Award Number: W81XWH-12-C-0154

TITLE: "Enabling Medical Device Interoperability for the Integrated Clinical Environment"

PRINCIPAL INVESTIGATOR: Julian M. Goldman, MD

CONTRACTING ORGANIZATION: Massachusetts General Hospital
Boston, MA 02114

REPORT DATE: December 2016

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
December 2016	Final	30 Jul 2012- 30Nov2016

4. TITLE AND SUBTITLE
"Enabling Medical Device Interoperability for the Integrated Clinical Environment"

5a. CONTRACT NUMBER
W81XWH-12-C-0154

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Julian M. Goldman, MD
Susan F. Whitehead

Email: jmgoldman@mgh.harvard.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Massachusetts General Hospital
Boston, MA 02114-2554

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for public release; distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This award built on other USAMRMC-funded MD PnP Program research to analyze technologies and develop software tools and shared data to advance the state of the art of safe medical device interoperability and enable adoption by a broad community of researchers, clinicians, manufacturers, regulators, and standards developers. Our team identified requirements for an ICE (Integrated Clinical Environment) Data Logger, collaborated with NIST on a research prototype (demonstrated to multiple federal agencies), and made iterative improvements. We built a Clinical Scenario Repository, defined governance, and fine-tuned it with feedback from clinicians. We created an open-source, freely available code-sharing environment on SourceForge. We demonstrated ICE bi-directional data transfers by implementing CONNECT to transfer device settings, creating an ICE app to remotely stream medical device data from our Lab, and connecting with the OSEHRA VistA EHR. We were invited to demonstrate these capabilities in the ONC/FHA area of the Interoperability Showcase at HIMSS in 2013-2015.

15. SUBJECT TERMS
Medical device, plug-and-play, interoperability, patient safety, health care, standards, data logger, clinical scenario, integrated clinical environment, code-sharing

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE	UU	97	19b. TELEPHONE NUMBER *(include area code)*
U	U	U			

This page intentionally left blank.

Table of Contents

Page

Final Report: Enabling Medical Device Interoperability for the Integrated Clinical Environment
Award Number W81XWH-12-C-0154
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 30 July 2012 – 30 November 2016

Introduction

Health Information Technology (HIT) systems should facilitate the collection and point-of-care access to accurate, comprehensive, contextually rich clinical data for all acuity levels of healthcare. Open platforms of plug-and-play medical devices and HIT systems could enable improved quality and timeliness of data access, as well as cost-effective development of innovative medical "apps" for diagnosis, treatment, research, safety and quality improvements, health technology management, and adverse event detection and reporting.

The Medical Device "Plug-and-Play" (MD PnP) Interoperability program was established in 2004 to lead the development and adoption of open standards and related technologies in order to achieve this vision. The MD PnP program is based at the Massachusetts General Hospital (MGH) Dept. of Anesthesia, Critical Care, and Pain Medicine, CIMIT (Consortia for Improving Medicine with Innovation & Technology), and Partners HealthCare System, with foundational support from USAMRMC (initially through TATRC – the U.S. Army Telemedicine & Advanced Technology Research Center). The clinically grounded MD PnP program has taken a multi-faceted approach to address key barriers to achieving interoperability, including the development and subject matter expertise resourcing of suitable open standards (e.g. ASTM F2761-09(13) for the Integrated Clinical Environment, or "ICE"); the elicitation, collection and modeling of clinical use cases and system engineering requirements for an open architecture instantiation of ICE as a platform and "ecosystem"; alignment of clinical organizational, manufacturer, and FDA regulatory expectations; and implementation of prototype use cases in an open "sandbox" or testbed environment.

The MD PnP program has built a geographically dispersed, interdisciplinary, multi-institutional team to develop and implement a strategy to address historical barriers and accelerate the achievement of safe device interoperability through collaboration. Since the program's inception, more than 1000 clinical and engineering experts, and representatives of more than 150 companies and institutions have participated in our plenary workshops, conferences, working group meetings, lab demonstrations, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our team of collaborators has included participants from healthcare delivery organizations (e.g. Kaiser Permanente, Johns Hopkins Medicine, University of Florida Hospital, VHA), federal agencies (including the FDA, NIST, Military Health System, and NSF), university computer and information science groups (e.g. Pennsylvania, Illinois/Urbana-Champaign, Kansas State), device manufacturers (e.g. Draeger Medical Systems, Philips Healthcare, GE Healthcare), DocBox, Moberg Research, Anakena Solutions, large technology companies (e.g. Intel, MITRE, Lockheed Martin), and the Partners HealthCare System biomedical engineering, clinical, and information systems communities (Massachusetts General Hospital and Brigham & Women's Hospital in particular). The collaborative research relationship with DocBox has proven especially productive.

The collaborative work of the MD PnP program has had a broad impact, and USAMRMC support for MD PnP program development has been the key enabler of significant progress towards the goal of achieving medical device interoperability. USAMRMC funding has leveraged additional synergistic project-specific funding from CIMIT, NSF, NIST, and NIH, but it is USAMRMC funding that has uniquely made possible our program's enabling efforts that are moving medical device interoperability and patient safety forward along synergistic streams of requirements, consensus standards, platform development, and regulatory science. A major outcome of USAMRMC funding has been enabling our team to form and grow a diverse community of involved and committed collaborators and stakeholders. Pertinent examples of our ability to coalesce interest and commitment around an

important issue are the support from the White House CTO, HHS, and standards bodies for improving the clock time accuracy of medical device data transmitted to EHRs, and the 2014-2015 Global City Teams Challenge project "Remotely Caring for Our Most Vulnerable Citizens In-Place During a Pandemic," performed with DoD collaborators from MHS, DHA, TATRC, CERDEC, and Edgewood, as well as the FDA, industrial partners, and universities. We led a rapid med-tech response to improve the safety of healthcare workers treating patients with Ebola Virus Disease, and held a four-day "hackathon" in our MD PnP Lab where twenty collaborators rapidly prototyped data interoperability-based innovations by leveraging our Lab and our team's subject matter expertise.

Body of Report

This award reflected new and emerging technologies and research, and built on prior and current MD PnP program work (USAMRMC awards #W81XWH-06-1-0651 and W81XWH-09-1-0705), to develop tools, applications, and sharable data to advance the state of the art of medical device interoperability and enable a broader community of software developers, manufacturers, regulators, clinicians, and standards writers to implement medical device interoperability.

The intent of our research for this funded project was to prototype and demonstrate tools to further enable Medical Device Interoperability, especially – but not limited to – Integrated Clinical Environments (ICE), building on what we had learned in our NIH Quantum Medical Device Interoperability (QMDI) cooperative research project. This USAMRMC project was funded for a base year plus two option-years, and the elapsed period of performance was four years and four months (30 July 2012 – 30 November 2016).

Aims and sub-tasks for this project evolved over the four years based on our research findings and the evolution of health information technology (HIT) during this period. The following aims and sub-tasks (updated with each option-year) have been edited for clarity and brevity:

Aim 1: ICE Data Logger
Develop a software research prototype of the Data Logger component conforming to the ICE standard (ASTM F2761). Data logging is necessary to address regulatory, safety, cybersecurity, and liability needs regarding networked medical device systems, and will improve the forensic analysis of clinical adverse events and near misses.

Base Year sub-tasks (30 July 2012 – 29 July 2013):

- Base the initial prototype on requirements identified through the NIH Quantum U01 project
- Develop an event recording and playback capability that demonstrates the potential for forensic analysis of activity in networked medical device systems, as well as improved adverse event analysis (useful for hospitals, FDA, manufacturers)
- Investigate the implementation of the FDA Unique Device Identifier (UDI) as it evolves, and inform the FDA of our research findings
- Assess the clinical usefulness of the Data Logger by analyzing simulated adverse events
- Publicly disseminate research results

Option-Year 1 sub-tasks (30 July 2013 – 29 November 2014):

- Collaborate with NIST to implement the NIST research prototype Data Logger on the MD PnP open platform
- Improve playback to support adverse event analysis
- Continue research with Unique Device Identifiers

Option-Year 2 sub-tasks (30 November 2014 – 30 November 2016):

- Add metadata such as location tracking and video to Data Logger
- Connect Data Logger information to Clinical Scenario Repository to demonstrate automatic logging of relevant clinical events

- Add updated version of medical device-transmitted Unique Device Identifier

Aim 2: Web-Based Clinical Scenario Repository
Develop a sharable repository of Clinical Scenarios that could be improved through better medical device and health IT integration. The scenario repository will provide use cases to inform design of the Data Logger, and can eventually be used by researchers, standards developers, regulators, and manufacturers to create innovative medical technology solutions for intractable clinical problems.

Base Year sub-tasks (30 July 2012 – 29 July 2013):
- Provide a web portal for users such as clinicians, clinical engineers, and other users to enter, revise, and annotate clinical scenarios
- Design database back-end and administrative system to organize users and permissions
- Use feedback from clinicians, industry, and the FDA, NIST, and VA to enhance usability
- Publicly disseminate details of repository

Option-Year 1 sub-tasks (30 July 2013 – 29 November 2014):
- Release beta version of Clinical Scenario Repository to collaborators for testing and feedback
- Gather scenarios and feedback from collaborator users about the site design and data collected
- Improve the site to incorporate and reflect feedback

Option-Year 2 sub-tasks (30 November 2014 – 30 November 2016):
- Promote Clinical Scenario Repository website to potential users
- Further fine-tune features of Repository based on actual experience
- Add new Repository features requested by users

Aim 3: Open Source Code Dissemination
Disseminate open-source code developed by the MD PnP program and collaborators, including the prototype Data Logger, in order to facilitate further development by others.

Base Year sub-tasks (30 July 2012 – 29 July 2013):
- Determine appropriate venues, tools, and processes for releasing code
- Help interested external parties to obtain code and documentation
- Manage the integration of external code that is received into official releases

Option-Year 1 sub-tasks (30 July 2013 – 29 November 2014):
- Release any NIH/QMDI app deliverables into ICE “AX” (App Exchange) repository/community
- Present work at open source conference or meeting, and invite volunteers to contribute
- Develop new reference implementation apps or app frameworks, and release to ICE AX repository/community

Option-Year 2 sub-tasks (30 November 2014 – 30 November 2016):
- Promote work and App Exchange to medical and open-source communities via publications and workshops

Aim 4: ICE External Interface Data Transfer
Identify and evaluate external interfaces to bi-directionally transfer medical device and patient contextual data between the integrated clinical environment and external systems of national interest.

Base Year sub-tasks (30 July 2012 – 29 July 2013):

- Investigate connectivity to the VHA Open VistA EHR
- Investigate connectivity to the Nationwide Health Information Network (NwHIN) and other appropriate and available systems
- Publicly disseminate research results

Option-Year 1 sub-tasks (30 July 2013 – 29 November 2014):

- Explore feasibility of connecting MD PnP Lab to hospital clinical information systems (CIS) such as MGH test Admission/Discharge/Transfer (ADT), Physician Order Entry (POE), and pharmacy systems
- Prototype connection to CIS interfaces

Option-Year 2 sub-tasks (30 November 2014 – 30 November 2016):

- Demonstrate capability to export data collected by an ICE App (e.g. Smart Alarm) into format suitable for later analysis

Research Accomplishments

Data Logger, Aim 1: Develop a software research prototype of the Data Logger component conforming to the ICE standard (ASTM F2761).

The MD PnP team compiled an initial set of needed attributes and technical requirements for the ICE Data Logger that specify what data will be recorded, the format of the data, the time-stamping, cryptographic considerations, and sequencing of data, and other technical details. These requirements also inform data playback, particularly where features of the Data Logger will influence what playback capabilities are possible.

Requirements were based upon:

- Content from the Integrated Clinical Environment (ICE) standard (ASTM F2761-09)
- Experience to date with clinical scenario implementations in the MD PnP Interoperability Lab
- Work with our collaborators on the NIH Quantum Medical Device Interoperability (QMDI) project
- Early data logger concept and an MD PnP paper presented at the International Conference on Biomedical Ontologies
- Clinician Interviews
- An FDA conceptual design for a stand-alone device data log

We planned to build a Data Logger implementation following these requirements, with the expectation that building it would reveal necessary refinements to the requirements, resulting in future iterations of the requirements document. We have updated and maintained these requirements to reflect lessons learned during development, as well as changes to the QMDI requirements that specify the system in which the Data Logger will operate.

Several months into our data logger research, a research group at NIST led by Dr. Kamran Sayrafian expressed interest in collaborating on this project, using NIST internal funding, and our project greatly benefited from this collaboration. Starting with documentation, requirements, and guidance from our team, NIST surveyed relevant data logger work in avionics, automotive, and other domains to identify additional requirements. NIST compiled this set of data logger requirements, and we collaborated on a technical white paper about the different levels or modes of logging that an ICE Data Logger will need to support.

This detailed comparison with other data loggers, such as aircraft flight data recorders and automotive loggers, enabled us to collaborate with NIST to leverage their unique engineering expertise to build a set of requirements to feed back to the NIH-funded QMDI project and the broader community, and to use for development of an ICE Data Logger standard. We began documenting the range of existing

data logging strategies in other domains – especially transportation – to serve as design inputs for our Data Logger and to serve as an informational resource for standards development.

We worked with NIST to plan their implementation of a research data logger prototype based on our program's OpenICE open-source ICE platform. This logger and playback prototype was based on our jointly developed requirements documents, and built using NIST's Data Flow middleware and data collected from medical devices in our MD PnP Lab. Studying the approaches used by different manufacturers to log data from legacy equipment can provide valuable insights about the state of the industry and technology, and refine requirements for future (fully plug-and-play interoperable) interfaces and data logging standards. We chose to collect some data with the commercially available Bedmaster system, which can collect and store data from a GE medical network and is cleared by the FDA for this use, and with the Cardio-Pulmonary Corporation (CPC) Bernoulli system, which is similarly approved by FDA for the purpose of collecting data from a variety of medical devices.

The Bedmaster and CPC integration systems impose their own constraints on what data is available and on the data's timeliness. To create data for NIST to use in developing their data logger prototype, we configured the Bedmaster system and the CPC system to log the data and then export the data files to SourceForge, where the data were available for NIST and were publicly available for the research community. During some of the sample runs, we made video recordings of the patient simulator and devices, so that the data logger playback application could display synchronized video.

This prototype implementation (illustrated in Figure 1) was demonstrated as part of a set of MD PnP and collaborator demonstrations held at NIH on August 21-22 2013, attended by more than 65 government representatives including MHS, FDA, NIST, NSF, NIH, ONC, and others. Feedback from the audience at the August demonstrations made it clear that there is considerable and widespread interest in this work.

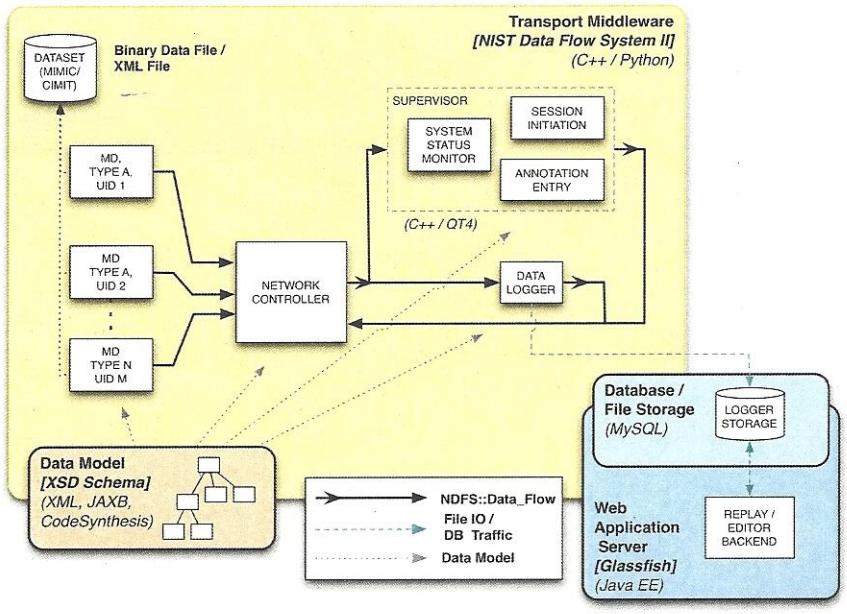


Figure 1: The ICE Data Logger & Playback Demonstration Architecture

Synchronized video may be important for revealing clinical context. For instance, part of the data logger demo at NIH included a scenario in which the patient received an overdose from a PCA pump. The device data shows the patient's physiologic response, the log from a PCA pump would show that the dose request button was pressed, but only the video could reveal that the button was pressed by someone other than the patient (called "PCA-by-proxy"). Thus, the root cause of the patient's overdose could only be found by including a video record with the device data.

We investigated Data Logger performance testing in the context of the collaborative NIST prototype implementation, as NIST's Data Flow System is designed to handle extremely large amounts of data. Our simulators were not able to generate enough traffic to stress-test the NIST middleware, so it was more than sufficient for our applications. This demonstrated the feasibility of different software approaches to implementation of a prototype ICE data logging system, and showed that one could scale performance (e.g. bandwidth) based on the software design.

For the next Data Logger implementation, we built preliminary data logging functionality on the RTI DDS middleware we were using for our OpenICE platform development, using our ICE Equipment Interfaces. DDS is an open middleware standard from Object Management Group (OMG). The DDS implementation we used was developed by Real-Time Innovations (RTI), and is used extensively in DoD applications like ship “command and control” networks and drone avionics. These applications require high performance and reliability, and RTI has extensively tested the performance of the middleware. We worked with RTI to make their tools freely available to our community through an ICE Community License.

We were able to successfully log data, as illustrated in the screen shots in Figures 2 and 3. Figure 2 shows an application that displays data on the network in real time. This application can also be used to record the data to a file.

Figure 2. Data Logging Application

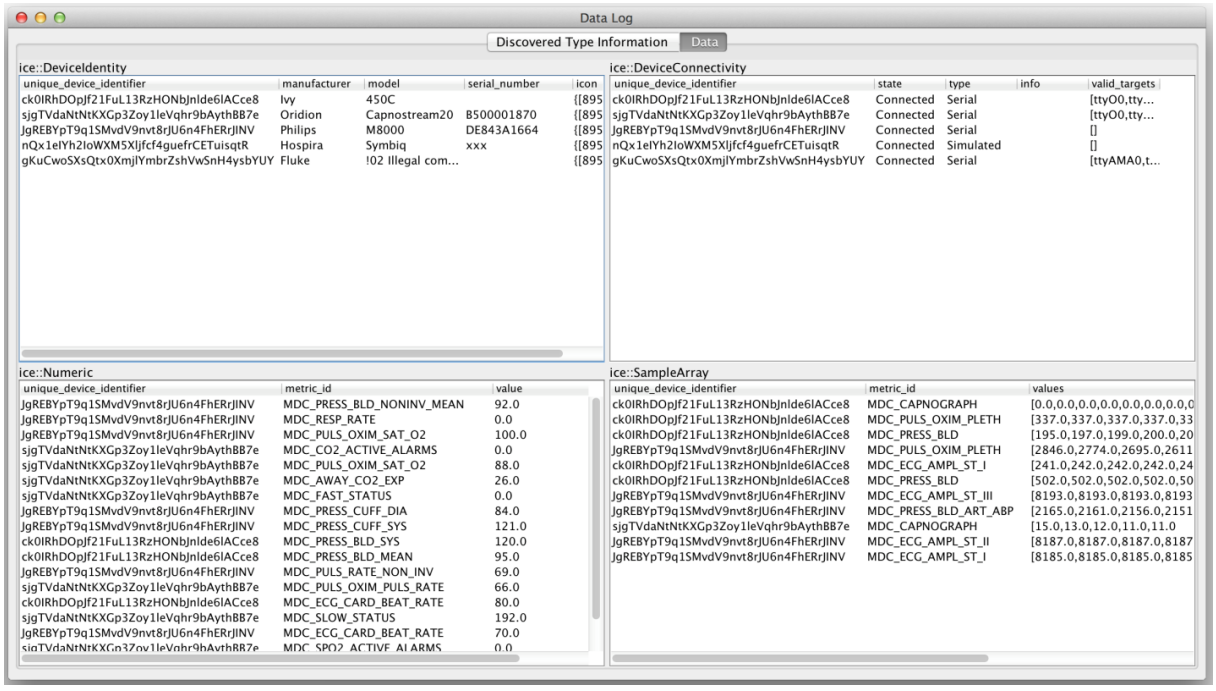


Figure 3 shows the logged data for a waveform. Figure 4 shows a capture from an engineering prototype, containing samples of data from several devices. This log includes the unique device identifier as well as synchronized timestamps and device data in a standardized nomenclature. These applications are engineering prototypes intended for application development and debugging. For the UDI we used an MD PnP lab-generated UDI as a placeholder for the FDA UDI, which for use in medical device interfaces was still under development.

Figure 3. Logged Waveform Data

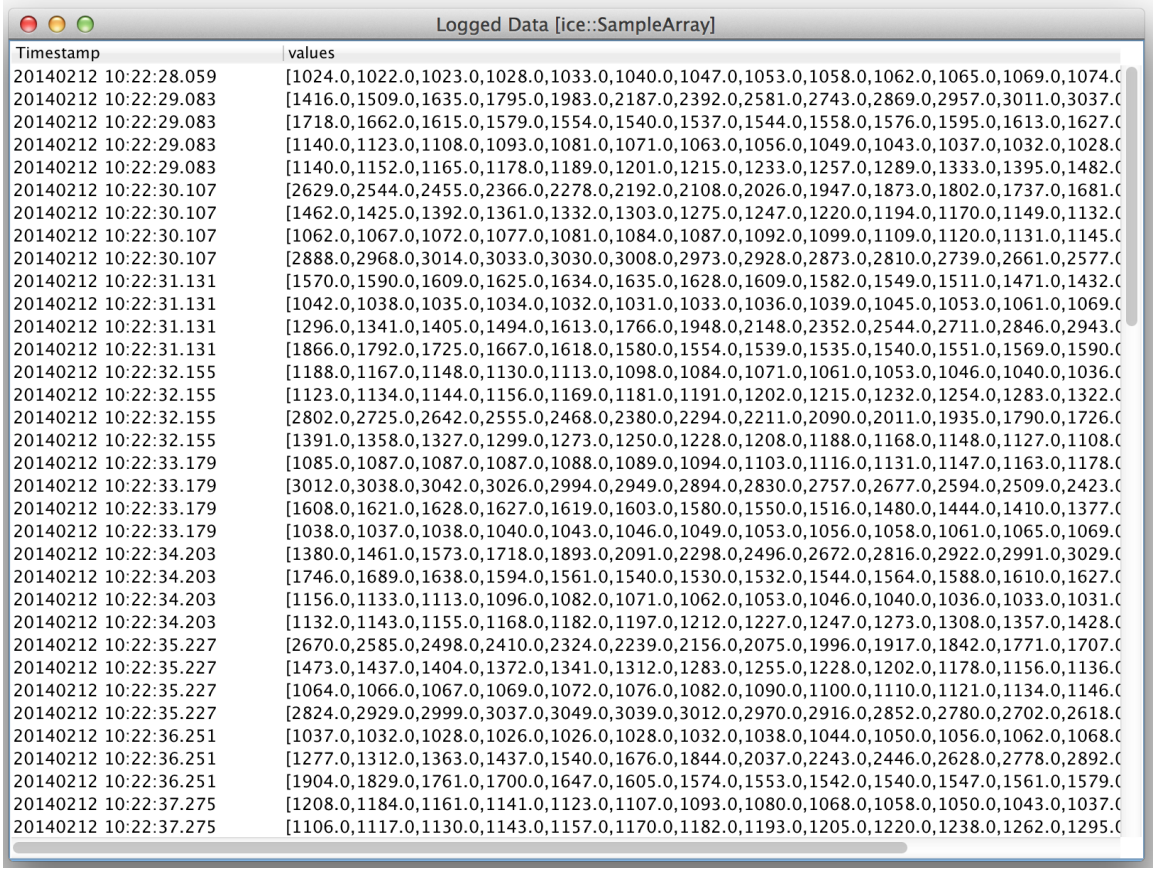
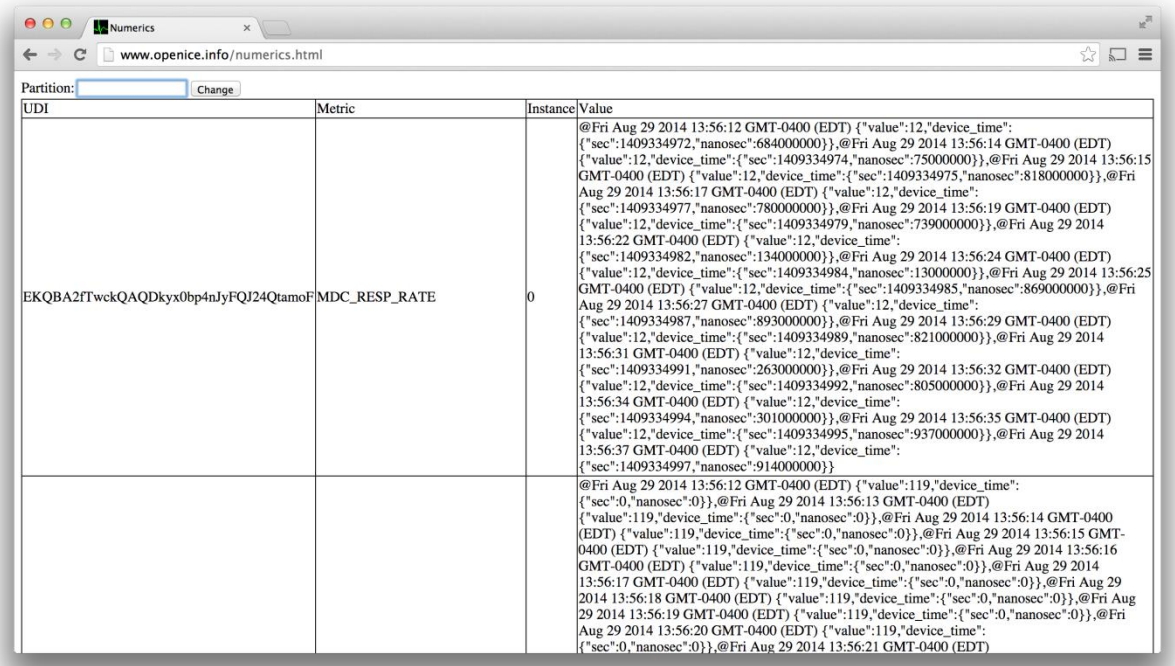


Figure 4. Data Samples with UDI and Time Stamps



Our continued work on developing core OpenICE infrastructure included a framework that allows for data logging without compromising system security or patient privacy. In collaboration with NIST, we performed research on the best approach to long-term storage of logged data that will facilitate forensic analysis of adverse events or other events of interest. After testing several strategies for data logging, we identified that a structured data archiving system is probably better for archival of complete patient data, and we developed a prototype for storing OpenICE streaming physiological data from medical devices in MySQL tables using flat data files read from the console terminal.

We conducted experiments to compare the performance of MySQL and other data stores for recording and searching data. This allowed us to perform end-to-end testing of the entire OpenICE system from the equipment interface to the Data Logger as we revised our OpenICE platform (see Figures 5-7). The OpenICE lab data interface uses the DDS middleware employing IDL structures in JSON format (Figure 5).

Figure 5. DDS Data Stream

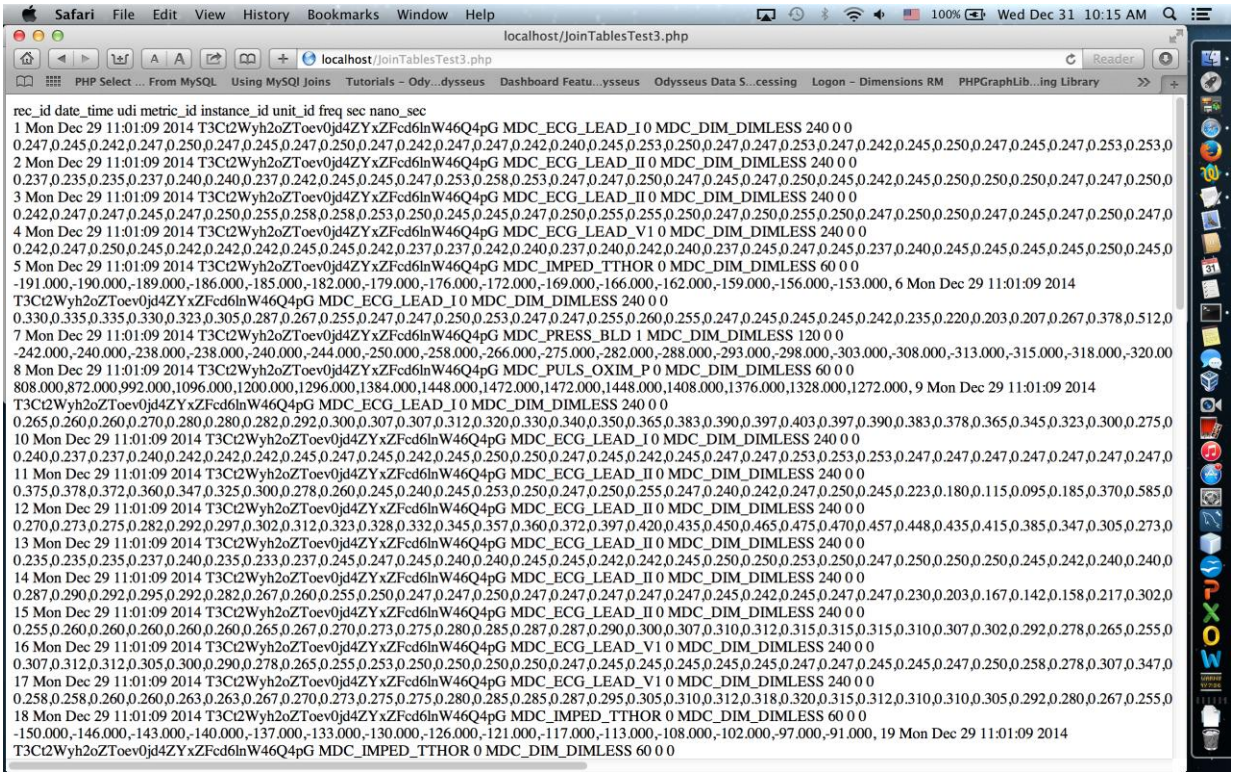
```
:
    unique_device_identifier: 7SpCWvMkvqk25Az7o5gJX4yiiDf0vDsnHlxX
    metric_id: MDC_PRESS_AWAY
    instance_id: 0
    unit_id: DRAEGER_mbar
    frequency: 125
    values :
        userData: 5.3, 5.4, 5.4, 5.5, 5.0, 5.3, 5.5, 5.5, 5.5, 5.0, 5.3, 5.0, 5.1, 5.0, 5.2, 5.6, 5.4, 5.1, 5.0, 5.3, 5.0, 4.8, 4.9, 5.3, 5.4
    device_time :
        sec: 1418187546
        nanosec: 408000000

:
    unique_device_identifier: 7SpCWvMkvqk25Az7o5gJX4yiiDf0vDsnHlxX
    metric_id: MDC_PRESS_AWAY
    instance_id: 0
    unit_id: DRAEGER_mbar
    frequency: 125
    values :
        userData: 5.0, 5.0, 4.9, 4.8, 4.9, 5.3, 5.4, 5.0, 5.1, 4.9, 5.4, 5.1, 5.6, 6.0, 6.3, 6.8, 7.2, 7.7, 8.3, 9.0, 9.5, 10.1, 10.7, 11.3, 11
.9
    device_time :
        sec: 1418187546
        nanosec: 408000000

:
    unique_device_identifier: 7SpCWvMkvqk25Az7o5gJX4yiiDf0vDsnHlxX
    metric_id: MDC_PRESS_AWAY
    instance_id: 0
    unit_id: DRAEGER_mbar
    frequency: 125
    values :
        userData: 12.5, 13.1, 13.6, 14.0, 14.6, 15.1, 15.6, 16.2, 16.7, 17.1, 17.4, 17.6, 17.6, 17.6, 17.6, 17.5, 17.4, 17.3, 17.3, 17.3, 17.2,
 17.2, 17.4, 17.4, 17.5
    device_time :
        sec: 1418187546
        nanosec: 408000000

:
    unique_device_identifier: 7SpCWvMkvqk25Az7o5gJX4yiiDf0vDsnHlxX
    metric_id: MDC_PRESS_AWAY
    instance_id: 0
    unit_id: DRAEGER_mbar
    frequency: 125
    values :
        userData: 17.6, 17.6, 17.6, 17.6, 17.6, 17.5, 17.5, 17.5, 17.5, 17.6, 17.6, 17.6, 17.7, 17.7, 17.6, 17.6, 17.5, 17.5, 17.5, 17.5, 17.4,
 17.5, 17.5, 17.5, 17.5
    device_time :
        sec: 1418187546
        nanosec: 408000000

:
```

To assess the feasibility of storing the data in a MySQL database, we tested methods to capture the data stream (for a user-specified number of seconds) from the console terminal and write it out to flat text files. Those files are then loaded into their corresponding MySQL tables via SQL scripts. The stored data can then be displayed on a browser via a PHP script that joins the records in the parent table (Figure 6) with the numerical arrays stored in the corresponding child tables.

