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14. ABSTRACT This award reflects new and emerging technologies and research, and builds on prior and current MD PnP program work (awards #W81XWH-06-1-0651 and W81XWH-09-1-0705), to develop tools, applications, and sharable databases to advance the state of the art of medical device interoperability and enable a broader community of developers to implement medical device interoperability. This year, we worked with NIST to develop a new ICE Data Logger prototype. We built a beta version of the Clinical Scenario Repository, and continued to share our work on the open-source code-sharing environment on SourceForge. For the ONC demonstration area in the Interoperability Showcase at HIMSS14, we demonstrated a new ICE app, "Real-Time Blue Button for Patients and Families," that streams physiological data (including waveforms) from medical devices connected at our lab in Cambridge, MA, as well as data from medical devices connected locally. At the SmartAmerica Challenge in December 2013, we formed the Closed Loop Healthcare team of collaborators. The team developed a prototype in our lab, demonstrated as "From Home to Hospital to Home" at the White House-sponsored SmartAmerica Expo in June 2014.					
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**Annual 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 2013 – 30 July 2014**

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 clinical information systems could enable improved quality and timeliness of data, as well as cost-effective development of innovative third-party medical “apps” for diagnosis, treatment, research, safety and quality improvements, equipment 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 affiliated with Massachusetts General Hospital (MGH), CIMIT (Consortia for Improving Medicine with Innovation & Technology), and Partners HealthCare System, with additional support from TATRC (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 support of suitable open standards (e.g. ASTM F2761-09(13), 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 device interoperability through collaboration. Since the program’s inception, more than 900 clinical and engineering experts, and representatives of more than 140 companies and institutions have participated in our plenary workshops / conferences, working group meetings, 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, the VA), federal agencies (including the FDA, NIST, TATRC, and NSF Cyber Physical Systems), 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, small companies (e.g. DocBox, Moberg Research, Anakena Solutions, large companies (e.g. Intel, MITRE, Lockheed Martin), and the Partners HealthCare System community (MGH Anesthesia, Critical Care, and Pain Management, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and Partners HealthCare Information Systems).

TATRC support for MD PnP program development has enabled significant progress towards the goal of achieving medical device interoperability. TATRC’s funding has leveraged additional synergistic project-specific funding from CIMIT, NSF, NIST, and NIH, but it is TATRC funding that has uniquely made possible our program’s enabling efforts that are moving medical device interoperability and patient safety forward along parallel pathways of requirements, standards, platform development, and regulatory approach. A major outcome of TATRC funding has been

enabling our team to form and grow a diverse community of involved and committed collaborators and stakeholders. A pertinent example of our ability to coalesce interest and commitment around an important issue is the support from the White House and standards bodies for accurate medical device clock time.

Body of Report

The goal of the Medical Device “Plug-and-Play” (MD PnP) Interoperability program is to accelerate medical device interoperability to enable the creation of complete and accurate electronic health records and the cost-effective development of innovative third-party medical “apps” for treatment, research, safety and quality improvements, equipment management, and adverse event detection and reporting when using networked medical devices for clinical care. TATRC support for MD PnP program development has enabled significant progress towards the goal of achieving medical device interoperability. This award reflects new and emerging technologies and research, and builds on prior and current MD PnP program work (awards #W81XWH-06-1-0651 and W81XWH-09-1-0705), to develop tools, applications, and sharable databases to advance the state of the art of medical device interoperability and enable a broader community of developers to implement medical device interoperability.

For Option-Year 1 of this award (scheduled to end 30 November 2014), we proposed the following aims:

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 and liability concerns regarding networked medical device systems, and will improve the forensic analysis of clinical adverse events and near misses.

- Implement NIST research prototype Data Logger on MD PnP open platform
- Improve playback to support adverse event analysis (work with FDA and ECRI Institute)
- Add support for narrative texts (e.g. clinician interviews) and placement of events on a timeline
- Continue experiments with Unique Device Identifiers in collaboration with the FDA

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 solutions for many intractable clinical problems.

- 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
- Implement a full public site launch, including promoting it to the Patient Safety and Clinical Engineering communities

Aim 3: Open Source Code Dissemination, or ICE Apps Exchange (ICE AX)

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.

- Release any NIH/QMDI app deliverables into ICE AX repository
- Present work at open source conference or meeting, and recruit volunteers to contribute
- Develop new reference implementation apps or app frameworks, and release to ICE AX repository

Aim 4: ICE External Interface Data Transfer

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):

- Explore feasibility of connecting MD PnP Lab to MGH test ADT (Admission/Discharge/Transfer), POE (Physician Order Entry), and pharmacy systems
- Prototype connection to hospital external interfaces, starting with ADT
- Use NwHIN connectivity in demo scenario, e.g. allergy list in drug administration

Research Accomplishments

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

Our Data Logger project has greatly benefited from our ongoing collaboration with a research group at NIST using their own internal funding. 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 produced a technical white paper about the different levels or modes of logging that an ICE Data Logger will need to support. We plan to write a paper, in collaboration with both NIST and FDA, based on this work that will compare our ICE Data Logger to data loggers in other domains, in order to highlight the specific needs that differentiate clinical data logging from aerospace or automotive data logging.

This detailed comparison with other data loggers, such as aircraft flight data recorders and automotive loggers, has enabled us to work with NIST to leverage their unique engineering expertise to build a consensus 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 have been documenting the range of existing data logging strategies to serve as design inputs for our Data Logger and to serve as an informational resource for the community.

Beginning in November 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.

