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SPECIAL FEATURE

SMaX: Early Data and Practical Applications

As part of our patient safety initiative, the North American Spine Society (NASS) introduced the Sign, Mark & X-ray (SMaX) program at the 17th Annual Meeting in Seattle, Washington, October 2001. This program, discussed in detail below, is intended to help reduce the incidence of wrong-site spinal surgery.

Awareness of the need for such a program comes from several sources. One source is the Institute of Medicine and its highly publicized report, *To Err is Human*,¹ which suggested that alarming numbers of complications and deaths occur in US hospitals as the result of medical errors. A second source has been the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO has established reporting of certain medical errors and has deemed these errors to be “sentinel events.” Reporting a sentinel event to JCAHO triggers the need for appropriate follow-up reporting by all involved and documentation of corrective actions.² Wrong-site surgery is considered a sentinel event and accounted for 15% of all sentinel events studied by JCAHO in 2002.³ And finally, the lay press has taken an increased interest in such catastrophic events as wrong-limb amputation and is increasingly reporting them to the public. This increased attention suggests, rightly or wrongly, that the incidence of wrong-site surgery may be increasing.

The AAOS Experience

The American Academy of Orthopaedic Surgeons’ (AAOS) Task Force on Wrong-Site Surgery, developers of a *Sign Your Site* wrong-site surgery prevention program,⁴ found that little hard data existed on the incidence of wrong-site surgery in 1998. The information

available came from malpractice carriers and either recorded the number of lawsuits filed over various periods of time, the number of lawsuits per the number of insured physicians or the number of lawsuits across geographic areas. This data surely underestimated the problem because many patients who experience a wrong-site surgery do not sue their physicians. However, the information available was meaningful. Wrong-site surgery claims accounted for only 1.8% of all malpractice claims for orthopedic surgeons and the average payment per closed event was less than half the payment for all other orthopedic claims. This was because in 70% of the cases, the wrong-site surgery resulted in no functional impairment. More disturbing, however, was the fact that the majority of malpractice claims involving wrong-site surgery were found to be indefensible and almost always resulted in a loss. Furthermore, this insurance data suggested that in an average 35-year career, one out of four orthopedic surgeons will operate at a wrong site.⁵

Several factors were repeatedly found to be involved in cases of wrong-site surgery. General anesthesia was almost always involved. The surgeon was often not in the operating room during the preoperative preparation or during induction of anesthesia. If present, the surgeon was often rushed or in a hurry. Finally, prone or lateral positioning of the patient after induction of anesthesia was disorienting to the surgeon and led to site misidentification at the time of incision. The AAOS Task Force concluded that, as is the case in most error-reduction programs, to prevent or significantly reduce the incidence of wrong-site surgery, two actions were



necessary:

1. Acknowledge that site misidentification will occur in the best of conditions.
2. Design a system that will allow identification of the error before surgery is begun and correct it.

The Task Force's goal was to design a system that was simple, reliable, not intimidating to the patient and resulted in the entire operating room (OR) staff being able to easily identify the operative site. The thrust of the AAOS program was to educate surgeons and their OR staffs to review the operative procedure with the patient prior to surgery, review the patient's chart in the operating room with the patient and staff and sign the operative site in indelible ink with the surgeon's initials prior to prepping the site.

The NASS Program

The relative lack of laterality of the axial skeleton and presence of multiple, similar levels, often indistinguishable even on open exposures, present uniquely different problems of site identification to the spinal surgeon. The data on wrong-site surgery in the spine is even sparser than in limb surgery. The largest study to date was a retrospective study of closed malpractice claims that focused on 11 cases.⁶ In this series of simple, one-level discectomies for herniated nucleus pulposus, **all** claims were found to be indefensible. Surgery was performed one level higher than intended in 10 of the 11 cases. It seemed to occur because of over-reliance on unreliable techniques to identify and mark the level. Two communication issues were repeatedly identified in these cases:

1. Failure to involve the patient in site identification.
2. Incomplete or inaccurate communication between surgical team members.

Additional risk factors have been identified as leading to wrong-site surgery: anatomical variations (especially at the lumbosacral junction), involvement of multiple surgeons, multiple procedures during the same anesthetic and time pressures.

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In response to the unique challenges of reducing wrong-site surgery in the spine, NASS introduced and recommended implementation of its SMAX program in 2001. SMAX stands for Sign your surgical site, Mark the intended level of intervention intra-operatively and X-ray the marked site to confirm during the procedure the correct level of surgery. To aid in accomplishing this improvement in patient safety, NASS proposed a checklist of seven items for the surgical team to complete:

1. Involve the patient in confirming the operative site either through informed consent or during the actual marking. The surgeon is encouraged to personally obtain the consent and the consent/operative permit should clearly state the site and side of proposed surgery and be shared with the patient, surgeon, anesthesiologist, assistant or scrub nurse and circulating nurse.
2. The surgeon should sign his/her name to the operative site with a marking pen when the patient is awake and aware in the operating room. Each member of the operative team should all verify the correct operative site prior to anesthesia.
3. Verify the correct patient is in the operating room and that the medical record and X-rays present are for that patient.
4. Each of the following should be checked against the signed site:
 - a. Medical record
 - b. Imaging studies marked left and right to prevent being placed on the view box backwards
 - c. Informed consent
 - d. OR/anesthesia record
5. Consider having the surgical assistant or scrub nurse always stand opposite the side where the primary surgeon stands.

