

# Challenges Faced In Developing Safe Interoperable Systems in Healthcare

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# Challenge

Develop and implement of open, safe and effective interoperable system of systems, based on clinical requirements, which enables the creation of evidence based improvements in clinical care.

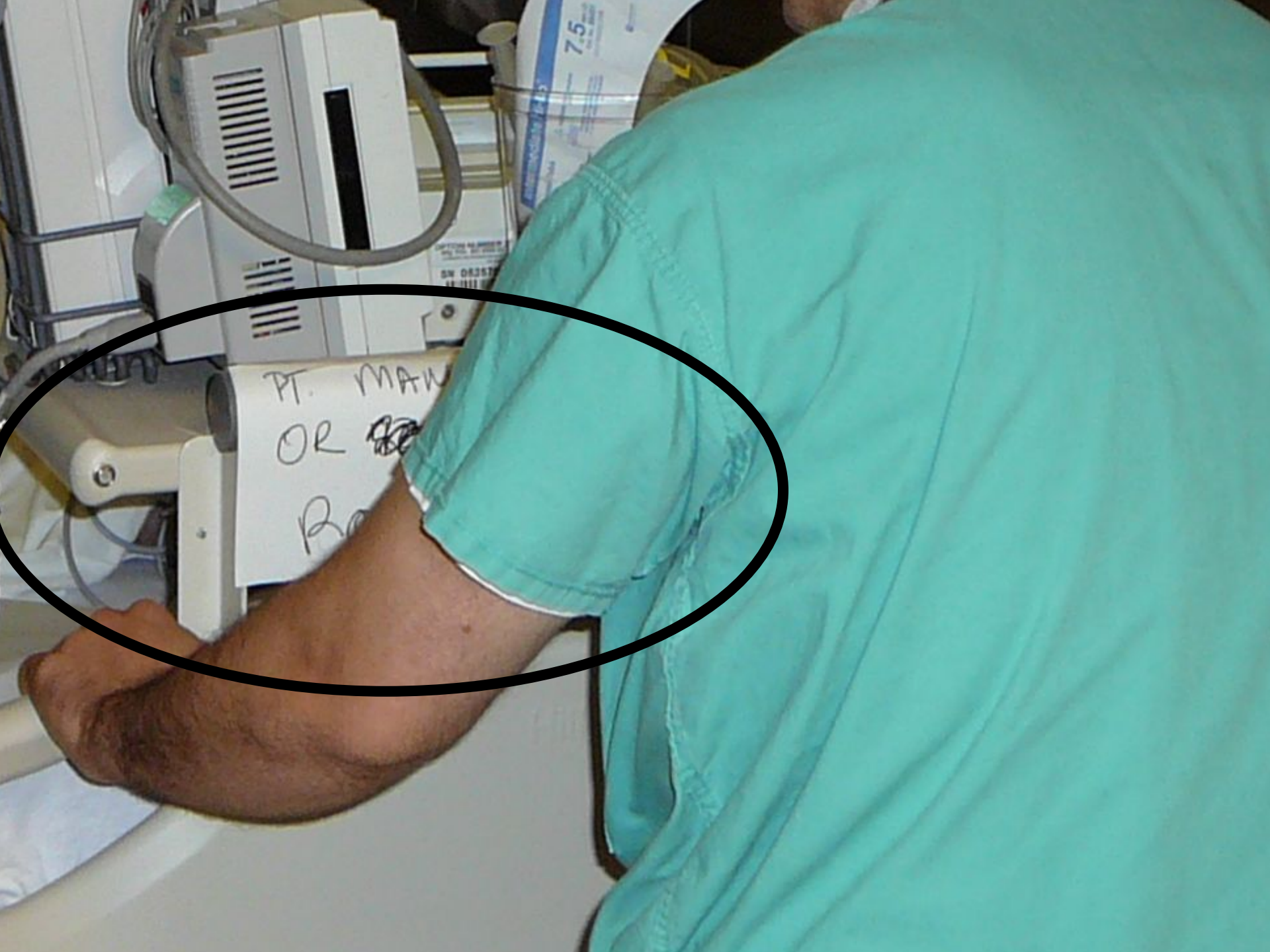
# Requirements from Providers

- Complete and Accurate Data
- Safe Systems
- Secure Systems
- Increased Efficiency
  - Clinical Workflow
  - Device and Systems Maintenance
- Improved Quality
- Flexible (Inpatient to Outpatient)
- Able to deal with new and legacy equipment
- Scalable
- Facilitation of decision support and data visualization









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OR ~~80~~  
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# Problems

- ~400,000 people a year die from medical errors.
- \$5000 - \$7000 per hospital admit is the estimated cost of adverse events.
- Data has incorrect or inaccurate time stamps
- Data is incomplete and incorrect
- Data lacks context
- Lack of data models systems level data models which describe the patient

# Current Device System Solutions

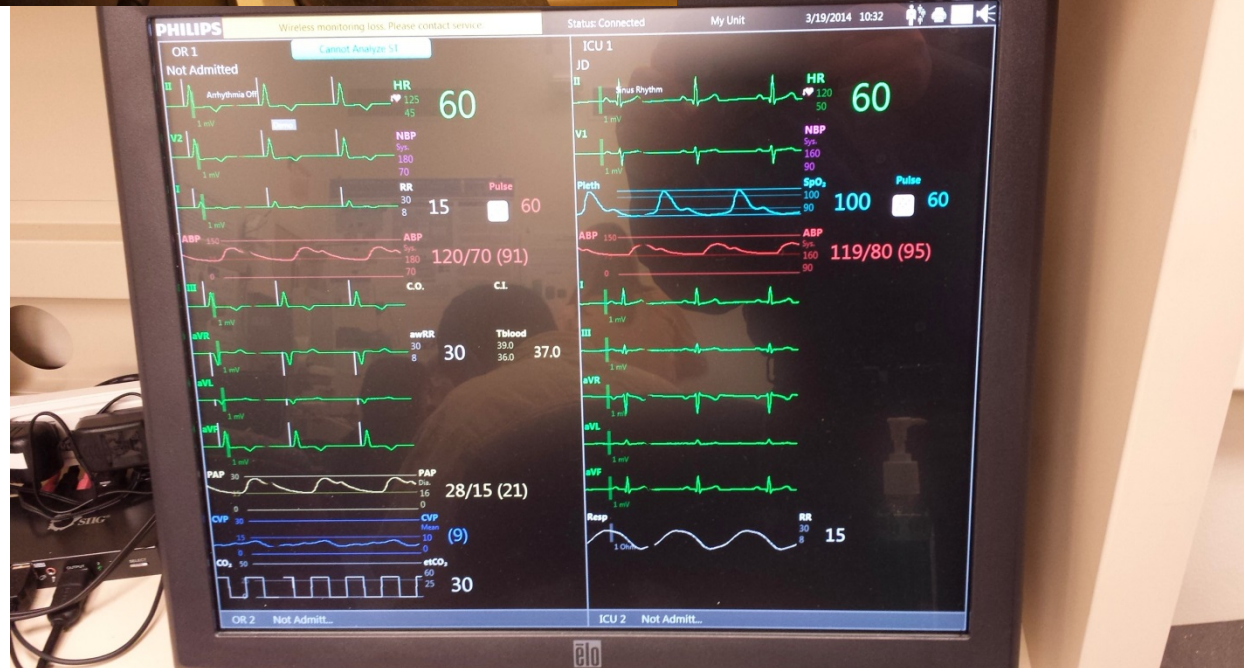
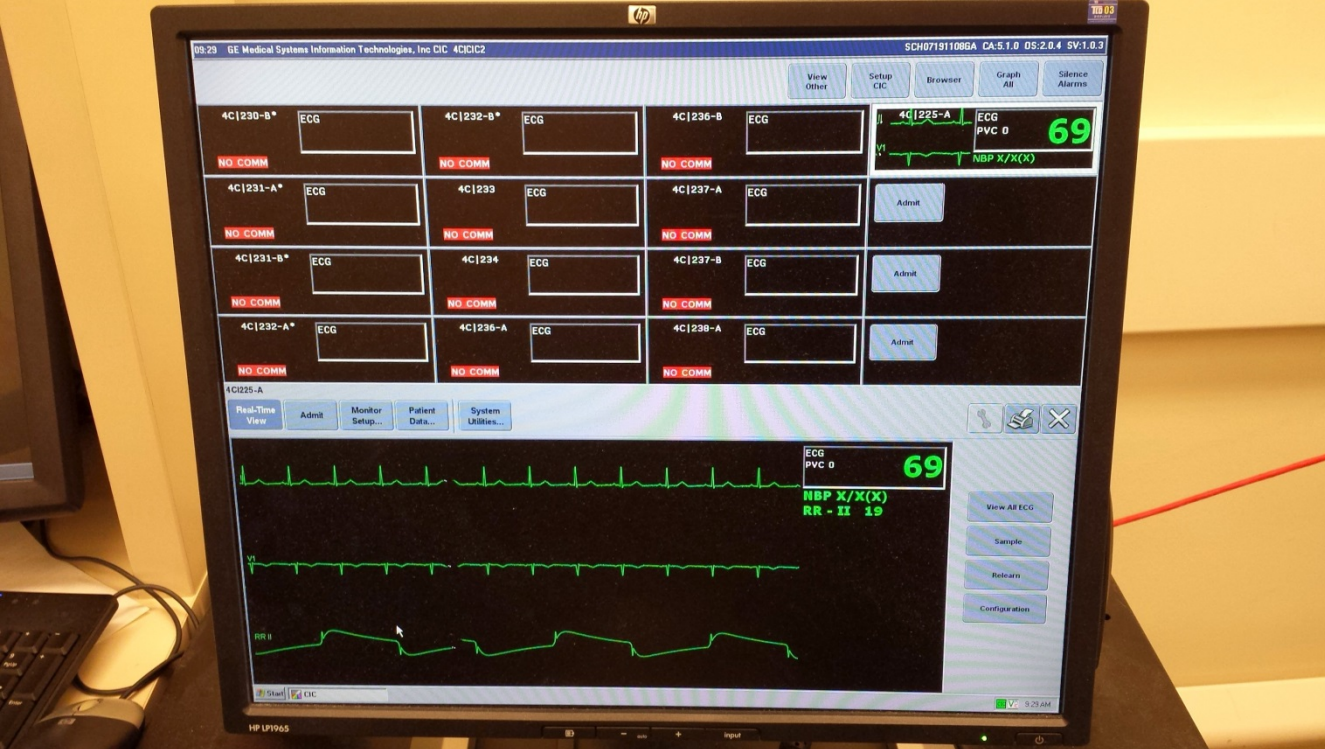
- Vertically Integrated
- Proprietary
- Lacks Data Models
- Lacks correct time stamps
- Lacks contextually complete data
- Alarms are currently mostly limit alarms or single source alarms.