Figure 6. Parent SQL table

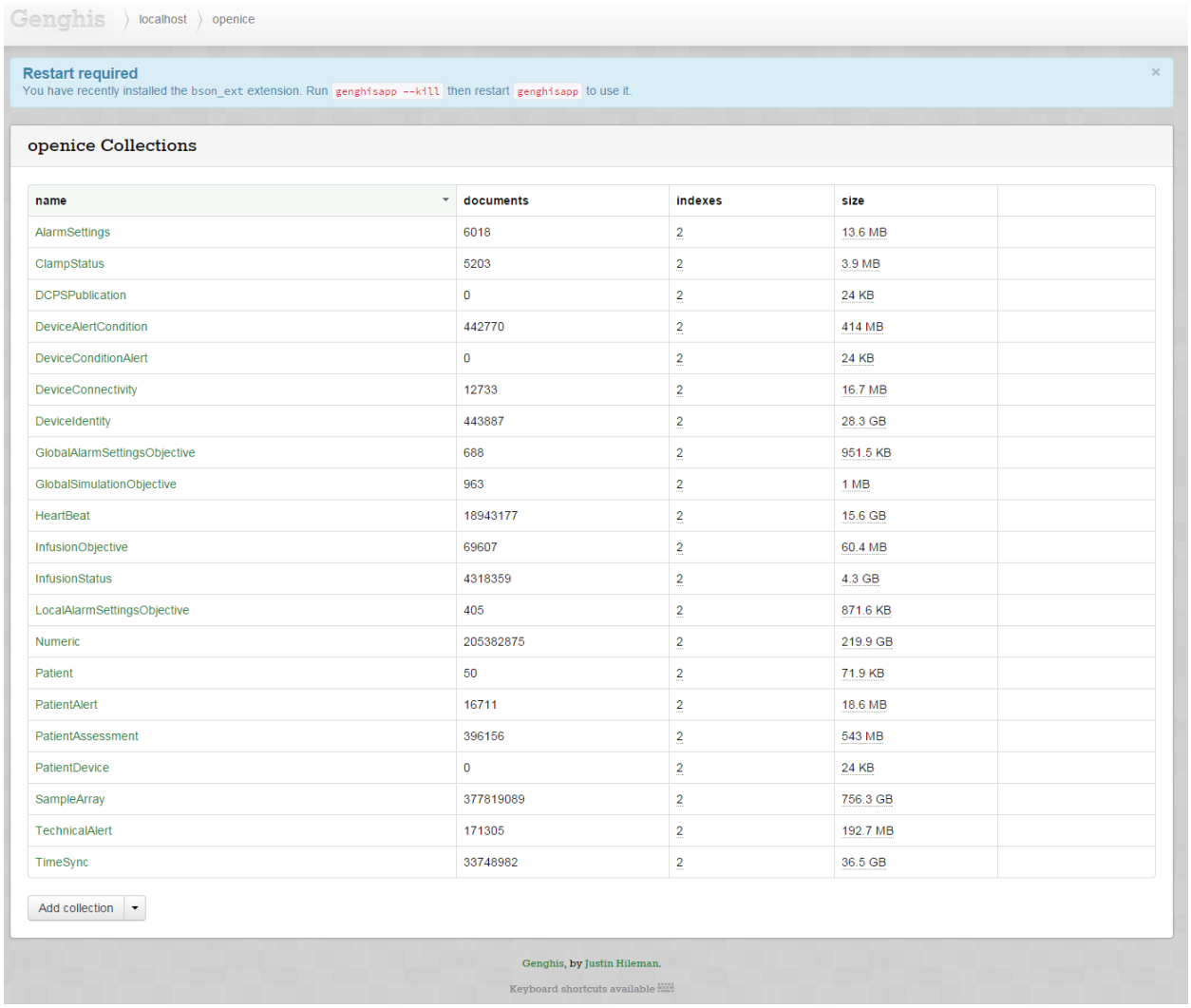
```
mysql>
mysql> select * from stream;
+--------+---------------------+----------------------------------+-----------------+-------------+-----------------+-----------+--------+-------------+
| rec_id | date_time           | unique_device_identifier         | metric_id       | instance_id | unit_id         | frequency | dt_sec | dt_nanosec  |
+--------+---------------------+----------------------------------+-----------------+-------------+-----------------+-----------+--------+-------------+
|      1 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|      2 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|      3 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|      4 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_V1 |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|      5 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_IMPED_TTHOR |           0 | MDC_DIM_DIMLESS |        60 |      0 |           0 |
|      6 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|      7 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_PRESS_BLD   |           1 | MDC_DIM_DIMLESS |       120 |      0 |           0 |
|      8 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_PULS_OXIM_P |           0 | MDC_DIM_DIMLESS |        60 |      0 |           0 |
|      9 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     10 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     11 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     12 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     13 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     14 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     15 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     16 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_V1 |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     17 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_V1 |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     18 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_IMPED_TTHOR |           0 | MDC_DIM_DIMLESS |        60 |      0 |           0 |
|     19 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_IMPED_TTHOR |           0 | MDC_DIM_DIMLESS |        60 |      0 |           0 |
|     20 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_PRESS_BLD   |           1 | MDC_DIM_DIMLESS |       120 |      0 |           0 |
|     21 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_PRESS_BLD   |           1 | MDC_DIM_DIMLESS |       120 |      0 |           0 |
|     22 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_PULS_OXIM_P |           0 | MDC_DIM_DIMLESS |        60 |      0 |           0 |
|     23 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_PULS_OXIM_P |           0 | MDC_DIM_DIMLESS |        60 |      0 |           0 |
|     24 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     25 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     26 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     27 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     28 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     29 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     30 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     31 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     32 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     33 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_I  |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     34 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     35 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     36 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     37 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     38 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     39 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     40 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     41 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     42 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     43 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     44 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     45 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     46 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     47 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
|     48 | Mon Dec 29 11:01:09 2014 | T3Ct2Wyh2oZToev0jd4ZYxZFcd6lnW46Q4pG | MDC_ECG_LEAD_II |           0 | MDC_DIM_DIMLESS |       240 |      0 |           0 |
```

Figure 7. Stored data displayed in a browser



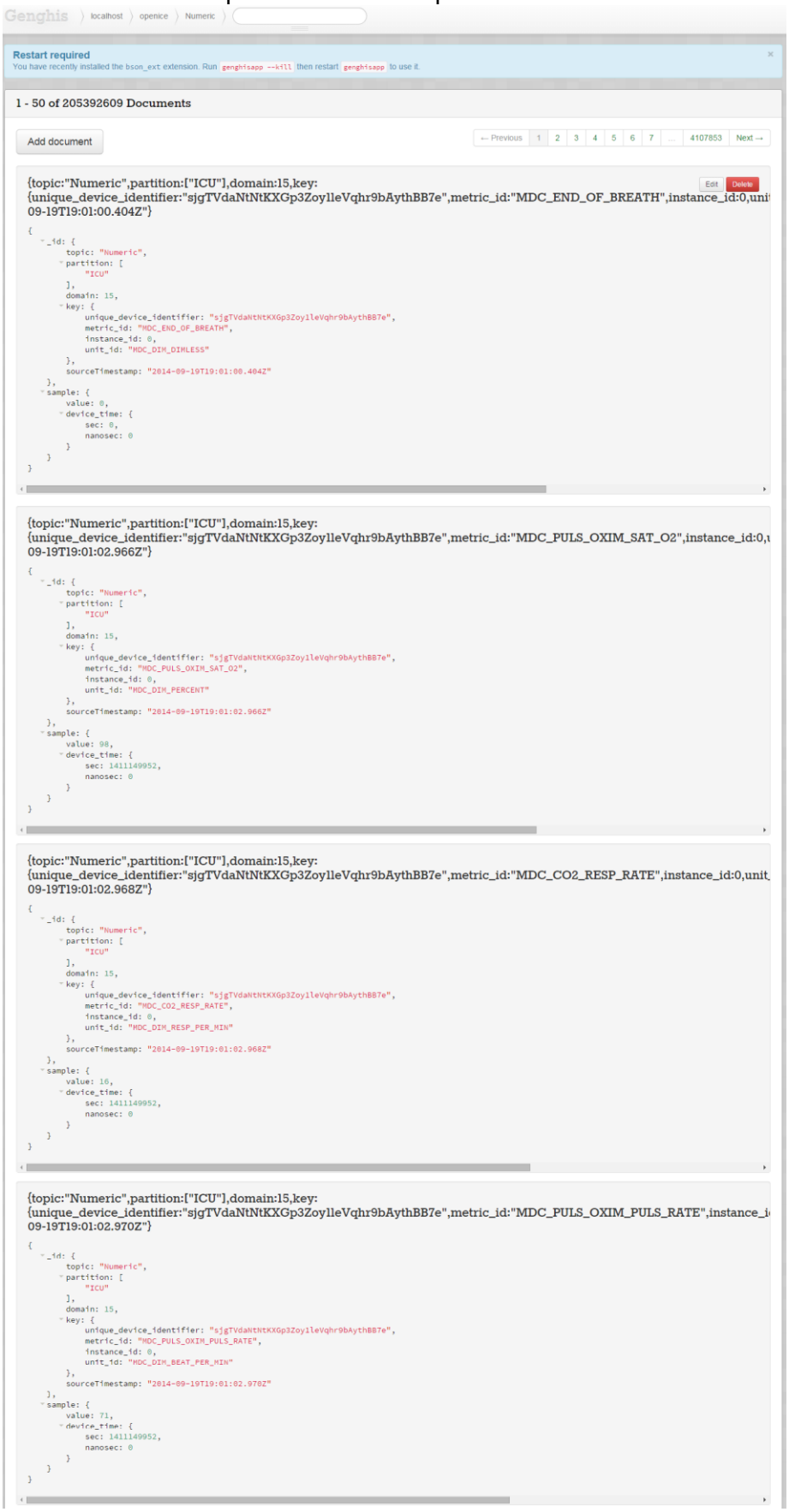
In experimenting with data representation and storage technologies, we had promising results with MongoDB, a new (initially released in 2009) open-source database specialized for large unstructured data sets. We streamed all data from our lab network – including all connected medical devices – to a MongoDB database over a month-long period, capturing a continuous record of data from the devices in the Lab during that time (see Figures 8 and 9): over 750 GB of waveform data and over 200 GB of numeric data, as well as 36 GB of time synchronization messages. We investigated how to store and compress this data, and whether it would be appropriate for clinical uses to remove duplicated or clinically irrelevant data such as the time synchronization messages.

Figure 8. Screenshot from OpenICE.info: Collections of Streamed Data Stored in MongoDB



name	documents	indexes	size
AlarmSettings	6018	2	13.6 MB
ClampStatus	5203	2	3.9 MB
DCPSPublication	0	2	24 KB
DeviceAlertCondition	442770	2	414 MB
DeviceConditionAlert	0	2	24 KB
DeviceConnectivity	12733	2	16.7 MB
DeviceIdentity	443887	2	28.3 GB
GlobalAlarmSettingsObjective	688	2	951.5 KB
GlobalSimulationObjective	963	2	1 MB
HeartBeat	18943177	2	15.6 GB
InfusionObjective	69607	2	60.4 MB
InfusionStatus	4318359	2	4.3 GB
LocalAlarmSettingsObjective	405	2	871.6 KB
Numeric	205382875	2	219.9 GB
Patient	50	2	71.9 KB
PatientAlert	16711	2	18.6 MB
PatientAssessment	396156	2	543 MB
PatientDevice	0	2	24 KB
SampleArray	377819089	2	756.3 GB
TechnicalAlert	171305	2	192.7 MB
TimeSync	33748982	2	36.5 GB

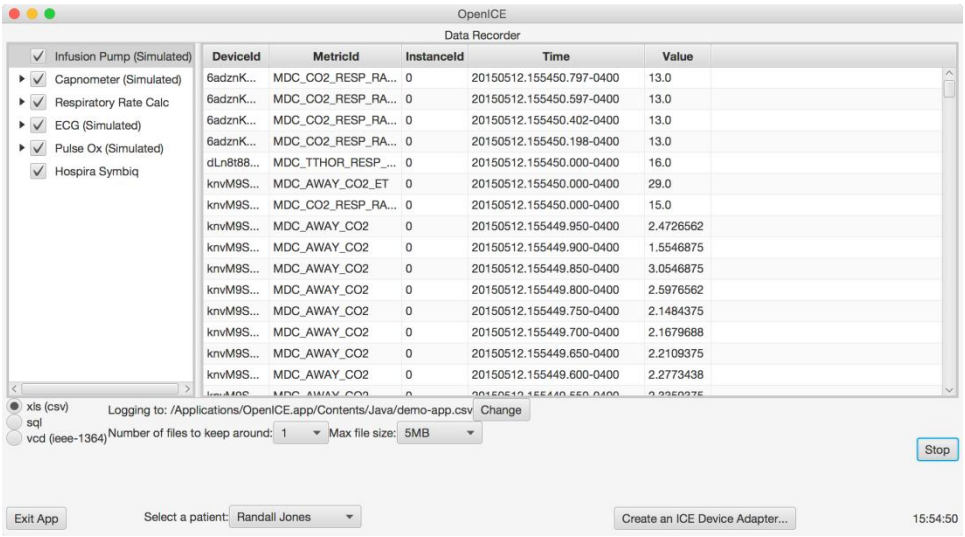
Figure 9. Screenshot from OpenICE.info: Example of Numeric Data Stored in MongoDB



Our latest OpenICE app features data capture, storage and export functionalities. We have enabled multi-patient–multi-device assignment, and the data generated from these devices can be logged to a variety of data formats (see https://www.openice.info/docs/3_apps.html#data-recorder).

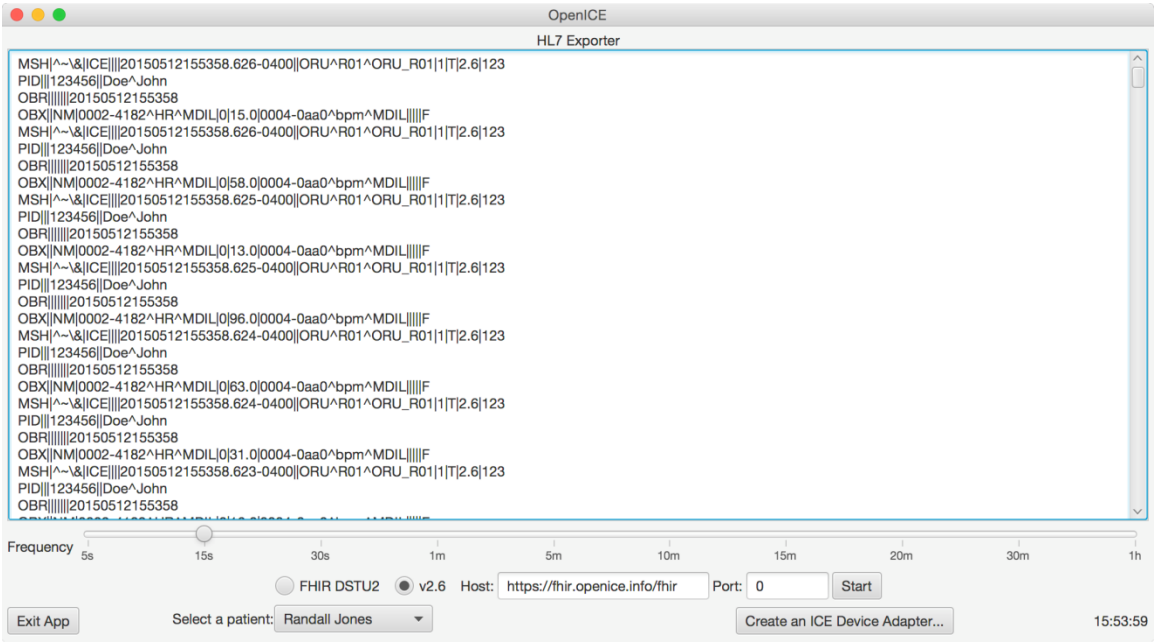
- csv – This document will save as a comma-separated values (csv) file, which may be imported by most data analysis programs, including Microsoft Excel
- sql – Structured Query Language storage format – used in many common databases including Microsoft Access
- vcd (IEEE-1364) – Value Change Dump – a waveform storage format defined by the Institute of Electrical and Electronics Engineers (IEEE) in the IEEE Standard-1364-1995 in 1995

Figure 10. Data Recorder reading data feeds from multiple devices



For HIMSS2015 we created and demonstrated an HL7 FHIR-compliant data export feed which can selectively send data points by patient at an adjustable frequency (see Aim 3 below).

Figure 11. HL7 FHIR format data export capabilities



Having demonstrated storing streaming device data from the OpenICE interface to MySQL tables using flat data files read from the console terminal with a Perl script, we next configured the Odysseus Studio Data Base Management System using a research tool from the University of Oldenburg (Germany) that provides a data handler for DDS interfaces, to accomplish this directly by intercepting the data stream and importing it into MySQL tables.

We created a short demo screen recording showing the database storage of the pulse oximeter data stream using the simulator in the MD PnP Demo Apps. Two tables are automatically created – one storing the records with the waveform data and the other storing the remaining records. We uploaded the video to the OneDrive website, to make it available for viewing. While this sharing site is no longer available, screen shots are shown in Figures 12 and 13 below.

Figure 12. Screenshot of Odysseus Studio 2 demo video on OneDrive website

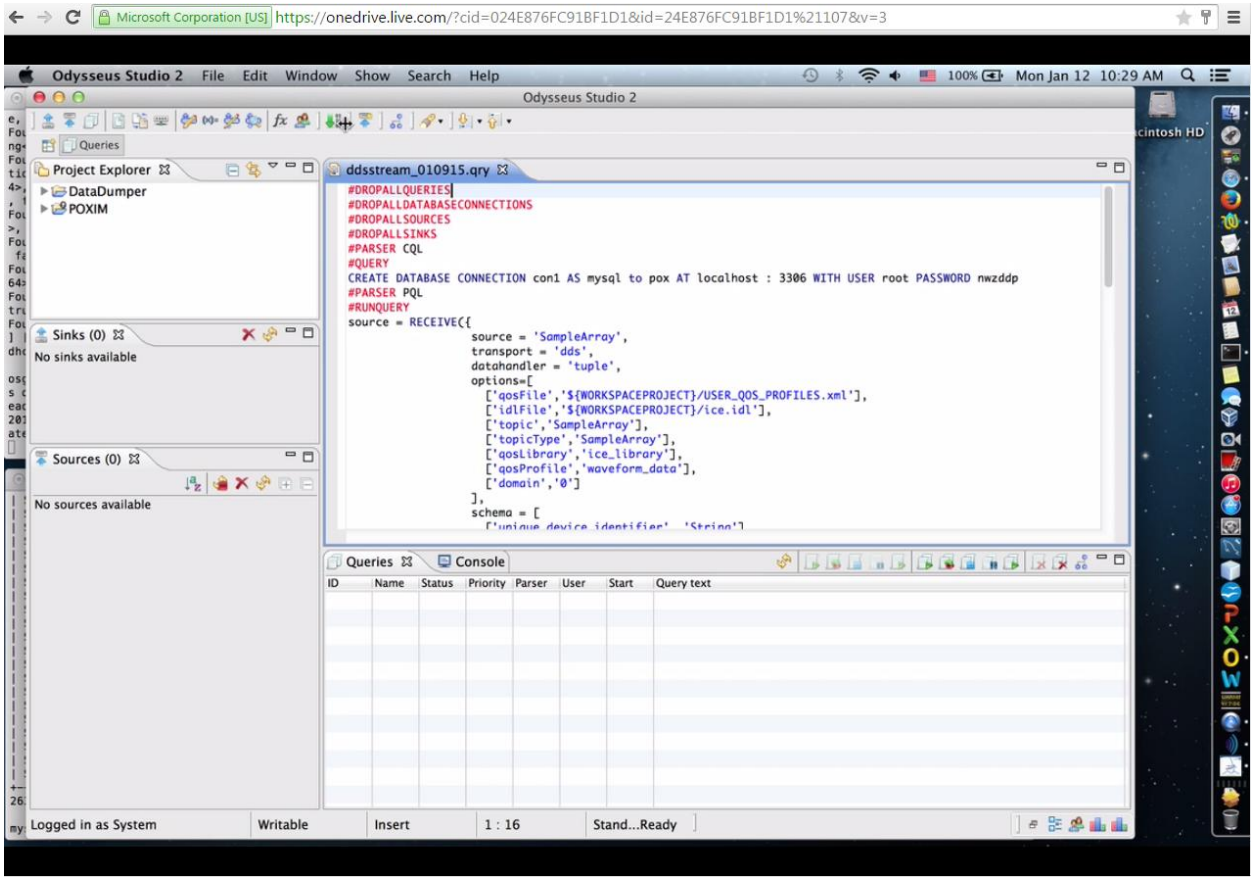
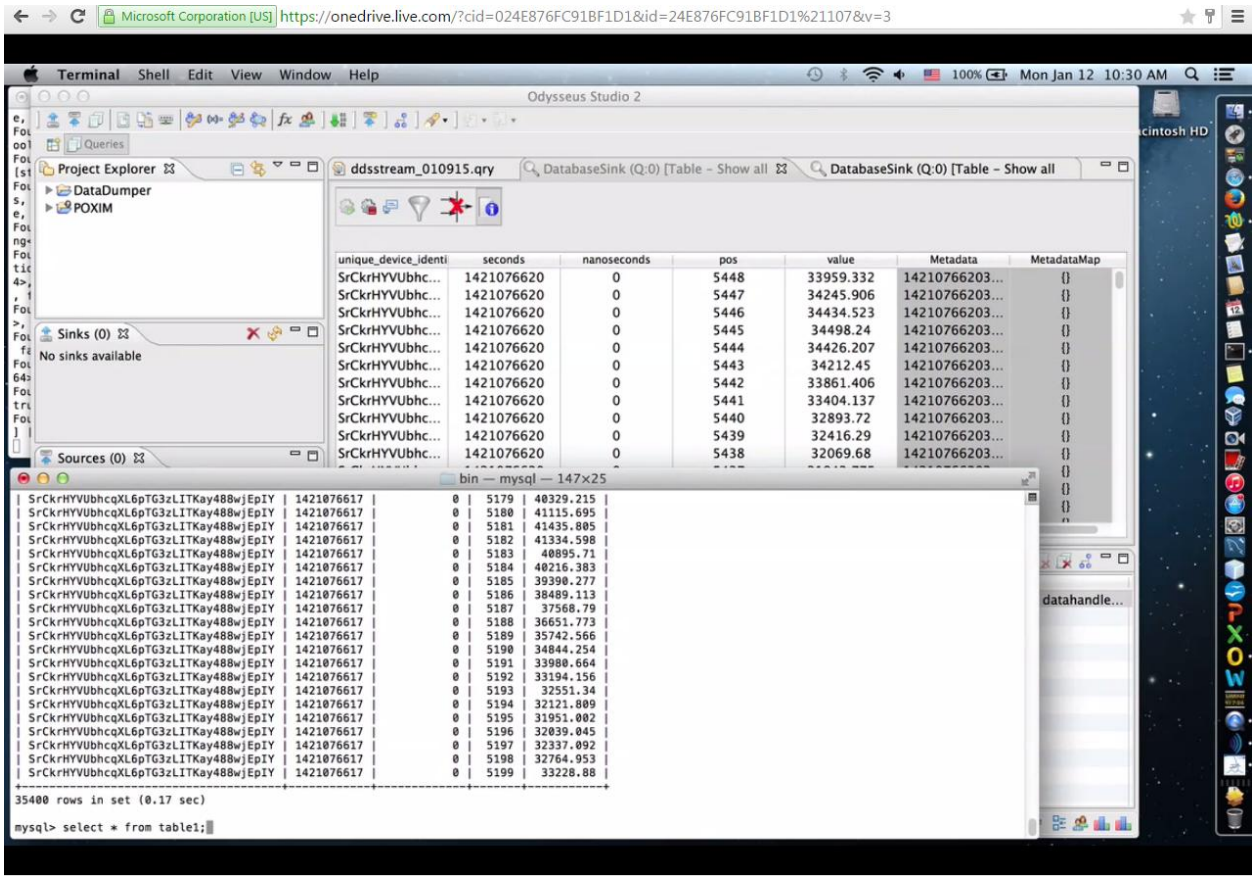


Figure 13. Screenshot of tables of waveform data in Odysseus Studio 2 database storage platform



Once we moved the prototype data logger to our DDS-based open source implementation, we performed extensive end-to-end performance testing to ensure that the entire system could handle large amounts of data. It was important for us to assess the maximum data throughput of the system. We found that the data logging rate was primarily dependent on storage hardware, not the ICE data acquisition or integration software. These results will allow us to specify the storage requirements for individual ICE data loggers and also for an architecture where all ICE data is backed up in a central data store at the Healthcare Delivery Organization. These findings have been valuable for the framing of the ICE Data Logger standard.

The NIST team visited our Lab in March 2014 as part of a three-day SmartAmerica “hackathon” (see http://smartamerica.org/teams/closed-loop-healthcare/ and http://mdpnp.org/smartamerica.php), and we collaborated to connect their prototype to our OpenICE platform to collect data. Based on the research results to date, NIST re-worked their prototype data logger to work with DDS, and demonstrated it at the SmartAmerica Expo in June 2014 (as part of the Closed Loop Healthcare team), including a demonstration of the data logging and analysis system based on OpenICE running on a PC as well as an iPad interfaced to that system. NIST subsequently posted their data logger source code to an online repository.

Once the FDA Unique Device Identifier (UDI) ruling was published in September 2013, we explored how to use the data format and content identified in the ruling within our OpenICE implementation. The UDI ruling lists information intended for printing on the packaging of medical devices and transmission by AIDC (Automated Identification and Data Capture) technologies such as bar codes and RFID, but not UDI transmitted over Electronic Data Interfaces (i.e. network connections). Dr. Goldman was part of a group convened by the FDA and Brookings Institute to promote adoption of UDI in registries and administrative health care claims. As part of the UDI Implementation Work

Group, he participated in discussions with FDA and Brookings about prototyping electronic communication of UDIs and the role of UDI in interoperable systems, and our team worked to determine how to extend our current UDI implementation with additional information from the ruling. This was expected to enhance data logging and playback with additional information about the device manufacturer, manufacturing date, batch ID, and so on.

Beginning in 2014 we focused much of our Data Logger effort on preparing a draft standard for the ICE Data Logger: *Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical network environment (ICE): Particular requirements for the forensic data logger*. We decided that taking time to write the draft standard would be valuable in identifying further requirements before the next round of development.

As part of the drafting of this standard, we extensively reviewed literature and standards associated with data loggers covering different modes of transportation, publications describing clinical data loggers, and earlier work on clinical requirements done by the MD PnP Program to highlight the specific needs of clinical data logging. In addition, FDA guidance and other documents (e.g. event codes, UDI guidance, medical device reporting regulations) and other ISO standards (e.g. clinical evaluations) were consulted and cited to ensure consistency of the requirements in the draft standard with these documents.

In order to provide additional supporting rationale for the draft standard, we explored the modification and inclusion of requirements related to patient privacy and data security. Our continuing participation in related standards activities – including ISO TC 121, IEEE 11073 POC/PHD, AAMI Interoperability Working Group, and the Joint AAMI/UL 2800 – has helped ensure harmonization with other standards work.

In May 2014 Dr. Goldman and a consultant, Michael Jaffe, presented the draft Data Logger standard to the team at NIST for feedback that was then incorporated into the draft. We circulated the draft to additional collaborators for review, and then to a broader group of domain experts. Much of this initial feedback was incorporated. Further iterations of the draft enhanced its suitability for submission into the standards development process as a new work item proposal (NWIP). The resulting ICE Data Logger proposed draft standard is attached to this report.

From 2014-2016, data logging capabilities were demonstrated in our MD PnP Lab in Cambridge, MA, to many medical device and software companies, computer scientists, clinicians, and standards developers. The insights obtained from our research were shared in those meetings and in public presentations, and feedback was used to refine the project. We added new capabilities and features to the OpenICE Data Recorder, including tracking of patient IDs, additional numeric vital signs, the ability to select data elements for recording by device or individually, and the ability to export data to MongoDB. The ICE data logging research capability was incorporated into the publicly available OpenICE software.

Clinical Scenario Repository, Aim 2: Develop a sharable repository of clinical scenarios that could be improved through better medical device and health IT integration.

Based on foundational research performed in our program and presented at a Scientific and Educational Exhibit at the 2006 American Society of Anesthesiologists Annual Meeting (http://mdpnp.org/uploads/MDPnP_Booklet_February_2007_p1-21.pdf), we developed a system-engineering-based model for the medical device interoperability ecosphere. Inputs to the system needed to begin with "Clinical Scenarios" – use cases from a clinical perspective that describe the clinical/functional capabilities of the interoperable system that can support innovative workflows in support of patient safety improvements.

As a result of earlier work on clinical requirements for medical device interoperability, the MD PnP team had built a prototype clinical scenario database as a student project during summer 2011, under funding from TATRC award W81XWH-09-1-0705. This database included a web-based user interface, a database back-end, and an administrative system to organize users and permissions, and collaborators at the FDA and NIST provided useful feedback. Based on this pilot work, we committed to build a scalable and user-friendly system under this new award (W81XWH-12-C-0154), beta-tested by our collaborators and refined via focus group input, then released to a broader audience.

Objectives for the first year included building and testing a robust preliminary web-based prototype of the Clinical Scenario Repository™ (CSR™), leveraging earlier work done under award W81XWH-09-1-0705. We invested substantial effort in a careful design and implementation that facilitated both administration and general usability of the Clinical Scenario Repository.

The clinical scenario repository web application was totally rebuilt from the original prototype, with numerous additions to functionality that were more efficiently implemented using newer frameworks. We used a common toolkit for building the site that gave it modern features, e.g. data saved automatically as a draft in progress while the user is working, with the option to manually "Save for later", and at the end of data entry, the user given the option to "Submit for approval."

