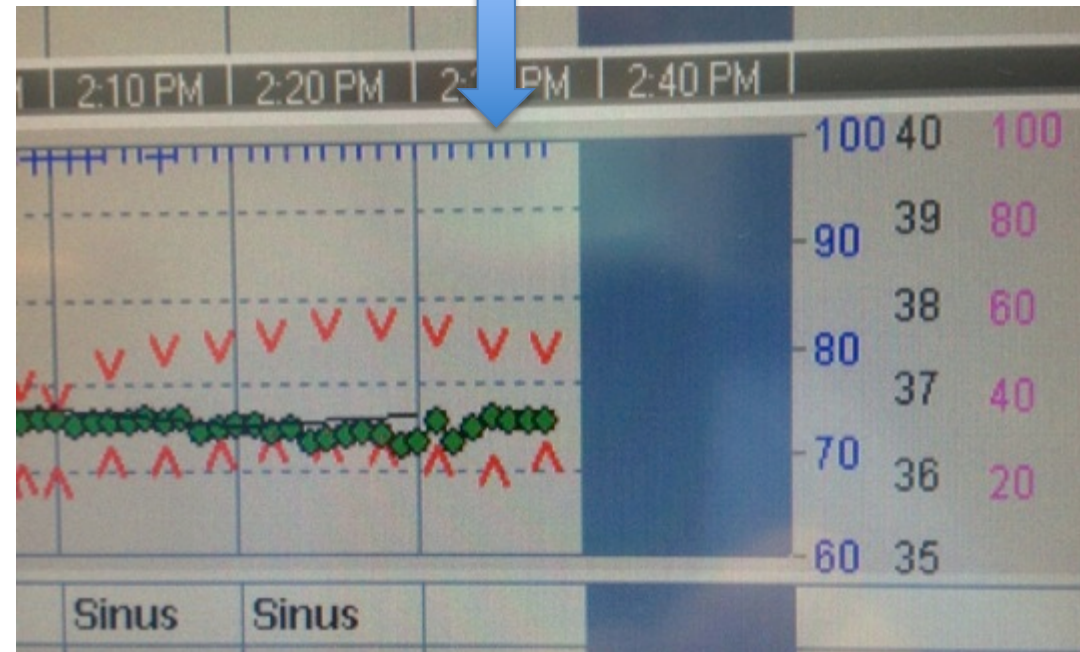
Blood returns to finger



Monitor Displays
Low Oxygen Level
(SpO₂) Alarm Event
"84%" at 2:07

Electronic record sampling rate may not
capture transient events

No evidence of 84% SpO₂ in EHR
(Blue ticks representing SpO₂ values
Note – NO decrease)



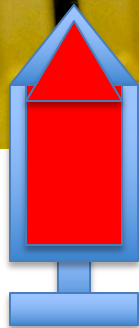
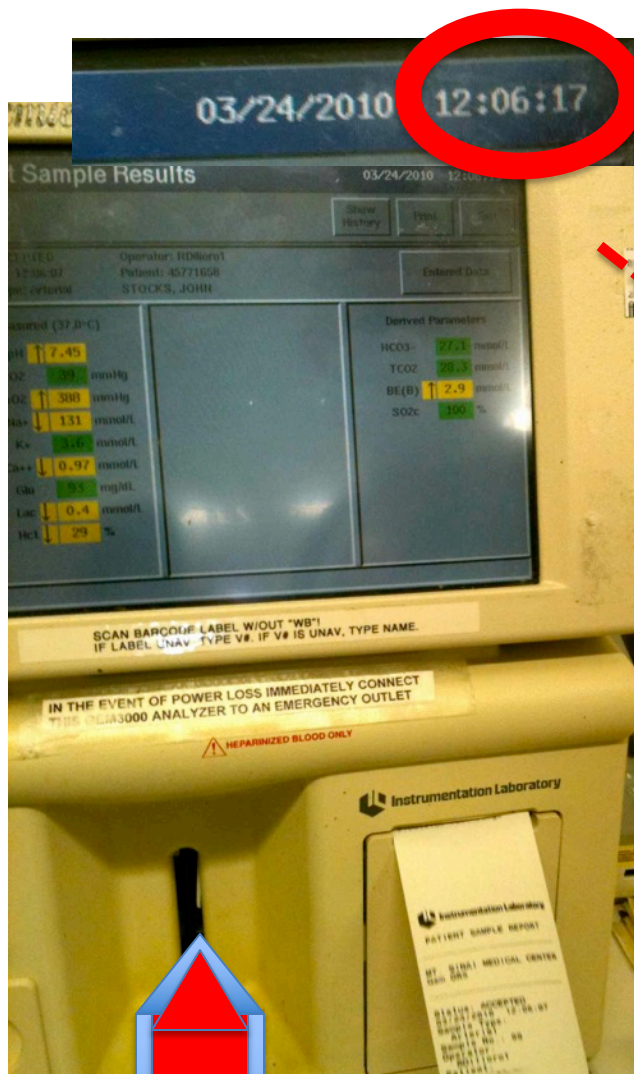
A ticking time-bomb

May 23rd 2012, 10:46 by M.H. | SEATTLE

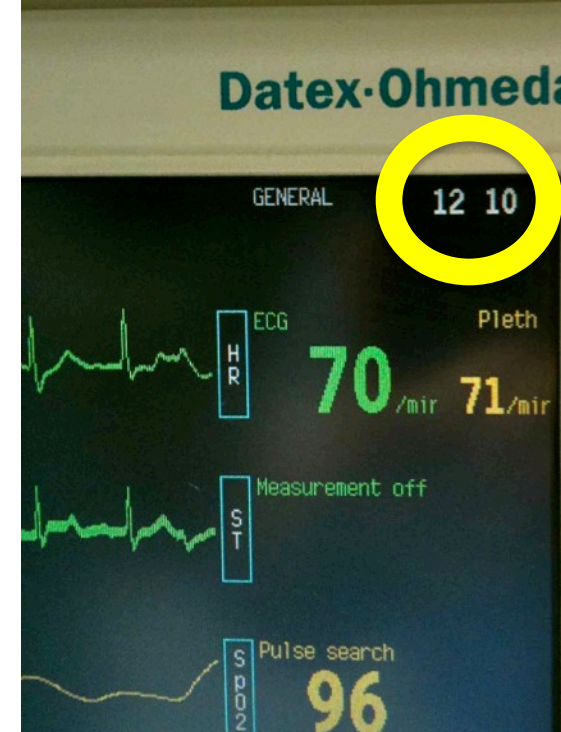
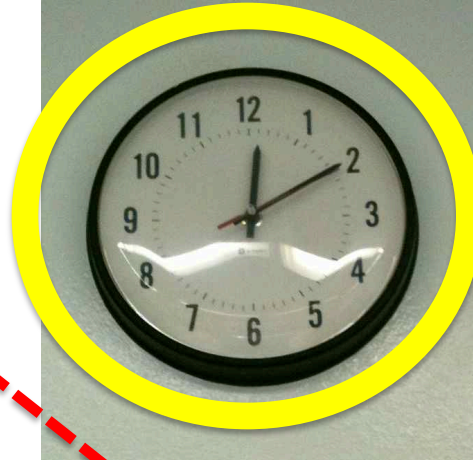
The
Economist



A MAN with one clock knows what time it is, goes the old saw, a man with two is never sure. Imagine the confusion, then, experienced by a doctor with dozens. Julian Goldman is an anaesthetist at Massachusetts General Hospital in Boston. Like many modern health care facilities, it has become increasingly digitised and networked, with hundreds of high-tech medical devices feeding data to a centralised electronic medical record (EMR), which acts as both a permanent repository for health information and a system that can be accessed instantly by doctors to assist with clinical decisions.



Blood gas analyzer in OR



EMR time stamp error

Lab Results

Select the lab results you wish to add to the case record. Click the 'Add' button to add the selected lab results to the case record.

