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New York
Patient Occurrence Reporting and
Tracking System
Report



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Executive Summary

Governor George E. Pataki and Antonia C. Novello, M.D., M.P.H., Dr. P.H., Commissioner of Health, have affirmed that the most important responsibility of the Department and the healthcare community is to assure the highest quality of care to patients in the safest possible manner. Recently, Commissioner Novello stated, "New York's Patient Safety Initiatives and the tremendous commitment made by healthcare providers across the state, build on Governor Pataki's commitment to ensuring New Yorkers access to one of the finest, most advanced healthcare systems in the world."

New York State has a long history of implementing efforts to improve patient safety by mandating that hospitals report and initiate improvement actions based on adverse events occurring at their facilities. The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is the third iteration of incident reporting for New York State. The evolution of NYPORTS spans 21 years, initially known as the Hospital Incident Reporting System (HIRS) followed by Patient Event Tracking System (PETS). NYPORTS is a culmination of lessons learned through analysis, evaluation and use of the systems. It has been very positively affected by the cooperative efforts of hospitals, hospital associations and a broad base of experts across the state.

The current system, beginning in 1985, is a mandatory adverse event reporting system statutorily based, pursuant to Article 28 Public Health Law 2805-1 and Section 405.8, Incident Reporting, of Title 10 New York Code, Rules and Regulations. The system captures predefined events specifically coined "occurrences". For the purpose of NYPORTS reporting, an occurrence is an unintended adverse and undesirable development in an individual patient's condition. It is important to acknowledge that all adverse events collected in the system are not medical errors and should not be considered as such. NYPORTS does collect reports on medical errors, but the volume of medical errors in the system is a small percentage compared to the overall volume of reporting.

The data collected in NYPORTS is used by the Department to assess the incidence and management of adverse occurrences across the state, as well as a basis for patient safety initiatives. Additionally, NYPORTS has proven to be a valuable tool for facilities in internal quality initiatives and medical error prevention. As a national leader in the evolution of reporting systems, much has been learned from NYPORTS.

This report will highlight the Department's commitment to patient safety through quality initiatives inspired and supported by the data collected in NYPORTS. These include:

- Building quality initiatives around selected NYPORTS codes, first through an Agency for Healthcare, Research and Quality (AHRQ) grant, and secondly through a process measure project.
- Participation in the NYSDOH led delegation of the AHRQ and VA National Center for Patient Safety (NCPS) sponsored Patient Safety Improvement Corps (PSIC) National Training.
- Providing extensive patient safety education to facility NYPORTS coordinators and quality improvement specialists of various disciplines across the state.
- Implementation of the first state protocol for thorough and credible Root Cause Analysis.
- Sponsoring a statewide patient safety conference.
- Publishing two articles, Qualitative and Quantitative Analysis of Medication Errors: The New York Experience and Lessons Learned from The Evolution of a Mandatory Reporting System.
- Sharing lessons learned through articles published in the NYPORTS News and Alert, presentations to the Statewide NYPORTS Council and regional hospital associations.
- Annual New York State Patient Safety Awards.
- Restructuring of the NYPORTS reporting system.
- Comprehensive enhancements of the NYPORTS electronic system.
- Revised NYPORTS policies, procedures and manual.
- Ongoing NYPORTS data assessment in collaboration with the School of Public Health.

The Department of Health acknowledges the efforts and improvement of New York State Hospitals and Diagnostic and Treatment Centers with regard to reporting. NYPORTS has been historically compared to data submitted to the Statewide Planning and Research Cooperative System (SPARCS). Below are some of the statistics related to NYPORTS reporting for the years 2002-2004.

The number of inpatient discharges reported through SPARCS increased from 2,466,849 in 2002, to 2,521,170 in 2003 and to 2,617,524 in 2004.

The number of reports submitted to NYPORTS increased from 30,416 cases in 2002, to 31,029 in 2003, and to 31,154 in 2004.

Reporting has changed from 1,225 reports per 100,000 discharges in 2002, to 1,203 reports per 100,000 discharges in 2003, to 1,150 reports per 100,000 discharges in 2004.

NYPORTS reporting per 100,000 discharges has remained relatively constant with a slight decrease of 6.1% from 2002 to 2004, largely due to increases in inpatient discharges.

Introduction and Background

The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is a mandatory adverse event reporting system implemented pursuant to New York State Public Health Law Section 2805-L, Incident Reporting. For the purpose of NYPORTS reporting, an adverse occurrence is specifically defined as an unintended adverse and undesirable development in an individual patient's condition. Some occurrences are meant to be tracked and trended as groups, while the most serious occurrences (specifically defined as patient deaths or impairments of body function in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards), are investigated internally and require facilities to conduct a Root Cause Analysis (RCA). All adverse events are not medical errors and should not be considered as such.

