FDA MDEpiNet 2012 Annual Meeting
Greenbelt, MD
September 11, 2012

Leveraging Interoperability for Device Health and Performance Assessment

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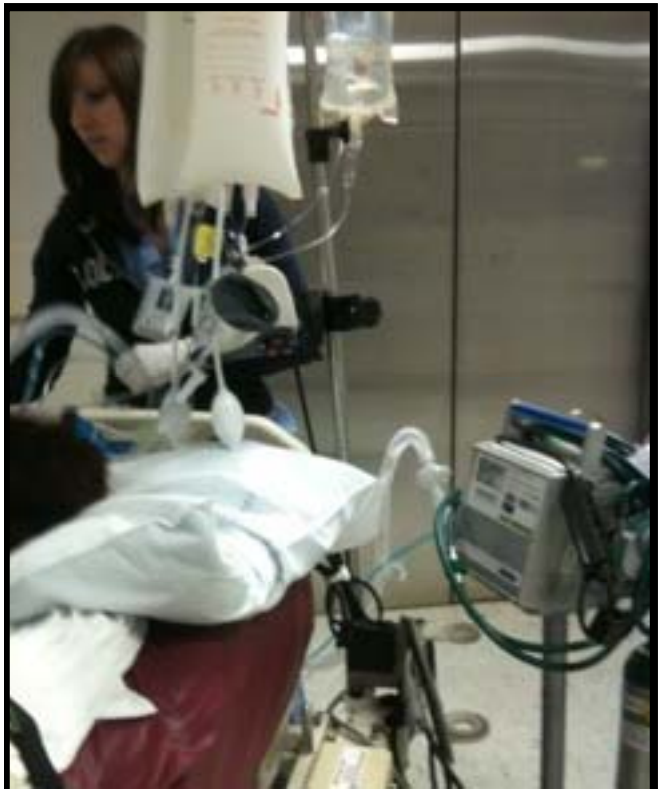
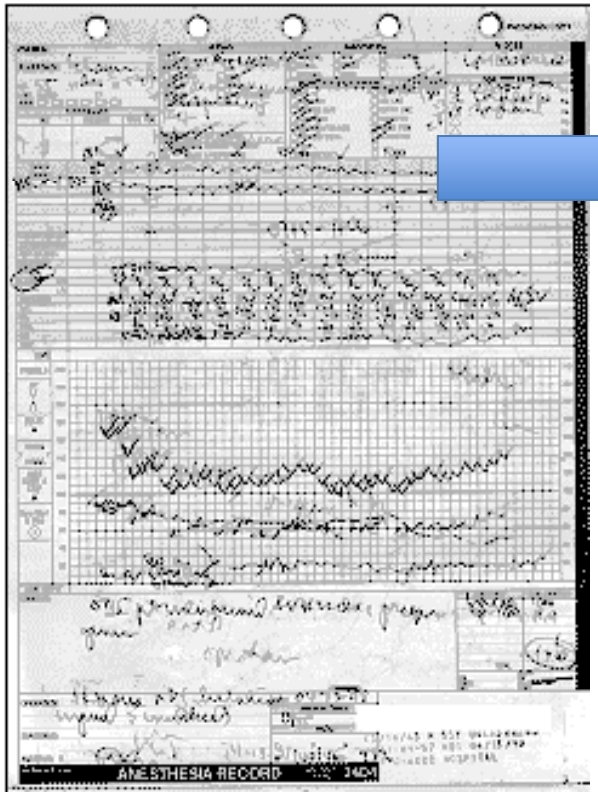
Clinical care: Is not neat and tidy



We have come a long way … in some areas …



Medical Device Data Logging

- Medical device data logs are essential , but
  - Are not universally implemented
  - Are incomplete
  - May be in a proprietary format or encrypted
  - Probably have incorrect time reference
  - Difficult to align with data from other devices and clinical interventions
- Other industries collect comprehensive data routinely, to improve reliability:
  - Diagnostics / troubleshooting
  - Device performance / health assessment
  - Profile normal behavior
  - Forensic analysis