What about EHR's?

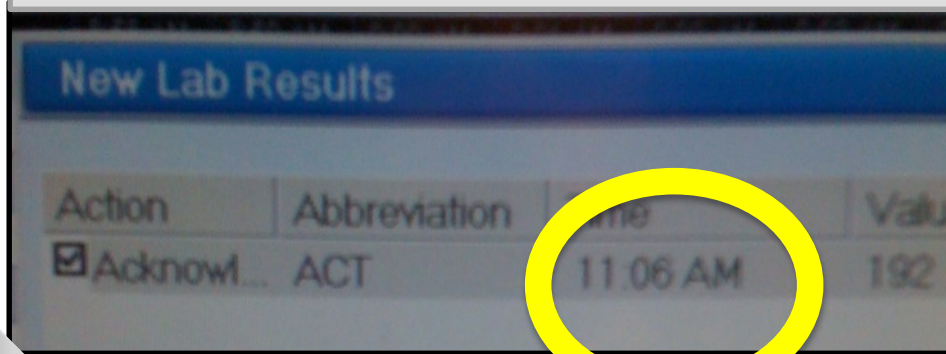
What about Big Data?

What about Quality Improvement  
Systems



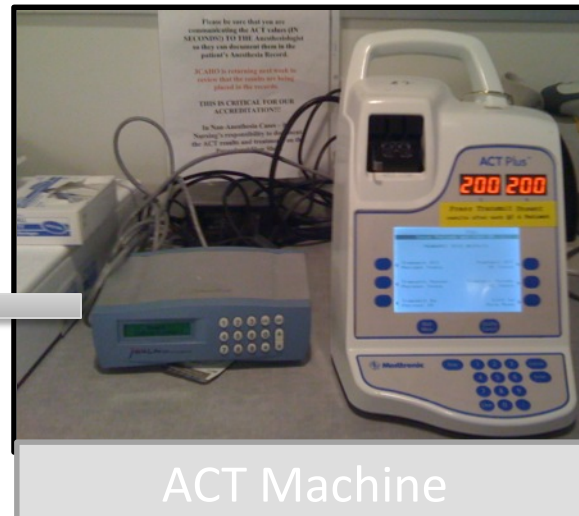
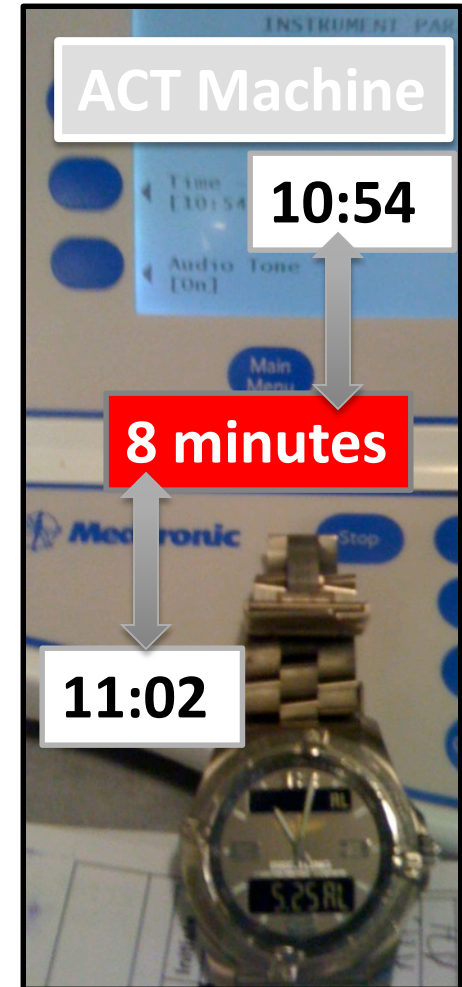


