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& Technology Leadership

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14. ABSTRACT Open platforms of plug-and-play medical devices and health IT systems can enable improved quality and timeliness of data access, as well as cost-effective development of innovative medical "apps" for diagnosis, treatment, research, patient safety and quality improvements, and health technology management. This award has enabled research, leadership, and information sharing to advance medical device interoperability standards (especially the ICE Data Logger or "clinical black box recorder" standard), and the development and sharing of clinical and safety requirements for safe and secure integrated clinical environments. The award enabled bringing together a diverse community of manufacturers, regulators, healthcare delivery organizations, standards developers, engineers, and governmental agencies to advance healthcare technology. For example, in an urgent Ebola Virus Disease medical-technology project, we demonstrated that the diverse community could be brought together to rapidly prototype potentially life-saving integrated medical technologies in our laboratory sandbox.				
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**Final Report: Medical Device Plug-and-Play Interoperability
Standards and Technology Leadership
Award Number W81XWH-09-1-0705
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 21 September 2009 – 14 January 2018**

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 health care. 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, patient safety and quality improvements, and health technology management.

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device “Plug-and-Play” (MD PnP) interoperability program at Massachusetts General Hospital. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. By 2005 we recognized that the need for interoperability encompasses the full continuum of healthcare environments (not limited to the OR), and we developed a strategy to accelerate the development of interoperability technologies, as well as standards. This strategy addressed the need for a vendor-neutral pre-competitive “sandbox” laboratory environment to facilitate the testing of devices, technologies, and new standards within a known HIT system; development of a “plug-and-play” system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors’ liability and regulatory concerns; and assuring the clinical relevance of all proposed interoperability solutions.

CDMRP support, through a prior BAA and conference grants, had enabled the MD PnP interoperability program to develop initial capabilities, to identify, access, and share numerous available resources, and to build collaborations to achieve MD PnP-identified objectives. CDMRP’s support enabled us to attract additional program funding from Partners Healthcare Information Systems, CIMIT, NSF, NIST, and NIH. We have created a multimillion-dollar medical device interoperability laboratory in Cambridge, MA as a vendor-neutral, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety, and have exhibited these demonstrations at national meetings and held demonstrations for international audiences in our MD PnP Lab.

Significantly, core program support from CDMRP through this nine-year BAA award enabled us to lead the writing of the first medical device integration system safety standard – the Integrated Clinical Environment (ICE) standard, ASTM F2761—Part 1, which includes functional (or “logical”) architecture, clinical scenarios, and risk mitigation strategies for networked, patient-centric interoperable medical devices. In addition, we led a successful collaborative effort involving four major healthcare delivery organizations to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement of medical device interoperability for improving patient safety by fourteen medical societies (including the American Medical Association). We additionally worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. CDMRP BAA support has been instrumental in providing “program glue” to effectively leverage these highly interdependent and synergistic activities to realize shared objectives.

With the FDA and Continua Health Alliance, the MD PnP program – through CIMIT – planned and co-sponsored a three-day workshop on Medical Device Interoperability in January 2010. The workshop was attended by over 200 participants from industry, health care, and federal agencies. (http://mdpnp.org/FDA_Workshop.html). We led a follow-on working group to address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and, in 2012-2013, the FDA initiated a Medical Device Interoperability Coordinating Council to bring together various groups working on different aspects of interoperability. MD PnP played leadership roles in these activities.

The collaborative work of the MD PnP program has had a broad impact, and CDMRP support for MD PnP program development has been the key enabler of significant progress towards the goal of achieving safe medical device interoperability. CDMRP funding has leveraged additional synergistic project-specific funding from CIMIT, NSF, NIST, and NIH, but it has been CDMRP funding that uniquely enabled our program's efforts to advance medical device interoperability and patient safety forward along synergistic streams of clinical and engineering requirements, consensus standards, platform development, and regulatory science.

A major outcome of CDMRP 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. For this initiative, 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 with twenty collaborating groups we rapidly prototyped data interoperability-based innovations by leveraging our Lab infrastructure and our team's interoperability subject matter expertise.

Body of Report

This award reflected new and emerging technologies and research, and built on prior and concurrent synergistic MD PnP program work (CDMRP awards #W81XWH-06-1-0651 and W81XWH-12-C-0154), 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 learned in our NIH Quantum Medical Device Interoperability (QMDI) cooperative research project. This CDMRP project was funded for a base year plus two option-years, and the elapsed period of performance was nine years and four months (21 September 2009 – 14 January 2018). The initial BAA award period ran through September 20, 2011, and the first option-year was exercised to run through September 2014. Option-Year 2 ran through June 2016 with a revised statement of work in April 2015, and Option-Year 3 began in January 2016 and was completed in January 2018. The project length was influenced in part by the lengthy standards-development cycle.

Over the course of this award, the MD PnP Program has become a recognized leader in demonstrating clinically derived technical solutions for improving patient safety and healthcare

efficiency through medical device interoperability. Interoperability enables the creation of complete electronic health records and will introduce advanced capabilities, such as clinical error resistance, into networked medical device systems. We have been producing a framework consisting of a functional architecture and requirements for implementing standards in a manner that will support safe interoperability for effective clinical deployment. This requires critical evaluation (or “gap analysis”) of potentially suitable candidate standards, as well as the modification of existing standards and contributing to the development of new standards for implementation in the MD PnP “standardization framework.” By leveraging available standards, we expect to accelerate the MD PnP standards framework development so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazard situations and mitigation thereof to help inform regulatory science for networked medical device systems. This has also involved developing the MD PnP Laboratory as a “sandbox” or “testbed” populated with medical devices and test equipment to serve as a pre-competitive vendor-neutral environment to evaluate proposed standards and technologies. Building on our accomplishments to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards Development
- Clinical and Engineering Requirements for Safe Medical Device Interoperability
- Interoperability and Security Requirements for Medical Device Procurement
- Regulatory Science for Safe Medical Device Interoperability
- Management of External Collaborations

Since the program’s inception, more than 1000 clinical and engineering experts, as well as representatives of more than 150 industrial and academic 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.

Option-Year 2 activities built upon all of our MD PnP program work to date and reflected our vision of progressing ICE (i.e. platform-based) medical device interoperability standards, continuing to develop and make available the clinical requirements for safe medical device interoperability, helping healthcare delivery organizations in general and the DoD in particular with strategies for the procurement of interoperable medical devices, working with the FDA to develop the regulatory science related to integrated medical device systems, and continuing to build the community of interest that will lead to widespread availability and adoption of medical device interoperability for the improvement of patient safety and clinical workflow efficiency. Our work has reached a level of federal interest, national recognition, and resource development that underscores our ability to provide strong clinical leadership in all of these areas.

By Option-Year 2 of this grant – based on progress to date and on the evolving socio-technical interoperability ecosystem – the original objectives of the award were refined in agreement with CDMRP into the following set of aims, including updates to Aims 1, 3, 4, 6, and 9 (effective April 2015):

Standards Development

- **Aim 1:** Work on development of the following: AAMI/UL2800, which will help with device interoperability certification; an AAMI standard for Integrated Clinical System for PCA (for implementation of PCA safety); and the AAMI Interoperability Working Group, which is developing interoperability standards strategy and overseeing standards development in that domain. **Aim 1 modified** effective April 2015: Continue to work closely with standards committees and standards development organizations to provide subject matter expertise and

functional examples of medical device interoperability, and shepherd the transition of F2761-09(13), the “ICE” standard, from ASTM to AAMI. (Dr. Goldman is chair of ASTM Committee F29, where the ICE standard was developed.)

- **Aim 2:** Develop foundational content for a standard for an ICE-compliant clinical environment Data Logger (“black box recorder”).
- **Aim 3:** Based on experience with our OpenICE open-source ICE platform in our MD PnP Interoperability Lab, provide expertise to other standards development organizations, such as IEEE, AAMI, IEEE, UL, ISO, ASTM, HL7, IHE (Integrating the Healthcare Enterprise), and OMG (Object Management Group). **Aim 3 modified** effective April 2015: Provide interoperability demonstrations and education at the AAMI annual meeting and standards meeting in June 2015; based on the feedback received at these meetings, refine our technology and document our findings.

Clinical and Engineering Requirements for Safe Medical Device Interoperability

- **Aim 4:** Create a database of the clinical requirements we have been developing through various projects and explore ways of making these requirements useful for the broader community. **Aim 4 modified** effective April 2015: Implement workflow to more effectively support standards activities using our research data, and demonstrate these capabilities for feedback at the next AAMI-UL JC2800 meeting in June 2015.
- **Aim 5:** Enhance our requirements gathering process through (1) the evaluation of collaborators’ prototype research implementations based on our OpenICE platform and tools, and (2) bringing subject matter experts to our lab as part of a Visiting Scholars program.

Interoperability & Security Requirements for Medical Device Procurement

- **Aim 6:** Identify requirements that are central to meet near-term and long-term needs of DoD and Healthcare Delivery Organizations (HDOs) for medical device procurement, including an adoption pathway roadmap that is reasonably aligned with expectations for industry adoption and that can serve as a basis for procurement strategy. **Aim 6 modified** effective April 2015: For the adoption roadmap, obtain additional input from academic and industry collaborators, such as members of the emerging IEEE-ISTO ICE Alliance.
- **Aim 7:** Continue to update MD FIRE procurement language to reflect new information.