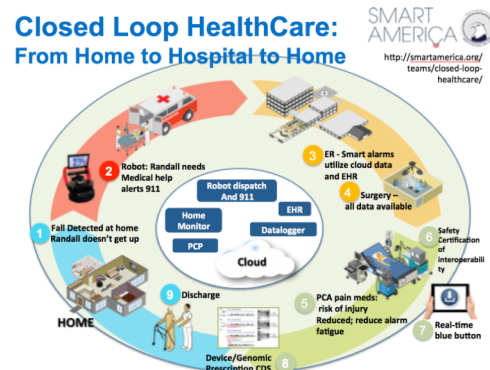
Select	Description	Amount	Observation Time
<input checked="" type="checkbox"/>	Arterial O2 Sat	100 %	03/24/2010 12:06
<input type="checkbox"/>	Base-Excess	2.9 mmol/L	03/24/2010 12:06
<input type="checkbox"/>	Ca++ (Ionized)	0.97 mmol/L	03/24/2010 12:06
<input type="checkbox"/>	Glucose	93 mg/dL	03/24/2010 12:06

What is the pathway to ...

- Use “near-patient” real-time data primarily from medical devices (device-device interoperability)
- Enable real-time caregiver decision support, analytics and data dashboards, improved (smarter) alarms, closed-loop workflow and closed-loop control, time-synced data sets for QA/after-action reports, data for biomed equipment management
- Improve data quality in EHR
- Build an inherently secure ecosystem?

Health environments need integrated technologies and rich data to improve patient safety and enable learning and transformational care delivery models

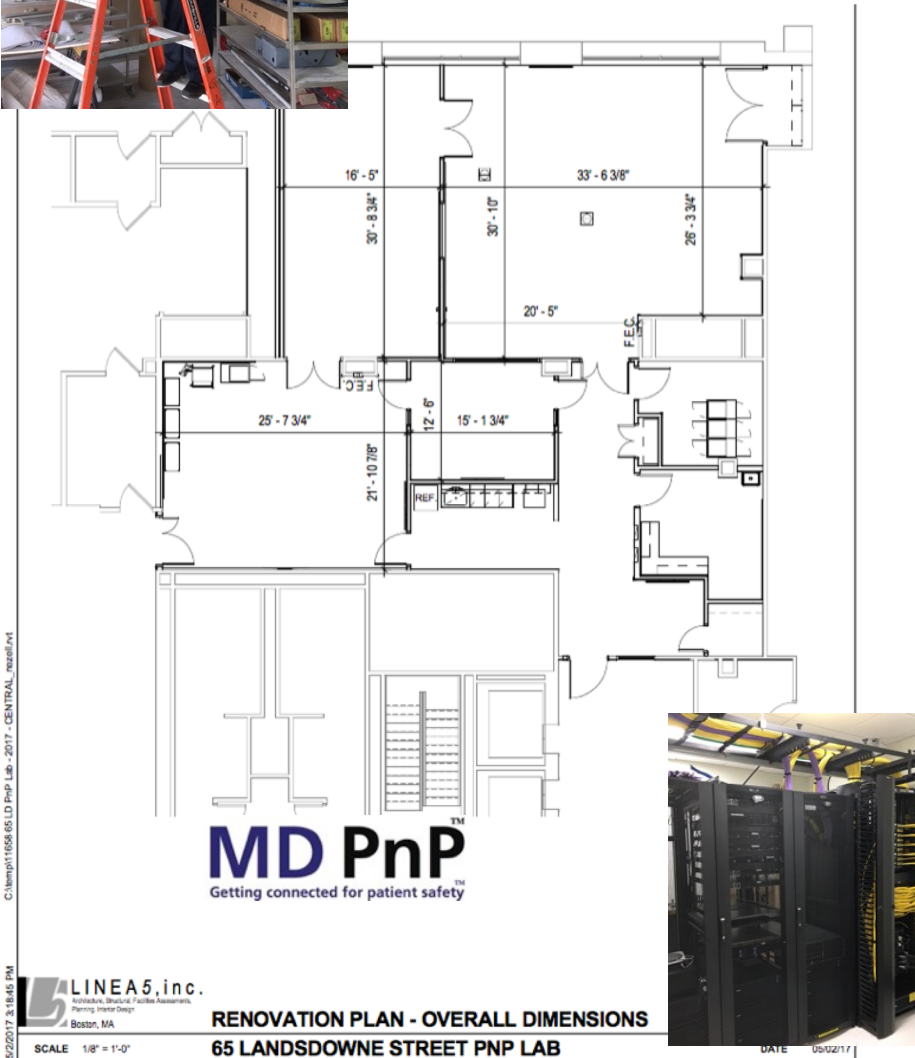
- Program established 2004 at Mass General Hospital/Partners Healthcare
- Lab opened 2006 for research on achieving safe, secure interoperable medical systems (standards, technologies, products). Expanded 2017.
- Clinical, biomed, computer science, and IT subject matter experts
- Publish research to enable safe interoperability
- Develops OpenICE open-source interoperability research platform www.openice.info
- \$22M research funding primarily from DOD, NIH, NSF, DHS (FDA-MITRE)
- Multiple collaborative lab prototyping and public demonstrations with industry, academia, and government
- Developed foundational content for standard ASTM F2761 on the Integrated Clinical Environment ("ICE") , AAMI-UL 2800, and other standards
- FDA “pre-submission” on safe platform-based interoperability, publicly shared
- “Go to” site for collaborative projects: Ebola response, SmartAmerica, Cybersecurity



Example of collaborators



<http://mdpnp.mgh.harvard.edu/>



New MD PnP 3200 sq ft lab 4-lab suite.

Provides research & operational testbed:

- Diverse medical devices, ICU to IoT, simulators
- Advanced networking infrastructure for:
 - Interoperability
 - Cybersecurity
 - Biomedical Engineering/Computer Science/Cyber Physical Systems/Medical IoT research
 - Clinical workflow simulation

2018 Initiatives:

- Hospital community Medical Device Cybersecurity Preparedness (w/FDA and MITRE)
- Device data for cybersecurity research community (DHS)
- Interoperability and cybersecurity of ICE systems (DOD)



Standard for ICE

“Integrated Clinical Environment”