NYPORTS does collect reports on medical errors, but the volume of medical errors in the system is a small percentage compared to the overall volume of reporting. It should be noted that New York State Public Health Law Section 2805-m Confidentiality prevents disclosure of incident reports under the Freedom of Information Law.

This report will provide information regarding NYPORTS enhancements, policy revision and analysis of data collected during the years 2002-2004. In addition, information relating to activities undertaken to assure optimal NYPORTS reporting and future plans will be discussed. Future plans include: ongoing improvement of the NYPORTS system, continued training and support and in-depth data analysis by occurrence code. The overriding goal of these activities is to improve the quality of care and safety of patients in facilities in New York State.

New York State has had a long history of implementing efforts to improve patient safety by requiring hospitals to report and initiate actions based on adverse events occurring in their facilities. Since October 1, 1985, a mandatory incident reporting system has been in place in New York State. Initially, the incident reporting system was a paper reporting system; later, an e-mail-based system was developed. Neither of these systems allowed adequate feedback to the hospitals, which limited the use of the data for quality improvement.

At the direction of Governor Pataki through a regulatory reform effort, NYPORTS was created to simplify reporting, streamline coding, coordinate with other reporting systems to reduce duplication and most importantly allow hospitals to obtain feedback on their own reporting patterns and compare them with other facilities in the region and the State.

The development of the electronic internet-based system began in 1995, utilizing a statewide workgroup of industry experts including consumer representative. The original workgroup included a practicing surgeon, a practicing anesthesiologist, facility medical directors, internal medicine practitioners, nursing, quality assurance and risk management professionals.

The Chair of the original workgroup, Dr. Robert Panzer, is the Chief Quality Officer of The University of Rochester Medical Center and continues to Chair the NYPORTS council today. The NYPORTS Council meets regularly; many of the original members of the first workgroup sit on the panel. The council sets goals and prioritizes patient safety projects, participates in analysis of NYPORTS data as well as clinical and system enhancements. The Department works in collaboration with the NYPORTS council, providing necessary support to carry out development and implementation activities.

Statewide hospital associations and their regional affiliates also participated in development and implementation of the group's activities. The resulting system is based on objective criteria and provides hospitals with clear definitions of what must be reported. This electronic version was extensively field tested, refined, and implemented on a statewide basis in April 1998. The system made it easier for hospitals to report adverse incidents, as required by law, and to obtain comparative data.

NYPORTS is an Internet based system with all the required security measures included in its construction. Hospitals can query the database to compare their experience with reported events to the statewide, regional or peer group experience. While the identity of individual hospitals in the comparative groups is not disclosed, the comparative database is a useful tool in support of hospital quality improvement activities. Additionally, hospitals can use the system to create comparative reports in a variety of graphic formats. With new Reports functionality, hospitals can produce assorted reports of local, Regional, statewide or peer group information.

NYPORTS electronic reporting is dynamic, evolving as technological advances and clinical changes necessitate. Significant system improvements were implemented effective June 1, 2000. These improvements included: improved definitions of reportable events, increased reporting requirements regarding medication errors, a detailed definition manual, a revised and improved instructional manual, and the ability to create root cause analysis reports (RCA's) for all serious occurrences.

System improvements implemented in 2001 included the installation of a new server, a "bulletin board" to post information and documents and a home screen to display changes in case status. Following extensive analysis, significant code revisions and technical changes were made to the electronic system, effective in 2004 and 2005. These changes included reprogramming the system using .net technology, revised user screens, reports, help and search functions.

The Department believes that before patient safety improvements can be made, there must be an awareness and recognition of adverse events by facilities (i.e., before one can fix a problem, it must be identified). Therefore, the Department views hospitals with the highest reporting rates as those most keenly aware of occurrences within their facilities and in the best position to bring about systems improvements. For events with significant negative or lasting impact on patients, facilities must conduct an internal investigation of the systems supporting patient care.

These investigations, known as Root Cause Analyses, must identify the root causes of such events, enact systems improvements and build in back-up, "fail-safe" strategies to prevent reoccurrence. Facilities are required to monitor the implementation and effectiveness of identified system improvements through their quality assurance activities, to assure strategies function as intended. For events of lesser patient consequence, facilities are expected to collect and aggregate data regarding these occurrences, to identify system weaknesses before more consequential events occur.

Through access to a comparative database, a hospital can identify through its own reporting circumstances where the hospital stands by comparison. This helps to identify the system of care upon which the hospital should focus its attention and efforts and to monitor the effectiveness of improvement efforts. By completing this process, the number of adverse events will be reduced and the quality of care and the level of safety for hospital patients will improve.

The Department oversees hospital compliance with NYPORTS reporting responsibilities to ensure the process is fulfilled. The Department also directly investigates a portion of the most significant occurrences. Further, through NYPORTS system management and analysis, the Department identifies areas of significant concern noted by individual hospitals and provides alerts to all hospitals in the State. It is expected that hospitals will institute measures, known as "risk reduction strategies", to prevent or reduce these occurrences in their own facilities. By sharing such pertinent information with all hospitals in the State, the Department endeavors to bring about industry-wide improvement in patient safety.