Regulatory Science for Safe Medical Device Interoperability

- **Aim 8:** Submit the supplement to the pre-IDE (also known as Pre-Sub or Q-Sub) document to the FDA, and provide new relevant information as needed and available.
- **Aim 9:** Once pre-IDE supplement has been submitted, release those documents into the public domain. **Aim 9 modified** effective April 2015: Based on the successful second FDA pre-IDE submission, respond to the FDA’s request that we formulate use cases to convey the differences between pair-wise and component-wise interoperability.

Management of External Collaborations

- **Aim 10:** Support and facilitate use of the MD PnP program artifacts and tools (including our Interoperability Lab/Test Bed) for interoperability R&D projects (including mobile applications and Visiting Scholars), “plug-fests”, and evolving clinical system integration activities.
- **Aim 11:** Leverage our research to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House and NSF-sponsored SmartAmerica Challenge.

- **Aim 12:** Coordinate our work under this award with standards development activities and device-related academic and industry initiatives.

Aims 2, 5, 7, 8, 10, 11, and 12 were completed for purposes of this award during Option-Year 2. Aims 1, 3, 4, 6, and 9 were completed during Option-Year 3.

Option-Year 3 activities under this award built upon all of our MD PnP program work to date and reflect our vision of progressing medical device interoperability standards, whether specifically ICE-related or more generally applicable, and continuing to develop and make available the clinical requirements for safe medical device interoperability, helping healthcare delivery organizations in general and the DoD in particular with strategies for the procurement of interoperable medical devices, working with the FDA to develop the regulatory science related to integrated medical device systems, and continuing to build the community of interest that will lead to widespread availability and adoption of medical device interoperability for the improvement of patient safety and clinical care. Our work has reached a level of federal interest, national and international recognition, and resource development that underscores our ability to provide strong clinically based leadership in all of these areas.

For Option-Year 3 of this grant, the following set of aims – recast as Tasks – was agreed on with our sponsor as our area of focus:

Standards Development

- **Task 1:** Lead transition of ASTM F2761 “ICE” standard to management by a new standards development organization (SDO):

Participate in 7-12 days of ASTM International and AAMI SDO committee meetings and liaise with senior SDO officers to lead an effective transition of the ICE standards portfolio (ASTM F2761 and future parts) from ASTM to AAMI. Assuring the availability and further development of the ICE standard is important to enable safe standards-based medical device integration for clinical care and equipment management applications of broad importance to the DoD.

Deliverable: Report on the success of the transition

- **Task 2:** Initiate consensus standard for Data Logger (black box recorder) for devices in Integrated Clinical Environments (ICE):

Develop, draft, submit, and present to a standards development organization a formal “new work item proposal” document to initiate a new consensus standard for medical device data logging in an integrated clinical environment (ICE Data Logger). Base the proposed standard on the analysis of clinical and system requirements and foundational medical device informatics research performed in our MGH/MD PnP Lab in coordination with NIST and the FDA pre-submission initiative. Identify additional engineering requirements via 2-3 meetings and weekly teleconference calls with the AAMI/UL JC2800 standardization committee, and liaison with the AAMI Interoperability Working Group and Medical Device Interoperability Safety Working Group. Data logging is an essential capability to enable continuous quality improvement in integrated clinical environments.

Deliverable: Submission of New Work Item Proposal (NWIP)

Interoperability and Patient Safety

- **Task 3:** Submit for peer-reviewed publication an article on the relationship between medical device interoperability and patient safety:

Include in this paper the potential national impact of reducing preventable medical errors by improving the ability of medical device-health IT systems to reduce preventable adverse events. Analyze published literature, leverage MGH / MD PnP research experience and subject matter experts (SME) community observations as inputs to article.

Deliverable: Submission of article

- **Task 4:** Expanded Release of the Clinical Scenario Repository (CSR):

The CSR web-based research repository of observations regarding how medical device-HIT integration barriers are impeding the implementation of patient-safety solutions was developed under W81XWH-12-C-0154 and has undergone pilot testing by physician-experts. We will expand the CSR user community to nurse informaticists, clinical engineers, and DoD clinicians. This will enable further research to refine the research tool's ability to inform opportunities to improve patient safety, and analysis of the effectiveness of the CSR to derive medical device interface and broader device-health IT system requirements. The findings of this research can inform MHS medical equipment procurement guidelines in support of improving healthcare delivery.

Deliverable: Enhanced CSR website and report on ability of CSR to generate requirements for improvements to healthcare delivery and medical device procurement

All aims and tasks have been completed for purposes of this grant/contract.

Research Accomplishments

Standards Development, Original Aim 1 (2009): Address remaining formal comments on the ICE standard (ASTM F-2761), Part I, resulting from balloting within ASTM, and see it through to publication.

Background: A multi-institutional writing group, led by Dr. Goldman and convened by ASTM International Committee F29 – including engineers and standards experts from health care, academia, industry, and government – had produced the preliminary draft of Part I of the multi-part ICE standard (“Integrated Clinical Environment”) that embodies the elements of the overall technology ecosystem to safely implement networked medical device systems. This draft was submitted by ASTM F29 as a New Work Item Proposal (NWIP) to the IEC/ISO international standards development organizations in late 2007, and received a tie vote in ISO, which was insufficient for adoption as a New Work Item. Many comments were submitted – supportive comments from healthcare delivery systems and criticism from companies with proprietary interests.

During the early part of this award, the ASTM ICE writing group systematically reviewed and addressed all 161 submitted comments on Part I, a lengthy effort but one that contributed to an improved standard: Part I was re-scoped and re-named “General requirements and conceptual model,” and outlines the more specific ICE parts still to be written. ICE Part I was successfully balloted within ASTM and ICE Part I, “Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE),” was published by ASTM as F2761-2009 in December 2009. The standard started being used immediately by international standards bodies and consortia, small companies with DoD SBIR and STTR support, and universities conducting related research.

The medical device interoperability standards and technology landscape received increased attention by the FDA, and the industry in general, following the jointly-sponsored workshop on Medical Device Interoperability held in January 2010. Many standards organizations (including ASTM) expressed interest in being involved in the further development of ICE and related standards. The FDA specifically asked AAMI (Association for the Advancement of Medical Instrumentation) to pursue the development of interoperability standards, and AAMI's ad hoc working group on HITI produced a draft report (to which we contributed) on the state of interoperability standards (see **Aim 4**). The FDA held a one-day meeting in July 2011 to bring together representatives of various standards development organizations (SDOs) to discuss how to progress the completion of device interoperability standards. Ultimately these activities led to the formation of the AAMI Interoperability Working Group under the AAMI Software and IT standards area.

Standards Development, Revised Aim 1 (2015): Continue to work closely with standards committees and standards development organizations to provide subject matter expertise and functional examples of medical device interoperability, and shepherd the transition of F2761-09(13), the "ICE" standard, from ASTM to AAMI.

As early as 2009 the MD PnP program and collaborators contributed content to Technical Note 905, written for the HITSP (Healthcare Information Technology Standards Panel) Common Device Connectivity Extension/Gap, which sought to define requirements for more tightly integrating medical devices into electronic medical record systems (EMRS). During the period of this grant, Dr. Goldman and other members of our team worked with IEEE 11073, IEC 80001 (risk management of medical devices connected to IT systems), and other standards groups to ensure the ICE standard research continued to inform related standards.

Our MD PnP team participated extensively in the AAMI Ad-Hoc Group on Health Information Technology and Interoperability (AAMI/HITI) that wrote a report for the AAMI Standards Board regarding the current state of interoperability and standards in the healthcare industry, and explored AAMI's potential role in medical device interoperability standards. The completed report was published by AAMI in January 2012. Our team also participated in the drafting of the New Work Item Proposal to develop a new standard for ICE-compliant system safety requirements for Patient-Controlled Analgesia infusions, the content for which ended up informing the AAMI/UL JC2800 standard and the ICE Data Logger standard initiatives. Our team led the Medical Device Interoperability Safety Working Group (MDISWG) (see **Objective 9**) and a subgroup of the FDA-convened Medical Device Interoperability Coordinating Council (MDICC). Our collaboration with UL resulted in mutual contributions to our architecture design and their new proposed standard AAMI/UL JC2800 for certifiable safety of medical device interfaces.

In September 2014 we collaborated with members of the AAMI/UL JC2800 standard committee to prepare the first draft of the "Systems Requirements from Clinical User Perspective" document, the "Clinical Requirements" document and the "Hazard Analysis" document. We received feedback from the UL and AAMI committees for these documents and incorporated suggested changes. We worked with members of the AAMI/UL JC2800 standards committee to continually engage in a detailed analysis of interoperability use cases and system performance and safety considerations. In December 2014 we presented our multi-vendor collaboration using the ICE environment for Ebola Virus Disease care, a demonstration we had prepared in response to a request from the White House. We also presented to AAMI/UL JC2800 and to engineers from the Center for Medical Interoperability our application of the commercial "Serena RM" requirements management tool, which is used internally for MD PnP development work and to host a database

of clinical requirements for standards development. The standards committees expressed interest in the content and using these tools to support requirements management for the standards work.

Standards Development, Task 1 (2016): Lead transition of ASTM F2761 “ICE” standard to management by a new standards development organization (SDO).

The MD PnP program has continued to play a leadership role in work with various standards development groups, especially the AAMI Interoperability Working Group and the AAMI/UL JC2800 standards for certification of safe medical device interoperability. This award enabled significant changes to the trajectory of standards and technologies to leverage interoperability in support of patient safety and innovation, and our team’s input has not been limited to the above committees. Several other standards are building on “ICE” (including medical device cybersecurity standards), and will inform changes to future revisions to ICE and the ICE Data Logger standard. (AAMI/UL JC2800 will require data logging based on requirements in the ICE Data Logger standard.)