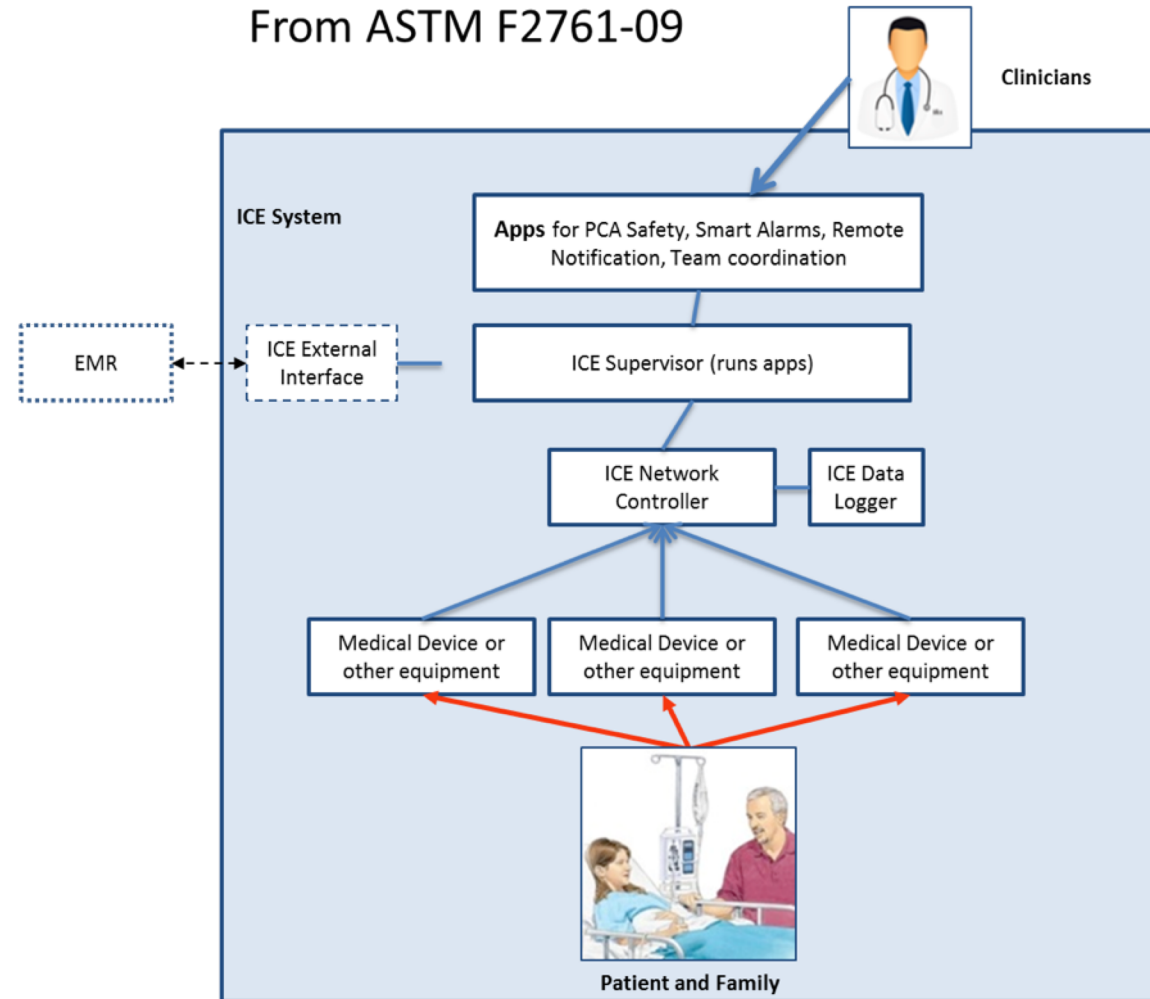
ASTM F2761-09

- “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model”
- F2761 provides a standards-based system architecture to support safe interoperable medical systems
- Transitioned from ASTM to AAMI Interoperability WG

Integrated Clinical Environment Architecture (ICE)

ICE provides an architecture to address:

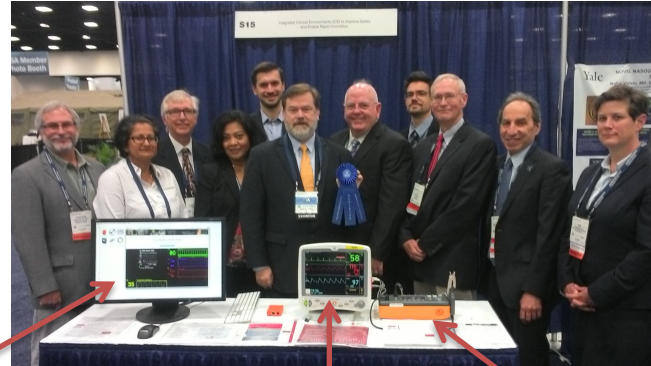
- App platform for clinical care and device management
- Safety and performance of the system
- Security (sandboxing)
- Patient ID-data binding
- Correct time stamp-data binding
- Data logging for forensic, QA, and liability
- Builds on medical device interoperability
- F2761 does not state “how” to implement



Standard recognized by FDA in August 2013

Demonstration from the American Society of Anesthesiologists meeting Oct 2015:

System to Automatically Detect Pulseless Electrical Activity (PEA) and Display a Cognitive Aid using interoperable research platform (OpenICE)



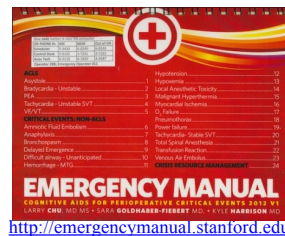
App running on OpenICE
www.openice.info

Physiologic
Monitor

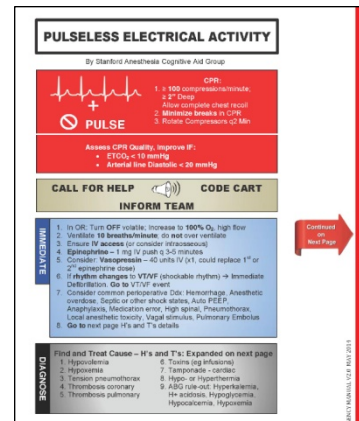
Simulator

App automatically displays correct
Page from Stanford Emergency Manual to treat PEA

Stanford Emergency Manual



<http://emergencymanual.stanford.edu>

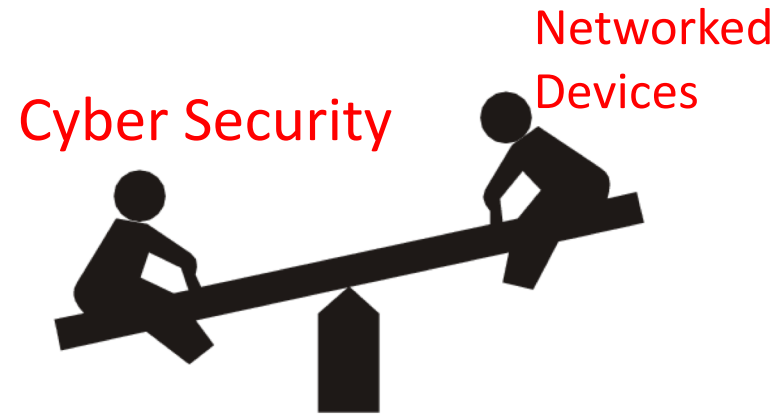


PEA page from the Emergency Manual



Non-EMR Clinical Decision Support

Must we Trade Interoperability for Cybersecurity?



Some say:

“Networked systems increase attack surface and vulnerabilities”

“Close ALL interface ports” (epoxy has been proposed!)

Is that possible today?

How would devices be patched? Upgraded?

How would data be integrated? Send data to EHR? Data Dashboard Analytics?

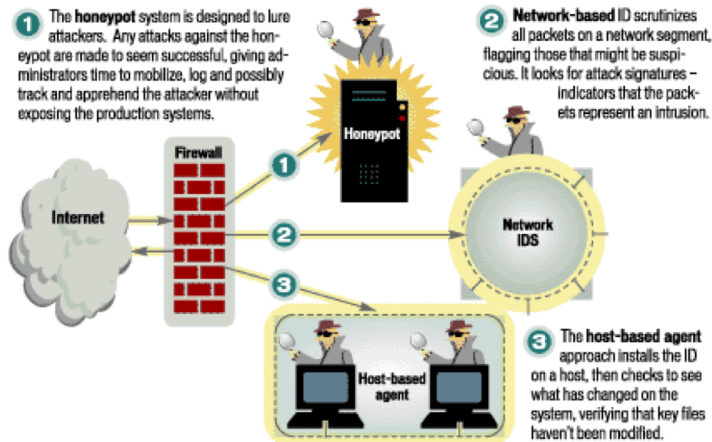
Relationship between Interoperability and Cybersecurity



Or?



Intrusion-Detection Systems ID stands for intrusion detection, which is the art of detecting inappropriate, incorrect or anomalous activity. ID systems that operate on a host to detect malicious activity are called host-based ID systems. ID systems that operate on network data flows are called network-based ID systems. These two systems can be used in conjunction with each other.



“Well designed interoperable systems can enable monitoring of device behaviors and clinical effects of nefarious activity”

Cybersecurity requires baselining, data, and monitoring – Black Box Recorder (system Data Logger)

Comprehensive, contextually rich data from networked devices, enables improved cybersecurity.

