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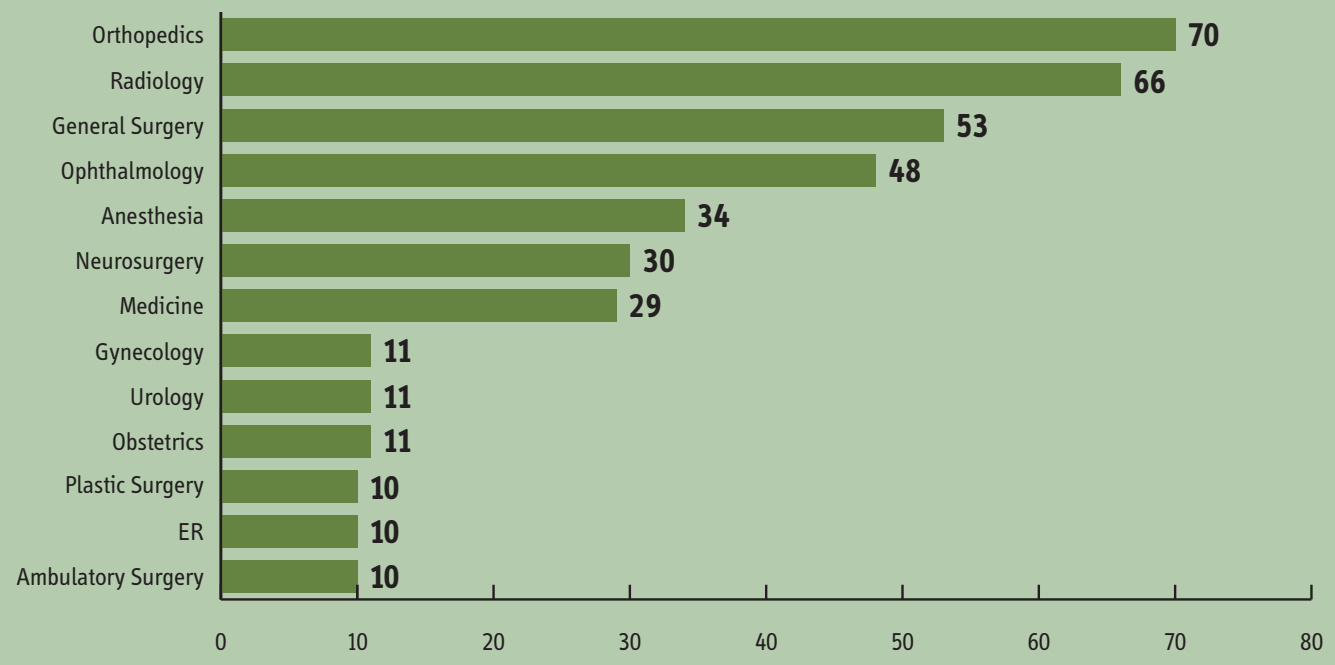
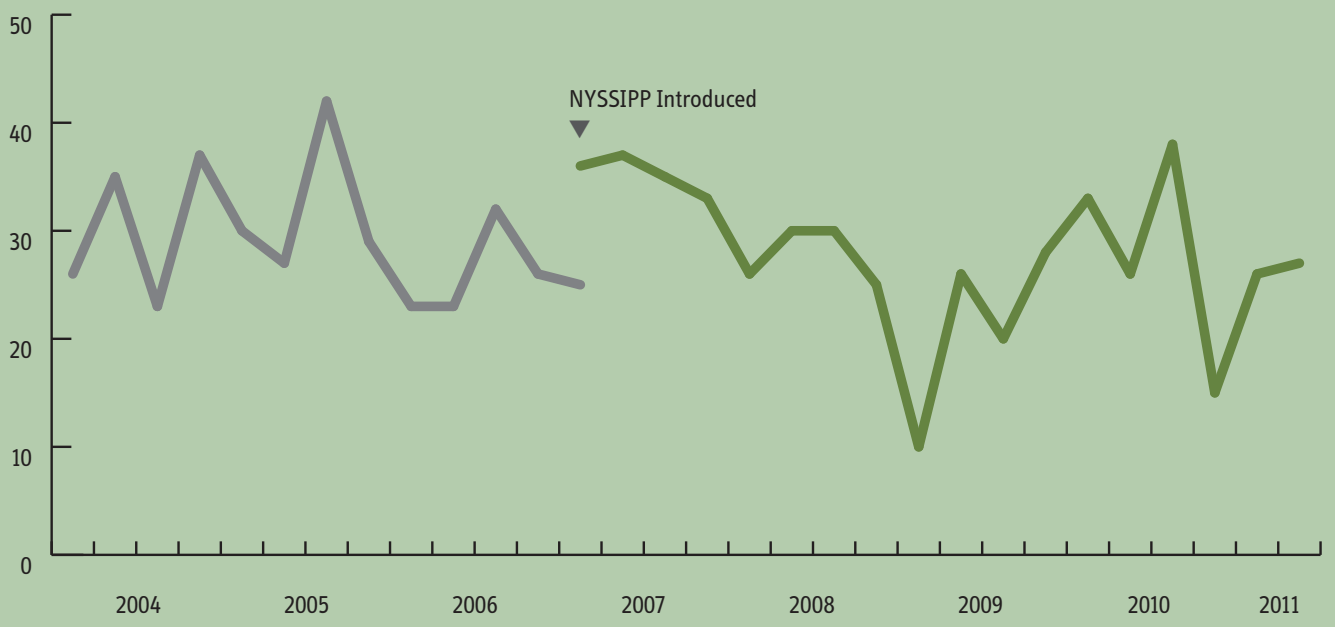
Wrong Surgery Dashboard

