Report on the Planning Meeting for the National NSF Workshop on Medical Device Innovation Using Cyber Physical Systems

July 18 - 19, 2012, National Science Foundation, Arlington, VA

Background

The emerging discipline of cyber physical systems (CPS) seeks to harness progress in science and technology to enable innovation in engineering modern systems, by integrating principles and practice from physical modeling, dynamics and control, real-time embedded computing, computing architectures, networking and wireless communication, and certification and assurance technology. Opportunities for CPS-enabled innovation in medical device technology include, as examples, the introduction of coordinated interoperation of autonomous and adaptive devices, as well as new concepts for managing and operating physical medical systems using computation and control, miniaturized implantable smart sensing and actuating platforms, energy harvesting, body area networks, programmable materials, and new fabrication approaches such as 3D printing. To this end, NSF plans to sponsor a National Workshop on Medical Device Innovation Using Cyber Physical Systems.

The proposed workshop is intended to bring together academic, clinical, and industry experts in technologies and processes, as well as government representatives, to identify and explore new CPS manifestations in design methods and platforms that would encourage radical innovation in next generation diagnostic and therapeutic devices and their control, integration, and manufacturing. The overarching goal is to find safer, more effective, more capable, and more reliable solutions than with current approaches, and to consider solutions that will cross the kinds of domains indicated in the examples below. The outcome of the workshop is expected to be a set of problems for the research community to address by breaking down boundaries that separate disciplines to enable the creation of safe, useful systems that embed cyber capability into physical systems. The workshop report will justify why this area needs substantial investment, and quantify the impact of this research on the quality of healthcare, as well as identifying challenges, opportunities, and roadmaps.

Research proposals would focus on science and technology that can affect the next generation of device systems, rather than incremental improvement of existing medical devices. This could be approached by identifying medical device problems in need of attention and determining the technology needed to solve them, or by identifying a possible capability and identifying which applications could utilize this capability. The transformation of the control, computation and communication of a system could empower us to do something that otherwise could not have been done, such as personalizing the quality of care, predicting events that otherwise couldn't be predicted, performing more tasks in real time, and adapting to emergent and faster technology. The workshop is expected to produce specific concrete examples to get researchers engaged and to help them see the research as relevant to healthcare.

Planning Meeting

A conference grant of $49,200 was awarded to PI Julian M. Goldman, MD, at Massachusetts General Hospital to convene a planning meeting to discuss the workshop goals and plan the workshop. A steering committee was formed for the planning meeting, consisting of:

- *Julian M. Goldman, MD, Mass General Hospital / MD PnP Research Program – Chair*
- John Baras, University of Maryland
- Insup Lee, University of Pennsylvania
- Patrick Lincoln, SRI International
- Banu Onaral, Drexel University

- Hunter Peckham, Case Western Reserve University
- Rick Satava, University of Washington
- Janos Sztipanovits, Vanderbilt University
- Ron Triolo, Case Western Reserve University

Government:

- Helen Gill, NSF
- Marc Rigas, NSF
- Kaiming Ye, NSF
- Grace Peng, NIH/NIBIB
- James Luo, NIH/NIBIB
- Kamran Sayrafian, NIST
- Sandy Weininger, FDA

Staff:

- Frankie King, Vanderbilt (VO)
- Joan Stanley, NCO NRD
- Sue Whitehead, Mass General Hospital (MD PnP)

This steering committee met regularly by telephone for three months prior to the meeting itself to create the agenda, to determine the content of the planning meeting, and to select the potential participants to be invited. The participant selection process consisted of (1) compiling a list of individuals who represented a broad range of related expertise, done through group brainstorming and recommendations from members of the committee, (2) reviewing this list as a group, (3) reaching out early to certain individuals on the list to assess their level of interest, availability, and recommendations for others to be invited, and (4) finalizing a list of 54 individuals to be formally invited, with a goal of about 50 participants (including government).

The July 2012 planning meeting for the National NSF Workshop on Medical Device Innovation Using Cyber Physical Systems – held on July 18-19 2012 at the NSF facilities in Arlington, VA – brought together 31 U.S. experts from academia, industry, and the clinical domain, as well as 11 representatives from federal agencies (full roster and reimbursement information included as attachments). This diverse group had expertise in CPS research, clinical research, medical device interoperability, critical care, rehabilitation, informatics, bioengineering, and other areas. In a combination of plenary and breakout sessions, the planning meeting participants discussed clinical challenges and opportunities where new enabling CPS technologies may be transformative to patient care, presented brief overviews of some of these technologies, identified synergies across research domains, and planned the Workshop (still to be scheduled). Participants were enthusiastic about the interactions and discussion in the planning meeting, and looked forward to participating in the full Workshop.

The goal of the planning meeting was to bring together invited experts from the clinical and technology domains to develop a program for the full workshop that will enable it to meet its key objectives: (1) educating the CPS community about over-the-horizon (next 5-20 years) medical technology needs and opportunities, and educating the medical device development community about emerging CPS technologies and capabilities; (2) encouraging investigators to think about CPS at the medical device design stage rather than as an afterthought; (3) envisioning how new CPS technology could influence new medical device capabilities and open up new device opportunities; and (4) providing FDA perspective on the pathway to integrate CPS technology and methods into medical technology to make devices more reliable and safe.