Can't monitor devices hidden behind “dongles”

FDA-MITRE Project Healthcare Cybersecurity Preparedness & Response

- Recent events, such as the WannaCry attack, have demonstrated that medical device cybersecurity preparedness and response activities are critical for HDOs
- FDA is actively helping HDOs evolve their medical device cybersecurity preparedness and response activities

Regional Healthcare Delivery Organization Medical Device Cybersecurity Workshop – December 2017

- MITRE and the MD PnP program organized a workshop to
 - Share lessons learned from managing medical devices during the WannaCry attack
 - Identify opportunities to better prepare health systems for future cyber attacks
 - Identify opportunities to improve regional and national sharing
 - Compile key meeting takeaways to inform FDA
- Brought together HDO IT staff, biomedical engineers, and clinicians from Boston-area hospitals

FDA Project: Medical Device Cybersecurity Sandbox Goals

- The ability to test and validate vulnerabilities, mitigation strategies, and cyber resilient, clinical configurations that enable continued clinical operation in the face of cyber-physical hazards, in support of local, regional, and national preparedness goals.
- A realistic, biomedical environment that supports both preparedness exercises and live cyber-physical incident response activities, with the capability to test solutions in real time.
- The identification and sharing of medical device vulnerabilities, vetted mitigation strategies, and cyber resilient configurations, in direct support of the FDA's postmarket guidance policy calling for greater transparency and adoption of coordinated vulnerability disclosures.

March 28, 2018

Julian M. Goldman, M.D.
Director, Medical Device Interoperability and Cybersecurity Program
Department of Anesthesia, Critical Care, and Pain Medicine, and Partners HealthCare Biomedical Engineering
Massachusetts General Hospital
65 Landsdowne Street
Cambridge, MA 02139

Dear Dr. Goldman,

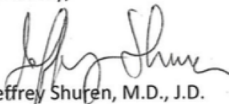
Thank you for reaching out to FDA's Center for Devices and Radiological Health's Emergency Preparedness / Operations and Medical Countermeasures Program.

We are pleased to learn of the formation of a Collaborative on Medical Device Cybersecurity Preparedness through Massachusetts General Hospital (MGH) Medical Device Plug-and-Play (MD PnP) Interoperability and Cybersecurity program, under the MITRE-FDA cybersecurity preparedness and response contract. This type of initiative informs the development of preparedness and response plans by leveraging the MD PnP Program's research and testing capabilities to enable the simulation of case scenarios, perform technical analyses, and prototype and evaluate remediation and mitigation solutions.

We recognize the importance of having a medical system-of-systems environment that can simulate cyberattacks, assess medical device vulnerabilities, and test out remediation/mitigation strategies, without exposing patients to risk. We understand that the MD PnP program's laboratory has the technological infrastructure, clinical knowledge, and configurations needed to make up a sandbox to evaluate medical device security, and support achieving safe and secure interoperability. We are highly supportive of efforts like these, envisioning the potential of test beds to enhance preparedness by serving as an excellent resource to address critical, unmet gaps in medical device cybersecurity. Medical device manufacturers and the healthcare community at large can indeed benefit from the availability of clinical simulation centers and sandboxes as a safe space to identify, analyze and manage security vulnerabilities, towards the goal of minimizing the potential impacts to device performance and enhancing patient safety.

We look forward to hearing about your progress as you engage members of the diverse medical device ecosystem to take advantage of and participate in MD PnP's collaborative. Please let us know how we might further foster these relationships so that we jointly advance the healthcare and public health sector's medical device cybersecurity preparedness and response.

Sincerely,



Jeffrey Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health

We are pleased to learn of the formation of a Collaborative on Medical Device Cybersecurity Preparedness through Massachusetts General Hospital (MGH) Medical Device Plug-and-Play (MD PnP) Interoperability and Cybersecurity program, under the MITRE-FDA cybersecurity preparedness and response contract. This type of initiative informs the development of preparedness and response plans by leveraging the MD PnP Program's research and testing capabilities to enable the simulation of case scenarios, perform technical analyses, and prototype and evaluate remediation and mitigation solutions.

We recognize the importance of having a medical system-of-systems environment that can simulate cyberattacks, assess medical device vulnerabilities, and test out remediation/mitigation strategies, without exposing patients to risk. We understand that the MD PnP program's laboratory has the technological infrastructure, clinical knowledge, and configurations needed to make up a sandbox to evaluate medical device security, and support achieving safe and secure interoperability. We are highly supportive of efforts like these, envisioning the potential of test beds to enhance preparedness by serving as an excellent resource to address critical, unmet gaps in medical device cybersecurity. Medical device manufacturers and the healthcare community at large can indeed benefit from the availability of clinical simulation centers and sandboxes as a safe space to identify, analyze and manage security vulnerabilities, towards the goal of minimizing the potential impacts to device performance and enhancing patient safety.

We look forward to hearing about your progress as you engage members of the diverse medical device ecosystem to take advantage of and participate in MD PnP's collaborative. Please let us know how we might further foster these relationships so that we jointly advance the healthcare and public health sector's medical device cybersecurity preparedness and response.

Agenda

- The Current State of Healthcare
- The IIoT as Potential Solution
- Challenges to Implementation
- The Case for an Open Standard Architecture in Healthcare
- **From Concept to Reality - The Development of a Commercial Offering**
- Summary
- Q & A



Tracy Rausch

CEO

Doc Box

United States, Boston, MA

Overview

- Problem
- Integrated Clinical Environment (ICE)
- Medical Internet of Things Platform
- DDS Connex
- Recording Service
- Security

User Requests

"We need complete, accurate and contextually aware data"

"Why can't this be automatically put in the medical record?"

"Can I know in real-time how many ventilators I have?"

"how do I take my 30 years of experience and use it to help a new physician provide high quality healthcare?"

"Health data must be contextually aware"

"Why can't I manage my devices remotely?"

"We need to change what is expected of technology in healthcare"

"Why can't I pause an infusion pump when the person is overdosing?"

"I need to keep a patient alive for 5 days without a doctor present with what I carry in my backpack"

"I want to monitor every patient at every bed"

PCA Scenario

- 100's of workflow steps
- Systems Impacted
 - EHR - Patient History, Drug Allergies, Current Medications,
 - Pharmacy – Current Medications, Drug Interactions, Pharmacological Model
 - Infusion Pump – Pump Interface, Capabilities, Accuracy, Alarms
 - Monitor – Accuracy, Body Site
 - Nurse Call
- Physiology

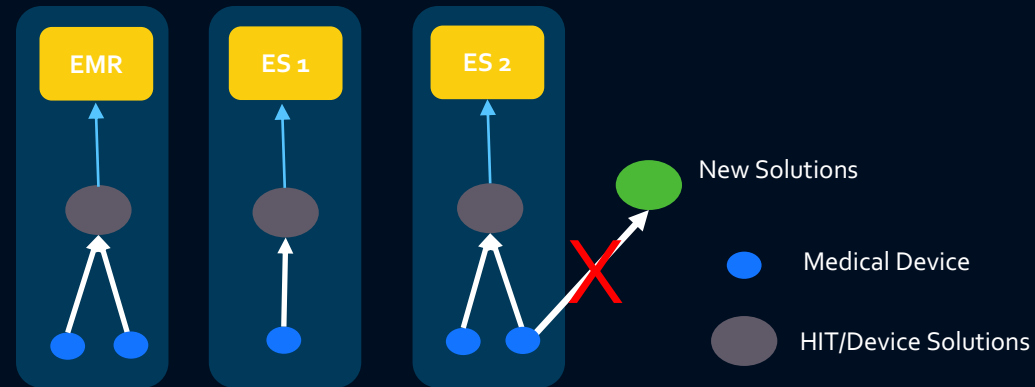
Remote Monitoring of Patient

- EHR – History, Diagnosis, Rx, Orders
- Labs – Interface, scheduled, results, Orders
- Pharmacy – Orders, Current Medications, Drug Interactions, Pharmacological Model
- Monitor, Ventilator, Infusion Pumps – Accuracy, Precision, Alarm States, Averaging Time
- Monitoring Algorithms – Averaging Time, Network Fidelity, Patient Suitability