Background regarding the need to transition the SDO for the “ICE” standard – ASTM F2761:

Standard ASTM F2761 describes a logical (or functional) architecture for platform-based medical device interoperability to enable the use of “apps” and devices to support innovation in clinical care, research, operations, and biomedical device management, and enhance the security of the clinical environment. ASTM F2761 was developed by ASTM Committee F29, based on three years of research performed by the MD PnP program and collaborators, supported by CDMRP. It was the first medical device platform architecture standard and was developed with safe interoperability and (FDA) regulatory conformance as a goal. In 2014-2015 ASTM decided to sunset committee F29, which initiated shepherding the F29 standards portfolio to a new Standards Development Organization (SDO). The F29 portfolio consisted of anesthetic and respiratory equipment (ventilators, anesthesia machines, fluid warmers, etc.). These more traditional device standards in the portfolio were likely to move to a new committee in a new SDO, but ICE required careful consideration of a new “home” to ensure its continued development and effective connection to an emerging portfolio of interdependent standards.

The desired goal of Aim 1 of this project was to successfully identify a new standards organization and committee which could adopt and would further develop ASTM F2761 “ICE” and its future Parts (including the ICE Data Logger). Through a series of meetings with the AAMI Senior VP of Standards and the ASTM F29 Executive Committee, we developed a consensus plan. All ASTM F29 standards were transferred to AAMI A/R (Anesthesia and Respiratory equipment), except for the ICE family of standards, which was assigned to the newly formed AAMI Interoperability Working Group (IOWG); both committees are co-chaired by Dr. Goldman. The IOWG offers the benefit of much broader stakeholder participation than the A/R committee, and the placement of ICE there has enabled several complimentary standards to be initiated by the experts who constitute the IOWG. As part of the ICE-standards transition plan, Dr. Goldman was appointed to a two-year term on the AAMI Committee on Standards Strategy (CSS) to provide input and direction on the alignment of medical device equipment, interoperability, cybersecurity, and HIT standards.

An IP agreement was reached between ASTM and AAMI to enable future revisions of the ASTM F2761-09(13) ICE standard Part I to be published by AAMI. Future Parts of the ICE standard may be developed within the AAMI Interoperability Working Group (IOWG). The list of proposed parts (subject to change) is currently:

- Part 1: ICE architecture – foundational standard. Published 2009 and 2013, based on research funded by base year of this award
- 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: Requirements for Data Logging (initiated under this award – see Task 2 below)

While this task is complete, we have continued to meet with a broad range of experts and stakeholders to share our research learnings and identify content and requirements for standards and technology. In May 2016 we were approached by the VA and asked to participate in the medical device cybersecurity initiative that was formed under a VA-UL CRADA. During this past year, we have been providing the VA CRADA team with subject matter expertise related to medical device interoperability and system safety as they relate to cybersecurity. In April 2017 we hosted an all-day meeting of the VA medical device cybersecurity CRADA team and members of the DoD/VA IPO team in our MD PnP Lab to meet our subject matter experts and see lab demonstrations. Weekly meetings with the VA CRADA team have continued.

Standards Development, Original Aim 2 (2009): Complete the gap analysis of the capability of the IEEE 11073 medical communication series of standards to support the use cases outlined in Part I of the ICE standard in partnership with DoD- and NSF-funded collaborators.

The ICE-PAC – a team of MD PnP collaborators that included leaders of medical device communication standards groups, medical device manufacturers (such as Philips, GE, and Draeger), small system integrators, and NIST – performed detailed workflow analysis of the clinical scenarios that were incorporated into the ICE Part I standard, and analyzed the ability of the IEEE 11073 set of standards to meet these requirements. The group completed most of the functions in the ICE standard example use cases, and their work fed our NIH project and other MD PnP-related activities, and enabled collaborative work with other organizations, notably the IHE (Integrating the Healthcare Enterprise). The NIST team led by Vince Stanford, Project Manager & Systems Architect, Information Technology Laboratory at NIST, with which we have collaborated, was also involved with this project. NIST publication “Demonstration Paper: Connecting Medical Devices Through ASTM-2761-09” is available at the website https://ws680.nist.gov/publication/get_pdf.cfm?pub_id=914710.

The ICE-PAC work was essentially completed in 2012, when that work transitioned to the new FDA-convened Medical Device Interoperability Coordinating Council (MDICC) (see **Aim 1**). Many of the same companies and federal agencies that had been involved in ICE-PAC – DocBox, Philips, MindRay, Baxter, FDA, Anakena, and NIST – became involved in MDICC. Dr. Goldman’s MDICC subgroup on Clinical Needs & Clinical Landscape (CNCL) was committed to reviewing the device interoperability landscape to identify relationships between different standards, including the gaps in meeting interoperability standards such as ASTM ICE (see <http://mdpnp.mgh.harvard.edu/projects/fda-mdicc/>).

Standards Development, Revised Aim 2 (2015): Develop foundational content for a standard for an ICE-compliant clinical Data Logger.

Work on this aim was transferred to our DoD Award W81XWH-12-C-0154 in 2012, the time at which the relevant standards organizations were ready to work on an additional Part for the ICE standard. When that award ended in 2016, with the achievement of AAMI approval of a 36-page proposed draft ICE Data Logger standard, further work on the standard was moved back to this award.

We researched several strategies to capture and store device data, including defining the optimal data architecture for various clinical scenarios and testing methods to directly intercept device data streams and import the data into MySQL tables that can be displayed on a browser.

In 2015 we completed the development of foundational content for the draft ICE-Compliant Data Logger standard for submission to a standards development organization, and discussed the adoption plan with ASTM and AAMI. We also discussed the adoption pathway for this standard with patient care and patient safety organizations such as MITRE and CRICO, and with USAMMA. The first steps included obtaining IOWG committee support and drafting a New Work Item Proposal to submit to the AAMI Standards Board to initiate the development of the new standard (see **Task 2** below). This completed Aim 2. At the time of the drafting of this report, the transition of ASTM F29 to AAMI has been completed, and the ICE Data Logger standard is being developed within the AAMI IOWG.

Standards Development, Task 2 (2016): Initiate consensus standard for Data Logger (black box recorder) for devices in Integrated Clinical Environments (ICE).

Background on ICE Forensic Data Logging:

Data Logging of mixed-vendor (heterogeneous) interoperable medical devices – which is medical network “system-level data logging” – is essential to achieve market success by addressing liability concerns and supporting continuous quality improvement of the system of devices. Data logging also drives standardization of interfaces to enable data logger connectivity. One of the key benefits of the ICE standard (F2761) is the provision of a systems architecture to enable complete, time-synchronized data logging. The “ICE Data Logger” is primarily intended for time-aligned logging of all devices connected to an ICE system to support forensic analysis of the ICE system. F2761 includes the role of an ICE Data Logger in the ICE Part I standard, which served as a placeholder for a future Data Logger standard.

The goal of this task was to work with the AAMI Interoperability Working Group (IOWG) to develop and submit for approval to the AAMI Standards Board, a New Work Item Proposal (NWIP) to initiate a consensus standard for an ICE Forensic Data Logger. AAMI procedure (and good standards-development practice) requires substantial evidence of progress toward a standard prior to submission of the NWIP.

In a series of AAMI IOWG meetings (chaired by Dr. Goldman), the IOWG refined the ICE Data Logger draft standard to meet committee consensus approval. An ICE Data Logger NWIP was prepared and submitted to IOWG committee ballot, using the draft data logger standard as foundational supporting content.

Following further document revisions, facilitated by our web-based project site on Basecamp (see Figure 1), the IOWG committee unanimously approved the NWIP for submission to the AAMI Standards Board. Updated NWIP documents were circulated to the Standards Board in October 2016 in preparation for their November 2016 meeting. These updated documents included a strong letter of support from Draeger, and five large medical device companies actively participated in this effort.

On initial review, the AAMI Standards Board identified two sections of the draft standard that required modification to meet with their approval. In conference calls with an AAMI standards director, Chair of the AAMI Standards Board, and IOWG subject matter experts, we edited the NWIP, and it was approved in a special meeting of the AAMI Standards Board in November 2016. With the approval of the NWIP, the deliverable for this task was complete.

While awaiting formal approval, AAMI advised the IOWG committee to begin editing the draft ICE Data Logger standard. In support of this project, we set up a web-based project site (see Figure 1) and Dr. Goldman chaired virtual meetings, approximately every two weeks in June - October 2016.

Figure 1. ICE Data Logger Basecamp Project

The deep technical analysis performed by the IOWG committee was documented in a committee-shared spreadsheet. In addition, two articles were published on this work: “Capturing Essential Information to Achieve Safe Interoperability” (Weininger, Jaffe, Rausch, Goldman) in *Anesth Analg* 6 Jul 2016, and “The Importance of State and Context in Safe Interoperable Medical Systems” (Weininger, Jaffe, Robkin, Rausch, Arney, Goldman) in *IEEE Journal of Translational Engineering in Health and Medicine*, 8 July 2016.

We continued to chair standards meetings and support meeting logistics (e.g. via Basecamp) to mature the ICE Data Logger standard until the end of the period of performance of this award. We responded to ICE Data Logger NWIP questions posed by the AAMI Standards Board. In June 2017 Dr. Goldman co-chaired a three-day meeting of the IOWG at which substantial progress was made on the ICE Data Logger standard. Regular IOWG meetings continue to be held to progress the Data Logger standard. A committee internal ballot is planned for April 2018 in advance of a face-to-face meeting at AAMI in June 2018.

