

## **New Paradigms for Verification and Certification of Systems of Cooperating Medical Devices**

Over the last two decades, rapid advances in computing power, personal computing platforms, computer networking, and interoperability standards and middleware for system integration have had a dramatic impact on many sectors of the national and international economy. These technological advances are now poised to revolutionize health care systems.

- Pervasive networking will enable integration of national networks, regional health care centers, local hospitals and clinics, primary care physician offices, home care systems, and body-area networks.
- Health-care information technology infrastructures will be oriented toward “systems of systems” architectures built upon middleware information backplanes that integrate and blend monitoring and treatment devices with other information producers and consumers in the extended healthcare network. Device data streamed into medical records will be automatically mined to extract knowledge that can drive a host of activities such as automated treatment, dosing, trend analysis geared toward health prediction, and large-population assessments of human health and treatment effectiveness.
- With information technology as a catalyst, health care systems will increasingly exhibit collective intelligence built upon the intelligence of individual devices and data mining and knowledge gathering components.
- Operating rooms and other diagnosis and treatment contexts will shift from the use of a collection of fixed monolithic devices to plug-and-play components that enable flexible and rapid re-configuration of diagnostic, recording, and treatment systems
- Precision robotics and high-speed networks will hasten advances in telemedicine and robotic surgery.
- Portable healthcare devices will support multiple care contexts, and boundaries of these component-based systems and their extended information environments will be difficult to define.
- As generations of technology-savvy healthcare consumers enter retirement, these consumers will embrace and even demand sophisticated home healthcare monitoring, treatment, and records systems integrated with national information databases (e.g., prescription drug information systems) and local hospital and primary care systems.

Considering the huge costs associated with transitioning increasing numbers of aging citizens into private and government-sponsored medical insurance plans, it is especially important that these advances provide quality medical care at a reasonable cost. The U.S. government must therefore facilitate technology innovations as well as innovations in medical processes, workflows, and regulatory policies that reduce the cost of medical care but still provide the highest levels of safety, security, and overall quality.

Unfortunately, industry and government find themselves in a rather shocking situation – the technology exists to *assemble* many of the types of medical systems described above, but the technology to *guarantee the safety and security* of these systems is lacking. Moreover, many government agencies such as the Food and Drug Administration currently *do not have the regulatory regimes in place* to provide oversight to ensure the safety and effectiveness of these systems.

While many modern medical devices have some form of connectivity that may be used to upload information to an electronic health record or provide computer-based audits, they are still monolithic in nature. Likewise, current Verification and Validation (V&V) techniques used in industry primarily target single monolithic systems. Moreover, FDA’s regulatory regimes are designed to approve single stand-alone devices – there are no guidelines in place for how the industry might bring to market a collection of cooperating medical device components from different vendors, where each component goes through a separate pre-market approval process. Today, V & V activities typically account for as much as 50% of the overall cost in bringing devices to market. The increasing amount of software in modern medical monolithic devices is already pushing current V&V technology and regulatory regimes to their limits.

Moving to highly integrated, componentized, distributed systems of medical devices such as those envisioned above renders current V&V and regulatory regimes obsolete. This situation will increasingly result in significant safety risks. In the best case, these emerging systems will be “shoe-horned” into existing V&V and regulatory frameworks that are unable to cope with their complexity. In the worst case, as health-care organizations are under significant pressure to reduce costs, clinical technicians will begin to “home roll” their own unapproved device integrations at extreme risks to patients.

## **Assessment**

To meet these challenges, a paradigm shift is needed in V&V technology, training, and regulatory paradigms. Bringing about this shift will require significant coordination and cooperation between academic researchers (to develop alternate V&V technologies), government regulators (to propose new regulatory regimes that recognize those technologies and can accommodate componentized systems of medical devices), and industry (to evaluate proposed technologies in realistic environments, and to jointly develop standards for integration). This cannot be achieved by incremental expansion of existing research programs at NSF and other agencies. Instead, a high-level coordinated inter-agency effort with new research programs targeted to this problem will be necessary. It should also be emphasized that this is not just a technology problem, but also a regulatory regime problem and culture problem. Significant funds must be devoted to developing and evaluating new regulatory regimes along with appropriate education and workforce training resources for those regimes.

## **Specific Recommendations**

- Develop new research programs at agencies such as NSF, NIH, and NIST that target V&V technology, new regulatory paradigms, and integration standards that can support complex “systems of systems” of medical devices. These programs should prioritize research programs that involve collaborations with industry and government agencies.
- Within existing software and embedded system research programs, emphasize research on technologies that can lead to higher confidence in large-scale safety/security critical systems. This includes new approaches to certification such as assurance cases as well as techniques that lead to the production of independently auditable evidence of correctness (e.g., as recommended in the National Academies study “Software for Dependable Systems: Sufficient Evidence?”)
- Provide infrastructure grants to develop test beds for medical device integration and coordination research that can be released as resources for academic, industry, and government research.
- Provide grants that support research internships at FDA that target medical device integration technology.
- Continue sponsorship of workshops and other meetings that bring together government regulators, clinicians, medical device developers, along with technical domain experts (e.g., in interoperability, verification/validation, and certification).