An Open-Source Medical Device Coordination Framework (http://mdcf.santos.cis.ksu.edu)

**Background:** As demand increases for better health care paradigms, it is evident to some that there is a need for integrated and cooperating (interoperable) medical devices. Many devices marketed today already include some form of connectivity (serial ports, Ethernet, 802.11 or Bluetooth wireless) – typically used to unidirectionally log data/events from these devices. In the future, it is likely that medical systems will undergo increased device integration, moving well beyond simple connectivity to provide functionality such as device data streaming directly into patient electronic health records (EHRs), integration of information from multiple devices in a clinical context (e.g., hospital room) into a single tailorable composite display, and automation of clinical workflows via computer systems that control networks of devices as they perform cooperative tasks.

A simple example of automating clinician workflows via cooperating devices addresses problems in acquiring accurate chest x-ray images for patients on ventilators. To keep the lungs' movements from blurring the image, doctors must manually turn off the ventilator for a few seconds while they acquire the x-ray image, but there are risks in inadvertently leaving the ventilator off for too long, as illustrated by the following tragic clinical event reported in 2005 in the *Anesthesia Patient Safety Foundation Newsletter*.

A 32-year-old woman had a laparoscopic cholecystectomy [gall bladder removal] performed under general anesthesia. At the surgeons request, a plane film x-ray was shot during a cholangiogram [bile duct image]. The anesthesiologist stopped the ventilator for the film. 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.*

Current research efforts such as the Medical Device Plug & Play project led by Dr. Julian Goldman (Massachusetts General Hospital) indicate that these risks can be minimized by automatically coordinating the actions of the x-ray imaging device and the ventilator: specifically, the ventilator can identify when the lungs are at full inhalation or exhalation (and thus experiencing minimal motion) so that the X-ray image can be automatically captured at the optimal time [Technology Review 2008].

More broadly, the technology exists to assemble many of types of medical systems that can substantially improve health care quality while lowering costs of medical care. It is, in fact, so easy to establish *ad hoc* networks and integrate devices that companies are rapidly pushing integration solutions into market, and increasing numbers of clinical technicians are "rolling their own" device networks.

This state-of-affairs is dangerous because the Verification and Validation (V&V) technology and regulatory processes to guarantee the safety and security of these systems is lacking.

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Challenges: Progress must be made on a number of fronts to address the challenges described above.

- Which middleware and integration architectures are candidates to support device integration across different clinical situations/contexts in which device coordination/collaboration might be employed?
- Which programming models are suitable for rapid development, validation, and certification of systems of interacting medical devices?
- What V & V techniques are appropriate for compositional verification of envisioned medical systems, and how can the effectiveness of the techniques be demonstrated so as to encourage adoption among commercial vendors?
- Can existing regulatory guidelines and device approval processes that target single devices be (a) extended to accommodate component-wise approval of integrated systems and (b) established in a manner that encourages innovation and rapid transition of new technologies into the market while upholding a mandate of approving safe and effective technologies?
- What interoperability and security standards are necessary to encourage development of commodity markets for devices, displays, EHR databases, and infrastructure that can support low cost deployment of integrated systems and enable flexible technology refresh?

We believe that only a community of individuals from that includes representatives from industry, academia, and government regulatory agencies can effectively address the challenges above. However, industry tends to pursue proprietary solutions, academics often do not have required domain knowledge or resources, and government regulators usually do not engage in software/systems development.

Our Contributions:
To facilitate exploration of the challenges above, we are working with health care IT industry engineers, clinicians, and government regulatory agencies to develop an open Medical Device Coordination Framework (MDCF) for designing, implementing, verifying, and certifying systems of integrated medical devices. The contributions of our framework and associated documentation (available for download at http://mdcf.santos.cis.ksu.edu) are as follows:

- We identify clinical contexts in which device integration has the potential to be especially effective, and we summarize performance and development requirements of these contexts. We propose coordination use-cases and device configurations that would be useful in those contexts.
- We provide a flexible publish-subscribe middleware architecture based on the Java Messaging Service (JMS) to support exploration of issues surrounding systems of integrated medical devices.
- We provide a model-based programming environment for rapid development of systems of integrated devices that we believe has the potential to support a new paradigm of regulatory oversight that can accommodate approval of device integration scenarios.
- We describe experiments that evaluate our infrastructure against the data formats, performance requirements, system functionality that we believe are representative of the requirements of envisioned clinical contexts for systems of integrated devices.
- Medical devices are typically very expensive and academic researchers do not have the resources to acquire collections of devices for evaluating research ideas in this domain. To address this issue, we are developing a collection of mock medical devices that “replay” real device data streams available from open databases such as Physionet. Currently available mock devices include a collection of ECG devices with data streams for both healthy and ill patients.

Participating KSU Faculty: Dr. Dan Andresen (networking, middleware), Dr. John Hatcliff (verification and certification, component modeling frameworks), Dr. Steve Warren (wearable devices, plug and play frameworks).

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