The prototype Clinical Scenario Repository was based on the template designed by the MD PnP research team for describing and documenting information related to clinical scenarios and use cases that could benefit from medical device interoperability. The application requests information from the user followed an easy and descriptive approach utilizing a series of tabs:

- **Scenario Description:** is where the user can describe in detail the adverse event or clinical challenge – the *current state*. They can also describe the enhancement in safety that can be accomplished by an integrated solution in a *proposed state*.
- **Hazards:** is used to describe the factors contributing to the risk represented by the scenario, including their level of severity and the expectation of occurrence.
- **Environments:** is used to capture the clinicians involved in the scenario (e.g. nurse, anesthesiologist, surgeon, etc.) and the environment where it took place (e.g. operating room, hospital ward, ambulance, etc.).
- **Equipment:** is used to describe the medical devices or sensors that play an important role in the scenario.
- **Proposed Solution:** allows for a more extensive description of an ideal state or workflow, and how it might affect or change the practice environment.
- **Benefits and Risks:** is used to gather information about the obstacles eliminated by the new process, as well as any new risks that might be introduced by the proposed solution, so these can be mitigated in advance.
- **Feedback:** available only to administrators reviewing a submitted scenario, this tab is used to approve the scenario (granting any registered user permission to see it) or to request clarification from the scenario submitter via email.

An alpha version of the prototype CSR™ was demonstrated in August 2013 to USAMRMC/TATRC and other federal agencies (see below). That CSR™ had user features to create new scenarios and search the existing database of scenarios, and system administrator features to review, approve, and manage scenarios. It was hosted on the Google Application Engine, which provided an easy and reliable way of managing the user log-in process, email communications, and data storage, and enabled our developers to use the web development technologies necessary to implement the browser side of the web portal. Features included a user registration and log-in process, as well as the persistence of administrative user information, the data from the scenario description, and other related data (such as keywords to tag the scenarios for search/indexation purposes).

Our implementation included a database schema that is a *superset* of the data specified in the clinical scenario template of Annex B of ASTM standard F2761-09(13) for the Integrated Clinical Environment (ICE). We normalized the schema to make it robust enough for the higher traffic anticipated on a generally available web site. We formally defined the *state model* for a scenario (e.g. In Progress, Pending Approval, Approved, etc.), which was a challenging task because the rules for transitioning from one state to another – or even the number of states – might change as we develop new features, receive feedback from our collaborators, and consider different behaviors in the users' interaction with the application.

Basic user roles were defined (unregistered visitor, registered collaborator, and system administrator), and a coherent set of functionalities and privileges was granted to each role. For example, system administrators can view all scenarios submitted, registered collaborators are able to view all approved scenarios as well as scenarios they have themselves entered, regardless of status, and unregistered visitors can view only scenarios that have been approved and are part of the viewable database – they cannot enter a scenario unless they register. We added the "unregistered visitor" role as a way to show some utility to a new visitor and provide them a motivation to register with our site.

Major features:

- **Registration:** The Google Application Engine provided a registration system for users using Google IDs. This relieved us from implementing our own registration system and requesting, encrypting and securely managing and maintaining usernames, passwords and other personal information from users; this allowed us to focus on the features at the heart of the repository. This registration process was extended to include "OpenID federated login" and other existing providers for Secure-Socket-Layer authentication and registration. The personal information shared in the registration process is kept private and is not shared with other users.
- **Scenario Entry:** For scenario entry our design follows a tabbed "breadcrumb" approach, allowing the user to move easily between sections of the scenario entry process without enforcing a strict path through those sections. This allows *Registered Users* to immediately enter the information they have readily available, and to easily return later to complete other sections. At the top of each text entry box, we include pop-up menus to provide an "example scenario" to show what to fill in. The clear explanation of fields will help users to enter more useful data, and is an example of using user feedback to identify additional ways to provide contextual assistance.
- **Search:** Our search functionality follows a "keyword" approach, offering the user the ability to search all data fields for keywords of interest.
- **Approval Workflow:** Our Repository Administrator is able to view new pending scenarios submitted by *Registered Users*, and will review and approve scenarios before they become part of the public repository. In anticipation that content clarification will be needed for many submissions prior to public sharing, we have facilitated communication between submitters and approvers using an email feature.

Traditionally web apps have followed a simple "form submission" model where a user fills out numerous fields and clicks *Submit*. We used a more modern approach (AJAX mechanism) that allows us to save a user's progress while they are working in order to ensure no data is lost. This introduced new challenges – for instance, we must store and manage all of a user's current draft work. We also had to make decisions about how often and with what granularity to send data back to the server.

For the storage of data, using Google App Engine presented new decisions. One option was to use a more traditional Relational Database Management System (RDBMS) hosted either in the cloud or on our own servers. A second option was to use the Google High Replication Datastore, a "big data" technology that scales far better than an RDBMS but creates other issues. We initially stayed within the confines of an abstraction layer ("Java Data Objects") that supports either storage subsystem.

Users can save the scenario information at any time, allowing them to enter the information available at the moment and to revisit these tabs at another time to complete or update the information. This approach relieves the user of being forced through a multitude of input fields and constrained data input workflow processes. We received positive feedback on the intuitive navigation from NIH demo attendees.

During the first year of this award, we leveraged the work performed under award W81XWH-09-1-0705 to build and test a robust preliminary web-based prototype of the Clinical Scenario Repository (CSR™). An alpha version prototype was developed, tested and shared among internal collaborators, who provided valuable feedback. The culmination of our first year's work was the opportunity to show the alpha version of the prototype Clinical Scenario Repository when we presented a series of demonstrations of our work at NIH on August 21-22 2013 for invited representatives from federal agencies. There were over 60 attendees from DoD, FDA, NIST, NIH, and other federal agencies, and we received positive feedback, encouraging us to develop additional features, e.g. advanced search capabilities that might include an ontology of terms and use of natural language processing of submitted text to auto-create keyword tags. Subsequently, the prototype repository was presented several times as part of our Lab Open House tours in September 2013 and other demonstrations of our work to visitors and collaborators.

In preparation for the initial beta test, the functionality of the CSR™ was greatly enhanced. While some of these features reflected needs we had already identified internally, many of them were the direct result of the feedback from federal attendees at the August technology demonstrations. We were careful to implement the requested features in a way that protects health information, while also responding to user expectations regarding usage and functionality. One challenge that surfaced in the August demos was related to a suggestion that repository users be able to annotate existing scenarios and increment the information contained within scenarios – this kind of feature raised issues about governance of the data contained in the repository, and underscored the need for a process that enforces our policy of not including any personal or defamatory information in the scenarios.

The beta version of the CSR™ was released in December 2013 to a pilot group of internal MGH users, has been shown to several groups visiting the MD PnP Interoperability Lab (including standards development committees and industry), and was shown publicly to clinicians and engineers at the annual meeting of the Society for Technology in Anesthesia (STA) in January 2014. The CSR™ had considerable exposure at STA – it was one of the hands-on stations in our two-hour OpenICE workshop, and was presented in a lecture and poster. The CSR™ had also been presented in a panel with Johns Hopkins and Mayo Clinic at the Society for Critical Care Medicine meeting in San Francisco the week prior to STA.

We received many new ideas and requests, as well as feedback, from STA. Both clinical and industry users expressed concern about information that the CSR™ could make available to the general public on specific medical device models and products, e.g. possible malfunctioning, less competitive array of functionality and features, general problems, etc. While some manufacturer representatives expressed interest in using the content of the repository as feedback to verify product functionality and address new features or product opportunities, they also proposed restricting access to the CSR™ content to the QA departments of hospitals and companies. This confirmed our own concerns about the extent of governance issues to be addressed, and about taking additional cautionary measures with the scenario approval workflow.

While we had anticipated the need for an approval process that could validate the content of CSR™ submissions before making the scenarios available to all users, additional aspects of the governance process surfaced. For example, STA attendees (clinicians and manufacturers) emphasized that even if a scenario does not contain specific defamatory information (names of doctors, hospitals, etc.), that is not enough to guarantee the absence of defamatory information – the CSR™ should not have any

kind of *implicit* defamatory information that could be derived from the content posted. Moreover, we had to reevaluate the consequences of opening a tool like the CSR™ to the general public – while it was our intent that this repository not substitute for other mandatory reporting systems (required for medico-legal and/or regulatory purposes), there could be submissions that would require CSR™ administrators to act upon receiving them, e.g. mention of abuse or other such reportable events. This underscored the importance of having a well-thought-out governance approach and process.

We examined how clinical scenarios in the CSR™ could be cross-referenced with other databases and with our other project work, e.g. linking to further documentation of ConOps (engineering Concept of Operations) or requirements. In the future, the CSR™ could be expanded to include the other artifacts that are necessary to follow a scenario all the way to implementation.

An important milestone accomplished during in the second year was successfully deploying the CSR™ web application on our own managed servers, moving away from the Google Application Engine that was used in the prototype's early stages.

Ensuring adequate authentication and authorization mechanisms was one of the CSR™ priorities. Several promising technologies were considered for this task, including Spring Security, a powerful and highly customizable authentication and access control framework, and BCrypt, the Java implementation of a hashing algorithm that would allow for hashing a password (ensuring that users' passwords and other sensitive data are not stored using plain text in the database) and SSL certificates. We also focused on obtaining the appropriate authentication and authorization mechanisms needed for the governance process.

The unique attributes of this CSR™ – i.e. not linked to a single medical device failure (in contrast to the FDA MAUDE database), not required to have a 1:1 relationship between a scenario event/idea and submission (like hospital adverse event reporting), not linked to a specific patient (or any patient), free text entry, etc. – opens the door for a new approach to healthcare quality improvement. Even with the limited release possible within this project, the CSR™ generated excitement and the contribution of ideas by leaders from industry, patient safety, and clinical domains. We envision even more interest if an improved CSR™ is publicly released. Moreover, we expect a linkage will develop between this work and the Federal initiatives around device/HIT safety, as well as patient safety societies and patient networks.

The Clinical Scenario Repository (CSR™) was presented at the Military Health System Research Symposium (MHSRS) in August 2014 in Fort Lauderdale, FL, where it received enthusiastic praise from DoD representatives excited about the idea of having a tool that would allow capturing "good ideas". They felt the CSR™ differentiated itself from other such systems, first, by eliminating the negative connotations of reporting mechanisms and tools (e.g. being perceived as tedious and time-consuming processes with potential negative repercussions for the reporter), and second, by encouraging users to share their own expertise and ideas, with the potential to improve many different aspects of the healthcare landscape. The scenario submission workflow had been simplified such that the limited mandatory information is provided via a description of the event in plain language and a title that summarizes the scenario in a way that easily identifies it.

The feedback provided by DoD encouraged us to incorporate the term "*good ideas for patient safety*" in the mission definition of the CSR™, to better explain that this tool is not only intended to point out technology gaps and raise awareness about events that would not otherwise be reported, but also allows sharing ideas and experience to improve these perceived gaps or patient care in general.

The CSR™ was also presented during the open house sessions for the Medical Device Plug and Play program's 10th anniversary in October 2014. Visitors stressed that the main difficulty in reconstructing and analyzing adverse events is having available the necessary information about the event; this aligns with our attempt to keep the submission process simple while capturing as much detail as users are willing to offer.

The primary functionality of the CSR™, capturing a clinical event or idea, was completed during this project. Users can develop a clinical scenario through a workflow that allows them to submit the basic information in plain language and expand it further to incorporate advanced technical details. While currently, for the sake of simplicity, each event has only a single solution, it should be possible to modify the CSR™ so that users can propose multiple solutions to the same event, in order to compare, discuss and evaluate different approaches to a problem affecting patient safety.

During 2015 and 2016 the CSR™ was shared with the Committee on Patient Safety and Quality of the American Society of Anesthesiologists (ASA), the AHRQ Patient Safety Organization (PSO) experts, the CRICO risk management foundation (https://www.rmf.harvard.edu/), and ISO TC 121, to optimize the user interface and help identify a pathway to obtain broad input into the CSR™. We made the CSR™ available to select groups by deploying the application in our own managed servers at https://csr.openice.info/, so that both the application and the data collected are easily managed and kept safe. The advice provided by these representatives highlighted the need to improve the data collection mechanism based on the feedback provided by users of the repository. Meetings with AHRQ, CRICO, and MGH were also part of our discussions of governance and application areas.

In order to maximize the leverage provided by the feedback for this project from these users of the CSR™, we continually updated the prototypes with new features motivated by the users' comments, ideas and needs for this project. Internal users tested these features before they were approved and deployed on the prototypes we shared on the worldwide web. The representatives from the CRICO, ASA, and AHRQ praised the idea of allowing users to describe events or ideas in plain language. This process contributed greatly to the refinement and evolution of the Clinical Scenario Repository™.

Based on research and feedback, we migrated the CSR™ to a different (third) platform, largely due to the unsuitability for reliable long-term data storage and easy user ID authentication provided by the Google technologies chosen to develop the early prototypes. Migrating from MySQL to a Mongo database proved a good match for the technical needs of the CSR™. One of the key challenges of this application was to offer simple yet detail-rich interfaces to enable users to provide as much (or as little) information as they wish or as they have available at the moment. This forces the data model to change frequently when new fields are suggested or requested by users. Mongo databases are ideal for unstable schemas, since adding a new field (for example, information related to the drugs involved in a scenario, such as name of the drug, dosage, etc.) won't affect existing rows or documents. This proved an advantage for both development and deployment of newer versions of the application, requiring less effort from database administrators.

In addition, an implementation using JavaScript, HTML and Mongo proved faster and more efficient when persisting and retrieving data than the former implementation using the Google Web toolkit and a MySQL database. We implemented a quick and easy way of creating user accounts that provides the option of using OAuth services, e.g. using the user's Google account to sign in to the CSR™. When creating a new user account, minimal information is requested of users to respect their privacy, but an email is required in case – in the process of reviewing a scenario – the reviewer needs to contact the submitter. The following figures illustrate the CSR™ interface.

Figure 14. Account creation

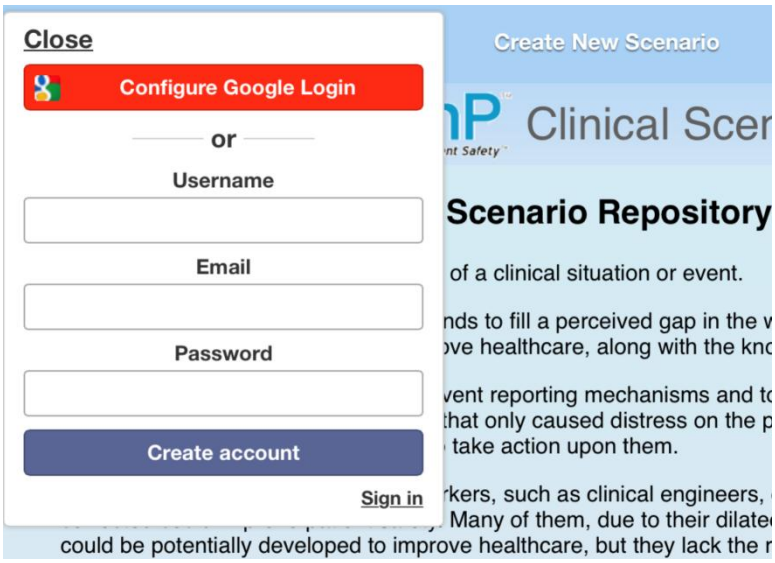
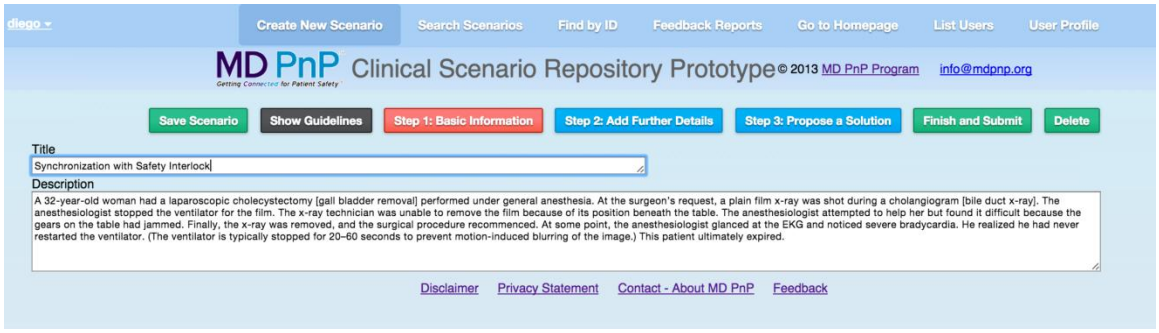
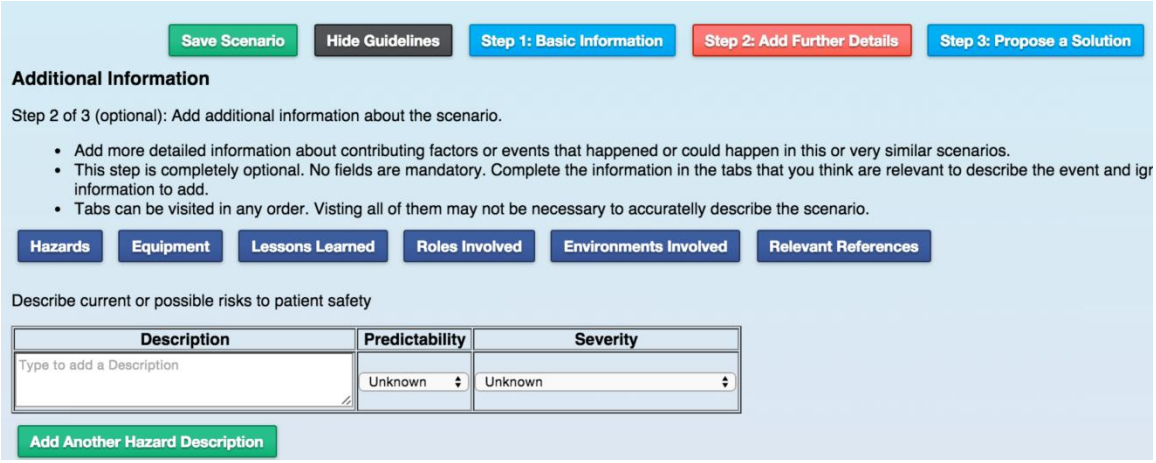


Figure 15. Step 1: Scenario described in plain language



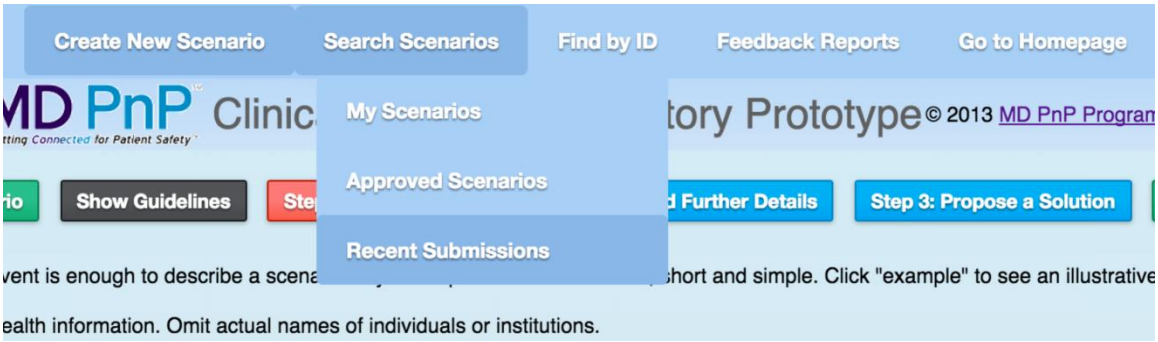
The workflow of the scenario submission process is clear, highlighting the different scenario steps using color codes: a first step with basic information consisting of a high level description of the scenario in plain language, a second optional step in which users can volunteer more technical information such as that related to the nature of the adverse events or the actors involved in the scenario, and a third optional step in which users can discuss possible solutions for the event. Each step includes contextual help that guides the user in the process of entering the correct information into the right sections.

Figure 16. Step 2: Advanced Details page with contextual help



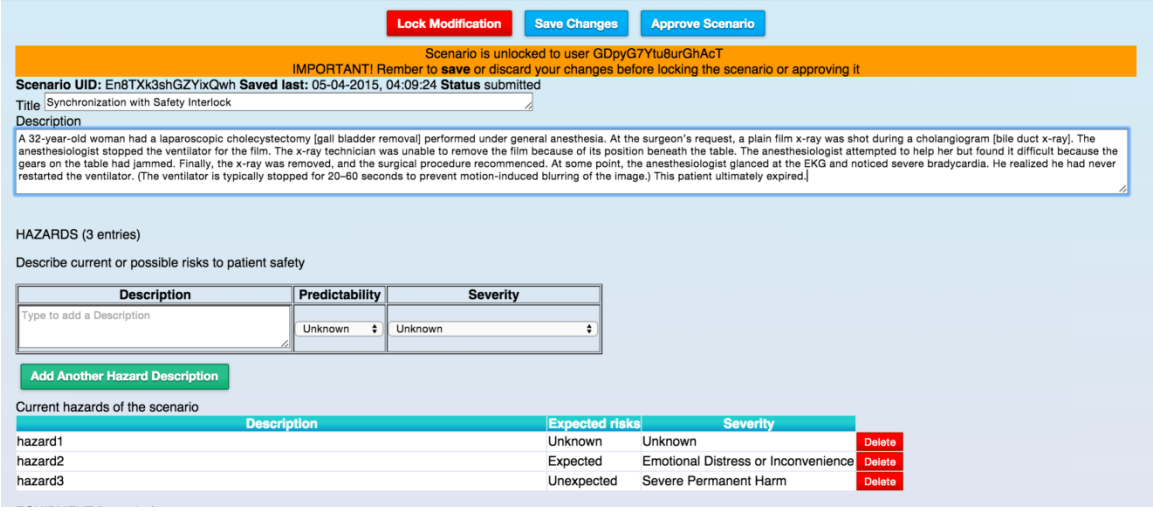
The CSR™ has a user-friendly navigation menu that helps both users and administrators understand where they are in the application and what their options are. This makes it easier for administrators to track new submissions pending revision.

Figure 17. A glimpse of different options on the navigation menu



The interface for revising submitted scenarios is a single-page report. As opposed to the scenario submission process, where the use of different steps and tabs helps keep interfaces simple, avoiding overwhelming requests for data, the scenario review panel displays all the scenario information in a single report, so the administrators reviewing the scenario don't risk skipping important information by navigation through different steps.

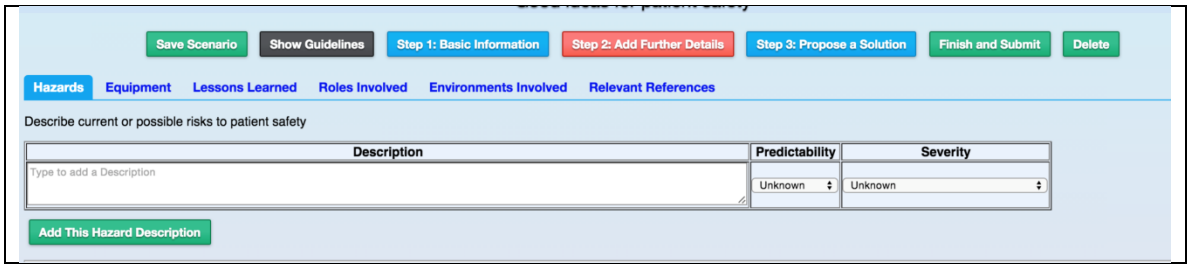
Figure 18. New panel for scenario revision



In order to simplify the life cycle of scenarios, the governance process for submitted scenarios enables administrators to modify either submissions or approved scenarios, avoiding the need of re-approving modified submissions. Based on the recommendations of contributors to the CSR™, administrators cannot delete scenarios from the database, nor can users delete their own contributions once they have been submitted. This is to protect the content collected by the CSR™. No user is allowed to perform irreversible actions that delete content from the scenario collection. Scenarios that are not suitable for the CSR™ are "hidden" from users, but are available to the researchers who are developing this web tool so that these kinds of contributions can help identify new governance problems or needs.

Understanding the visual aspect is key to providing a satisfying CSR™ user experience when submitting new contributions. Design enhancements have included an improved navigation bar (providing a clear way to contact the program for parties who are interested in collaborating with the development of this web tool, contributing content to the repository, assisting with usage of the tool, or simply interested in the work being done at this research program). The tabbed panel displays the kinds of advanced information that can be submitted in a scenario (in order to clarify the scenario submission workflow or to facilitate users' understanding of the non-mandatory information they can volunteer).

Figure 19. Comparison of the *Scenario Hazards* interface before and after updates completed



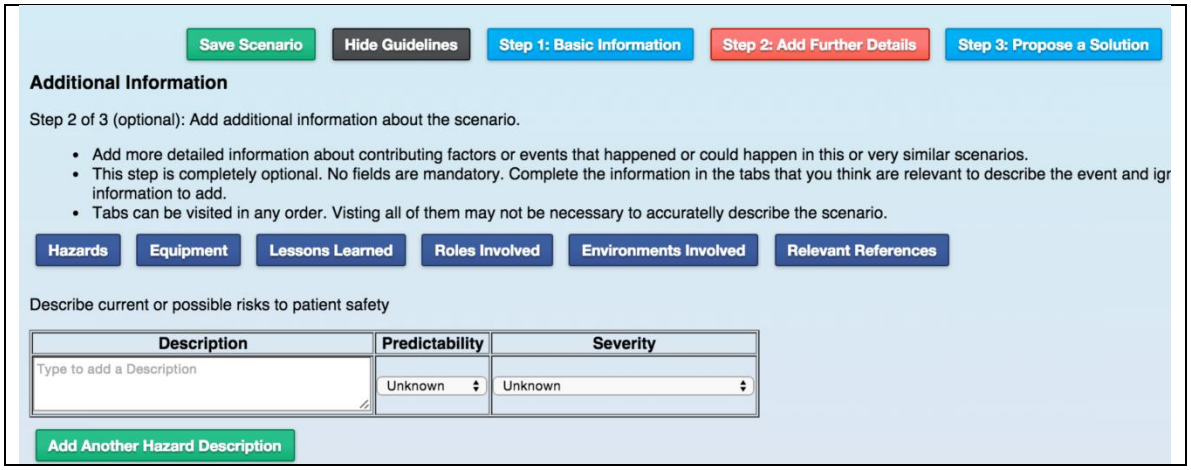
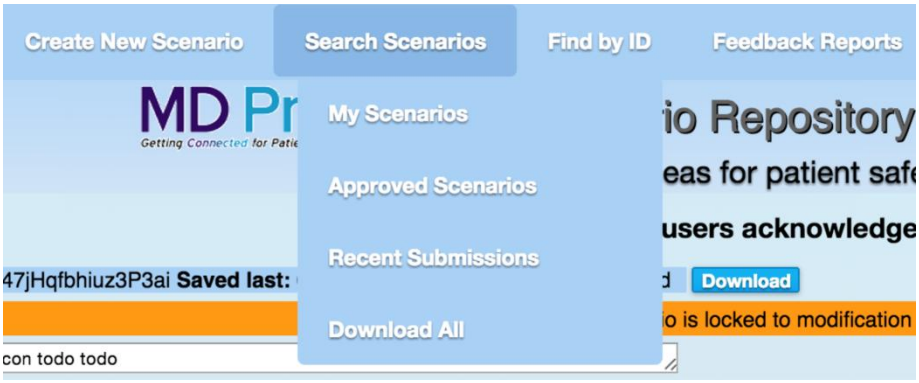


Figure 19 illustrates some of the improvements performed on the interfaces. For this particular interface the size of the text field for the description of hazards was expanded and color was used to highlight the input fields. Also, the visual aspect of the interface changed to look more like a tabbed panel (which for the user clarifies where the information lies).

Along with the migration process new features were implemented. The latest release of the prototype allows downloads of approved scenarios as either a single scenario or all approved scenarios contained in the database (see Figure 20).

Figure 20. *Scenario Download* features (from the main menu or from the *View Scenario* Interface)



In order to facilitate sharing scenarios among researchers, apart from the *Download Scenario* feature, the CSR™ was enhanced to improve its web presence, with upgrades such as a Twitter Summary Card, which could increase the impact of sharing online scenarios contained in the CSR™.

Figures 21 and 22 show CSR™ scenarios submitted by physician members of the ASA Committee on Patient Safety and Quality.

Figure 21. Individual submitted scenario

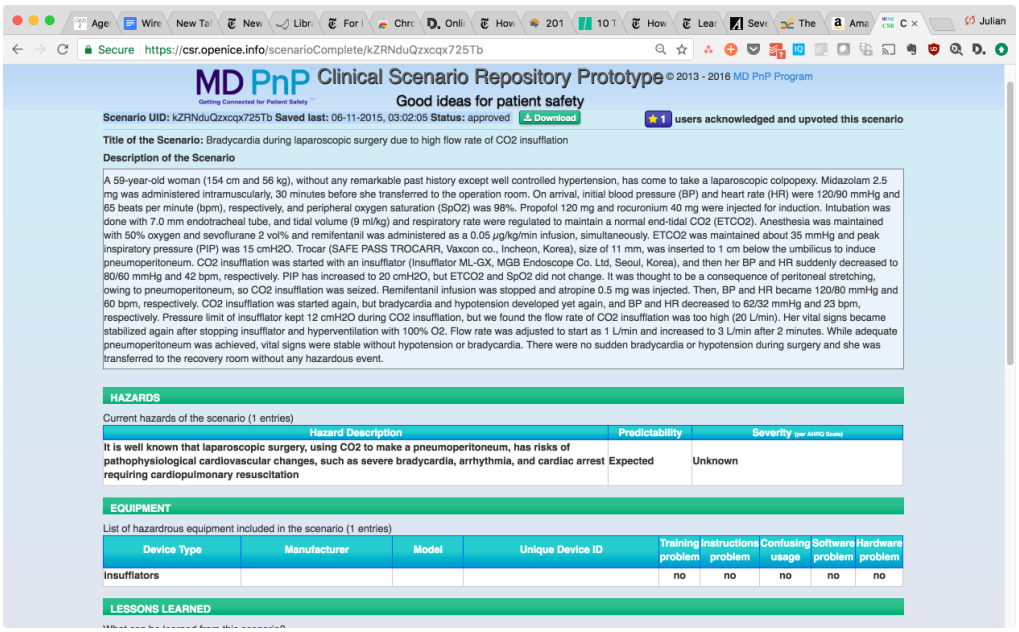
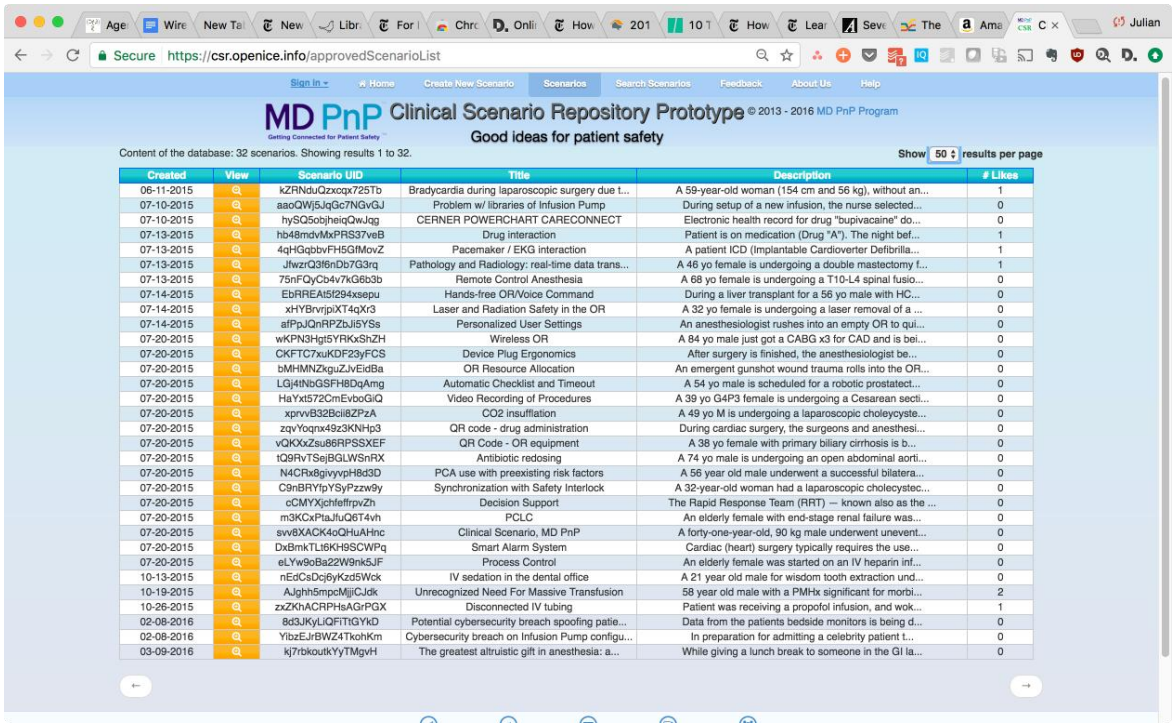


Figure 22. List of submitted scenarios



With the completion of Aim 2, we demonstrated that the CSR™ has appeal and value to the medical device commercial, standards, health care delivery organizations, and patient safety sectors. We built on this foundation to perform a pilot with the ASA Committee on Patient Safety and Quality in September 2016 under Option-Year 3 of USAMRMC award W81XWH-09-1-0705.

