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## Plug-and-Play in the Operating Room of the Future

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**H**ow safe would a car be if key components, such as the brakes and cruise control, didn't work together? Can you imagine flying in an airplane that wouldn't provide a warning if the landing gear didn't deploy? Would you buy a new computer that would not allow you to upgrade the mouse, keyboard, or other peripheral components? Would your new "USB memory stick" be useful if it only worked with one brand of computer? The kinds of interoperable plug-and-play control and communication systems that we take for granted in automobiles and consumer electronics are lacking in operating rooms (OR) today.

Although intraoperative patient safety has improved significantly, the OR is still a complex and potentially hazardous environment where clinicians depend on teamwork and a patchwork of systems to mitigate hazards instead of using automated safety systems. Surprisingly, smart alarms and automated decision support tools are still absent from the clinical environment. Clinical engineers and clinicians have proposed innovative technical solutions to mitigate clinical hazards, but they cannot affordably implement novel solutions when real-time medical device data acquisition or control is required. Partly as a result of the lack of medical device interoperability, many self-evident improvements have been precluded, and safety

and economic benefits have not been realized.

Interoperability is not a new word to the health care industry. Just type “medical device interoperability” in the search field of an Internet search engine and watch the pages of hyperlinks that appear. Practitioners have commented on the need for medical device interoperability and have produced a wealth of guidance in the literature. The industry responded by providing products that sit on their proprietary architectures, and if you dig deep enough, you will find a few consultants or small technology firms that provide the products to tie it all together. The process of designing a wholly integrated system is still very fragmented for several reasons. For example:

- The diverse clinical groups have complex needs for knowledge-based decision support systems, automated record keeping and reporting, and for freely communicating devices that display a predefined set of parameters, given (1) the patient's history, (2) the protocol, and (3) the clinician's preference.
- The manufacturers recognize this opportunity and initially wanted to own as many pieces of this value chain as possible. Some will admit that they cannot successfully deliver the entire health care information and control system, but the limitations of corporate culture and the legacy of proprietary architecture keep development to a snail's pace.
- As of press time, the authors were not aware of a bottomless well of money or time to support the research and design needs for each institution to

create and support a system to meet their specific needs.

In an attempt to start addressing these issues, the program on Plug-and-Play (PnP) Interoperability of Medical Devices for the Operating Room of the Future provides the clinical and technical communities with an opportunity to finally take all of the pieces and put them together (see figure on page 195). The term “PnP” was adopted because the required technology infrastructure has many elements in common with the PnP approach used in other computer systems. First steps for the ORF PnP program include bringing the diverse stakeholders together in a series of forums, identifying the user needs and priorities, and building upon existing frameworks to develop the ORF PnP standard. A historical overview of medical device connectivity efforts clearly demonstrates the need for such a standard and provides the foundation for the ORF PnP project.

### Medical Device Connectivity History

As early as 1986, there were presentations at the AAMI Annual Meeting on microcomputer applications and maintenance. The potential to apply the new technology to point-of-care health care was quickly recognized, and early work commenced on IEEE 1073, which came to be known as the “Medical Information Bus” (MIB). Citations can be found on the web for some of this health care work going back to at least 1988.

### Why a Standard?

The demand, as present in 1988 as today, is to get data

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*John Petrozza, MD, performing surgery with a KTP laser in the ORF.*

from the instruments at the bedside into the bedside chart and the myriad of clinical information systems. The development of device interfaces is a known art that has long been reduced to practice. So why does the medical device community require its own standard?

By explicitly establishing attributes and behaviors for an interface, a medical device communications standard informs device and systems designers as to what they can expect of its features and performance. Where in the stack are errors trapped and how are they communicated? How are varying degrees of device complexity managed? How is remote control managed? What about alarms? Where standards are not present as guidance, the odds are small that independently working designers will address these and other design concerns in a similar fashion. The risk of creating a “Tower of Babel” is obvious; perhaps less so is the loss of potential value-add incurred by spending design cycles on developing interfaces rather than applications that improve patient care and/or safety.

Reportedly, there was initially great interest among a relatively large group of clinicians, as well as manufacturers, in getting a standard developed. But by the late 1980s, detailed focus on technical issues had

choked off clinical interest and soon thereafter manufacturer interest began to wane.

During the early 1990s, the defense industry spin-off LinkTech expressed interest in adapting its specialized communications products for the military to needs it perceived in the medical market. Review of the IEEE 1073 Web site shows meeting minutes going back to 1994 citing work involving LinkTech as well as members of the medical device and clinical engineering communities.

Coincident with the acceleration in device connectivity development was increased standards-related activity focused on hospital information systems. In 1996, Hewlett Packard formed the “Andover Working Group,” a consortium focused on extending the work of Health Level 7 (HL7) by defining the content, structure, and communications infrastructure for specific messages. This group soon allied with 1073 to form a Special Interest Group for Medical Information Bus (MIB) within HL7. And in 1997, the first hospital adoption of 1073 was reported at McKay-Dee (Ogden, UT).