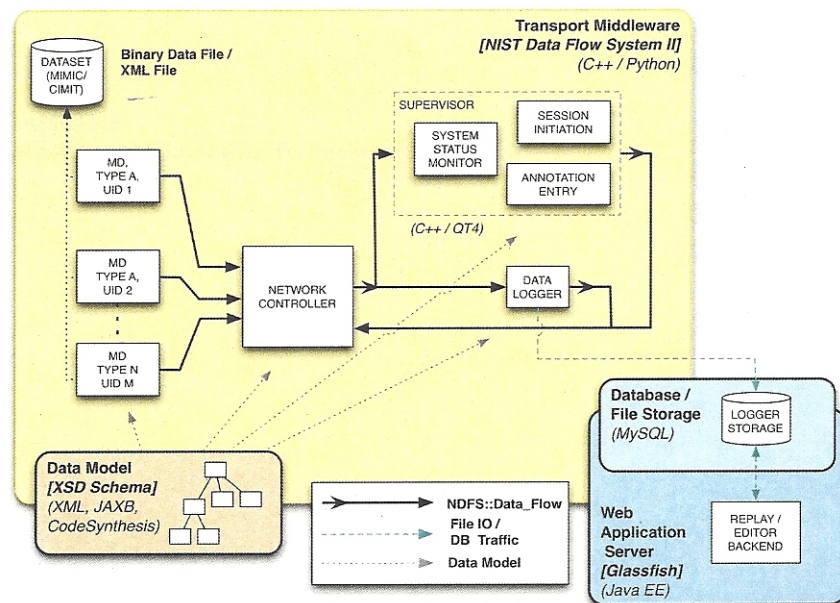
As part of the drafting of this standard, we reviewed literature and standards associated with data loggers covering different modes of transportation, publications describing clinical data loggers, and earlier work on requirements done by the MD PnP Program to highlight the specific needs of clinical data logging. In addition, FDA guidance and other documents (e.g. event codes, unique device identification 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.

Work continues on a companion supporting paper tentatively titled “The Case for Routine Use of and Standardization of Forensic Clinical Data Loggers”, a version of which is intended for publication in a journal with a medical technology readership, and on a concept of operations document for the ICE Data Logger standard. In order to provide additional supporting rationale for the draft standard, we are exploring 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, and the Joint AAMI/UL 2800 – will help ensure harmonization with other standards work.

In May Dr. Goldman and consultant Michael Jaffe presented the draft Data Logger standard to the team at NIST for feedback that we have since incorporated into the draft. In preparation for sharing this draft standard with a broader group of domain experts, we have circulated the draft to additional selected collaborators for review. Much of their initial feedback has been incorporated, and we plan to distribute the updated draft to a larger group of experts for comment. The draft Data Logger standard needs further iterations to enhance its suitability for submission into the standards development process as a new work item proposal (NWIP). In view of expanding awareness of the importance that ICE data logging could play in emerging complex HIT environments, we are considering whether to hold a workshop on clinical data logging to obtain broader community involvement.

We worked closely with NIST on their implementation of an initial research data logger prototype – implementing many of the identified requirements, and intended to demonstrate some of the challenges and our approach to logging and playback for ICE – on their in-house developed Data Flow System. This prototype 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 representatives from TATRC and federal agencies including FDA, NIST, NSF, NIH, ONC, and others.

Figure 1: The ICE Data Logger & Playback Demonstration Architecture



For the next Data Logger implementation, we built preliminary data logging functionality on the OMG DDS (standards-based) middleware we are using for our OpenICE platform development, using our ICE Equipment Interfaces. We are successfully logging 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 3 shows the logged data for a waveform. These applications are engineering prototypes intended for application development and debugging. Figure 4 shows a capture from our current 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. We are still using our proposed UDI format, since FDA guidance on UDI is focused on device labeling, barcodes, and RFID.