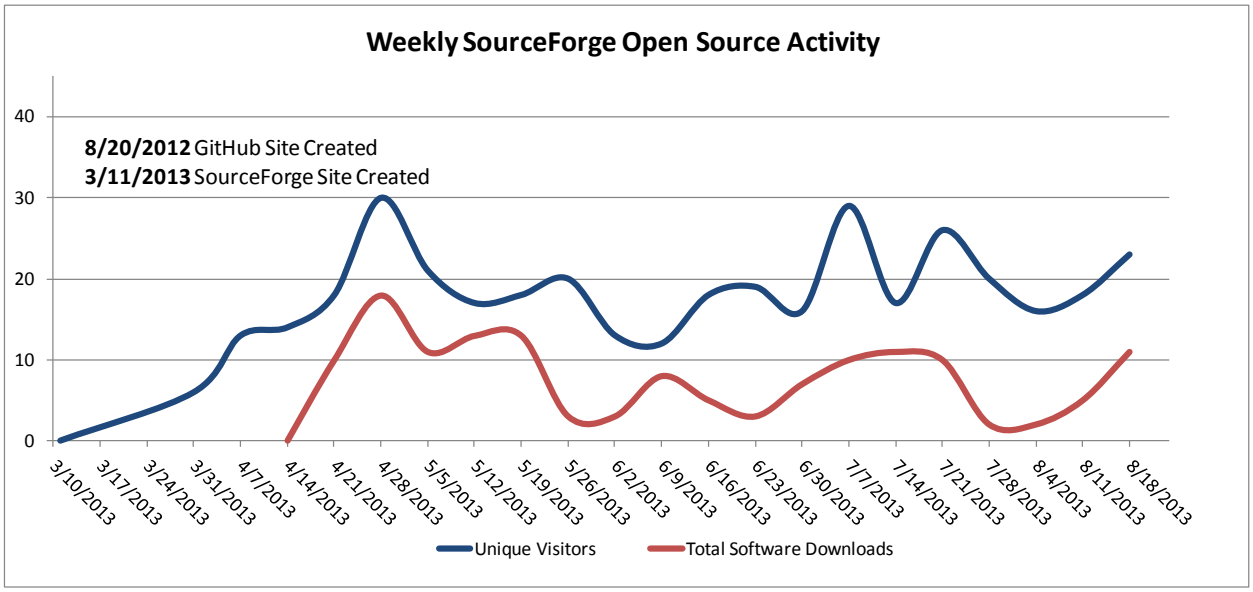
Open Source Code Dissemination, Aim 3: Disseminate open-source code developed by the MD PnP program and collaborators, including the prototype Data Logger, in order to facilitate further development by others.

We began working with Open Health Tools (OHT) in March 2012 to consider a process for sharing code and other tools. This relationship informed our thinking about the challenges of sharing code and the possible approaches. In addition, our NIH Quantum U01 sponsors strongly and consistently encouraged us to share code and other artifacts from that work, but this award enabled us to do the necessary research and organization to develop a plan and an open-source approach for doing so.

We began in September 2012 posting several projects on GitHub, a popular open-source project hosting platform. However, we subsequently identified limitations in tracking page views and downloads of source code. For this reason, we started hosting projects in March 2013 on SourceForge, which supports more metrics: http://sourceforge.net/projects/mdpnp/. Unlike GitHub, SourceForge allowed us to easily share artifacts that were not source code. For instance, we obtained ECG and pulse oximeter data from a GE Central Station and patient monitor, and posted this data on SourceForge for use by other researchers.

We subsequently added a diverse set of software to our code repository on SourceForge, and this site became the focus of all development activity for MD PnP for this award, our NIH U01, and other projects. Our repository includes software components for interfacing with devices in our Interoperability Lab, as well as the speculative software we built to connect those devices and implement demonstration applications. By making our work available at various phases of development, we aimed to facilitate involvement by the broader research community. We recorded hundreds of downloads from dozens of countries within several months of launching the repository (see Figure 23 for activity over this time period). This site has been a key point of synchronization with our collaborators.

Figure 23. Weekly SourceForge Access Activity March – August 2013

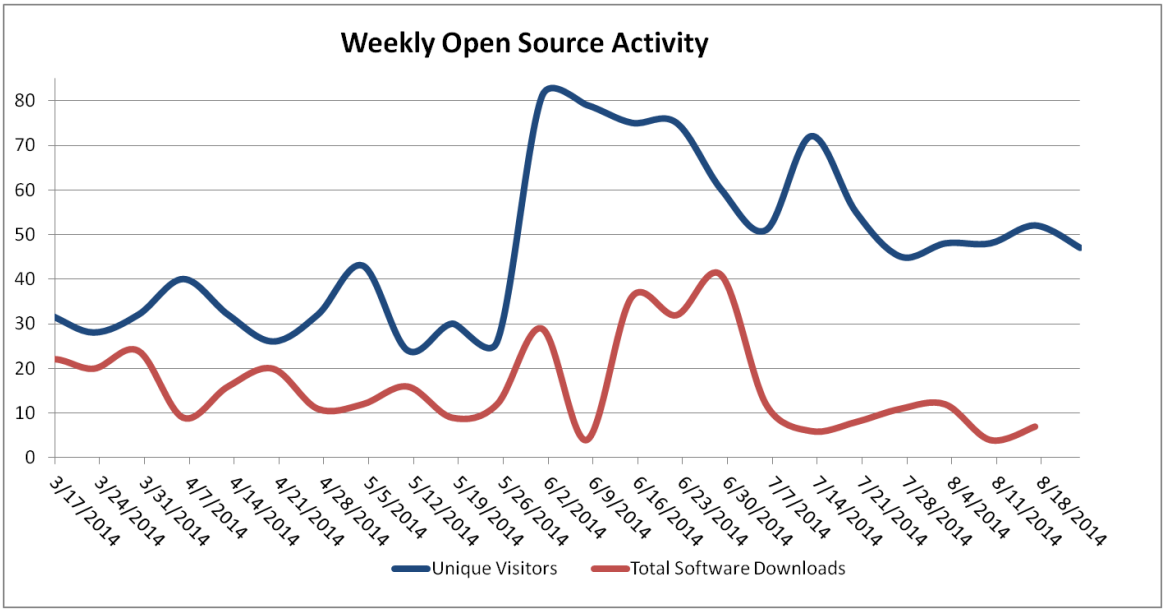


A coherent build system makes it easier for community members to modify the code because it automatically creates an environment on their computer amenable to building the software (gathering third party libraries, configuring the compiler, etc). Continuous integration enabled us to monitor changes made to the code repository and it reports in real time on any changes to the code that prevent its building successfully or any failed unit tests. We exercised these processes among our own team as preparation for involvement of the broader community.

Although we did not initially publicize our repository while we were adding material and beta-testing it with our collaborators, potential users were still finding our code and downloading it.

During the second year of this award, our SourceForge site (http://mdpnp.sourceforge.net) saw 955 downloads of our prototype OpenICE platform and tools (see Figure 24 below). Anyone who downloaded that software package could use our basic device simulators to begin development of clinical apps for the platform. In addition to sharing with the public at large, we engaged in specific interactions to pave the way for development of the first ICE AX apps as well as the first frameworks. We found ourselves challenged to balance supporting these nascent external activities against our need to use insights gained to enhance and iterate on the platform itself. With each engagement we streamlined the documentation of the platform to immediately surface its value to groups who might benefit from its use for clinical research.

Figure 24. Weekly SourceForge Access Activity March – August 2014



Following are several examples of the use of our code-sharing resources by researchers:

- A researcher at the University of Florida at Gainesville successfully downloaded, built and ran our code from SourceForge; he was building a system for automatic patient assessment using our open source Philips interfaces and DDS backbone. In working with them we realized that our current interface software utilizing the device's Ethernet port would not be usable with a monitor connected to its central station in such a study, so we rewrote our interface to also support direct RS-232 connection to the monitor.

- In November 2014 the MD PnP Lab hosted undergraduate students from Harvard and MIT for a "hack-a-thon" organized in conjunction with the Hacking Medicine group. This gave us the opportunity to expose our platform work to students who were tasked with creating innovative healthcare apps based on problem areas we outlined. While it was difficult for the students to produce complete apps within the time constraints of the event, several students expressed interest in returning to the Lab and utilizing both our physical equipment and software platform for further work.

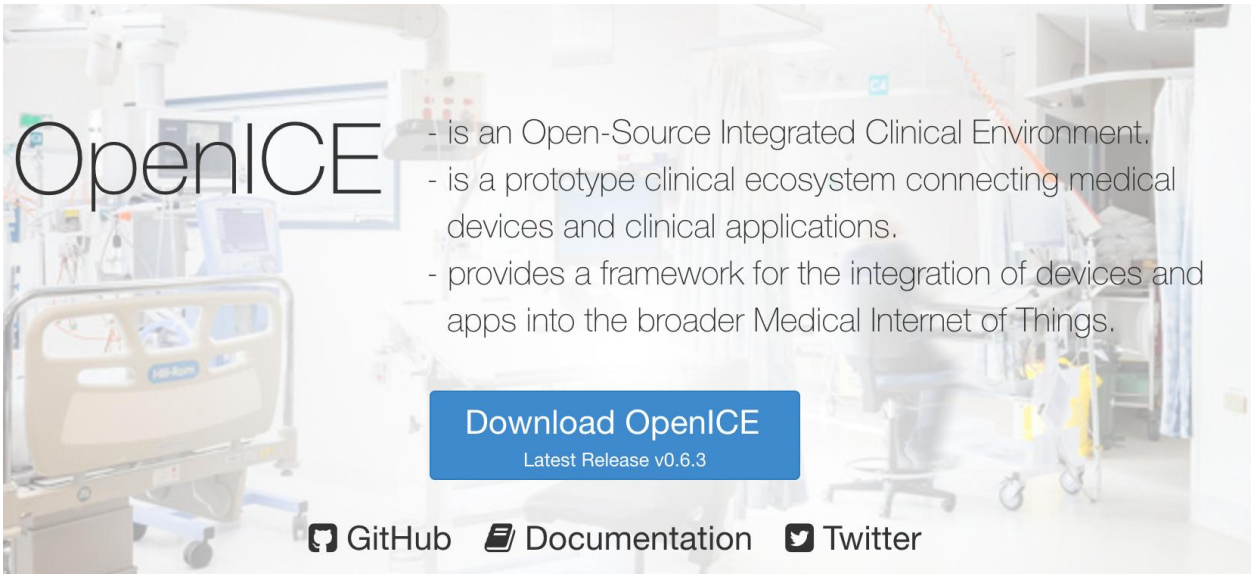
- Researchers at the United States Army Institute of Surgical Research began analyzing the source code and our software and architectural approach to interoperability.

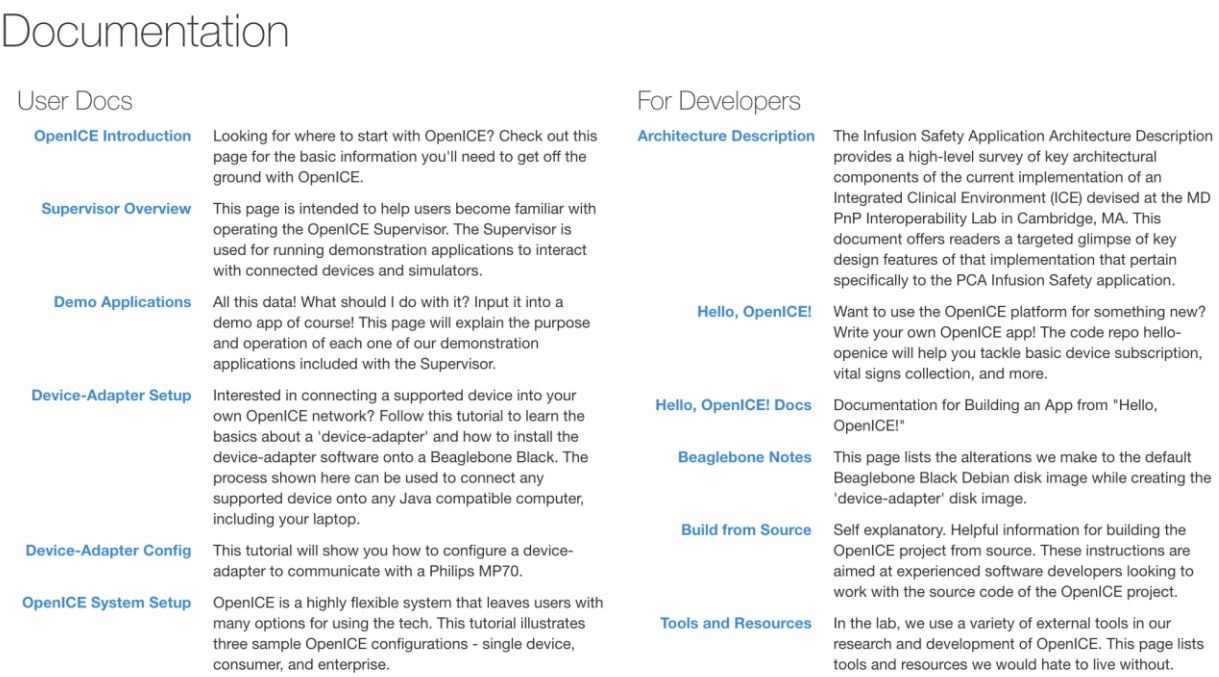
- We became connected with pre-release work in the area of frameworks being done at Mathworks Inc. on a MatLab interface to RTI's DDS middleware. By participating in that

project, we were able to ensure that when this MatLab “BlockSet” was eventually released, it would be compatible with the DDS middleware used in our ICE platform.

We built a new website to support remote use of the MD PnP Interoperability Lab's capabilities: OpenICE.info. This site was intended to allow diverse users – potentially students, clinicians, biomedical engineers or others interested in using medical device data – to easily access and use data from devices and patient simulators in the MD PnP Lab. This capability was expected to permit broad access to OpenICE tutorials, information, apps, and source code.

Figure 25. Screenshot from OpenIce.info: a Web Resource for Education and Dissemination

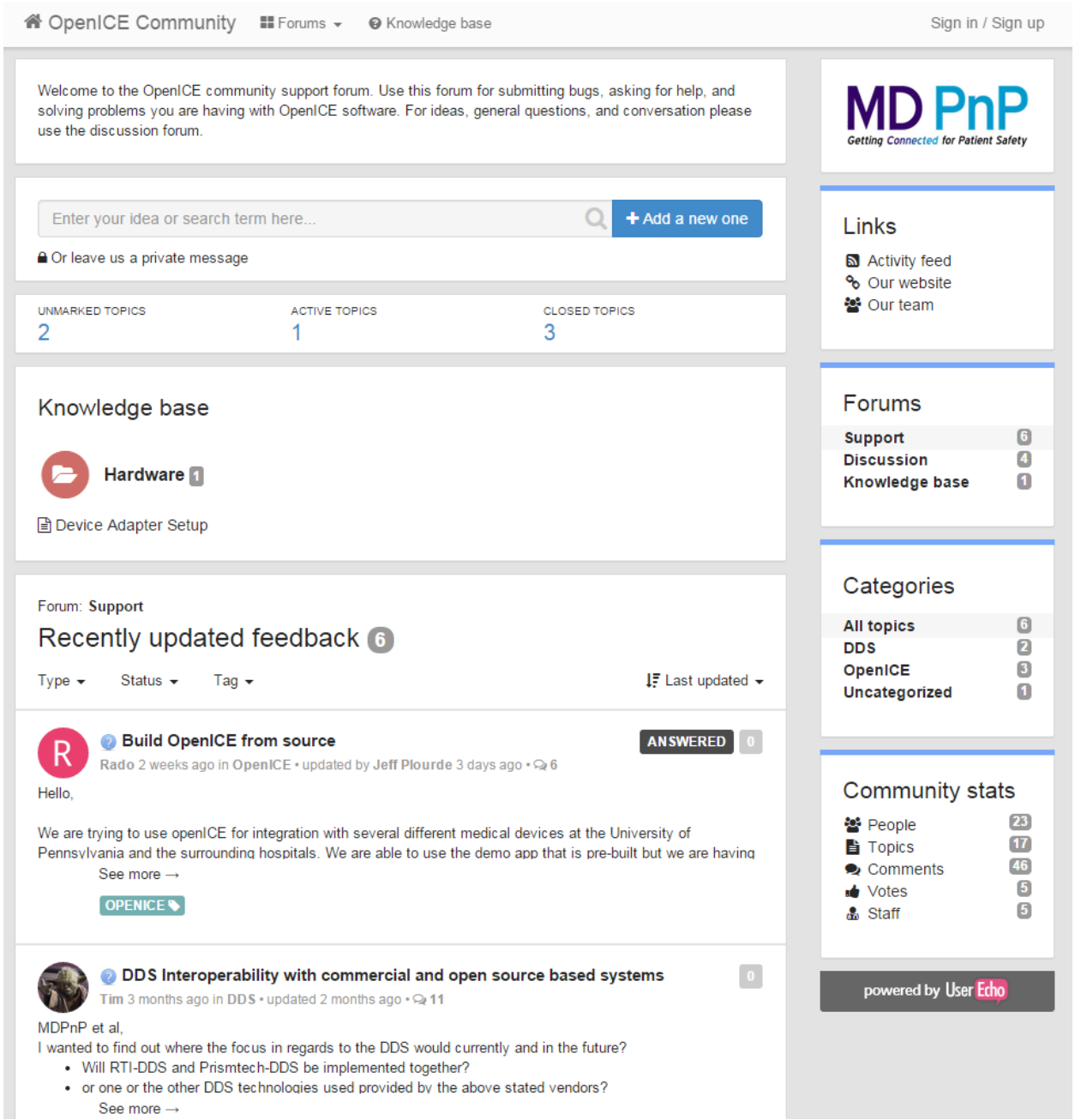




We extended the capabilities of the OpenICE website (http://openice.info) to include a community support forum in which OpenICE users from around the world can submit questions, code, and other information to be discussed with the MD PnP team and each other (http://community.openice.info). In

addition, this forum, powered by UserEcho, is useful as a tool to track the growth of the worldwide OpenICE user community and to identify shared development interests or issues. However, staffing a response team while performing our other required funded work proved challenging. Figures 26-28 show illustrative screen shots of the forum.

Figure 26. Screenshot of OpenICE Community Forum

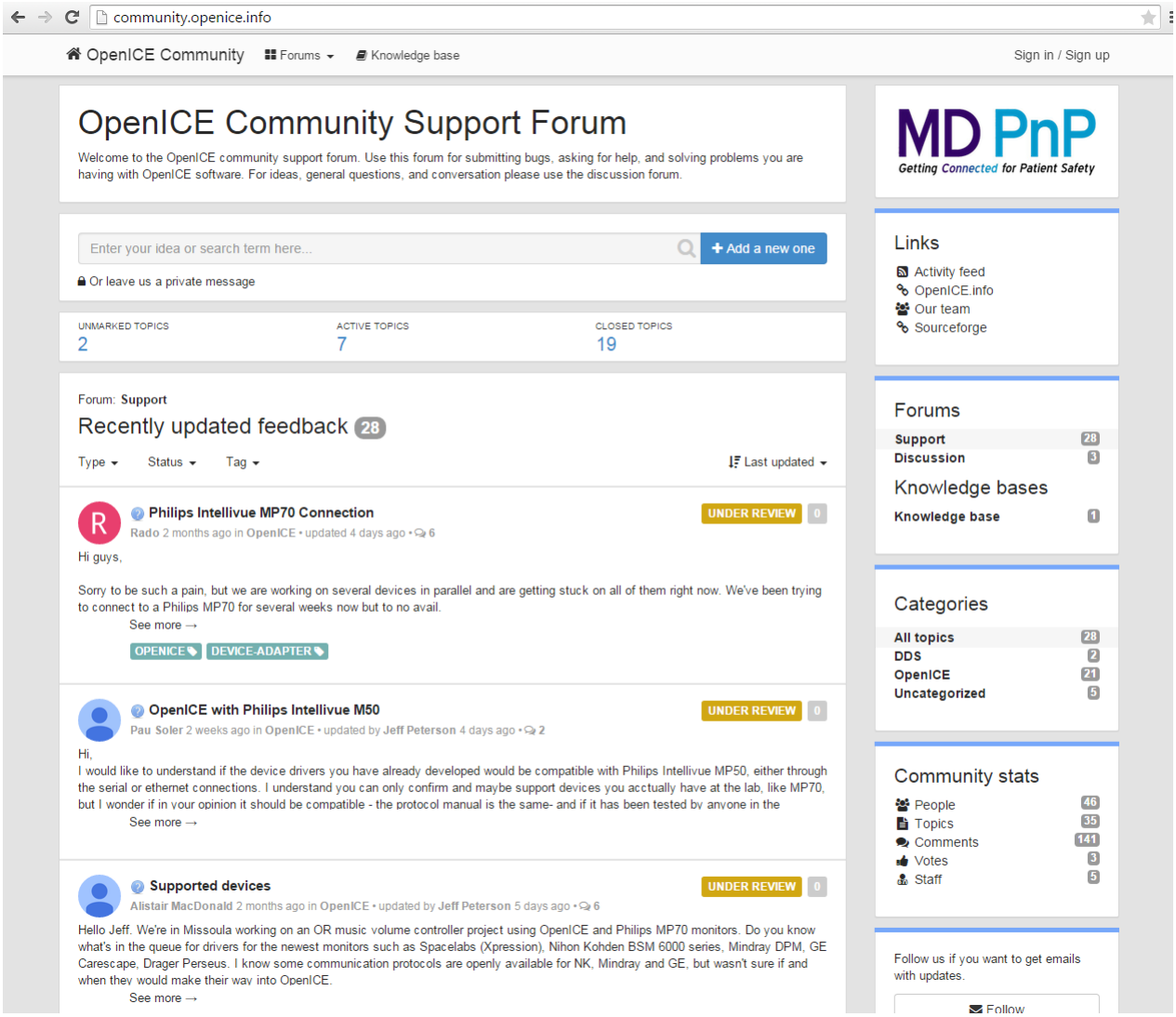


During the first four months of 2015, the community support forum for OpenICE users grew substantially (Table 1). In addition to a 200% increase in unique users and 300% increase in community postings, we identified several shared development interests / issues across the community, such as OpenICE connection to the Philips Intellivue line of patient monitors.

Table 1. Community statistics for OpenICE support forum website

User Stat	January 2015	April 2015	% Growth
People	23	46	200%
Topics	17	35	206%
Comments	46	141	306%
Votes	3	3	-----
Staff	5	5	-----

Figure 27. Screenshot of OpenICE community forum showing feedback



Two months later, the community support forum for OpenICE users had experienced a further 164% growth rate in unique users and 224% growth rate in community postings, as shown in Table 2. Some added features of the OpenICE.info forum included:

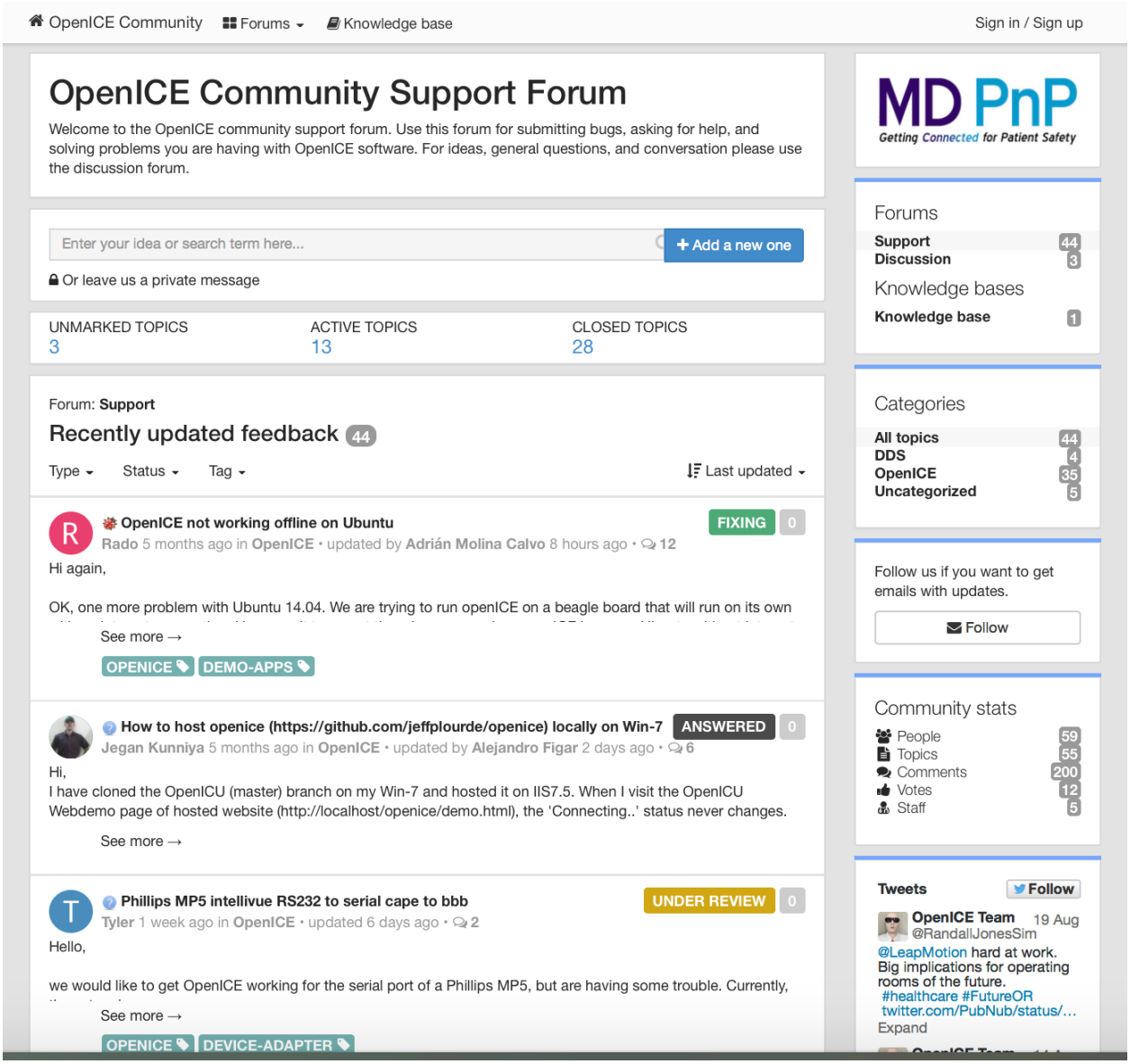
- Front-page access to all source code, documentation, and streaming data
- Live twitter feed of updates from the OpenICE team
- OpenICE Developer Blog
- Video tutorials of OpenICE and lab tour of MD PnP

- More detailed documentation for OpenICE system architecture, demonstration apps and app architecture, device adapter set-up and configuration, white paper description of ICE Supervisor, and notes on functionality and use of the Beaglebone appliance

Table 2. Community statistics for OpenICE support forum website

User Stat	January 2015	April 2015	June 2015	% Growth
People	23	46	59	164%
Topics	17	35	55	181%
Comments	46	141	200	224%
Votes	3	3	12	250%
Staff	5	5	5	-----
Twitter followers	---	---	203	-----

Figure 28. Screenshot of OpenICE community forum



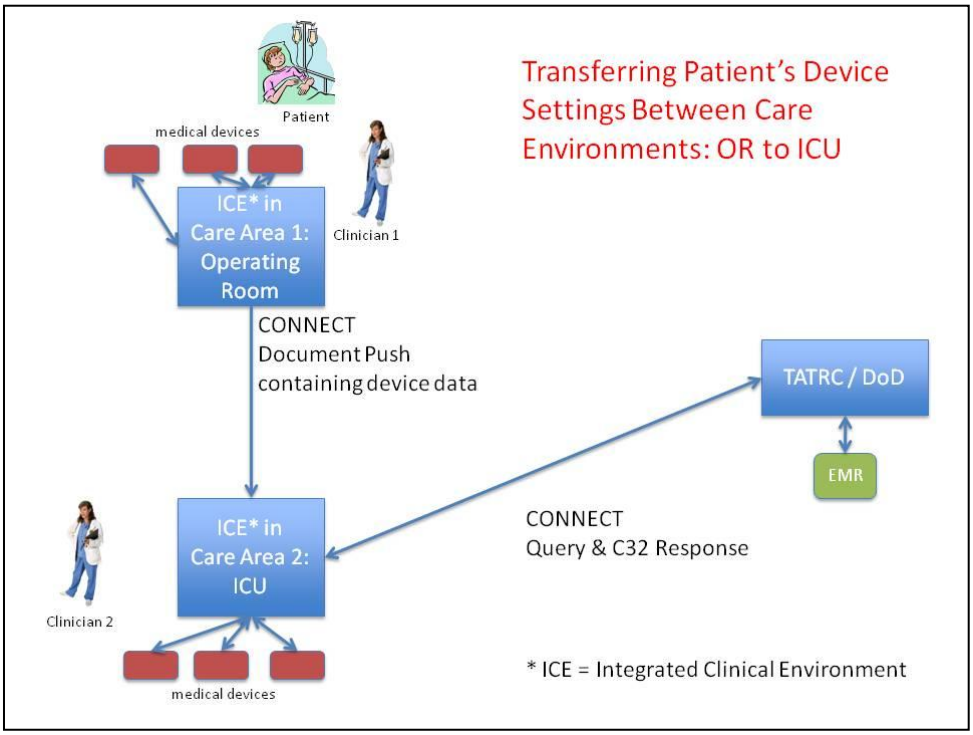
ICE External Interface Data Transfer, Aim 4: Define and document external interfaces to bi-directionally transfer medical device and patient contextual data between the integrated clinical environment and external systems of national interest. Demonstrate the interface to/from one or more of these systems (depending on which are ready and accessible).

To achieve this aim, we built on learnings from a CIMIT-sponsored project on Veterans Healthcare Data Exchange, which involved connectivity and exchange of data between the Partners HealthCare electronic health record and both the VistA and AHLTA systems. While limited in scope by design, that earlier project provided a good foundation for the bi-directional transfer work on this project, including the establishment of good collaborations with contacts at both USAMRMC and the VA.

We built on this earlier CONNECT and DIRECT work to develop a technology demonstration of our use of CONNECT in two ICE systems in a demonstration at HIMSS13 (Healthcare Information & Management Systems Society annual conference) in March 2013. CONNECT uses the Nationwide Health Information Network (NwHIN) standards and specifications, including the DIRECT project specifications, to exchange health data (see https://www.healthit.gov/FHA/CONNECT). Our demo was selected by the Office of the National Coordinator for Health IT (ONC) to be part of the ONC's demonstration area in the Interoperability Showcase. The MD PnP team collaborated with DocBox Inc. and Kansas State University to produce a demonstration on "Transferring a Patient's Device Settings between Care Environments," which conveyed the significance of device data as part of national interoperability efforts.

