Inside the Operating Room of the Future

An Inside Look into General Hospital / Partners HealthCare/ CIMIT's Medical Device Plug-and-Play Interoperability Lab

We at the **Software Design for Medical Devices** are very excited to invite you to join us for an in-depth tour of *Massachusetts General Hospital / Partners HealthCare/ CIMIT's state-of-the-art, Medical Device Plug-and-Play Interoperability Lab on* **Monday, January 22** in Cambridge, MA. A true pioneer in the industry, experience first hand how the MD PnP Interoperability Lab is making interoperability the foundation of next generation patient care.

In anticipation of the site tour, we sat down with **Julian M. Goldman, MD., Director and Founder of the MD PnP Program** to learn more about their facility, what projects they're currently working on and how the adoption of open standards and interoperable technologies have the potential to dramatically improve patient care.

According to the MD PNP Blog, the MD PnP lab just recently moved to a new location. How's the new space working out and, for those who may not be familiar with your work, what exactly will you be studying in this lab?

Yes, after spending 11 years in our old lab, we just moved to a new space this past July. Our new lab is a 4 suite, 32,000 SQFT space in a research building that is part of Mass General Hospital and Partners Healthcare System. In our research lab we have expensive, advanced networking infrastructure that enables us to serves as a "test bed" for integrated clinical environments. We have 4 labs in operation that focus on:

- Medical device interoperability
- Cybersecurity
- Medical device integration to connect devices and send data into the electronic health record
- Electronics

Our new, state of the art facility boasts a highly reconfigurable network environment and over a million dollars worth of medical devices that we can connect or reconfigure depending on the project. Because of the way our infrastructure is set up, we have the ability to emulate unique hospital network environments. Hospitals often have a lot of constraints when it comes to how the network is configured and system requirements for medical devices often vary from hospital to hospital. Though manufacturers are certainly experts when it comes to their own devices, *what we do is help them find out how their equipment performs as part of an ecosystem made up of multiple systems and devices.*

Simply put, we're a nexus of clinicians, clinical engineers, computer scientists, hospital operations and IS Operation experts who work closely with medical device manufacturers, standards organizations, software companies and other collaborators *to evaluate interoperability, plan future products that are interoperable and conceptualize the medical internet of things as the next generation of devices.*

Can you give us a little background about the MD PnP Medical Device Interoperability Program? How did you guys get started?

Back in the early 2000's my colleagues and I worked on a major clinical innovation and adoption project at Mass General Hospital called the "Operating Room of the Future." During this time, we developed a wonderful advanced operating room facility where we were able to demonstrate innovative technologies which are typically very hard to pilot in a hospital due to the complexity of the environment and the priority of patient safety and patient comfort above all.

Though the OR of the Future helped us to create reachable deploy technology, we had a lot of great ideas that we weren't able to implement due to a lack of interoperability. Companies would bring new technologies or clinicians and engineers would have great ideas for how we could improve patient safety, and improve workflow, and improve efficiency but they were simply too complex and too expensive to implement in that environment.

For example, it took six months and over a hundred thousand dollars of engineering development to connect an iPod to the network setting so surgeons could play music in the OR. Of course, playing music in an OR is not an essential need but it just shows how integrating something as trivial as an iPod can still be very difficult. And, as you can imagine, changing mission critical clinical technology is even more complicated and expensive. So, basically, because OR systems in general were not designed to be easily reconfigurable, there many things we wanted to implement to improve patient safety during surgery, after surgery, during recovery but couldn't because the technology ecosystem wouldn't permit it
That was a big part of the impetus for the OR for the Plug and Play program, or as we started, MDP&P for Medical Device Plug and Play.

We officially started in 2004 and opened our first lab in 2006 where we have been working

ever since on core capabilities - use cases, technology deployment and software development – under, primarily, federal funding from the NIH, DOD, NSF and NIST. Over the past 12 years and, we've built a lab that allows us and collaborators to implement use cases in which better interoperability or integrated clinical environments can improve patient safety, the quality of care delivery and support innovation. So that's what we do in our lab – we build apps, we demonstrate prototypes, we implement use cases to improve patient care.

What would you say is your core mission? What drives your work?

In a nutshell, our work has been driven by the clinical need to improve patient safety and clinical care. It hasn't been driven by the focus on implementing specific technologies - a better widget, a better gadget or a specific device –it's about changing the healthcare technology ecosystem so that devices can work together and be part of the ecosystem more effectively to take care of patients.

In addition, all of us know there are brilliant clinicians, brilliant nurses and brilliant engineers all over the world. They become renowned for what they do and their great ideas on how to improve patient care. However, usually these ideas only last as long as they do and you often have to go to their hospital to be treated because great thinkers have no way to share their knowledge to the extent it can be easily duplicated. In this day and age, we should be able to transfer that knowledge and apply those great ideas to take care of patients anywhere just by duplicating the workflow, the tools to duplicate the workflow, and the technology environment.

