

The Medical Device Plug-and-Play Interoperability Program (MD PnP)



MD PnP
Getting connected for patient safety™

www.MDPnP.org

About this document

The Medical Device “Plug-and-Play” (MD PnP) interoperability program was established in 2004 by Julian M. Goldman, MD, an anesthesiologist at the Massachusetts General Hospital (MGH) who practices in the Operating Room of the Future (ORF) and also serves as a clinical advisor to the MGH Biomedical Engineering Department. The medical device integration requirements of the ORF exposed the barriers caused by the absence of interoperability standards. Dr. Goldman took the lead in seeking “plug-and-play” standardization for medical device connectivity and launched this multi-institutional program.

This document provides information about the MD PnP program’s goals and methodologies, and is based on material presented at the October 2006 Annual Meeting of the American Society of Anesthesiologists (ASA) in Chicago. Dr. Goldman moderated and presented at a two-hour session on Medical Device Interoperability that was sponsored by the ASA EMIT Committee (Electronic Media & Information Technology), and we had a Scientific Exhibit that included a series of posters and a demonstration of the potential clinical benefits of medical device interoperability.

More information on the MD PnP program can be found on our web site: www.mdnp.org. Your input and participation are welcome!



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MD PnP Program Overview

Medical devices are essential to the practice of modern medicine. Physiologic measurements like blood pressure and temperature, x-ray and ultrasound imaging, administration of intravenous medications, and support of critical life functions are all routine procedures that use medical devices. However, unlike the connected “plug-and-play” world of modern networked computers and consumer electronics, most medical devices are designed to operate independently, do not employ open networking standards for data communication or for device integration and control, and are difficult to bring together into interoperable (inter-connected) systems. Networked medical device systems will support the widespread clinical use of medical device data and enable medical device integration to produce complete and accurate electronic health records, improve workflow, reduce medical errors, and reduce healthcare costs.

The MD PnP program was established to lead the evaluation and adoption of a standards-based ecosystem for networked medical devices to support clinical solutions. Led by Julian M. Goldman, MD, the program is affiliated with Massachusetts General Hospital and the Center for Integration of Medicine and Innovative Technology (CIMIT), and also receives support from the U.S. Army’s Telemedicine & Advanced Technology Research Center (TATRC) and from Partners HealthCare Information Systems. Three two-day plenary sessions, many working group meetings, and clinical focus groups have elicited input from a geographically dispersed, multi-disciplinary group of stakeholders to articulate the issues and to identify clinical requirements for interoperability. These stakeholders include clinicians, biomedical engineers and clinical engineers, integrated healthcare delivery systems (IHDNs), regulatory agencies, and medical device manufacturers and vendors. More than 500 clinical experts and representatives of more than 65 institutions have participated.

The MD PnP program continues to elicit clinical scenarios from clinicians and engineers, and has developed a methodology to analyze clinical scenarios to derive engineering requirements. To support this activity, the MD PnP Lab opened in May 2006 to provide a vendor-neutral “sandbox” to evaluate the ability of candidate interoperability standards to meet clinical requirements, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and conformance testing.

Overview (continued)

The Scope of Effective Medical Device Interoperability:

There are two distinct – but closely related – requirements for interoperable medical device systems:

1. **Data communication** capability will support complete and accurate data acquisition by the EMR from vital signs monitors, infusion pumps, ventilators, portable imaging systems, and other hospital and home-based medical devices. Comprehensive data acquisition will also enable the development of remote monitoring, advanced clinical decision support systems, intelligent alarms, robust databases for quality assurance, and remote patient management to support healthcare efficiency and safety (e.g. “e-ICU”).
2. **Medical device control** capability will permit the integration of distributed medical devices to produce “error-resistant” systems with safety interlocks between medical devices to decrease “use errors”, and closed-loop systems to regulate the delivery of medication and fluids.

Goals of the MD PnP Program:

1. Guide the development and adoption of open standards to support medical device interoperability. The adoption of safe and effective networked medical device systems requires an ecosystem of ancillary devices and functions. An ecosystem standard, called the Integrated Clinical Environment Manager (ICEMan), is under development and will address:
 - Privacy/security/audit trail – to assure confidentiality and reliability of data
 - Authorization/digital certificates – to prevent non-conforming devices from affecting the network
 - Clinical/business rules and rule engine – to run clinical algorithm scripts (sometimes called a “context manager”)
 - “Black-box” recording – of network traffic and other data to support forensic analysis and to detect/prevent system problems
2. Define a safe “least-burdensome” regulatory pathway for any proposed system in partnership with regulatory agencies (e.g. FDA).
3. Elicit high-level user requirements for proposed interoperable systems to improve safety and efficiency.
4. Use the MD PnP vendor-neutral laboratory “sandbox” that opened in May 2006 to:
 - Evaluate ability of candidate interoperability standards to meet clinical requirements
 - Model clinical use cases (in a simulation environment)
 - Develop and test related network safety and security systems, especially to enhance the understanding of the technical issues at the intersection of Biomedical Engineering and Information Systems
 - Support interoperability and conformance testing
 - Serve as an international resource for the medical device interoperability community