Standards Development, Revised Aim 3 (2015): Provide interoperability demonstrations and education at the AAMI annual meeting and standards meeting in June 2015; based on the feedback received at these meetings, refine our technology and document our findings.

We provided interoperability demonstrations and education at the AAMI annual meeting and standards meeting in Denver in June 2015. OpenICE was demonstrated by MD PnP clinical engineer Jeff Peterson at an exhibit. An accompanying lecture on the Medical Internet of Things was delivered by Dr. Goldman. The AAMI venue, which our team attends regularly, provides important feedback on interoperability, system integration, and adoption from the perspectives of Clinical Engineers and Health Technology Managers. Based on the feedback received at these meetings, we updated the OpenICE.info web site with tutorial content and refined our technology and documented our findings.

Clinical and Engineering Requirements, Original Aim 4 (2009): Create a database of the clinical requirements we have been developing through various projects, and explore ways of making these requirements useful for the broader community.

Early work on this aim was focused on a design for a web-deployable secure requirements database to facilitate capture of critical elements as we and collaborators added clinical scenarios. We developed and demonstrated an initial web-based prototype and received feedback on our prototype design by collaborators at FDA and NIST, but we had insufficient resources to complete a robust design and implementation of this use case repository, as well as a plan for managing a web-based interface to facilitate broader collection of new use cases and refinement of existing ones, while protecting the integrity of the database. In agreement with CDMRP, work on this Clinical Scenario Repository (CSR) was transferred to our DoD Award W81XWH-12-C-0154 in 2012 to enable more refined development and testing of a prototype system. When that award ended in 2016, the CSR had been through three prototype iterations based on diverse user feedback and requirements of potential deployment environments. More testing from a broader audience was needed, so further work on the CSR was moved back to this award.

Clinical and Engineering Requirements, Revised Aim 4 (2015): Implement workflow to more effectively support standards activities using our requirements tools, and demonstrate these capabilities for feedback at the next AAMI/UL JC2800 meeting in June 2015.

We implemented the requirements database in Serena RM (“Requirements Manager”), a commercial requirements management database well suited to support collaboration. We used RM to incorporate the requirements we developed under our NIH grant – including generic and ICE-specific requirements, PCA-specific safety and clinical requirements and associated attributes, and collaborator comments on these requirements. We also used Serena RM to export requirements and comments, and presented them to AAMI/UL JC2800 in the “Systems Requirements from Clinical User Perspective” document.

At the December 2014 AAMI standards meeting week, the response to initial sharing of Serena RM requirements output was very positive, and we subsequently received renewed interest from the joint committee in utilizing our tools to aid standards development. In response, we created a demonstration schema and workflow within Serena RM to more closely align with the standards development work by AAMI/UL JC2800. This enables our MD PnP internal and external standards development work to continue in parallel. We demonstrated this schema and workflow to members of the AAMI/UL JC2800 team at a working session in our Lab prior to their June 2015 meeting and in an on-site meeting at our program’s offices that included engineers from the Center for Medical Interoperability.

The implementation of requirements in Serena RM is very powerful because of the capability to export Excel documents and re-import them with tracking of edits to requirements. This enables a pathway of “crowd sourcing” requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation. We tested a workflow based on exporting Serena RM content to Excel format, sharing the Excel document with standards committee members, and importing and tracking committee input using Serena RM’s specialized importation capabilities. While technically effective, we found that this approach may be too resource-intensive to maintain as the AAMI/UL specialized working groups proliferated.

We have provided AAMI/UL JC2800 with extensive use case materials and have used our Lab’s subject matter expertise to contribute to a wide range of committee documents. In addition, we host six AAMI/UL JC2800 committee working groups on a secure MD PnP-resourced project site (via Basecamp). The site continues to be provided without charge to the committee, and is open to all standards development committee members to enable discussion and sharing.

The Serena RM installation used to store and share requirements as described above, was also used to document new clinical requirements for our DoD Joint Warfighter Medical Research Program contract related to a heat-stress clinical scenario (award #W81XWH-15-C-0064). This demonstrates the extensibility and reusability of our research products.

Interoperability and Patient Safety, Task 4 (2016): Expand the release of the Clinical Scenario Repository (CSR).

The CSR is a prototype web-based tool our MD PnP team developed to enable researchers, engineers, clinicians, and patients to describe solutions to healthcare technology gaps that interfere with optimal patient care. The CSR resulted from investigating methods to identify persistent care-delivery gaps that could be addressed through improved interoperability. It became clear to us that the voice of the customer (clinicians, biomedical engineers, patients, and others) could provide detailed information about current or foreseeable problems and also propose solutions if the right tool were available. With separate DoD funding we developed and demonstrated three iterations of a web-based prototype, based on diverse user feedback and requirements of potential deployment environments. Questions related to management of PHI, governance, stakeholders, and user communities have been investigated. The results have shown that CSR input can spur healthcare improvements by driving the development of new healthcare technologies and refining the implementation of legacy technologies. CSR data can be used to inform compliance/certification criteria for risk-mitigation of specific scenarios, such as persistent hazards or cybersecurity vulnerabilities. The CSR is not intended to replace any mandatory reporting systems.

The goal of Task 4 was to expand trial usage of our current prototype to determine how it might best be further developed. A pilot implementation of the Clinical Scenario Repository (CSR) (aka Good Ideas for Patient Safety) was performed with the physician members of the American Society of Anesthesiologists (ASA) Committee on Patient Safety and Education (CPSE). (The ASA is an educational, research and scientific association of more than 52,000 physicians.) Unique logon credentials were created for the CPSE members of, and several web tutorials were held to demonstrate how to use the website. At the annual meeting of the ASA in Chicago in October 2016, the 25 clinical scenarios submitted in the CSR were discussed within the committee, and a plan was formulated to develop a report for ASA leadership. The CPSE reported on the CSR pilot to ASA leadership in a formal committee report.

The ASA CPSE users identified additional usability and data access functions that could be included in a future iteration of the CSR. As the current version of the CSR is still a research build, requirements such as those identified in the ASA pilot will be helpful to develop a more robust

version. In addition to the initial intent of using the CSR to identify barriers and opportunities related to device and data integration, we have found that the CSR can be used to capture scenarios related to cybersecurity threats.

Clinical and Engineering Requirements, Revised Aim 5 (2015): Enhance our requirements gathering process through (1) the evaluation of collaborators' prototype research implementations based on our OpenICE platform and tools, and (2) bringing subject matter experts to our lab as part of a Visiting Scholars program.

In 2014 several graduate students in the Technology Management program at Georgetown University completed their capstone projects in the MD PnP Lab. A second class of graduate students began their capstone projects and conducted research and training activities in the MD PnP Lab during 2015.

Several research collaborations were established to test prototype implementations of OpenICE in different clinical scenarios at various locations. These projects forced specificity into requirements for the communication of interoperable medical device data elements to enable each use case. For example, a team of clinicians and computer science students at the University of Montana worked with our team and OpenICE remotely on a project on the audibility of intraoperative alarm systems. From this collaboration we learned a new clinical scenario with its related requirements and the nuances of the software implementation needed to achieve a successful OpenICE research implementation. An OpenICE ventilator alarm management study led by an investigator at Johns Hopkins University (JHU) was proposed, and we supported a pre-clinical pilot installation at JHU in 2015. Requirements for a comprehensive neuromonitoring suite were explored by MGH neuro-critical care experts.

We established a visiting scholars program to bring subject matter experts to our Lab during 2014-2015. These included the Chief Innovation Officer for Montgomery County, MD; students of our collaborator Insup Lee, Professor of Computer Science at University of Pennsylvania; the Executive Director of the Martinos Center for Biomedical Imaging; the Solutions Architect at PrismTech; a medical student at Boston University; technical and strategic leadership teams from Draeger USA; and residents and research fellows from the Department of Anesthesia, Critical Care, and Pain Management at MGH.

Interoperability and Patient Safety, Revised Aim 6 (2015): For the adoption roadmap, obtain additional input from the members of the new IEEE-ISTO ICE Alliance.

We believe that ICE systems may be deployed in a wide variety of settings, with potentially different interoperability and/or security requirements. For example, the MD PnP OpenICE implementation includes a web gateway that enables streaming of device data through a standard web browser on a computer or phone. These various domains have very different needs for security, and at times the requirements are contradictory. For instance, an ICE system in a secure clinical setting (e.g. ED, OR) needs to allow instant access by anyone in the area during what are called "break the glass" scenarios. This functionality may not be appropriate in a more publicly accessible installation such as a mobile or home healthcare setting. As we built our OpenICE implementation, we were tracking these issues and evaluating a variety of security technologies ranging from RFID access control to security testing products.

Recently, there has been a dramatic increase in the healthcare community's concerns about medical device cybersecurity, and the need to maintain security to support reliable operation of networked medical devices. An obvious issue is that increased connectivity can lead to increased cybersecurity risk, implying that there must be a trade-off between maintaining security and promoting interoperability. Our program has expressed concern that advancement in

interoperability may be subjugated to emerging concerns about cybersecurity, thereby delaying the adoption of much-needed interoperability capabilities. To help define a path forward, we have been developing a framework to clarify that effective interoperability can improve cybersecurity by enabling system-level base-lining, forensic data logging (such as through the ICE Data Logger), and monitoring. We have been developing collaborations with several academic, commercial, and governmental security experts, as well as standing up formal medical device cybersecurity capabilities in our MD PnP Lab environment.

