



American Academy of
Orthopaedic Surgeons®

AAOS

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Andrew C. Von Eschenbach, M.D.
Acting FDA Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Dear Dr. Von Eschenbach:

The American Academy of Orthopaedic Surgeons (AAOS/Academy), representing over 19,000 Board certified orthopaedic surgeons, welcomes the opportunity to comment on the Food and Drug Administration's Unique Device Identification (UDI) open public meeting and request for comments [Docket No. 2006N-0292]. The Academy appreciates the efforts of the FDA to facilitate this meeting in a transparent manner in which stakeholders were invited to present their perspectives in a public forum.

RATIONALE FOR A SYSTEM

While the AAOS is cognizant of the FDA's regulatory authority, FDA's collaboration and communication on UDI systems with other federal agencies including but not limited to the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, the Veteran's Administration, and the Department of Defense is laudable and of great benefit to the global healthcare community.

Many arguments exist to support the development of unique device identification system. Of foremost concern to the healthcare community are patient safety and the reduction of medical errors. While the peer-reviewed patient safety scientific literature is not as robust for medical devices as for pharmaceutical drugs, evidence continues to increase to create a rationale for device identification leading to safer patient care.

Patient safety, through better human factors design, is a critical device safety problem. Gathering more data in post-market surveillance may provide information on sub-optimal device design that could be a cause of medical errors, such as buttons on an infusion pump control pad located too closely together. Human factors engineering is a critical element in the use of medical devices. Device design is often a factor in adverse events,

not just human error. By implementing a UDI system, early device problems will be captured more quickly and will prevent multiple events from occurring.

AAOS Unpublished Patient Safety Study

In an as yet unpublished AAOS Patient Safety study by David A. Wong, MD et.al., the AAOS conducted a survey¹ of the Academy fellowship about observed medical errors in the last six months of practice. Dr. Wong employed the National Quality Forum and the National Coordinating Council for Medication Error Reporting and Prevention taxonomies to classify errors and incidents.

The most frequent category of errors was in equipment at 30%. Members reported incidents of failed sterilization, wrong implants, wrong components of implants, wrong equipment, a sponge left in a patient, mislabeled drums of fluids used on devices, and incorrect laterality of devices provided in the operating rooms. Many of these incidents caused a delay in surgery or an increased hospital stay and added to our nations' healthcare costs.

These incidents could have been prevented if devices contained a UDI and an electronic health record (EHR) was utilized. The Academy will make this study available to the FDA when it is published in a peer-reviewed journal.

DEVELOPMENT OF A SYSTEM OF UNIQUE DEVICE IDENTIFIERS

The AAOS wholeheartedly endorses the development of a UDI system. As the U.S. is the largest manufacturer of medical devices, the implementation of such a system could and may well prove to be a global initiative. This system must be mandatory to be effective as voluntary collection is random and inefficient for all stakeholders.

Notwithstanding the initial expense, the health care industry stands to benefit significantly. The AAOS will reserve advocating for a specific type of technology identification system. Several different types of technologies are currently in use including radiofrequency, bar coding, optical systems, and others. Many factors will need to be quantified in the Agency's decision-making process for a UDI. We are pleased at the FDA's thoughtful deliberation on UDI to date by holding stakeholder's meetings and commissioning white papers.

Identification should be placed on devices at the unit of use level. UDI could occur at more than one level but is necessary at the unit of use level for health care utility. A UDI could occur on the devices themselves with the noted exception of implantable devices. The Association of Medical Device Reprocessors has implemented such a marking and tracking system for reprocessed devices including very small devices, such as drill bits. The FDA should use a reasonableness test with regard to patient safety in determining the unit of use for devices. For instance, items such as gloves, cotton balls, cotton swabs, and many Class I devices sold over the counter, do not require identification of every single item. Efforts to identify the box should be sufficient to accomplish appropriate patient safety, with these low risk devices.

Use of International Harmonization/Standards

As codified in the Food and Drug Administration Modernization Act (FDAMA) in 1997, FDA officials were directed to meet with representatives of foreign countries to reduce the burdens of global regulation and harmonize regulatory requirements. Additionally, officials were directed to engage in efforts to accept mutual recognition agreements relevant to the regulation of devices and good manufacturing practices between the European Union and the United States. FDAMA recognized national and international standards in the review of medical devices. The AAOS thanks the FDA for its leadership on global harmonization task forces and the advances in standardization accomplished over the past few years.

