

# ASA Exhibit Collaborators

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PARTNERS HEALTHCARE SYSTEM  
INFORMATION SYSTEMS

CIMIT: CENTER FOR INTEGRATION OF  
MEDICINE AND INNOVATIVE  
TECHNOLOGY

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Over 500 experts (clinicians and clinical engineers)  
and representatives of more than 65 institutions  
have participated in the MD PnP program.



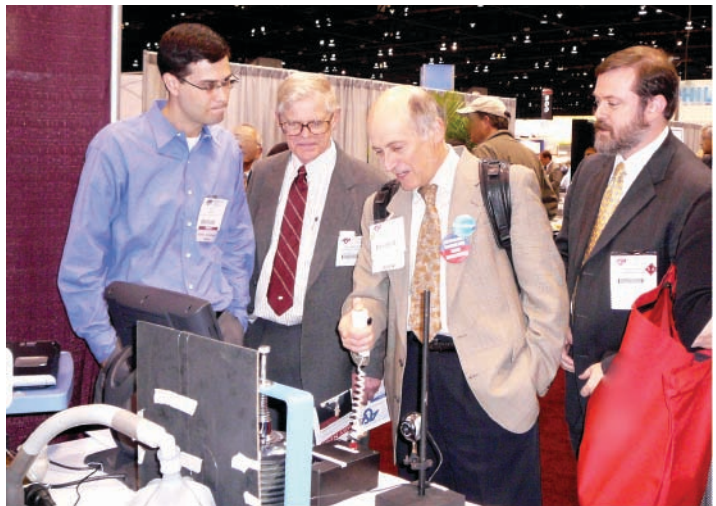
GEISINGER

# Use Case Demonstration: X-Ray/Ventilator

The clinical message we presented illustrated that morbidity and mortality can be reduced by connecting medical devices into “plug-and-play” networks (as is done every day with computers, printers, and the internet). Patients are still at risk because clinicians turn off the anesthesia ventilator for an x-ray and may forget to turn it back on afterwards. Using a case study reported by the Anesthesia Patient Safety Foundation in 2004, we demonstrated a system in which automatic synchronization of the x-ray exposure with ventilation obviates the need to turn off the ventilator to obtain an x-ray. This was accomplished by triggering the x-ray (simulated with a web camera) with the respiratory flow signal.

Draeger Medical supplied an Apollo anesthesia ventilator and a training “lung” that was used to simulate the patient’s lung for purposes of the x-ray. Users interacted with a touch screen that allowed them to select the phase of respiration at which the x-ray was to be taken, and then held the button down on the x-ray control until the x-ray (camera) flashed. The resulting picture of the “lung” then appeared on the screen, with a measure showing that the x-ray matched the selected phase of respiration.

This demo was an example of a connected – but not interoperable – system that had to be custom integrated and programmed in the MD PnP Lab. It demonstrates the types of safety improvements that could be widely implemented if manufacturers adopt medical device interoperability standards. (The ventilator / x-ray synchronization idea is an old one, for which we take no credit. The fact that the idea has been around for years but still cannot be clinically implemented underscores the need to solve this problem.) The demo’s emphasis on



improving patient safety through device interoperability resonated with the visitors to the booth, who included sales and engineering staff from many of the device vendors who had commercial exhibits at the conference, as well as anesthesiologists, biomedical engineers, and other clinicians.

# The Interoperability Session

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The session on **Medical Device Interoperability for Improving Safety and Efficiency**, chaired by Julian M. Goldman, was held at the 2006 meeting of the ASA, attracted some 60 attendees. This session provided an overview of recent national activities in this area, and addressed the clinical and regulatory implications. Speakers included:

**Keith J. Ruskin**, MD, Chair, ASA Committee on Electronic Media & IT (EMIT), who talked about the new EMIT focus on interoperability.

**Jeffrey B. Cooper**, PhD, Executive Vice President, Anesthesia Patient Safety Foundation, who addressed the question “Can interoperability support improvements in patient safety?”

**William G. Horton**, MD, ASA Lansdale [Congressional] Public Policy Fellow, who gave a perspective on “What Interoperability means for anesthesiologists: a view from The Hill”

**Donald E. Martin**, MD, Chair, ASA Committee on Technology & Facilities, who spoke on “What drives the adoption of new technology?”

**Sandy Weininger**, PhD, Senior Engineer, U.S. Food & Drug Administration, Office of Science & Engineering Laboratories, who described an approach to “Using interoperability to support clinical requirements”

**Julian M. Goldman**, MD, Session Chair, President, Society for Technology in Anesthesia, who talked about “Recent advances in achieving interoperability: the MD PnP Program”

Following the talks, there were a number of questions from the audience, many of which were addressed to Dr. Weininger.

The net effect of the Scientific Exhibit and the Interoperability session was to generate awareness of the clinical importance of adopting interoperability solutions, and to garner increased interest among organizations that have been only peripherally involved in the MD PnP program in the past and several device vendors who have not previously participated in our plenary meetings or discussions. Being able to show a successful demo of an important clinical scenario proved invaluable in conveying the concept of device interoperability, as well as showing the success of our multi-institutional collaborative efforts.