The demonstration (see Figure 29) showed connectivity between two ICE systems (standards-based Integrated Clinical Environments) in the OR and ICU, and use of the NwHIN to automatically return current device data in response to a clinician query. The demo showed reading and changing of device settings between the OR and ICU, external query via CONNECT to the TATRC test EMR with a return of allergy information, coordination between multiple apps, and coordination via CONNECT between a commercial ICE implementation (developed by DocBox) and a research ICE implementation using the open-source Medical Device Coordination Framework (MDCF) provided by collaborators at Kansas State University.

Figure 29. HIMSS13 Demo on Transferring Device Settings between Care Environments



The HIMSS demo was visited by over 300 HIMSS attendees, and was one of the few ONC demos visited by the HHS National Coordinator for Health IT, Farzad Mostashari, MD – who said it was the "most exciting" demo in the ONC area. Afterwards we published our CONNECT code on SourceForge (see Aim 3 above).

We continued to seek opportunities for further bi-directional connectivity. An appropriate challenge was that hospitals do not typically have a monolithic record system requiring only a single interface. Instead, there are large catalogs of available services, each with its own specification. Thus, developing bilateral interfaces between ICE and each of these services individually requires never-ending development. Instead we worked to integrate a DDS system into a larger Enterprise Service Bus. Aligning ourselves with ongoing efforts by DDS vendors, we worked with Apache Camel to create an endpoint for our system. Camel allowed us to align our system interface with interfaces to myriad other systems without any tight coupling. For example, our Camel interface could be connected to the Camel component for HL7 to interface with an Electronic Health Record (EHR). With a simple reconfiguration, we could also use 150 other Camel components, allowing us to connect with systems via technologies ranging from flat files to web services. We connected our Camel interface with the Camel component for "websockets", which are bi-directional protocols for streaming data to a web browser client. Such an interface allowed us to easily export data from ICE to a wide range of other terminals running on desktops, laptops, tablets, and smartphones. This research demonstrated a viable pathway for making the type of interface shown in our next HIMSS ONC demonstration opportunity – a Real-Time Blue Button.

The Office of the National Coordinator for Health IT invited us to participate again in their ONC/FHA (Federal Health Architecture) area of the Interoperability Showcase at the annual HIMSS conference and exhibition in February 2014. We developed a new ICE application for this demonstration that runs on Android tablets and smartphones and streams physiological data (including waveforms) from medical devices connected at our MD PnP Lab in Cambridge, MA, as well as data from medical devices connected locally at HIMSS. While much of our ongoing work focuses on the patient bedside, we wanted to demonstrate to the HIMSS audience how a bedside ICE network can connect to external resources. For this demo we built a Real-Time Blue Button – a prototype ICE External Interface suitable for live streaming data, an Android app to display the data, and an ICE application that packages up the data and sends it to the phone or tablet. We had the opportunity to show this demonstration to the National Coordinator for Health IT, Dr. Karen DeSalvo, and to Col. Dan Kral, TATRC Director, as well as many other attendees over the course of three days (see Figure 30).

Figure 30. ICE External Interface Demonstration at HIMSS 2014

National Coordinator for Health IT, Dr. Karen DeSalvo
at MD PnP Demonstration, "Real-Time Blue Button for Patients and Families"
ONC Area of HIMSS Interoperability Showcase, February 2014

This type of system is suitable for remote display of patient data, including waveforms and alarms, and could be used either for live display or for streaming data to a research database. A robust ICE system can constitute a more informative peer to other hospital systems. For example, an electronic medical record (EMR) system could archive real-time data from the ICE system. The EMR can also benefit from the richer set of information provided by ICE as compared with individual devices. At HIMSS we demonstrated that even patient engagement systems, such as those inspired by the VA Blue Button initiative, can benefit from the availability of the suite of rich contextual data made available in real time by an ICE system. Afterwards we made the Real-Time Blue Button demo publicly available (see video of this demo at http://vimeo.com/87434601).

In socializing the concept of remote bi-directional connectivity to our MD PnP Interoperability Lab, we found that there was great interest in this capability, especially as a means to provide simulated data to computer science and engineering research groups that have limited access to clinical devices, data, and domain expertise. In addition to working on collaborations with UIUC and UMass Amherst, we responded to the initial Presidential Innovation Fellows' SmartAmerica Challenge with a white paper proposing a "Virtual Hospital CPS Test Bed" building directly on Aim 4 of this award; this led to the inclusion of Dr. Goldman in the inaugural SmartAmerica Challenge project initiation meeting held at the White House in December 2013 and the involvement of our team in subsequent SmartAmerica activities.

As a result of his presentation at the White House SmartAmerica Challenge meeting, Dr. Goldman was invited to co-chair the Closed-Loop Healthcare team formed there. In March 2014 we hosted this team for a three-day meeting and "hackathon" in our Interoperability Lab, where we made progress with multiple collaborators. The team from NIST was able to streamline the acquisition of data for later replay by their playback application for the ICE Data Logger. They had acquired a Philips patient monitor, so we configured a BeagleBone for them with an ICE Equipment Interface for further testing and development. We also had an opportunity to bring together two vendors of DDS middleware, RTI and PrismTech, to assess interoperability between their implementations. We discovered a few small incompatibilities and identified a solution pathway in the course of the meeting. Our Closed Loop

Healthcare collaborators shared integration strategies at the enterprise level, both for data integration and for data storage. The prototype developed during the March hackathon was demonstrated at the White House-hosted SmartAmerica Expo in Washington, DC in June 2014.

The ICE External Interface prototype we built for our HIMSS demo was highly customized to that application and not suitable for large numbers of patients or client applications, so we worked to connect ICE to a generalized Enterprise Service Bus (ESB). While DDS is an appropriate backbone for a high-criticality distributed system, our connection to an ESB created alignment between our system and a library of modular components for exposing ICE data to other systems via a wide range of existing technologies.

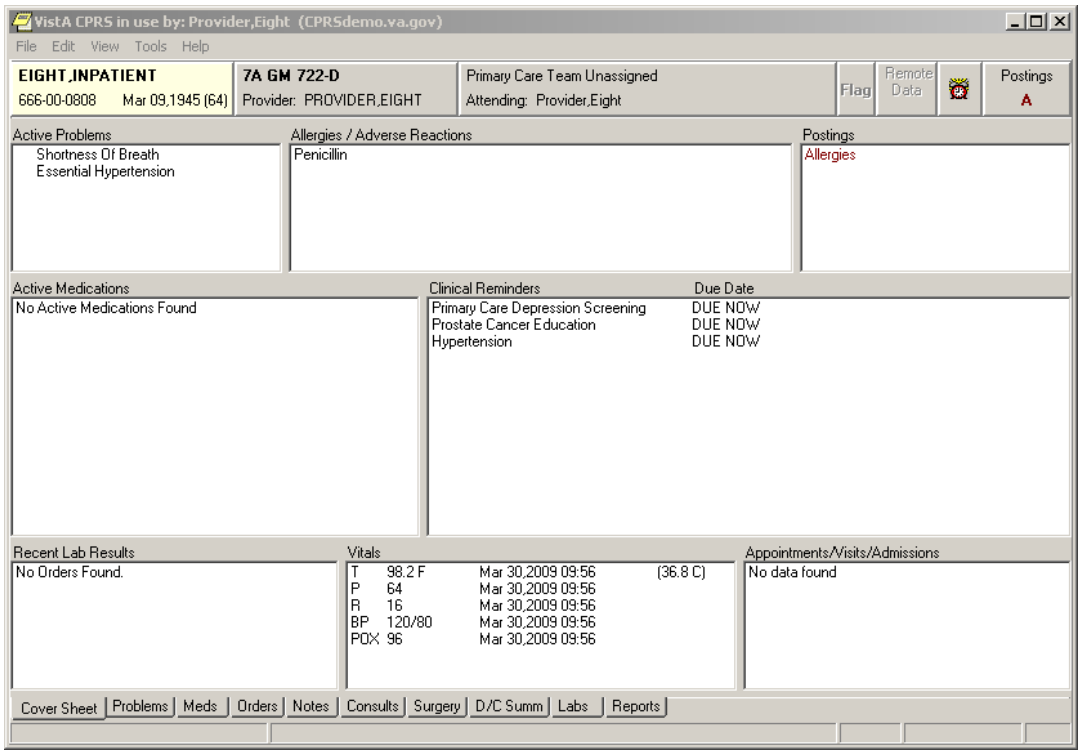
In April 2014 two members of our team presented this work at the International Conference on Cyber-Physical Systems (ICCPS) in Berlin. Our short paper describing key considerations, or pillars, for selecting middleware for ICE systems was presented at the workshop on Medical Cyber-Physical Systems. A poster describing our work on OpenICE was presented during the ICCPS poster session. We received considerable interest from members of the CPS community who understood that they need common data streams to enable their work on closed-loop control systems. At the workshop we also presented a poster describing our work on gathering clinical requirements, as well as our Clinical Scenario Repository (CSR™). Several participants expressed interest in the description of clinical scenarios, and some participants volunteered to become beta testers of the CSR™.

Connecting with external systems matured our approach to handling multiple patients. Within the scope of a single ICE instance, only a single patient is involved, but most external systems are managing entire patient populations. This research benefited our subsequent USAMRMC Joint Warfighter award to use OpenICE to provide re-configurable COTS-based clinical monitoring and decision support capability to improve the efficiency and effectiveness of monitoring and evaluation of patients in forward holding areas. Elaborating on how many ICEs will be coordinated also aided our ability to communicate with health information technology experts, bridging a gap and demonstrating the relevance of ICE to the real world systems that drive clinical environments today.

Our understanding of potential interactions between ICE and other hospital systems also matured greatly during this project. We first worked with a developer at MGH to understand the catalog of currently available test interfaces. Then, in 2014 Partners HealthCare (MGH and partner hospitals) began changing their electronic health record (EHR) systems to EPIC, a major undertaking expected to take five years to complete. Because all of the interfaces to the EHR would be changing, with the first round of changes scheduled for mid-2015, this was not the right time to prototype new connections to MGH systems. Therefore, we reached agreement with USAMRMC/TATRC to pursue the work needed for our milestone related to ADT systems by working with support from the U.S. Department of Veterans Affairs (VA) to install VistA in our Lab.

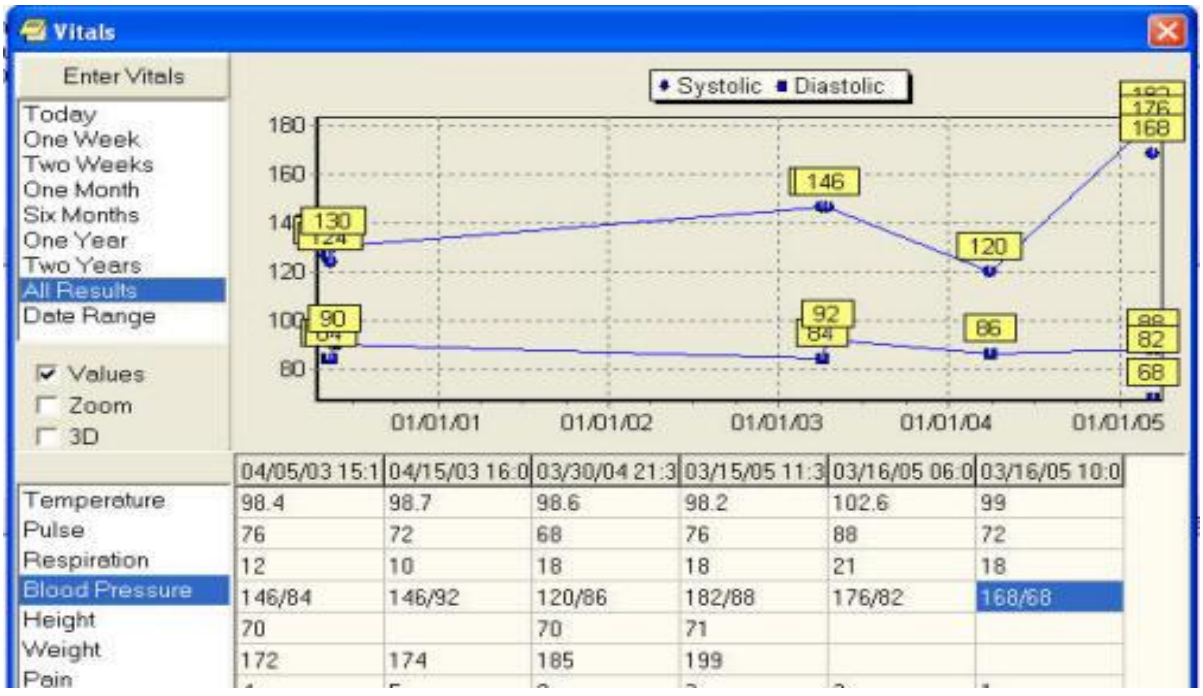
VistA (Veterans Health Information Systems and Technology Architecture) is an enterprise-wide information system built around an EHR used throughout the VA medical enterprise. It consists of nearly 160 integrated software modules for clinical care, financial functions, and infrastructure. The MD PnP team chose to test our ICE integration with VistA, because it is widely used and is freely available as an open-source program. With several VistA variants available, we decided to work with OSEHRA (Open Source Electronic Health Record Alliance) to install OSEHRA VistA. We installed the client-server packages of Astronaut-VistA, one of the open source versions of VistA available with the OSEHRA suite, as well as the GUI-based client application called CPRS (Computerized Patient Record System). Figures 31 and 32 show the healthcare record of our demo patient.

Figure 31. Screenshot of Demo Patient's EHR CPRS



We successfully used the command line interface to access and manipulate the data on the server, and we were able to access and edit our demo patient's vital signs, including waveform data.

Figure 32. Screenshot of Demo Patient's Vital Signs in CPRS



We learned that the various versions and patches available for Astronaut-VistA have been developed by an open source community and contain many bugs. The client-server versions that are publically available are not reliable in a research setting. We consulted experts in this field to guide us with the

configuration of a reliable system, and worked closely with the development team at OSEHRA to get VistA installed and functional in the MD PnP Lab. The basic system was installed and running in the fall of 2014, and we then focused on understanding the different potential ways of integrating VistA with the ICE infrastructure in our Lab.

As part of our effort to export an ADT feed from the EHR to the Lab, we added the functionality to our app for importing streaming device data for logging and analysis from medical devices in our Lab. We planned to learn about the EPIC EHR system being installed at Partners HealthCare, and to obtain access to a research license for EPIC and test data feeds, as they were made available.

We also explored integrating ICE with other EHR systems such as that of Athena Health. As part of their MDP (More Disruption Please) campaign, Athena Health released a number of API's freely available on Mashery. Athena Health integrates with a number of healthcare software products on the market, such as Clockwise.MD, Intuit's DemandForce, healthgrades, Entrada, iTriage, Vitals, and PatientPoint Coordinated Care Platform. Their API is RESTful and uses JSON. The documentation covers basic functionality such as authentication, the format of the responses (normally JSON), and workflows. There is also a reference documentation section and information for API output (see Figures 33 and 34).

Figure 33: Athena Health API keys

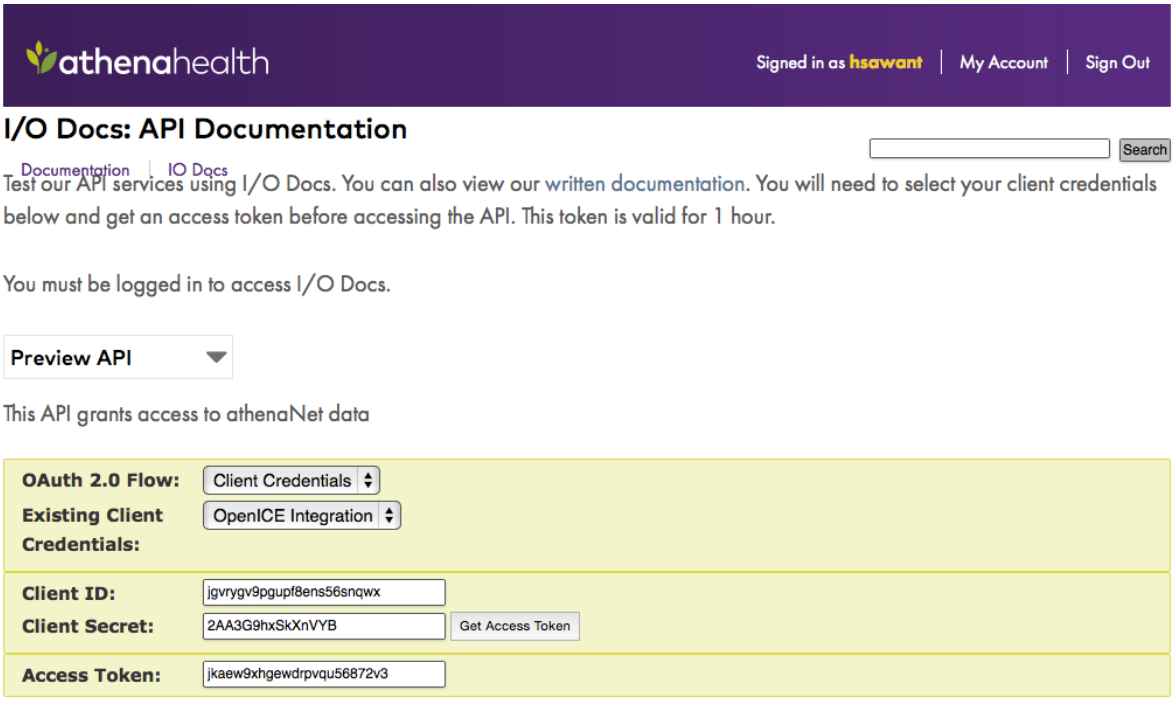
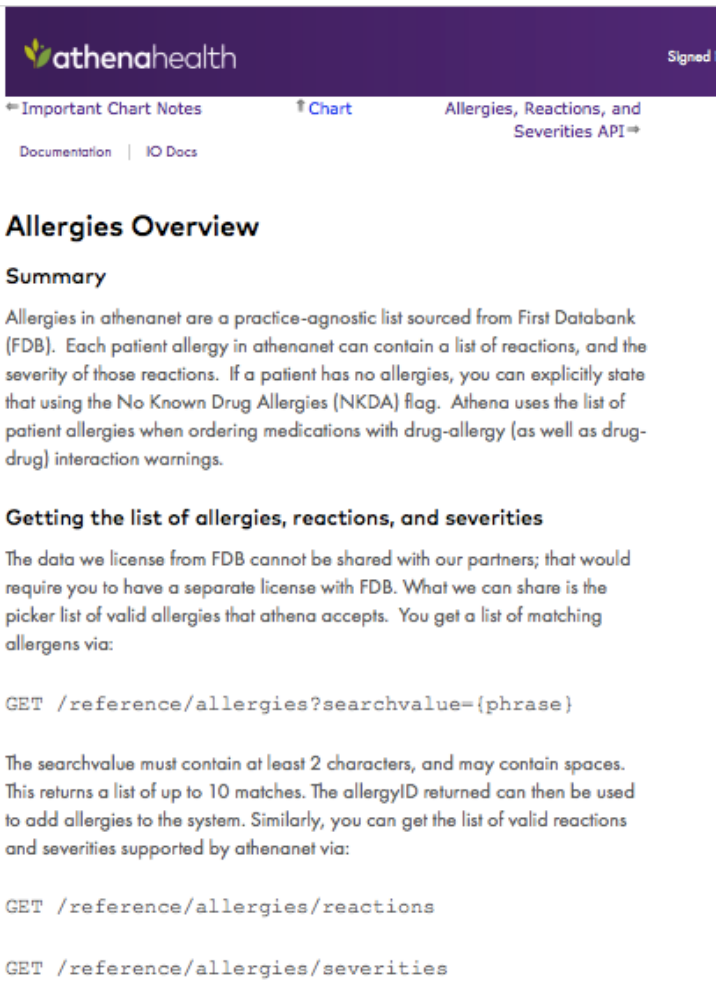


Figure 34. Athena Health Allergy Documentation



athenahealth

Signed

⇐Important Chart Notes ⇑Chart Allergies, Reactions, and Severities API⇒

Documentation | IO Docs

Allergies Overview

Summary

Allergies in athenanet are a practice-agnostic list sourced from First Databank (FDB). Each patient allergy in athenanet can contain a list of reactions, and the severity of those reactions. If a patient has no allergies, you can explicitly state that using the No Known Drug Allergies (NKDA) flag. Athena uses the list of patient allergies when ordering medications with drug-allergy (as well as drug-drug) interaction warnings.

Getting the list of allergies, reactions, and severities

The data we license from FDB cannot be shared with our partners; that would require you to have a separate license with FDB. What we can share is the picker list of valid allergies that athena accepts. You get a list of matching allergens via:

```
GET /reference/allergies?searchvalue={phrase}
```

The searchvalue must contain at least 2 characters, and may contain spaces. This returns a list of up to 10 matches. The allergyID returned can then be used to add allergies to the system. Similarly, you can get the list of valid reactions and severities supported by athenanet via:

```
GET /reference/allergies/reactions
```

```
GET /reference/allergies/severities
```

Figure 35 shows our code for reading out the patient's allergy history. We explored other functionality, including writing into the EHR.

Figure 35. Code for reading out Patient Allergy history

GET GET /chart/{patientid}/allergies /preview1/:practiceid/chart/:patientid/allergies

Returns the list of allergies for this patient.

Parameter	Value	Type	Description
:patientid	1	int	patientid
:practiceid	195900	int	practiceid
departmentid	1	int	The department for this patient. A patient may have multiple charts, and the department determins which chart to retrieve.
showinactive	false	string	Include deactivated allergies

Try it! Clear Results

Request URI

```
https://api.athenahealth.com/preview1/195900/chart/1/allergies?departmentid=1&showinactive=false
```

Request Headers Select content

```
Authorization: Bearer jkaew9xhgewdrpvqu56872v3
X-Originating-Ip: 24.61.12.186
```

Response Status Select content

```
200 OK
```

Response Headers Select content

```
Cache-Control: no-cache
Cneonction: close
Content-Type: application/json
Date: Wed, 18 Feb 2015 14:26:02 GMT
Expires: Mon, 06 Jan 1975 16:00:00 GMT
Pragma: No-cache
Server: Apache
Vary: Accept-Encoding
X-Mashery-Message-Id: 5c129f6c-4ce9-4d07-8cda-4f3628608f09
X-Mashery-Responder: prod-j-worker-us-east-1b-62.mashery.com
Content-Length: 202
Connection: keep-alive
```

Response Body Select content

```
{
    "nkda": "false",
    "allergies": [{
        "allergenname": "wasp venom",
        "allergenid": "18035",
        "reactions": [{
            "severitysnomedcode": "24484000",
            "reactionname": "anaphylaxis",
            "snomedcode": "39579001",
            "severity": "severe"
        }]
    }]
}
```

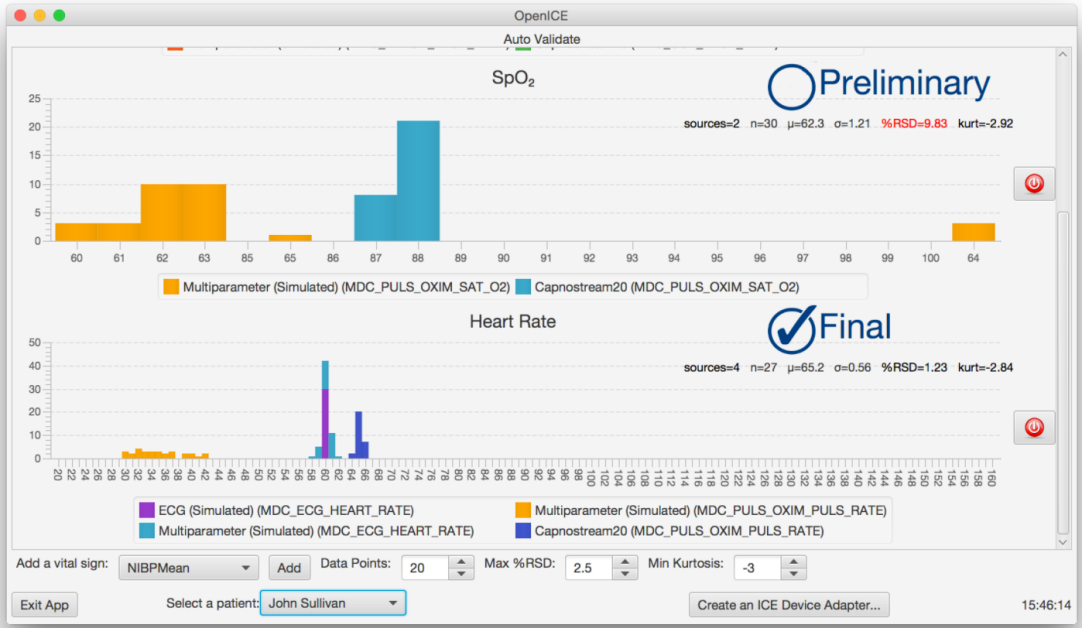
In April 2015, at the invitation of the Office of the National Coordinator of Health IT, the MD PnP team again participated in the HHS ONC/FHA area of the Interoperability Showcase at the annual HIMSS conference.

In an effort to eliminate erroneous vital signs data from clinical data repositories, most EHRs are configured to require that all vital signs data be manually “validated” by a nurse or clinician before the data enters the EHR. This manual validation introduces delays in propagating data to clinical decision support systems and introduces human selection bias by clinicians choosing not to validate correct but irregular data points. The demonstration application of the automatic validation algorithm enables Integrated Clinical Environments to provide EHRs with accurate, pre-validated vital signs data through

the use of digital signal processing, statistics, and business rules. More details can be found on the OpenICE website at https://www.openice.info/docs/3_apps.html#auto-validate.

The screenshot in Figure 36 shows the Autovalidation app display, where the checkmark indicated as “Final” has been Autovalidated. “Preliminary” denotes data that has not met Autovalidation data integrity criteria.

Figure 36. OpenICE Autovalidation App showing histograms of vital signs data from multiple monitors

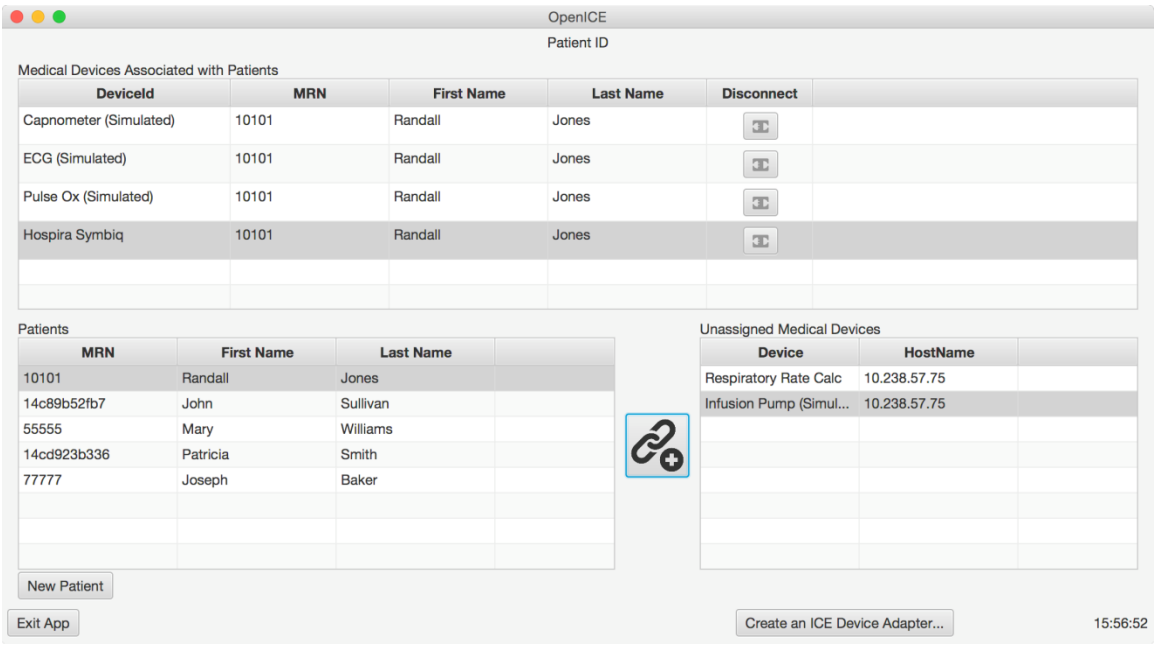


At HIMSS15, in collaboration with DocBox Inc, we demonstrated this EHR data auto-validation tool and OpenICE app, and storage and export functionalities to connect two ICE systems (see Figure 37).

Figure 37. HIMSS15 Exhibit of OpenICE Autovalidation App with output transmitted to and displayed by a DocBox flowsheet application

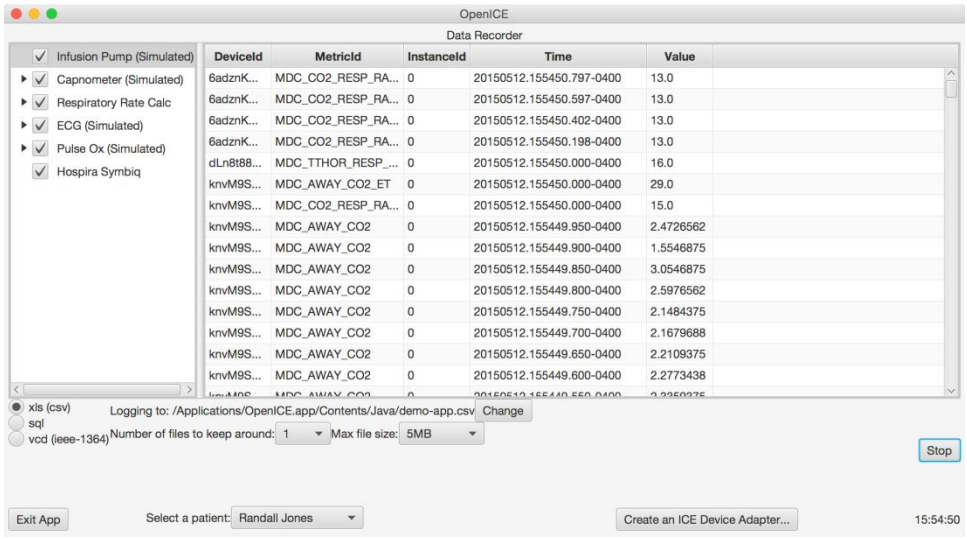
As seen in Figure 37, we enabled ICE-to-ICE communication. The patient monitor (left) measures signals from a patient simulator (not shown). Patient monitor data is acquired by OpenICE and analyzed to automatically assess data quality over 20-second epochs. Data of acceptable quality is transmitted over an open bus to a prototype DocBox ICE platform, and displayed in a DocBox flowsheet application.

