# The New York Model: Root Cause Analysis Driving Patient Safety Initiative to Ensure Correct Surgical and Invasive Procedures

Lawrence L. Faltz, MD, FACP; John N. Morley, MD, FACP; Ellen Flink, MBA;
Peg DeHont Dameron, BSN

## Abstract

Available data have not yet demonstrated a reduction in the incidence of wrong-patient, wrong-site procedures. In an effort to reduce these occurrences, a panel of experts was convened to update New York State's 2001 Pre-Operative Protocol. The panel analyzed 254 root cause analyses submitted to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) and reviewed the Joint Commission's Universal Protocol and the current literature. Emerging themes related to wrong procedure events included communications, team dynamics, patient identification, orientation/training, use of available information, site marking, "time out," and time pressures. The scope and specificity of the New York State Surgical and Invasive Procedure Protocol (NYSSIPP) are expected to reduce the incidence of procedural maloccurrences. NYPORTS provides useful information about systems errors and effectiveness of prevention strategies. This paper provides a model for other agencies interested in establishing protocols to reduce these preventable events.

## Introduction

Wrong-patient, wrong-side, or wrong-site surgical and invasive procedures, while unusual,[1] are the most obvious examples of systems failures in health care. Despite more than a decade of attention to these occurrences, the development of protocols by professional organizations,[2, 3, 4, 5, 6] State agencies,[7] the Veterans Health Administration,[8] and the Joint Commission,[9, 10] and the tasking of hospitals to implement systems under the Joint Commission's "Universal Protocol,"[11] events continue to be reported in undiminished numbers[12] in the operating room and in other clinical areas where invasive procedures take place. Whether improved reporting has contributed to this trend is not clear. Although a minority of these events result in significant harm to patients,[1] major injuries and death have been reported. In addition, they waste time, effort, and resources and bring discredit to health care providers.

The Institute of Medicine (IOM) report, *To Err is Human,*[13] recommended mandating and standardizing clinical error reporting systems in order to provide a body of information that can

be used for process improvement. Many States have mandatory error-reporting requirements, and the Federal voluntary reporting program[14] that is an outgrowth of IOM's recommendation is under development. In New York State, a mandatory reporting requirement was implemented in 1985 pursuant to State legislation designed to reduce medical malpractice. The reporting system has gone through several design changes to reach its present form as the New York Patient Occurrence and Tracking System (NYPORTS). Hospitals and diagnostic and treatment centers must report certain defined types of events, using standardized case definitions, via a Web-based system. Serious events warranting a root cause analysis (RCA) must be reported within 24 hours and the analysis completed within 30 days. Reports have been used to provide "best practice" examples to providers and to implement quality improvement projects.[15]

In January 2006, after a serious wrong-side surgery event at a New York hospital in 2005 and a review of recent NYPORTS adverse events, the New York State Department of Health convened the Procedural and Surgical Site Verification Panel with the goal of strengthening the State's 2001 guidelines. The 21-member panel comprised experts in their fields including: orthopedic surgery, neurosurgery, ophthalmologic surgery, ob/gyn surgery, general surgery, anesthesia, and radiology, as well as operating room (OR) registered nurses, certified registered nurse anesthetists, OR clinical nurse specialists, nurses, hospital association representatives, and attorneys. The Department of Health provided staff support to the committee.

The Panel analyzed wrong-site, wrong-side, and wrong-invasive-procedure cases meeting NYPORTS definitions from 2003 to 2005 to provide detailed information on actual events, causes, and corrective actions taken by hospitals to reduce future errors. They used a consensus process to develop the New York State Surgical and Invasive Procedure Protocol (NYSSIPP),[16] which sets a standard of care for New York hospitals and diagnostic and treatment centers. This protocol was released in September 2006 and is currently the standard of care for invasive procedures in New York State.

This paper describes the findings of the case analysis and how the details of the protocol were chosen in response to those findings.

## Methods

Hospitals in New York State are required to report wrong-side, wrong-patient, and wrong-procedure surgery and other invasive procedures to NYPORTS. Required information includes date, location, type of surgery/procedure, and other demographic data about the patient; a narrative description of the event; and an in-depth RCA with a report of corrective actions, including systems improvements and a literature search. These events fall into one of two NYPORTS codes (Table 1).

Between 2003 and 2005, 347 events were reported. All of the Code 911 cases and 2 years of Code 912 cases were analyzed by at least one nurse and one physician to ascertain causative factors and collect corrective actions. The distribution of causative factors was compared to data from the Joint Commission's Sentinel Event reporting process.