We have expanded our involvement in the medical device cybersecurity realm by building on our competency in medical device interoperability and operational biomedical/HIT cybersecurity applied to product deployment within the Partners HealthCare System. Our collaborator at the University of Pennsylvania, Professor Insup Lee, led a research project on authentication for OpenICE: “Protecting the interoperable clinical environment with authentication” (Medical Cyber Physical Systems '16 Vienna, Austria, c 2016 ACM, ISBN 978-1-4503-2138-9, DOI: 10.1145/1235).

In one-on-one and group meetings with medical, IT, and security companies (including founding members of the ICE Alliance), it has become evident that non-medical device companies may not have sufficient healthcare domain knowledge to efficiently contribute their cybersecurity expertise. Therefore, we have been educating the community through meetings and presentations in order to promote knowledge sharing to accelerate effective healthcare cybersecurity solutions. These venues have included the Industrial Internet Consortium, IEEE EMBS, and the FDA Workshop on Collaborative Approaches to Medical Device Cybersecurity (January 2016).

The potential cybersecurity benefits of the ICE architecture for “sandboxing” devices and apps in the patient environment are also becoming increasingly clear.

We have been providing medical device interoperability domain expertise to assist the Veterans Administration in a medical device cybersecurity CRADA that the VA initiated with UL to pilot a new cybersecurity standard (UL 2900). We hosted a VA CRADA outcomes meeting in the MD PnP Lab in 2017.

Interoperability and Patient Safety, Aim 7 (2009): Continue to update MD FIRE procurement language to reflect new information.

The Medical Device Interoperability Program group at the VA (formed in October 2010 with Dr. Goldman as a mentor) set a goal of producing a version of MD FIRE by December 2011 to propose for VA adoption. TATRC re-engaged in an effort to integrate MD FIRE in the DoD procurement process. The Indian Health Service also asked to join the process of refining the MD FIRE language.

During 2011-2012 we continued to work with various organizations on updates to the MD FIRE contracting language, which was originally published in 2008. Version 1.5 was published on the mdnpn.org website in October 2011.

After considerable work with the Medical Device Interoperability Program Council at the VA and feedback from other groups, we reorganized the MD FIRE document to facilitate the “cut and paste” of sections relevant to RFIs, RFPs, and contracts, and we added more references to other related materials. We shared MD FIRE version 1.7 with several Hospital Delivery Organizations that participated in a meeting we hosted at HIMSS12 to discuss MD FIRE, implementation of the FDA’s Medical Device Data System ruling, and other HIT issues common to HDOs.

In June 2015, MD FIRE was approved by the VA's Chief Technology Officer, and version 2.0 was published on the [mdnp.org](http://www.mdnp.org) website with the VA as a signatory. Other organizations are reviewing MD FIRE for potential adoption. The MD FIRE website has almost 30,000 page views (<http://www.mdnp.org/mdfire.php>).

Interoperability and Patient Safety, Task 3 (2016): Submit for peer-reviewed publication an article on the relationship between medical device interoperability and patient safety

Two journal articles were accepted for peer-reviewed publication and published both online and in print:

- The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems. Weininger S, Jaffe MB, Goldman JM, *Anesthesia and Analgesia* (published online). DOI: 10.1213/ANE.0000000000001386. Published in *Anesth Analg* 2017 Jan;124(1):127-135
- Capturing Essential Information to Achieve Safe Interoperability. Weininger S, Jaffe MB, Rausch T, Goldman JM, *Anesthesia and Analgesia* (published online.) DOI: 10.1213/ANE.0000000000001351. Published in *Anesth Analg* 2017 Jan;124(1):83-94

Anesthesia & Analgesia is a monthly peer-reviewed medical journal established in 1922 and covering anesthesia, pain management, and perioperative medicine. The journal has a 2015 impact factor of 3.827, ranking it fourth out of 31 journals in the category "Anesthesiology."

Regulatory Science, Aim 8: Submit the supplement to the pre-IDE document to the FDA, and provide new relevant information as needed and available.

Background on Regulatory Science aims:

Following months of planning that began prior to the implementation of this award and that included Dr. Goldman and members of our team as well as representatives from the FDA and the Continua Health Alliance, our co-sponsored FDA Workshop on Medical Device Interoperability was held in January 2010 at the FDA. More than 150 technical, clinical, and regulatory experts attended in person, including medical device manufacturers, IT and communications vendors, healthcare providers, researchers, consultants, and government experts from the FDA, NIH, VA, NSF, and NIST. Another 50-60 participated in the live web-cast of the workshop. The program consisted of plenary speakers to define the issues and set the context, use case presentations and discussions by a range of stakeholders, and breakout sessions to allow groups with similar interests to target important issues and to delve deeper into the problems and possible solutions.

This workshop was at that time the strongest action the FDA had taken to show its commitment to medical device interoperability. The heads of CDRH and the Office of Device Evaluation both spoke, 25 FDA staff were in attendance, and the workshop was considered an informative and educational event by all who attended. An important outcome of the workshop was the shared recognition that improved, interoperable product designs are the key to reducing adverse events (e.g. via automated safety interlocks) and enabling new clinical treatments that are greater than the sum of their components. Slides and streaming video of the workshop presentations are available at our MD PnP web site: http://www.mdnp.org/FDA_Workshop.html (videos are no longer on the FDA web site).

An important follow-up to this FDA workshop was the formation of a working group of 20 participants from industry, clinical care, standards development organizations, and regulatory agencies who met regularly for two-plus years to develop a detailed risk / regulatory model for an integrated "prototype" regulatory submission. This instantiated model – essentially a combination

of existing devices and virtual interoperability functionality for specific use cases – was intended to allow FDA and interoperability stakeholders to identify and address issues in the process for regulatory approval. This group handed off its work products to the FDA in the Spring of 2011, for further internal development at FDA, and continued to meet under Dr. Goldman’s leadership as the Medical Device Interoperability Safety Working Group (MDISWG). The MDISWG further developed these concepts and completed a pre-IDE document, submitted to the FDA in February 2012 and discussed in a face-to-face meeting with the FDA in April 2012. The MDISWG continued to refine the document. This activity was the basis of Aims 8 and 9 as redefined in 2015. (Note – The FDA renamed the Pre-IDE to “presubs” or “Q-subs”.)

The multi-institutional Medical Device Interoperability Safety Working Group (MDISWG), which Dr. Goldman co-chairs, submitted the Pre-IDE supplement to FDA in March 2014. MDISWG submitted an important follow-up Pre-IDE submission, which included (1) questions that could not be included in the Pre-IDE submission, (2) follow-up questions based on the final FDA response from the Pre-IDE meeting, and (3) deeper and expanded issues on medical device interoperability, partially based on ICE, partially based on the progress made by AAMI/UL JC2800 (i.e. use of conformity assessment standards), and partially based on the interoperability aims of this grant. The FDA response was received in early 2015, and the MDISWG held regular teleconferences during this period of performance to work on providing additional details to the FDA.

As part of our response to a White House Office of Science & Technology Policy request to explore medical-technology solutions for the Ebola epidemic, we reached out to FDA for their support. Our response focused on (1) remote operation of infusion pumps and ventilators used in a quarantine setting, with the aim of reducing the number of times caregivers need to enter the room, and (2) more effective sensor data acquisition and integration to improve surveillance. Dr. Jeffrey Shuren, director of FDA’s Center for Devices and Radiological Health, wrote a letter of support that said in part, “CDRH recognizes the importance of these efforts and is ready and willing to collaborate with you, the clinical community and your industry partners to demonstrate the potential of this technology in serving this particular public health emergency.”

This letter was instrumental in bringing together device manufacturers and enabled them to share technologies that they had not previously disclosed publicly out of concern that FDA would not permit remote operation of medical devices. This scenario is an example of the kind of leadership and liaison role the MD PnP Program is able to play as a result of our long-term collaboration with federal agencies like the FDA, and trusted relationships with manufacturers.

Regulatory Science, Revised Aim 9 (2015): Based on the successful second FDA pre-IDE submission, respond to the FDA’s request that we formulate use cases to convey the differences between pair-wise and component-wise interoperability.

After receiving the FDA response on the supplemental pre-IDE submission, we worked with the pre-IDE project team (MDISWG) in weekly teleconference meetings and with the FDA to release more complete “adoptable” information about the pre-IDE for interoperability. The FDA requested that we be precise in how the information is framed and released, and in particular that we formulate use cases to better convey the differences between pair-wise and component-wise interoperability. This use case work began in March 2015 and has been ongoing in through the remainder of this grant. We are committed to disseminating the information in the pre-IDE document via publications and other means. The pre-IDE supplement was posted on the MD PnP web site in May 2014 (http://mdpnp.org/MD_PnP_Program_MDISWG.html).

We are writing a manuscript intended for publication in the *Journal of the Regulatory Affairs Professionals Society*.

We have worked with the FDA/CDRH on implementing a Research Collaboration Agreement (RCA) on medical device interoperability. This MGH-FDA Public Private Partnership agreement will facilitate joint projects on interoperability and cybersecurity and sharing of regulatory science results, such as the Pre-IDE research. The five-year RCA was fully executed in 2015.

External Collaborations, Aim 10: Support and facilitate use of the MD PnP program artifacts and tools (including our Interoperability Lab/Test Bed) for interoperability R&D projects (including mobile applications and Visiting Scholars), “plug-fests”, and evolving clinical system integration activities.

In October 2014 the MD PnP Program hosted an open house to celebrate the 10-year anniversary of the MD PnP Interoperability Program and to demonstrate to the broad community our current progress in standards development and reference implementations thereof. More than 70 individuals representing over 25 academic, industry, and regulatory bodies were in attendance. The technical demonstrations were well-received and resulted in several new collaborations being established.