Services Most Often Reported with Errors Related to Surgery and Other Invasive Procedures in NYPORTS, New York State, 2007-2010



Number of Errors Related to Surgery and Other Invasive Procedures Reported to NYPORTS by Quarter, New York State, 2004-2010



Is That Right? When Surgery Goes Wrong

The New York State Surgical and Invasive Procedure Protocol, when followed in its entirety, lessens the likelihood of wrong side, wrong site and wrong patient procedures being performed

INTRODUCTION

In the realm of patient safety, perhaps nothing terrifies – and outrages – the public more than serious, yet avoidable surgical errors, such as surgery performed on the wrong anatomic site, the wrong side, or even the wrong patient. Surely there must be systems in place to prevent these catastrophic mix-ups, they wonder, and rightly so.

Indeed, hospitals and providers have made great efforts to prevent mistakes and improve patient safety. One way to prevent errors is to make processes uniform from one patient to the next; thereby assuring that the same degree of checking is done for each patient. In 2003, for example, the Joint Commission's Universal Protocol was implemented to prevent precisely these types of adverse events in surgery, often called WSS events (wrong-side, wrong-site, wrong-person and wrong-implant). Here in New York State, a more extensive protocol was adopted in 2007. The New York State Surgical and Invasive Procedure Protocol, or NYSSIPP, was developed in response to what appeared to be a steady trend in WSS events over time. Yet despite the standardized protocols, practices used presently have not eliminated what we believe are entirely preventable surgical errors.

The New York State Department of Health monitors WSS events occurring in hospitals using reports and root causes analyses (RCAs) submitted to the New York State Patient Occurrence Reporting and Tracking System (NYPORTS). One goal of WSS reporting is to create a body of information that can be used to identify the causes of harmful events and direct, if necessary, corrective actions, ultimately reducing their incidence. We believe that by sharing WSS information with hospitals, ambulatory surgical centers and others statewide, facilities and practitioners will be able to identify potential problems within their own systems and take proactive steps to prevent errors before they occur.

This report provides an update on WSS surgical cases in New York State. Based on 148 WSS occurrences reported to NYPORTS in 2008-2009 (radiology cases excluded), it describes three cases studies, discusses factors identified in RCAs, and highlights risk reduction strategies implemented by facilities reporting occurrences. Fortunately, more than 80% of WSS-reported events did not result in significant harm to the patient. However, 15 patients were determined to have experienced permanent harm that was moderate to severe in nature – harm that could have and should have been prevented.

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Is That Right? When Surgery Goes Wrong *(continued)*

WHAT WENT WRONG...