However, the lower layers were single solution, single sourced. The buzz was that they were too expensive for a medical device. In 1998, members of the 1073 General Committee developed a document describing the motivation for developing and adopting alternative lower layers. That same year, LinkTech closed its doors.

Remaining Andover Working Group members persevered and went on to develop new lower layers, demonstrating an implementation in February 1999 involving an infusion pump, patient monitor, and clinical information system workstation. That same day they announced the formation of a group intended to support the definition of new lower layers, forums for multi-vendor demonstrations, and participation in national and international standards organizations.

Since then, a core set of standards has been developed. Efforts directed at involvement and harmonization with standards groups resulted in establishment of connections with the European Committee for Standardization (CEN), International Organization for Standardization (ISO), Healthcare Informatics Standards Board (HISB), National Committee on Vital and Health Statistics (NCVHS), National Institute of Standards and Technology (NIST), and Healthcare Information & Management

CAPABILITY	SAFETY	EFFICIENCY
Ubiquitous data acquisition and presentation	✓	✓
Decrease technology deployment barriers		✓
Enable safety interlocks	✓	
Extend connectivity of health care environment	✓	✓
Enable decision support	✓	✓
Enable adaptive alarms, closed loop control, sensor networks	✓	✓
Hot-swappable networked medical devices	✓	✓

**Table 1.** Necessary attributes of an ORF PnP system.  
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Systems Society (HIMSS). 1073 now also identifies itself as “x73,” reflecting its connection to CEN, where 1073 is known as 11073. CEN and IEEE are sharing the standards development workload, effectively increasing the rate at which standards can be developed. Through HISB, x73 has become even more connected to the full set of U.S. informatics groups. In 2002, NCVHS included x73 with standards such as DICOM and HL7 in its recommendations to the U.S. Secretary of Health and Human Services regarding patient medical records information. And NIST has started collaborating with x73 to develop conformance tests.

### The ORF PnP Project—Vision, Scope, Timeline, Achievements to Date

Against this background, one of the authors (Goldman) launched the ORF PnP initiative as an offshoot of the Operating Room of the Future at Massachusetts General Hospital (see article titled “Inside the OR of the Future” in this issue). Tapping into interest from the ORF clinicians and the U.S. Army Telemedicine & Advanced Technology Research Center (TATRC) at the Department of Defense, Dr. Goldman worked with the Center for Integration of Medicine and Innovative Technology (CIMIT) to plan a forum for bringing together the diverse group of stakeholders to explore their interest in achieving a standard for interoperability of medical devices in the OR. The result was a unique

symposium that was held in May 2004 at CIMIT in Cambridge, MA.

The May kick-off symposium, jointly sponsored by TATRC and CIMIT, met its objective of convening for the first time a diverse group of stakeholders (84 attendees) that included clinical users (Kaiser Permanente, Partners Healthcare, and others), biomedical engineers, medical device manufacturers and other companies, federal regulatory staff, and standards experts. FDA announced its commitment to the PnP process, opening the door for dialogue about new paradigms for regulatory evaluation and validation. There was a broad consensus among the participants to launch a PnP initiative and a strong commitment to participate, moving the perception of PnP standards development from stagnant to inevitable.

The core team created a vehicle for communication through an ORF PnP Web site and online open forums for discussion. Four areas were identified for development within working groups:

- WG1 clinical requirements
- WG2 legal/regulatory
- WG3 communication architecture
- WG4 user interface requirements

Working Group leaders are experts recruited from among the May participants. The distribution list for information about the PnP initiative was expanded as a result of contacts developed through the May attendees. The FDA offered to host a second PnP meeting so that regulatory issues could be more thoroughly explored with increased FDA participation.

The two-day November meeting at FDA moved the ORF PnP standardization effort to the next level by broadening the base of participation, assessing the regulatory framework via open interchange with FDA staff, and beginning the process of defining clinical requirements and user interface requirements. The 75 attendees, many of whom were new participants, included representatives of 22 companies, Kaiser Permanente, clinicians, 10 FDA staff (three speakers), and staff from TATRC, the National Science Foundation, and NIST, broadening the interest from federal agencies. FDA and TATRC affirmed their continuing commitment to the ORF PnP process, and there was ongoing strong support from Kaiser Permanente and industry. The initial exploratory work on defining clinical requirements clarified how extensive the requirements effort will be. Standards



*Some of the device-specific interface cables required to deploy the commercial electronic anesthesia medical record (EMR) system in use at the Massachusetts General Hospital. (Photo inspired by W. Driscoll.)*

experts identified related standards already in process (e.g. IEEE 1073) that are relevant to ORF PnP, setting the stage for future collaboration.