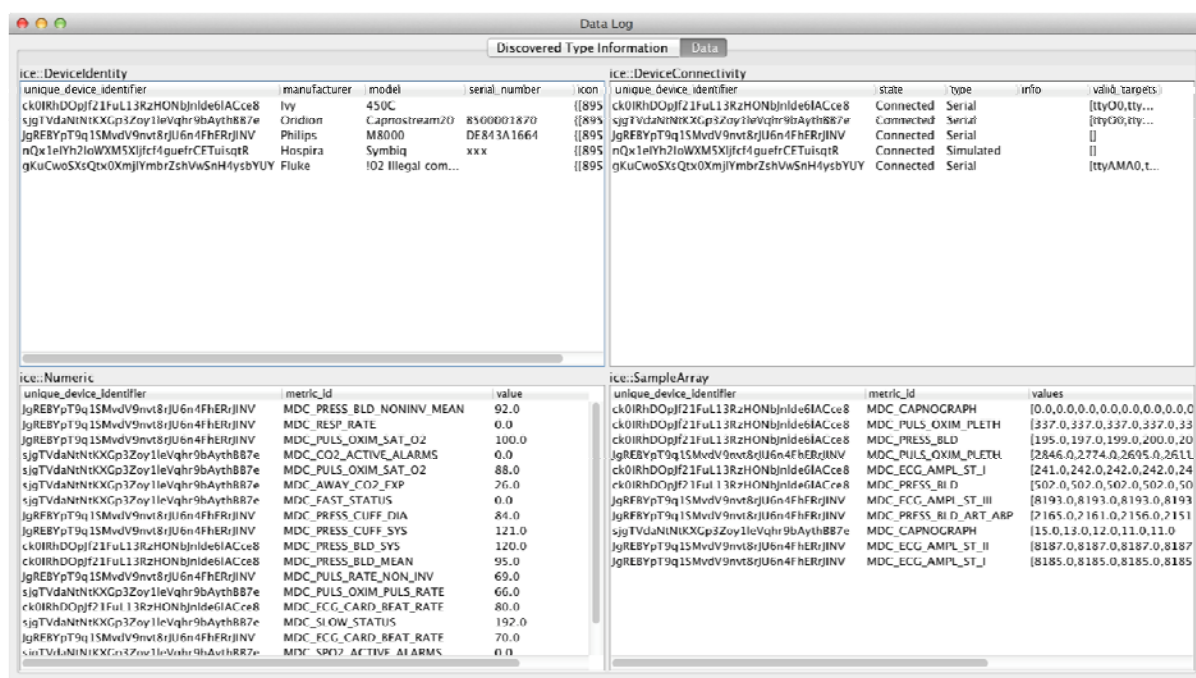


Figure 2: Data Logging Application

Logged Data [ice::SampleArray]	
Timestamp	values
20140212 10:22:28.059	[1024.0,1022.0,1023.0,1028.0,1033.0,1040.0,1047.0,1053.0,1058.0,1062.0,1065.0,1069.0,1074.0,
20140212 10:22:29.083	[1416.0,1509.0,1635.0,1795.0,1983.0,2187.0,2392.0,2581.0,2743.0,2869.0,2957.0,3011.0,3037.0,
20140212 10:22:29.083	[1718.0,1662.0,1615.0,1579.0,1554.0,1540.0,1537.0,1544.0,1558.0,1576.0,1595.0,1613.0,1627.0,
20140212 10:22:29.083	[1140.0,1123.0,1108.0,1093.0,1081.0,1071.0,1063.0,1056.0,1049.0,1043.0,1037.0,1032.0,1028.0,
20140212 10:22:29.083	[1140.0,1152.0,1165.0,1178.0,1189.0,1201.0,1215.0,1233.0,1257.0,1289.0,1333.0,1395.0,1482.0,
20140212 10:22:30.107	[2629.0,2544.0,2455.0,2366.0,2278.0,2192.0,2108.0,2026.0,1947.0,1873.0,1802.0,1737.0,1681.0,
20140212 10:22:30.107	[1462.0,1425.0,1392.0,1361.0,1332.0,1303.0,1275.0,1247.0,1220.0,1194.0,1170.0,1149.0,1132.0,
20140212 10:22:30.107	[1062.0,1067.0,1072.0,1077.0,1081.0,1084.0,1087.0,1092.0,1099.0,1109.0,1120.0,1131.0,1145.0,
20140212 10:22:30.107	[2888.0,2968.0,3014.0,3033.0,3030.0,3008.0,2973.0,2928.0,2873.0,2810.0,2739.0,2661.0,2577.0,
20140212 10:22:31.131	[1570.0,1590.0,1609.0,1625.0,1634.0,1635.0,1628.0,1609.0,1582.0,1549.0,1511.0,1471.0,1432.0,
20140212 10:22:31.131	[1042.0,1038.0,1035.0,1034.0,1032.0,1031.0,1033.0,1036.0,1039.0,1045.0,1053.0,1061.0,1069.0,
20140212 10:22:31.131	[1296.0,1341.0,1405.0,1494.0,1613.0,1766.0,1948.0,2148.0,2352.0,2544.0,2711.0,2846.0,2943.0,
20140212 10:22:31.131	[1866.0,1792.0,1725.0,1667.0,1618.0,1580.0,1554.0,1539.0,1535.0,1540.0,1551.0,1569.0,1590.0,
20140212 10:22:32.155	[1188.0,1167.0,1148.0,1130.0,1113.0,1098.0,1084.0,1071.0,1061.0,1053.0,1046.0,1040.0,1036.0,
20140212 10:22:32.155	[1123.0,1134.0,1144.0,1156.0,1169.0,1181.0,1191.0,1202.0,1215.0,1232.0,1254.0,1283.0,1322.0,
20140212 10:22:32.155	[2802.0,2725.0,2642.0,2555.0,2468.0,2380.0,2294.0,2211.0,2090.0,2011.0,1935.0,1790.0,1726.0,
20140212 10:22:32.155	[1391.0,1358.0,1327.0,1299.0,1273.0,1250.0,1228.0,1208.0,1188.0,1168.0,1148.0,1127.0,1108.0,
20140212 10:22:33.179	[1085.0,1087.0,1087.0,1087.0,1088.0,1089.0,1094.0,1103.0,1116.0,1131.0,1147.0,1163.0,1178.0,
20140212 10:22:33.179	[3012.0,3038.0,3042.0,3026.0,2994.0,2949.0,2894.0,2830.0,2757.0,2677.0,2594.0,2509.0,2423.0,
20140212 10:22:33.179	[1608.0,1621.0,1628.0,1627.0,1619.0,1603.0,1580.0,1550.0,1516.0,1480.0,1444.0,1410.0,1377.0,
20140212 10:22:33.179	[1038.0,1037.0,1038.0,1040.0,1043.0,1046.0,1049.0,1053.0,1056.0,1058.0,1061.0,1065.0,1069.0,
20140212 10:22:34.203	[1380.0,1461.0,1573.0,1718.0,1893.0,2091.0,2298.0,2496.0,2672.0,2816.0,2922.0,2991.0,3029.0,
20140212 10:22:34.203	[1746.0,1689.0,1638.0,1594.0,1561.0,1540.0,1530.0,1532.0,1544.0,1564.0,1588.0,1610.0,1627.0,
20140212 10:22:34.203	[1156.0,1133.0,1113.0,1096.0,1082.0,1071.0,1062.0,1053.0,1046.0,1040.0,1036.0,1033.0,1031.0,
20140212 10:22:34.203	[1132.0,1143.0,1155.0,1168.0,1182.0,1197.0,1212.0,1227.0,1247.0,1273.0,1308.0,1357.0,1428.0,
20140212 10:22:35.227	[2670.0,2585.0,2498.0,2410.0,2324.0,2239.0,2156.0,2075.0,1996.0,1917.0,1842.0,1771.0,1707.0,
20140212 10:22:35.227	[1473.0,1437.0,1404.0,1372.0,1341.0,1312.0,1283.0,1255.0,1228.0,1202.0,1178.0,1156.0,1136.0,
20140212 10:22:35.227	[1064.0,1066.0,1067.0,1069.0,1072.0,1076.0,1082.0,1090.0,1100.0,1110.0,1121.0,1134.0,1146.0,
20140212 10:22:35.227	[2824.0,2929.0,2999.0,3037.0,3049.0,3039.0,3012.0,2970.0,2916.0,2852.0,2780.0,2702.0,2618.0,
20140212 10:22:36.251	[1037.0,1032.0,1028.0,1026.0,1026.0,1028.0,1032.0,1038.0,1044.0,1050.0,1056.0,1062.0,1068.0,
20140212 10:22:36.251	[1277.0,1312.0,1363.0,1437.0,1540.0,1676.0,1844.0,2037.0,2243.0,2446.0,2628.0,2778.0,2892.0,
20140212 10:22:36.251	[1904.0,1829.0,1761.0,1700.0,1647.0,1605.0,1574.0,1553.0,1542.0,1540.0,1547.0,1561.0,1579.0,
20140212 10:22:37.275	[1208.0,1184.0,1161.0,1141.0,1123.0,1107.0,1093.0,1080.0,1068.0,1058.0,1050.0,1043.0,1037.0,
20140212 10:22:37.275	[1106.0,1117.0,1130.0,1143.0,1157.0,1170.0,1182.0,1193.0,1205.0,1220.0,1238.0,1262.0,1295.0,