The National Academy for State Health Policy (NASHP) supports mandatory reporting systems, such as NYPORTS, as a tool to address quality and safety issues related to hospital care. They cite, "Proponents of mandatory reporting view it as a way to make healthcare organizations responsive to public expectations for safe, high quality health care". "Mandatory reporting systems are intended to hold providers accountable for performance in two ways: First, they may help assure that serious mistakes are reported and investigated and that appropriate follow-up action is taken and Second, they provide disincentives (e.g., citations, penalties, sanctions, possible public exposure, and possible loss of business) for organizations to continue unsafe practices". By fulfilling and exceeding these criteria set forth by NASHP, NYPORTS has distinguished itself as a model state reporting system.¹

Completeness of Reporting in NYPORTS

As noted in previous NYPORTS annual reports, the completeness of reporting is an important concern when using NYPORTS for quality improvement and adverse event reduction purposes. If the data is not reported completely and accurately, the occurrence frequency or the occurrence rate (number of occurrences per number of discharges or number of occurrences per number of procedures of a given type) for hospitals or region cannot be accurately computed.

Nationally it is recognized that a "gold standard" does not exist from which complete reporting can be measured, however using the number of discharges reported in the Statewide Planning and Research Cooperative System (SPARCS) as a denominator allows for some measure of frequency. SPARCS is a database containing information on all inpatient stays in New York State acute care hospitals. The Department does take active steps to identify compliance with complete reporting, stemming from statewide educational sessions and patient safety projects to record reviews through the surveillance process and retrospective review process.

¹ Lynda Flowers and Trish Riley, "State-based Mandatory Reporting of Medical Errors: An analysis of the legal and Policy Issues", March 2001 pg.5.

Matching Select NYPORTS Occurrences with Inpatient Hospital Discharge Data from the Statewide Planning and Research Cooperative System - SPARCS

Optimal reporting is crucial when utilizing NYPORTS data as a tool for quality improvement and adverse event reduction efforts. This report will show that reporting for occurrence codes 401 (New acute pulmonary embolism), 402 (new documented deep vein thrombosis), 604 (acute myocardial infarction not related to a cardiac procedure) and 808 (post-op wound infection requiring drainage during the hospital stay or inpatient admission within 30 days) improved significantly in 15 New York State hospitals involved in an Agency for Healthcare, Research and Quality (AHRQ) funded Patient Safety Demonstration Project.

The goals of the \$5.4 million grant in support of patient safety improvements were accomplished through two initiatives: assuring more complete reporting in NYPORTS, for more meaningful analysis and oversight of three demonstration projects involving hospital groups or networks that would study specific types of adverse outcomes, then develop and test interventions that could reduce their occurrence.

Findings from the projects have been distributed statewide so that other facilities may also concentrate on identification of these occurrences and implement or reinforce successful protocols. The protocols included thrombo-prophylaxis to reduce the incidence of thromboembolic episodes (deep vein thromboses or pulmonary embolisms commonly referred to as "blood clots"), peri-operative risk assessment and appropriate use of beta-blocker prophylaxis to prevent myocardial infarction in a non cardiac related procedure; and standardized surgical anti-microbial prophylaxis protocols to reduce post-operative wound infections.

Monitoring of occurrence reporting is a high priority for the Department of Health. The Department continually seeks innovative ways to assist facilities in meeting their mandatory reporting requirements. SPARCS was instrumental in assessing completeness of reporting in the four NYPORTS codes (401/402, 604 and 808) included in the AHRQ grant mentioned above.

Please see Appendix B for the list of NYPORTS codes with their included and excluded criteria.

By linking NYPORTS and SPARCS to identify potentially missed events, the Department was successful in assisting hospitals to identify cases. The methods used and results of this process are described below:

Process for Measuring Completeness of Reporting of Select Occurrences

1. Use SPARCS data to identify all patients with specific diagnosis codes identified in the International Classification of Diseases (ICD-9).
NYPORTS 401 (pulmonary embolism): ICD-9 diagnosis codes not in the primary position, 415 Acute pulmonary heart disease (415.1, 415.11, 415.19, 415.0), 673.2 Obstetrical blood-clot embolism.

NYPORTS 402 (deep vein thrombosis): ICD-9 diagnosis codes not in the primary position, 451 Phlebitis and thrombophlebitis (451.1, 451.11, 451.19, 451.2, 451.81, 451.83, 451.84, 451.89), 453 Other venous embolism and thrombosis (453.2, 453.8, 453.9), 671 Venous complications in pregnancy and the puerperium.

NYPORTS 808 (post-op wound infection): ICD-9 diagnosis code in any diagnosis field, 998.5 other complications of procedures, postoperative infection (998.51, 998.59, 998.5).