IMPLEMENTING UNIQUE DEVICE IDENTIFIERS

Privacy/ Informed consent issues

The AAOS is aware that some companies are use laser etching as an identification marker on implantable devices, specifically hip stems. Some of the etchings on the devices led to early weakening and failure², necessitating revision surgery for the patient. The AAOS finds this situation to be untenable and strongly recommends against the use of unique identification on the implants themselves. This information should be contained in the packaging of devices, not on the implantable device itself.

A UDI etched or marked on an implantable device also raises many privacy issues. News reports have questioned the security of smart cards used with radio frequency identification (RFID) systems. Engineers have been able to break the codes and accessed confidential information. RFID systems currently can be read within a distance of forty feet. Ultimately, the goal of the UDI system is to be linked to an electronic health record. As smart card systems are insufficiently encrypted, a UDI system on implantable devices would not be HIPAA compliant.

Furthermore, some devices are resorbable and are incorporated into a patient's anatomy. Presumably only an identification chip would be left on such devices if the identification system were incorporated on the device. If a patient was a multiple user of devices, systems would need to accommodate data from multiple devices, including, for example, dissolving sutures. AAOS is aware that devices are currently marketed to contain a patient's entire medical record and are percutaneously implanted below the skin. Reading such a system with RFID if not properly encrypted would provide access to confidential information of a medical and financial nature. Patients could choose to change their informed consent policy necessitating an operation to remove an implantable device. For all of these reasons, the AAOS strongly recommends that implantable devices are uniquely identified on the packaging not the devices themselves

Hospital Interface

As with other initiatives, the UDI system will have little utility if it is not incorporated at the hospital level. Bar-codes are currently required on pharmaceutical drugs and at present are systematically used at few hospitals. Similarly, though a 2005 JCAHO requirement, hospitals are required to track allograft tissue. The AAOS is aware that tissue processors could identify and track tissue immediately following the Biomedical

Tissue Services and Donor Referral Services recalls. However, hospitals did not immediately notify surgeons (and patients) due to lengthy hospital chart abstractions. Most hospitals track their recalls manually by a lengthy chart review. Some hospitals manage their own bar-coding systems and synchronize their data with manufacturers, distributors or others in the supply chain. This additional layer adds the possibility of medical error and is expensive to maintain.

Hospitals must implement tracking and identification of drugs, devices, and biologicals on a national level to increase safety for patients. The AAOS encourages the FDA to coordinate efforts on UDI with the American Hospital Association and the Joint Commission on Accreditation of Healthcare Organizations.

Guidance Document Development

The AAOS strongly advocates that the FDA streamline their internal processes. While it is important to provide a solid legal foundation for regulatory actions, the FDA has become encumbered in its legal review of documents. Internal processes should be more efficient with only the most important matters designated for the review of Chief Counsel. Guidance documents are critically important toward the functioning of the Agency and establishing a least burdensome pathway.

Progress is being significantly hampered at the agency by the lack of guidance document development and subsequent guidance publishing. Manufacturers report receiving increased questions during product reviews when guidance is not clear to both industry and the FDA review staff. The slower review times directly impact the amount of work the Agency is able to accomplish.

The AAOS acknowledges the success of the utilization and development of FDA guidance documents. These documents assist in predictability and transparency for manufacturers in the development of pre-market device submissions as well as expediting the review process. Manufacturers often cite receiving different interpretations of product reviews. Guidance documents assist in the standardization of FDA policy and interpretation. Additionally, guidance documents are often used as special control documents to support a downclassification. The AAOS and the Orthopaedic Device Forum stand ready to assist the FDA in revising and creating guidance documents to address critically important, clinical information.

AAOS and the Orthopaedic Surgical Manufacturers Association (OSMA) with the Orthopaedic Device Forum deliberated and drafted a level 1 guidance document, “*Clinical Trial Design for Hip Replacement Systems*” to the Agency on January 1, 2004. The guidance has yet to be published by the FDA. Similarly, members of the spinal community drafted a guidance document, “*Preclinical and Clinical Trial Design for Cervical and Lumbar Disc Replacement Systems*” and submitted it to the Agency on March 10, 2005. This document has yet to be published.

Members of the AAOS have engaged in several discussions with senior staff about guidance document priorities of the Division of General, Restorative, and Neurological

Devices, the Office of Device Evaluation, and the Center for Devices and Radiological Health. While we are cognizant of the Medical Device User Fee Modernization Act (MDUFMA) goals and metrics, the critically important function of disseminating guidance documents is not being adequately addressed. When a UDI system is implemented by the FDA, the agency must publish substantial guidance for industry and FDA staff. The AAOS strongly suggests that changes are implemented at the highest levels within the Agency to prioritize the issuance of guidance documents.