Figure 3: Logged Waveform Data

Partition: Change			
UDI	Metric	Instance	Value
EKQBA2fTwekQAQDkx0bp4nJyFQJ24QramoF	MDC_RESP_RATE	0	@Fri Aug 29 2014 13:56:12 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334972,"nanosec":684000000}},@Fri Aug 29 2014 13:56:14 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334974,"nanosec":750000000}},@Fri Aug 29 2014 13:56:15 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334975,"nanosec":818000000}},@Fri Aug 29 2014 13:56:17 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334977,"nanosec":780000000}},@Fri Aug 29 2014 13:56:19 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334979,"nanosec":739000000}},@Fri Aug 29 2014 13:56:22 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334982,"nanosec":134000000}},@Fri Aug 29 2014 13:56:24 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334984,"nanosec":130000000}},@Fri Aug 29 2014 13:56:25 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334985,"nanosec":869000000}},@Fri Aug 29 2014 13:56:27 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334987,"nanosec":893000000}},@Fri Aug 29 2014 13:56:29 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334989,"nanosec":821000000}},@Fri Aug 29 2014 13:56:31 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334991,"nanosec":263000000}},@Fri Aug 29 2014 13:56:32 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334992,"nanosec":805000000}},@Fri Aug 29 2014 13:56:34 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334994,"nanosec":301000000}},@Fri Aug 29 2014 13:56:35 GMT-0400 (EDT) {"value":12,"device_time":{"sec":1409334995,"nanosec":937000000}},@Fri Aug 29 2014 13:56:37 GMT-0400 (EDT) {"value":12,"device_time": {"sec":1409334997,"nanosec":914000000}}
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Figure 4: Data Samples with UDI & Time Stamps

It is important for us to quantify the maximum data throughput of the system. This will ultimately be limited by the speed of the data storage system, and 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.

The NIST team visited our lab in March as part of a three-day SmartAmerica “hackathon” (see <http://mdpnp.org/smartamerica.php>), and we collaborated with them to connect 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 prep meeting in May. They presented their latest work on the prototype data logger and analysis system, followed by a demonstration of that system running on a PC as well as an iPad interfaced to that system.

Our continued work on developing core OpenICE infrastructure includes a framework that allows for data logging without compromising system security or patient privacy. In collaboration with NIST, we are performing 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. We are performing experiments to compare the performance of MySQL and other data stores for recording and searching data. This allows us to perform end-to-end testing of the entire OpenICE system from the equipment interface through to the Data Logger as we revise our OpenICE platform.

The privacy and security of patient data are now major areas of focus. We have worked with MGH IT staff to stand up a new server to support the logging of large amounts of protected patient data in a secure environment. This server is hosted in the Partners Data Center and will be available for storing data collected during clinical research trials.

Since the FDA Unique Device Identifier (UDI) ruling was published on September 24 2013, we have been exploring how to use the data format and content identified in the ruling within our OpenICE implementation. The UDI ruling lists information that must be printed on the packaging of medical devices, but it does not address electronic communications. Dr. Goldman has been part of a group convened by the Brookings Institute to discuss capturing unique device identifiers (UDIs) in administrative health care claims. As part of the UDI Implementation Work Group, we have been in discussions with FDA and Brookings about prototyping electronic communication of UDIs and the role of UDI in interoperable systems, and we are in the process of determining how to extend our current UDI implementation with additional information from the ruling. This will enhance our data logger and playback with additional information about the device manufacturer, manufacturing date, batch ID, and so on. We plan to complete and test this expanded UDI implementation during the remaining months of this Option-Year and provide our results to the FDA.

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

During the first year of this award, we leveraged the work done under TATRC 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 limited 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 Hopkins and Mayo 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 pointed out that making sure that a scenario does not contain any specific defamatory information (names of doctors, hospitals, etc.) is not enough to guarantee the lack of defamatory information – the CSR™ cannot have any kind of *implicit* defamatory information that could be derived from the content posted. Moreover, we are reevaluating the consequences of opening a tool like the CSR™ to the general public – while it is our intent that this repository does not substitute for other medico-legal and/or regulatory mechanisms, there may nonetheless be submissions that would require CSR™ administrators to act upon receiving them, e.g. mention of suicide attempts or child molestation. This has underscored the importance of our governance approach and process.

We are considering how the clinical scenarios in the CSR™ can 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, we may also expand the

CSR™ to include the other artifacts that are necessary to follow a scenario all the way to implementation.

An important milestone accomplished during the past quarter involved 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. This will help prepare for a broader MGH pilot.

The MD PnP Program had already tested different technologies to carry out this migration (e.g. the Hibernate framework to persist Java objects into a MySQL database, and Oracle's GlassFish open-source application server to serve the web application). We tested simple functionality to gain better insights into both the newer technical requirements brought by the migration and the consequences of choosing one technology over others. During the past quarter, the team considered security and performance aspects such as acquiring digital certificates to encrypt data sent between the user's web browser and our servers, work that aligns perfectly with the needs of the CSR™.