## Medical Device Connectivity for Improving Safety and Efficiency

*Julian M. Goldman, M.D.*

*Committee on Electronic Media and Information Technology*

***"Use wireless technologies to eliminate the 'malignant spaghetti' of cable clutter that interferes with patient care, creates hazards for the clinical staff and delays positioning and transport."***

***"Synchronize the respiratory cycle of the anesthesia machine ventilator with portable X-ray exposure so that an X-ray will be triggered at end-expiration, thus avoiding the need to turn-off the ventilator for an intraoperative cholangiogram."***

***"Trigger the portable X-ray at end-inspiration by synchronizing with the ICU ventilator."***

***"Why can't a pulse oximeter be connected to a PCA infusion and automatically interrupt the infusion and activate an alarm when a patient is hypoxemic?"***

***"Support the recording of infusion pump data in the electronic anesthesia information system and permit control of the infusion rate at the anesthesia machine."***

These are only a few examples of clinical scenarios provided by anesthesiologists to articulate their vision of improvements in clinical care that could be achieved by interconnecting medical devices.<sup>1</sup> The barriers to medical device connectivity (or "interoperability") are well known to those anesthesiologists and clinical engineers who have tried to install anesthesia information management systems (AIMS) or to interconnect devices and computers for clinical research. In contrast to the ubiquitous USB memory devices that support effortless connectivity on all brands and types of modern computers, or the Internet browser programs and Web sites that enable secure banking over the Internet, we have not implemented equivalent secure, ubiquitous connectivity technology to support vendor-neutral medical device networks. As a result, the cost and complexity of seamless connectivity is interfering with widespread deployment of AIMS, remote monitoring, use of comprehensive (laboratory + monitor) data to develop clinical decision support systems and smart alarms.

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The importance of interoperability to support improvements in health care has been underscored by the establishment of the position of the National Health Information Technology (HIT) Coordinator on April 27, 2004, to provide leadership for the “development and nationwide implementation of an interoperable health information technology infrastructure to improve the quality and efficiency of health care.”<sup>2</sup>

The vision includes developing “a nationwide interoperable health information technology infrastructure that:

- “2a. Ensures that appropriate information to guide medical decisions is available at the time and place of care;
- 2b. Improves health care quality, reduces medical errors and advances the delivery of appropriate evidence-based medical care;
- 2c. Reduces health care costs resulting from inefficiency, medical errors, inappropriate care and incomplete information; and
- 2d. Promotes a more effective marketplace, greater competition and increased choice through the wider availability of accurate information on health care costs, quality and outcomes.”

Similarly the 2005 Institute of Medicine Report, Building a Better Delivery System: A New Engineering /Health Care Partnership, emphasizes the need for a National Health Information Infrastructure “to support the information-driven practice of contemporary medicine. This infrastructure would consist of standards for connectivity, system interoperability, data content and exchange, applications and laws.”<sup>3</sup>

The absence of effective medical device connectivity has been due in part to an absence of implemented open standards, the lack of financial incentives for device manufacturers to provide systems to support vendor-independent connectivity, legal and regulatory concerns and unclear clinical specifications — or “clinical requirements” — for the proposed systems.

The national HIT agenda includes making the interoperability of electronic health care records (EHR) a reality, but we are concerned that EHRs will be neither complete nor accurate until the inclusion of medical device data is automated.

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There are two distinct, and closely related, facets of medical device interoperability:

- Data communication standards will support accurate data acquisition by the EHR from monitors, infusion pumps, ventilators, portable imaging systems and other hospital and home-based medical devices. Reliable data will support complete and accurate EHRs and robust databases for continued quality improvement use.
- Medical device control standards will permit the control of medical devices to produce “error-resistant” systems with safety interlocks between medical devices to decrease use errors, closed-loop systems to regulate the delivery of medication and fluids and remote patient management to support health care efficiency and safety (e.g., remote intensive care unit, management of infected/contaminated casualties).

The Medical Device Plug-and-Play (MD PnP) program was initiated in May 2004 at the Center for Integration of Medicine and Innovative Technology, or CIMIT, and Massachusetts General Hospital to identify and implement connectivity standards while ensuring that they remain clinically grounded <[www.mdnp.org](http://www.mdnp.org)>.<sup>4,5</sup> The program has convened diverse stakeholders (clinicians, the Food and Drug Administration, manufacturers, biomedical and clinical engineers, clinical societies and others) to develop a roadmap for open-standards-based, vendor-neutral medical device interoperability. The early identification of the importance of basing interoperability solutions on clinical requirements led us to begin compiling the unique body of clinical requirements represented in the examples above. The clinical requirements were elicited from clinicians and engineers who were asked to provide examples of connectivity that could a) solve current clinical problems, b) improve safety or efficiency or c) enable innovative clinical systems of the future. A major goal is to identify potential solutions to perceived shortcomings of current clinical practice or ideas for future innovations that require improved interoperability for implementation. The MD PnP Lab, scheduled to open in the second quarter of 2006, provides a vendor-neutral environment in which to evaluate the feasibility of implementing some of these clinical scenarios, including evaluating connectivity products and standards as they are developed. The Lab thus provides the protected environment that will enable latent opportunities for improving patient safety to be explored and realized.

We will hold an open session at the ASA 2006 Annual Meeting in Chicago to gather your clinical requirements for inclusion in the master requirements list, which will guide national solutions. Feel free to get started now by sending your ideas to us at <[asa@mdnp.org](mailto:asa@mdnp.org)> or posting your ideas and initiating discussion on the discussion area of <[www.mdnp.org](http://www.mdnp.org)> (free registration required to post information).

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