NSF CPS Large Site Visit
PRECISE Center at Penn
Jan 31, 2012

Medical Device Interoperability Ecosystem Updates: Device Clock Time, Value Proposition, and the FDA Regulatory Pathway

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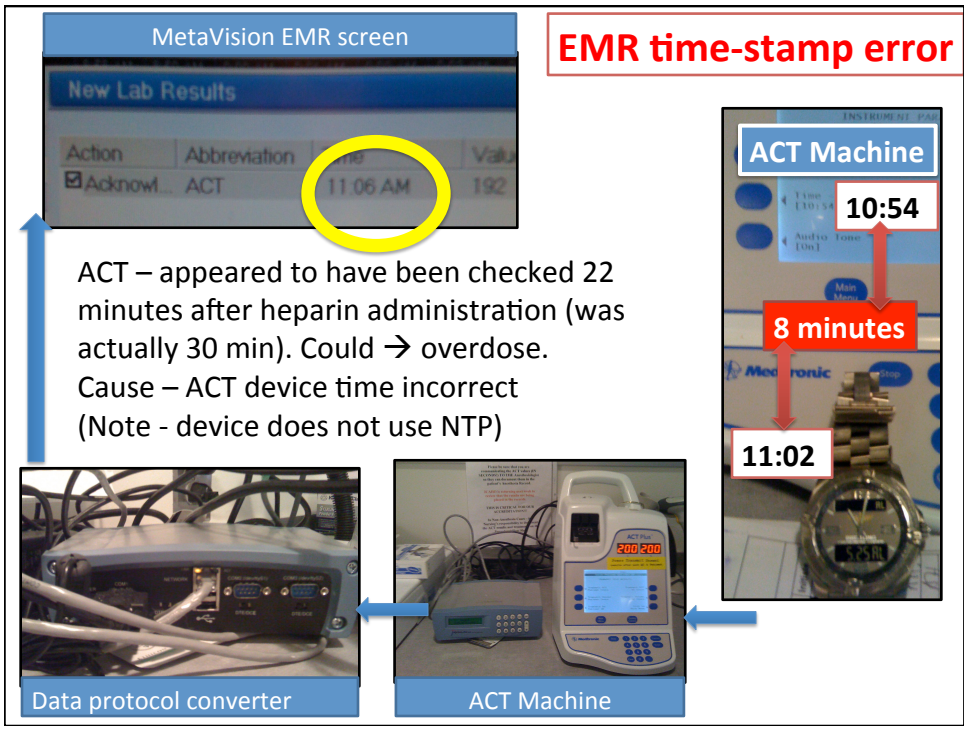
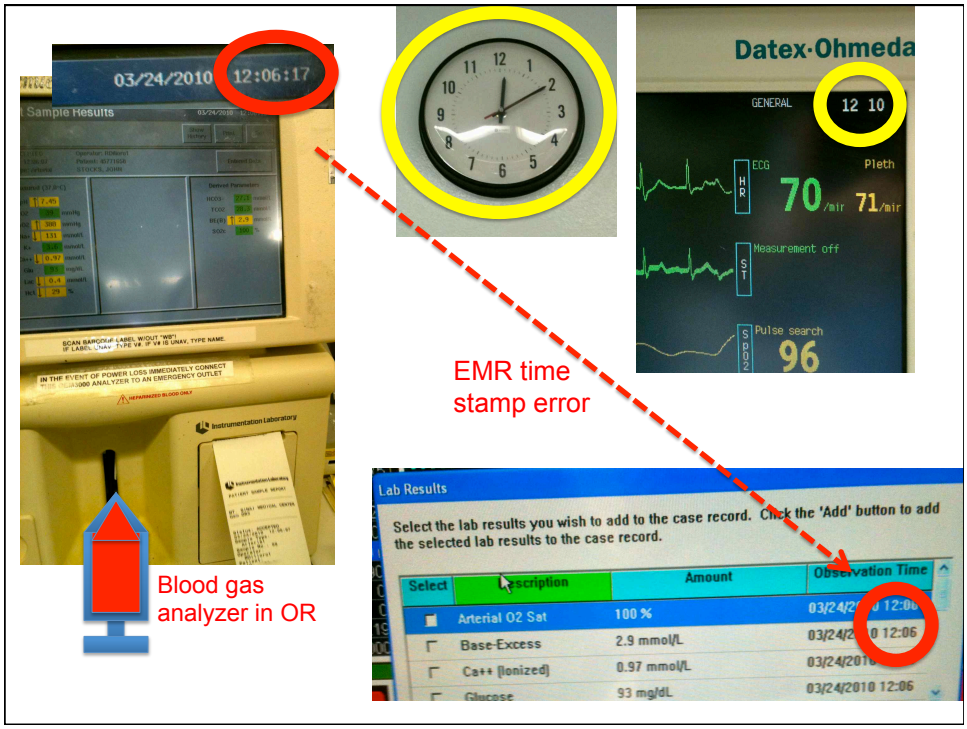