MetaVision EMR screen



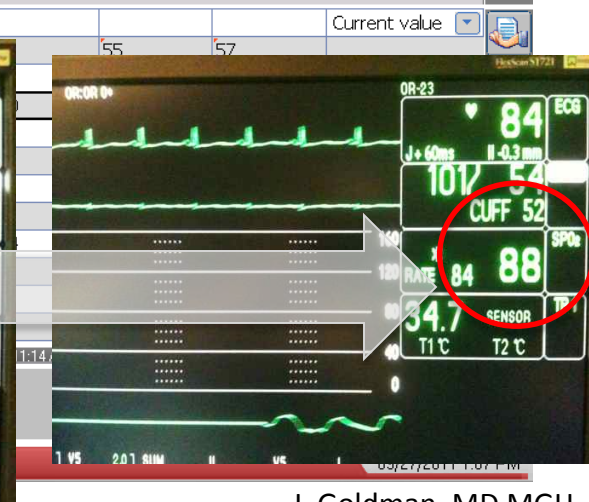
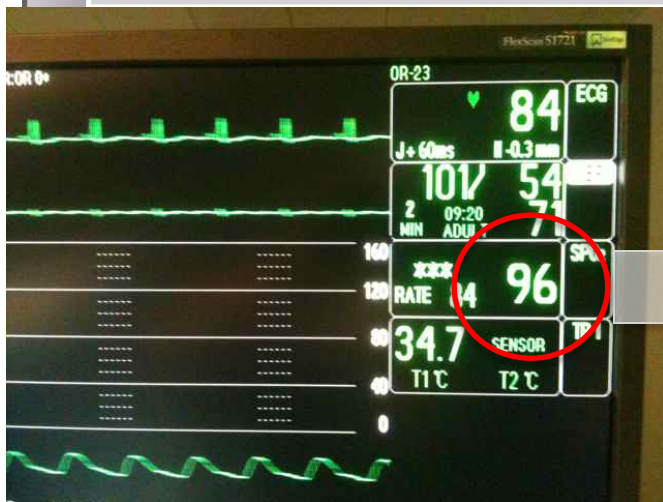
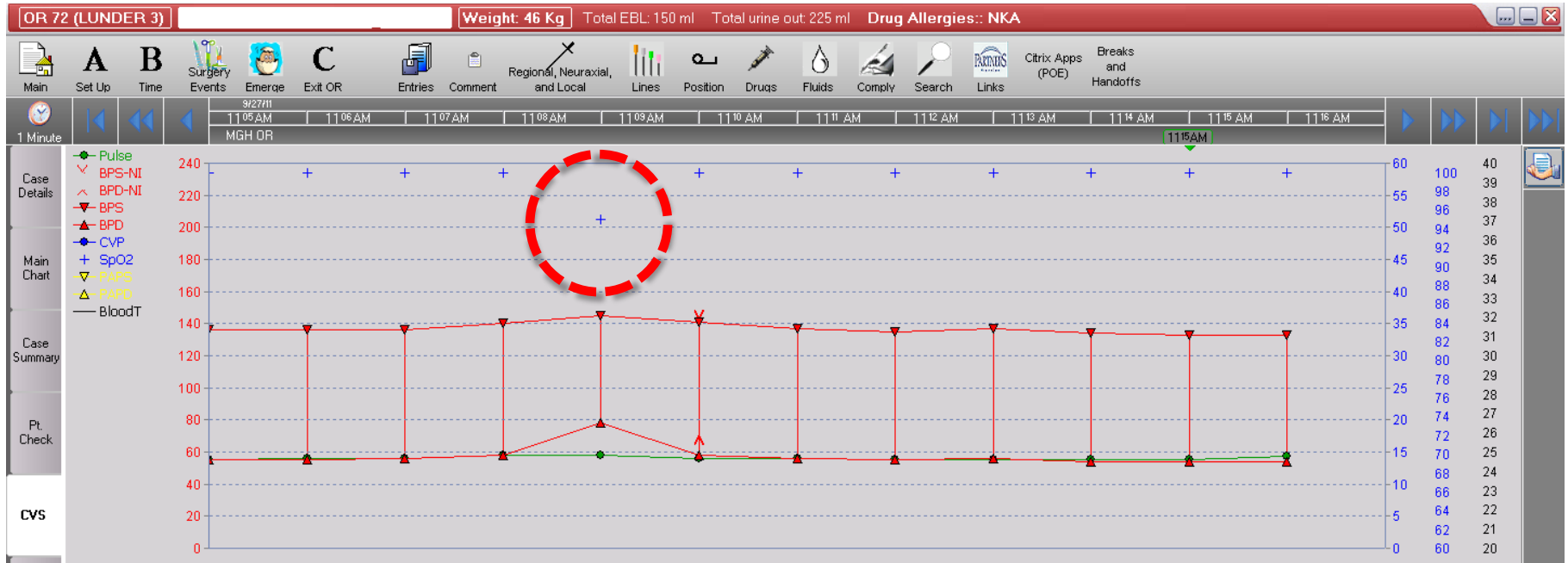
## EMR time-stamp error

ACT – appeared to have been checked 22 minutes after heparin administration (was actually 30 min). Could → stroke.  
Cause – ACT device time incorrect  
(Note - device does not use NTP)



“smarter algorithms” need to consider time course of device operations and interactions

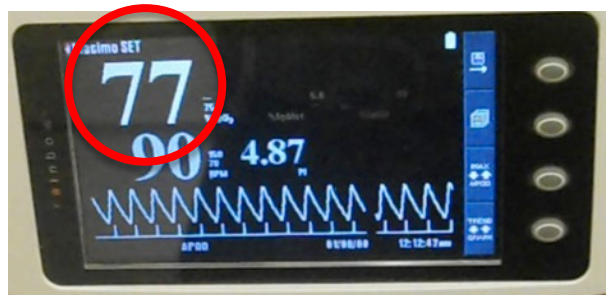
# BP Cuff-SpO<sub>2</sub> Interaction (same arm)



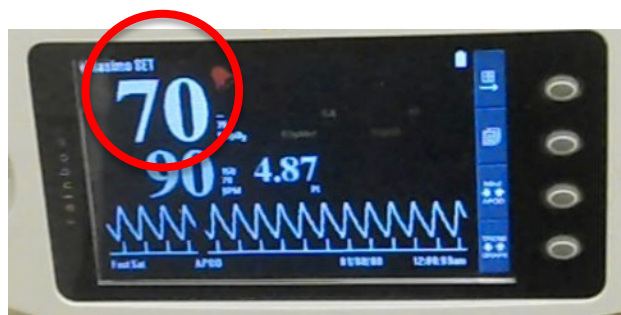
Pulse Ox is set to:  
16 sec averaging time



8 sec averaging time

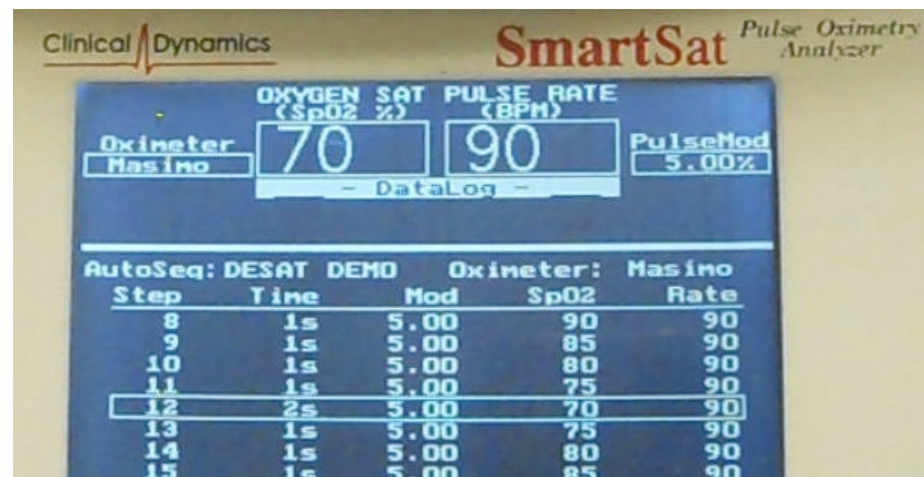


2 sec averaging time



**What is the real O<sub>2</sub> saturation?  
Which value will be recorded in EHR  
or used by analytics engine**

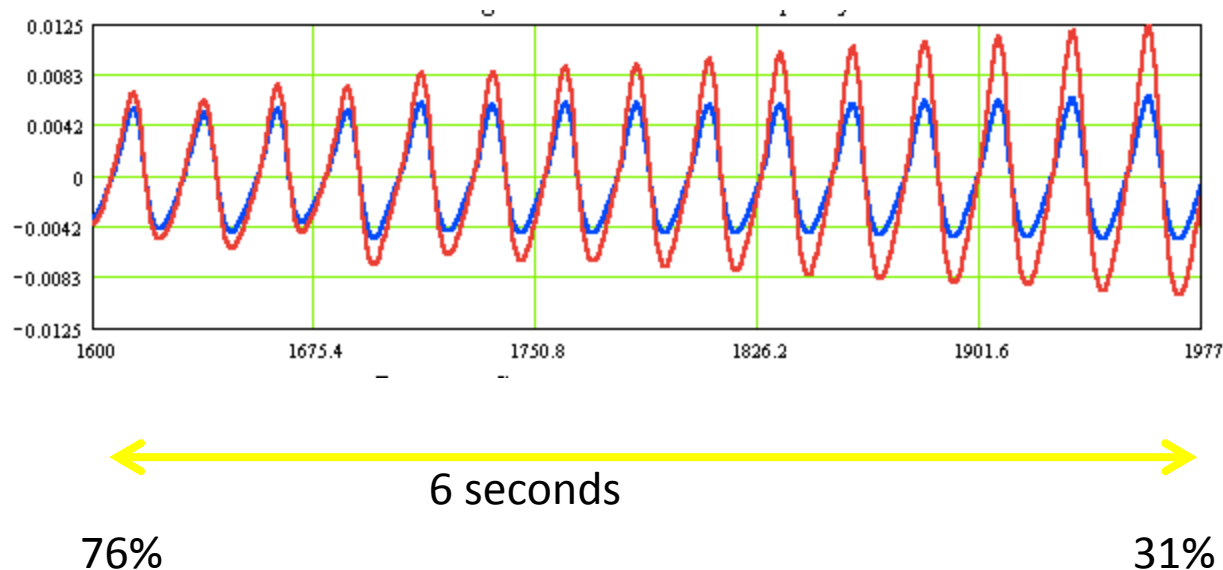
Experiment: Pulse Oximetry  
Simulator is set to create transient  
de-saturation  
99%→70%→99%