Figure 38. Multiple patient identities with unique device assignments



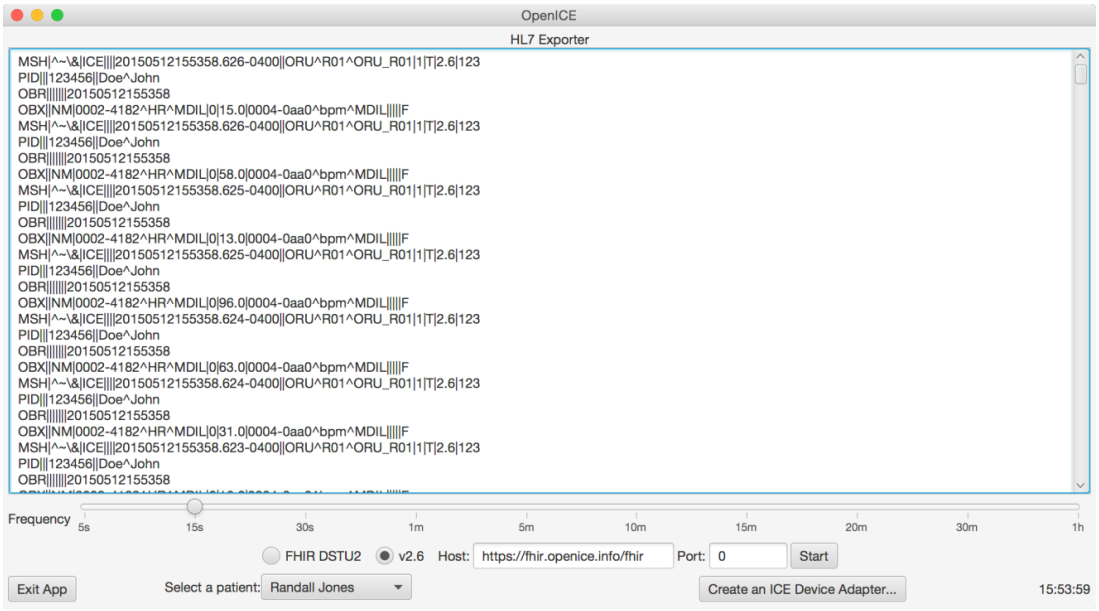
The data generated from these devices are being logged to a csv file (Excel), as shown in Figure 39.

Figure 39. Data Recorder reading data feeds from multiple devices



We also created an HL7-compliant data export feed which can selectively send data points by patient and at an adjustable frequency (shown in Figure 40). We validated our feed with our test server, built using HAPI-FHIR, a 100% open-source Java implementation of the FHIR (Fast Healthcare Interoperable Resources) specification (see https://www.openice.info/docs/3_apps.html#hl7-exporter). This external interface was bundled as an application included in the OpenICE distribution. (FHIR implementation by EHR vendors has been slow but steady; we can send HL7 FHIR data to EHRs as they add this capability.)

Figure 40. HL7 format data export capabilities



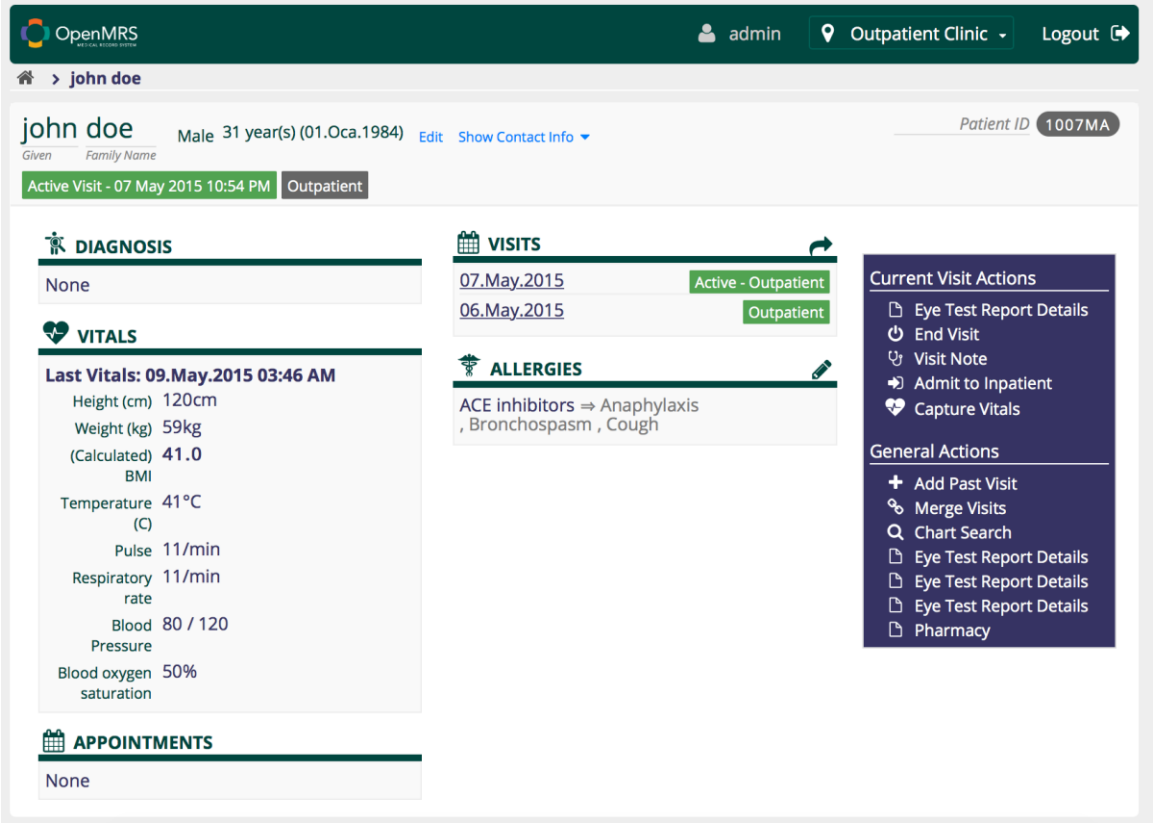
During the summer of 2015 we worked on integrating our export feed into an open source Electronic Health Record, coordinating with the support staff at **OpenMRS** and **OpenEMR** for seamless integration.

OpenMRS (Open Medical Record System) was created in 2004 as an open source medical record system platform for developing countries. It is a multi-institutional non-profit collaborative led by Regenstrief Institute and Partners in Health. OpenMRS is now in use around the world, including in South Africa, Kenya, Rwanda, Lesotho, Zimbabwe, Mozambique, Uganda, Tanzania, Haiti, India, China, United States, Pakistan, the Philippines, and many other places.

Some of its key features include:

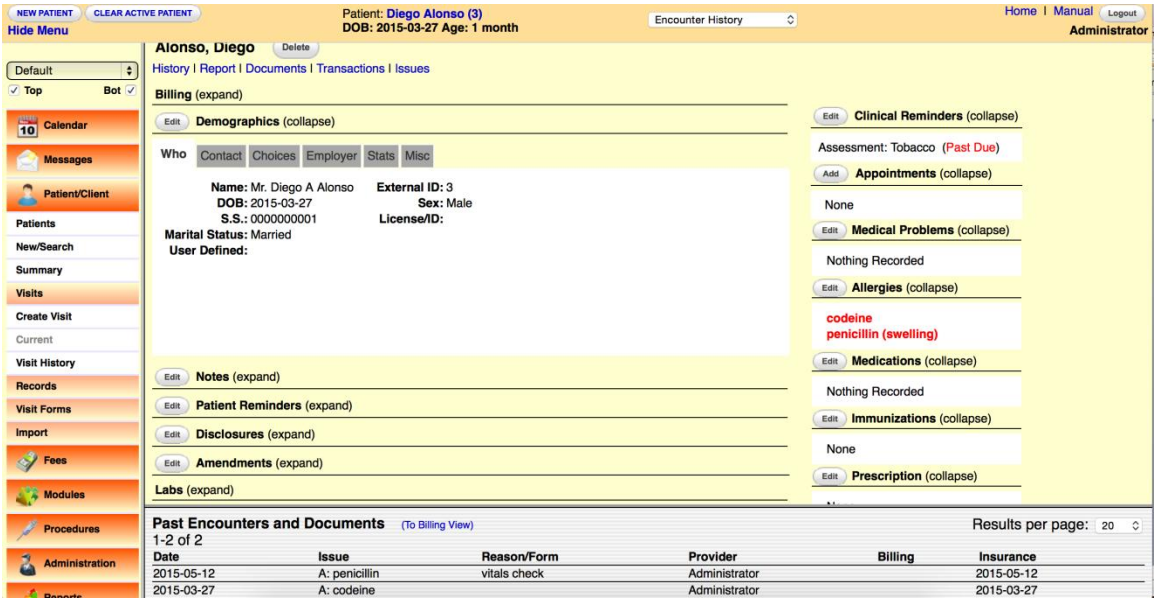
- Data entry: With the HTML FormEntry module, forms can be created with customized HTML and run directly within the web application
- Data export: Data can be exported into a spreadsheet format for use in other tools (Excel, Access, etc.)
- Standards support: HL7 engine for data import

Figure 41. Patient Record in OpenMRS



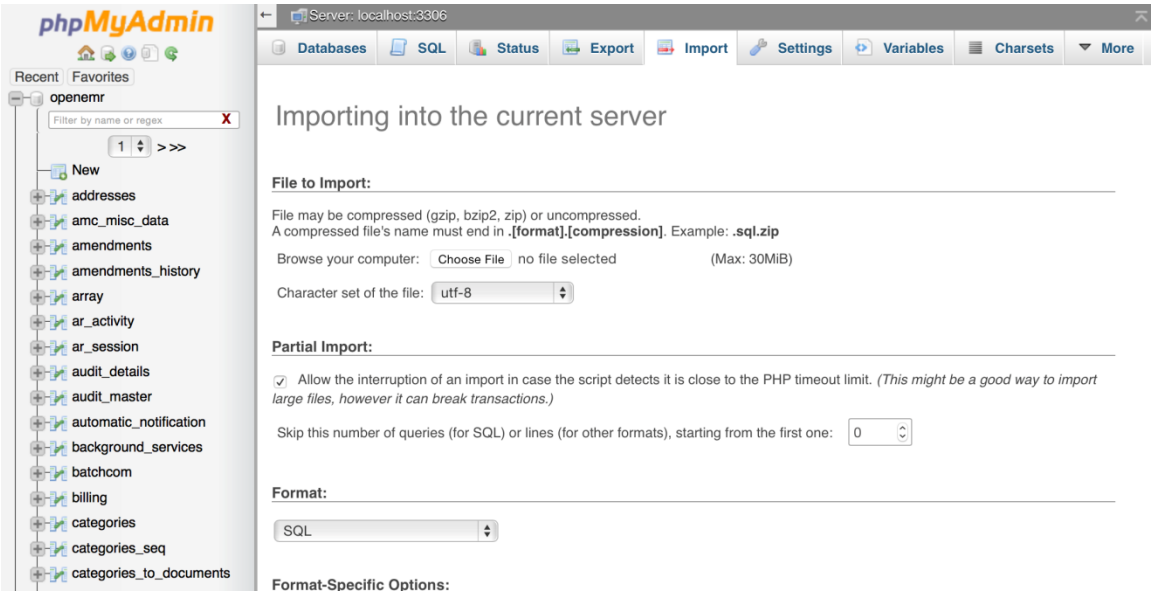
OpenEMR is a Free and Open Source electronic health records and medical practice management application that can run on Windows, Linux, Mac OS X, and many other platforms. It is certified by the Office of the National Coordinator for Health IT and is one of the most popular open source electronic medical records in use today, with over 3,700 downloads per month. Internationally, it has been estimated that OpenEMR is installed in more than 15,000 healthcare facilities, translating into more than 45,000 practitioners using the system, and serving over 90 million patients.

Figure 42. Patient Record in OpenEMR



The server side is written in PHP and can be employed in conjunction with a LAMP "stack", although any operating system with PHP is supported. It accepts data in sql format that can be exported from OpenICE.

Figure 43. Import capabilities of OpenEMR



Key Research Accomplishments

- **Implementation of a prototype ICE Data Logger.** In collaboration with NIST, we defined requirements for and built several prototypes of medical device system forensic data loggers (“black box recorders”) that leveraged the standards-based ICE architecture and software. An extensive review of existing forensic data logging approaches informed our prototypes. We used our open-source OpenICE platform for this research. With NIST, we researched the best approach to long-term storage of logged data and performed experiments to compare the performance of MySQL and other data stores for recording and searching data. This allowed us to perform end-to-end testing of the entire OpenICE system from the equipment interface through to the Data Logger as we revised our OpenICE platform.

- **Clinical Scenario Repository™.** We presented a beta version of the Clinical Scenario Repository™ (CSR™) at the annual meeting of the Society for Technology in Anesthesia and a meeting of the Society for Critical Care Medicine, where valuable feedback was gathered. We successfully transitioned the CSR™ web application to our Lab managed servers, as we discovered that the Google Application Engine used in the prototype’s early stages could not support newly identified privacy and security requirements. We implemented several prototypes based on feedback from physician evaluators at the Committee on Patient Safety and Quality of the American Society of Anesthesiologists (ASA), the AHRQ Patient Safety Organization (PSO) experts, the CRICO risk management foundation, and the ISO TC 121 international medical device standards development committee.

- **Open-Source Code-Sharing Repository**. We created an open-source code-sharing environment using SourceForge and Github, where our project code, including ICE Data Logging capability, is freely available for downloading by research and manufacturer communities. To date, we have recorded hundreds of downloads from around the world.

- **HIMSS13 Demonstration.** We implemented CONNECT as part of an ICE system demonstration in the ONC/FHA demonstration area in the Interoperability Showcase at HIMSS13 (Healthcare Information & Management Systems Society annual conference). CONNECT leverages the Nationwide Health Information Network (NwHIN) standards and specifications, to exchange health data. At HIMSS we were able to share our experience in implementing CONNECT with other researchers and manufacturers. The HIMSS demo was visited by over 300 HIMSS attendees, and was visited and applauded by the National Coordinator for Health IT, Farzad Mostashari.

- **Demonstrations for Federal Agencies.** In August 2013 we spent two days at NIH presenting a series of demonstrations of our work for invited representatives from federal agencies. These demonstrations included the initial prototype Data Logger and Clinical Scenario Repository. Over 60 visitors from DoD, FDA, NIST, NIH, and other federal agencies attended, and we received insightful and positive feedback that informed subsequent research.

- **HIMSS14 Demonstration.** In the ONC/FHA area of the Interoperability Showcase at HIMSS14, we demonstrated a new ICE app inspired by the VA Blue Button data-sharing initiative. In contrast to static patient records, our "Real-Time Blue Button for Patients and Families" streamed physiological data (including waveforms) from medical devices connected remotely at our Lab in Cambridge, MA, as well as data from medical devices connected locally at HIMSS. For this demo we built a prototype ICE External Interface suitable for live streaming data, an Android app to display the data, and an ICE application that packaged the data and sent it to the phone or tablet. We were honored to demonstrate this research to the National Coordinator for Health IT, Dr. Karen DeSalvo, and Col. Dan Kral, TATRC Director.

- **HIMSS15 Demonstration.** Once again in the ONC/FHA area of the Interoperability Showcase at HIMSS15, we demonstrated Automated Validation of Medical Device Data for EHRs using an OpenICE installation with a GE Dash patient monitor and an ICE Supervisor running a new Autovalidation app and transferring validated data to a DocBox ICE implementation running a charting app. The exhibit demonstrated the ability to interconnect two different ICE systems and the benefit of using ICE as a platform to prototype apps for HIT innovation. To minimize artifactual data in the EHR, vital signs data is typically manually validated – usually by an RN – prior to permanent inclusion in the EHR. The Autovalidation app, by analyzing 1200 vital signs data points within a 20-second window, identified artifact-free data that was tagged "validated" for inclusion in the DocBox charting application. Autovalidation can overcome nursing workflow limitations to enable inclusion of substantially more high-quality data in the EHR. This research demonstrated the versatility of ICE platforms and the potential value of access to all data from patient monitors to enable advanced apps for patient care.

- **SmartAmerica Challenge.** The Closed Loop Healthcare team, comprised of groups from academia, industry, research and government, was formed at the Presidential Innovation Fellows' SmartAmerica Challenge initial meeting in December 2013. During a three-day meeting and "hackathon" hosted in our MD PnP Lab "sandbox" in March 2014, the team developed prototypes for demonstration at the White House-led SmartAmerica Expo in Washington, DC in June. We moved NIST forward on the Data Logger work, brought together vendors of DDS middleware to demonstrate interoperability between their implementations, and Closed Loop Healthcare collaborators shared integration strategies at the enterprise level, both for data integration and for data storage.

- **Ebola Medical-Technology Response and Global City Teams Challenge (GCTC).** In response to a White House/OSTP request to contribute to solutions for the rapidly progressing Ebola Virus Disease (EVD) epidemic in 2016, we formed a twenty-collaborator team which during twenty days developed and demonstrated safety-enhancing and patient-care-improving research prototypes. The project inspiration was based on our participation in the NIST GCTC

initiative on “remotely caring for our most vulnerable populations during a pandemic.” Upon receipt of the White House inquiry, we used our relationships, our team’s subject matter expertise, and our Lab sandbox, to immediately spin up a team of researchers, manufacturers, governmental collaborators, and FDA/CDRH leadership to rapidly prototype EVD solutions. The demonstrated use cases included sensor integration and data acquisition to improve Ebola screening, monitoring and diagnosis in quarantine, and remote control, closed loop control, and remote data access to improve patient care and reduce the exposure of hospital personnel by limiting the number of times caregivers enter the patient environment to change device settings. This was the only known med-tech innovation response to EVD of its kind and was possible only due to our existing collaborative research and Lab sandbox. The teams used our Medical Device Interoperability Lab "test bed" and open platform for medical device and data integration – OpenICE – to rapidly prototype technology solutions during a three-day hackathon in November 2016.

In addition to the specific achievements above, the MD PnP program has continued to gain increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are helping to further the aims of the program.

Synergistic Activities. The activities under this award have enabled the PI and the MD PnP program to remain actively involved with national health IT developments to support inclusion of medical device interoperability on the agenda.

The MD PnP program has continued to work with the FDA, NIST, NSF, and the Office of the National Coordinator for Health IT. Recognition of the critical role of device interoperability in the national health IT agenda has increased greatly, as evidenced by the following activities:

- Dr. Goldman served as invited co-chair of the Regulations Subcommittee of the Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup of the Health IT Policy Committee. In the Subcommittee’s final recommendations, the importance of healthcare data logging was cited.
- Our work under this award, as well as our larger body of MD PnP program work, was foundational to the new AAMI/UL JC2800 device safety certification standard, which is under development with participation from our team.
- The Data Logger work under this award formed the basis of an ICE Data Logger standard New Work Item Proposal to AAMI in 2016.
- During the course of this project, Dr. Goldman continued to participate in meetings with the DoD regarding procurement of medical devices – one of the key requirements is for devices in future to communicate the data needed for interoperability.

Reportable Outcomes

Presentations on Medical Device Interoperability Topics:

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

- September 11 2012 at MDEpiNet (Medical Device Epidemiology Network) Annual Meeting at FDA, Washington, DC (Role of ICE and Data Logging to support medical device performance assessments for MDEpiNet)
- October 2-3 2012 – Lectures and panel presentation at FDA AAMI Interoperability Summit, Washington, DC

- October 15 2012 – Panel moderator at American Society of Anesthesiologists (ASA) Annual Meeting, Washington, DC
- October 25 2012 – Presentation at NSF Time Workshop, Baltimore, MD
- November 2 2012 – Keynote and closing panel at Medical Device Connectivity Conference, Boston, MA
- November 5 2012 – Invited lecture at University of Illinois at Urbana-Champaign, Urbana, IL
- November 29 2012 – Panel at Wireless Connectivity in Medical Devices Conference, Boston, MA
- December 3 2012 – Panel moderator at FCC mHealth Summit, Washington, DC
- January 10 2013 – Panel at Society for Technology in Anesthesia Annual Meeting, Phoenix, AZ
- February 16 2013 – Panel at Advancing Science, Serving Society Annual Meeting, Boston, MA
- March 4-7 2013 – Lecture and Technology Demonstrations at HIMSS Conference, New Orleans, LA
- March 4 2013 – Keynote at IBM systems engineering symposium, Waltham, MA
- May 20 2013 – Grand Rounds lecture on interoperability at Tufts Medical Center, Boston MA
- May 23 2013 – Grand rounds lecture on interoperability at Geisinger Health System, Danville, PA
- July 3 2013 – Lecture at meeting of Food and Drug Administration Safety Innovation Act (FDASIA) Regulations Subgroup, Washington, DC
- September 16 2013 – Keynote, “Integrity of Medical Device Interoperability” at AHIMA Health Information Integrity Summit, Alexandria, VA
- September 17-18 2013 – Lecture and panel, “Advanced Medical Technology Training and the APSF Recommendations: Perspectives from my Vantage Point” at meeting of the Anesthesia Patient Safety Foundation, Phoenix, AZ
- September 24-25 2014 – MD PnP Lab Open House with technology demonstrations
- October 12-15 2013 – Research updates at annual ASA meeting, to Scientific & Educational Exhibits Committee; Committee on Technology; Equipment, Monitoring & Engineering Technology Committee; Equipment & Facilities Committee; and Electronic Media & Information Technology Committee, San Francisco, CA
- November 18-20 2013 – Plenary, “The SHARP Program and the Next Generation of Health Information Technology” at the SHARP ONC plenary at AMIA Annual Symposium, Washington, DC
- November 21 2013 – Keynote “Introduction to an Open-Source Integrated Clinical (ICE) Environment Platform,” Keynote Panel “The Regulatory Future for Health IT, Mobile Applications, and Interoperability” and Plenary Panel “Interoperability Standards: How Far Can They Take Us?” at Medical Device Connectivity Conference, Herndon, VA
- December 12 2013 – Presentation of Virtual Hospital CPS Testbed Proposal at White House SmartAmerica CPS Testbed Challenge, Washington, DC
- January 10 2014 – Panel, “Interoperability: A Cornerstone of Systems Integration” at Society of Critical Care Medicine Annual Congress, San Francisco, CA
- January 21-22 2014 – Chaired Meetings for US TAG ISO TC 121 on Anesthetic and Respiratory Equipment to lead the transition of the US TAG from ASTM to AAMI
- February 24-26 2014 – Technology Demonstration, “Real-Time Blue Button^{TM} for Patients & Families” in the ONC/FHA area of the HIMSS’14 Interoperability Showcase, Orlando, FL
- February 26 2014 – Lecture, “Safe Interoperability: What are the Challenges?" in the HIMSS’14 Interoperability Showcase Theater, Orlando, FL
- April 1 2014 – Lecture, “Enabling Innovation Through Medical Device Interoperability: from architecture to analytics” at the Children’s Hospital of Philadelphia

- April 10 2014 – Lecture, “Towards Better Critical Care: From data to information to decision to action” at Society of Critical Care Medicine Research Summit, Emory Conference Center, Atlanta, GA
- May 14 2014 – Panels, “Conformity assessment – Role in assuring safety and innovation.” and “Standards and Interoperability” at NIST/FDASIA Public Workshop: Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology, Washington, DC
- May 15 2014 – Panel, “Health IT Safety Center” at NIST/FDASIA Public Workshop: Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology, Washington, DC
- June 10-11 2014 – Lecture and technology demonstrations, “Closed-Loop Healthcare: From Home to Hospital to Home” at White House SmartAmerica Expo, Washington, DC
- July 9 2014 – Congressional briefing on Medical Device Inoperability and Safe Medical Integration, Washington, DC
- July 22 2014 – MD PnP Lab Open House with technology demonstrations
- August 4 2014 – “Setting the Stage for the Next Generation of Clinical Care Through the Procurement of Interoperable Medical Devices and Health IT Systems,” AHRRM Annual Conference, Orlando, FL
- August 16 2014 – “Interoperability,” Panel at Military Health Smart Monitoring 2014, Ft Lauderdale, FL
- August 19 2014 – “Web-Based Clinical Scenario Repository™ (CSR™), Military Health System Research Symposium (MHSRS), Ft Lauderdale, FL
- September 10 2014 – “Challenges: The Digital Health Platform (System of Systems).” Panel moderator at the National Academies’ Innovation Policy Forum Workshop on Medical Devices Innovation: Opportunities, Threats, and Challenges, Washington, DC
- September 29 2014 – “Remotely Caring for Our Most Vulnerable Citizens In-Place During A Pandemic,” Global Cities Challenge: SMART America II, Washington, DC
- September 30 2014 – “Overview of OpenICE Federally funded open-source medical device integration, data acquisition, and app research platform for use by coalition members,” Webinar
- October 9 2014 – “MD PnP Program Updates” at University of Pennsylvania PRECISE Center, Philadelphia, PA
- October 11-14 2014 – Updates on MD PnP research to several committees at ASA Annual Meeting, New Orleans, LA
- October 20 2014 – “Medical Device Interoperability,” Congressional Staff Briefing, Washington, DC
- October 22 2014 – MD PnP Research Demonstrations at Lab Open House, Cambridge MA
- November 4-6 2014 – “Open Medical Device and Data Integration Platforms to support the management of Ebola,” presentations to press and lab visitors, Cambridge MA
- November 20 2014 – “A Systems Oriented Approach to Optimize the Performance of Clinical Alarms,” keynote address at Clinical Alarms Safety Symposium, Washington, DC
- November 21 2014 – Grand Rounds at San Diego Naval Hospital, San Diego, CA
- December 6-7 2014 – “Technology Advancements in the Intelligent Medical Home: From the Leaders Perspective,” keynote and panel at mHealth Symposium, Washington DC
- December 8 2014 – “Open Medical Device and Data Integration Platforms to support the management of Ebola,” White House briefing, Washington, DC
- December 16 2014 – “Overview of MGH MD PnP Program / MD PnP,” Georgetown University Visiting Scholars presentations, Massachusetts General Hospital, Cambridge, MA
- January 8 2015 – “Innovations in Standards for Interoperability,” STA Annual Meeting, Phoenix, AZ
- January 21 2015 – “Answering the White House’s call to innovate safer ways to treat Ebola patients” / Invited Lecture Newton Inspires, Newton, MA

- January 28 2015 – “Integrated Healthcare Platforms to Enable Safety, Security, and Interoperability,” Indian Institute of Technology, Chennai, India
- February 13 2015 – “Open Medical Device and Data Integration Platforms to Support the Management of Ebola Care,” Webinar
- February 19 2015 – “Achieving Interoperability in Medical Device Technology to Support Innovation” / Panelist Medical Devices Summit, Boston, MA
- February 24 2015 – “Medical Device and Data Integration Platforms to Support the Management of Ebola,” NIST Testbed Workshop, Rockville, MD
- February 24-25 2015 – Panel at Agency for Healthcare Research and Quality (AHRQ) Headquarters, Rockville, MD
- February–March 2015 – “Overview of MGH MD PnP Program,” lectures for Boston University, Bentley University, and Georgetown University graduate students, MD PnP Visiting Scholars presentations, Cambridge, MA
- March 17 2015 – “Medical Device Interoperability Roadmap” lecture at Interoperability Advisory Group meeting, Washington DC
- March 25 2015 – Keynote and panel at Object Management Group Conference, Washington DC
- March 25 2015 – “Open Sourced Technology Advancements in Medical IIC,” invited lecture at Industrial Internet Consortium meeting, Washington DC
- March 26 2015 – “Medical Device Interoperability” / Grand Rounds Hershey Medical Center, Hershey PA
- December 24 2015 – “Medical Internet of Things (MIoT)” / Grand Rounds Department of Anesthesia, Critical Care, and Pain Medicine, Massachusetts General Hospital, Boston, MA
- April 15 2015 – “Introduction to The ICE Alliance,” HIMSS15, Chicago, IL
- April 13-16 2015 – “Auto-Validation of Medical Device for EMR Data Entry,” presentations and demonstrations at HIMSS15, Chicago, IL
- April 17 2015 – “Open Medical Device and Data Integration Platform for Medical IoT,” Conference of IoT in HealthCare, Costa Rica
- April 27 2015 – “Technology Advancements in Medical Interoperability,” UL Health Sciences Council, Chicago, IL
- June 4 2015 – “Auto-Validation of Medical Device for EMR Data Entry,” presentations and demonstrations at AAMI Expo, Denver, CO
- June 10 2015 – “Innovations in Standards for Interoperability,” presentation and panel at AAMI Standards week, Denver, CO
- August 15-16 2015 – Participated in FDA panel and presented “Ebola Care Medical-Technology Response: Open Medical Device & Data Integration Platforms to Support Management of Ebola Virus Disease,” Smart Monitoring Conference, Ft Lauderdale, FL
- August 19 2015 – “Autovalidation of Medical Device Data for EHRs Using Apps on an Open Medical Device Integration Platform (ICE Platform),” Military Health System Research Symposium Training & Informatics session (MHSRS-15-1192), Ft Lauderdale, FL
- Sept 18 2015 – “Remote Caring for Vulnerable Population during a Pandemic: Demonstrating the Vision of the Medical Internet of Things,” Internet of Things Solutions World Congress, Barcelona
- September 30 2015 – Presentation at Cybersecurity for Healthcare and Medical Devices conference, Minneapolis , MN
- October 24-28 2015 – American Society of Anesthesiologists, presentations at MD PnP Exhibit (1st Place Award), San Diego, CA
- February 8 2016 – Presentation at Boston Medical Devices Summit, Boston, MA
- March 2 2016 – Presentation at HIMSS Conference, “Advancing Health Equity through Precision Medicine and HIT Innovation,” Las Vegas, NV
- April 6 2016 – Presentation at HxR Conference, Boston, MA

- April 27 2016 – Presentation at AAMI OR Systems Engineering Conference, Washington, DC
- May 6 2016 – Invited Speaker for Grand Rounds, “The Medical Internet of Things,” Tufts Medical Center, Boston, MA
- June 28 2016 – Keynote Lecture, “Implementing the Medical Internet of Things (MIoT) to Enable Healthcare Transformations,” Council of Engineering Systems Universities (CESUN), Washington DC
- August 15 2016 – Invited Speaker, “Integrating Medical Devices – Better Clinical Decisions – Efficient & Controlled Patient Care,” MSRS, Ft Lauderdale, FL
- August 19 2016 – MD PnP Poster Presentation at IEEE EMBS Annual Conference, Orlando, FL
- September 13 2016 – JPC-1 Medical Simulation & Information Sciences Internal Project Review, Ft Detrick, MD

Presentations on behalf of the PI:

- December 6 2013 – Technology demonstration at FCC mHealth Innovation Expo by David Arney and Jeff Plourde, Washington, DC
- April 2 2014 – Poster presentation on “Web-Based Clinical Scenario Repository to Improve Patient Safety” at Mass General Hospital Scientific Advisory Council poster sessions by Diego Alonso
- April 14 2014 – “Design Pillars for Medical Cyber-Physical System Middleware" by David Arney and Jeff Plourde at Medical CPS Workshop, Berlin, Germany
- April 14 2014 – Poster presentation on "Potential Advantages of Applying Assurance Case Modeling to Requirements Engineering for Interoperable Medical Device Systems” by David Arney and Jeff Plourde at Medical CPS Workshop, Berlin, Germany
- April 16 2014 – Poster and Work in Progress talk on "OpenICE: An Open, Interoperable Platform for Medical Cyber-Physical Systems” by David Arney and Jeff Plourde at the International Conference on Cyber-Physical Systems (ICCPS), Berlin, Germany
- August 19, 2014 – Poster Presentation on “OpenICE Prototype: A New, Open Interoperable Medical Device Clinical Research Platform” by Jeff Plourde, Military Health System Research Symposium (MHSRS), Ft Lauderdale, FL
- November 5-6 2014 – “Open Sourced Interoperability,” by Jeff Peterson, Northeastern Healthcare Technology Symposium, Groton, CT
- December 16 2014 – “Open Source Interoperability: A Technical Review of OpenICE and DDS,” by Jeff Peterson, Georgetown University MD PnP Visiting Scholars presentations, Cambridge, MA
- February 12 2015 – “Open Source Interoperability - Intro to OpenICE,” by Jeff Peterson, Educational Webinar session, Innovators Showcase: Three Clinical Engineers Leading the Way, Cambridge, MA
- February 26 2015 – “Healthcare IoT: The Impact in the Hospital,” by David Arney, MIT Connected Things Forum, Cambridge, MA
- March 23 2015 – “Requirements Management for Open Source Interoperability” by Harshal Sawant at the Serena Conference, Washington DC
- June 4-7 2015 – “Auto-Validation of Medical Device for EMR Data Entry” presentations and demonstrations by David Arney and Jeff Peterson at AAMI Expo, Denver, CO
- June 8 2015 – Presentation by Harshal Sawant at AAMI Standards Week, Denver, CO
- October 13-14 2015 –“Software Implementation of Controllers: Hardware considerations for sensors and actuators” by David Arney at FDA PCLC workshop, Silver Spring, MD
- October 15 2015 – “‘The Internet of Things’ and Its Impact on Software Development for Medical Devices” by David Arney at Software Design for Medical Devices 2015, Boston, MA

- October 14 2015 – OpenICE Workshop at AMIA Transdisciplinary "Maker Health Faire," by David Arney at American Medical Informatics Association annual conference, San Francisco, CA (https://www.amia.org/amia2015/tutorials)
- February 8 2016 – "Medical Device Interoperability and Cybersecurity" by David Arney at Cybersecurity Workshop, Medical Devices Summit, Boston, MA
- March 20-23 2016 – "Securing Medical Cyber-Systems: Challenges and Future Directions" by David Arney at ISMICT 2016, Worcester Polytechnic Institute, Worcester, MA (http://www.cwins.wpi.edu/ismict16/)

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program. The website provides access to the ICE standard, MD FIRE contracting language, publications, posters, talks from plenary meetings and from the FDA Workshop, and downloads of sharable documents and code from our GitHub public project via www.OpenICE.info.

