

Second Wrong Site Surgery Summit – February 23, 2007

"Performance of the Correct Procedure at the Correct Body Site"

Statement of the Problem

Wrong site, wrong procedure and wrong person surgeries are sentinel events (an unexpected occurrence involving death or serious physical or psychological injury) that The Joint Commission tracks through its voluntarily reported Sentinel Event Database. The occurrence of these particular events – as reported to The Joint Commission - persists as a problem at the current rate of 5-8 new cases per month and recently became the most frequently reported sentinel event in the database (nearly 550 events reported since 1996). Similarly, persistence of this patient safety issue is well recognized in those states with mandatory reporting systems for medical errors that include wrong site surgery. These infrequent, though not rare, occurrences provide an important opportunity for better understanding the complexities involved in achieving organizational and professional cultural change that may be relevant to the resolution of other patient safety issues.

Persistence of the Problem

The launching of the Joint Commission's Universal Protocol (described below) in July 2004 was followed by a sustained increase (not decrease) in the number of reported cases of wrong site surgery in the United States. This may simply be a reflection of expanded reporting, but the fact remains that the apparent incidence and frequency of this problem is not decreasing.

Recognizing the significance of this persistent problem, The Joint Commission convened a second Wrong Site Surgery Summit in February 2007. This follow-up Summit sought to objectively review experience to date with the Universal Protocol, to examine the barriers to achieving consistent compliance with the performance expectations set forth in the Universal Protocol, and to explore other potential strategies for eliminating wrong site surgery. Over 50 organizations participated in the Summit, which was co-convened with following organizations:

- American Academy of Orthopedic Surgeons
- American College of Physicians
- American College of Surgeons
- American Dental Association
- American Hospital Association
- American Medical Association
- Association of Operating Room Nurses
- Partnership for Patient Safety

Principal Components of the Universal Protocol

The Universal Protocol was the product of the first Wrong Site Surgery Summit that convened in 2003, and consists of the following components:

- A pre-procedure verification process to confirm the details of the procedure.
- Marking of the operative/procedure site with an indelible marker.
- Taking a 'time out' with all team members immediately before starting the procedure.
- Adaptation of the requirements to all procedure settings, including bedside procedures.

Summary of 2007 Summit Discussions

Consensus on the following points reached at the 2007 Summit:

- That the Universal Protocol is effective if properly implemented and consistently followed.
- Further refinements to and elaboration of the Universal Protocol to make it most directive (i.e., prescriptive). This may require the establishment of something akin to a “Standardized Universal Protocol” that details expected process steps.
- There should be “zero tolerance” for failure to follow the Universal Protocol as a short-term goal, and that the long-term goal should be zero tolerance for these sentinel events.
- It needs to be made clear that the Universal Protocol applies to all types of procedures in all types of procedure areas. These include the administration of regional anesthetics and radiological interventions.
- Consideration should be given to a campaign-like strategy for improving the adherence to the Universal Protocol. This campaign should seek to engage both the medical community and the general public.
- Professional societies need to play a stronger role in promoting compliance with the Universal Protocol and advocating for related concepts such as care process re-design and teamwork.
- There exists a general misperception that time pressures are a hindrance to compliance with the Universal Protocol. There are no data to support such an assertion.
- Effective organization management of this issue requires local ownership of changes in relevant policies and procedures and active engagement by the CEO and the Board.

Other Salient Discussion Points

- Cultural transformation occurs over years and/or decades (generations).
- There should also be zero tolerance for disruptive behaviors among all care-givers.
- Autonomous performance should be discouraged, and inter-disciplinary team performance with mutual accountability should be encouraged.
- Confirmation bias and behavioral automaticity in the use of checklists are barriers to improvement processes and should be recognized as such.
- Effective methods of direct observation and measurability of success are still required that are effective across settings and institutions. These should include attention to “near-misses and good catches” in order to maximize learning opportunities.
- The multiple systems and processes active in operative/procedural environments such that a “stop the line” mentality should be encouraged.
- Demonstration of the business case and for patient safety and its return on investment are still needed.