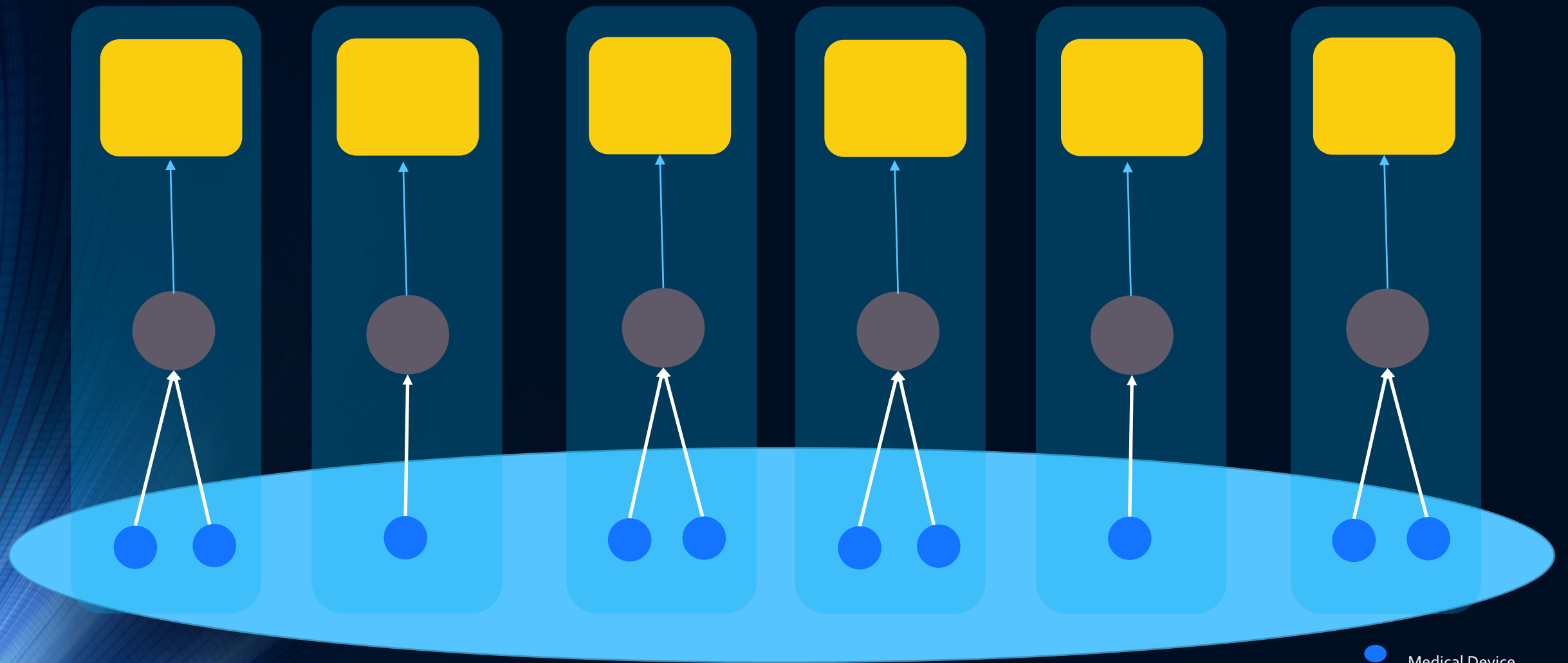
J. Goldman, MD MGH

Architecture



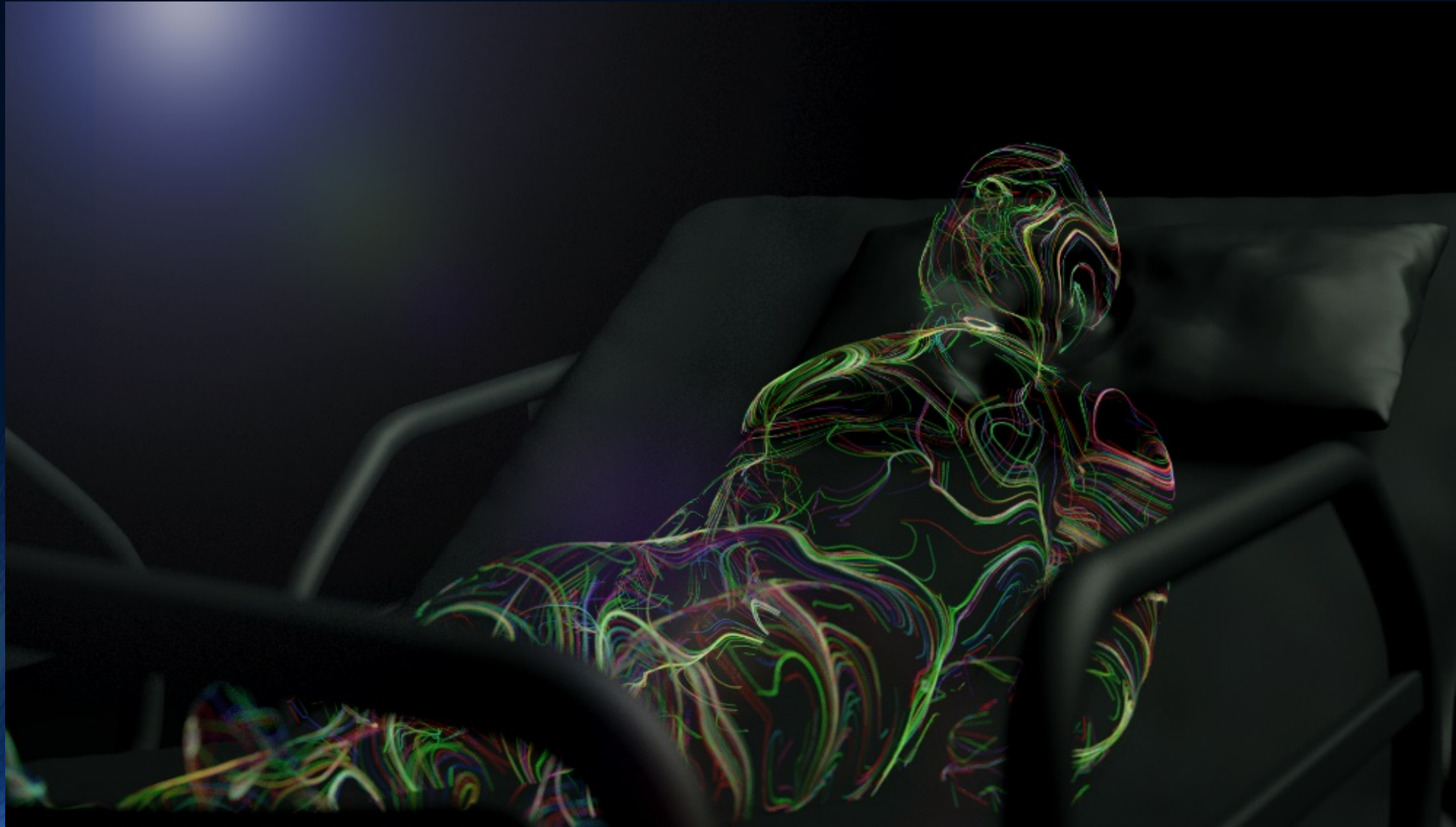
- Device, point solutions and EHR are proprietary and vertically integrated.
- Integration is expensive, complicated & incomplete
- No way of bringing the data back to innovate