Also in October 2014, Dr. Goldman was contacted by the White House Office of Science & Technology Policy about upcoming robotics workshops focusing on Ebola patient care. He was asked to rapidly identify relevant medical technology-based solutions to the Ebola threat. We had been involved in an early stage of the NIST Global Cities Team Challenge (GCTC) evaluating improved monitoring and response for pandemics. We based the Ebola project on the GCTC scenario. Over a 20-day period in October-November 2014, the MD PnP Program convened via teleconference and face-to-face meetings, a group from government, academia, and industry to prototype innovative approaches to improve patient care and reduce the risk of healthcare workers’ exposure to Ebola. Using our Medical Device Interoperability Lab & Test Bed and the OpenICE platform for medical device and data integration, the participants rapidly prototyped technology solutions during a three-day November hackathon focused on two use cases:

- Quarantine: Sensor integration and data acquisition to improve Ebola screening, monitoring, and diagnosis in quarantine
- Hospital: 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 ventilator and infusion pump settings

In addition to the letter officially expressing their support (see **Aim 8** above), FDA/CDRH sent a representative to the hackathon to meet with collaborators, observe the demonstrations, and answer questions. The hackathon drew a considerable amount of press; links to articles and video about the work can be found at <http://mdpnp.org/ebola.html>. This work demonstrated how our team could respond quickly to the challenges of a national medical threat by providing leadership, convening, and interoperability resources such as subject matter expertise, a neutral technical convening environment, and OpenICE tooling.

Dr. Goldman discussed our project on interoperability solutions for Ebola safety and implications for healthcare transformation at a White House OSTP briefing that December. Dr. Goldman also presented the Ebola response project at the Global Cities Summit at NIST in Rockville, MD, in February 2015. This important work continued under the SmartAmerica Global City Teams Challenge (GCTC) banner.

In January 2015 Dr. Goldman met with senior leadership of Kaiser Permanente to discuss adoption of the Integrated Clinical Environment (ICE) concepts. Topics of discussion included ICE reference implementations, clinical and system requirements, feedback to SDOs to help

standards conform to ICE requirements, a forum to express clinical needs for ICE implementations, and test tools.

Dr. Goldman spoke at the February 2015 Medical Devices Summit in Boston, MA, about “Achieving Interoperability in Medical Device Technology to Support Innovation.” He addressed interoperability barriers and solutions, considerations for the medical internet of things to improve patient care, integration vs. interoperability, and the relationship between security and interoperability.

In February 2015 MD PnP Lead Engineer Dave Arney gave presentations and panels on safety, security, scalability, and other considerations for medical device interoperability at the NIST CPS TestBed workshop. Representatives from the MITRE Corporation visited the MD PnP Interoperability Lab to discuss a potential FDA medical device cybersecurity project in collaboration with MD PnP. Dr. Goldman and the MD PnP technical team led discussions related to the needs of the healthcare security space and the capabilities of ICE-compliant technologies to meet this need.

External Collaborations, Aim 11: Leverage our work to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House sponsored SmartAmerica NSF Challenge.

“SmartAmerica Round 2: Global City Teams Challenge” Expo was convened by Presidential Innovation Fellows in June 2015 in Washington DC. Dr. Goldman and Betty Levine (TATRC) presented a use case on “Remotely Caring for Our Most Vulnerable Citizens In-Place during a Pandemic.” This use case was formulated at the NIST GCTC kickoff meeting in September 2014, and featured automated detection, triage, and treatment of severe contagious disease outbreaks, with a focus on enabling remote support of local treatment. The Ebola-focused application became the central application of the more general GCTC use case as a result of the Ebola epidemic and the White House request in October 2014. At the GCTC Expo in DC, our extended team of collaborators demonstrated the Ebola responses from the hackathon, which led to some ongoing work with the vendors that were involved.

As we have in past years, the MD PnP Program provided demonstrations of our work at the annual HIMSS 2015 conference (Healthcare Information Management & Systems Society) held in Chicago, IL. Our demonstration (Automated Validation of Medical Device Data for EMRs) was part of the Office of the National Coordinator for Health Information Technology (ONC) section of the Interoperability Showcase. The demonstration (shown in Figure 2 below) included an OpenICE installation with a GE Dash patient monitor and an ICE Supervisor running several apps, as well as a DocBox ICE Implementation running a charting app. The OpenICE Validation App, running on the OpenICE Supervisor, was the focus of the demonstration.

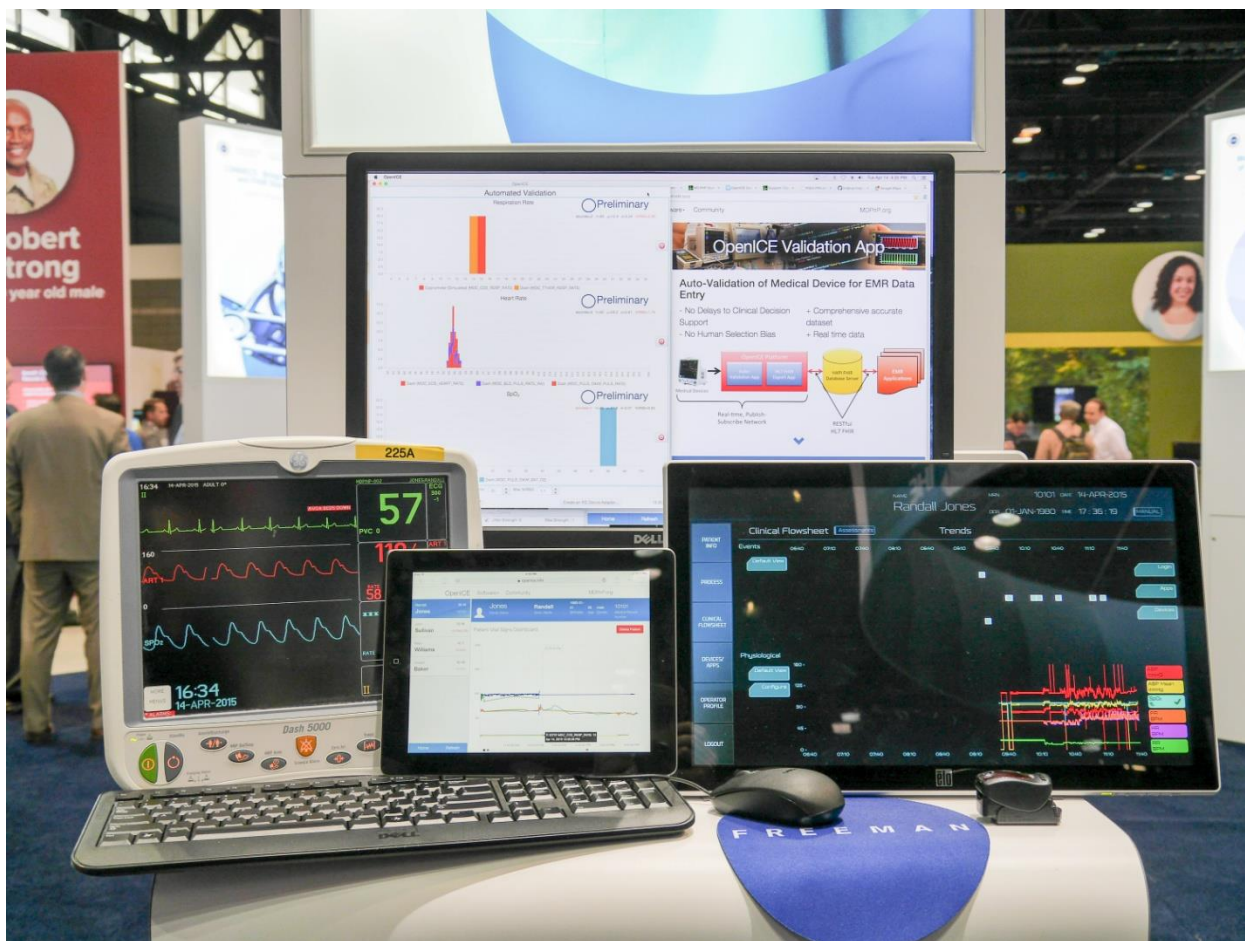


Fig 2. MD PnP Demonstration at HIMSS 2015 Conference

Background screen shows real-time analysis, vital sign monitor is connected to a physical vital signs simulator (not shown), OpenICE charting application is shown on tablet, and DocBox application is shown at bottom right receiving and charting data from the validation app

Patient data from medical devices like patient monitors must be validated before it is stored in electronic health record (EHR) systems. Currently, validation is a manual process, and is performed intermittently for a few vital signs. As more devices are connected, and as device interfaces begin to support communication of more information, many more vital signs will be able to be recorded. To address this problem, we created an automatic validation app that acquires the patient's vital signs and compares multiple sources to determine whether to categorize the data as either "preliminary" (i.e. the vital sign data does not appear to be correct) or "final," based on a user-specified standard deviation. We implemented connectivity to an EHR as an HL7 FHIR gateway from OpenICE. The monitor we used can measure heart rate from EKG, from the pulse oximeter, or from an invasive blood pressure line. If those sources all reported exactly the same heart rate, then the app would categorize them as "final." The vital sign data with the automated assessment was transmitted to an ICE-system-based charting application (developed by DocBox, Inc.) for display.

External Collaborations, Aim 12: Coordinate our work under this award with standards development activities and device-related academic and industry initiatives.