WSS events are not limited to the operating room; patients undergoing an invasive procedure anywhere in a facility – from the ER to the bedside – are at risk. That said, errors are most common in settings where patients are most likely to undergo invasive procedures: the operating room (OR) (98 occurrences), specialty procedure areas, such as the endoscopy suite (27 occurrences), and lastly, on patient floors/at the bedside (20 occurrences). The proportion of occurrences was evenly distributed among inpatients and outpatients. In three quarters of the procedures in which errors were made, the procedure was completed before the error was detected. And in nearly two thirds of all reports, some element or multiple elements of the NYSSIPP standard of care was not followed.

...IN THE OPERATING ROOM

Five types of surgery accounted for nearly 70% of the 98 reported cases from the operating room: orthopedic surgery on joints of the limbs (shoulders, elbows, knees and hips) (23%), spinal surgery (12%), ophthalmology (12%), hand or digit surgeries (10%) and gynecologic surgeries (9%). Of all the different types of errors that can occur, the most common, accounting for 62% of the cases, were surgeries on the wrong body part – either the wrong side of the body – left versus right (39 occurrences) – or the wrong site, such as the wrong vertebrae of the spine (11 occurrences) or wrong finger of the hand (4 occurrences). Surgeries that involve implanting a device are at risk of errors in the type of device implanted, such as the wrong lens in ophthalmology (11 occurrences) or the wrong orthopedic implant (5 occurrences). There was also one occurrence of the wrong implant in a breast reconstruction.

A more complicated scenario is when the patient had the wrong type of procedure. There were 20 occurrences that were considered the wrong procedure. About half of these had misdiagnosis identified as a root cause, including six surgeries scheduled to remove organs that had previously been taken out (four cholecystectomies, one hysterectomy, and one appendectomy), one misdiagnosis of ectopic pregnancy, one misdiagnosis of an ovarian cyst, and one miscommunication between pathology and the OR resulting in an additional biopsy procedure being performed that was later found to be unnecessary. The remaining ten wrong procedure errors were split between intra-operative errors related to the extent of the surgery (performing an additional salpingo-oophorectomy when only a hysterectomy was intended) and pre-procedural errors originating in scheduling, consenting, verification or "time-out" that resulted in the wrong surgery (performing a trans-abdominal hysterectomy when the patient consented to a trans-vaginal procedure).

Another important characteristic of the reported errors was how far a surgery/procedure progressed before the error was detected. Out of the 98 occurrences, 20 were detected after administration of anesthesia (usually regional anesthesia blocks) but before the initial incision for the intended surgical procedure was made; 10 were detected after the initial incision; in 8 cases, a partial procedure was performed; and in 60 cases the error was not detected until the wrong surgery/procedure was completed.

...IN SPECIALTY PROCEDURE AREAS

As was the case with errors in the OR, we found a broad distribution in the *kinds of errors* occurring in specialty procedure areas, again split between errors involving the wrong body part versus errors involving the patient or procedure type. All patients with errors involving the wrong body part were outpatients: six involved

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removal of the wrong tooth in hospital-based dental clinics, three involved wrong side regional blocks in pain management clinics, and two were a biopsy of the wrong lesion in outpatient surgery. Four wrong patient/wrong procedure errors involved the endoscopic suite, four involved radiology or interventional radiology, and one was in obstetrics.

...AND ON PATIENT UNITS OR AT THE BEDSIDE

The placement of central/PICC lines, chest tubes, and thoracentesis led to nearly three quarters of the errors reported from this setting (70%). Out of 23 cases, five involved wrong-patient errors; another six cases were reported for wrong-procedure; and 12 cases entailed wrong-side errors. In the majority of these cases, the procedure was completed before the error was detected.