UDI BENEFITS AND COSTS

AAOS Hip and Knee Registry

The AAOS continues to meet with several agencies within HHS about developing a national hip and knee registry. The goals of the registry are to improve patient outcomes, decrease revision rates, and to identify early problem components. The Swedish registry decreased their revision rates by 50% by identifying best surgical practices and best-performing implants in total joint replacements³.

The demand for total joint replacements is projected to increase dramatically by 2030. Primary total knee replacements are projected to rise by 673% to 3.48 million by 2030. Primary hip replacements are projected to increase by 174% to 572,000 in 2030⁴. Costs of total, partial and revision hip replacement amounted to \$12.01 billion dollars in 2003, while total and revision knee replacement cost \$12.85 billion in 2003⁵.

The Comptroller General, the Honorable David M. Walker of the U.S., in his 2006 fiscal wake-up tour, presentation, "Saving Our Future Requires Tough Choices Today," stated that from 2005-2030 in constant dollars, Medicaid spending is projected to increase 166% while Medicare spending is project to increase 331%. Healthcare was our nation's top tax expenditure in 2005 at a cost of 118.4 billion dollars. The Comptroller General also stated that the current U.S. fiscal policy is unsustainable.⁶

In order to institute a hip and knee registry, hip and knee devices must have electronic identification so that they may be used in a registry format. Chart abstraction is costly, time intensive, and the margin of error is significantly higher than an electronic means of capture. We strongly urge the FDA to mandate UDI for all medical devices to aid in patient safety, to decrease medical errors, and to decrease healthcare costs for our nation.

OTHER BENEFITS

The AAOS acknowledges an increased cost to manufacturers but believes the benefits outweigh the risks. The use of a UDI will lead to efficient reimbursement when used in tandem with an EHR. As one-third of every healthcare dollar is wasted, the implementation of a UDI system will save needed resources. A UDI system will encourage cost-effectiveness in the supply chain efficiency of the manufacturing community. Such a system would ultimately decrease healthcare costs by standardizing inventory and associated costs through the hospital system.

Recalls of devices would be more readily and thoroughly accomplished. Manufacturers report that they do not always locate all recalled devices as some are lost in the system.

Depending on the framework of the UDI regulation, the FDA could capture device denominator data. With such data, the FDA would be more informed as to the extent of the risk/benefit ratio and have more data to determine a public health risk. The Agency could feasibly capture lot and model numbers which are not usually provided by voluntary reporters to MedWatch adverse event reporting system.

Device interoperability could be programmed into an electronic health record. Additionally, a UDI system would significantly prevent the counterfeiting of devices by allowing purchasers to assess the pedigree of their shipment.

Equipment could be easily and more quickly located in a hospital setting with UDI. Moreover, in tandem with an EHR, a UDI system could identify devices that are incompatible with MRIs in addition to identifying a patient's allergies to certain metals.

CONCLUSION

The AAOS thanks the FDA for their efforts to meet with stakeholders and provide thoughtful consideration of the issues with unique device identification. The Academy urges the FDA to mandate a UDI system to improve our nation's healthcare and associated healthcare costs. We again, strongly urge the FDA to require a UDI system for all medical devices to aid in patient safety, to decrease medical errors, and to decrease healthcare costs for our nation. The AAOS looks forward to working with the FDA in its efforts to regulate unique identification systems for medical devices that will aid in quality patient care.

Sincerely,



Richard F. Kyle, MD
AAOS President

David A. Wong, MD, MSC, FRCS(C)
Patient Safety Committee Chair

¹ Wong, D, Aug.2006, AAOS Member Patient Safety Survey: A first look, *AAOS Bulletin*, <http://www.aaos.org/News/Bulletin/aug06/fline11.asp>

² Lee EW, Kim HT, 2001, Early fatigue failures of cemented, forged, cobalt-chromium femoral stems at the neck-shoulder junction, *J Arthroplasty*, Feb;16 (2):236-8.

³ Malchau, H et al, 2002, The Swedish Total Hip Replacement Register, *J. Bone Joint Surg. Am.*, 84:2-20, 2002

⁴ Ong, KL, Mowat, FS, Chan N, Lau E, Halpern MT, Kurtz, SM, May 2006, Early burden of revision hip and knee arthroplasty in Medicare enrollees, *Clin Orthop Relat Res*, 446:22-8.

⁵ Frankowski, J. Patient Demographics: Information about orthopaedic patients and conditions <http://www.aaos.org/Research/stats/patientstats.asp>

⁶ Walker, DM, Aug. 2006, Saving Our Future requires Tough Choices Today, US Government Accountability Office, <http://www.gao.gov/> GAO-06-1084CG.