NYPORTS 604 (acute myocardial infarction) ICD-9 diagnosis code not in the primary position, 410.X1 Acute myocardial infarction, initial episode of care.
2. Match all of the patients identified in SPARCS (with the corresponding diagnosis codes) with patients who were identified using administrative data and reported in NYPORTS.
3. Records identified in SPARCS as potential NYPORTS cases were provided to an independent review agent, IPRO, for medical chart review. IPRO used registered nurses to conduct retrospective medical record reviews using a standard validation review instrument to determine if a reportable event occurred.
4. Hospitals entered cases into NYPORTS, which IPRO determined were reportable and the hospitals agreed were reportable.
5. The estimated completeness of reporting (percentage of cases that were reported) is the total of matched cases (SPARCS and NYPORTS) divided by the total number of cases identified in SPARCS using the diagnosis codes.

Results of Process

The hospitals that participated in the demonstration project were evaluated on the completeness of NYPORTS reporting for two time periods, the first half of 2001 and the second half of 2001.

Using the methods described above, 67 SPARCS cases were identified as reportable under NYPORTS occurrence code 401/402, from January 1, 2001 to May 31, 2001 for the five hospitals participating in the DVT/PE demonstration project. Of these patients, a total of 16 cases (24%) were reported by the hospitals to NYPORTS as of June 18, 2002.

Using the same methods, 38 SPARCS cases were identified as reportable under NYPORTS occurrence code 604, from January 1, 2001 to May 31, 2001 for the five hospitals participating in the post operative AMI demonstration project. Of these patients, a total of 11 cases (29%) were reported by the hospitals to NYPORTS as of June 18, 2002.

For NYPORTS occurrence code 808, 43 SPARCS cases were identified as reportable from January 1, 2001 to May 31, 2001 for the four hospitals participating in the post operative wound infection demonstration project. Of these patients, a total of 5 cases (12%) were reported by the hospitals to NYPORTS as of June 18, 2002.

After the facilities were notified of the results of the evaluation of completeness for the first half of 2001, the DOH directed them to initiate a process of locating and re-evaluating these occurrences, with a goal of assessing and making improvements to their own internal identification processes. After these improvements were made, facilities were directed to identify and report any 401/402, 604 or 808 events which had not been previously reported for the second half of 2001.

The facilities were then re-evaluated by examining completeness of reporting for the second half of 2001. For the facilities in the 401/402 demonstration project, 128 SPARCS cases were identified as reportable to NYPORTS from June 1, 2001 to December 31, 2001. Of these patients, a total of 113 cases (88%) were reported by the hospitals to NYPORTS as of January 2003.

Using the same methods, 45 SPARCS cases were identified as reportable under NYPORTS occurrence code 604, from June 1, 2001 to December 31, 2001 for the five hospitals participating in the post operative AMI demonstration project. Of these patients, a total of 21 cases (47%) were reported by the hospitals to NYPORTS as of January 8, 2003.

For NYPORTS occurrence code 808, 46 SPARCS cases were identified as reportable from June 1, 2001 to December 31, 2001 for the four hospitals participating in the post operative wound infection demonstration project. Of these patients, a total of 38 cases (83%) were reported by the hospitals to NYPORTS as of January 8, 2003.

Conclusion

The completeness of reporting of NYPORTS events identified by using SPARCS data for code 401/402, increased from 24% to 88%. Completeness of reporting for 604 increased from 29% to 47% and completeness of reporting for 808 increased from 12% to 83%. This increase in reporting percentages is a direct result of the efforts taken by the Department of Health to encourage reporting and hospital compliance with reporting responsibilities

It should be noted that the process described above to measure completeness used only records reported to NYPORTS that can be identified using SAPRCS data with specific ICD9 diagnosis codes. The hospitals involved in the demonstration projects did identify additional records using other methods, including Computerized Patient Order Entry (CPOE), clinical laboratory results databases, imaging scans, autopsy and infection control department reports.

Examination of Regional Variation in Reporting NYPORTS Data

A strategy for assessing the completeness of NYPORTS reporting is to examine differences in reporting frequency among large groups of hospitals within certain geographical regions of the state. In order to accomplish this goal, the number of inpatient discharges was compared with the number of NYPORTS cases per region. The statistic used is the number of NYPORTS cases per 100,000 discharges.

The table below reflects the results of data collection that was entered into the NYPORTS system as of December 31st of the following year (for example NYPORTS occurrences in 2002, submitted to NYPORTS through the end of 2003). The regions are defined as Western New York, Finger Lakes, Central New York, Northeastern New York, Hudson Valley, Long Island, and New York City. The counties comprising these regions are listed in Appendix A.