System Data Logging

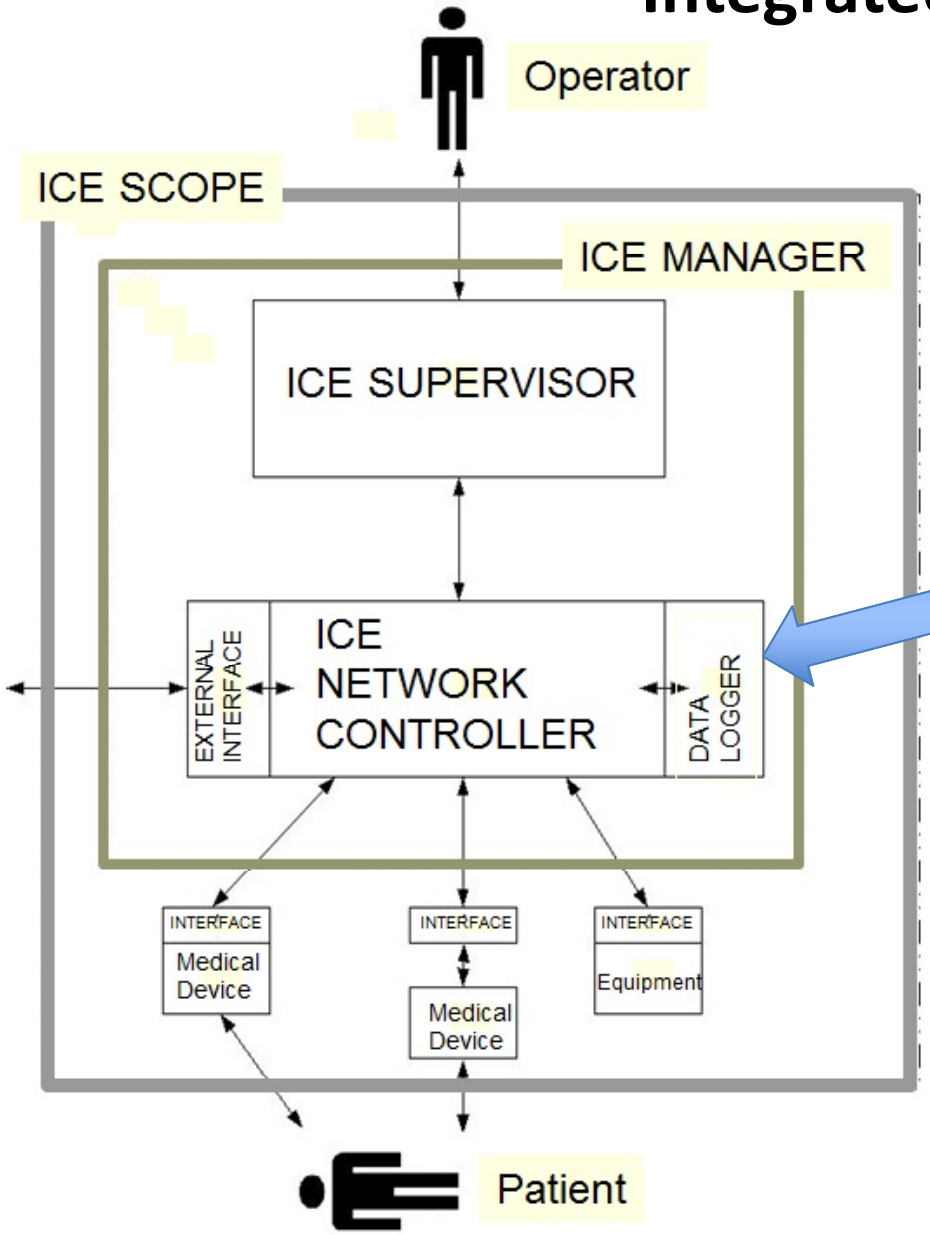
- Is logging of one device that is independent of the "system" sufficient for our needs?
  - A device may function correctly, but can still have AE; analysis requires system data to address "device is OK, but patient is not"
  - How can one assess the clinical impact of a ventilator problem without complete data from
    - Ventilator – airway pressure, flow, etc.
    - Oxygenation monitor / pulse oximeter
    - Hemodynamic data (blood pressure etc.)
  - Aviation and automotive - use system logs
- Proactive assessment of "device health"
  - BMW TeleServices – monitors auto health and contacts owner when a problem is detected.
  - Why not detect IV pump performance deviations and investigate prior to patient injury? Pump? Drug? Tubing?
    - How did BMW gain access to diagnostic data from diverse devices? Can we?