Time & Clock Errors

- Most of the data is entered manually
  - Reported times in the records may come from
    - Clock on the wall
    - A medical device
    - Clinician's wristwatch
    - Device adapter
    - Device gateway
    - EMR
- Thus, even something as simple as the start time of surgery or the time an infusion was started may be different in the nursing record versus the device clock time versus the anesthesia record.

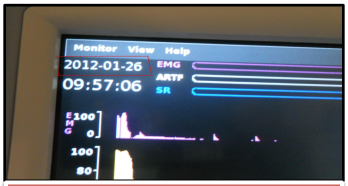
Clock Sync Challenges

- Many medical devices do not set their clock using a network time reference (eg: NTP)
- Manually twice a year – Daylight Saving Time Change
- No adopted standard for medical device time management
- EMR time stamping is configurable:
  - time stamp from medical device
  - time stamp when the data is acquired
- No method to maintain consistency among all time stamps contained in the patient's EMR.

Why is this important?

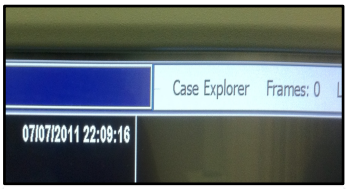
- Undermine integrity of EMR
- May lead to inappropriate therapy
- Complicate QA analysis
- Introduce liability concerns
- Security implications
- Who owns this problem? Med device manufacturers? EMR vendors? System integrators? Middleware vendors?
- What will it take to have medical devices with accurate clock?

Sample Pictures



Reference Date=07/11/11
Reference Time = 08:07:24

Brain Function Monitor (SED Line)



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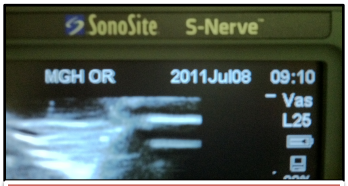
Imaging System



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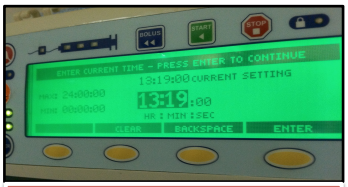
Ultrasound Machine



Reference Date=07/08/11
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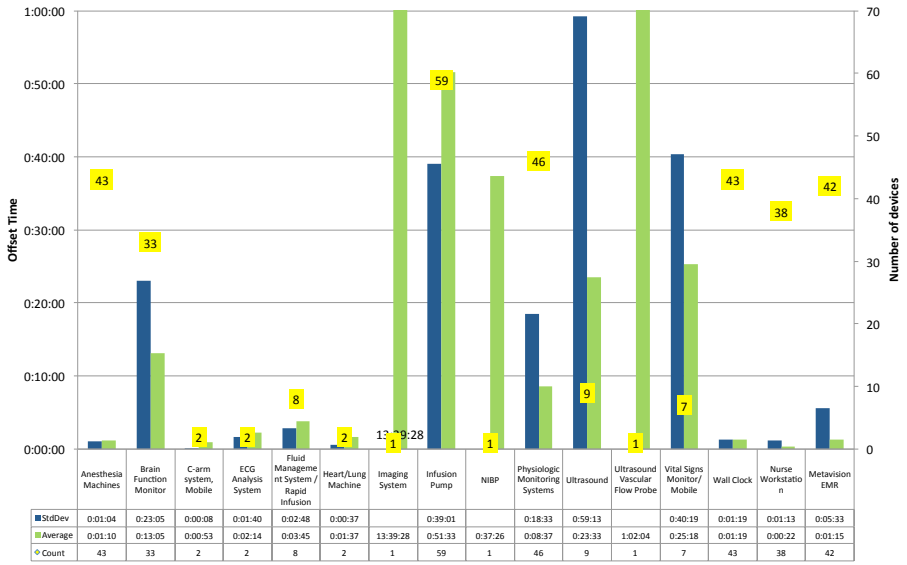
Infusion Pump