Research Areas Discussed
Three primary research areas of interest for the Workshop were identified by breakout groups at the planning meeting:

- Health & Wellness and Telemonitoring
- Reanimation, High Acuity Health Care, Surgery and Intensive Care
- Closed-Loop Control Systems and all that they entail

Area 1: The Health & Wellness and Telemonitoring research area involves personalization, compliance, control, and communication to motivate behavior modification – collecting data in standard formats, analyzing data, determining the security level of the data and how to comply, and integrating the data into an intervention that will return the patient to the baseline of wellness. Telemonitoring could also be used to predict risk in a patient who is not sick, using personal data and epidemiologic patterns, with validation and verification. This research area would need to be clearly differentiated from other mHealth and eHealth areas.

Area 2: The research area of Reanimation, High Acuity Health Care, Surgery and Intensive Care involves defining the robustness of a system – e.g. how early we can identify a deviation from a trajectory – and how this can be adjusted to heal patients in a shorter period of time. This area focuses on integrating the information from medical devices, data streams, and recommendation streams as a patient gets sicker and the timeline becomes shorter, allowing for better decision-making in clinical settings like the Intensive Care Unit (ICU). Work in this area will require embracing applied mathematics and computational sciences in addition to computer, control, and big-data sciences to improve the data-gathering capabilities of devices, detect deviations on a trajectory, analyze the data and react automatically. Data security and confidentiality must be addressed, as the de-identified information would be available globally for population research purposes, and each individual patient would control their own aggregate information and the ability to share it with whomever they chose. The future might provide the opportunity at a system level for much more automatic diagnoses based on what can be learned from having access to large amounts of patient data. There may be new problems that don't exist yet, such as issues with sequencing data.

Area 3: The Closed-Loop Control Systems research area involves investigation of existing or potential closed-loop control technology systems interacting with biology for medical care that could be embedded and expanded to embrace cyber physical systems, thus transforming healthcare, in particular medical disease domains. This research could be applied to diabetes or blood/glucose control, cardiopulmonary or cardiovascular control, defibrillation technologies with embedded sensors, neuromuscular control, neuro-cognitive epilepsy technologies, and local bionyms for drug delivery. These technologies would be incorporated into a system with a hierarchy of control – local control, continuous remote monitoring and control of the data and system, and adjustment of the algorithm – and could be personalized for management of specific patients without the need for them to revisit the hospital. This area of research would need to examine current and emerging sensing technologies, safe medical device interoperability and system integration, the role of communications super-processing, and the best way to design such systems to facilitate an innovation platform. Closed-loop control is ubiquitous enough to affect both acute and chronic situations, medical device and physiological loops, and Reanimation applications and Health & Wellness applications.

Each breakout group identified potential workshop speakers to be invited for that research area.

Synergies Identified across Research Areas
Planning meeting participants discussed the following synergies across the three research areas:

- Motivation (social aspects of self-ownership of behavior modification and wellness management; how to make the right thing easy to do)
- Integration of care from home to hospital and back to home
- Data security and confidentiality
- Monitoring, detection, and feedback (future technologies in this area, automation, and managing uncertainty and incomplete information)
- Evolution of dynamic state descriptors and responses
- Diagnoses and trajectories (patient could be on the right trajectory but the system is very fragile; predictability)
- Prediction of the attractors and the stable points with regard to diagnosis of clinical phenotypes
- Senescence and reanimation
- Complexity
- Safety issues
- Lack of knowledge
- Non-linearity of biological systems
- Trajectory of the system vs. robustness of the system
- Sensitivity in principal components
- Control
- Energy efficiency and electromagnetics
- Medical device and system testbeds
- Integrated clinical environment platform to accelerate clinical research on new sensors, actuators, and control loops

Significant Findings
The planning meeting clarified that it is challenging to articulate the distinction between CPS applications and CPS science and technology – the latter is what the Workshop is intended to cover, but discussion of the science is difficult without falling back on application-specific examples. This meeting achieved the dual goals of educating this group – the clinical participants learned about technologies that could help them, and the CPS researchers got a clear picture of the kinds of healthcare problems that could benefit from technology solutions – and igniting interest in working together to organize and present these concepts to a broader audience, both CPS and clinical. In many ways, the planning meeting served as a microcosm of the kinds of interactions that are desired for the full Workshop. The observation was made that this workshop may work best as an every-other-year conference similar to the Gordon Research Conference model.

Plan for Workshop
The National NSF Workshop on Medical Device Innovation Using Cyber Physical Systems will seed the vision of devices that could exist in the future (in 5-10 years), highlighting the science and technology issues and finding a place where researchers can work together on these issues. Invitees to the Workshop will include speakers and panelists from academia, industry, and the clinical domain. To encourage academic and clinical participation, an announcement will be sent out broadly to professional societies asking for white papers from individuals or groups. A Program Committee will be formed to select papers for presentation and to select industry participants by identifying five or more application areas and inviting the leading

companies in those areas. The size of the Workshop is expected to be about 125 participants – speakers and panelists will be invited, but registration will otherwise be open.

Engaging the computer science, engineering, and clinical research communities in visioning medical device innovation using cyber physical systems will be the overall goal of the Workshop. Key objectives include (1) educating the CPS community about over-the-horizon medical technology needs and opportunities, and the medical device development community about emerging CPS technologies and capabilities; (2) encouraging investigators to think about CPS at the medical device design stage rather than as an afterthought; (3) envisioning how new CPS technology could influence new medical device capabilities and open up new device opportunities; and (4) providing FDA perspective on the pathway to integrate CPS technology and methods into medical technology to make devices more reliable and safe. The Workshop is expected to develop a report by NITRD NCO that guides future science applications for CPS research technology.