

**Report on the Results of the Medical
Devices Metrology and Standards
Needs Workshop**

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Outline

- **Workshop Sessions**
- **Computer Assisted Surgical Navigation**
- **Accuracy Assessment of Surgical Robots**
- **Validation of Surgical Simulation Systems**
- **Neurostimulation Implants**
- **Patient-Centric Networked Medical Device Interoperability**

Medical Devices and Standards Needs

Workshop Sessions

Tuesday 14th November 2006, Atlanta, GA

Computer Assisted Navigation and Surgery

David A Heck, MD FAAOS, Baylor Health Care System

Surgical Robots (Mostly Manual Control Mode)

Prof. William J. Peine, Purdue University

Surgical Robots and Phantom (Artifact) Devices

Prof. Peter Kazanzides, Johns Hopkins University

Stimulation Devices

Dr. Chiao, J.C., ARRI/University of Texas at Arlington

Drug-delivery and Physiologic Monitoring Devices

Julian M. Goldman, MD, Massachusetts General Hospital

Medical Devices and Standards Needs

Computer Assisted Surgical Navigation (CAS)

David A Heck, James B Stiehl

Technological Innovation at Stake:

- An emerging technology that rely on 4 dimensional (3D + Time) positioning of instrumentation and prosthetic components within a human reference frame.
- Advance optimum device positioning, to improve surgeons' spatial orientation and to reduce positioning errors that may risk reoperation.
- CAS devices have no known clinical traceability characteristics or process capabilities.
- Variation in performance based on technology employed, the vendors' implementation, the user, the specific surgical procedure and the degree(s) of freedom being evaluated.
- No standardized approaches to the evaluation of the technology employed, usage and reporting of intra-operative findings exist.

Medical Devices and Standards Needs

Computer Assisted Surgical Navigation (CAS)

Economic Significance:

- **Based upon AHRQ 2004 Health Care Utilization Project (HCUP) data:**
 - **431,485 primary and 35,048 revision total knee replacement procedures**
 - **225,900 primary and 37,115 revision hip replacements**
- **\$26 Billion in annual health care system charges and 1,454 Deaths / Year.**
- **Preliminary results would suggest that a significant proportion of revision procedures performed may be eliminated through the improved prosthetic positioning associated with the use of CAS at the time of surgery.**

Medical Devices and Standards Needs

Computer Assisted Surgical Navigation (CAS)

Technical Barrier:

Traceable metrological standards, validated testing protocols that simulate the end-use environment, standardized reporting and electronic health reporting standards.

- **Phantoms that support traceability to standards organizations.**
- **Metrics to establish validity and facilitate comparison between systems.**
- **Phantoms are required that replicate “standard” and “outlier patients”.**
 - **From the geometric perspective, (“Short” , “Normal”, “Tall”).**
 - **From the soft tissue perspectives (Asthenic, Normal, Morbidly Obese).**
- **Phantoms with X-Ray absorption characteristics comparable to the range of human presentations.**

Medical Devices and Standards Needs

Computer Assisted Surgical Navigation (CAS)

Technical Barrier:

- **Standardized and representative anatomic referencing landmarks (fiducials).**
- **Standardized test environments and protocols that replicate the operating room environment**
- **Devices and protocols that create interference and would be used to evaluate the impact on errors of measurement through mechanisms such as electro-magnetic interference.**
- **Large Scale, Multi-Center, Clinical investigations to refine our understanding of device position on clinical outcomes.**
- **Protocols must address anatomic site, referencing approach, component positioning, navigational technologies being employed, prosthetic technologies, metadata, and calibration status such that process capabilities can be established.**

Medical Devices and Standards Needs

Accuracy Assessment of Surgical Robots Peter Kazanzides, William Peine

Technological Innovation at Stake:

- **Teleoperated or “remote control” robots that enhance a surgeon’s visualization and dexterity during minimally invasive procedures.**
 - **The daVinci System from Intuitive Surgical has been used for urology, cardiology, pediatrics, OB/GYN, and general surgery.**
- **Surgical “CAD/CAM” robots that accurately execute a series of motions based on a preoperative plan.**
 - **Some used for neurosurgery (Neuromate) and orthopedics (ROBODOC)**

Accuracy Assessment of Surgical Robots

Economic Significance:

- **Worldwide market for medical robotics and computer-assisted surgery (MRCAS) devices and equipment is expected to be (BCC Research, 7/1/2006):**
 - **\$1.3 billion in 2006**
 - **\$5.7 billion by 2011**
- **Projected surgical robots U.S. AAGR > 43% between 2006 and 2011.**
- **Potential for significant impact on overall healthcare delivery system**
 - **minimally invasive surgery provides large cost savings over traditional surgery**
 - **robotic surgery can reduce inventory and sterilization costs by eliminating the need for other instruments.**

Accuracy Assessment of Surgical Robots

Technical Barrier:

- **For CAD/CAM robots, positional accuracy is critical to maintain patient safety and achieve best clinical results.**
- **For teleoperated robots, positional accuracy is important to enable integration with medical imaging and to facilitate design of new smaller, cheaper systems.**
- **Validating accuracy is difficult due to complexity of recreating operating room conditions in laboratory.**
 - **For example, reproducing anatomy to test registration (alignment) methods, such as those utilizing points on bone surface and/or dynamic localization of center of joint rotation.**

Accuracy Assessment of Surgical Robots

Technical Barrier:

- **Measurement objects (phantoms/artifacts) that sufficiently reproduce the clinical scenario**
 - **Features may be difficult to measure with existing devices (i.e. precisely measuring tip position of divot)**
- **For teleoperated robots, new force and position sensors are needed to implement and validate haptic feedback and advanced control algorithms.**

Medical Devices and Standards Needs

Validation of Surgical Simulation Systems William Peine

Technological Innovation at Stake:

- Traditionally, surgical training is done through clinical observation and mentoring from an expert surgeon at the patient's side.
- Teleoperated surgical robotics impede this process and introduce challenges for both the student and teacher – ultimately decreasing patient safety.
- Virtual reality based surgical simulation trainers have been cited as a solution, allowing surgical residents and fellows to practice and learn at their own pace in a safe, reduced stress environment.
- Since the induced instrument motions are captured in software, performance metrics can be implemented to evaluate the skill of the student and chart their improvement over time.
- Experienced surgeons can be certified and practice difficult situations.
- Surgical simulators may be combined with patient specific anatomic models created from preoperative imaging to allow surgeons to realistically practice a procedure before the actual case.

Medical Devices and Standards Needs

Validation of Surgical Simulation Systems

Economic Significance:

- **Worldwide market for medical robotics and computer-assisted surgery (MRCAS) devices and equipment is expected to be (BCC Research, 7/1/2006):**
 - \$1.3 billion in 2006
 - \$5.7 billion by 2011
 - Projected surgical robots U.S. AAGR > 43% 2006 to 2011.
- **MRCAS has the potential to reduce medical errors and improve patient outcomes.**
- **Adoption of surgical robotics has been slowed due to the complexity, cost and a lack of training techniques.**
- **Improved training through simulation will certainly increase the utilization of MRCAS.**

Medical Devices and Standards Needs

Validation of Surgical Simulation Systems

Technical Barrier:

- **Specialized haptic interfaces, stereo visualization, advanced graphics, and accurate modeling of deformable tissues in real-time.**
- **Recreate the feel and performance of real surgery.**
- **Training basic skills may be possible with simple block-like objects, while teaching proper technique for suturing soft tissues may require very realistic tissue motions.**
- **Set performance requirements and metrics based on what aspects of the simulation are important.**
- **Measurement of real tissue deformations (bulk stiffness and local shape changes), contact interactions with instruments, realistic coloring and texturing of tissues, and force feedback.**
- **Validated skill evaluation metrics are needed to quantify training level.**

Neurostimulation implants J.C. Chiao

Technological Innovation at Stake:

Neurostimulation is the stimulation of the neural tissues with relatively low electrical impulses. It can be used to reduce chronic pain by blocking the transmission of pain messages to one's brain.