Draft – unpublished data

MGH OR Device Offsets

Blue – StdDev, Green-Avg, Yellow-Count

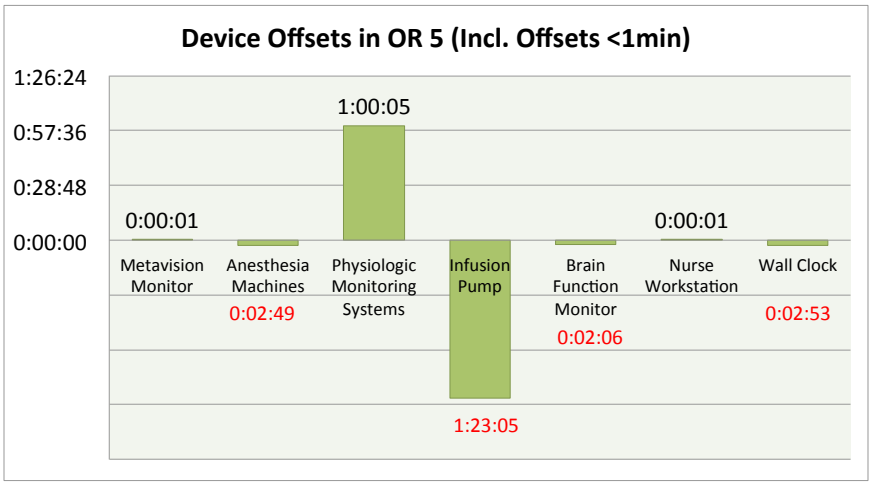
Device Offsets at MGH OR



	Anesthesia Machines	Brain Function Monitor	C-arm system, Mobile	ECG Analysis System	Fluid Management System / Rapid Infusion	Heart/Lung Machine	Imaging System	Infusion Pump	NIBP	Physiologic Monitoring Systems	Ultrasound	Ultrasound Vascular Flow Probe	Vital Signs Monitor/ Mobile	Wall Clock	Nurse Workstation	Metavision EMR
StdDev	0:01:04	0:23:05	0:00:08	0:01:40	0:02:48	0:00:37		0:39:01		0:18:33	0:59:13		0:40:19	0:01:19	0:01:13	0:05:33
Average	0:01:10	0:13:05	0:00:53	0:02:14	0:03:45	0:01:37	13:39:28	0:51:33	0:37:26	0:08:37	0:23:33	1:02:04	0:25:18	0:01:19	0:00:22	0:01:15
Count	43	33	2	2	8	2	1	59	1	46	9	1	7	43	38	42

Draft – unpublished data

Example of OR Data



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MGH OR Offsets Summary

Maximum Offset:	Minimum Offset:	St. Dev. Of Offset:	Average Offset:	Total number of devices	Number of devices with -ve offset	Number of devices with +ve offset	Number of devices with Zero Offset
13:39:28	0:00:00	0:52:30	0:16:00	337	166	163	8

Offset Duration	Count of Devices	% of Devices
more than 2 sec	303	89.9%
more than 1 min	179	53.1%
more than 5 min	84	24.9%
more than 10 min	66	19.6%
more than 15 min	65	19.3%
more than 30 min	58	17.2%
more than 1 hour	38	11.3%

Medical Device Clock Accuracy Study

- Institutions (4) :
  - Massachusetts General Hospital (MGH),
  - Brigham and Women's Hospital (BWH)
  - Hospital of University of Pennsylvania (HUP)
  - Johns Hopkins Hospital (JHH)
- Total number of clocks: 1732
- Total number of medical devices (Excl. Work Stations & Wall Clocks): 1323

- Types of devices, included:
  - Physiological Monitors
  - Infusion Pumps
  - Anesthesia Machines
  - Ventilators
  - Ultrasound Machines
  - Portable Vital Signs Monitors
  - Transport Monitors
  - Pulse Oximeters
  - Dialysis Machines
  - Defibrillators
  - EKG Analysis Systems
  - And others…