It's well documented that over 400 thousand patients each year die in the US due to preventable medical errors in hospitals. It's the third leading cause of death. It's after heart disease and cancer in terms of cause of death. It's something between 200 and 400 thousand patients a year. And you have to work really hard to convince me that improved technology and better technology ecosystems around every patient could not reduce that number from 400 thousand, down to a much, much lower number- that we couldn't have a ten-fold reduction in death.

That's the big picture of what drives this for us. This is a means to transform the way we approach healthcare delivery. In our lab, we bring together different sensors and actuators, both medical and non-medical, and have the ability to write apps that allow us to essentially aggregate the knowledge of leading-edge clinicians into on, easily accessible place and, just like we do with an iPhone or other smartphones, enable other doctors, nurses, etc. to instantiate that knowledge at the patient's bedside thereby improving care and democratizing access to healthcare knowledge.

What are some examples of projects you've worked on in the past? Furthermore, what types of projects are you working on now that our attendees can expect to see in action?

To give you a better idea of some of the work we do, in our lab we've demonstrated how apps can improve patient safety by stopping pain medication - such as morphine - when the app detects a drop in the patient's respiratory rate or oxygen levels. We've demonstrated the effectiveness of the open ice platform – which we built and is an open-source software platform for open, integrated clinical environment. We've demonstrated data application as well as how an app can detect when a patient is in cardiac arrest and automatically categorize the problem and display the treatment information directly to the physician at the bedside thereby minimizing the delay both in detecting and identifying the information required to treat the patient.

The reason we do the implementation and demonstration, is so that we could determine: What are the requirements? What are the engineering requirements, the system requirements, the interoperability requirements, cybersecurity requirements? What is really needed in an ecosystem like this? We then take that information and the things we learn and share that with standards development organizations, federal agencies such as the FDA and with medical device manufacturers.

A couple of year's ago we were asked to work on a medical technology response for Ebola. So we brought together 20 organizations in 20 days and the people from the manufacturers all came together, collaborated and, within those 20 days, showed how we could remotely control medical devices to treat Ebola patients. Using the technology we developed, we can remotely control the ventilator, the infusion pump and more effectively monitor people who have been exposed to Ebola. Considering it takes clinicians upwards of 20 minutes to put on all of the protective gear required when treating a patient with Ebola, not only do these remotely controlled devices reduce the risk of exposure, they also significantly increase the speed of treatment.

Earlier this month we started a four year, 6 million dollar contract with the Department of Defense to work on interoperability and cybersecurity of ICE platforms- for interoperable medical devices. We've worked with the DOD for a couple of years now and one of the projects we finished this past year was to help them learn how to deploy these advanced technology platforms to take better care of injured soldiers- injured war fighters. For example, we used Open Ice to demonstrate how to improve the monitoring of overheated soldiers. We've shown that we can build smarter apps capable of monitoring heat stroke patients and identifying when someone is beginning to get worse.

So definitely, our focus extends beyond the OR and applies to anywhere you may have sick patients who need a higher level of care. For example. patients at home on ventilators, dialysis, suffering from all sorts of very serious illnesses would benefit from integrated clinical environments with apps that help support their healthcare.

So that's an example of some of the kind of work we've done also. So convening and facilitating and leading in response to public need. As for why we are unique, well I've been told repeatedly we're the only lab in the world doing this.

What are three things that you hope attendees take away from their visit? Is there anything you're especially excited about showing them or discussing?

First of all, I want people to see for themselves that the medical community is hungry for better, more integrated technology to improve patient care. And that we are tired of seeing one off solutions that are not extendable, they are not future-proof, they are not interoperable, and that don't take into account the environment of care, the technology ecosystem of care.

I'm also excited to show people that there is that there is a pathway to thoughtfully introducing new technology and not be frustrated, which is what happens. We see that all the time.

I think they will also walk away inspired to think about how they can contribute to the medical internet of things from their perspective. They'll learn about a larger body of work that's been done that can be leveraged to accelerate their own product development so they don't have to reinvent the wheel.