Photos of pulse ox screens when  
they display the lowest  
saturation



# Pulse oximeter signal averaging can hide physiological changes



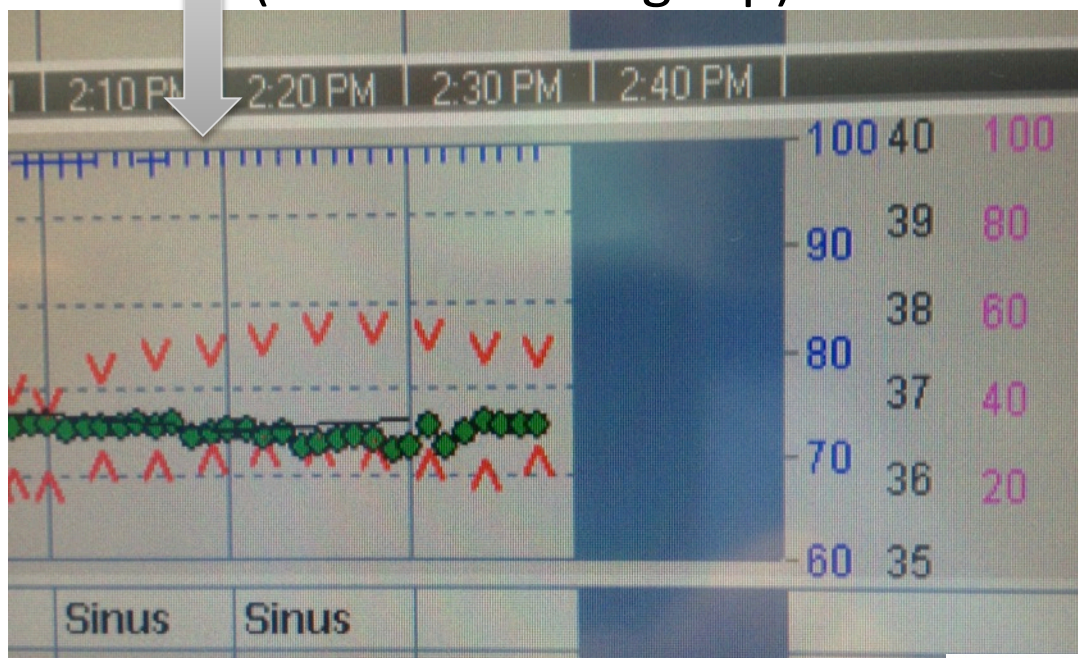
Studies suggests that in pre-term infants the desaturation rate may be as high a 7-10% per second (Poets et.al. Early Human Dev. 26, 1-12).



- 84% oxygen saturation detected by bedside physiological monitor
- Not recorded in permanent record

Patient Monitor  
Recorded Low  
SpO<sub>2</sub> Alarm Event  
"84%"

No evidence of low SpO<sub>2</sub> in EHR  
(blue ticks along top)



# EHR data – 1 point collected

←----- 60 Seconds -----→

Example of possible EHR sample point

Pulse Oximeter Displayed  
SpO2 at 8-second  
averaging time SpO2= 75

**Based on this example,  
EHR May record SpO2 as:  
75%**

Patient's "actual" SpO2 minimum = 70%





# Sources of variation in EHR documentation d/t Data Sampling

←----- 60 Seconds ----->

Example of possible EHR sample points for 1-minute recording

Pulse Oximeter Displayed  
SpO2 at 8-second  
averaging time SPO2= 75

Patient's "actual" SpO2 minimum = 70%

Based on this example,  
EHR May record SpO2 as:  
**98%**  
**92%**  
**80%**  
**75%**  
**Etc.**



The Future is Now!



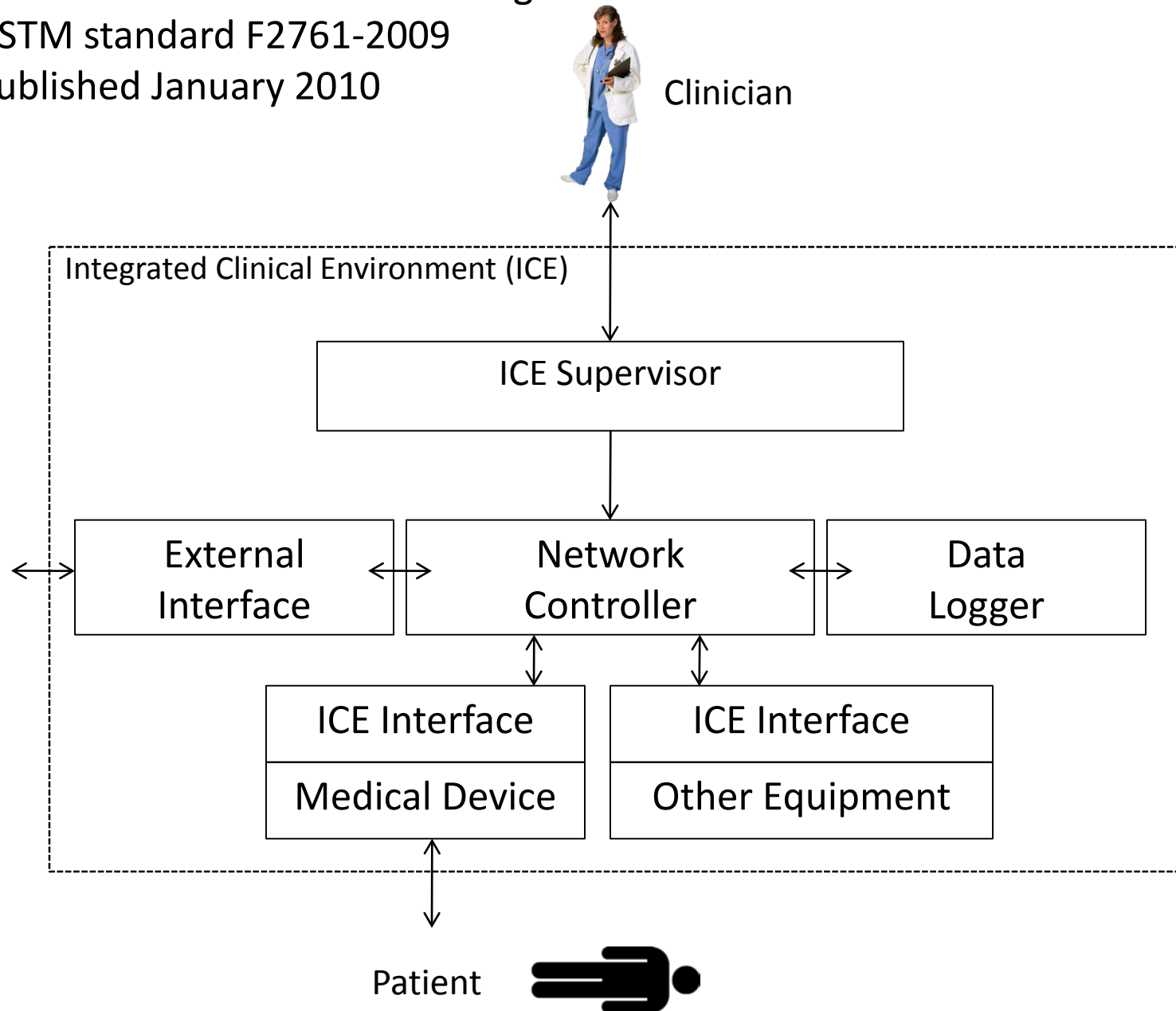
# The Future

- Requirements Requirements Requirements
- Consider the System
- Re-think Architecture
- Open Communication across vendors
- Design the System to be a learning System
- Learning System (black box recorder)
- Regulatory Considerations
- Modeling of data using a patient/data-centric approach.