Overview (continued)

How Individuals and Organizations Can Participate:

- *Clinicians* can contribute clinical scenarios to ensure that new standards and solutions solve real clinical problems.
- *Engineers* can analyze clinical use cases to generate functional specifications.
- Health care delivery systems can require adherence to medical device interoperability language in vendor contracts, thereby supporting the adoption of interoperable systems.
- *Regulatory agencies* can create new paradigms for verification and validation for networked medical devices.
- *Medical device vendors* can propose interoperability solutions, contribute devices and engineering support to the MD PnP program, provide financial support to accelerate the program's success, and adopt the standards that emerge.
- *Standards development organizations* can revise existing standards to meet MD PnP ecosystem requirements, and shepherd new standards through the adoption process.

Adoption of medical device interoperability will support:

- Clinical decision support systems
- Medical device safety interlocks
- Physiological closed-loop control of medication, fluid delivery, and ventilation
- Monitoring of device activity and performance
- Automated system readiness assessment (prior to starting invasive clinical procedures)
- Support of "e-ICU" implementations
- Safeguarding of protected patient information through real-time encryption
- "Plug-and-play" modularity to support "hot swapping" of "best of breed" devices
- Facilitation of disaster preparedness: real-time inventory of hospital equipment in-use and national stockpiles, and rapid deployment of devices in makeshift emergency care settings
- Avoidance of unnecessary redundancy by using shared resources
- Reduction of the cost and implementation barriers to technology dependent innovation

The Scientific Exhibit

Our Scientific Exhibit at the 2006 Meeting of the American Society of Anesthesiologists (ASA) was the result of a multi-institutional effort that is typical of the collaborative approach at the heart of this program. (Contributors are listed on page 23.) The exhibit included a series of posters and a demonstration of the potential benefit of medical device interoperability, and it attracted more than 400 ASA visitors in the two-and-a-half days. The posters conveyed the essence of the program, framed the current effort with previous work on device interoperability and data from a Kaiser Permanente study of its potential benefit, and described our requirements methodology of taking clinical scenarios and turning them into engineering requirements.



MD PnP program exhibit at the 2006 American Society of Anesthesiologists Meeting in Chicago – October 2006 – x-ray/ventilator demo on right

Medical Device Plug-and-Play (MD PnP) Program

WHAT WE ARE

Medical Device Plug-and-Play (MD PnP) is a multi-disciplinary, multi-institutional program committed to promoting the adoption of medical device connectivity standards in support of improving patient safety and healthcare efficiency. Networked medical device systems will support the widespread clinical use of medical device data and will enable device and data integration as well as decision support, to produce complete and accurate electronic medical records, reduce medical errors, and reduce healthcare costs.

WHO WE ARE

A geographically-dispersed and diverse group of stakeholders who want to improve patient safety and healthcare efficiency through innovation enabled by medical device connectivity:

- Clinicians
- Biomedical Engineers and Clinical Engineers
- Healthcare Delivery Systems
- Regulatory Agencies
- Medical Device Manufacturers and Vendors
- Standards Development Organizations

WHAT WE ARE DOING

The MD PnP program is leading the evaluation and adoption of a standards-based ecosystem for networked medical devices to support clinical solutions for improving patient safety and healthcare efficiency. We are eliciting clinical requirements from clinicians, creating use case scenarios, and implementing a vendor-neutral “sandbox” laboratory for testing devices against potential standards.