Manuscripts/Publications:

- Arney D, Goldman JM, Bhargav-Spantzel A, Basu A, Taborn M, Pappas G, Robkin M. Simulation of Medical Device Network Performance and Requirements for an Integrated Clinical Environment. Biomed Instrum Technol. 2012 Jul-Aug;46(4):308-15. doi: 10.2345/0899-8205-46.4.308. This is a report on our work with Intel on network and computer infrastructure design and operations to support interoperability.
- Liddle S, Grover L, Zhang R, Khitrov M, Brown JC, Cobb JP, **Goldman J**, Chou J, Yagoda D, Westover B, Reisner AT. Safety evaluation of a Medical Device Data System. Conf Proc IEEE Eng Med Biol Soc 2014; 5899-902.
- **Goldman JM**. The Challenge of Acquiring Accurate, Complete, Near-Patient Clinical Data for Data Science Analysis. NIST Data Science Symposium Proceedings March 4-5 2014, Gaithersburg, MD; 2014. p. 43-44.
- Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup. FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework. Published April 2014. [Contributions by **Dr. Goldman** as part of Workgroup] Available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf.
- Wu Po-Liang, Raguraman D, Sha Lui, Berlin RB, **Goldman JM**. A treatment validation protocol for cyber-physical-human medical systems. In: 2014 40th EUROMICRO Conference on Software Engineering and Advanced Applications; 2014: 183-190.
- Arney D, Plourde J, Schrenker R, Mattegunta P, Whitehead SF, **Goldman JM**. Design Pillars for Medical Cyber-Physical System Middleware. In: Turau V, Kwiatkowska M, Mangharam R, Weyer C, editors. In: Proceedings of the 5th Workshop on Medical Cyber-Physical Systems; 2014 April 14; Berlin, Germany. Dagstuhl: Schloss Dagstuhl; 2014. vol. 36 p. 124-132.
- Arney D, Plourde J, Schrenker R, Mattegunta P, Whitehead SF, **Goldman JM**. Design Pillars for Medical Cyber-Physical System Middleware. In: OpenAccess Series in Informatics (OASIcs); 2014; 36.
- Schrenker Rick, Plourde J, Alonso D, Arney D, **Goldman JM**. Potential Advantages of Applying Assurance Case Modeling to Requirements Engineering for Interoperable Medical Device Systems. In: OpenAccess Series in Informatics (OASIcs); 2014; 141.
- Wu PL, Raguraman D, Sha L, Berlin RB, **Goldman JM**. WiP abstract: A treatment coordination protocol for cyber-physical-human medical systems. In: Cyber-Physical Systems (ICCPS); 2014: 226.
- Plourde J, Arney D, **Goldman JM**. OpenICE: An open, interoperable platform for medical cyber-physical systems. In: Cyber-Physical Systems (ICCPS); 2014: 221.

- **Goldman JM**. The Challenge of Acquiring Accurate, Complete, Near-Patient Clinical Data for Data Science Analysis. In: NIST Data Science Symposium Proceedings, March 4-5 2014, Gaithersburg, MD; 2014. p. 43-44.
- Kang W, Sha Lui, Berlin RB, **Goldman JM**. The design of safe networked supervisory medical systems using organ-centric hierarchical control architecture. In: IEEE Journal of Biomedical and Health Informatics. 2014; 19: 1077-1086.
- Wu Po-Liang, Raguraman D, Sha Lui, Berlin RB, **Goldman JM**. A treatment validation protocol for cyber-physical-human medical systems. In: 2014 40th EUROMICRO Conference on Software Engineering and Advanced Applications; 2014: 183-190.
- Rahmaniheris M, Sha L, Berlin RB, **Goldman JM**. Towards a cyber-medical model for device configuration safety in acute care. In: Healthcare Innovation Conference (HIC), 2014: 118-124.
- **Goldman JM**. 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
- Weininger S, Jaffe MB, Rausch T, **Goldman JM**. Capturing Essential Information to Achieve Safe Interoperability. Anesth Analg 2017;124:83-94.
- Dain S, Rausch T, **Goldman JM**. Domain Information Model for Alarm Systems for the Patient Centric Integrated Clinical Environment (ICE DIM). In: Anesth Analg; 2016; 122.
- **Goldman JM**. Leadership and Vigilance Essential as Health Information Technology Expands. In: ASA Monitor; 2016; 80: 18-19.
- Weininger S, Jaffe MB, Robkin M, Rausch T, Arney D, **Goldman JM**, The Importance of State and Context in Safe Interoperable Medical Systems. IEEE J Transl Health Med 2016; 99: 2168-2372. 4:2800110.
- Weininger S, Jaffe MB, **Goldman JM**. The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems. Anesth Analg 2017; 124:127-135.

Funding Applications Facilitated by this BAA to Date (total costs shown):

- W81XWH-15-C-0064 – 2015-2016
  1-Year award for $453,799 Total
  Description: Building on our prototype open platform for integrating devices in the clinical environment ("OpenICE") to provide re-configurable COTS-based clinical monitoring and decision support capability to improve the efficiency and effectiveness of the monitoring and evaluation of patients in forward holding areas, with a focus on monitoring patients with illness related to heat stress.

- BAA for Joint Warfighter II – recommended for award August 2016 but funding pending
  4-Year award for $5,823,887 Total
  Description:
  1. Develop Real Time CDS apps as described above (apps that will be useful in their own right), and define the ICE platform, device interoperability, and cybersecurity capabilities that are necessary for broad commercial development and adoption of advanced app capabilities that will rely on networked medical devices.

  2. Define a testing methodology and certification program to allow medical device manufacturers to demonstrate that their products acceptably conform to interoperability standards and mitigate known cybersecurity threats.

  3. Define medical device interoperability success metrics and applicable standards; work with the broader community to build a consensus on hazard analysis, standards, and mitigation for cybersecurity-related threats.

4. Implement in our Lab a test and certification program whereby manufacturers can have their devices tested and certified.

5. Together with CIMIT, focus throughout this research project on development of a business and commercialization plan.

Conclusions

There is increasing recognition that interoperable medical device and Health IT systems are needed for healthcare delivery. Platforms such as ICE, including reference implementations of standards and architectures, are needed for the adoption of interoperability. These capabilities must be fully and freely available to the community of hospitals, manufacturers, standards developers, computer science and engineering students, app developers, regulators, and everyone else who is eager to work together to mature the healthcare technology ecosystem to enable the next generation of safe and intelligent medical device and HIT systems.

ICE Data Logging: The ICE Data Logger is an essential component of the ICE platform. With the exception of clinical care settings, safety critical environments like aircraft have “black box recorder” forensic data loggers. The inability to create a synchronized, reliable log of data communicated to and from all connected medical devices used in the treatment of a patient has served as a barrier to quality improvement initiatives such as after-action reports for medical device-related and network performance issues. Furthermore, liability and safety concerns related to networked medical device systems – especially the use of new devices and apps to enable innovation – cannot be effectively addressed without a forensic data log to identify whether, for example, an app, sensor, operator, or malware contributed to an action, and the resultant outcome. Finally, ICE data logging will help drive improvements in medical device interoperability and cybersecurity – data must be communicated to the data logger to be logged, and the data logs are necessary to analyze the effects of cybersecurity exploits.

The clinical and business rationales, technical and standards pathways, and community acceptance for ICE Data Logging, have all been facilitated by research funded under this award as described in detail above. A key accomplishment was the drafting of a 35-page proposed draft standard for:

> *Requirements for the forensic (black box) data logger for an integrated clinical environment (ICE) or Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical environment (ICE) — Part x: Particular requirements for the forensic (black box) data logger*

The draft was based primarily on research performed under Aim 1 (ICE Data Logger), but it was informed by research performed under Aim 4 (ICE External Interface Data Transfer) with community support strengthened by Aim 2 (Web-Based Clinical Scenario Repository) and Aim 3 (Open Source Code Dissemination). Due to the extensive research performed under this award, the draft standard is ready for submission to AAMI for consideration as a new standard under the AAMI Interoperability Working Group.

Clinical Scenario Repository™: When our MD PnP program embarked on enabling and promoting medical device interoperability to improve patient safety and healthcare outcomes, we convened several workshops to identify historical interoperability barriers and define a pathway for success. One of the identified barriers was the disconnect between clinical needs, commercial solutions, and medical device/HIT standards that manufacturers use. In a small pilot project we learned that each manufacturer and almost every standards committee attempt to identify clinical user needs on their own, but there were no common tools, methods, or information sharing, and no pathway for customer-initiated descriptions of scenarios in which interoperability could improve specific workflows or reduce specific patient risks.

The CSR™ is intended to enable the voice of the customer to be captured to guide the development of standards and technologies. It differs from conventional "safety reports" that are based on mandatory reporting of adverse events. The CSR™ is intended to contain clinical scenarios or "good ideas" that if implemented, could improve safety, improve workflow, and facilitate innovation. These scenarios can serve as design inputs for a system of standards and technology development, and help ensure that interoperability solutions are clinically driven. It could become a core means by which the clinical user community can clarify expectations of new technologies and integrated medical device-HIT system capabilities for use by developers, regulators, researchers, and equipment procurers.

Through this award we refined the interoperability ecosystem gaps that the CSR™ could improve, researched data entry methods and templates, iterated deployment platforms, identified essential governance requirements, socialized prototypes with standards development committees to ensure the CSR™ output will be useful to align standards, and performed pilots with clinicians to refine the prototypes and acquire useful scenarios.

While demonstrating the CSR™ to clinicians and hospital risk-management professionals, we found that it was a tool they didn't know they needed, but now they wish they had. Clinicians are familiar with mandatory reporting systems that are used to report adverse events – not to capture general experiences with technology or "good ideas" for innovative interoperable products. As a result of performing this research and communicating the research findings, a strong healthcare delivery organizational (market) interest in adopting data logging and implementing CSR™ tools has been cultivated.

Code Sharing, ICE External Interface, and Demonstrations: As the report describes, this research award enabled our team to engage in numerous activities to disseminate research results, share diverse technical and clinical insights on the pathway, benefits, and challenges of enabling medical device interoperability for Integrated Clinical Environments.

The progression of medical device interoperability – especially ICE – in medical device, HIT, and cybersecurity standards, clinical and hospital interest in CSR™ reporting paradigms, and ICE implementations of commercial interest, have been spurred by the research supported by this grant. The exhibits and demonstrations at HIMSS and other venues have provided governmental and commercial leaders with a view of the healthcare benefits that can be accomplished as we identify technical and administrative means to share information and integrate medical equipment and Health IT systems into ICE systems. Moreover, the demonstrations and shared software code have lowered the barrier for others to leverage our research and prove that the proposed innovations are achievable.

References

1. Goldman JM, Jackson JL, Whitehead SF, Rausch TL, Weininger S, "The Medical Device 'Plug-and-Play' (MD PnP) Interoperability Program," part of Schrenker RA, "Software Engineering for Future Healthcare and Clinical Systems," *IEEE Computer,* April 2006.
2. Goldman JM, "Medical Device Connectivity for Improving Safety and Efficiency," *American Society of Anesthesiology Newsletter* 70:5, May 2006.
3. Goldman JM, "Patient-Centric Networked Medical Device Interoperability," part of Dagalakis NG, "Report on the Results of the NIST Medical Devices Metrology and Standards Needs Workshop," November 2006. http://www.nist.gov/el/isd/upload/USMS_Med_Dev_Needs.pdf
4. Goldman JM, Whitehead S, Weininger S, "Eliciting Clinical Requirements for the Medical Device Plug-and-Play (MD PnP) Interoperability Program," *Anesthesia & Analgesia* 2006;102:S1-54.

5. Cooney E, “Getting medical devices to talk to each other,” in “White Coat Notes,” *the Boston Globe online* (http://www.boston.com/yourlife/health/blog/2007/06/getting_medical_1.html), June 2007.
6. Carr S, “Plug and Play for Patient Safety,” *Patient Safety & Quality Healthcare*, July-Aug 2007. http://www.psqh.com/julaug07/editor.html
7. Lesh K, Weininger S, Goldman JM, Wilson B, Himes G, “Medical Device Interoperability – Assessing the Environment,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, pp. 3-12. IEEE Computer Society Press, 2008.
8. Rausch T, Jackson JL, “Using Clinical Workflows to Improve Medical Device/System Development,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, pp. 133-134. IEEE Computer Society Press, 2008.
9. Schrenker RA, “Ensuring Sufficient Breadth in Use Case Development: How Should Non-Functional Requirements Be Elicited and Represented?” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, pp. 135-136. IEEE Computer Society Press, 2008.
10. Cortés P-A, Krishnan SM, Lee I, Goldman JM, “Improving the Safety of Patient-Controlled Analgesia Infusions with Safety Interlocks,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007)*, *Cambridge, MA, June 25-27, 2007*, pp. 149-150. IEEE Computer Society Press, 2008.
11. Arney D, Goldman JM, Lee I, Llukacej E, Whitehead S, “Use Case Demonstration: X-Ray/Ventilator,” *Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), Cambridge, MA, June 25-27, 2007*, p. 160. IEEE Computer Society Press, 2008.
12. McBride R, “Doc: Plug-and-play med devices could save lives,” *Mass High Tech* 26:4, p. 7, Jan 18-24, 2008. http://www.bizjournals.com/masshightech/stories/2008/01/21/story11.html?ana
13. Whitehead SF, Goldman JM, “Getting Connected for Patient Safety,” *Patient Safety & Quality Healthcare* 5:1, Jan-Feb 2008.
14. Chiao JC, Goldman JM, Heck DA, Kazanzides P, Peine WJ, Stiehl JB, Yen D, Dagalakis NG, “Metrology and Standards Needs for Some Categories of Medical Devices,” *J. Res. Natl. Inst. Stand. Technol.* 113, 121-129, 2008.
15. Wallroth C, Goldman J, Manigel J, Osborn D, Roellike T, Weininger S, Westenskow D, “Development of a Standard for Physiologic Closed Loop Controllers in Medical Devices,” *Anesth Analg* 106, S-21, 2008.
16. Wallroth C, Goldman J, Manigel J, Osborn D, Weinstein W, Weininger S, Westenskow D, “Development of a Standard for the Interoperability of Medical Devices,” *Anesth Analg* 106, S-23, 2008.
17. Coop CE, Mosher R, Kun L, Geiling J, Grigg E, Long S, Macedonia C, Merrell RC, Satava R, Rosen JM, “Future Delivery of Health Care: Cyber Care,” *IEEE Engineering in Medicine & Biology* 27:6, 29-38, Nov/Dec 2008.
18. Agres T, “Model Contract Gives Momentum to Interoperability Movement,” *Anesthesiology News* 34:12, December 2008.
19. Johnson C, “Medical devices lag in iPod age,” *The Boston Globe*, December 29 2008.
20. Whitehead SF, Goldman JM, “Hospitals Issue Call for Action on Medical Device Interoperability,” *Patient Safety & Quality Healthcare* 6:1, Jan-Feb 2009.

21. Arney D, Goldman JM, Whitehead SF, Lee I, "Synchronizing an X-ray and Anesthesia Machine Ventilator: A Medical Device Interoperability Case Study", *Proceedings of BioDevices 2009*.
22. Anand M, Fischmeister S, Lee I, "Resource Scopes: Toward Language Support for Compositional Determinism," *Proc. of the 12th IEEE International Symposium on Object/component/service-oriented Real-time Distributed Computing (ISORC)*, Tokyo, Japan, Mar 2009.
23. Fischmeister S, Lam P, "On Time-Aware Instrumentation," *Proc. of the 15th IEEE Real-Time and Embedded Technology and Applications Symposium (RTAS)*, San Francisco, April 2009.
24. Whitehead SF, Goldman JM, "Connectivity to Improve Patient Safety: Making Medical Device 'Plug-and-Play' Interoperability a Reality," *Patient Safety & Quality Healthcare* 7:1, 26-30, Jan-Feb 2010.
25. Kowalczyk L, "MGH death spurs review of patient monitors," *The Boston Globe*, February 21 2010.
26. Kowalczyk L, "'Alarm fatigue' linked to patient's death," *The Boston Globe*, April 3 2010.
27. Arney D, Pajic M, Goldman JM, Lee I, Mangharam R, Sokolsky O, "Toward Patient Safety in Closed-Loop Medical Device Systems," In: *Proceedings of International Conference on Cyber Physical Systems*, April 2010.
28. Saver C, "Integrating Devices for Patient Safety," *OR Manager* 26:6, 21-24, June 2010.
29. Fischmeister S, Azim A, "Design Choices for High-Confidence Distributed Real-time Software," *Proc. of the International Symposium on Leveraging Applications of Formal Methods, Verification and Validation (ISoLA)*, Heraclion, Crete, 2010.
30. Goldman JM, Schrenker R, Melendez L, Hampton R, Driscoll W. Implications of the New FDA Medical Device Data System (MDDS) Regulation for Automated Clinical Documentation. *Proceedings of American Society of Anesthesiologists*: Equipment, Monitoring and Technology. October 2011.
31. Arney D, Goldman JM, Bhargav-Spantzel A, Basu A, Taborn M, Pappas G, Robkin M. Simulation of Medical Device Network Performance and Requirements for an Integrated Clinical Environment. Biomed Instrum Technol 2012 Jul-Aug;46(4):308-15. http://mdpnp.org/publications_UN9U.html
32. Arney D, Plourde J, Schrenker R, Mattegunta P, Whitehead SF, Goldman JM. Design Pillars for Medical Cyber-Physical System Middleware. In: Turau V, Kwiatkowska M, Mangharam R, Weyer C, editors. Proceedings of the 5th Workshop on Medical Cyber-Physical Systems; 2014 April 14; Berlin, Germany. Dagstuhl: Schloss Dagstuhl; 2014. vol. 36 p. 124-132.
33. Plourde J, Arney D, **Goldman JM**. OpenICE: An open, interoperable platform for medical cyber-physical systems. In: Cyber-Physical Systems (ICCPS); 2014: 221.
34. Dain S, Rausch T, **Goldman JM**. Domain Information Model for Alarm Systems for the Patient Centric Integrated Clinical Environment (ICE DIM). In: Anesth Analg; 2016; 122.
35. **Goldman JM**. Leadership and Vigilance Essential as Health Information Technology Expands. In: ASA Monitor; 2016; 80: 18-19.
36. Weininger S, Jaffe MB, Robkin M, Rausch T, Arney D, **Goldman JM**, The Importance of State and Context in Safe Interoperable Medical Systems. IEEE J Transl Health Med 2016; 4:2800110.
37. Weininger S, Jaffe MB, Rausch T, Goldman JM. Capturing Essential Information to Achieve Safe Interoperability. Anesth Analg 2017;124:83-94.
38. Weininger S, Jaffe MB, **Goldman JM**. The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems. Anesth Analg 2017; 124:127-135.
39. www.mdpnp.org
40. https://www.openice.info/docs/3_apps.html#auto-validate
41. http://mdpnp.org/MD_PnP_Program___MDISWG.html
42. http://mdpnp.org/ebola.htm

Appendix

Draft ICE Data Logger Standard

IMPORTANT:

Background and attribution:

This document was drafted by the Massachusetts General Hospital MD PnP Research Program[1] during 2014-2016, with support by the DOD[2] for the preparation of a standard for the ICE Data Logger in alignment with requirements in ASTM F2761-09(13). The proposed standard is based on research conducted in part under DOD, NIH[3], and NIST grant funding performed by the MD PnP and collaborators in industry and academia.

This document has been reviewed, edited, and approved by the AAMI SM WG03 Committee 2016-06-07 to provide content in support of an AAMI NWIP for an ICE Data Logger standard.

The document is based on an ISO template for convenience. It is anticipated to require revision if published by another SDO.

Error! Reference source not found.

(This is an ISO format template, for convenience) Error! Reference source not found.

`

Secretariat: TBD

~~Error! Reference source not found.~~

Requirements for the forensic (black box) data logger for an integrated clinical environment (ICE) or Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical environment (ICE) — Part x: Particular requirements for the forensic (black box) data logger

Error! Reference source not found.

---

[1] MD PnP Medical Device Interoperability Research Program, Founder and PI – Julian M. Goldman, MD. Based at MGH/CIMIT/PHS – see www.mdpnp.org for more information.

[2] W81XWH-12-C-0154 The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

[3] Research reported in this publication was supported in part by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) of the National Institutes of Health under award number 5U01EB012470-05. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Copyright notice

Contents

Page

Foreword (this text is from an ISO template – but the document may be submitted to an SDO other than ISO)

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ["ISO"] The authors and the SDO shall not be held responsible for identifying any or all such patent rights.

This is the first edition.

This work is based in part on research and concepts developed within the program on Medical Device "Plug-and-Play" Interoperability ("MD PnP" program, founded 2004), enriched and disseminated through publications, workshops, and website, funded in part by US Federal Grants and contracts. MD PnP is a research program founded by Julian M. Goldman, MD, based at the Massachusetts General Hospital and affiliated with CIMIT, Partners HealthCare, and Harvard Medical School. ICE data logging concepts contained in this document are based in part on a research collaboration with NIST.

The MD PnP program and academic and manufacturer collaborators have developed an extensive body of scientific and technical knowledge, much of which has been placed in the public domain to accelerate the development of platforms for Integrated Clinical Environments to improve the quality, safety, and value of healthcare delivery.

~~The intellectual property provided as the basis for this standard shall remain with the developer or owners of the intellectual property, and is not intended to become exclusively the rights of any SDO XXX, inclusing the SDO publishing this international standard.~~ ~~[section removed as required by AAMI SB]~~

The "ICE" family of standards has been proposed in ASTM F2761-09 ("Part 1") to consist of the following parts, under the general title *Medical devices and medical systems — Basic safety and essential performance of the patient-centric integrated clinical network environment (ICE)*

— *Part 1: General requirements and conceptual model, published as ASTM F2761-09 (13)*

— *Part 2: Requirements for network control and equipment interface*

— *Part 3: Requirements for device models*

— *Part 4: Requirements for supervision*

— *Part 5: Requirements for safe and reliable integration*

— *Part 6: Particular requirements for the forensic data logger – This standard*

In this Standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN THIS STANDARD OR AS NOTED: SMALL CAPITALS TYPE.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the maintenance result date) indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

– reconfirmed;

– withdrawn;

– replaced by a revised edition; or

– amended

The attention of Member Bodies (“member bodies” is an ISO and IEC term) is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised [insert SDO name here] (may state “ISO”) publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. ~~It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.~~

Introduction

MEDICAL DEVICES are essential for the practice of modern medicine. The capability of logging of data from individual MEDICAL DEVICES and single manufacturer multi-parameter monitoring devices is well known. This capability is available to varying degrees [needs explanation in rationale]. MEDICAL DEVICES have had some data logging capabilities for several decades. The device-level DATA STORE (or Data Log) is not standardized as to content or format and may include proprietary device performance metrics for technical troubleshooting and maintenance, and clinical data for patient care. These logs are acquired when performing ADVERSE EVENT analysis, but even if one device log is fairly "complete", a log of the entire clinical picture including data from the system of all devices in use at that time, is not available. For example, in typical complex clinical environments (e.g. OR, ICU, ED) the time-aligned integration of data streams from multiple devices – each with its own proprietary communication protocols and algorithms, time base, and physical interfaces – offers numerous challenges. An integrated data logging capability is needed for the entire clinical environment in which the patient is being monitored or is receiving therapy – to include logging of network-communicated commands, user interaction with devices – such as key presses, device connection and disconnection, physiologic and technical alarms, patient physiologic data, and other device status information.

The Integrated Clinical Environment (ICE) Standard, ASTM F2761-09(13), Part 1 of this standard series, established the general principles for the design, verification, and validation of a model-based integration system that enables the creation of an INTEGRATED CLINICAL ENVIRONMENT intended to facilitate cross-MANUFACTURER MEDICAL DEVICE interoperability (heterogeneous interoperability). Part 2 of this series focuses on the requirements of ICE DATA LOGGER. Regulatory and clinical needs, particularly with respect to ADVERSE EVENT and incident reporting and investigation [insert notion of time-synchronized log and notion of regulated and non-regulated equipment used for clinical care], are influencing the development of this ICE system data logging standard, also known as the ICE DATA LOGGER. It is easily imagined that with the widespread availability of an integrated forensic DATA STORE, opportunities for new and improved capabilities for forensic data analysis, post and real-time clinical analytics, quality assurance, and healthcare delivery organization and clinician credentialing will emerge. Other parts of this standard series are intended to focus on communication of PATIENT data and on equipment command and control, as well as on the functionality necessary for the seamless creation of an INTEGRATED CLINICAL ENVIRONMENT.

The approach defined and described by this series of standards for the INTEGRATED CLINICAL ENVIRONMENT (ICE) includes provisions for error resistance, and continual improvements in PATIENT safety, treatment efficacy and workflow efficiency based on device interoperability and safe system integration.

Error! Reference source not found.

1 Scope

~~This standard specifies general requirements, a model and framework for a (forensic) data logger, the ICE DATA LOGGER, a component of the INTEGRATED CLINICAL ENVIRONMENT.~~

~~This standard is intended to define the requirements essential for safety and thereby facilitate regulatory acceptance.~~

This standard provides requirements for system data logging capabilities in support of forensic analysis of ICE systems. Data logs, data logging, and data loggers play important roles in the basic safety and essential performance of integrated clinical environments. This standard is intended to provide additional requirements for users and manufacturers of a data logger as described in ASTM F2761-09(2013), subclause 4.2.4, 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 (i.e. ICE standard).

This standard specifies general functional and interoperability requirements, a model and a framework for a data logger which is a component in an integrated clinical environment. The standard will identify use cases for the types of data to be collected.

Note: This type of data logger is also referred to as a “black box recorder” in other sectors.

Note: The development activities of this standard are intended to align with related content in ASTM F2761-09(2013) and its successors, be complementary with related AAMI-UL 2800 documents that are under development, and build on several years of research and prototypes that have been funded by US governmental grants in collaboration with NIST.

Note: This standard is intended to be useful for regulatory purposes.

NOTE These requirements were derived to support the clinical scenarios or clinical concepts of operations described in Annex B.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ASTM F2761-09(2013) *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*.

ISO 14971:2007, *Medical devices -- Application of risk management to medical devices*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in*

medical electrical equipment and medical electrical systems
+Amendment 1:2012

IEC 62304:2006, *Medical device software – Software life cycle processes*

ISO 14155:2011, *Clinical investigation of medical devices for human subjects -- Good clinical practice*

IEC 80001-1:2012, *Application of risk management for IT-networks incorporating medical devices*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply / the terms and definitions given in ISO 14971:2007, IEC 60601-1-8:2006, F2761-09:2009 and the following apply.

NOTE An index of defined terms is found beginning on page 29.

4.1
ADVERSE EVENT
AE
any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other persons, whether or not related to the investigational medical device

NOTE 1 This definition includes events related to the investigational medical device or the comparator.

NOTE 2 This definition includes events related to the procedures involved.

NOTE 3 For users or other persons, this definition is restricted to events related to investigational medical devices.

[SOURCE: ISO 14155:2011, definition 3.2]

4.2
DATA LOGGER
equipment that can be used to store (log) data

4.3
DATA STORE (OR DATA LOG)
data repository of a set of integrated objects. These objects are modelled using classes defined in database schemas. Data store includes not only data repositories like databases; it is a more general concept that includes also flat files that can store data.

[SOURCE: (Wikipedia for now)]

4.x
ELECTRONIC MEDIA
(1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or

(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

[SOURCE: 45 CFR 160.103]

4.x
ELECTRONIC PROTECTED HEALTH INFORMATION
PROTECTED HEALTH INFORMATION stored on ELECTRONIC MEDIA

4.4
ICE DATA LOGGER
DATA LOGGER that meets the requirements of this standard

4.x
INCIDENT
any fortuitous or unexpected event, not being a reportable accident, by which the safety of a person is threatened

[SOURCE: EUROCAE doc number:date, subclause#]

4.5
LOGGED DATA

4.x
PROTECTED HEALTH INFORMATION
means individually identifiable health information

[SOURCE: US 45 CFR 160.103]

4.x
PERSONALLY IDENTIFIABLE INFORMATION
relating to an identified or identifiable natural person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity

[SOURCE: European Union Directive on Data Privacy doc number:date, subclause#]

4.x
RECORDING
act of making certain data persistent, with a view to subsequent replay or analysis

[SOURCE: EUROCAE doc number:date, subclause#]

4.x
REPLAY
act of reconstructing the recorded situations/scenarios

[SOURCE: EUROCAE doc number:date, subclause#]

4.x
TIMEBASE
signal that provides the reference time for other recorded signals

[SOURCE: EUROCAE doc number:date, subclause#]

4 * Forensic data logging

4.1 * Recorder technology

The ICE DATA LOGGER shall use a digital method of RECORDING.

The ICE DATA LOGGER shall not, under normal or single fault conditions, impair the safety or performance of the system in which it is installed. Particular attention shall be directed to the needs of life support systems to ensure appropriate physical and electrical segregation of the information sources at the recording system interface.

The ICE DATA LOGGER shall perform its intended function under foreseeable operating conditions.

The maintenance tasks required to ensure the serviceability and continued performance of the ICE DATA LOGGER shall be established by the equipment manufacturers and the equipment installers.

The ICE DATA LOGGER shall be independently powered from systems from which data is being recorded and shall have backup power capabilities to allow continued recording from remaining powered devices and to retain recorded data. [Note – power may be provided by the device in which the ICE DATA LOGGER is physically integrated]

4.2 * Recorder operation

4.2.1 * Interface

The ICE NETWORK CONTROLLER shall be interfaced with the ICE DATA LOGGER, to provide data logging, stamped with a common time base, of the accessible "state-of-the-clinical environment". Accessible "state-of-the-clinical environment" shall mean those devices connected to the ICE NETWORK CONTROLLER that are capable of transmitting compliant data to the ICE NETWORK CONTROLLER. This includes waveforms and derived parameters as well as images, video or audio. [maybe. May be too much data to require. Optional?]

4.2.2 * Monitoring of proper operation

There shall be aural or visual means for pre-use checking of the ICE DATA LOGGER for proper recording of the information in the recording medium. – should communicate status to ICE Network Manager which can monitor …

4.2.3 * Start and termination of recording

The ICE DATA LOGGER shall start automatically to record prior to the initiation of patient monitoring [or: of ICE-attached medical device or equipment use] and continue to record until the termination of the patient monitoring [of the ICE session]. In addition, (in the case of a surgical procedure), the ICE DATA LOGGER shall start to record as early as possible during the pre-use checks (pre-op) prior to the beginning of a medical or surgical procedure and terminate following patient disconnection from monitoring at the end of the procedure.

4.2.4 * Normal operation

When electrical power is applied to the ICE DATA LOGGER and the start logic is satisfied, the ICE DATA LOGGER shall commence and continue to store information, in accordance with the requirements of this standard. [probably need to tie logging in to ICE system check for use on a patient, not power up]

4.2.5 * Time base characteristics

A stable time base or reference signal? shall be provided to the ICE DATA LOGGER having an average accuracy of at least 0.1% obtained during information retrieval. The recorded time base shall be reproducible with an accuracy of 0.1%, averaged over a period of at least 1 minute.