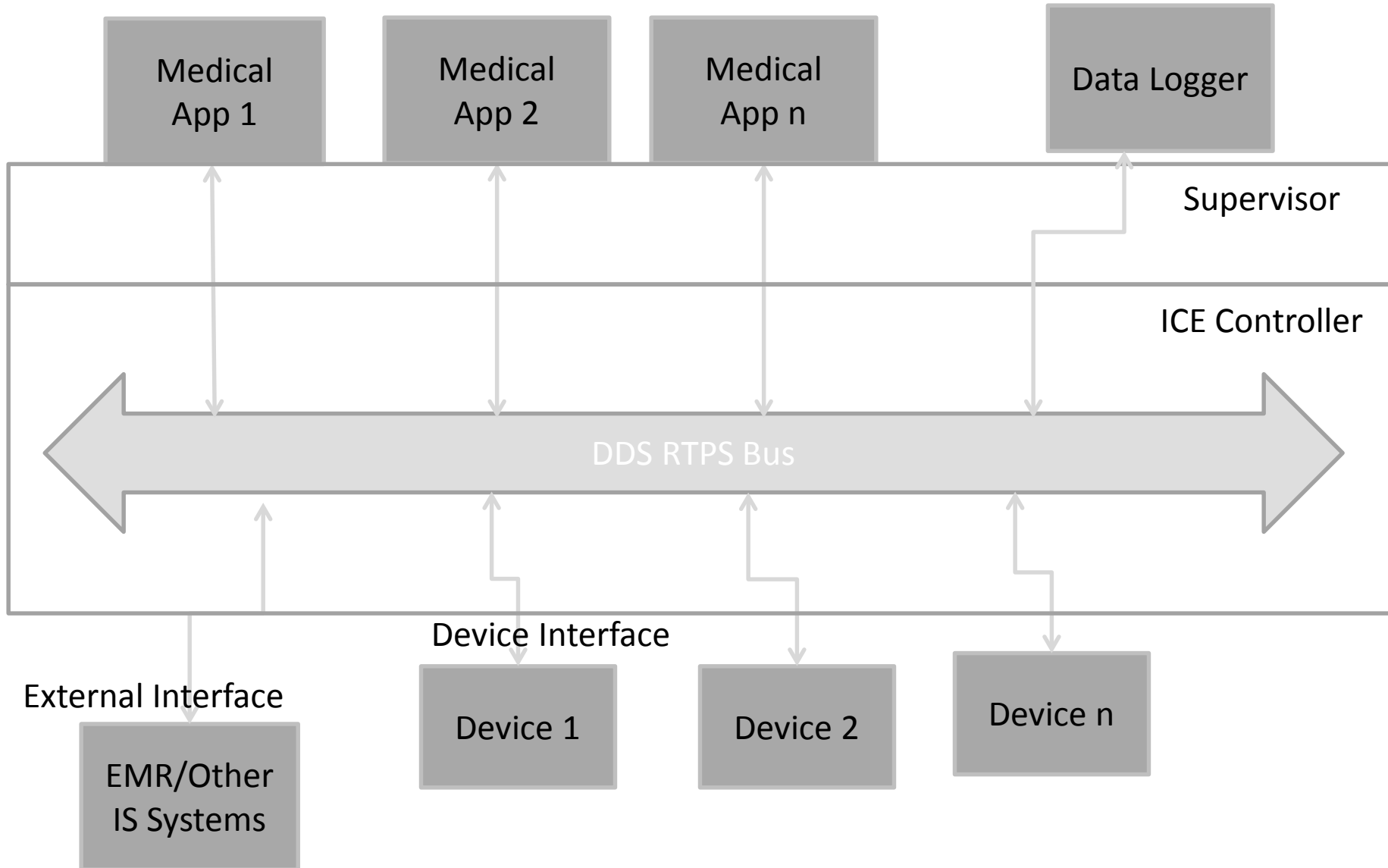
# Functional Elements of the Integrated Clinical Environment