6. Consider or suggest an intraoperative X-ray during the procedure, after exposure using markers that do not move to confirm the vertebral level to be operated. The X-ray should contain as much regional anatomy as possible with a marker as close to the intended disc space as possible – it is optimal to have both the surgeon and a radiologist read this film during the procedure and agree on the correctness of the level.

The use of the above checklist will assure correct implementation of the SMAX program and fulfill the goals of an appropriate system to prevent wrong-site surgery. In addition, the SMAX program provides patients with a Take Home Diagnosis Diagram that provides an educational and preventive component. The take home sheet provides a diagram for the physician to outline the site(s) of pathology to the patient during office discussions. It provides space to specify the differential diagnosis and plan of treatment (including the side and levels of any proposed surgery). The patient can share this summary of the office visit with other health care providers such as physical therapists. When brought to surgery, the handout serves as an additional check of side and level to avoid wrong-site surgery.

When a new process is suggested to improve patient safety, a cycle of quality improvement is initiated. In this cycle, a problem is identified by collecting data on the safety problem such as wrong-site surgery. A process is proposed to remedy the problem, such as the SMAX program. The process is then implemented. Finally, the effect of the process on the problem is assessed with further data collection to close the circle. If the effect on the problem



is not satisfactory, the process is modified and another circle of quality improvement is initiated.

The Canadian Data

NASS' SMAX program is too new to evaluate its impact on the incidence of wrong-site spinal surgery nationally at this time. However, some preliminary data available from two sources suggest this type of program is having a positive impact. The first group of data comes from the Canadian Orthopedic Association (COA). In an article published in the February/March 2002 COA Bulletin, note was made of two similar position papers published in the Canadian literature: *Wrong Sided Surgery in Orthopedics* and *Wrong Level Spinal Surgery*. These two papers also recommended initialing the operative site prior to surgery. The Canadian national medical malpractice insurance carrier, the Canadian Medical Protective Association, has been collecting data on the occurrence of wrong-site surgeries since the publication of these two papers more than a decade ago. Their data, which is national in scope, shows a clear downward trend since 1987.⁷ Because it takes a prolonged period of time to institute this type of program on a national basis, these data are very encouraging.

A Real World Experience

A second source of data specific to wrong-site spinal surgery comes from my own hospital which instituted an SMAX program prior to its presentation at NASS in 2001. This program has now been in place for three years. The hospital is a 900-bed institution affiliated with the Baylor College of Medicine in Houston, Texas. It has 40 operating rooms and does over 2,400 spinal procedures a year. A sentinel event occurred in this hospital in 1999. In this event, a one-level fusion with internal fixation was performed at a wrong level in spite of an intraoperative X-ray with a marker on the spinous process read by the surgeon. The X-ray was not formally read by radiology until later in the day (after surgery) when the marker was then identified to be at the wrong level. Unfortunately, the surgery was

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already done.

The SMAX program was instituted at this facility in the year 2000 and remains in place today. Initiation of the SMAX program requires the cooperation of the surgeon, the OR staff, the radiology department and the hospital administration. The difficulties initially encountered in our hospital were in monitoring the process while assuring confidentiality, in achieving a high level of process compliance and bringing radiology "online."

The issues of monitoring the process and confidentiality were solved by having the Quality Improvement Committee initially review every spinal surgery chart and verify the presence of a note from radiology and an operative note that both noted the X-ray film and identified the same operative level. Information gathered by a hospital Quality Improvement Committee is protected from discovery in the state of Texas and thus confidential. Compliance was assured by educating the surgeons, operating room staff and anesthesia to be self-checking with each other as to the patient, procedure and site. The patient is directly involved in this process, which takes place in the operating room and no patient is anesthetized until all are in agreement. Compliance was further assured by feedback from the Quality Improvement Committee.

Finally, obtaining timely reports from the radiology department presented difficulties because of their time demands. It was not possible or realistic to have a radiologist come to the operating room and consult with the surgeon for each surgery. But it often proved difficult even to get a report phoned to the OR before the case was closed. This problem was solved by implementing a digital imaging system and

the hospital administration's demand that radiology give a real time reading for this type of X-ray. Both the radiologist and the surgeon discuss their interpretation of the operative level by intercom before either commits to a reading.

Since implementing SMAX at our institution, surgeon compliance has gone from 60% to 100%. Compliance continues to be monitored by chart sampling. At least five sentinel events have been avoided by this process. The radiologists, surgeons and OR staffs have all become a part of this process and it is now part of the "culture" of our operating room.

Copies of the NASS Sign, Mark & X-ray program are available online at <http://www.spine.org/smax.cfm> or by contacting the NASS office at (708) 588-8080.

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