**Table 1. NYPORTS codes related to wrong-side, wrong-patient, and wrong-procedure surgery and other invasive procedures**

| | NYPORTS Code 911 | NYPORTS Code 912 |
|---|---|---|
| | **Wrong-patient, wrong-site surgical procedure** | **Incorrect procedure or treatment – invasive** |
| Definition | • Any procedure performed in the operating room or ambulatory surgery suite.<br>• Only include procedures that have proceeded to surgical incision. | • Invasive procedures are defined as those involving puncture or incision of the skin, or insertion of an instrument or foreign material into the body.<br>• Includes procedures performed in settings other than the OR. |
| Exclusions | • Occurrence with the administration of anesthesia only (Code as 912). | • Venipuncture for phlebotomy, diagnostic tests without contrast material. |

An expert panel was formed to consider the information and propose modifications to the Department of Health's existing guideline for site marking, consistent with the Joint Commission's Universal Protocol. The Committee met in person twice and communicated through weekly telephone conferences for several months to develop a protocol that would address the information provided by the case review. The Panel came to a consensus and created the New York State Surgical and Invasive Procedure Protocol,[16] which was published in September 2006. Hospitals and diagnostic and treatment centers across New York State were required to implement the protocol by March 2007.

## Results

In 2003, 2004, and 2005, 347 wrong-side, wrong-site, or wrong-procedure events were reported to the New York State Department of Health NYPORTS database. Each of these cases required that an RCA be performed and that corrective actions be implemented and monitored.

Of the Code 911 cases, 23 (44 percent) were wrong site, 27 (52 percent) were wrong side, and 2 (4 percent) were wrong patient. The most common wrong-site procedures were fingers (seven events) and spinal levels (seven events). The most common wrong-side cases were herniorrhaphies (three cases). The two wrong-patient cases were: (1) a lens intended for patient A was implanted into patient B after the sequence of patients

**Table 2. Cases reported**

| | 2003 | 2004 | 2005 |
|---|---|---|---|
| Code 911 | 9 | 21 | 22 |
| Code 912 | 93[a] | 104 | 98 |

a 2003 Code 912 cases were not analyzed

was changed from the original operative schedule, and (2) a resident placed a triple-lumen catheter into the wrong patient.

Of the Code 912 cases analyzed, 68 (34 percent) were wrong-procedure cases, 51 (25 percent) were wrong side, 33 (16 percent) were wrong patient, 29 (14 percent) were wrong equipment, and 21 (11 percent) were wrong site. These errors occurred in a wide variety of locations (Table 3).

**Table 3. Settings of Code 912 cases**

| Setting | N | % |
|---|---|---|
| OR | 75 | 37 |
| Radiology | 52 | 26 |
| Bedside | 20 | 10 |
| Interventional radiology | 15 | 7 |
| Endoscopy suite | 6 | 3.5 |
| Dental clinic | 6 | 3.5 |
| Dialysis | 5 | 2.5 |
| Emergency room | 5 | 2.5 |
| Delivery room | 3 | 1 |
| Other (clinic, NICU, ICU, PACU) | 15 | 7 |
| **Total** | **202** | **100** |

NICU = neonatal intensive care unit; ICU = intensive care unit; PACU = post-anesthesia care unit

Among cases reported from the OR, a number were due to inadequate or inaccurate historical information, such as a planned appendectomy in a patient whose appendix had already been removed and a planned inferior vena cava filter (IVC) insertion in a patient who already had a functional IVC filter. One patient had a partial mastectomy based on another patient's pathology report because of specimen mislabeling. Some intraoperative errors were reported under this code (e.g., wrong segment of colon connected to a colostomy).

Of the Code 912 cases, 19 were reported because of wrong-side administration of local or regional anesthetic, including blocks of the wrong shoulder (five), eye (five) and knee (femoral block, four). Wrong-equipment cases were primarily intraocular lenses (70 percent) or knee components (20 percent). Of the latter, two of the four cases occurred when the vendor representative handed the wrong component to the surgeon.

Code 912 cases frequently involved radiology. Almost half of the cases involved the incorrect procedure, sometimes varying widely from what had been ordered (e.g., MRI of head instead of an esophagram). However, the majority were due to different modalities in the same area (e.g., CT scans with or without contrast or different isotopes than what had been ordered). There were

15 cases in interventional radiology, six of which were wrong side, and three that were wrong site. Three patients had the wrong type of catheter inserted.

Of the 20 Code 912 errors in bedside procedures, eight were chest-tube cases (two wrong patient, six wrong side). In all cases, the pre-procedural verification had not been performed; in each case, other contributing root causes were identified. Of the remaining bedside cases, three involved infusion of the wrong medication into various body cavities.