In 2015 the IEEE-ISTO (Industry Standards & Technology Organization) founded the non-profit ICE Alliance – an interoperability standards consortium – to promote ICE-based solutions for interoperability and cybersecurity, driven in part by the Ebola initiative. Several medical device and technology companies, medical societies, and healthcare delivery organizations contributed to found the Alliance. The members provided valuable input for ICE-based clinical and technology requirements and solutions. However, after careful consideration of the financial model, it was determined that sustaining the Alliance was not feasible. Despite the absence of the formal IEEE entity, the organizations that founded the Alliance remain engaged in the related activities.

Key Research Accomplishments

- **The ICE Standard ASTM F2761-09(13) and its emerging portfolio of related standards have been successfully transferred from ASTM to AAMI.** ASTM, an ANSI-recognized Standards Development Organization (SDO) sunsetted the committee that developed the ICE standard, requiring a transition to a new SDO. AAMI welcomed the ICE-related standards into the AAMI Interoperability Working Group for standards maintenance and the development of future component parts of the ICE standard portfolio.
- **ICE Data Logger proposed draft standard accepted as New Work Item Proposal by AAMI.** The ICE Data Logger proposed draft standard, which was drafted under Option Year 2, was modified by the AAMI Interoperability Working Group and submitted to AAMI to accompany the submission of the ICE Data Logger New Work Item Proposal (NWIP). The NWIP was submitted to the AAMI Standards Board and accepted. As a result of the NWIP, the Interoperability Working Group began formal development of the ICE forensic Data Logger standard.
- **Interoperability procurement language.** Our MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise) sample procurement language has been shared with many organizations. The most recent version of MD FIRE (2.6) is available on the MD PnP website (<http://mdpnp.org/mdfire.php>). The web page has had almost 30,000 visitors. The MD FIRE document text is being re-assessed by several organizations to add new requirements, especially related to cybersecurity. MD FIRE is also under consideration for inclusion in a National Academy of Medicine report on interoperability.
- **Clinical and Engineering Requirements for Safe Medical Device Interoperability.** Our Serena RM requirements management database has enabled us to collect generic ICE requirements and PCA Safety clinical requirements and associated attributes, along with collaborator comments. Using Serena RM, we have presented requirements to AAMI/UL JC2800 to establish the scope of the exemplar used for AAMI/UL JC2800, based on our design documentation (requirements and hazard identification), and Serena RM has attracted considerable interest in the standards community as a facilitating tool for standards development based on requirements. MD PnP research is thus able to demonstrate a pathway of “crowd sourcing” requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation.
- **Clinical and Engineering Requirements for Safe Medical Device Interoperability.** Requirements for safe medical device interoperability and for data logging have been shared with the AAMI/UL Joint Committee 2800 on interoperability and with the IEC committee developing an updated standard for Pulse Oximeters. A Healthcare Task Group (co-chaired by Dr. Goldman) and a Connected Care Test Bed initiative have been formed within the Industrial Internet Consortium (IIC). Plans are in place to host the

Testbed in the MD PnP Lab to provide a community forum to disseminate interoperability research findings that are applicable to products being developed for the Medical Internet of Things.

- **Interoperability and Security Requirements for Medical Device Procurement.** Security requirements based on the new UL 2900 standard, as well as the NIST security framework, are under review for inclusion in the next version of the MD FIRE procurement document for interoperable medical devices. MD PnP program interoperability research findings and subject matter expertise are being shared with the Veterans Administration to inform the VA/UL medical device cybersecurity CRADA.
- **Regulatory Science for Safe Medical Device Interoperability.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept of platform-based interoperability – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Following the January 2010 three-day workshop on medical device interoperability that was planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA (http://mdpnp.org/FDA_Workshop.html), a working group of companies, standards organizations, clinical and legal participants, and the FDA met weekly to work on the development of a prototype regulatory submission of an interoperable medical device system. The Medical Device Interoperability Safety Working Group (MDISWG) completed and submitted to FDA a pre-IDE document, followed by a supplement based on FDA response, in 2012-13. An additional supplement was submitted in 2014 and has been made publicly available on the MD PnP program's web site (http://mdpnp.org/MD_PnP_Program_MDISWG.html). This work has advanced regulatory science, thereby facilitating industry regulatory submissions related to interoperable systems.
- **Regulatory Science for Safe Medical Device Interoperability.** The FDA Pre-submission (formerly “pre-IDE”) on medical device interoperability, led by the MD PnP program, has informed the FDA in support of their interoperability guidance document (<https://www.federalregister.gov/documents/2017/09/06/2017-18815/design-considerations-and-premarket-submission-recommendations-for-interoperable-medical-devices>), which was released in September 2017.
- **Two peer-reviewed papers were published on the relationship between interoperability and patient safety.** These papers detailed the need to understand the system level performance aspects of interoperable systems, the value of basing technical requirements on clinical scenarios, and the importance of using this information to develop safe and usable standards.
- The expanded **Clinical Scenario Repository (CSR)** research pilot demonstrated the value of eliciting clinician user-needs with a self-guiding tool, and using the data as system engineering inputs for interoperable systems.

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 and cybersecurity.

Key Outcomes

Noteworthy Presentations on Medical Device Interoperability Topics:

Over the course of this award, Dr. Goldman delivered a great many invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency; the most noteworthy were to the following groups:

- July 2010 keynote address at INCOSE annual meeting, Chicago, IL
- August 2010 at the Veterans Administration Joint Interoperability Ventures meeting, Washington DC
- September 2010 keynote address and regulatory panel at Second Annual Medical Device Connectivity Conference & Exhibition, San Diego, CA
- October 2010 at Veterans Health Administration Biomedical Engineers national meeting, San Diego, CA
- January 2011 at kick-off meeting of VA Medical Device Interoperability Program (MDIP) Stakeholder Council (webinar)
- June 2011 to VA "Medical Device Interoperability Program" (MDIP) Stakeholder Council
- September 2011 keynote address at Third Annual Medical Device Connectivity Conference, Boston, MA
- November 2011 at OSEL (Office of Science & Engineering Lab) science seminar, FDA, Silver Spring, MD
- December 2011 at mHealth Summit, Washington, DC
- March 2012 at AAMI/FDA International Conference on Medical Device Standards and Regulation, Washington, DC
- September 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 2012 – Lectures and panel presentation at FDA AAMI Interoperability Summit, Washington, DC
- October 2012 – Presentation at NSF Time Workshop, Baltimore, MD
- November 2012 – Keynote and closing panel at Medical Device Connectivity Conference, Boston, MA
- November 2012 – Panel at Wireless Connectivity in Medical Devices Conference, Boston, MA

- December 2012 – Panel moderator at FCC mHealth Summit, Washington, DC
- February 2013 – Panel at Advancing Science, Serving Society Annual Meeting, Boston, MA
- March 2013 – Lecture and Technology Demonstrations at HIMSS Conference, New Orleans, LA
- March 2013 – Keynote at IBM systems engineering symposium, Waltham, MA
- May 2013 – Grand Rounds lecture on interoperability at Tufts Medical Center, Boston MA
- May 2013 – Grand rounds lecture on interoperability at Geisinger Health System, Danville, PA
- July 2013 – Lecture at meeting of Food and Drug Administration Safety Innovation Act (FDASIA) Regulations Subgroup, Washington, DC
- September 2013 – Keynote, “Integrity of Medical Device Interoperability” at AHIMA Health Information Integrity Summit, Alexandria, VA
- October 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 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 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 2013 – Presentation of Virtual Hospital CPS Testbed Proposal at White House SmartAmerica CPS Testbed Challenge, Washington, DC
- January 2014 – Panel, “Interoperability: A Cornerstone of Systems Integration” at Society of Critical Care Medicine Annual Congress, San Francisco, CA
- January 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 2014 – Technology Demonstration, “Real-Time Blue Button™ for Patients & Families” in the ONC/FHA area of the HIMSS’14 Interoperability Showcase, Orlando, FL
- February 2014 – Lecture, “Safe Interoperability: What are the Challenges?” in the HIMSS’14 Interoperability Showcase Theater, Orlando, FL
- April 2014 – Lecture, “Enabling Innovation Through Medical Device Interoperability: from architecture to analytics” at the Children’s Hospital of Philadelphia
- April 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 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 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 2014 – Lecture and technology demonstrations, “Closed-Loop Healthcare: From Home to Hospital to Home” at White House SmartAmerica Expo, Washington, DC
- July 2014 – Congressional briefing on Medical Device Inoperability and Safe Medical Integration, Washington, DC