NYPORTS Cases Submitted/100,000 Discharges by Region: 2002, 2003 and 2004

Region	2002			2003			2004		
	NYPORTS	SPARCS	Rate per 100,000	NYPORTS	SPARCS	Rate per 100,000	NYPORTS	SPARCS	Rate per 100,000
Central	2660	193421	1375.2	3012	199363	1510.8	3435	202446	1696.7
Finger Lakes	2464	148605	1658.1	2694	149472	1802.3	2678	153462	1745.1
Hudson Valley	2717	251083	1082.1	2865	268244	1068.1	2703	276740	976.7
Long Island	4365	362795	1203.2	4059	357700	1134.7	4457	379736	1173.7
New York City	12063	1153598	1045.7	12057	1183619	1018.7	11811	1239268	953.1
Northeastern	3191	171643	1859.1	3124	174255	1792.8	2703	177821	1520.1
Western	2766	185704	1489.5	2511	188517	1332.0	2315	188051	1231.0
Total Inpatient	30226	2466849	1225.3	30322	2521170	1202.7	30102	2617524	1150.0

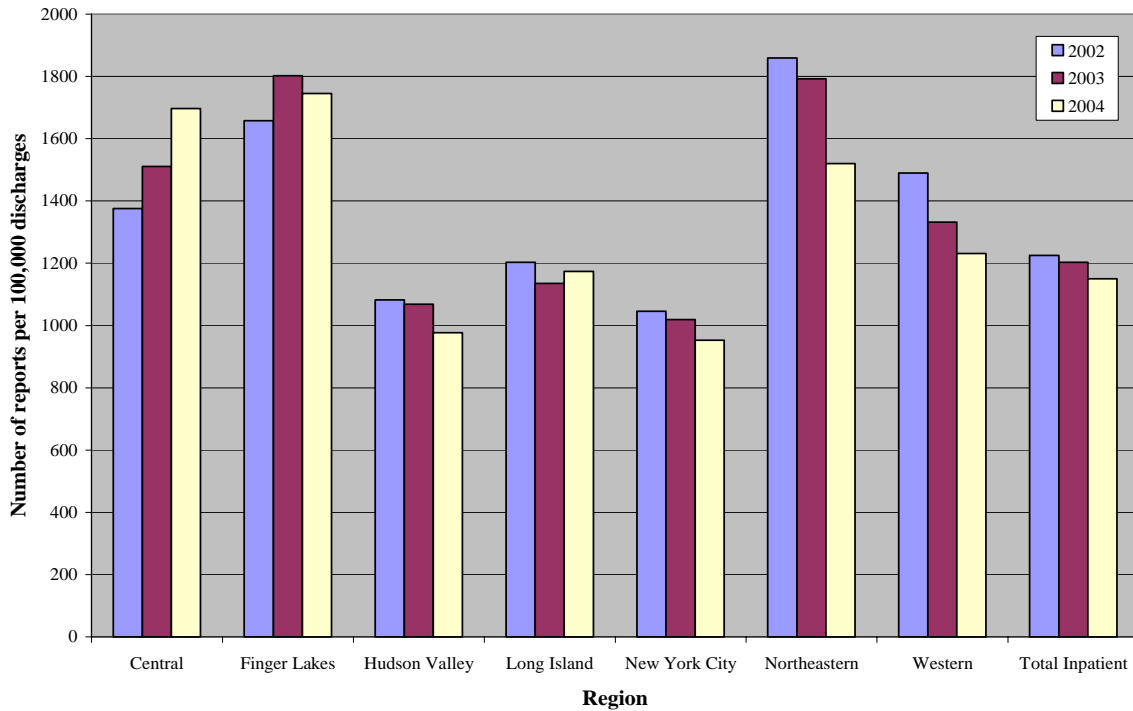
For the year 2002, there were 30,226 NYPORTS cases submitted for all of the inpatient occurrence codes and 2,466,849 SPARCS cases submitted by December 31, 2003. The number of NYPORTS cases submitted per 100,000 discharges for 2002 in New York State was 1,225.

As indicated in the table above, a total of 30,322 NYPORTS cases occurred in 2003 and were submitted by December 31, 2004 for all inpatient occurrence codes in NYPORTS, and a total of 2,521,170 patients were discharged from New York State acute care hospitals in 2003, based on data submitted by December 31, 2004. The number of NYPORTS cases submitted per 100,000 discharges for 2003 in New York State was 1,202.

Also indicated in the table above, a total of 30,102 NYPORTS cases occurred in 2004 and were submitted by December 31, 2005 for all inpatient occurrence codes in NYPORTS, and a total of 2,617,524 patients were discharged from New York State acute care hospitals in 2004, based on data submitted by December 31, 2005. The number of NYPORTS cases submitted per 100,000 discharges for 2004 in New York State was 1,150.

The following bar chart compares the NYPORTS occurrences for year 2002 (submitted as of December 31, 2003), year 2003 (submitted as of December 31, 2004) and year 2004 (submitted as of December 31, 2005) by region and for the entire state.