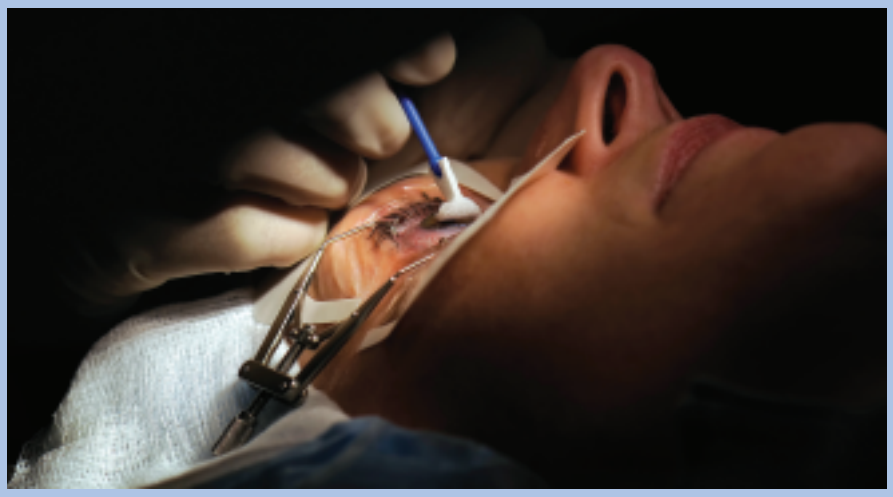
Case 1

CAN YOU SEE ME NOW? WRONG STRENGTH LENS PLACEMENT

"An elderly man was admitted for cataract extraction and insertion of an intraocular lens. During the procedure, the surgeon determined that a different strength lens than the one originally planned would be needed. The surgeon asked the circulating nurse to go to the cabinet where the lenses were stored and verbalized the required lens strength. In the process, two digits were transposed: 25.0 diopters versus 20.5 diopters. Subsequent communication between the surgeon and circulating and scrub nurses did not include read back to confirm the strength of the lens before its insertion. The error was detected when the surgeon was updating the patient's chart after the procedure was completed. The patient was still in the operating room, so the surgeon was able to remove the incorrect lens and implant the intended one with no long term harm to the patient."

Ophthalmologic surgeons occasionally need an alternative lens during surgery, for example when complications necessitate changing from posterior to anterior chamber placement. But risk of error can be reduced with pre-procedural planning, verification and effective intra-operative communications. In this occurrence, the RCA team identified two overarching issues that could be addressed in their policies:

- Lens availability: The facility expanded their intraocular lens policy to include requirement for the surgeon to order three lenses before the surgery (posterior chamber lens for capsule fixation and sulcus fixation as well as one anterior chamber lens) and for those three lenses to be present in the OR pre-procedure the day of surgery. This way the availability of the correct implants is verified during the surgical "time-out."
- Communication: The facility also expanded their policy to require the use of active communication to validate that the correct lens is being handed off during the procedure. The scrub nurse repeats the lens strength requested by the surgeon and waits for verbal read back of the strength by the surgeon before proceeding. The circulating nurse also confirms with the scrub nurse before opening the package.



Eleven of the twelve ophthalmologic surgeries we reviewed concerned a wrong implant or lens. In addition to issues related to intra-operative changes in lens and the availability of alternative lenses, several occurrences involved implanting lenses intended for other patients. These root causes included having more than one patient's lens in the operative room at a time, or using the wrong patient's chart during the verification process due to having multiple charts present.

Other root causes related to pre-procedural verification of the lens strength included not cross checking the strength when the initial order is filled, not using the correct scanner settings, and not having the medical chart for verification on day of procedure. The risk reduction strategies for many of these root causes boil down to better adherence to NYSSIPP. For example, NYSSIPP specifies actual review of relevant documentation prior to the start of surgery.

Pre-procedural planning can also help reduce risk in orthopedic implant surgery, where the complexity of the

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Is That Right? When Surgery Goes Wrong *(continued)*

components and frequent emergence of new products/technologies demands extraordinary vigilance during the verification process. There exists, at the very least, the potential for errors as operative staff must continually familiarize themselves with new components. In one knee replacement case, for instance, four people checked the various components, focusing on correct side, size and thickness. Unfortunately, a meniscal bearing component, a polyethylene liner, came in several thicknesses, which was not checked, so the small-size liner implanted in the patient did not match the medium-sized femoral component.

Case 2

WHY CAN'T I FEEL MY LEG? WRONG SIDE REGIONAL BLOCK

"A young adult male was scheduled for anterior cruciate ligament repair of his left knee in the ambulatory surgery suite. Appropriate consents were signed on the day of surgery, and the left knee was initialed by the surgeon. The patient was brought into the operating room and prepped for a femoral nerve block, which was to be placed before the surgery for the purpose of postoperative pain management. The anesthesiologist entered the room and proceeded to the right side of the bed, where the ultrasound machine had been set up for the block. After the block was administered, the patient asked why his right leg was numb, instead of the left, and at this point the team realized the wrong leg had been blocked. The error necessitated an unplanned overnight admission to the facility."