- July 2014 – MD PnP Lab Open House with technology demonstrations
- August 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 2014 – “Interoperability,” Panel at Military Health Smart Monitoring 2014, Ft Lauderdale, FL
- August 2014 – “Web-Based Clinical Scenario Repository™ (CSR™), Military Health System Research Symposium (MHSRS), Ft Lauderdale, FL
- September 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 2014 – “Remotely Caring for Our Most Vulnerable Citizens In-Place During A Pandemic,” Global Cities Challenge: SMART America II, Washington, DC
- October 2014 – “MD PnP Program Updates” at University of Pennsylvania PRECISE Center, Philadelphia, PA
- October 2014 – “Medical Device Interoperability,” Congressional Staff Briefing, Washington, DC
- October 2014 – MD PnP Research Demonstrations at Lab Open House, Cambridge MA
- November 2014 – “Open Medical Device and Data Integration Platforms to support the management of Ebola,” presentations to press and lab visitors, Cambridge MA
- November 2014 – “A Systems Oriented Approach to Optimize the Performance of Clinical Alarms,” keynote address at Clinical Alarms Safety Symposium, Washington, DC
- November 2014 – Grand Rounds at San Diego Naval Hospital, San Diego, CA
- December 2014 – “Technology Advancements in the Intelligent Medical Home: From the Leaders Perspective,” keynote and panel at mHealth Symposium, Washington DC
- December 2014 – “Open Medical Device and Data Integration Platforms to support the management of Ebola,” White House briefing, Washington, DC
- December 2014 – “Overview of MGH MD PnP Program / MD PnP,” Georgetown University Visiting Scholars presentations, Massachusetts General Hospital, Cambridge, MA
- January 2015 – “Integrated Healthcare Platforms to Enable Safety, Security, and Interoperability,” Indian Institute of Technology, Chennai, India
- February 2015 – “Achieving Interoperability in Medical Device Technology to Support Innovation” / Panelist Medical Devices Summit, Boston, MA
- February 2015 – “Medical Device and Data Integration Platforms to Support the Management of Ebola,” NIST Testbed Workshop, Rockville, MD
- February 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 2015 – “Medical Device Interoperability Roadmap” lecture at Interoperability Advisory Group meeting, Washington DC
- March 2015 – Keynote and panel at Object Management Group Conference, Washington DC
- March 2015 – “Open Sourced Technology Advancements in Medical IIC,” invited lecture at Industrial Internet Consortium meeting, Washington DC
- March 2015 – “Medical Device Interoperability” / Grand Rounds Hershey Medical Center, Hershey PA
- April 2015 – “Auto-Validation of Medical Device for EMR Data Entry,” presentations and demonstrations at HIMSS15, Chicago, IL

- April 2015 – “Technology Advancements in Medical Interoperability,” UL Health Sciences Council, Chicago, IL
- June 2015 – “Auto-Validation of Medical Device for EMR Data Entry,” presentations and demonstrations at AAMI Expo, Denver, CO
- June 2015 – “Innovations in Standards for Interoperability,” presentation and panel at AAMI Standards week, Denver, CO
- August 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 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 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 2015 – Presentation at Cybersecurity for Healthcare and Medical Devices conference, Minneapolis, MN
- March 2016 – Presentation at HIMSS Conference, “Advancing Health Equity through Precision Medicine and HIT Innovation,” Las Vegas, NV
- April 2016 – Presentation at AAMI OR Systems Engineering Conference, Washington, DC
- May 2016 – Invited Speaker for Grand Rounds, “The Medical Internet of Things,” Tufts Medical Center, Boston, MA
- June 2016 – Keynote Lecture, “Implementing the Medical Internet of Things (MIoT) to Enable Healthcare Transformations,” Council of Engineering Systems Universities (CESUN), Washington DC
- August 2016 – Invited Speaker, “Integrating Medical Devices – Better Clinical Decisions – Efficient & Controlled Patient Care,” MHSRS, Ft Lauderdale, FL
- August 2016 – MD PnP Poster Presentation at IEEE EMBS Annual Conference, Orlando, FL
- September 2016 – JPC-1 Medical Simulation & Information Sciences Internal Project Review, Ft Detrick, MD
- October 2016 – DoD/VA Industry Interoperability Roundtable: Interoperability Opportunities
- October 2016 – American Society of Anesthesiologists Annual Meeting, Chicago, IL. Clinical requirements processes were shared with the ASA Committee on Patient Safety and the Committee on Electronic Media and Information Technology.
- October 2016 – Wireless Health Conference, held at the NIH (Dr. Goldman was General Co-chair)
- December 2016 – Chaired AAMI IOWG and participated in associated committee meetings at AAMI Standards Meeting week, Orlando, FL
- March 2017 – Dr. Goldman chaired the IEC/ISO JWG5 Physiologic Closed-Loop Control Systems standard meeting, Arlington, VA. MD PnP research findings on safe interoperability and system integration informed a number of key technical discussions.
- April 2017 – DoD/VA Interagency Program Office and members of VA-UL Medical Device Cybersecurity CRADA team participated in all-day meeting with our MD PnP team at our Lab and offices in Cambridge, MA
- May 2017 – Dr. Goldman chaired the ISO TC 121 international standards meeting for anesthetic and respiratory equipment in Boston. Over 105 delegates from 19 countries participated. Many discussions were held related to medical device interoperability, safety, and security.

Presentations by MD PnP Team:

- April 2011 – Talk by David Arney at the MD PnP / High Confidence Medical Device Software & Systems workshop at the NSF Cyber Physical Systems conference, Chicago, IL
- July 2011 – Talk by David Arney at Adverse Event Analysis Workshop at the International Conference on Biomedical Ontology, Buffalo, NY
- April 2012 – Poster presentation on “Device Time, Data Logging, and Virtual Medical Devices” by David Arney at the “Design of Medical Devices” conference organized by the University of Minnesota, Minneapolis, MN
- December 2013 – Technology demonstration at FCC mHealth Innovation Expo by David Arney and Jeff Plourde, Washington, DC
- April 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 2014 – “Design Pillars for Medical Cyber-Physical System Middleware” by David Arney and Jeff Plourde at Medical CPS Workshop, Berlin, Germany
- April 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 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 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 2014 – “Open Sourced Interoperability,” by Jeff Peterson, Northeastern Healthcare Technology Symposium, Groton, CT
- December 2014 – “Open Source Interoperability: A Technical Review of OpenICE and DDS,” by Jeff Peterson, Georgetown University MD PnP Visiting Scholars presentations, Cambridge, MA
- February 2015 – “Open Source Interoperability – Intro to OpenICE,” by Jeff Peterson, Educational Webinar session, Innovators Showcase: Three Clinical Engineers Leading the Way, Cambridge, MA
- February 2015 – “Healthcare IoT: The Impact in the Hospital,” by David Arney, MIT Connected Things Forum, Cambridge, MA
- March 2015 – “Requirements Management for Open Source Interoperability” by Harshal Sawant at the Serena Conference, Washington DC
- June 2015 – “Auto-Validation of Medical Device for EMR Data Entry” presentations and demonstrations by David Arney and Jeff Peterson at AAMI Expo, Denver, CO
- October 2015 – “Software Implementation of Controllers: Hardware considerations for sensors and actuators” by David Arney at FDA PCLC workshop, Silver Spring, MD
- October 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
- February 2016 – “Medical Device Interoperability and Cybersecurity” by David Arney at Cybersecurity Workshop, Medical Devices Summit, Boston, MA
- March 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:

- Our MD PnP program web site (original site www.mdnp.org, new site <http://mdnp.mgh.harvard.edu/>) is maintained as a major communication vehicle for the program and all major programmatic initiatives, including MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop. The OpenICE project information and downloads of shared documents and code are located at www.openice.info.

Personnel:

- Julian M. Goldman, MD, PI
- Susan Whitehead, Program Manager (2009-2014)
- David Arney, Lead Engineer
- Jeff Plourde, Senior Software Engineer
- Rick Schrenker, Senior Biomedical Engineer
- Diego Alonso, Application Developer
- Pratyusha Mattegunta, Clinical Engineer
- Jeff Peterson, Clinical Engineer
- Harshal Sawant, Biomedical Engineer
- Ken Auerbach, Database Engineer
- Diana Lu, Program Manager (2015-2016)
- Michael Feinberg, Senior Software Engineer
- Dylan Bagshaw, Biomedical Engineer
- Drayton Freeman, Project Administrator

Manuscripts/Publications:

- 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.
- 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*.
- 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.
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our work with Intel on network and computer infrastructure design and operations to support interoperability

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- 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):

- NIST 70NANB10H258 – 2010-2013
- NSF Subcontract, CNS-10-35715, to University of Pennsylvania – 2010-2016
- DoD W81XWH-12-C-0154 – 2012-2016
- NSF Subcontract, IIS-1239242, to University of Massachusetts – 2012-2016
3-Year CPS collaborative research award for \$500,000 Total
- DoD W81XWH-15-C-0064 – 2015-2016
- DoD W81XWH-16-C-0175, Subcontract to Real-Time Innovations – 2016-2018
- NIH/NIBIB Subcontract to President and Fellows of Harvard – 2016-2019
- DoD JPC-JW160063 – 2017-2021
- Homeland Security HSHQDC-17-R-00030 – 2017-2019

Conclusions

The research activities enabled by this award have had a broad impact in enabling the achievement of interoperable medical device and health IT systems that can support improvements in the safety and security of healthcare delivery. This award supported diverse research initiatives and the leadership that is essential to bridge a complex socio-technical ecosystem of device manufacturers, regulators, healthcare delivery organizations, standards developers, engineers, and governmental agencies. In contrast to traditional research funding that is restricted to siloed initiatives, or to industry-led initiatives that are often constrained to near-term competitive outcomes, this funding was directed broadly to identify synergistic needs across the stakeholder community, perform foundational research, and enable sharing of pre-competitive information to support advancements in standards, regulations, and technology, thereby enabling much-needed innovation in healthcare systems technology.

As detailed in the report, there has been substantial progress in all of these areas over the period of performance. However, there is more work still to be done to realize the vision of interoperable devices that enable fully integrated clinical environments. And as important as these needs were in the past, the clinical and operational risks due to poorly integrated and insecure devices have become more profound as cyber-attacks proliferate and the need to accelerate the development of automated and autonomous medical systems to support prolonged care and related applications gains awareness. Therefore, it would be valuable for the groundwork that has been laid under this project to be continued.

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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.

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All relevant documents are referenced or linked from within the text of the report.