Regional Variation in NYPORTS Reporting 2002-2004



Changes In Statewide Reporting

The statewide number of NYPORTS cases reported per 100,000 discharges in 2002 was 1,225. This rate was 1,150 NYPORTS cases reported per 100,000 discharges in 2004. Consequently, the NYPORTS reporting rate per 100,000 discharges has relatively constant, with a slight drop of 6.1% between 2002 and 2004. Examining the number of NYPORTS events and the number of SPARCS records reveals that this decline is due primarily to an increase in SPARCS records between 2002 and 2004.

Changes In Reporting by Region

The percentage change in NYPORTS cases reported per 100,000 discharges between 2002 and 2004 ranged from a decrease of 18.2% (from 1,859 to 1,520) in the Northeast New York region to an increase of 23.4% (from 1,375 to 1,696) in the Central New York region.

For the year 2002, the number of NYPORTS cases submitted per 100,000 discharges per region varied by a factor of 1.7. This regional variation stayed substantially the same in 2003 and 2004.

For the year 2002, two regions New York City and Hudson Valley had very similar reporting rates (1045 and 1082 occurrences per 100,000 discharges respectively). Northeastern New York had the highest reporting rate (1,859 occurrences per 100,000 discharges). New York City reported the fewest occurrences per 100,000 discharges (1045).

For the year 2003, Finger Lakes and Northeastern New York had very similar reporting rates (1,802 and 1,792 occurrences per 100,000 discharges respectively). Finger Lakes had the highest reporting rate (1802). New York City again reported the fewest occurrences per 100,000 discharges (1018).

For the year 2004, two regions New York City and Hudson Valley had very similar reporting rates (953 and 976 occurrences per 100,000 discharges respectively). Finger Lakes had the highest reporting rate (1,745 occurrences per 100,000 discharges). New York City reported the fewest occurrences per 100,000 discharges (953).

All regions except for New York City, Hudson Valley and Long Island Regions are above the statewide average for reporting for years 2002 and 2003. New York City and Hudson Valley are below the statewide reporting average for 2004. These variations in reporting frequencies could be a result of a variety of factors including quality of care, types of hospital admissions, procedures performed, accuracy and completeness of reporting.

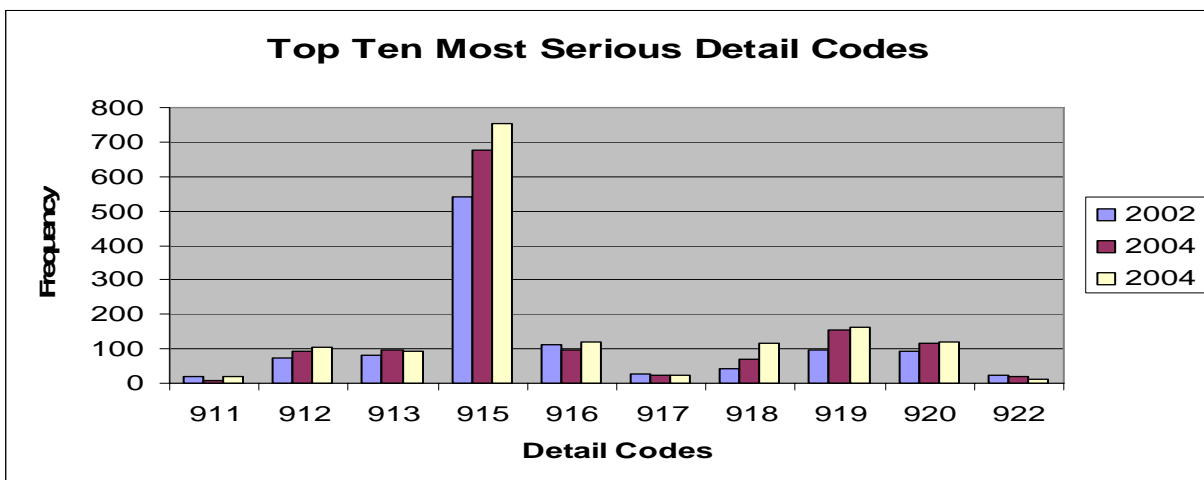
It is likely that accuracy and completeness of reporting is the reason for most of the differences in the table above. Since over-reporting is unlikely, under-reporting in regions with the lowest reporting rates is likely the cause of variation. Although the size of the regions are believed large enough to compensate for variations, methodology must be further scrutinized to identify any impact of the difference in types of facilities and procedures performed within a region.

One of the strategies that the department employs to assess reporting is medical record review (either through surveillance activities or retrospective chart review processes). The Department does impose citations and in some instances, fines for non-reporting or late reporting of statutorily mandated codes. To optimize reporting the Department encourages re-evaluation of internal processes that identify reportable events as well as collaboration in projects that assist facilities to identify reportable events. The Department has provided extensive education and support for interpretation and understanding of the system both clinically and technically.

Changes in Reporting by Individual NYPORTS Codes

As indicated above, the total number of NYPORTS records reported decreased from 1,225 per 100,000 discharges in 2002 to 1,150 per 100,000 discharges in 2004, resulting in an overall decrease in the occurrence rate of 6.1%.