In the root cause analysis, the facility identified a few gaps in their policies for regional blocks:

- Site marking: Because regional blocks are invasive procedures, all elements of NYSSIPP should be followed, including site marking and "time-out," Eighteen of the wrong side events reported to NYPORTS were wrong side regional blocks, and most RCA teams reported ineffective policies or not adhering to procedures regarding marking and "time-out" prior to the blocks. In this occurrence, the facility created a Regional Block Protocol that included marking and "time-out" requirements and made a video of the correct procedure to be used for ongoing reinforcement.
- Communication: The anesthesiologist, who stepped into the room just prior to the block, assumed the ultrasound was set up on the "correct" side of the bed, and initialed the pre-op verification paperwork. The anesthesiology team nurse, who had stepped out of the room for a minute just prior to the block, looked at the paperwork and assumed that the "time-out" had been done in her absence. The team, working like a well-oiled machine, forgot to actually talk to each other. The facility implemented TeamSTEPPS training (http://teamstepps.ahrq.gov/) for the anesthesia team, and leadership took an active role in reinforcing both policy and teamwork.

Good communication can help prevent errors in many ways. Consider, for example, an error made while scheduling surgery, but not detected at subsequent checkpoints – at least in part because facility practice was to use the scheduling book to create the consent form, pre-procedural verifications, etc. In fact, several NYPORTS RCA teams reported occurrences related to errors in scheduling, when communication breakdown between patient and provider during consenting did not catch the error. Of course, not all patients understand medical terminology or know the exact name of their intended procedure. Planned procedures may be modified too, sometimes several times. Patient pain, anxiety, or language barriers can confound comprehension as well.

Accuracy in scheduling requires the communication of exact clinical and demographic data between multiple sites, a back-and-forth process between providers that increases the potential for error. And while a hospital cannot control the actions of staff at physicians' offices,

it *can* control what information comes in, with systems to identify potentially incomplete information, or details not likely to be specific enough. A facility should examine the entire surgical system – from scheduling to "time-out" – to reduce the points at which errors may be perpetuated from one process to another. Pay special attention to steps that call for active communication practices between patients and providers, such as verifying patient identification with two unique identifiers. An up-and-down nod isn't enough.