Draft – unpublished data

Clock Study Collaborators

Hospital of University of Pennsylvania (HUP)

- Dr. Insup Lee - Cecilia Fitler Moore Professor, Department of Computer and Information Science, Upenn.
- Dr. Oleg Sokolsky - Research Associate Professor, Department of Computer and Information Science, Upenn.
- Soojin park, MD - Director of Neurocritical Care Monitoring and Informatics
- Margie Fortino, MSN, RN - Operations Director, Penn e-lert eICU

Johns Hopkins Hospital (JHH)

- James C. Fackler, MD – Anesthesiology & Pediatrics
- Maria Cvach MS, RN, CCRN - Assistant Director of Nursing, Clinical Standards
- Dina A. Krenzischek, PhD, MAS, RN, CPAN – PACU Nurse Manager
- Jeff Frank – Clinical Engineering Manager
- Judy Ascenzi, MSN – Clinical Nurse Specialist, Pediatrics

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Consolidated 4 Hospital Summary (Draft)

Device Type	Count	StdDev Offset	Average Offset	Maximum Offset
Medical Devices (Excl. Workstations & Wall Clocks)	1324	1:32:34	0:33:26	16:42:10
All devices	1732	1:22:12	0:25:58	16:42:10
Networked Devices that Auto-Sync	291	0:02:16	0:00:53	0:31:16
Stand-alone Devices	950	1:46:38	0:46:06	16:42:10
Hospital A	52	0:31:11	0:30:25	1:52:00
Hospital B	495	1:41:23	0:32:55	16:42:10
Hospital C	468	0:47:12	0:17:10	13:39:28
Hospital D	717	1:27:24	0:26:35	13:18:47

Draft – unpublished data

Sample Device Offsets by Device Type

Device Type	Count	StdDev of Device Offset	Average of Device Offset
Anesthesia EMR	66	0:04:27	0:00:53
Anesthesia Machine	70	0:24:31	0:18:23
Bladder Scanner	10	2:57:14	2:20:10
Cerebral/Somatic Oximeter	12	3:36:58	1:36:49
Defibrillator	42	0:10:39	0:04:50
EEG machine	14	0:17:00	0:05:10
EKG Analysis System	32	0:25:05	0:16:26
Glucometer	10	0:00:22	0:00:34
Heart Lung Machine	6	5:12:09	2:32:43
Hemodialyzer	16	0:02:23	0:03:20
Infant Warmer/Incubator	17	0:23:50	0:43:52
Infusion Pump	359	2:01:27	1:01:49
Infusion Pump (Ambulatory)	11	0:22:43	0:48:10
Infusion Pump (Epidural)	12	0:44:09	1:13:02
Infusion Pump (Rapid Infusion)	8	0:02:48	0:03:45
Medication Mgt. Sys	64	0:01:02	0:02:03
Medication WorkStation	15	0:00:01	0:00:01
Nurse Workstation	98	0:05:45	0:01:02
Phys Monitor	382	0:22:25	0:06:08
Transport Monitor	20	1:06:12	0:36:37
Ultrasound	34	2:52:57	1:10:25
Ventilator	67	0:25:21	0:18:05
Vital Signs Monitor/ Mobile	51	2:45:03	1:20:49
Wall Clock	229	0:13:54	0:02:23

Draft – unpublished data

Incorrect dates

Device Location	Device Location (Room)	Device Type	Manufacturer/ Model	Date Picture Taken	Date on Device	Device Offset (DAYS)
General Unit	Patient Tower	Bladder Scanner	BVI 3000	11/7/2011	1/8/2012	62D
Adult ER	Emergency Department	Bladder Scanner	Verathon Medical/ BVI 9400	11/22/2011	11/2/2011	-20D
Adult ER	Emergency Department	Bladder Scanner	Verathon Medical/ BVI 9400	11/22/2011	11/16/2011	-6D
OR	Hallway 1	Imaging System	Volcano S5 Cart Monitor	7/8/2011	7/7/2011	1D
Neuro Angio	Neuro Angio	Radiology Display	*N/A*	11/21/2011	11/18/2011	-3D
PACU	PACU	Ultrasound	Sonosite M-Turbo	11/29/2011	1/1/1970	42 years
NICU	NICU	Ventilator	Drager/ Evita XL	11/29/2011	11/1/2016	5 years