The expert committee assembled to review the data derived from the RCAs, identified commonalities in the causes of the adverse events, and grouped them into categories (see list below). Some of the categories overlapped within cases. We noted that most Code 911 and Code 912 events had at least three root causes (suggesting a specific and direct causal relationship), as well as multiple contributing factors (e.g., "environmental conditions" increasing the chance of the adverse event). Complex cases had as many as 10 root causes. Findings in the New York State data were similar to those reported nationally to the Joint Commission.[10]

Common root causes of NYPORTS Code 911 and Code 912 cases, listed in no specific order, included:

- Communication failures.
- Inadequately designed procedures/systems.
- Noncompliance with existing procedures.
- Team issues: informal norms, hierarchy problems.
- Inadequate orientation and training.
- Inaccurate/incomplete scheduling information.
- Consent – availability, legibility, accuracy, and consistency with other documents.
- Incomplete history and physical.
- Inadequate patient identification and assessment.
- Inadequate pre-operative/pre-procedural verification process.
- Inconsistent, absence of, or unclear site marking.
- Room set-up, positioning, prepping, and draping variation.
- Lack of, or inadequate "time-out."
- Failure to have complete information available (x-ray, lab, or pathology reports).
- Failure to correlate available information.
- Production/time pressures, including case urgency.
- Lack of compliance monitoring of existing systems.

The committee also reviewed the corrective actions undertaken by each facility in response to their RCA. These fell into two general areas: (1) facilitating accurate communication, and (2) redesigning processes along the continuum of the procedural event. Many facilities lacked effective policies regarding patient identification and site marking, and policy violations were frequent. Corrective actions frequently involved strengthening the policy or policing it more

effectively, but the committee evaluated a significant number of detailed suggestions as it sought to create a protocol that encompassed as many "best practices" as it could. During its deliberations, the committee evaluated the relative safety merits of specific requirements against the likelihood that more rules would be perceived as onerous and disruptive by a busy staff.

In August 2006, the committee came to consensus on the New York State Procedural and Surgical Site Verification Protocol. After review by the Department of Health and approval by the Commissioner of Health, the protocol was distributed to hospitals and diagnostic and treatment centers during the fall of 2006. A series of educational forums were held across New York State to present and promote adoption of the protocol.

Effective March 1, 2007, the protocol became the official standard for all sites in New York State where surgery and invasive procedures were performed. Over 750 participants from hospitals and diagnostic and treatment centers attended, including nurses, physicians from multiple specialties, (e.g., internists, radiologists, surgeons), quality and risk-management professionals, and hospital association and personnel administrators. Presentations included a detailed description of a recent wrong-sided surgical sentinel event that occurred at a community hospital in New York State; background information on medical errors; in-depth analyses of the occurrences reported; root causes, contributing factors, corrective actions/risk reduction strategies; and the process the committee followed in developing the protocol and NYSSIPP itself. Time was allotted for questions from the audience related to the protocol at each forum.

## Discussion

According to the National Quality Forum (NQF), "never events" are "errors in medical care that are clearly identifiable, preventable, and serious in their consequences for patients, and that indicate a real problem in the safety and credibility of a health care facility."[17,18] The NQF identified 27 such events (increased to 28 when the report was revised in 2006). Surgery on the wrong side of the body, wrong site, or wrong patient led the list.

These events occur for a variety of reasons, such as poorly designed systems, inadequate training, communication errors, and failure to follow policy and procedures. In addition, there are human factors that can disrupt even well-designed systems, including the traditional operating room hierarchy. In its ground-breaking report *To Err is Human,*[13] the Institute of Medicine recommended mandatory State-level reporting of significant health care errors.

The goal of reporting is to create a body of data that can be used to identify the causes of errors and direct corrective actions at the systems level. Such a reporting program has been in place in New York State for many years. In 1998, the system was revised to its current form, the New York Patient Occurrence and Tracking System.[19] This system uses rigorously defined data definitions and a Web-based electronic reporting tool to capture a variety of patient occurrences in hospitals and diagnostic and treatment centers, including many on the NQF's list.

Wrong-side, wrong-site, wrong-patient events continue to be reported to State agencies and the Joint Commission in undiminished numbers. One study estimated that 1,200 to 2,700 events occur annually in the United States.[20] Based on a review of 20 years' experience at Harvard in over 2 million surgical cases, the incidence of such errors was estimated to be 1 in 112,000. In 3 years, 337 cases were reported in New York State. Of these, two-thirds occurred in settings other than the operating room. Increasingly complex and invasive procedures now occur routinely in other settings, particularly imaging areas. Such units might not have the experience that operating room personnel have with systematic patient and site identification and an orderly flow of information. Bedside procedures, such as thoracentesis, might be performed by house staff or consultants who might not have primary source information, such as x-ray images, readily available.