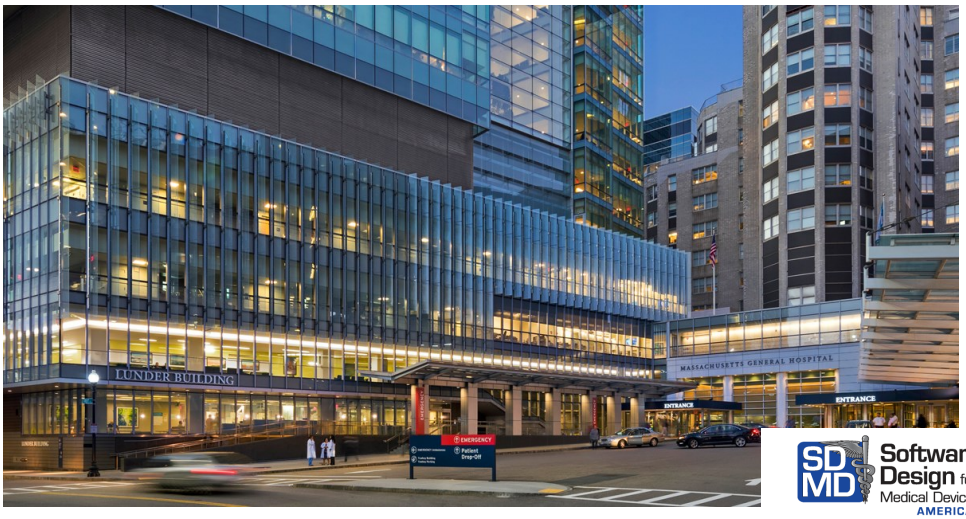
Looking forward, how do you see the MD PnP program evolving over the next 5-10 years? Are there any emerging challenges, innovations or trends you foresee taking on increased importance?

A key focus for us now and, I expect, for years to come is cyber security. It's something that's pretty much everyone is concerned about and has become the primary driver for advancing network medical technology. However, it's almost impossible to have effective cyber security without well thought out interoperability because each strengthens the other. So, with that in mind, we will simultaneously be addressing cyber security as well as interoperability on all projects going forward.

The other major change in the next decade will be moving towards platform based technologies for sensors and actuators, as opposed to the old approach of, you know, a large, heavy, expensive box that has all the computing and al the technology in the box.

In addition, smartphones have increased consumer expectations for access to information and devices. People don't understand why they can buy some small, cheap censer on their phone yet it's so difficult to get information for a physician. Doctors and hospitals leaders too also wonder why medical devices can't be small and light weight and connect to platforms like smartphones do. So miniaturation in platform based connectivity is going to be a key direction of change and with interoperability and cyber security built in to enable these future environments.

Lastly, the application of Artificial Intelligence. In fact, AI, neural networks and fuzzy logic was the kind of stuff that I cut my teeth on at the beginning of my career back in the 90's. For a couple of years I worked to develop AI for real time diagnosis of clinical problems in the operating room and developed a system that effectively analyzed respiratory data or blood pressure data and provided smart alarms. I also created another system that would provide advice on how to take care of a patient that was having cardiopulmonary bypass, heart-lung machine or open heart surgery. However, I eventually realized there wasn't a pathway to implement these ideas because of the absence of interoperability. But my early goal, my interest, my vision, was to deploy AI so I'm personally very excited that it's a hot topic again.



That's my crystal ball. I just polished it yesterday afternoon.

Visit the MD PnP Lab Monday, January 22nd for a full day tour of the facility! Download our **Brochure** to learn more.

About Julian

Julian M. Goldman, MD is Medical Director of Biomedical Engineering for Partners HealthCare System, an anesthesiologist at the Massachusetts General Hospital, and Director of the Program on Medical Device Interoperability based at MGH, Partners, and CIMIT.

Dr. Goldman founded the Medical Device "Plug-and-Play" (MD PnP) Interoperability research program in 2004 to promote innovation in patient safety and clinical care by leading the adoption of safe, secure, patient-centric integrated clinical environments. The MD PnP team has been recognized by multiple awards, including the Edward M Kennedy award for Healthcare Innovation.

Dr. Goldman is Board Certified in Anesthesiology and Clinical Informatics. He completed anesthesiology residency and research fellowship in medical device informatics at the University of Colorado. He departed Colorado as a tenured associate professor to work as an executive of a medical device company. Subsequently, Dr. Goldman joined Harvard Medical School and the Department of Anesthesia, Critical Care, and Pain Medicine at MGH in 2002 as a staff anesthesiologist, where he served as a principle anesthesiologist in the MGH "Operating Room of the Future".

Dr. Goldman co-chaired the FCC mHealth Task Force, the HIT Policy Committee FDASIA Workgroup regulatory subgroup, and the FCC Consumer Advisory Committee healthcare working group. He served on the NSF CISE Advisory Committee, as a Visiting Scholar in the FDA Medical Device Fellowship Program, and as a member of the CDC BSC for the NCPHI. Dr. Goldman currently serves in leadership positions in several healthcare standardization and innovation organizations including Chair of ISO Technical Committee 121, Co-Chair of the AAMI Interoperability Working Group, Co-Chair of the Healthcare Task Group of the Industrial Internet Consortium, and Chair of the Use Case Working Group of the Continua Health Alliance (now the Personal Connected Health Alliance).

Dr. Goldman is an IEEE EMBS Distinguished Lecturer, and the recipient of the International Council on Systems Engineering Pioneer Award, American College of Clinical Engineering (ACCE) award for Professional Achievement in Technology, the AAMI Foundation/Institute for Technology in Health Care Clinical Application Award, and the University of Colorado Chancellor's "Bridge to the Future" award.