Draft – unpublished data

How much time and money are we spending every year? (Daylight Saving Time Change twice a year)

	MGH Hours/Year (For 868 Beds*) *From MGH Website	National Projection (For 944,277 Beds**) **From AHA
Number of person-hours	320	3,35,066
Number of devices	~1060	
Total cost (Does not include overtime charges)	$ 16,160	$ 17,580,088
Number of people involved	5 people * 2 days	
% Devices auto-timed on network	Less than 5%	

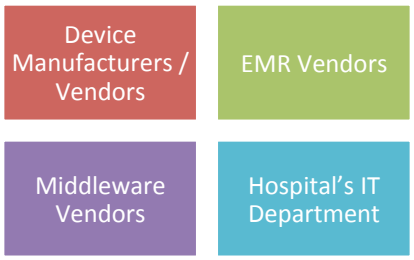
Preliminary data of study-in-progress by MD PnP program

DST – Efforts at MGH

- ***Patient monitoring system:*** At 2:00 am the time on all bedside monitors and central stations will roll back to 1:00 am. Full disclosure data for the hour immediately preceding the rollback (1:00 - 2:00 am) will not be available after the rollback. Clinicians are advised to PRINT any desired full disclosure data from this hour shortly before the rollback occurs.
- ***Large volume and syringe infusion pumps:*** are always set to Greenwich Mean Time (GMT) and will not be adjusted.
- ***PCA/epidural infusion pumps:*** are set to EST year-round and will not be adjusted. During DST the pumps are behind by one hour. When DST ends the pumps will display the correct local time. Clinicians are reminded to carefully note the time on the pump when calculating shift totals.
- ***Laboratory information system-***-- Shuts down for 1 hour.
  - A delay in the online availability of new Lab results from 2 to 3 am.
  - In-patient order entry impact:
    - During the downtime will not print and manual requisitions should be used.
    - Scheduled batch prints for AM labs will not occur during the downtime.
    - After the downtime is over, labels for orders that were written during the downtime will print. Staff will need to review labels printing after the downtime and discard any that may have been drawn during the downtime using manual reqs.
  - No data transmission from POCT handheld devices.

Potential Solutions

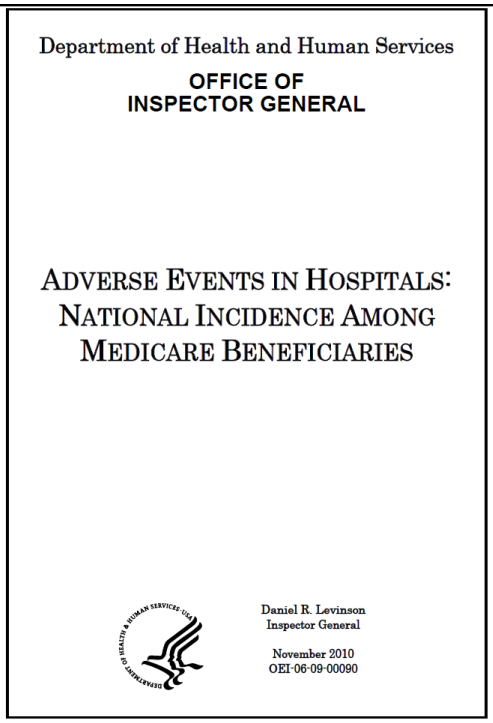
- Device manufacturers could implement automatic clock-setting capability
- Implement time-correction in middleware or the EMR, but
  - Concerns about legal and regulatory issues with altering medical device data
  - Transport monitors?



Manufacturer Issues w/implementation

- No clearly identified standard
- Old/closed code; V&V=$, FDA approval
- Will have to adhere to public spec
- Competitive issues with disclosure
- Revenue from proprietary software
- +/- end user demand
- Patient safety & Cost of healthcare is not their top priority – only providing reliable equipment for intended use

"MD PnP Value Proposition"


Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

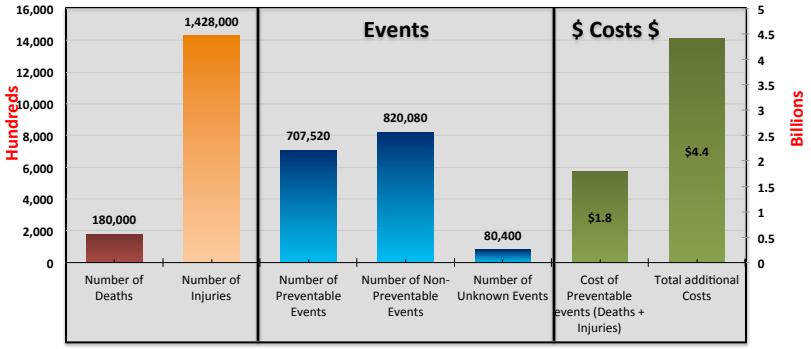
ADVERSE EVENTS IN HOSPITALS: NATIONAL INCIDENCE AMONG MEDICARE BENEFICIARIES

Daniel R. Levinson
Inspector General

November 2010
OEI-06-09-00090

Draft – unpublished data

Adverse Events In Hospitals: National Incidence Among Medicare Beneficiaries, 2008-09



Source: Department of Health and Human Services , OFFICE OF INSPECTOR GENERAL, Nov 2010

- National Medicare patients from the National Claims History (NCH).
- 13.5 % (134k/month) experienced an adverse event (injuries and deaths), defined as an event that met at least 1 of the following 3 criteria:
  - the event was on the NQF list of Serious Reportable Events;
  - the event was on Medicare's list of HACs; or
  - the event resulted in 1 of the 4 most serious categories on the NCC MERP 4 index

  (prolonged hospital stay, permanent harm, life-sustaining intervention, or death).

Preventable and Non- preventable Events resulting in injury/death

Table 8: Events by Physician Preventability Rationales

Preventability Rationale	Percentage of Events*	Estimated Reduction	ESTIMATED Mitigation with ICE (20%)
Preventable Events			= 17.6%
Error was related to medical judgment, skill, or patient management	58%		
Appropriate treatment was provided in a substandard way	46%		
The patient's progress was not adequately monitored	38%	7.6%	Integrated data and smart alarms can reduce by 20%
The patient's health status was not adequately assessed	23%	4.6%	Contextual data display, smart alarms, condition-specific decision support
Necessary treatment was not provided	17%		
Event rarely happens when proper precautions and procedures are followed**	14%	2.8%	Contextual data display, WHO-style checklists
Communication between caregivers was poor**	8%	1.6%	Automatic documentation of device data, smart alarms
Facility's patient safety systems and policies were inadequate or flawed**	3%	0.6%	Can enable implementation of safety policies
Breakdown in hospital environment occurred (equipment failure, etc.)**	2%		
Non-Preventable Events			= 28%
Event occurred despite proper assessment and procedures followed	62%	12.4%	Better data availability and contextual data display
Patient was highly susceptible to event because of health status	50%		
Care provider could not have anticipated event given information available	35%	7.0%	Better data availability and contextual data display
Patient's diagnosis was unusual or complex, making care difficult	29%	5.8%	Contextual data display, smart alarms, condition-specific decision support
Harm was anticipated but risk considered acceptable given alternatives**	14%	2.8%	Reduce risk for these procedures with smart alarms and safety interlocks

See Appendix F for confidence intervals.

*Percentages do not add to 100 because physician reviewers often selected more than 1 rationale.

**Given the small percentages, confidence intervals for projected numbers exceed 50-percent relative precision.

Source: OIG analysis of hospital stays for 780 Medicare beneficiaries discharged in October 2008.

Draft – unpublished data

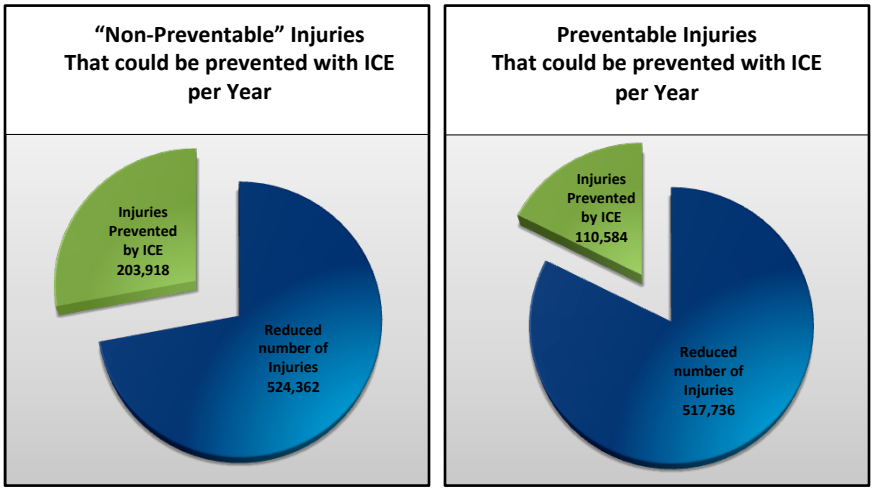
Standard for the "Integrated Clinical Environment" ASTM F2761-09

"Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model"

Provides a standards-based system architecture intended to support safe medical system composition

Draft – unpublished data

Proposed ICE Mitigation - Injuries

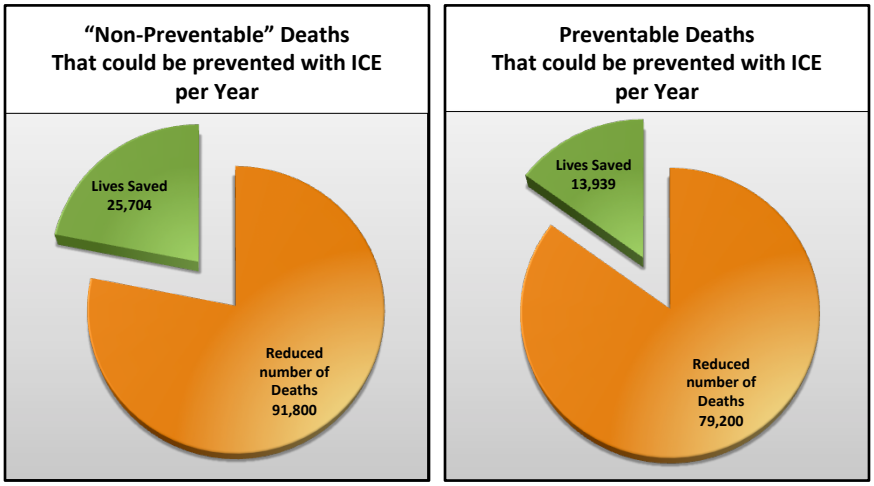


=28% of 728,280 Total "Non-Preventable" Injuries

=17.6% of 628,320 Total Preventable Injuries

Draft – unpublished data

Proposed ICE Mitigation - Deaths

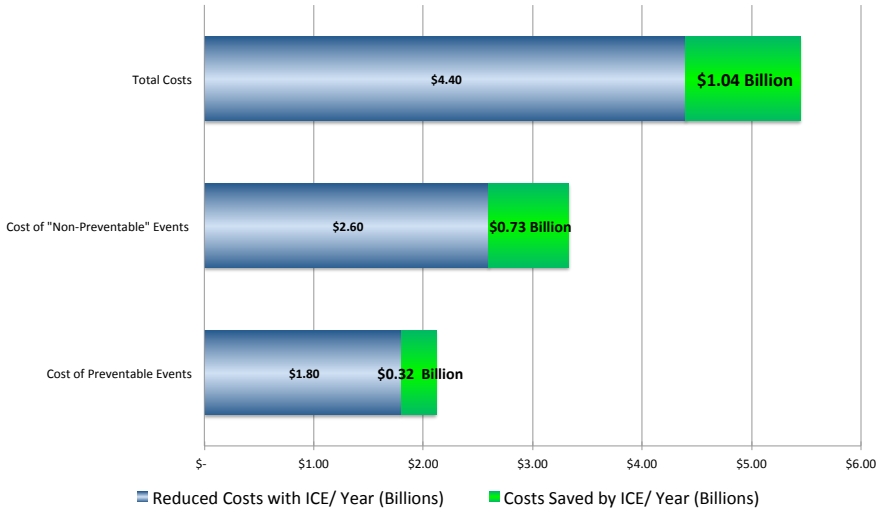


=28% of 117,504 Total "Non-Preventable" Deaths

=17.6% of 93,139 Total Preventable Deaths

Draft – unpublished data

Costs Saved

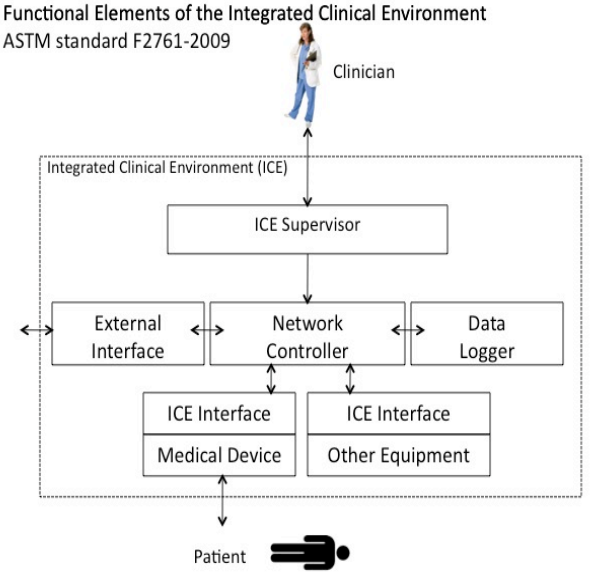


MDIS WG – Medical Device Interoperability Safety Working Group Meeting ~ weekly since January 2010 FDA Workshop

Pre-IDE Project Problem Statement (DRAFT)
We have identified four specific high level goals of the required regulatory pathway that enable Plug-and-Play interoperability.

1) Connecting PNP interoperable medical devices must not make the Hospital an FDA-regulated medical device manufacturer.
2) It must be possible for the interface function (meaning both SW and HW) of a medical device to be cleared by the FDA separately from the classic medical device function of the device. This itself has four possible levels of pathway that will each be discussed:
a. The interface can be approved separately from the device itself (e.g. a dongle).
b. The interface can be "swapped out" without needing new clearance (e.g. no new 510(k) for the whole device.
c. The interface doesn't need clearance at all (e.g. like a commercial infrastructure).
d. The interface can be cleared for near-universal functionality.