4.3 * Data recording and storage

4.3.1 * Stored data

The ICE DATA LOGGER shall save LOGGED DATA in a DATA STORE (OR DATA LOG). This data shall include all user/operator interactions with ICE components such as key-presses, connections/disconnections of

equipment, starting/ending of procedure(s), and data on the device operating mode (or “state” such as calibration, standby, active). [JG note - If this is a clinical procedure, this may not possible. If equipment-based procedure, it may be]

All data in the data store shall be in non-proprietary formats.

NOTE : Available standards for data encoding should be applied.

Master index of data recorded shall be maintained and updated during the recording session.

NOTE 1 While all “user-equipment” interactions may not be accessible to the ICE, those interactions identified as important in mitigating identified patient hazards and which are accessible should be logged, and those not capable of being logged but identified as important in hazard mitigation should be considered as future product enhancements by relevant device manufacturers and future additions to device and communication standards by standards development organizations.

Note 2 The MDIDS project documents could provide a list of device outputs and inputs suitable for data logging

NOTE 2 The DATA STORE may be physically co-located to the ICE or may be remotely located as long as the ICE DATA LOGGER is sufficiently robust to comply with the requirements of this standard. [need requirement for local data store to manage network interruption – including deliberate/malicious interruptions]

4.3.2 * Volume and velocity

The ICE DATA LOGGER shall be able to record a sufficient number of hours of LOGGED DATA in the DATA STORE sufficient for the intended environment of use, equipment configuration and the specifics of the patient.

NOTE 1 The volume, velocity and type of LOGGED DATA can vary over a wide range, and a DATA STORE should be capable of storing in real time the maximum expected volume of data for the intended environments of use. [probably need to add a minimum number of hours– 72 hours?] [Will data be over-written in circular buffer? Dependent on Mode Section 4.4?]

4.3.3 * Time stamping

The ICE DATA LOGGER shall record time stamps associated with each received data packet. These time stamps should be based on the ICE Network Controller clock time reference and using real-time clock synchronization mechanisms (such as Network Time Protocol) on every message for the time the message was received and the time the message/data was stored.

4.3.4 * Quality of service

Quality of Service indicators of the ICE DATA LOGGER shall be recorded and shall include metrics on the accuracy of the synchronization, and degree of lossless compression.

NOTE 1 Quality of Service (QoS) indicators may include bandwidth, latency, and jitter.

4.3.5 * Patient and device identification

Patient demographics shall be stored in the DATA STORE (OR DATA LOG). Each data transmission from a device to the ICE shall include a unique numeric or alphanumeric code which identifies the specific device, including manufacturer, model and serial number.

NOTE 1 The FDA’s unique device identifier (UDI) encoding is expected to satisfy these requirements.

4.3.6 * Security

Access to the DATA STORE shall be controlled by, at a minimum, password protection and shall be consistent with the general principles of confidentiality, integrity and availability. Means shall be provided to restrict access to the DATA STORE to the responsible organization and responsible parties.

4.3.7 * Privacy

PROTECTED HEALTH INFORMATION shall be encrypted using a confidential process consistent with NIST Special Publication 800-111, Guide to Storage Encryption Technologies for End User Devices.

NOTE Compliance with the HIPAA Security Rule which states “the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key” is encouraged (45 CFR 164.304 definition of encryption).

4.3.8 * Reliability

Features to enhance reliability and security include use of a unique incremental sequence number for each log entry by the ICE DATA LOGGER, use of a protected data store, and use of a cryptographic signature to each log entry.

4.4 * Operating recording modes

An ICE DATA LOGGER, fully compliant with this standard, shall support the following operating recording modes:

a) clinical mode

b) technical/ troubleshooting mode

c) complete mode

Only one logging mode shall be supported concurrently. The contents of the DATA STORE for each logging mode shall stack in incremental layers: clinical < technical < complete (Figure x). The level of compliance shall be determined by qualification testing.

	Clinical Mode	Technical Mode	Complete Mode
Network packets, protocols			X
Diagnostic data		X	X
Waveforms, parameters, error codes, alarms, alerts, user entered data, key presses, configuration	X	X	X

Figure x – Stacking of data contents for each logging mode (may need to redraw figure based on committee suggestion) [WG03 note - Consider level of prescription indicated in this figure, i.e. is it too prescriptive or not enough. Also consider the forensic purpose of the data logger and evaluate that the image reflects that purpose.]

4.4.1 * Clinical mode

An ICE DATA LOGGER operating in Clinical Mode shall store in the DATA STORE the following:

a) all available physiologic waveforms;

b) all available clinical parameters;

c) any error codes;

d) any alarms or alerts;

e) any change in status;

f) any user-entered data;

g) any key presses; and

h) configuration information (including software versions)

from all the ICE-connected devices.

NOTE 1 Physiologic waveform includes waveforms that are displayed and those waveforms that are selectable for display on ICE-connected devices. This may change during the course of a surgical case or an intensive care unit stay.

NOTE 2 Clinical parameters include all parameters that are displayed and are selectable for display. Relevant to care of particular patient???? [standard must reinforce notion of what is required from devices, i.e. for devices to be good actors in this ecosystem, they must do x and y. Example: Device EDI should communicate all data that is capable of being displayed for use by the operator, technical and clinical alarm messages, clinical arm threshold settings, device state and changes in state (such as standby, operational, calibrating, infusing, stopped infusing, catheter blockage, low battery, time remaining on battery, service needed, sensor expired, operating temp exceeded, cal required, etc. Insert reference from STA meeting that describes above concept]

Q: What data goes into the data store? Data relevant to clinical situation? All parameters that can be displayed or transmitted?

Figure with data flows???

4.4.2 * Technical/ troubleshooting mode

An ICE DATA LOGGER operating in Technical/Troubleshooting Mode shall store in the DATA STORE the following:

a) All data stored in Clinical Mode and

b) Diagnostic data from connected devices.

4.4.3 * Complete mode

An ICE DATA LOGGER operating in Complete Mode shall store in the DATA STORE the following:

a) All data stored in Technical/Troubleshooting Mode and

b) All network packets/traffic available to the ICE DATA LOGGER.

4.5 * Post-data analysis, data reduction and retrieval

The logged data shall be stored in a data store (data log) which shall permit the post-recording data retrieval for data analysis and reduction of identified and de-identified data to 3rd party applications.

The replay of a RECORDING made by any ICE DATA LOGGER shall be capable of being synchronized in time with any other required RECORDING to within 1 second.

The bit error rate arising from differences between the input and the retrieved data caused by corruption of the data during processing, recording and retrieval shall not exceed one error in 10^5 bits. In addition, where data compression is used, the word error rate shall not exceed one error in 10^5 words.

Following the removal of electrical power to the ICE DATA LOGGER, the recording medium shall be capable of retaining the information recorded during the preceding operating time for a period of at least 2 years. [within a storage temp range? And humidity?]

NOTE 1 These applications include automated data extraction for ADVERSE EVENT reports and automated screening for ADVERSE EVENTs and incidents.

4.5.1 * Adverse events

Existing ADVERSE EVENT ontologies should be used, such as the device problem and evaluation codes as specified for the FDA's Medical Device Reporting (MDR) system. [placeholder to extend/improve as the terms expand?]

4.6 * Archiving

The DATA STORE for a patient stay or procedure shall be stored securely on electronic media for the duration of a patient's stay in the hospital plus 30 days, consistent with written policies of the institution.

(life of data? storage? Media? - cloud? Passive storage?

5 * General requirements

5.1 RISK MANAGEMENT PROCESS

A RISK MANAGEMENT PROCESS complying with ISO 14971:2007 shall be performed for an ICE DATA LOGGER.

In applying ISO 14971:2007:

— The term 'medical device' shall assume the same meaning as a MEDICAL DEVICE incorporating an ICE EQUIPMENT INTERFACE.

— The policy for determining acceptable RISK and the acceptability of RESIDUAL RISK(S) shall be established by the MANUFACTURER.

Check compliance by inspection of the RISK MANAGEMENT FILE. The requirements of this subclause are considered to be satisfied if the MANUFACTURER has:

— *established a RISK MANAGEMENT PROCESS;*

— *established acceptable levels of RISK; and*

— *demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).*

5.2 * ICE EQUIPMENT INTERFACE qualification test

The MANUFACTURER of equipment that includes an ICE EQUIPMENT INTERFACE shall develop a qualification test suitable for use by a RESPONSIBLE ORGANIZATION to verify those portions of the BASIC SAFETY and ESSENTIAL PERFORMANCE of that ICE-COMPATIBLE EQUIPMENT that can be affected by the ICE EQUIPMENT INTERFACE of the ICE DATA LOGGER. This qualification test shall be disclosed in the technical description.

The technical description shall include a reference to IEC 80001-1 and the necessity of the RESPONSIBLE ORGANIZATION to perform RISK MANAGEMENT, including the qualification test for the ICE-COMPATIBLE EQUIPMENT, prior to placing the system into service.

The instructions for use shall include an indication that this qualification test is described in the technical description and is required to be performed prior to placing the equipment into service.

Check compliance by inspection of the instructions for use and technical description.

5.3 Software

The requirements of IEC 62304:2006 shall apply to the software of an ICE DATA LOGGER.

Check compliance by inspection of the validation reports demonstrating compliance with the requirements of IEC 62304:2006.

5.4 Communication management

The ICE DATA LOGGER shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in NORMAL CONDITION and SINGLE FAULT CONDITION. The following principles are intended to guide the development of the other parts of this standard:

a) The connected ICE-COMPATIBLE EQUIPMENT does not fail due to receipt of messages or other information; and

b) The ICE NETWORK CONTROLLER does not fail due to receipt of messages or other information that do not conform to the DEVICE MODEL of the sending connected ICE-COMPATIBLE EQUIPMENT;

Specific error scenarios to be considered in the verification of ICE-COMPATIBLE EQUIPMENT should include the following:

c) failures caused by direct or indirect connection, electrical and logical, of ICE components to the ICE-COMPATIBLE EQUIPMENT;

d) failures caused by erroneous commands;

e) failures caused by receiving and processing erroneous data or commands; and

f) failures caused by not adhering to the non-functional requirements of the communication specification.

Check compliance by application of the tests of the remaining parts of ASTM F2761-09(13).

Annex A [start here]

(normative)

Annex title

A.1 General

A.2 Clause

Annex B
(informative)

Guidance and rationale

B.1 General guidance

This Annex provides a rationale and guidance for certain requirements of this standard and is intended for those who are familiar with the design and use of the ICE DATA LOGGER but who have not participated in its development. An understanding of the reasons for these requirements is provided to aid in the application of this standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate a revision of this standard necessitated by those developments.

B.2 Rationale and guidance for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses and subclauses in this document.

Clause 1 Scope

The following 2 paragraphs were written for a previous scope statement. There is a need to revisit this section.

Part 1 of this standard series introduces a specific conceptual functional model for defining the ICE. The model defines separate functions that comprise the ICE and includes the ICE DATA LOGGER A clinical benefit of integrating standalone MEDICAL DEVICES is the ability to combine the data collected from different sources to yield new information, in ways that are not possible with stand-alone MEDICAL DEVICES and equipment. Additional clinical benefits of integration by the ICE include decision support, the ability to implement distributed control of MEDICAL DEVICES for safety interlocks and closed loop control and the ability to record the state of the clinical environment using an ICE DATA LOGGER (the subject of this standard). Examples of such benefits are found in Annex B of Part 1 of this standard series.

Part 2 of this "ICE" standard series (this standard) presents requirements of and a model of a forensic data logger that is intended to be interfaced to ICE NETWORK CONTROLLER. A forensic data logger is intended to record data during the time a patient is undergoing care ~~monitored~~ (such as during a surgical procedure or treatment in the Intensive Care Unit). All playback and analysis of the recorded data is intended to occur after termination of the recording period

Why use a data logger?

- Change our reactive safety culture
- Lack of useful information in incident/accident investigations
- Lack of aggregate safety data to make long term safety improvements
- How do you fix what you don't know?
- Discrepancy reports

(From American Eurocopter presentation – why do we need flight data?)

Data recorders have been used for forensic purposes in transportation over the last century and have become through the development of standards and passage of legislation required and/or commonplace in commercial aircraft, automobiles, and larger ships. Logging the data of the "clinical environment for forensic, quality and other purposes remains limited in scope and scale. The experiences of these transportation data loggers improves the understanding and facilitation of solutions relative to likely issues to encountered with its wide-scale implementation,

Table 1 - Data Recorder Types and Standards in Transportation

Mode/Type*	**Photo**	**Standard(s)**	**Legal Ref.**	**Status**	**Notes**
Airplanes FDR		EUROCAE ED-112	14 CFR 25.1459 14 CFR 121.344	Mandatory	Larger aircraft
Helicopters FDR		Guidelines only	49 USC 44730 **	Optional	Video included
Motor vehicles (cars/trucks) EDR		IEEE 1616a SAE J2728 (2010)	49 CFR 563	Soon to be mandatory	Rules different between cars/trucks
Trains EDR		IEEE 1482.1 GM/RT 2472	49 CFR 229.135		
Ships SVDR		IEC 61996 (2013)	SOLAS	Mandatory?	

* FDR- flight data recorder, VDR – voyage data recorder, EDR – event data recorder

**Air ambulances

The data logging capabilities and characteristics of selected medical devices with varying capabilities – including ambulatory data loggers (e.g. digital Holter recorders), handheld monitors (e.g. combined SpO2 and CO2), laboratory data recorders (e.g. sleep diagnostics systems), multi-parameter respiratory monitors, multi-parameter physiologic monitoring systems , anesthesia workstations, and ventilators – vary significantly with respect to the capabilities, data formats, and bandwidth requirements.

INSERT SECTION ON importance of data logging to manage manufacturer product liability related to interoperability and logging as a driver for adoption of interoperability (cannot log what cannot be accessed) [JMG to add}

INSERT – section on history of ICE DAT LOGGER foundational work – see http://mdpnp.org/MD_PnP_Program_DataLogger.html and publications, web sites. [JMG to add]

Table x – Comparison between Individual Device and ICE Data Logger Capabilities

	Individual Devices	**ICE Data Logger**	**Notes**
Data logging	Capabilities limited by design choices of each manufacturer. Manufacturer proprietary data may be stored. May be mandated by new and emerging standards.	Allows for time-synchronized log of ICE-connected device in use (medical devices and other equipment). Can provide greater flexibility including virtual and distributed models of data logging	
Types of logging	Varies, often only averaged data is logged	Allows for clinical data logging, event logging and debugging data logging	Debugging logging includes recording of network traffic
Adverse Event/Near Miss Analysis	Difficult to undertake if greater than a single device is in use, due in part to difficulty of time-aligning data logs.	Allows for a more complete picture of the clinical environment to be captured with less effort and cost	ICE data logger provides opportunities for quality control and ongoing monitoring and assessment
Protocols	Priority protocols and encoding formats	Data formatted in common or known ontology for each device	Aspects of 11073, HL7 or SNOMED can be adopted as the common protocol and encoding approach
Time synchronization	Different time bases unless all devices are synced via NTP or other approach	Common time base	ICE data logger has common time base, records time from devices and will use logical clocks to assure proper sequencing
Security and Trustworthiness of Log	Dependent on design of each device	Vendor-neutral record	Vendor-neutral record to serve as ?legal record?

Given the wide range and differences in device output data streams and capabilities, it is daunting to try to combine measurements from devices from different manufacturers and sometimes even the same manufacturers. This is further complicated by the need for efficient mechanisms for data playback for adverse event/near-miss investigation and reporting. The idea of playback of limited (usually from a single device) data sets does exist. For example, ambulatory recording devices have developed a sophisticated suite of tools for analysis of limited clinical data sets.

A data/patient-centric approach will allow plug-and-play devices using data-centric protocols and an ICE data logger to work seamlessly, in an open, standardized, and time-synchronized manner, as compared to individual device-based approaches. These advantages include more efficient adverse event/near miss analysis, common protocols and time base, and improved security. Such an approach permits new opportunities for improved patient monitoring and safety. This is distinct from the capabilities of the EHR, which uses lower granularity data storage (e.g. one minute) and can fail to capture clinically significant outliers. [xxx]

With each device uniquely identified (e.g. by UDI) and data formatted in a common or known ontology, new opportunities for improvements in adverse event investigation will be enabled, similar to those enabled by the data recorders used in transportation such as the flight data recorder. Challenges with current approaches to adverse event analysis, including device location and sequestering, manual data entry, differences in clock timing, and problems with data extraction, are reduced. Debugging logs including network interactions can facilitate sophisticated debugging of device interactions, which may assist with clinical event analysis. Significant work will be required to develop effective playback tools.

The DL is intended to be a highly secure and reliable data store. The DL – although interfaced to the ICE Network Controller (INC) – need not be a physical "black-box" recorder but may reside locally or in the cloud. It must meet demanding data requirements, including high reliability, time synchronization, privacy and security (compliant with HIMSS Information Security Best Practices). The DL is intended to be limited to the capture and storage of data with no interpretation of data content performed by the DL. That function is intended for components external to the DL that run post-data capture on the DL data store.

Duncan Radiology Management

Improvement strategy has three major components

1.Continually capturing data on current performance

2. Analyzing that data to identify improvement opportunities

3. Allowing the frontline staff to pursue small tests of change as they strive to improve their performances

minimum data set - per FDA form 3500

The data logger records all data requests, transactions and flows and as such represents a complete audit trail of all activities carried out by and through the ICE. These logs should have similar uses as a "black box" flight recorder in modern aircraft. It is desirable that the logs be as complete as possible, and can be "replayed" after the fact, e.g. to allow for forensic reconstruction of events that lead to a specific outcome. It must, therefore, only be accessible through a controlled environment, i.e. an ICE, even if that ICE is for the specific purpose of accessing the data logger's logs. Physical and cryptographic protection mechanisms will be used to prevent improper access or tampering.

4* Forensic data logging

5.5 Recorder technology

5.6 Recorder operation

5.6.1 Interface

5.6.2 Monitoring of proper operation

.

5.6.3 Start and termination of recording

.

5.6.4 Normal operation

.

5.6.5 Time base characteristics

xx.

5.7 * Data recording and storage

5.7.1 Stored data

5.7.2 * Volume and velocity

The intended environment of use is intended to include all clinical environments in which a patient may be connected to medical devices which are capable of transmitting electronic data.

The equipment configuration can range from a heavily monitored environment which may include waveforms, numeric parameter, images, video and auditory inputs to a more simple ambulatory environment. The connected devices can include multi-parameter monitors with the capability of transmitting numerous parameters, simple devices communicating a single parameter to wearable sensors which may transmit data directly to or through a hub to the ICE.

The volume, velocity and type of data can vary significantly and the DATA STORE should be appropriately sized to accommodate such data. (automatic estimation of data store needs at the start of a case or monitoring session?? To determine if potential problem?) The volume of data

The velocity of physiologic waveform varies on the type of physiologic signal (and body system being measured) and tend range from several samples per second to hundreds of samples per second.

Table x

Signal	Data sampling Range
Capnogram	20-100 samples/sec
ECG	100-250 samples sec
Neuro	

5.7.3 Time stamping

Medical device clock errors are a pervasive problem that negatively impacts the accuracy of time data in EMRs and in the reconstruction of clinical events, as well as posing a direct hazard to patient safety. Most medical devices contain an internal clock that is used to timestamp data in internal logs as well as any information the device sends over its network interfaces. There is no adopted standard for medical device time management, and many medical devices do not set their clocks using a network time reference, but are typically set manually twice yearly for daylight savings time. The absence of automatic clock-setting capabilities in most devices, and the lack of time synchronization among the wide array of different clocks in use in a typical OR or ICU, can result in inaccurate time-stamps on clinical data recorded in the EMR.

A study at MGH and 4 other institutions [ref] showed that erroneous clock times are pervasive. Given the absence of automatic clock setting capabilities in most medical devices, and typical clock drift, these finding are not surprising, but consequences are underestimated. The collected data indicates a need for a central network controller to monitor and adjust device clocks. Networking medical device clocks would not only improve medical record accuracy, but also greatly reduce technician man-hours spent setting and resetting clocks during power outages, surges, or daylight saving time. The networked devices show a much lower standard deviation as compared to standalone devices which show a high deviation from the average values since their only means of synchronization is by detection and manual correction from the hospital staff

5.7.4 * Quality of service

Quality of Service indicators of the ICE DATA LOGGER shall be recorded and included metrics on the accuracy of the synchronization, and degree of lossless compression.

NOTE 1 Quality of Service (QoS) indicators may include bandwidth, latency, and jitter

5.7.5 * Patient and device identification

Patient demographics

Unique device identification..

5.7.6 * Security

The access to the DATA STORE is intended to be consistent with accepted cybersecurity principles including those outlined in FDA's draft Guidance titled "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. The access of restricted information should be to only trusted users. Safeguards should be in place to ensure that the information is accurate and not improperly modified and that information should be accessible on a timely basis.

The cybersecurity of the DATA STORE should be validated by hazard analysis and design. Software to access the data store should be regularly screened by anti-virus software, firewall use to users?

Ensure secure data transfer from medical devices to data store and post-recording from data store to analysis software, use accepted methods of encryption.

Fail-safe features to protect critical functionality

Features that allow security compromise to be recognized, logged and acted upon

*** Privacy**

PROTECTED HEALTH INFORMATION

HIPAA

Different definitions between EU and US

5.7.7 * Reliability

Features to enhance reliability and security include use of a unique incremental sequence number for each log entry by the ICE DATA LOGGER, use of a protected data store, and use of a cryptographic signature to each log entry.

5.8 * Operating recording modes

Rationale for different modes

5.8.1 Clinical mode

Data recorded in Clinical mode is intended to capture the information representing the Accessible "state-of-the-clinical environment.

Figure with data flows???

5.8.2 Technical/ troubleshooting mode

In addition to the clinical parameters and waveforms interpreted by the clinician, medical devices transmit data for diagnostic and safety purposes data on the status of various components of devices including aspects of their measurement and control systems.

Waveform/ Clinical Measurement(s) (if applicable)	Technology	Ancillary Data (examples)	Potential Clinical Value
Capnogram (e.g. PetCO2)	Infrared Spectroscopy	a.Temperature of heating element, b. flow rate of sampling pump	a. risk of injury? b. reliability of measurement
Blood Pressure (e.g. Systolic/Diastolic pressure)	Oscillometry	a.Maximum cuff pressure b. indication of start and end of inflation	a. injury? b. input to decision support regarding pulse oximeter on same limb
Infusion pump			

5.8.3 Complete mode

.

5.9 Post-data analysis, data reduction and retrieval

The ICE Data Store contains sensitive data and protected health information. Procedures shall be established to control the release and transfer of such data. In the event of an adverse event or incident, assigned staff and external regulatory staff (e.g. FDA) should be allowed unfettered access. Software tools are imagined to perform post-event analysis of the data store. A report consistent with Federal, State and Local regulatory requirements can be generated from the data store permitting a more transparent, robust and rapid analysis to performed of the adverse event.

5.9.1 * Adverse events

The Medical Device Reporting (MDR) regulation (21 CFR 803.1) requires that manufacturers and health professionals "report deaths and serious injuries that (a) device has or may have caused or contributed to." These reports are used to "protect the public health by helping to ensure that devices are … safe and effective for their intended use." The adverse event reports focus on capturing and documenting the event data (e.g.

date of event, date of report, description of event), details on the medical device (e.g. manufacturer, serial number) and basic patient demographics. In contrast to the MDR, the perspective of the availability of a forensic data store call help automate the data collection for MDRs and help to identify events and/or elicit ideas for system-level solutions that cross the boundaries of specific manufacturers, regulated and non-regulated products, diverse users, and practice variability.

Developers of analysis and automated reporting tools are strongly encouraged to use the Event Problem Code terminology for the reporting of medical device problems developed by CDRH. This code terminology consists of three term sets, covering Patient Problem Codes, Device Component Codes, and Device Problem Codes. Patient Problem Codes include patient conditions/dieases (e.g. Adult Respiratory Distress Syndrome). Device Problem Codes include codes for device operational issues (e.g. device stops intermittently, therapy delivered to incorrect body area), facilities issues (e.g. Failure to Service), human factors issues (e.g. difficult to program or calibrate), and physical property issues (e.g. Device emits odor) and Component Code Hierarchy (e.g. vaporizer).

5.10 Archiving

The DATA STORE for a patient stay or procedure shall be stored securely on electronic media for the duration of a patients stay in the hospital plus 30 days consistent with written policies of the institution.

(life of data? storage? Media? - cloud? Passive storage?

Annex C
(informative)

Clinical context and clinical scenarios

C.1 Purpose and introduction

C.1.1 Purpose

The purpose of this Annex is to provide the clinical context for the development of standards for integrated medical device systems. The Clinical Scenarios below illustrate serious adverse events that could have been prevented through integrated medical systems, thus representing unmet safety and performance needs. The examples are representative, not exhaustive.

The Medical Device "Plug-and-Play" Interoperability program [18]**Error! Reference source not found.** has identified high-level Clinical Scenarios from clinical publications, web sites, and interviews ("focus groups") with clinicians and engineers. [19],[19] These scenarios have been expanded into "use cases" to aid in the development of appropriate integrated medical device system standards.[22][40]

C.1.2 Methodology

For participants in the focus groups, a context statement and sample questions were used to stimulate their thinking.

C.1.3 Clinical scenario

A Clinical Scenario is a brief description of a clinical situation or event. The purpose of the Clinical Scenarios in this document is to provide background and illustrate the need for the development of technical solutions. Two Clinical Scenarios are provided for each situation:

a) the Current State typically describes an adverse event that has occurred to a patient;

b) the Proposed State is a brief illustration of the improvement in safety and effectiveness obtained by applying an integrated solution.

C.1.4 Clinical concept of operations (CConOps)

A Clinical Concept of Operations (CConOps) is a more detailed description of how devices and clinical staff could interoperate in a clinical environment.

This description provides details of:

— The type of equipment utilized;

— The clinical processes required;

— The type or category of clinical staff;

EXAMPLES Surgeon, intensivist, anesthesia provider, chief nurse, nursing assistant, respiratory therapist.

— Potential changes or new/novel equipment or workflow that does not exist today but that could improve the process (optional);

— Benefits of the proposed process; and

— Risk analysis of the proposed process.

Each CConOps detailed below permits an improvement in safety and effectiveness via a specific solution implementing the Proposed State.

C.2 Clinical Examples

Adverse events/incidents examples – current method CSR abstract text

Investigation of possible events

Quality control

Clinician assessment

Duncan references!!!

00

601

602 # (informative)

603

604 # Reference to the Essential Principals

605 This standard has been prepared to support the essential principles of safety and performance of
606 INTEGRATED CLINICAL ENVIRONMENT as MEDICAL DEVICES according to ISO/TR 16142:2007. This
607 standard is intended to be acceptable for conformity assessment purposes.

608

609 Compliance with this standard provides one means of demonstrating conformance with the specific essential
610 principles of ISO/TR 16142:2007. Other means are possible.

11

612
613 (informative)
614
615

Bibliography

[1] ISO 7498-1:1994, *Information technology - Open systems interconnection - Basic reference model*

[2] ISO 8802 (series), *Information technology — Telecommunications and information exchange between systems -- Local and metropolitan area networks — Specific requirements*

[3] ISO 11073 (series), *Health informatics — Point-of-care medical device communication*

[4] IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

[5] IEC 60601-1-10, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

[6] IEC 62366:2007, *Medical devices — application of usability engineering to medical devices*

[7] CIMIT, Center for Integration of Medicine and Innovative Technology [4]

[8] CSDL-422944:D.1, *Draft Standard for an Integrated Clinical Environment Manager (ICEMan)*, Prepared for the MD PnP Program by The Charles Stark Draper Laboratory, Inc., June 1, 2006

[9] AHRQ. (n.d.). Web M&M. Web M&M Morbidity & Mortality Rounds on the Web: http://webmm.ahrq.gov/caseArchive.aspx, accessed July 17, 2008.

[10] *Society*

[11] Global Harmonization

[12] IEEE 1073:1996, *IEEE Standard for Medical Device Communications—Overview and Framework*

[13] IHE Technical Frameworks, *Patient Care Devices Technical Framework* [5]

[14] Institute of Healthcare Improvement. (n.d.). Establish a Rapid Response Team. Retrieved July 16, 2008

[15] LOFSKY, A.S., Turn Your Alarms On. *APSF Newsletter*, Winter 2005, p. 43. Verified August 28, 2008

[16] NUCKOLS, T.K. Programmable Infusion Pumps in ICUs: An Analysis of Corresponding Adverse Drug Events. *Journal of General Internal Medicine*, 2007 pp. 41-45

[17] REID, P., et al, *Building a Better Delivery System: A New Engineering/Health Care Partnership*, The National Academies Press, Washington, DC, 2005

[18] Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007). IEEE Computer Society Press, 2008.

[19] Medical Devi

---

4) http://www.cimit.org, accessed February 2, 2009

5) http://www.ihe.net, accessed November 1, 2009

[20] Eliciting Clinical Requirements for the Medical Device Plug-and-Play (MD PnP) Interoperability Program. Anesth Analg. 2006;102:S1-54.

[21] Improving

[22] American

[23] Use Case Demonstration: X-Ray/Ventilator. In: Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), 149-150. IEEE Computer Society Press, 2008. P. 160.

[24] http://www.sei.cmu.edu/library/abstracts/reports/96tr006.cfm, accessed December 19, 2009

[25] Advanced Cardiac Life Support provider manual, American Heart Association 2006, p. 17.

[26] Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis. Anesthesiology. 87(4):741-748, October 1997.

[27] Getting

[28] Synchronization of Radiograph Film Exposure with the Inspiratory Pause Effect on the Appearance of Bedside Chest Radiographs in Mechanically Ventilated Patients. American J of Resp and Crit Care Med, V160, p2067, 1999.

[29] Chiao J.C. et al, Metrology and Standards Needs for Some Categories of Medical Devices. J. Res. Natl. Inst. Stand. Technol. V113, No2, 121-129, 2008.

[30] x

[31] x

[32] Interoperability

[33] APSF

[34] American.

[35] American.

[36] CIMIT/MGH

[37] Schrenker,

[39] PRIELIPP, R.C., et.al., Ventilator Failure in the ICU: Déjà Vu All Over Again. *Anesthesia Patient Foundation Newsletter*. Wilmington, DE, **13**(3), 1998, http://www.apsf.org/resource_center/newsletter/1998/fall/09vent.html, verified Nov. 11, 2008

[40] Arney, D., Goldman, J.M., Whitehead, S.F., Lee, I., "Synchronizing an x-ray and anesthesia machine ventilator: A medical device interoperatbility case study," *Proceedings of BioDevices 2009*.

1. Arney D, Weininger S, Whitehead SF, Goldman JM. Supporting Medical Device Adverse Event Analysis in an Interoperable Clinical Environment: Design of a Data Logging and Playback System. ICBO International Conference on Biomedical Ontology – Representing Adverse Events Workshop, July 26, 2011.
2. Spainhour S, Dombrowski K, Kolls B, Naglich M, Riemen K, and Olson D. Documented ICP values are not adequate for use in clinical research. ANIM Manneim (January 23-26, 2013).
3. Jaffe MB, Arney D, Weininger S, Dain S, and JM Goldman. THE INTEGRATED CLINICAL ENVIRONMENT (ICE) DATA LOGGER – OPPORTUNITIES AND ADVANTAGES RELATIVE TO INDIVIDUAL DEVICE DATA LOGGING, [Abstract] Society for Technology in Anesthesia meeting, January 2014.
4. http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/EventProblemCodes/ucm134760.htm

Ref – 3 STA abstracts on data loggers

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Draft guidance document (6/14/2013)
http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm356186.htm

Alphabetical index of defined terms used in this particular standard