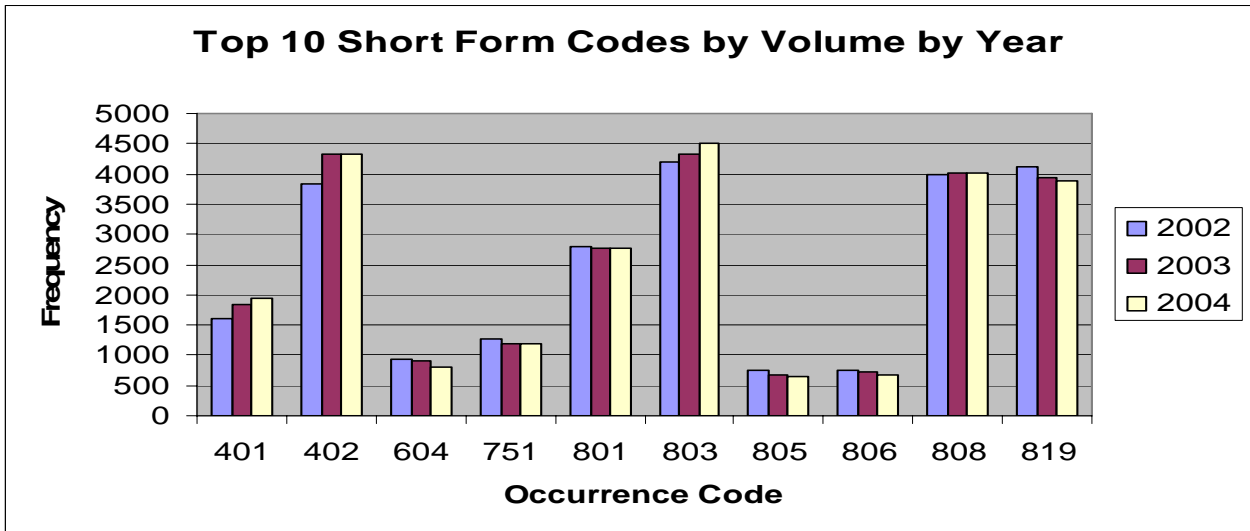
The following bar charts present changes in reporting between 2002 and 2004 for individual NYPORTS codes. The codes have been divided into two groups based on volume. The first group is the top ten most serious codes.



Code 911: Wrong patient, wrong site surgical procedure	Code 916: Unexpected cardiac and/or respiratory arrest requiring ACLS intervention
Code 912: Incorrect procedure or treatment – invasive	Code 917: Loss of limb or organ
Code 913: Unintentionally retained foreign body	Code 918: Impairment of limb
Code 915: Unexpected death	Code 919: Loss/Impairment of body functions
Code 920: Errors of omission/delay resulting in death or serious injury related to the patients underlying condition	Code 922: Inpatient suicides or attempted suicides with serious injury

Short Form Codes

The ten short form NYPORTS codes with the highest volume are presented next. The percentage change between 2002 and 2004 in these codes ranged from an increase of 21.7% for code 401 (New, acute pulmonary embolism) to a decrease of 13.6% for code 805 (Wound dehiscence requiring repair).



Code 401:	New Pulmonary Embolus
Code 402:	New Deep Vein Thrombosis
Code 604:	Acute Myocardial Infarction, unrelated to a cardiac procedure
Code 751:	Falls resulting in x-ray proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage or internal trauma
Code 801:	Procedure related injury requiring intervention
Code 803:	Hemorrhage or hematoma requiring intervention
Code 805:	Wound dehiscence requiring repair
Code 806:	Displacement, migration or breakage of an implant, device, graft or drain
Code 808:	Post-operative wound infection
Code 819:	Any unplanned operation or re-operation

Analysis of Procedures Associated with NYPORTS Codes

As part of NYPORTS reporting, hospitals are required to enter the ICD-9-CM procedure code most closely associated with the adverse event, if a procedure was associated with the event. In support of its primary focus, improvement of patient care and safety, NYPORTS continues to accumulate and analyze data reported to the system, including the procedure code. Analysis of procedures associated with reportable cases, however, is difficult due to the large number of individual procedure codes that are reported to NYPORTS.

The Agency for Healthcare Research and Quality has developed a tool for clustering patient diagnoses and procedures into a manageable number of clinically meaningful categories. This tool is called Clinical Classifications Software (CCS). This "clinical grouper" makes it easier to understand the types of procedures that are most frequently reported to the NYPORTS system.

CCS aggregates procedures into 231 mutually exclusive categories, most representing single types of procedures. Some procedures that occur infrequently are grouped together by their clinical or administrative characteristics (for example, operating room vs. non-operating room). Examples of CCS procedure categories are heart valve procedures, coronary artery bypass graft (CABG), bone marrow biopsy and procedures on the spleen.