Ensuring adequate authentication and authorization mechanisms is one of the CSR™ priorities that is still under development. Several promising technologies have been 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.

The process of migrating the CSR™ away from the Google Application Engine has led to a revision of the necessary capabilities for the system and the interfaces needed to implement them. As feedback indicated that the earlier tabbed interface for "*Scenario Submission*" was considered a burdensome process, we sought further insights into how users of diverse clinical and technological expertise levels or professional backgrounds try to enter relevant information into a reporting system such as the CSR™.

Figures 5 and 6 show screenshots of the current prototype interface for submitting a scenario. In order to facilitate the scenario submission process, we have divided it into different stages. The first step is a description of the problem, which is the minimum information for entering a clinical scenario. After completing this basic information, the user can opt to add extra details to their story in Step #2.

Guidelines

- A brief explanation of an event is enough to describe a scenario. Try to keep information relevant, short and simple. Click on "example" to see an illustrative example on how an actual scenario would complete each field.
- Do not include protected health information. Omit actual names of individuals or institutions.
- Try avoid submitting scenarios redundant to the ones already in the repository.
- Once you have described the risk to patient safety you are welcome, but not required, to enter some additional information by clicking the "Add Further Details" button.

Scenario Title Example of a Title

Story / Scenario Description Example of a Story

Steps in the submission workflow

Save Finish and Submit Add Further Details Add a Solution Suggest Tags Switch View Mode

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Figure 5: Scenario Submission Prototype Interface (Step #1)

Step 2 (optional): Add additional information about the scenario.
 Add further details about contributing actors or events that happened or could happen in this kind of scenario.
 No fields are mandatory. Complete the information in the tabs that you think is relevant for the case and submit when it is ready.

[Hazards and Dangers](#)
[Equipment: Related Software](#)
[Equipment: Related Hardware](#)
[Roles Involved](#)
[Places Involved](#)
[Lessons Learned](#)
[References](#)

Add online links to relevant internet references for this scenario

Figure 6: Scenario Submission Prototype Interface (Step #2)

This approach provides a common starting point for all users, with an easy and basic first step followed by optional steps to enhance the scenario. We hope that a multi-step workflow will facilitate users' understanding and comfort level with the process, especially for users who might feel overwhelmed with the technology or with how much extra information could be associated with a scenario.

We are revisiting whether a "possible solution" description should be added as a step of the scenario submission process or in a different way. Potential optimizations and changes in functionality and interfaces need to be considered carefully, which has slowed the migration process but has provided a useful review of system functionality.

We are considering new approaches for other system capabilities. For example, instead of making an administrator-approved scenario visible to the general public, we may want to maintain the confidentiality of information such as the manufacturer or model of the devices involved. This device information could be made available for research, but not for the general public, thus eliminating the risk of publicly implying that a specific model does not perform as expected. In the next several months, we will complete evaluation and implementation of the CSR™ functionality and bring the second prototype to beta status.

While we are reimplementing the CSR™, collaborators still have access to the previous beta version and are continuing to provide valuable feedback.

We have begun to investigate potential opportunities to align the CSR™ with the recently released OpenFDA APIs (<https://open.fda.gov/>), and we will also look at potential integration with other frameworks. We are also focusing 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 (like FDA MAUDE), not required to have a 1:1 relationship between a scenario event/idea and submission (like hospital and insurance 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 before general release, this CSR™ is generating excitement and the contribution of ideas by leaders from industry, patient safety, and clinical domains. We envision even more interest when the CSR™ is publicly released. Moreover, we expect a linkage will develop between this work and the new Federal initiatives around device/HIT safety, such as FDASIA, and new initiatives at the Brookings Institute and at Duke. TATRC's longtime support of this project reflects an early and continuing vision and has enabled us to be way ahead of the curve in this important area.

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.

The MD PnP application code-sharing site on SourceForge (<http://mdpnp.sourceforge.net>) saw 955 downloads of our prototype OpenICE platform and tools over the past year (see Figure 7 below). Anyone who downloads that software package can use our simple device simulators to begin development of clinical apps for the platform. In addition to sharing with the public at large, we have engaged in specific interactions to pave the way for development of the first ICE AX apps as well as the first frameworks. We continue 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 are also streamlining the documentation of the platform to immediately surface its value to groups who might benefit from its use for clinical research.