3) Component-Wise clearance pathway versus the current "pair-wise" clearance. Currently a whole system must be presented for clearance (pair-wise clearance). PNP interoperablity requires that a component can be cleared with an intended purpose of acting as a component of a larger system (component-wise clearance).
4) The Accessory Rule must not apply across the entire system. The current application of the accessory rule is a significant barrier to component-wise clearance because the highest classification component in a system brings that classification to the entire system. We will show how current precedent can be applied to mitigate hazard and risks such that such that the components would be considered stand-alone devices with behavioral boundaries and thus not be accessories of a complete medical device.

Functional Elements of the Integrated Clinical Environment
ASTM standard F2761-2009



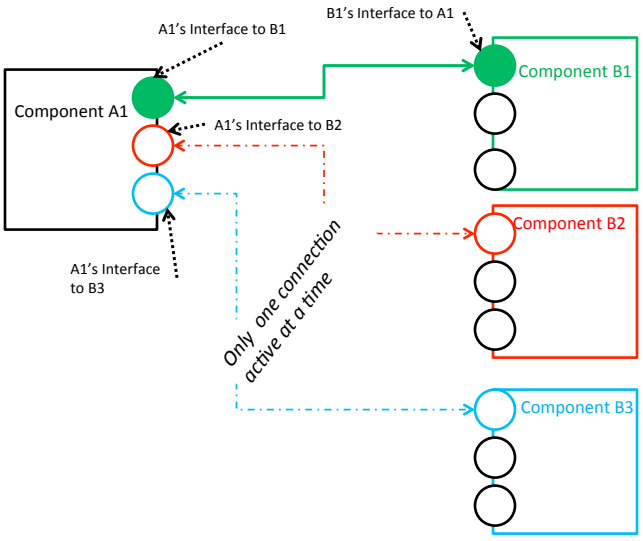
ICE Interface permits a medical device or IT system to communicate with the ICE Network Controller.

ICE Network Controller handles all aspects of communication to and from the ICE Supervisor to all other attached components be they medical devices or IT systems.

ICE Interface provides the **ICE Network Controller** with all the information about device type, classification, identification, capability, performance and control through metadata.

ICE Manager (ICE Supervisor + ICE Network Controller) contains the required data, processes, actions for implementing a Use Case

Published January 2010



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