The level of interest and commitment expressed to date by the stakeholders affirms that the time is right for proceeding with the definition of requirements and eventually with the development of a bus-independent consensus standard for ORF device interoperability. In January, the first of several planned focus group sessions on clinical requirements for PnP in the OR was held at the Society for Technology in Anesthesia (STA) meeting. The 50 session attendees enthusiastically contributed pages of ideas related to requirements for PnP and obstacles to achieving it, and the Society affirmed an ongoing commitment to the project.

### Upcoming Plans

Similar sessions to gather clinical requirements are planned for surgeons (at the Society of American Gastrointestinal and Endoscopic Surgeons annual meeting in April 2005) and nursing staff in the next several months, as well as at the AAMI annual conference in May 2005. We are capturing and refining this process from one session to the next. The ORF PnP program was presented at the HIMSS annual meeting in February, and efforts are underway to collaborate with the HIMSS initiative on Integrating the Healthcare Enterprise (IHE) and with the Office of the National Coordinator for Health Information Technology, headed by Dr. David Brailer.

### The Need for Clinical Engineering

At AAMI 2005 in Tampa, FL, the health care technology management community will have the opportunity to participate in one of these forums, representing several stakeholders in this process. In the health care setting, the project leader, the operational manager, the technical educator, and the risk manager all have a unique perspective and can provide the input necessary to define what the “ideal” system should look like and how it should behave.

Those acting as the local project leader for medical technology can provide input about how to bring this new PnP technology into the health care setting. For example, in new construction or new replacements, how is the PnP framework incorporated with a new system install?

The operational manager can comment on what should be required for regular maintenance and repair. How should the system react if a single device needs to be removed for repair? Should the system send a notification to alert the designated person about the failure? For specific systems, are there certain errors that you want to know about before a real failure occurs? Can you define those errors or give examples?

Whether the training is scheduled or on the spot, there is a need to effectively demonstrate and teach how to use a specific device or system. Two contributions that the technical educator can make are a review of the user interfaces that are best designed to minimize the learning curve and a description of the feedback that will be useful for improving an on-site training program.

### URLs of Cited Activities and Agencies

[www.orfpnp.org](http://www.orfpnp.org)  
[www.cimit.org/orfuture.html](http://www.cimit.org/orfuture.html)  
[www.ncvhs.hhs.gov](http://www.ncvhs.hhs.gov)  
[www.nist.gov](http://www.nist.gov)  
[www.himss.org/](http://www.himss.org/)  
[www.ieee1073.org](http://www.ieee1073.org)  
[www.cenorm.be/cenorm.index.htm](http://www.cenorm.be/cenorm.index.htm)  
[www.iso.org](http://www.iso.org)  
[www.aami.org](http://www.aami.org)  
 HISB: [www.ansi.org/standards\\_activities/standards\\_boards\\_panels/hisb/overview.aspx?menuid=3](http://www.ansi.org/standards_activities/standards_boards_panels/hisb/overview.aspx?menuid=3)



*Minimally invasive surgery is aided by monitor placement in the MGH/CIMIT OR of the Future.*

The risk manager must evaluate systems for patient and clinician safety controls; with interoperability, one needs to understand how one integrated device's failure will affect the entire system. When incidents need to be investigated, the system or device can supply some information or tools, but those features still need to be designed. Will a simple event log listing all time-stamped button presses and transmitted messages suffice? Or does the investigator need a more visual playback? And what are the implications for operating a set of devices in a coordinated fashion during a code?

Each member in the health care technology management matrix has an experience or an idea that can be shared, and these ideas are highly sought after. Contributions from these valuable stakeholders—the project leader, the operational manager, the technical educator, and the risk manager—can make a tremendous impact on the final definition of the ORF PnP standard. This model provides a forum not only to influence by contributing, but also to be influenced by the contributions of allied professionals.

### The Time is Now

While earlier efforts at moving toward interoperability of medical devices were indicative of the clinical interest at the time, they sank in a morass of detail and proprietary interest—in some ways, a matter of “too little, too soon.” Today we are seeing a convergence of


many factors that are key to success—improved technology, more open-sourcing, technically savvy clinicians, and a willingness on the part of regulatory authorities to consider new validation paradigms. Manufacturers who are involved in the PnP program are clearly saying that what they need to move forward is an understanding of the demand for interoperability and of the clinical user requirements and functional specs for how it will work in practice. There is a huge interest in developing use cases that can lead to the identification and development of standards. We believe we have a reasonable and realistic way to respond to that request, and we need your help.

The opportunity for clinical engineers, biomedical engineers, operational managers, risk managers, and others in our community to be heard is at hand. Participating in the definition of requirements will enable all of us to be part of the solution when it comes. And there is little doubt that it is coming. ■

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