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 interoperable medical systems

ASTM F2761-09 standard for Integrated Clinical Environment



ICE "Data Logger"

ASTM F2761-09
Sub-clause 4.2.4 Forensic data logging

“The purpose of the forensic data logging is to provide information that can be used to distinguish between, for example, use error, abnormal use, ICE-compatible equipment failure, ICE supervisor failure, or ICE network controller failure. Forensic data logging is expected to be used to analyze incidents and near incidents, analogously to an airplane's flight data recorder.

…

The forensic data logging is intended to facilitate system integration, system deployment, and retrospective analysis of performance, incidents and near incidents. To accomplish these tasks the forensic data logging should collect:

a) ICE-COMPATIBLE EQUIPMENT technical variables and TECHNICAL ALARM CONDITIONS available to the ICE NETWORK CONTROLLER;

b) PATIENT physiological variables and PHYSIOLOGICAL ALARM CONDITIONS from ICE-COMPATIBLE EQUIPMENT available to the ICE NETWORK CONTROLLER;

c) ICE NETWORK CONTROLLER commands to ICE-COMPATIBLE EQUIPMENT;

d) ICE NETWORK CONTROLLER status;

e) Any other significant events and errors.

Draft – unpublished data

Medical Device Clock Time Errors 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

http://mdpnp.org/devicesynchronization.html

MD PnP™
Getting connected for patient safety™

Data Logger Project

MD PnP - Medical Device Interoperability research program at CIMIT/MGH has been funded to by DoD/TATRC to develop a prototype software data logger to:

- Create a coordinated, time-synchronized log of all externally-visible network activity from a device
- Capture clinical requirements for data logging to support adverse event analysis, post-market surveillance, and hospital biomedical engineering device acceptance and support activities
- Explore leverage FDA MDR vocabularies
- Conform/inform to ASTM F2761 requirements
- Include UDI (Unique Device ID)
- Explore different logging levels, and the usefulness of each. E.g., logging 'everything' on the network for a few seconds vs logging only pre-defined 'clinically relevant for this application' data for several days. Examining storage, bandwidth, and processing requirements for each.

Logging demands playback …

- Working on data presentation and toolsets for filtering and other data manipulation to support various clinical and engineering needs
  - Patient, Hospital, Manufacturer, Regulators, etc.
- Proposed Tools:
  - High level / Clinical: Presents a timeline of data inputs (like pump programming) and device outputs (infusion stop, defibrillation, etc)
  - Biomed / Adverse Event analysis: As above plus ICE system info (device joins / leaves network etc.)
  - Technical / Network Engineer / Manufacturer: (almost) all packets with time stamps. Allows analysis of networking faults, etc.

Conclusions

- Goal: Use data for prevention of device and system failures especially if high risk of patient injury
- Develop standardized “minimum data set” for device data log
- Include UDI, accurate time reference, and requirements based on F2761 and other standards
- Data log should be “open”, preferable in a standardized format
- Coordinated system data logging is necessary to achieve transformative healthcare improvements