HOW YOU CAN PARTICIPATE

- Clinicians can contribute clinical scenarios to ensure that new standards and solutions solve real clinical problems.
- Engineers can analyze clinical use cases to generate functional specifications.
- Healthcare delivery systems can require adherence to medical device interoperability language in vendor contracts.
- Regulatory agencies can create new paradigms for verification and validation for networked medical devices.
- Medical device manufacturers can contribute devices and engineering support to the MD PnP Program, provide financial support to accelerate the program’s success, and adopt the standards that emerge.
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Brief History of Medical Device Interoperability Activities

Medical Information Bus (“MIB”) 1982-1984

- First well-known effort to develop medical device-specific communication standard and supporting hardware.
- Focused on intravenous infusion devices and RS-232 hardware.
- Not adopted by medical device manufacturers due to low clinical demand, complexity, and proprietary hardware requirements.
- Main institutional proponents were
 - > LDS Hospital (Salt Lake City, UT; ongoing)
 - Started using standard 1073 hardware in 1998
 - > Mayo Clinic (Rochester, MN; abandoned)
 - > MGH (Boston, MA)

IEEE 1073 (1991-present)

- Family of standards formed to build on MIB concepts.
 - > Technically, non-standardized MIB focused on “lower layers” of the networking stack.
 - > IEEE 1073 initiated efforts to standardize and improve “lower layers” while adding work on “upper layers” (referring to a 7 layer ISO communication model).
 - “Black boxes” to convert RS-232 to new standard hardware and protocols.
 - > While officially designated 1073, the historical but imprecise MIB moniker persists.
- ISO 11073: Transition of 1073 to an ISO (international) standard, mainly due to broader European involvement and government requirements.
 - > Reflects further harmonization with ISO/CEN standards.
 - > Work continues in IEEE 1073 committees, then “elevated” for international ISO approval as 11073.
- Recently, work continues on 11073 and has accelerated.
 - > Early lower layers have been superseded, new “lower layer” transports have been defined, and new proposals are under consideration.
 - > Clinical input regarding ICU interoperability needs was strong, but limited in other areas.
- Still no motivating Supply-Demand Market
 - > Adoption and promotion of 11073 by medical device manufacturers has been slow.
 - > User knowledge and demand are almost nonexistent.
- (For further information: see www.ieee1073.org)

History (continued)

HL7 (Health Layer 7)

- HL7 is a standards development organization that is best known for standards that are used to communicate patient data between clinical information systems at the application level, the “top layer” of the 7 layer ISO model. (see www.HL7.org)
- Lacking device connectivity
 - > Never intended for Point-of-Care devices and monitors
 - > To fill that need, IEEE 1073 meetings have been scheduled concurrently for cooperation since 1999.

ASA 1994 Scientific Exhibit

- An automatic anesthesia record keeper (Bicker and Gage, SUNY Stony Brook)
 - > Standard device interfaces (unique, medical device only cable connector)
 - > Manufacturer independence
- Live demonstration of Plug-and-Play
 - > An “Aha!” experience for a few hundred viewers.

Medical Device Plug-and-Play Program (MD PnP)

The MD PnP program is a multi-disciplinary, multi-institutional program started in early 2004 (initially as ORF PnP for “OR of the Future” plug-and-play) to support the development and adoption of clinically grounded solutions for medical device interoperability. Clinical scenarios are being elicited from clinicians and clinical engineers to identify settings in which patient safety and healthcare efficiency could be improved by seamlessly integrating medical devices. MD PnP connectivity will support both comprehensive data acquisition by the EMR and safety interlocks to reduce errors. The MD PnP lab opened in May 2006 to evaluate technical solutions to clinical scenarios. (see www.mdnpn.org)

ICEMan

The MD PnP program has defined functional elements of an “ecosystem” to support the safe implementation of medical device integration. The proposed ICEMan (Integrated Clinical Environment Manager) standard includes requirements for “black box” recording of data, security and authentication, and a “plug-and-play” architecture.

IHE

The Integrating the Healthcare Enterprise initiative (IHE) has been defining data transmission requirements to support clinical and enterprise workflow. IHE identifies existing standards, but does not create new standards. In 2005, IHE started work on point-of-care devices to EMR connectivity. Initial work is concentrating on transfer of patient ID and physiological data (not including waveforms). (see www.ihe.net)

Kaiser Permanente's Analysis of Implementing Integrated Systems

PURPOSE

- Analyze the current state of medical device integration.
- Quantify the potential benefits on efficiency, patient safety, quality of care.
- Assess the potential savings of adopting interoperability standards.