- **Reduction or discontinuation of narcotic consumption in a recent 20-year literature review.**
- **Used or studied in treatment of essential tremors, Parkinson's disease, dystonia, obsessive-compulsive disorder, depression, tinnitus, epilepsy, respiratory support, malignant pain, spasticity, amyotrophic lateral sclerosis, Huntington's disease, gastroparesis, irritable bowel syndrome, profound deafness (cochlear implant), headaches, traumatic brain injury, angina pain, peripheral vascular disease pain, pelvic pain, incontinence and sexual dysfunction with deep brain, occipital nerve, pulmonary, gastric, vagus nerve, peripheral nerve, spinal cord, or sacral nerve stimulation.**

Medical Devices and Standards Needs

Neurostimulation implants

Economic Significance:

- **FDA-approved neurostimulation applications include chronic pain management, Parkinson's disease deep brain stimulation and incontinence control.**
- **Testimony before the Subcommittee on Health of the House Energy and Commerce indicated that 25% Americans suffer from chronic pain, which results in 40 million physician visits per year, \$50B are lost due to workday loss and \$100B in medical expenses are due to chronic pain.**
- **The market for pain management, which comprises broadly of pharmaceuticals and devices, is at \$18B in 2000 growing at an average annual growth rate of 12% to reach \$32B in 2005.**
- **60,000 new cases of Parkinson's disease are diagnosed each year.**
- **15 million Americans suffer from incontinence with total annual cost of care estimated at \$28B.**
- **U.S. market for neurostimulation products, including cochlear implants, in 2005 was at \$830M, expected to \$1.8B in 2010.**

Neurostimulation implants

Technical Barrier:

- **Neuroscience, neurology and neurophysiology are complicated sciences and animal test models are not well established, human tests are risky and time-consuming and there is a lack of standardized means to define and characterize the effectiveness of neurostimulation.**
- **There are needs for technology innovation in implant power sources, wireless communication, miniaturization, safe implant electrodes, recorders and biocompatibility**
- **There are needs for clinical investigation in surgical apparatus, procedures, training and characterization methods.**

Medical Devices and Standards Needs

Patient-Centric Networked Medical Device Interoperability Julian M. Goldman

Technological Innovation at Stake:

- Most medical devices are designed to operate independently, and do not employ open Information and Communication Technology (ICT) networking standards for data communication or for device control.
- The integration of individual medical devices (such as physiologic monitors and medication delivery systems) into networked systems can provide:
 - Comprehensive connectivity to the electronic medical record.
 - Automated system readiness assessment.
 - Physiologic closed loop control of medication delivery, ventilation, and fluid delivery.
 - Decision support, safety interlocks, monitoring of device performance, plug-and-play “hot swapping” of modules, selection of “best of breed” components.
 - Integration of surgical robot activities with other surgical and physiological events.
- Currently there are no cross-vendor standards-based interoperability for medical device communication.
- Patient-centric medical device interoperability would benefit clinical areas as diverse as the OR, ICU, out-of-hospital transport, and general hospital clinical and ward care.

Medical Devices and Standards Needs

Patient-Centric Networked Medical Device Interoperability

Economic Significance:

- **More people die in a given year as a result of medical errors than from motor vehicle accidents, breast cancer, or AIDS, with a total national costs of between \$17 billion and \$29 billion.**
- **Kaiser Permanente recently presented a financial analysis of deploying comprehensive medical device-electronic medical record (EMR) connectivity with or without standards based ICT solutions.**
- **Kaiser projects that the cost of EMR integration adds 40% to the cost of medical device acquisition, and that adoption of standards-based medical device connectivity will reduce Kaiser's implementation costs by 30% or approximately \$12M annually for the next 10 years.**

Medical Devices and Standards Needs

Patient-Centric Networked Medical Device Interoperability

Technical Barrier:

- **Absence of vetted standards for medical data communication and control.**
- **Suitable plug-and-play system architecture.**
- **The architecture must enable devices to function autonomously in a safe manner and support the deployment of smart alarms, clinical decision support, closed-loop control, enhanced diagnostics, reconfigurability, semantic interoperability, and allow implementation using currently available technology.**
- **Absence of requirements for an integrated clinical environment “ecosystem” that would include data logging, data security, and device authorization.**
- **New measurement technology and testing protocols are needed to assess the suitability of proposed standards, plug-and-play architecture, and ancillary devices.**
- **Interoperability and conformance testing tools will be needed to assess compliance of new devices to proposed solutions.**

Conclusions

- **Successful identification of needs in five categories of medical devices.**
- **Five USMS needs have been submitted for authentication and review.**
- **A journal level paper report will be prepared and will be submitted to the NIST Journal of Research for possible publication.**