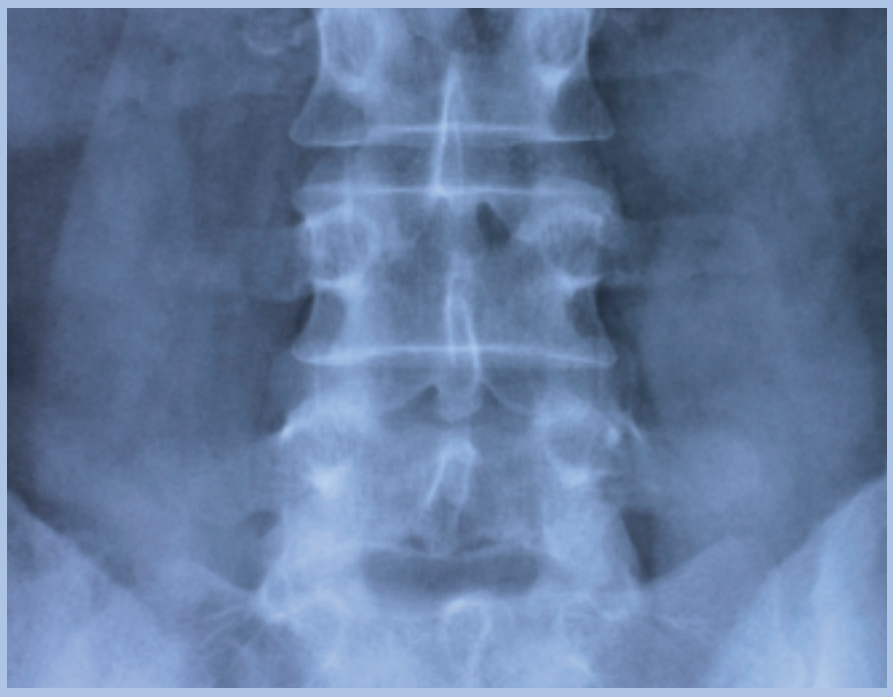
Case 3

WHY IS IT STILL NUMB? WRONG LEVEL SPINAL SURGERY

"A middle-aged female with lumbar stenosis at L4-5, complaining of lower extremity numbness, was admitted for spinal decompression. In the holding area, the surgeon reviewed imaging studies and marked the patient's back at the appropriate surgical level. During the procedure, the surgeon placed clamps on the spinal processes of L4-L5 and used intra-operative fluoroscopy to confirm the levels. Satisfied the level was correct, the surgeon removed the clamps and the procedure proceeded. An uneventful post-operative course followed. At her follow-up visit, lumbar spine X-rays revealed the patient was status post L3 laminectomy, with degenerative disease at L4-L5 and L5-S1."

Surgeries associated with the spine continue to present unique challenges. In wrong level spine surgeries, a variety of factors – congenital variations, co-morbidities, or extensive disc pathology at multiple levels – can make it difficult to identify and confirm the correct spinal levels, even when intra-operative imaging is used.

- Intra-operative marking: The above-referenced hospital noted in their RCA that as spinal surgeries become less invasive, with smaller operative incisions, it is harder for surgeons to identify correct levels without the use of permanent markers. In this occurrence, where the proper level had been confirmed by imaging and intra-operative markers, hospital policy did not expressly stipulate how to verify the operative spinal level once markers were *removed*. The revised spine surgery policy states that before an intra-operative marker can be removed, a permanent mark (e.g. cutting a burr hole) must be made on the posterior element of the correct spinal level and/or marking the skin at the level where the marker was placed.
- Technology limitations: Wrong level spinal cases can stretch the limits of available technology, particularly when patients present with singular challenges like spinal deformities and/or co-morbidities, such as osteoporosis or obesity. Facilities have turned to a variety of methods to address these overarching issues. One hospital makes special fluoroscopic equipment and/or a radiologist available for immediate consultation in the operating room.



It is, in fact, part of the spinal surgery booking process to ask if a surgeon would like one or both of these services. Another hospital purchased additional cabling so that data ports in the operating room would be capable of sending 'real time' images to the Radiology Suite, further supporting the availability of radiologist interpretation of films or fluoroscopy taken during surgery.

Human error was also identified as a frequent root cause of wrong spinal level events. In a number of cases, RCA teams found that pronounced pathology and/or deformity may have contributed to surgery at an unintended level, the result of miscalculation/miscounting of involved vertebrae. In one case, for example, difficulty in visualizing the disc space between two vertebrae led to an incorrect interpretation of the radiology. In another, marked osteopenia made X-rays difficult

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to interpret. Some hospitals have put new practices in place to bypass human errors like these. Following an adverse event, one facility realized they lacked a standardized process for identifying correct spinal level. This led them to investigate the pros and cons of several different methods: a single clamp; dual clamps above and below the level; and use of a needle to directly enter the site. Then they defined best practices for marking and verification of the spinal levels, and developed a standardized process. Another hospital initiated the practice of ordering a preoperative plain anteroposterior (AP) and lateral spine film where the vertebral bodies are marked by a radiologist to provide a visual landmark for the neuro-surgeon to use as a contrast when completing the intra-operative marking radiographic views.

CONCLUSION

NYSSIPP was created in 2007 to expand upon the Joint Commission Universal Protocol in an effort to further reduce the occurrence of WSS events. Since its implementation, the department has evidence that the number of some types of WSS cases reported to NYPORTS has decreased, especially the number of incorrect invasive procedures, although the role of NYSSIPP in this decline is not fully known. Even so, we believe root causes analyses have much to teach us about factors that contribute to these unfortunate events and how improvements might be made.

It is our hope that this report will catalyze facility leadership to evaluate adherence to the NYSSIPP standard of care, and consider the need to implement additional risk reduction strategies in their institutions. The findings of this review support the conclusion that if you apply the protocol completely, you *can* make a difference.