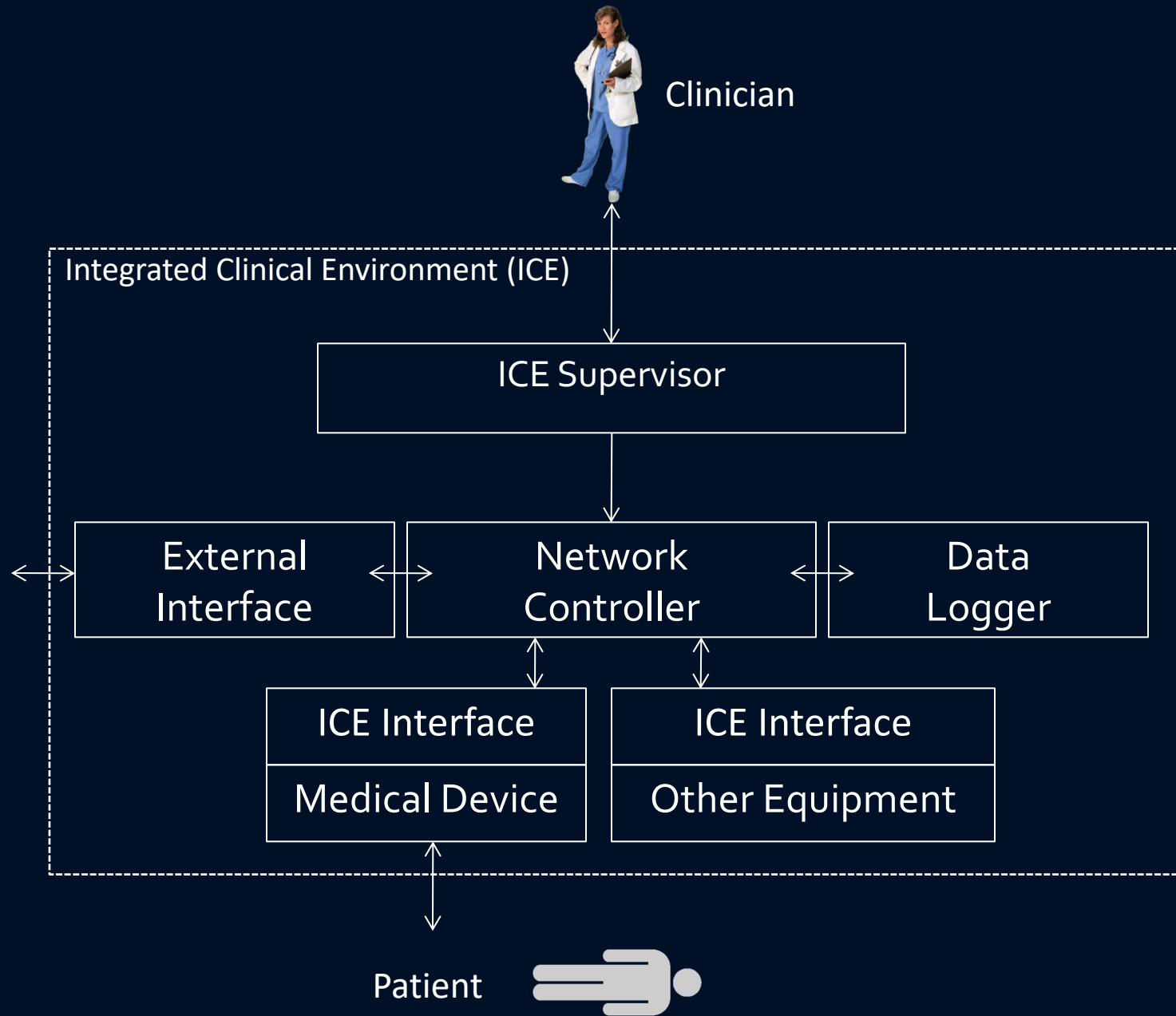
Architecture



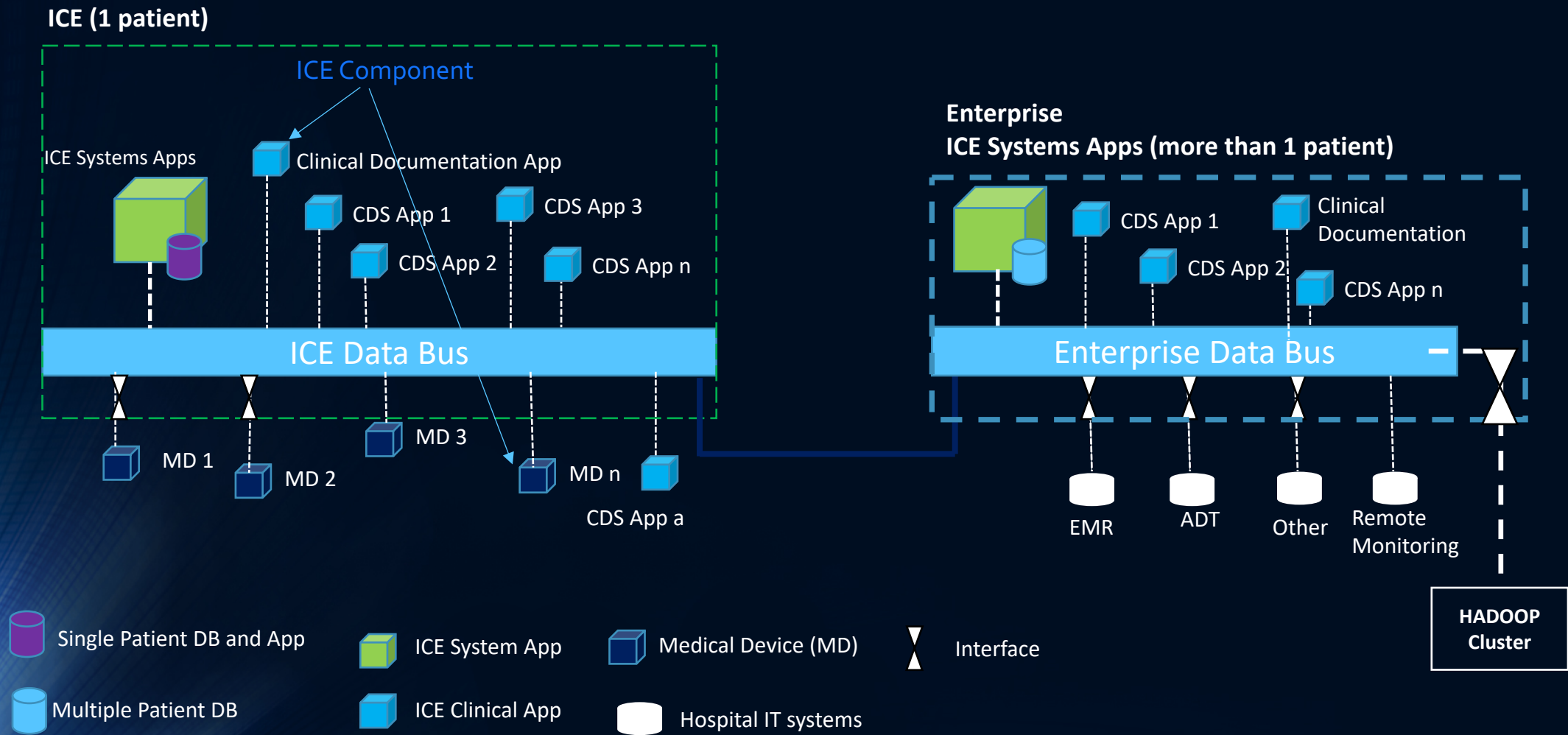
- Medical Device
- HIT/Device Solutions

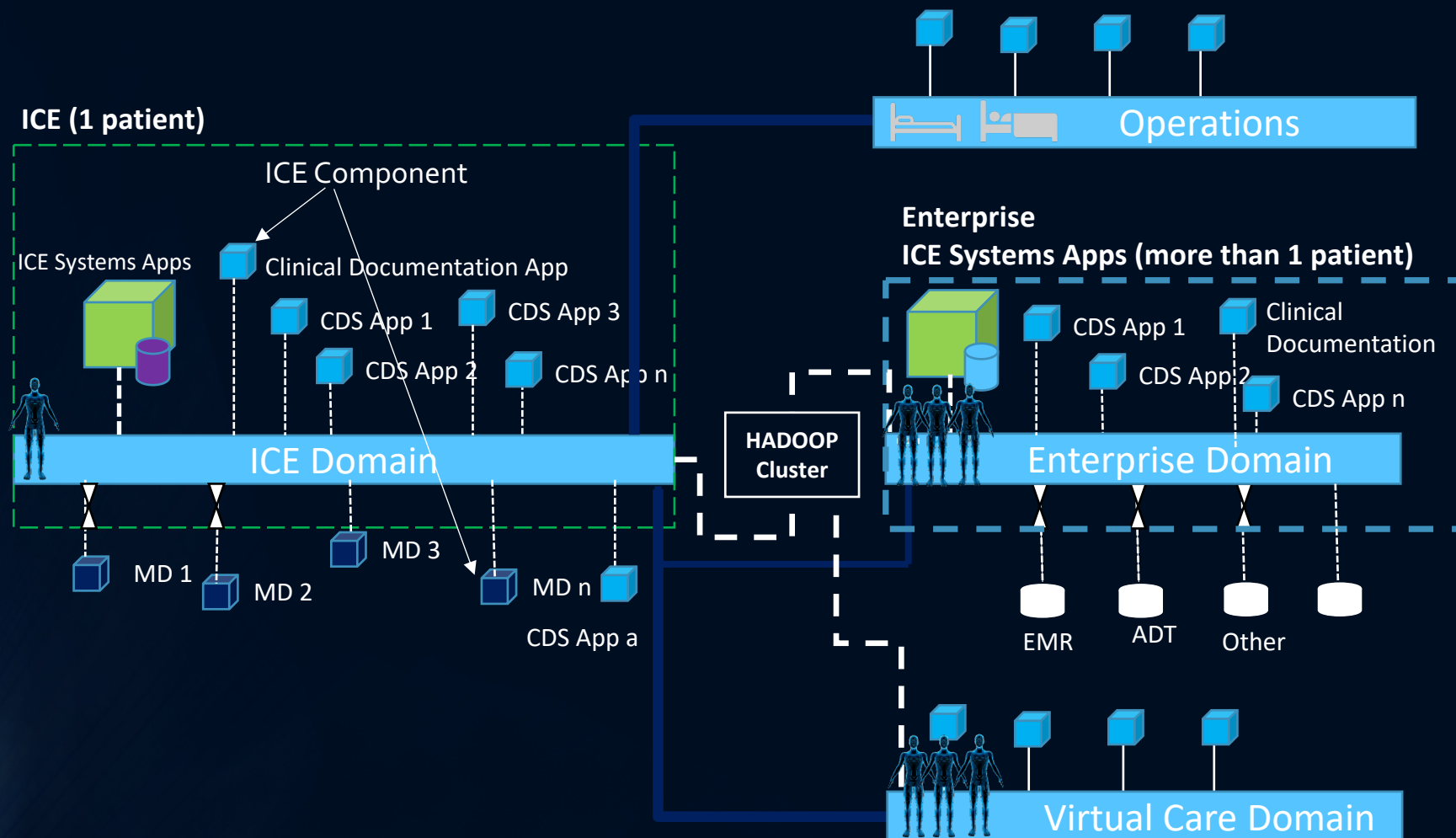
Patient Centered + Data Centric