Original Development of the Universal Protocol

The Joint Commission had previously issued two Sentinel Event Alerts on the subject of wrong site surgery. The first was published in 1998, and the next was published in 2001. In response to continuing reports of wrong site, wrong procedure and wrong person surgery, The Joint Commission determined that it had been essential to bring together the key organizations that might have roles in efforts to prevent wrong site, wrong procedure and wrong person surgery.

On May 2003, The Joint Commission hosted a Wrong Site Surgery Summit, with the goal of obtaining consensus on the adoption of a “universal protocol” for preventing wrong site, wrong procedure and wrong person surgery. The Summit was hosted by The Joint Commission in collaboration with: American Medical Association, American Hospital Association, American College of Physicians, American College of Surgeons, American Dental Association, and American Academy of Orthopedic Surgeons. The leaders of more than 30 other professional groups participated in the Summit. Summit participants agreed that a universal protocol would help prevent the occurrence of wrong site, wrong procedure and wrong person surgery; that the protocol should be specific, so as to eliminate confusion about site-marking and facilitate communication among surgical team members; and that it should provide the flexibility needed for unique surgical situations.

The Joint Commission pursued broad consensus on the draft of the Universal Protocol in order to assure that it would be relevant and applicable to a broad range of practitioners and settings. The public comment period generated more than 3,000 responses from surgeons, nurses and other health care professionals, which were overwhelmingly in support of the Universal Protocol. The comments also provided the basis for a number of refinements to the Protocol. The final [Universal Protocol and its Implementation Guidelines](#) are available on the Joint Commission website. Following approval by the Board, The Joint Commission sought and received endorsement of the Universal Protocol from over 50 leading professional associations and organizations.

The Universal Protocol became effective July 1, 2004 for all accredited hospitals and ambulatory care and office-based surgery facilities. Compliance with the Universal Protocol is assessed during Joint Commission accreditation surveys.

Excerpts from the 2007 WHO Alliance for Patient Safety Solution: *Performance of the Correct Procedure at the Correct Body Site*

The following strategies should be considered by WHO Member States:

1. Establish the performance of correct surgery at the correct body site as a health-care facility safety priority that requires leadership and the active engagement of all frontline practitioners and other health-care workers.
2. Ensure that health-care organizations have in place protocols that:
 - Provide for verification—at the pre-procedure stage—of the intended patient, procedure, site, and, as applicable, any implant or prosthesis.
 - Require the individual performing the procedure to unambiguously mark the operative site with the patient’s involvement, to correctly identify the intended site of incision or insertion.
 - Require the performance of a “time-out” with all involved staff immediately before starting the procedure (and the related anesthetic). The time-out is to establish agreement on the positioning of the intended patient on the procedure table, procedure, site, and, as applicable, any implant or prosthesis.
3. Member States should also consider:
 - Monitoring the ongoing frequency and incidence of wrong site procedures as part of voluntary reporting systems.
 - Using any incident reports to promote multidisciplinary collaborations to promote systems-based change in all procedure areas.

Applicability

- Hospitals, ambulatory care facilities, and office-based surgical facilities.

Opportunities for Patient and Family Involvement

- Involve patients at all points in the preoperative verification process to reconfirm with the procedure staff of their understanding for the planned procedure.
- Involve patients in the surgical site marking process, whenever possible.
- Discussion of these issues during the informed consent process and confirmed decisions at the time of signature for the consent.

Potential Barriers

- Lack of surgeon “agreement” to the standardized approach and difficulty to change the culture.
- Failure to recognize risks in procedural settings other than the operating room.
- Reluctance of nurses and other staff to question the surgeon when a possible error is identified.
- Inadequate human resources and knowledge for facilitating processes to be challenged.
- “Automatic” behavior during the time-out process (“going through the motions” but without meaningful communication).
- Insufficient generally accepted research, data, and economic rationale regarding cost-benefit analysis or return on investment (ROI) for implementing these recommendations.

Risks for Unintended Consequences

- Inconsistent interpretation of an “X” marking to “operate here” versus “do not operate here”.
- Inconsistency of Universal Protocol procedures among several hospitals within a geographic area, staffed by the same surgeons operating at more than one of the hospitals.
- Permanent tattooing of immature skin (premature infants).
- Perception of increased workload by staff and decreased efficiencies.