BACKGROUND

- Kaiser Permanente is the nation's largest non-profit HMO
- 8.4 million members, in 9 states and the District of Columbia
- 30 Hospitals, 431 outpatient clinics
- 300,000 pieces of medical equipment
- Multi-billion dollar network-wide electronic medical record (EMR) system

METHODS

- Examined the national medical device inventory (300,000+ devices)
- Excluded laboratory and imaging equipment (except ultrasound)
- Classified each device into ECRI device categories
- Analyzed each category initially for the clinical need for interoperability (e.g. Do you need to connect a cast saw to the network?)
- Evaluated each category which had quantifiable data for the following:
 - Number of devices
 - Model and manufacturer variations
 - Type of data I/O
 - Storage capabilities
 - Real time capabilities
 - Current communication methods
 - Hardware and software requirements
 - Built-in safety features
 - HIPAA concerns and safeguards
 - Connectivity requirements (e.g. EMR)
 - Projected volume increase – based on changing population and acuity
 - Relationship of connectivity to quality of care and patient safety
 - Conformance to interoperability standards
 - Timing and syncing requirements
 - Impact on patient safety
 - Safety interlock and closed loop control ("smart system") requirements
- The following areas were evaluated:
 - Impact on quality of care
 - Impact on implementation costs
 - Impact on infrastructure and facility design

The Kaiser Story (pg. 2 of 3)

RESULTS

- 36 Medical device types were identified to have potential interoperability requirements.
- Over \$100M annually is projected for updating devices and infrastructure to achieve EMR connectivity over the next 10 years.

IMPACT OF INTEROPERABILITY ON EFFICIENCY, PATIENT SAFETY, AND QUALITY OF CARE

- On an average patient visit to an outpatient clinic, the staff spends five minutes obtaining patient information and five minutes transcribing this information. Eliminating the transcription time through interoperability will save five minutes per patient of clinical time.
- A physician spends five minutes reviewing this information. With the implementation of interoperability, a saving of two minutes per patient could be achieved.
- In the inpatient setting, this device/EMR automatic charting and analysis of vital signs and related procedure information is expected to save 50% of support staff's charting time and 20% of practitioner charting time.
- By eliminating transcription and reading errors, more accurate data will be recorded to the EMR.
- Data can be accessed almost instantly throughout the healthcare enterprise.
- Interoperability will enable enhanced decision support capabilities.

CONCLUSIONS AND NOTES

The results of this study are being combined with a facility and infrastructure study to determine the requirements to implement interoperable systems.

Medical device and EMR integration is necessary for improved efficiency, patient safety, and improved quality of care.

The cost to integrate medical devices is currently ~40% of the cost of the devices, or ~\$40M annually over 10 years.

Utilizing a device communication standard will reduce implementation costs by up to 30%, or ~\$12M annually.

The Kaiser Story (pg. 3 of 3)

IMPACT OF ANALYSIS

Contract language has now been stipulated in equipment purchasing contracts to state:

“Medical Device Plug and Play. Supplier agrees to participate with [Kaiser] in the development of a medical device plug and play integration standard (the ‘Integration Standard’), and where, in Supplier's sole judgment, it determines participation to be commercially, legally, practically, and otherwise viable, will make reasonable efforts to conform to the Integration Standard when approved and formulated by the parties in writing. Until the Integration Standard is approved and formulated by the parties in writing, Supplier intends to continue, in its sole judgment and so long as it continues to be commercially, legally, practically, and otherwise viable, to provide open interfacing protocols to enable third parties and end users to access data from its Products, as defined in the Agreement ...

*“As part of the acceptance testing process, and once there is an agreed Integration Standard between Supplier and the [Kaiser] Customers for the testing, **Supplier must demonstrate this successful interoperability of the Products with the EMR system and must have such interoperability tested and verified at either the [MD PnP Lab at the] Center for Integration of Medicine and Innovative Technology (CIMIT) and/or Kaiser's Sidney Garfield Center. Supplier may use an independent lab for the testing, only with the prior approval of the [Kaiser] Customers.**”*

Kaiser is currently exploring ways to actively integrate legacy systems via a similar method.

Kaiser is dedicating resources to participation in standards based work and interoperability.

The table showing the analysis details for selected individual devices can be viewed in the pdf file of the poster on the MD PnP web site: www.mdnpnp.org

From Clinical Needs to Innovative Solutions

A method to transform clinical needs into systems engineering requirements in order to improve efficiency, patient safety, and the quality of care.

CLINICAL SCENARIO

Description of the current clinical situation and related problems identified from clinical stories, adverse event reports, etc.

Includes proposed workflow/technology enhancement to prevent unwanted outcomes.

Value statement (impact on patient safety, quality of care, or the cause of adverse events).



CLINICAL WORKFLOW

A paragraph or diagram describing the sequential events that occur during a specific patient/clinician interaction including:

- Human interactions with equipment and each other
- Equipment used
- Supplies used
- Movement of clinicians and patients through clinical environment
- Sequential timeline of events



TECHNICAL SOLUTION AND CLINICAL IMPLEMENTATION

A device or system which improves the quality, safety, efficiency, of a clinical scenario.