DocBox's Platform





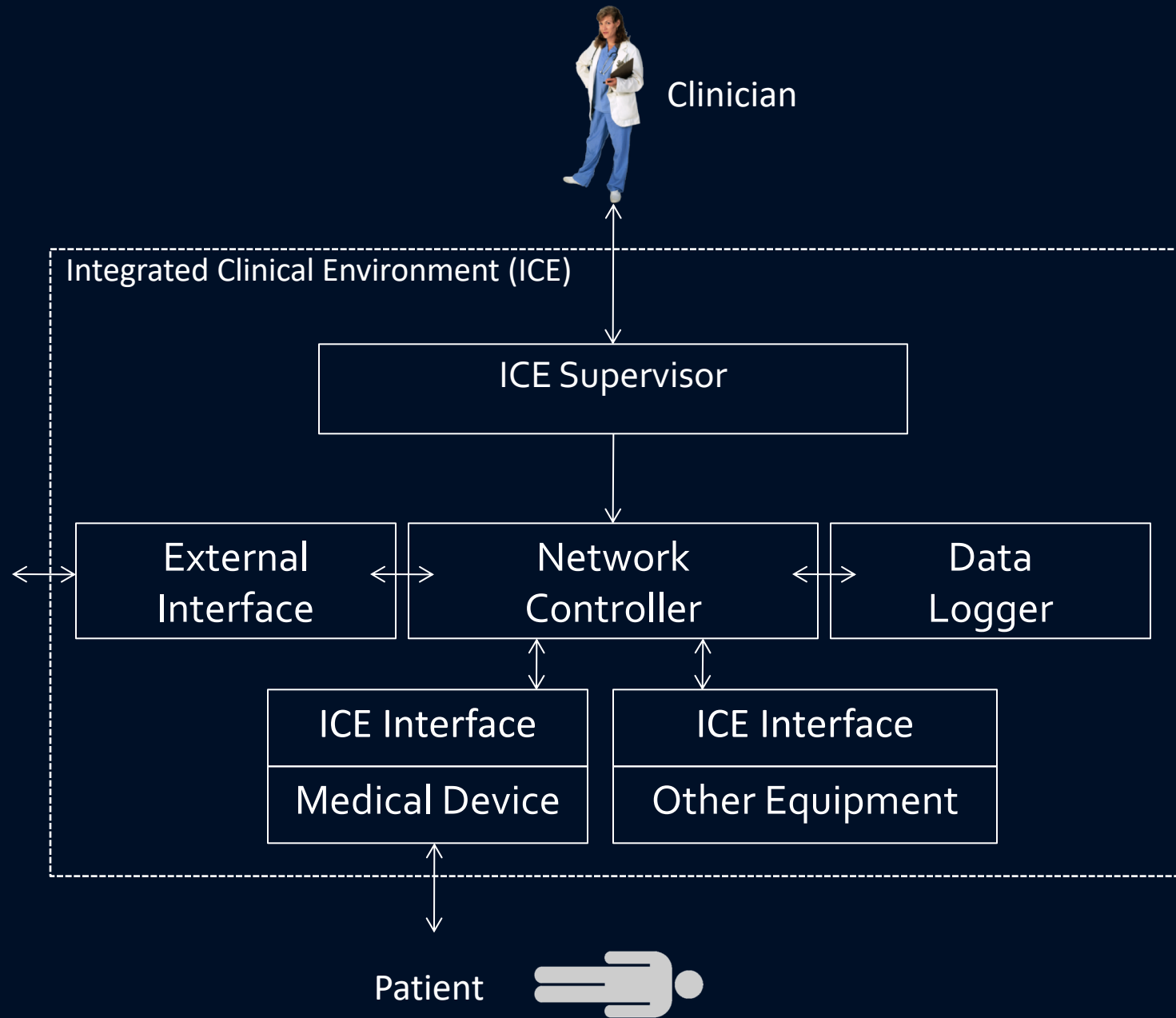
- Single Patient DB and App
- ICE System App
- Medical Device (MD)
- Interface
- Multiple Patient DB
- ICE Clinical App
- Hospital IT systems