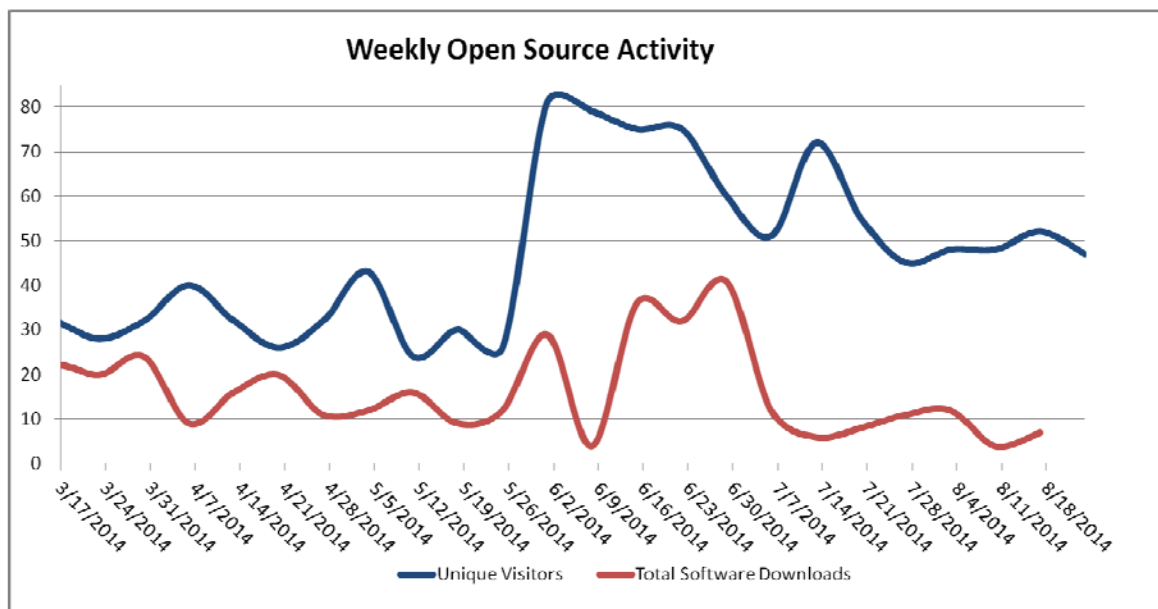


Figure 7: Weekly Open Source Activity on MD PnP SourceForge Site

A researcher at the University of Florida at Gainesville has successfully downloaded, built and run our code from SourceForge; he is building a system for automatic patient assessment using our public Philips interfaces and DDS backbone. His team was unable to implement the desired system without our tools and support. 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 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 have been analyzing the SourceForge code and our approach to data integration. We have begun technical discussions and code sharing, and we expect this work to expand.

In the area of frameworks, we became better connected with pre-release work being done at Mathworks Inc. on a MatLab interface to RTI's DDS middleware. By involving ourselves in that project now, we can ensure that when this MatLab "BlockSet" is eventually released, it will be compatible with and allow access to our ICE platform for MatLab users. We will have some examples and documentation prepared in advance of that release. We have also been in contact with an anesthesiologist at Loma Linda University Medical Center who is interested in helping provide a framework for the use of those who wish to integrate their iOS (iPad and iPhone) devices. He would like to develop this framework in anticipation of his own app development in the area of smart alarms.

We are continuing our association with Open Health Tools – we hosted their board meeting in September 2013, including a tour of our Interoperability Lab.

After seeing our demos at NIH in August, Tim Rajah at the NIH Clinical Center wanted to use OpenICE to collect data from Philips patient monitors. We provided a BeagleBone and despite substantial remotely provided technical support, the outdated Philips monitor software could not connect. Our two senior engineers spent a day at the NIH CC in February, and set up a complete OpenICE system (laptop, network switch, and device adapters) that can successfully obtain data from the old Philips monitor.

The Office of the National Coordinator for Health IT invited us to participate again this year in their area of the Interoperability Showcase at the annual Healthcare Information & Management Systems Society (HIMSS) conference and exhibition in Orlando in February. 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 lab in Cambridge, MA, as well as data from medical devices connected locally. 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 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 new National Coordinator for Health IT, Dr. Karen DeSalvo, and to Col. Dan Kral and others from TATRC, as well as to many other attendees over the course of three days.





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 constitutes 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. A video of this demo is available at <http://vimeo.com/87434601>.

In March we hosted the Closed Loop Healthcare team participating in the Presidential Innovation Fellows’ SmartAmerica Challenge. During the three-day meeting and “hackathon” in our lab, we made progress with a number of 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 have 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 at the SmartAmerica event to bring together two vendors of DDS middleware, RTI and PrismTech, to demonstrate interoperability between their implementations. We discovered a few small incompatibilities (due to configuration) and remedied them 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.

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. We have been working to connect ICE to a generalized Enterprise Service Bus (ESB). While DDS is a great backbone for a high-criticality distributed system, our connection to an ESB creates 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 two members of our team presented our 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™). A number of participants expressed interest in the description of clinical scenarios, and some participants plan to become beta testers of the CSR™.

At the request of the Presidential Innovation Fellows who organized the SmartAmerica Challenge, MD PnP also announced in June 2014 the SmartAmerica / MD PnP Healthcare App Challenge (SAMHAC), enabled by our construction of a web-facing WebSocket API for accessing data from our lab testbed environment. As part of the contest launch, we showed a demonstration “app” running in several different web browsers and on several types of devices streaming physiological data from medical devices in our lab in Cambridge, MA. The Gordon & Betty Moore Foundation has donated \$30K in prize money for the App Challenge. The idea has drawn the attention of HHS, who will now be hosting it on challenge.gov with a new timeline to be announced in September 2014.

External Interfaces for Bi-Directional 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.

In socializing the concept of remote bi-directional connectivity to our MD PnP Interoperability Lab, we have found that there is 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 White House SmartAmerica Challenge with a white paper proposing a “Virtual Hospital CPS Test Bed” building directly on Aim 4 of this award; this led to inclusion of Dr. Goldman in the SmartAmerica Challenge meeting held at the White House in December 2013.

This concept of using our interoperability lab as a test bed, including remote bi-directional connectivity, gained considerable momentum this year. There has been specific interest from both the White House (OSTP) and NSF. As a result of his presentation of the “Virtual Hospital CPS Test Bed” at the White House SmartAmerica Challenge in December, Dr. Goldman became co-chair of the Closed-Loop Healthcare team formed there. During a three-day meeting and “hackathon” in our lab in March, the team implemented some specific scenarios and prepared to demonstrate them at a SmartAmerica Expo in Washington DC in June. We also incorporated data transfer through a bi-directional interface in our HIMSS14 demonstration in

February (see **Aim 3** above). Widespread interest is developing around this test bed concept as a means to provide simulated data to research groups.

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 would be a dead-end for development. Instead we have worked to integrate a DDS system into a larger Enterprise Service Bus. Aligning ourselves with ongoing work by DDS vendors, we have worked with Apache Camel to create an endpoint for our system. Camel allows 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 have connected our Camel interface with the Camel component for “websockets”, which are bidirectional protocols for streaming data to a web browser client. Such an interface allows us to easily export data from ICE to a wide range of other terminals running on desktops, laptops, tablets, and smartphones. We expect that this will be a viable pathway for making the type of interface shown in our Real-Time Blue Button HIMSS demo publicly available.