STATE DIAGRAM (PRE-CODE)

A methodological approach utilized by programmers and engineers to script the behavior of a system in all possible states. This is utilized for technical development and analysis of a system.

Adverse event reports
Clinical experiences
Clinical and engineering focus groups



USE CASES

Use cases are a detailed look at a specific part of the clinical workflow. A work flow may not be required for a use case, but is helpful for examining human interaction.

Textual Use Case

- Clinical alarms required
- Proposed process or technological improvement
- Event sources of required data and sources of potential error
- Proposed solution to correct the problem statement and enhanced alarm requirements
- Description of the required data to solve the problem
- Required feedback to the clinician

Graphical Use Case

- Graphical layout of the textual use case
- Diagram of new process
- Clarifies input and output of data between related systems
- Shows interdependencies between devices/systems
- Focuses on systems interactions (states) vs clinical work flow



LOGIC MAP

Breakdown of each step of graphical use case in order to analyze and define behavior of the system.

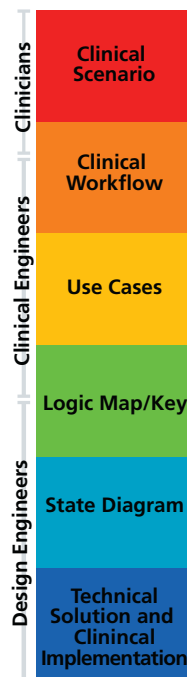
- Provide accurate and detailed data
- List of variables for each graphical step and the expected interactions (logic map variable key) including units, range, data type, system output, input, and derived variables.
- Form of data (discrete, waveform, setting)
- Failure analysis done at each location
- Terminology defined utilizing standard terms
- Graphical pre-code of technological enhancement



From Clinical Needs to Innovative Solutions

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Adverse event reports
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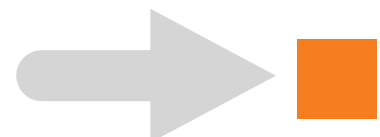


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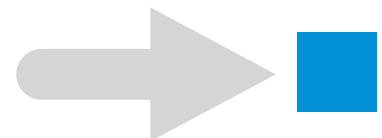
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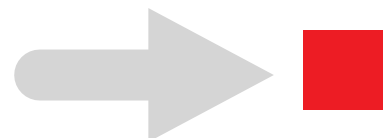
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TECHNICAL SOLUTION AND CLINICAL IMPLEMENTATION

A device or system which improves the quality, safety, efficiency, of a clinical scenario.

further iteration



Examples of Clinical Scenarios that Would Benefit from Interoperability

The Medical Device Plug and Play (MD PnP) program has been acquiring clinical scenarios related to interoperability. Additional scenarios can be contributed by emailing to clinical@mdpnp.org

We ask clinicians: *"Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by medical device interoperability?"*

CLINICAL SCENARIOS

Example 1

Current Clinical Experience:

"A 32-year-old woman had a laparoscopic cholecystectomy [gall bladder removal] performed under general anesthesia. At the surgeon's request, a plane film x-ray was shot during a cholangiogram. The anesthesiologist stopped the ventilator for the film [to prevent movement of the diaphragm and blurring of the image]. The x-ray technician was unable to remove the film because of its position beneath the table. The anesthesiologist attempted to help her, but found it difficult because the gears on the table had jammed. Finally, the x-ray was removed, and the surgical procedure recommenced. At some point, the anesthesiologist glanced at the EKG and noticed severe bradycardia. He realized he had never restarted the ventilator. This patient ultimately expired."

(APSF Newsletter, Winter 2004)

Proposed Clinical Scenario with technology/workflow enhancement to prevent unwanted outcome:

A 32-year-old woman had a laparoscopic cholecystectomy performed under general anesthesia. At the surgeon's request, an x-ray was shot. *The x-ray and anesthesia machine ventilator are synchronized so that the x-ray is taken at the desired phase of ventilation, such as end-inspiration or end-expiration. When the technician pushes the exposure button, the image is taken at a synchronized point triggered by the respiratory waveform. If necessary, the ventilator is instructed to supply a brief breath-hold.* The technician was unable to remove the film because of its position beneath the table. The anesthesiologist attempted to help. *The ventilator was not stopped for the x-ray, so the patient was never in danger from hypoventilation.* Finally, the film was removed, and the surgical procedure recommenced.