FACILITIES CAN...

- As with all areas of patient safety, effective communication is needed to prevent adverse surgical events. In particular, patient-provider misunderstanding during consenting or patient identification was identified as a root cause in several events. As part of promoting a culture of safety, *facilities can* identify opportunities to improve communication skills and provide communication aids when needed.
- Many RCA teams discovered that policies and procedures were not in compliance with NYSSIPP. *Facilities can* review their policies and procedures to assure that all elements of NYSSIPP are addressed.
- Rapidly changing technology and unfamiliarity with new equipment may contribute to errors, but *facilities can* identify and mitigate this risk proactively – for instance, by addressing equipment and technology issues during pre-op verification or making understanding of equipment a question to be addressed at the "time-out."
- Some errors occur after the pre-operative "time-out." NYSSIPP specifically addresses intra-operative marking for spine surgery, but *facilities can* evaluate the potential for an intra-operative error for other procedures as well. If a case involves *choices* – i.e. several possible implants, or an anatomical choice between left and right – implement an intra-operative risk reduction strategy, such as a second intra-operative "time-out."
- Because regional blocks are invasive procedures, all elements of NYSSIPP should be followed, including pre-procedure verification, site marking and "time-out." *Facilities can* review their policies regarding pre-procedure verification, marking and "time-out" prior to regional blocks, and monitor adherence to procedures.

Identified Root Causes for WSS Events Reported to NYPORTS, 2008-2009 (N = 176)

Note: 1: These cases include radiology events (not described elsewhere in this report).
2: The characteristics of each event, listed under the major error groups, are not mutually exclusive. As such, they may not add up to the total.

WRONG PATIENT ERRORS (N = 33)

10 Patients had no identification performed

10 Had errors made in scheduling

8 Patients with similar demographics mixed up in identification or in order entering

7 Patients with sound alike names

5 Patients responded to wrong name or misheard name when called

6 Patients ID incorrect or ineffective (i.e. an alternate form of patient ID was used and failed)

5 Patients had incorrect procedure because mix-up in medical record or specimens

WRONG PROCEDURE ERRORS (N = 42)

11 Procedures had ineffective pre-procedure verification

12 Procedures had ineffective "time-out"

10 Procedures had an error made at the time of scheduling

11 Procedures had scheduling errors or the patient was consented to the wrong procedure

15 Procedures were incorrect due to diagnostic errors

- Pathology errors = 3
- Radiology/Imaging errors = 8
- Incomplete diagnostic work-up = 6

5 Procedures involved contrast when it was not ordered

6 Procedures were more extensive than indicated/consented

WRONG IMPLANT ERRORS (N = 14)

5 Implants were not verified prior to procedure

2 Errors were made because implants were not available when needed, and changes were not appropriately anticipated

3 Implants were mixed-up due to packaging issues such as small labels

8 Implant errors involved not performing verification or "time-out" prior to insertion during surgery

WRONG SITE OR SIDE ERRORS (N = 87)

Teams had inadequate "time-out" (N = 39):

- **10** Had no "time-out"
- **10** "Time-out" was incomplete or did not include the entire team
- **9** Had no anesthesia "time-out"
- **8** Did not have an intra-operative "time-out" when needed (for intra-operative marking or implants)
- **8** Did not use the films or they were not available during "time-out"
- **7** Did not use the medical record or it was not available during "time-out"
- **6** Did not stop other activity during "time-out"
- **6** Did not utilize active communication during "time-out"
- **4** Performed the "time-out" too long before the procedure
- **5** Did not have a visible site mark or it was not verified during "time-out"

Sites were inadequately marked (N = 25):

- **12** Did not have an anesthesia site mark
- **11** Did not mark the surgical site
- **13** Had errors in the intra-operative marking (for spine surgeries)
- **11** Had multiple marks
- **3** Had confusing or misleading marks
- **2** Had incorrect side or site marked
- **2** Needed an alternative mark
- **2** Patient was not involved in the marking process

13 Patients where the correct structure and/or laterality was not listed or was listed incorrectly during consent for procedure

9 Patients where the correct structure and/or laterality was not listed or was listed incorrectly during scheduling of procedure

11 Errors made in medical records/documentation/films that carried through to surgery

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