ASTM standard F2761-2009

Published January 2010

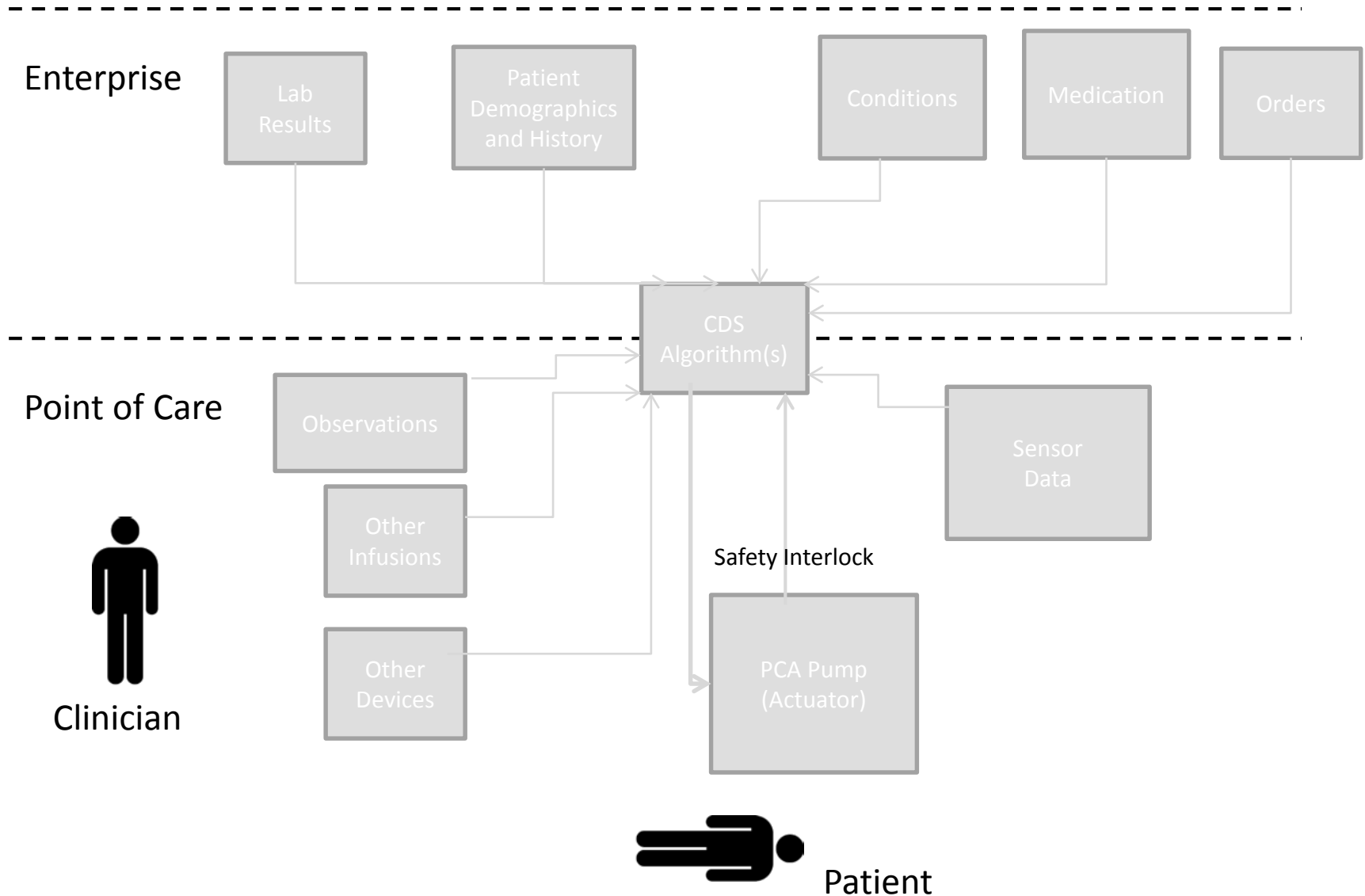


# Data-centric Approach

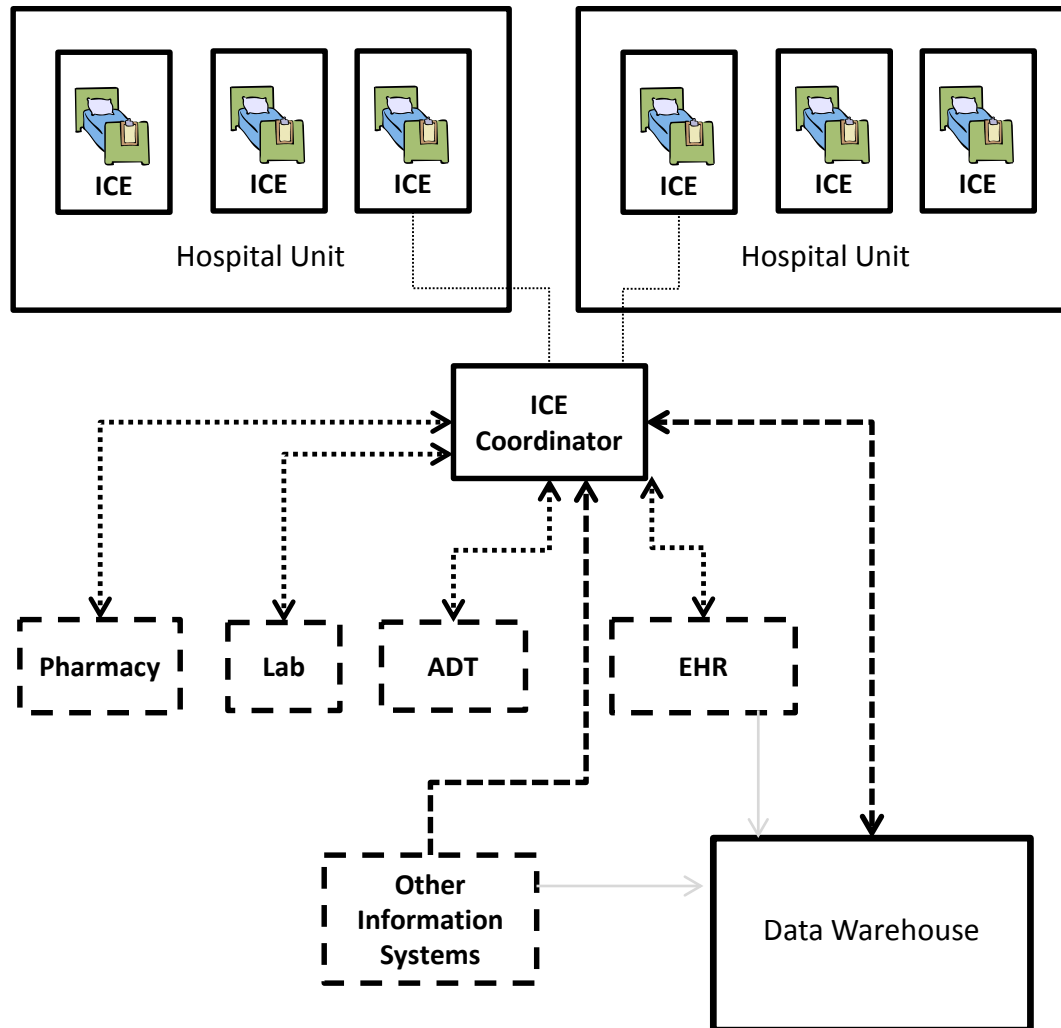




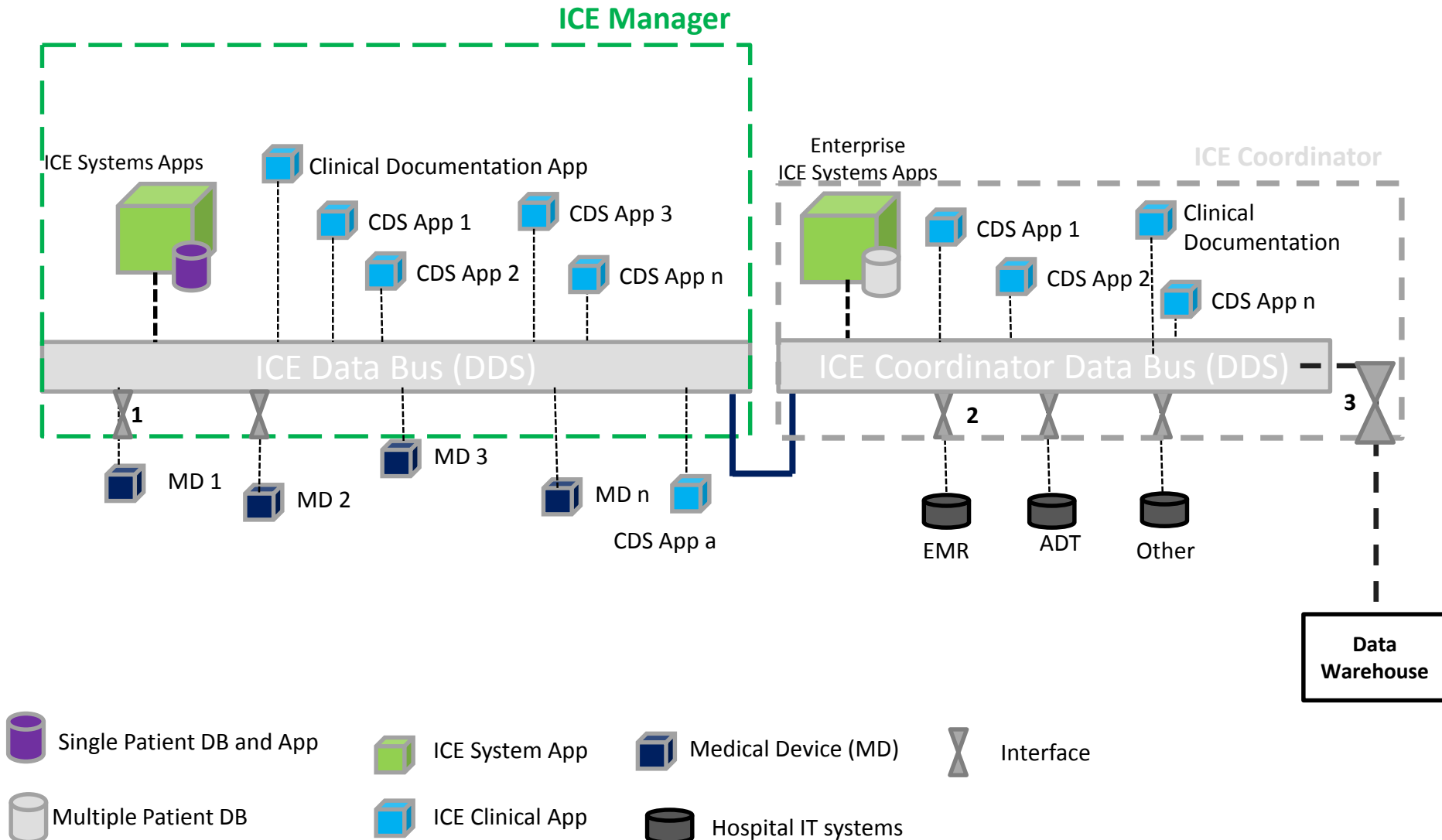
# Smart PCA System App

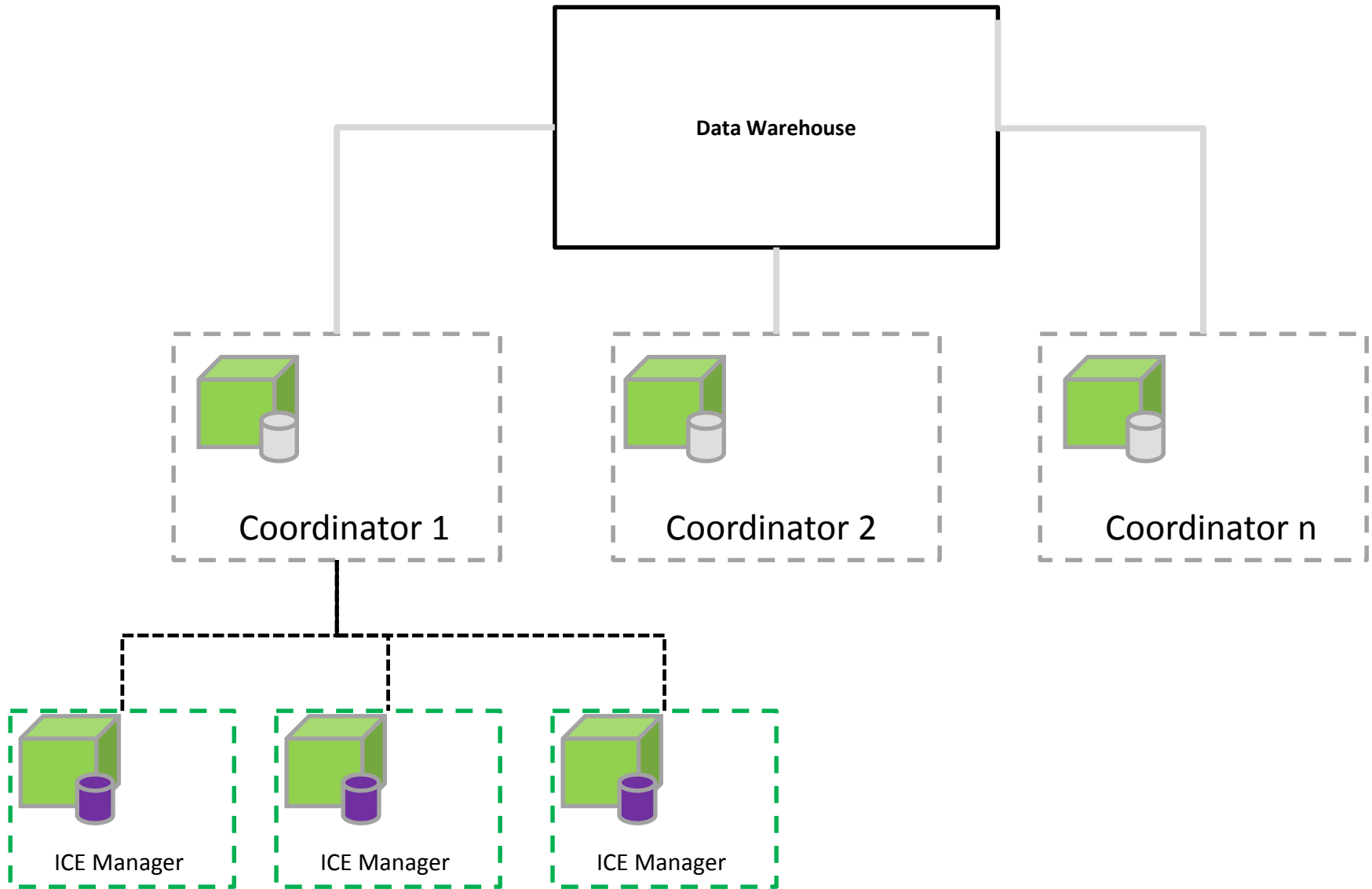