The expert committee that analyzed the NYPORTS data created a protocol that addressed the complete scope of the invasive procedure process, from initial scheduling through actual procedure. Although built on, and consistent with, the Joint Commission's Universal Protocol, it has a greater level of detail in order to make it clear to users what the members of the Panel viewed as "best practice" (Table 4). The Panel concluded that the Universal Protocol would have had a greater impact in preventing the wrong-sided/wrong-sited events we reviewed if there had been increased process standardization (i.e., include scheduling, consent, and imaging components in the protocol) and greater adherence to the protocol (e.g., total participation by all members of the team in the "time out"; monitoring for compliance with the protocol).

Can protocols substantially reduce (or eliminate) error? In one study,[1] the authors felt that the Universal Protocol would have been ineffective in preventing the error in five cases of the 13 charts available for review. Of those five cases, one was caused by failure to properly identify the patient when printing MRI images. This is covered by the National Patient Safety Goals and need not be included in an invasive procedure protocol. Another case, involving a change in the surgical plan, could have been avoided by restarting the verification process. Two cases involved failure to properly describe lesions; the NYSSIPP protocol dictates that such confusion should stop the procedure until a definitive identification can be made. A case of a wrong-rib resection was a true operative mistake, although clinical guidelines—such as using fluoroscopy during such procedures—might reduce the likelihood of this error.

Any system can be undermined by failures of common safety behaviors. Good systems for reducing procedural maloccurrences need to extend as far as they can into error-prone elements at the margins of the procedure. This is why the NYSSIPP protocol addresses surgical scheduling and consent and has such detailed specificity on radiologic image availability, orientation, and confirmation. Ultimately, the success of any protocol depends on the culture of safety that surrounds it.

**Table 4. Differences between NYSSIPP and the Universal Protocol**

| Section of NYSSIPP | NYSSIPP comparisons to Universal Protocol (UP) |
|---|---|
| Scheduling | • Not included in UP.<br>• Detail required in scheduling (implant, equipment, no abbreviations).<br>• Information received must be verified. |
| Consent documentation | • Increased detail required (layman's terms; spell out side/sites; no changes permitted after signatures obtained). |
| Pre-operative verification process | • Multiple specific steps with increased detail in NYSSIPP.<br>• Must take place before entering OR (exception detailed). |
| Pre-operative checklist | • A pre-operative or pre-procedural verification checklist is ***required***. |
| Marking & verifying the operative site | • Images required to be present in OR, viewed by 2 individuals, and orientation of images confirmed.<br>• Second time out for spine surgery including second image.<br>• Alternative to patient marking in specific exceptions – special purpose wristband. |
| Time out | • *All* work should cease during the "time out."<br>• *All* members of the team (surgical, anesthesia, nursing) must focus on the "time out." |
| Required policy and procedure | • The institutional policy and procedure must specify the actions to be taken when a discrepancy occurs at any step in the process.<br>• Responsibilities must be more specifically defined. |
| Compliance monitoring | • Compliance monitoring of NYSSIPP is an integral part of a facility's performance improvement/quality assurance activities.<br>• The role of monitoring and leadership in setting expectations is key. |

NYSSIPP = New York State Surgical and Invasive Procedure Protocol; UP = Universal Protocol; OR = operating room

# Conclusions

Analysis of cases reported to a centralized database under a mandated statewide reporting system formed the basis for extending The Joint Commission's Universal Protocol to reduce the incidence of wrong-patient, wrong-side, or wrong-site surgical and invasive procedures. We found that the elements necessary for success included in-depth analysis of NYPORTS events, a literature search, formation of an expert panel, consensus-driven protocol development, and educational forums several months before the implementation date. This protocol has become the standard of institutional performance in New York State.

## Author Affiliations

Phelps Memorial Hospital (Dr. Faltz); New York State Department of Health (Dr. Morley, Ms. Flink, Ms. Dameron).

*Address correspondence to:* Ellen Flink, Director of Research in Patient Safety and Quality Initiatives, Empire State Plaza, Corning Tower Building, Rm 2164, Albany, NY 12237; telephone: 518-402-5875 or 518-474-4987; e-mail: emf02@health.state.ny.us.

