

December 10, 2008

Carolyn M. Clancy, M.D.
Director, Agency for Healthcare Research and Quality
Center for Quality Improvement and Patient Safety
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

RE: Surgical Safety/Surgical Checklist Meeting

Dear Dr. Clancy,

The American Academy of Orthopaedic Surgeons (AAOS), on behalf of more than 17,000 Board-certified orthopaedic surgeons, is writing to express our concerns over the potential implementation strategies for the World Health Organization's (WHO) Surgical Safety Checklist. While the AAOS supports the use of the WHO checklist in nations outside of the U.S., we suggest that a mandated implementation of this checklist in the U.S. will be redundant and thereby lead to a potential for decreased patient safety.

The WHO checklist provides a baseline in improvement for emerging patient safety systems but does not add value to robust programs, such as those that exist in the US. According to the Joint Commission's website, approximately 88 percent of the nation's hospitals are currently accredited by that organization.¹ These hospitals are required to comply with standards that include the items on the WHO checklist to gain and maintain their accreditation such as adverse event reporting, surgical site marking, use of blood and tissue products, and medication safety. Another 201 hospitals are accredited by the American Osteopathic Association's Healthcare Facilities Accreditation Program which has similar patient safety policies.² While WHO's website assures that the "...checklist can help countries and facilities evaluate their own processes of care and improve surgical safety," the hospital accreditation process in the U.S. presently serves that function.

Historically, the AAOS has been a leader in surgical site marking by developing the Sign Your Site program in 1998. Additionally, the AAOS instituted a time-out procedure to promote a culture of safety in the operating room to ensure that the surgical team verifies the correct patient, procedure and surgical site. Other organizations have been long-standing proponents of safety checklists and programs. The overlap of these initiatives with the WHO checklist is illustrated in Figure 1 of the attached Appendix. The United States has many programs, voluntary and mandated, from federal, state, local, and institutional sources, which address the issues included in the WHO checklist. The introduction of another checklist may create confusion, decrease adherence to other positive practices, and

dilute the effectiveness of existing patient safety initiatives. If usage of the WHO checklist is mandated, surgeons and their healthcare colleagues would need to rework established processes to incorporate redundant documentation. Furthermore, there is no apparent mechanism to compel compliance with the use of this checklist, nor any incentive to add it to the protocols currently employed. Without such means of incentives or penalty, it is unclear how enforcement would be possible.

The AAOS recognizes the potential benefit of collecting data to enhance existing patient safety programs but questions the utility of the WHO checklist as a data gathering tool. The agenda for the AHRQ November 4, 2008 meeting included a discussion of how to track the checklist's impact on surgical deaths and complications. Nonetheless, there does not appear to be a central repository to contain the data from the checklists, or a reporting system in place to provide feedback to participating sites. As previously noted, many, if not all, of the metrics on the checklist are captured under existing protocols and programs that have the added benefit of established infrastructure for the evaluation of these data. The AAOS suggests that a more responsible application of resources would be to standardize these data collection sources to enable analysis across the spectrum of existing programs.

The administration of some of the items on the WHO checklist may be in conflict with recognized policies and procedures in U.S. hospitals. For instance, the identification of patient allergies is part of the history and physical and is completed prior to patient admission, confirmed as part of the admission procedures, and again by the staff at various times throughout the hospital stay. While another check prior to anesthesia is reasonable, the presence of any allergies is usually documented and known well before the patient reaches the surgical arena. Potential blood loss is another critical event that should be identified several days before the patient reaches the pre-operative holding area. A College of American Pathologists study cites a three day standard for procuring a type and screen in anticipation of a potential transfusion.³ Again, an additional check on potential blood loss may have use, but the risk should be identified and procedures taken to anticipate the potential need for blood well in advance of the surgical procedure. Finally, the timing of the time out (prior to skin incision) is not in line with the updated Joint Commission Universal Protocol which calls for a time out "ideally, prior to the introduction of the anesthesia process." Adherence to the WHO checklist would put hospitals out of compliance with Joint Commission protocols and would, thereby, endanger their accreditation.

Finally, there is a real concern that more is not always better. Checklists are important safety tools; they are inexpensive, convenient tools that serve as reminders and records of the completion of critical steps in complicated procedures. Their employment in industries from aviation to healthcare is a testament to their

effectiveness. However, adding another checklist to the surgical environment may result in the unintended consequence of desensitizing surgical team members to the importance of the tasks contained on the checklist. Building redundancy into critical systems is vital but can be overdone and, in this scenario, any mandate for the use of the WHO checklist may harm the system, thereby ultimately decreasing patient safety. As discussed at the November 4th meeting, quantitative compliance through a mandate does not necessarily result in qualitative improvement in patient care, as demonstrated by the rise in wrong site surgery incidence since the mandated implementation of Joint Commission Universal Protocol.

We strongly encourage the AHRQ to carefully weigh any perceived benefits from the WHO checklist against the possibility of harm to functional systems. Implementation of protocols that do not have a track record of a measured positive effect on patient care should be reconsidered for change or removal. The AAOS believes the improvement of existing programs is a more beneficial use of healthcare resources.

Mandating this program and adding four minutes to each of the 65 million operations done in this country annually without better data and insurance of qualitative implementation is not warranted. We believe compliance with the stated goals will occur by obtaining the buy-in of healthcare personnel prior to implementing it as a governmental mandate, preferably using existing and established systems. Thank you for considering the Academy's comments on the proposed implementation of the WHO Safe Surgery Checklist. We look forward to continued interaction with AHRQ to address these concerns.

Sincerely,



E. Anthony Rankin, MD
President, American Academy of Orthopaedic Surgeons

¹ Facts about Hospital Accreditation. Retrieved October 25, 2008 from http://www.jointcommission.org/AccreditationPrograms/Hospitals/AccreditationProcess/hospital_facts.htm.

² Healthcare Facilities Accreditation Program Patient Safety Initiatives. Retrieved October 25, 2008 from https://www.do-online.org/pdf/acc_hfpatientsafetyinitiatives.pdf.

³ Friedberg RC, Jones BA, Walsh MK (2002). Type and Screen Completion for Scheduled Surgical Procedures: A College of American Pathologists Q-Probes Study of 8941 Type and Screen Tests in 108 Institutions. *Archives of Pathology and Laboratory Medicine*: 127(5), 533-540.

Appendix

Figure 1.

WHO Checklist Item	AAOS	Joint Commission	North American Spine Society
Patient confirmed identity, site, procedure, and consent	✓	✓	✓
Site marked/not applicable	✓	✓	✓
Anesthesia safety check completed		✓	
Surgeon, anesthesia, nurse verbally confirm patient, site, procedure, position	✓	✓	✓
Antibiotic prophylaxis given in last 60 minutes	✓	✓	
Essential imaging displayed	✓	✓	✓

Figure 2.

<p>American Academy of Orthopaedic Surgeons “Wrong-Site Surgery” – www.aaos.org/about/papers/advistmt/1015.asp “Recommendations for the Use of Intravenous Prophylactic Antibiotics in Primary Total Joint Arthroplasty” – www.aaos.org/about/papers/advistmt/1027.asp</p> <p>North American Spine Society Sign, Mark & X-ray (SMaX): Prevent Wrong-Site Surgery – www.spine.org/Pages/PracticePolicy/ClinicalCare/SMAX/Default.aspx</p> <p>The Joint Commission Universal Protocol – www.jointcommission.org/PatientSafety/UniversalProtocol/</p>