# ICE System within Hospital IT Systems



# Architectural Diagram

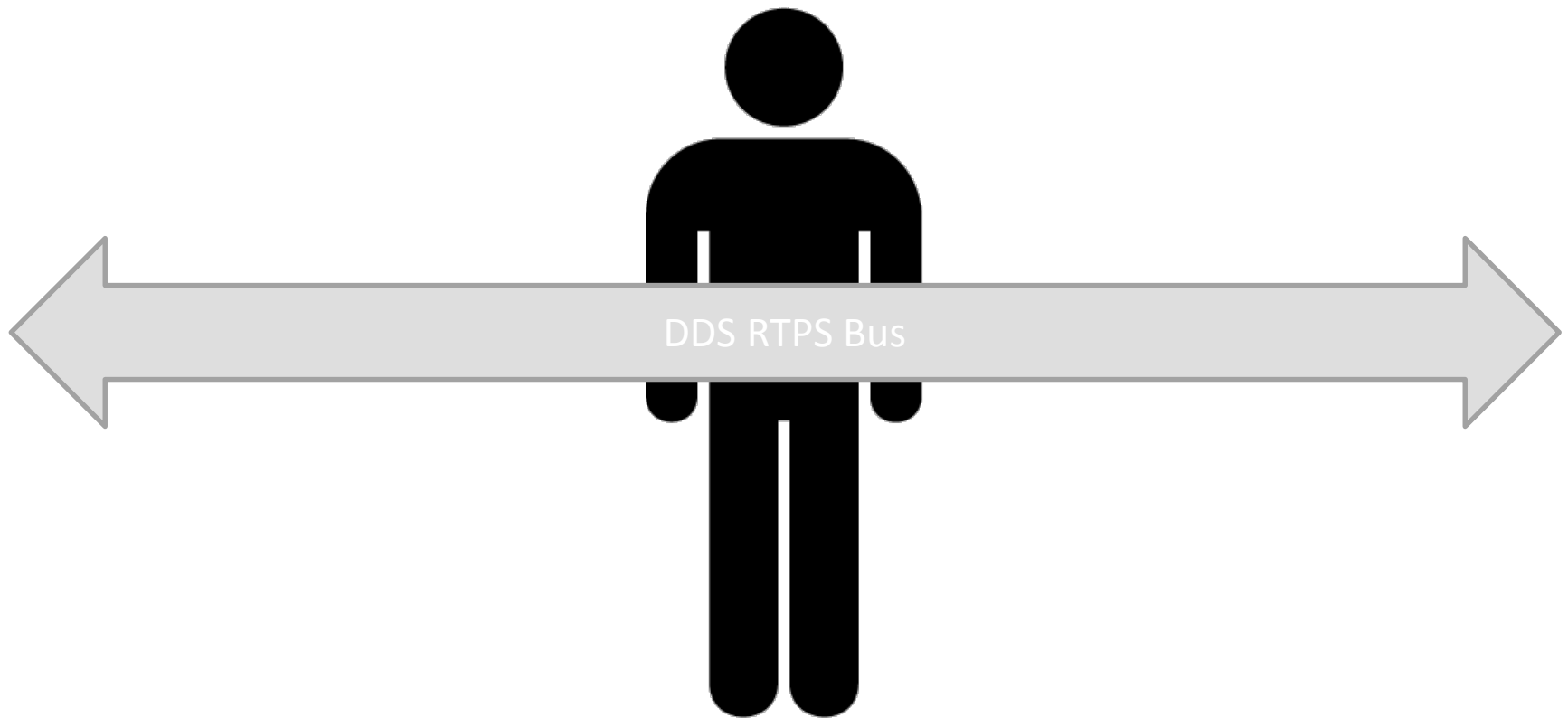




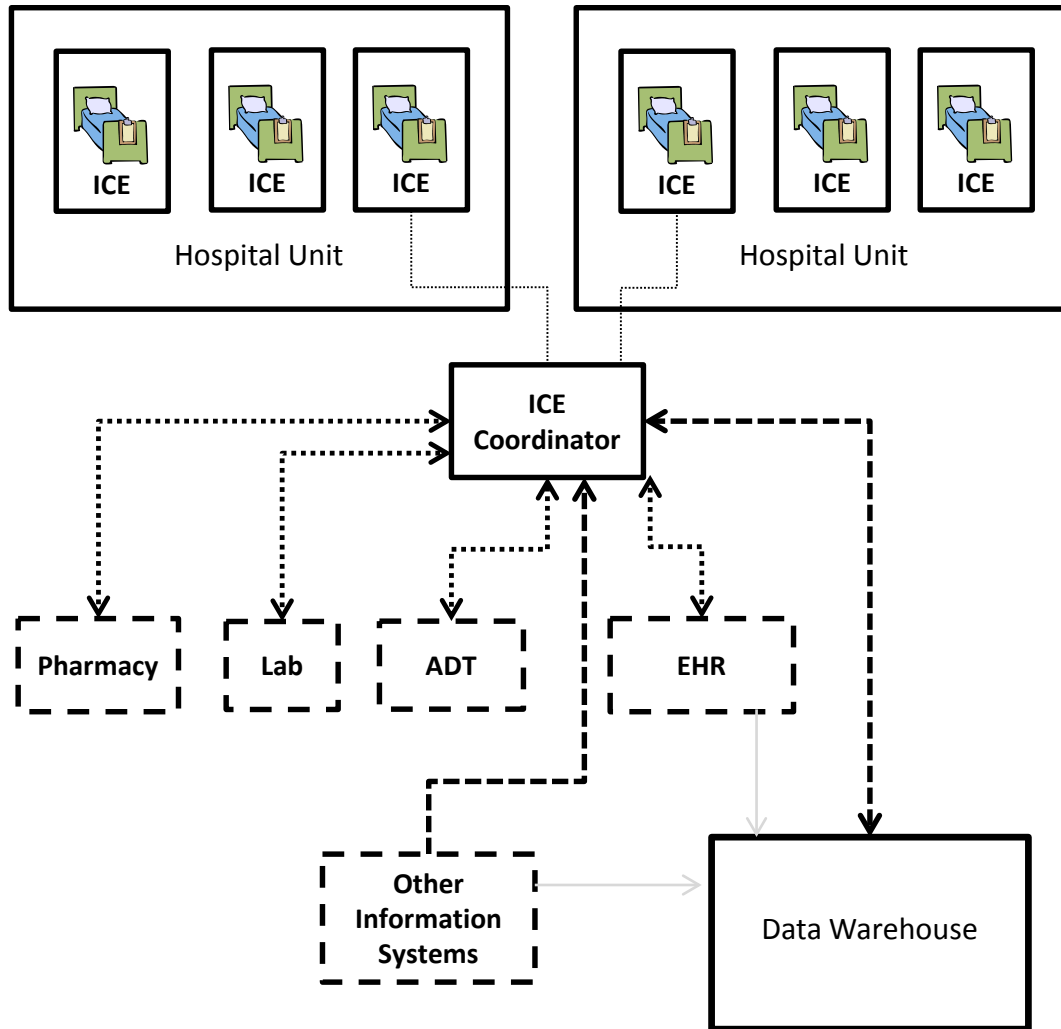


# Patient Information Model

- System of Systems model based on the patients data.