# References

1. Kwaan MR, Studdert DM, Zinner MJ, et al. Incidence, patterns and prevention of wrong-site surgery, Arch Surg 2006; 141: 353-358.
2. Statement on ensuring correct patient, correct site and correct procedure surgery. Chicago, IL: American College of Surgeons; 2002 Available at www.facs.org/fellows_info/statements/st-41.html. Accessed March 27, 2008.
3. Eliminating wrong site surgery, Patient Safety Bulletin #1; A joint statement of the American Academy of Ophthalmology, the American Society of Ophthalmic Registered Nurses, and the American Association of Eye and Ear Hospitals; 2001. Available at www.aao.org/education/statements/safety/site.cfm. Accessed March 27, 2008.
4. Sign, mark & x-ray (SMaX): Prevent wrong-site surgery. Burr Ridge, IL: North American Spine Society; 2001. Available at: www.spine.org/Pages/PracticePolicy/ClinicalCare/SMAX/Default.aspx. Accessed March 27, 2008.
5. Association of PeriOperative Registered Nurses (AORN) Statement on correct site surgery. Denver, CO: Association of PeriOperative Registered Nurses; 2005. Available at: www.aorn.org/PracticeResources/AORNPositionStatements/PositionCorrectSiteSurgery/. Accessed March 27, 2008.
6. Advisory statement on wrong site surgery. Rosemont, IL: American Academy of Orthopaedic Surgeons; 2003. Available at: www.aaos.org/about/papers/advistmt/1015.asp. Accessed March 27, 2008.
7. New York State surgical and invasive procedure protocol for hospitals, diagnostic and treatment centers, ambulatory surgery centers, and individual practitioners; 2006. Available at: www.health.state.ny.us/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf. Accessed March 27, 2008.
8. Ensuring correct surgery and invasive procedures. VHA Directive 2004-028. Washington, DC: Veterans Health Administration; 2004. Available at: www.va.gov/NCPS/SafetyTopics/CorrectSurg/CorrectSurgDir.DOC. Accessed March 27, 2008.
9. Sentinel Event Alert, Issue 6. Lessons learned: Wrong site surgery; Oakbrook Terrace, IL: The Joint Commission; 1998 Aug 28. Available at: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_6.htm. Accessed March 27, 2008.
10. Sentinel Event Alert, Issue 24. A follow-up review of wrong site surgery; Oakbrook Terrace, IL: The Joint Commission; 2001 Dec 5. Available at: www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_24.htm. Accessed March 27, 2008.
11. Universal protocol for preventing wrong site, wrong procedure, wrong person surgery™. Oakbrook Terrace, IL: The Joint Commission; 2003. Available at: www.jointcommission.org/NR/rdonlyres/E3C600EB-043B-4E86-B04E-CA4A89AD5433/0/universal_protocol.pdf. Accessed March 27, 2008.

12. Sentinel event trends: Wrong-site surgeries reported by year. Reported on Joint Commission teleconference on Wrong Site Surgery, June 21, 2007. Available at: www.jointcommission.org/NR/rdonlyres/6F94288C-EC8E-4B95-91F6-0A1C96C09708/0/se_trends_wss_reported.gif. Accessed March 27, 2008.

13. Kohn, LT, Corrigan, JM, Donaldson, MD, eds. To err is human: Building a safer health system. Washington, DC: National Academies Press; 1999.

14. The Patient Safety and Quality Improvement Act of 2005. Overview, June 2006. Rockville, MD: Agency for Healthcare Research and Quality. Available at: www.ahrq.gov/qual/psoact.htm. Accessed March 27, 2008.

15. Novello AC. New York State patient occurrence and tracking system report, 2002-2004. Available at www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2002-2004/docs/2002-2004_nyports_annual_report.pdf. Accessed March 27, 2008.

16. Novello AC. New York State surgical and invasive procedure protocol; 2006. Available at: www.health.state.ny.us/professionals/protocols_and_guidelines/surgical_and_invasive_procedure/docs/protocol.pdf. Accessed March 27, 2008.

17. National Quality Forum. Serious reportable events in healthcare: A consensus report. Washington, DC: National Quality Forum; 2002.

18. Kizer KW, Stegun MB. Serious reportable events in healthcare. Advances in patient safety: From research to implementation. Vol. 4, Programs, tools, and products. AHRQ Pub. 05-0021-4. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol4/Kizer2.pdf. Accessed March 27, 2008.

19. Flink, E, Chevalier, EC, Ruperto, A, et al., Lessons learned from the evolution of mandatory adverse event reporting systems. Advances in patient safety: From research to implementation. Vol. 3, Implementation issues. AHRQ Pub. 05-0021-3. 2005. Rockville, MD: Agency for Healthcare Research and Quality; 2005. Available at: www.ahrq.gov/downloads/pub/advances/vol3/Flink.pdf. Accessed March 27, 2008.

20. Seiden, SC, Barach, P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? Arch Surg 2006; 141: 931-939