Connecting with external systems has 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. Elaborating on how many ICEs will be coordinated has 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 has also matured greatly this year. We have been working with a developer at MGH to understand the catalog of currently available test interfaces. Partners HealthCare (and MGH as a Partners hospital) is in the process of changing electronic health record systems, a large undertaking that is expected to take at least five years. This change means that all of the interfaces to the EHR will be changing, with the first round of changes scheduled for July. This is not, therefore, a good time to prototype new connections to MGH systems, and has resulted in our not being able to perform the work needed for our milestone related to the ADT systems. However, we have been learning about the new systems that are being installed and how to obtain access to the new test data feeds as they are started, so we hope to perform this work at an appropriate later time. As an alternative to connecting to MGH’s test services, we have been working with support from the United States Department of Veterans Affairs (VA) to install the OSEHRA Veterans Health Information Systems and Technology Architecture (VistA) in our lab.

VistA is an enterprise-wide information system built around an EHR used throughout the VA medical system. It consists of nearly 160 integrated software modules for clinical care, financial functions, and infrastructure. Our team at MD PnP has chosen to test ICE integration with VistA, as it is a widely used EHR in the U.S and is freely available as an open-source program. There are several VistA variants available. We have been working with OSEHRA (Open Source Electronic Health Record Alliance) to install OSEHRA VistA. In the past quarter, we installed the client-server packages of Astronaut-VistA and have successfully used the command line interface to access and manipulate the data on the server. We installed the GUI based client application called CPRS (Computerized Patient Record System).

The various versions and fixes/patches available for Astronaut-VistA have been developed by an open source community and have many bugs. The client-server versions that are publically available do pair up well. We are currently approaching experts in this field to guide us with the configuration of a reliable system. We have been working closely with the development team at OSEHRA to get VistA installed and functional in the MD PnP Lab. At this point, the basic system is installed and running, and we are working with OSEHRA to understand the many possible ways of integrating VistA with the lab. We next plan to export an ADT feed from the EHR to the lab and will add the ability to import device data for logging and analysis from medical devices in our lab.

Milestones:

Milestone	Aim	Qtr Due	Status
Screen shots: Data Logger on MD PnP platform	1	Q2 Rpt	Completed
Screen shots: Data Logger playback for adverse event analysis, narrative text, events on timeline	1	Annual Rpt	Will be completed by end of November
Data Logger results with UDI	1	Annual Rpt	Will be completed by end of November
Beta release of Scenario Repository to collaborators	2	Q2 Rpt	Completed
Launch of public Scenario Repository website	2	Annual Rpt	Delayed until Option-Year 2
Present ICE AX at conference or meeting	3	Q3 Rpt	Completed
App framework description	3	Annual Rpt	Completed
Screen shots: prototype connection to MGH test ADT system	4	Q3 Rpt	See below

- Screen shots of Data Logger on the MD PnP platform are shown in Aim 1 of this report.
- Work on the Data Logger playback capability and other remaining functionality will be completed by the end of Option-Year 1 (November 30).
- Work on the Data Logger UDI functionality will be completed by the end of Option-Year 1 (November 30).
- Release of the beta version of the Clinical Scenario Repository to collaborators took place in December.
- We are delaying any public launch of the CSR™ until we can first resolve governance issues; anticipated for Option-Year 2.
- Present ICE AX at conference or meeting – Photos from our demonstration at the HIMSS14 annual conference in February are included in Aim 3 of this report.
- A description of the app framework – We set up OpenICE.info to support developers in using our framework to build apps. The site contains documentation, code, and a live demo of streaming device data from the MD PnP lab in Cambridge. The data is sent using WebSockets, a technology supported by all modern web browsers, and which is usable in many programming languages including C, C++, and Java. Our OpenICE demo code is written in JavaScript and runs in the web browser in order to make it as easy as possible for clinical users, who may not be trained programmers, to use the platform. The live demo is viewable at www.openice.info

- Screen shots: prototype connection to MGH test ADT system – as described in Aim 4 of this report, impending changes in the MGH EHR and related systems has forced the postponement of this work to a later time, and we have instead pursued work with OSEHRA VistA.

Key Research Accomplishments

- **New implementation ICE Data Logger.** In collaboration with NIST on the next Data Logger implementation, we built preliminary data logging functionality on the OMG DDS (standards-based) middleware we are using for our OpenICE platform development, using our ICE Equipment Interfaces, and are successfully logging data. With NIST, we are researching the best approach to long-term storage of logged data and performing experiments to compare the performance of MySQL and other data stores for recording and searching data. This allows us to perform end-to-end testing of the entire OpenICE system from the equipment interface through to the Data Logger as we revise our OpenICE platform.
- **Beta version Clinical Scenario Repository.** We presented a beta version of the Clinical Scenario Repository at the STA annual meeting and a meeting of the Society for Critical Care Medicine in January 2014, where valuable feedback was gathered. We have successfully deployed 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. This will help prepare for a broader MGH pilot.
- **SourceForge Code-Sharing Repository.** We started an open-source code-sharing environment on SourceForge in March 2013 where our project code is available for downloading – to date, we have recorded hundreds of downloads from dozens of countries.
- **HIMSS14 Demonstration.** In the ONC area of the Interoperability Showcase at HIMSS14, we demonstrated a new ICE app, “Real-Time Blue Button for Patients and Families,” that streams physiological data (including waveforms) from medical devices connected at our lab in Cambridge, MA, as well as data from medical devices connected locally. 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 packages up the data and sends it to the phone or tablet. We were able to share the demo with the new National Coordinator for Health IT, Dr. Karen DeSalvo, and to Col. Dan Kral and others from TATRC.
- **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 in December 2013. During a three-day meeting and “hackathon” in our lab in March 2014, we made progress with a number of collaborators as the team developed a prototype to be demonstrated at the White House-hosted 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.

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.