# ICE and Analytics



## Categories of Analytics

Real Time Analytics  
Patient Specific CDS

Unit Level Analytics

Hospital and  
Hospital Systems  
Analytics

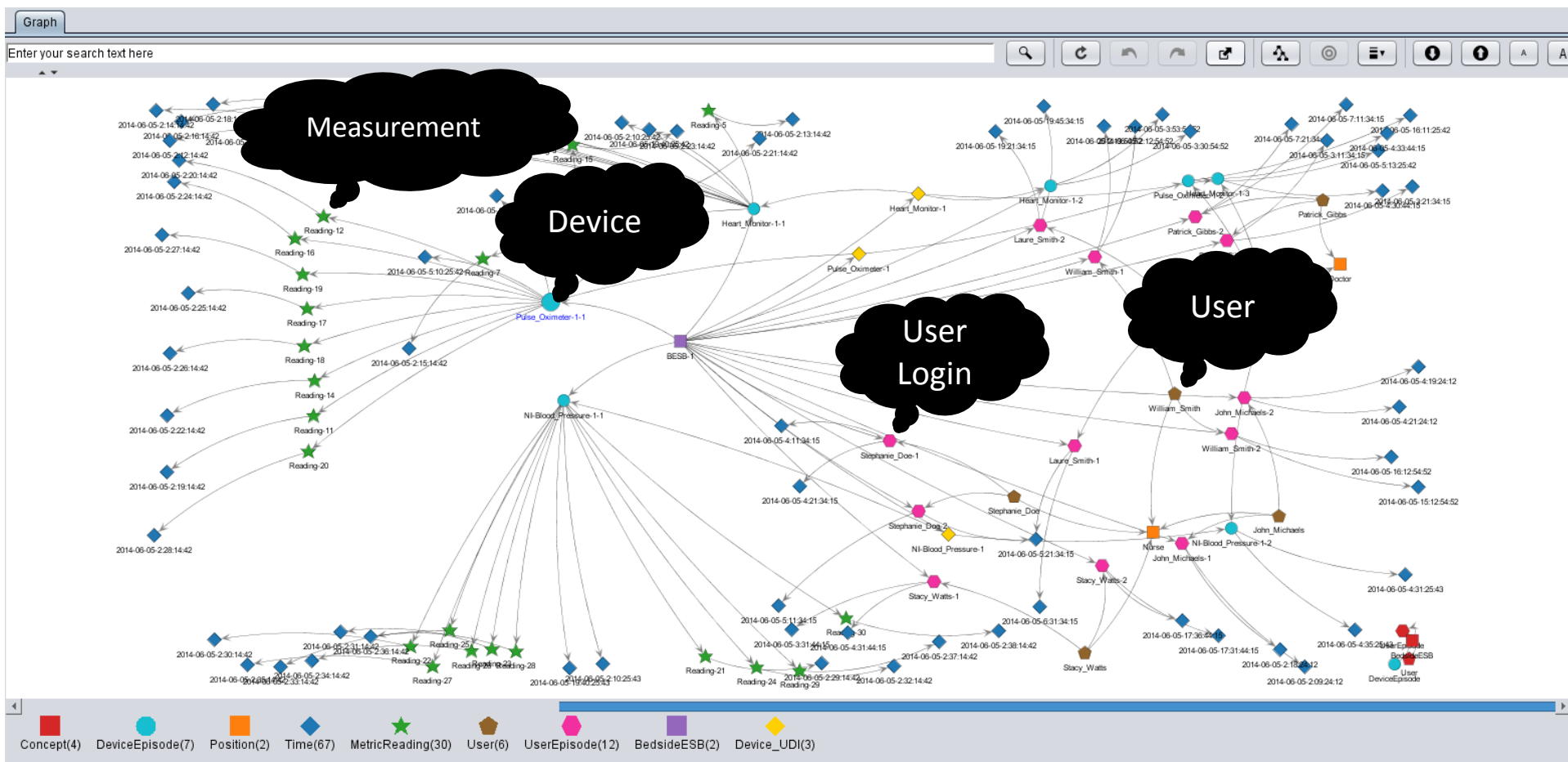
Clinical Studies  
and  
Outcomes Analytics

Real Time

Long Term &  
Retrospective

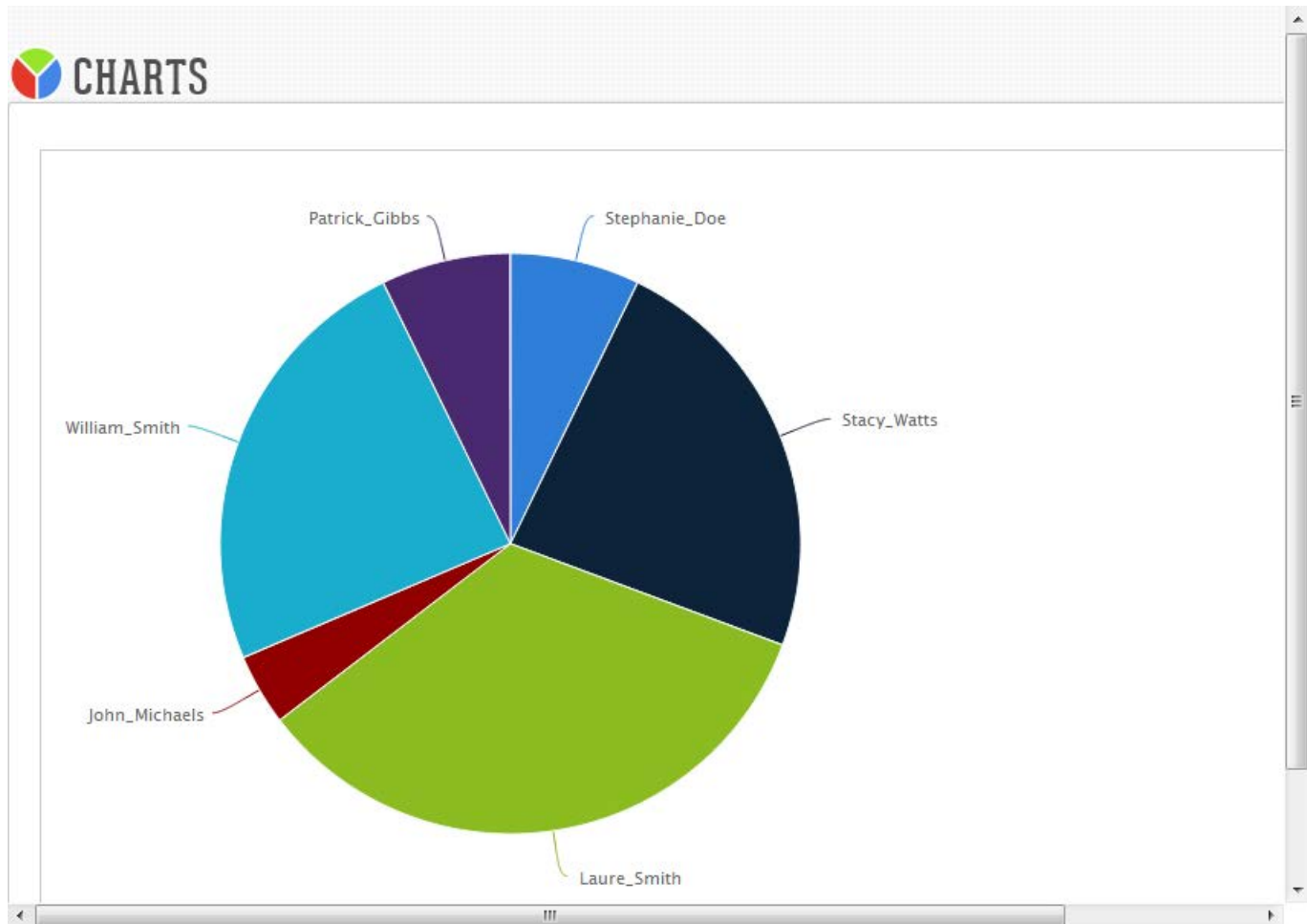


# Relationships of Data





# Clinical Staff Patient Care





# Questions??

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