Data Logging – Black Box Recorder

- Systems integrate together generate new risk profiles
- Multiple Vendors could be part of root cause
- Black Box Recorder/Data Logger in ASTM F2761
- RTI Recording Service utilized as mechanism
- Recording service subscribes to every topic
 - Records transactions
 - Records data
- Re-playable

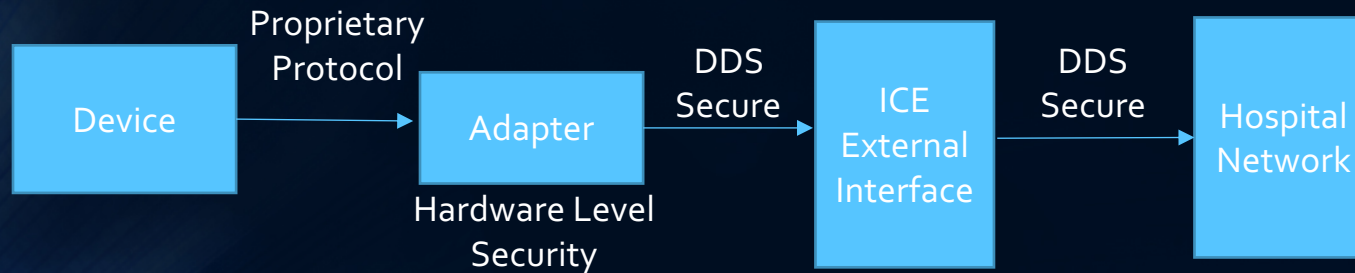
Cyber Security

- Medical Devices are at risk for cyber attacks
- Legacy devices are at greater risk
 - Patching is difficult
 - Hospital Architecture uses isolation as primary mitigation
 - Lack sophisticated communication
 - Lack network visibility
 - Security is a Patient Safety Issue
 - Protect patient first then hospital network
 - Who was impacted by vulnerability? Did it cause patient harm (Operations Analytics)



Potential Solutions

- Smart Micro-isolations (ICE)
- Device off hospital network – Data Available
- Data specific configuration
- Configurable
- Data Centric
- Can protect PHI
- Protect Legacy Devices



Agenda

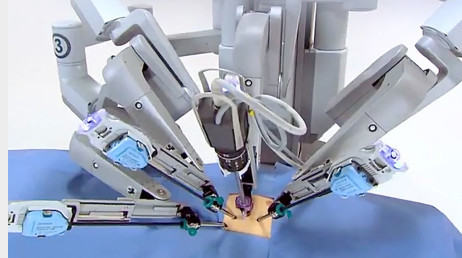
- The Current State of Healthcare
- The IIoT as Potential Solution
- Challenges to Implementation
- The Case for an Open Standard Architecture in Healthcare
- From Concept to Reality - The Development of a Commercial Offering
- **Summary**
- Q & A



David Niewolny

Director, Healthcare Market
Real Time Innovations (RTI)
United States, Austin TX

DDS: A Databus for Intelligent Medical Devices



Streaming Analytics
& Control

HMI/UI

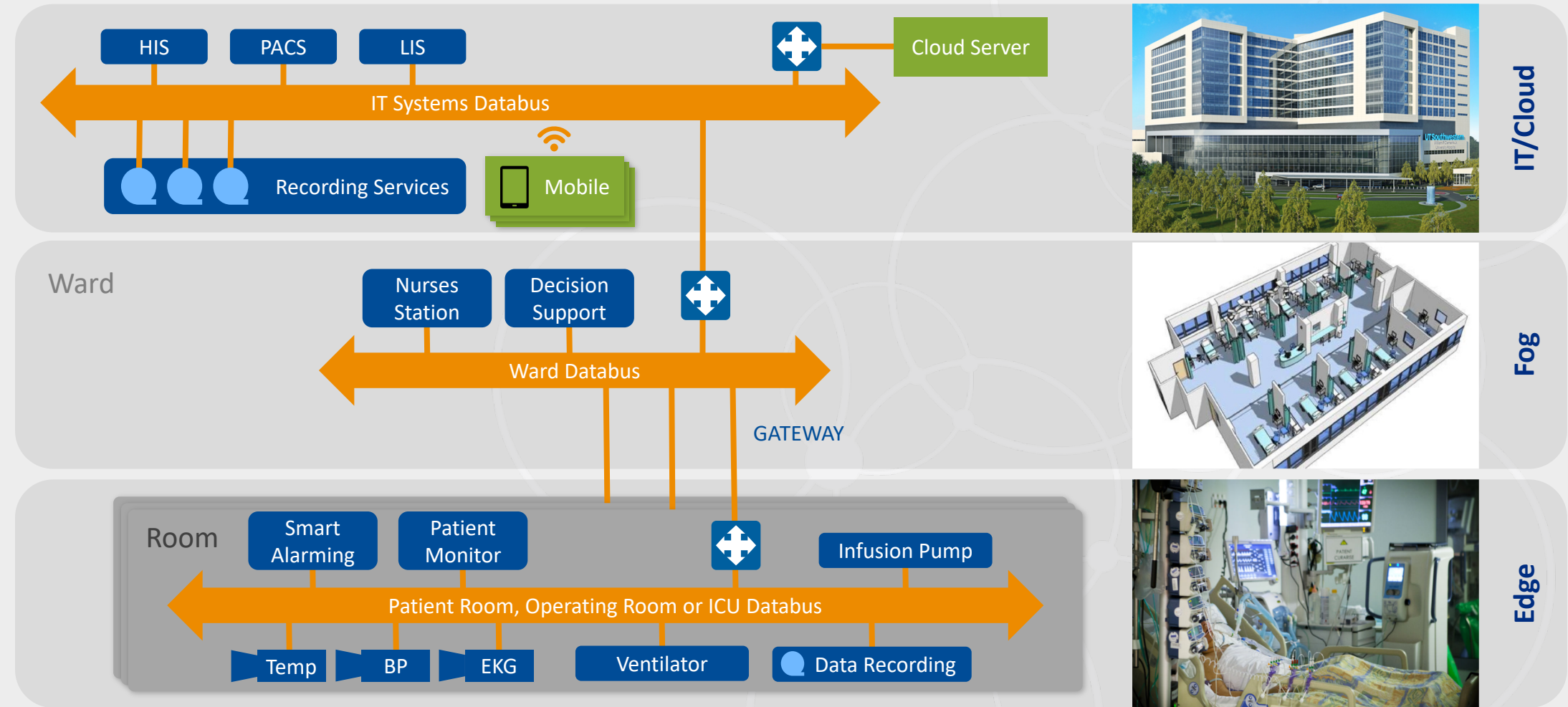
IT, Cloud &
System of Systems
Connectivity

RTI Connexx Databus

Sensors

Actuators

RTI Connex DDS Solution for Healthcare IIoT



Questions?



rti.com/industries/healthcare



[rti_software](https://twitter.com/rti_software)



[rtisoftware](https://www.facebook.com/rtisoftware)



blogs.rti.com



[connextpodcast](#)



Learn More

- Contact MD PnP - Dr. Julian Goldman
 - <http://www.mdpnp.org/>
 - jgoldman@mdpnp.com
 - 617-395-5692
- Contact Doc Box – Tracy Rausch
 - www.docboxmed.com
 - tracy@docboxinc.com
 - 857-598-2819
- Contact RTI – David Niewolny
 - www.rti.com/industries/healthcare
 - David.Niewolny@rti.com
 - 512-785-9255



rti.com



rti_software



rtisoftware



blogs.rti.com



connextpodcast

Thank You!



rti.com/industries/healthcare



[rti_software](https://twitter.com/rti_software)



[rtisoftware](https://www.facebook.com/rtisoftware)



blogs.rti.com



[connextpodcast](#)