Reportable Outcomes

150+ Meetings:

- August 2013 – July 2014 – weekly teleconference calls of the Medical Device Interoperability Safety (MDIS) working group (successor to the PRS, the Prototype Regulatory Submission working group) to refine the Pre-IDE submission to FDA
- August 2013 – July 2014 – 31 MD PnP lab demonstrations for device manufacturers, standards groups, and researchers
- August 2013 – October 2013 – 6 teleconference calls of the HIT Policy Committee's FDASIA Workgroup
- August 2013 – July 2014 – regular teleconference calls of the MDIS working group on AAMI/UL 2800 coordination, followed by telcons (weekly starting end of March 2014) of the Committee working on the AAMI / UL 2800 family of standards
- August 1 2013 – FDA Telcon on Mobile Medical Apps
- August 2 2013 – FCC Consumer Advisory Committee meeting, Washington, DC
- August 21-22 2013 – MD PnP technology demonstrations for federal agencies at NIH, Rockville, MD
- September 10 2013 – Panel on Smart Healthcare Technologies for NSF SBIR/STTR program, Arlington, VA
- September 12 2013 – Meeting of the DoD JPC1 HIT working group, Washington, DC
- September 27 2013 – Hosted Open Health Tools Board meeting, Cambridge, MA
- November 2013 - April 2014 – 5 telcons for the FCC Consumer Advisory Committee Healthcare Working Group
- December 4 2013 - DICOM Working Group 24 conference call
- December 11 2013 - FCC mHealth Summit, Washington, DC
- December 16 2013 - FCC Consumer Advisory Committee Plenary Meeting, Washington, DC
- December 19 2013 - AAMI HTSI Alarm Steering Committee conference call
- January 2014 – June 2014 – 15 telcons for the SmartAmerica Closed Loop Healthcare group, formed at the December 2013 CPS Testbed Challenge in Washington, DC
- February 6 2014 – NSF CPS Workshop, Washington, DC
- February 11 2014 – SmartAmerica Challenge Workshop held at NIST, Washington, DC
- March 5 2014 – VA Time Workshop, Washington, DC
- March 18-20 2014 – SmartAmerica Closed Loop HealthCare team “hackathon” in the MD PnP Interoperability Lab, Cambridge, MA
- March 26 2014 – Workshop on NSF CPS References Architecture, Washington, DC
- March 28 2014 – Meeting of the FCC Consumer Advisory Committee Healthcare Working Group, Washington, DC
- April 24-25 2014 – Meetings of the AAMI Alarms Coalition, Washington, DC
- April 2014 – 2 telcons of the Committee working on US TAG ISO TC 121 on Anesthetic and Respiratory Equipment and the transition from ASTM to AAMI
- May 4-6 2014 – Meetings of the UL Health Council, Chicago, IL
- May 7 2014 – Chaired (via WebEx) AAMI/AR Committee meeting on US TAG and ISO TC 121 standards work

- May 13-15 2014 – Meetings of the HIT Policy Committee's FDASIA Workgroup, Washington, DC
- May 29 – June 3 2014 – AAMI Standards Week meetings, Philadelphia, PA
- June 10-11 2014 – SmartAmerica Expo, Washington, DC
- June 16-20 2014 – Dr. Goldman chaired 43rd Plenary Meeting of ISO/TC121 and Subgroups, Incheon, Republic of Korea
- July 21 2014 – Meeting with The Open Group, open standards and global interoperability organization
- July 25 2014 – Meeting of the FCC Consumer Advisory Committee Healthcare Working Group, Washington, DC

29 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 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
- October 17 2013 Lecture, "CPS Test Beds: Medical Devices" at CPS Pls meeting, Washington, DC
- 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™ 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

5 Presentations on behalf of the PI:

- December 6 2013 Technology demonstration at FCC mHealth Innovation Expo by Dave 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 Lecture on paper "Design Pillars for Medical Cyber-Physical System Middleware" by Dave 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 Dave 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" at the International Conference on Cyber-Physical Systems (ICCPs) by Dave Arney and Jeff Plourde, Berlin, Germany

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program and had a major redesign this past year. The website provides access to the ICE standard, MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop, and downloads of sharable documents and code via our SourceForge public project at http://www.mdpnp.org/Download_Files.html. On the website we now advertise General Membership in the MD PnP community, offering updates in our occasional eNewsletter, access to documentation, software, and educational materials, and an invitation to the RTI Infrastructure Community for Implementation of DDS. We currently have 194 members, and the website receives about 1,000 visits per week.

Manuscripts/Publications:

- Pajic M, Mangharam R, Sokolsky O, Arney D, Goldman JM, Lee I. Model-Driven Safety Analysis of Closed-Loop Medical Systems. IEEE Transactions on Industrial Informatics 2014; 1:3-16.
- 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.
- 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>
- 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.

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

- NSF 14-1 Solicitation under CNS - CYBER-PHYSICAL SYSTEMS (CPS)
3 Year award for \$1,500,000 Total
Proposal for an MCPS Testbed distributed between Massachusetts General Hospital and University of Pennsylvania, providing a physically and remotely accessible resource that allows researchers to access streaming of medical device data and software simulated patient data, use these data as inputs to a variety of algorithms, control medical devices based on the outputs of these algorithms, and evaluate the effects of these control activities using patient models.

Conclusions

This award is supporting the development of core capabilities for medical device interoperability for the healthcare technology ecosystem to enable the next generation of safe and intelligent medical device and HIT systems.

The Clinical Scenario Repository (CSR) is enabling 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 for interoperability” that if implemented, could improve safety, improve workflow, and facilitate innovation. These “Good Ideas” can serve as design inputs for a system of standards and technology development, and help insure 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.

Open platforms, including reference implementations of standards and architectures, are needed for the adoption of interoperability. These 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 that 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. The ICE Data Logger is an essential component of the ICE platform and the collaboration with NIST and updated standards-based technology approach (OMG DDS) are important steps towards adoption. As detailed in the report, we have been broadly sharing software and implementation instructions to support and grow the community.

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3. Goldman JM, "Patient-Centric Networked Medical Device Interoperability," part of Dagalakakis NG, "Report on the Results of the NIST Medical Devices Metrology and Standards Needs Workshop," November 2006.
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Relevant documents are linked to from the text of the report.