The next page lists the procedure groups that represent the largest proportion of all NYPORTS cases for the years 2002, 2003 and 2004. The distribution of cases into CCS groups for these years was similar and therefore combined. In other words, for adverse events reported to NYPORTS that occurred in 2002, 2003 and 2004, the table lists the CCS groups that have the largest number of cases. For example, cases in NYPORTS with the procedure codes partial excision of large intestine, total intra-abdominal colectomy, pull-through submucosal resection of rectum, other pull-through resection of rectum, abdominoperineal resection of rectum, and other resection of rectum, are grouped into the CCS group "colorectal resection". There are 3,590 cases in this group, or 3.9% of the total cases in NYPORTS from 2002, 2003 and 2004 ($3590 / 90650 = 3.9$).

Procedure Groups Reported Most Frequently in NYPORTS in 2002, 2003, 2004

CCS Group	2002 + 2003 + 2004 Count	% of All NYPORTS Cases in CCS Groups for 2002 - 2004
Colorectal resection	3590	3.96%
Hysterectomy; abdominal and vaginal	2594	2.86%
Other OR procedures on vessels other than head and neck	2429	2.68%
Hip replacement; total and partial	2273	2.51%
Arthroplasty knee	1914	2.11%
Cholecystectomy and common duct exploration	1821	2.01%
Other OR gastrointestinal therapeutic procedures	1721	1.90%
Cesarean section	1730	1.91%
Coronary artery bypass graft (CABG)	1511	1.67%
Other OR upper GI therapeutic procedures	1465	1.62%
Peripheral vascular bypass	1553	1.71%
Other vascular catheterization; not heart	1368	1.51%
Treatment; fracture or dislocation of hip and femur	1499	1.65%
Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator	1294	1.43%
Spinal fusion	1301	1.44%

An alternative way of using NYPORTS data to describe the frequency of adverse events by procedure involves using both NYPORTS and SPARCS data to describe the percentage of the time that particular procedure groups are reported to NYPORTS. Using this approach, SPARCS data provides an estimate of the total number of procedures that are being performed each year. NYPORTS data are used to estimate the percentage of these procedures that result in a reported event. The table above presents procedure groups that occur most frequently compared to all cases that are reported in SPARCS. This comparison uses all NYPORTS records within a given group of procedure codes in the numerator and all SPARCS cases with the same group of procedure codes in the denominator. For example, there were 1,000 kidney transplants recorded in SPARCS for 2004. Of these cases, 81 (8.1%) involved events which were reported to NYPORTS.

The distribution of cases in the CCS categories in the following table represents all procedure groups, which had a complication rate of at least 4% in any of the 3 years. This table also presents the percent change in the rate of occurrence between 2002 and 2004.

It is also informative to see which procedures are associated with specific NYPORTS codes. The following tables show us that certain procedures occur with high frequency in selected NYPORTS codes. These codes were selected because they occur with high frequency, have patient safety implications or were included in the AHRQ Patient Safety Demonstration Project.

Procedures Associated with Code 401: Pulmonary Embolus

Description	2002	2003	2004
Arthroplasty knee	51	72	99
Colorectal resection	67	62	62
Other OR procedures on vessels other than head and neck	59	55	69
Hip replacement; total and partial	41	59	66
Treatment; fracture or dislocation of hip and femur	40	48	37
Hysterectomy; abdominal and vaginal	38	46	37
Coronary artery bypass graft (CABG)	31	27	32
Incision and excision of CNS	32	28	28
Spinal fusion	22	33	21
Other therapeutic procedures	20	23	32

Procedures Associated with Code 402: Deep Vein Thrombosis

Description	2002	2003	2004
Arthroplasty knee	261	236	243
Other OR procedures on vessels other than head and neck	174	186	156
Hip replacement; total and partial	144	122	103
Other vascular catheterization; not heart	122	107	134
Colorectal resection	91	90	90
Incision and excision of CNS	79	82	80
Other therapeutic procedures	72	62	76
Treatment; fracture or dislocation of hip and femur	71	72	58
Tracheostomy; temporary and permanent	42	57	69

Procedures Associated with Code 604: Post-Operative AMI

Description	2002	2003	2004
Colorectal resection	73	70	67
Treatment; fracture or dislocation of hip and femur	55	60	56
Peripheral vascular bypass	51	58	56
Hip replacement; total and partial	50	64	47
Cholecystectomy and common duct exploration	43	34	35
Other OR procedures on vessels other than head and neck	33	26	34
Arthroplasty knee	26	27	34
Endarterectomy; vessel of head and neck	31	24	29
Amputation of lower extremity	21	22	26
Aortic resection; replacement or anastomosis	13	19	14
Spinal fusion	16	11	14

Procedures Associated with Code 808: Post operative Wound Infection

Description	2002	2003	2004
Colorectal resection	202	195	212
Hysterectomy; abdominal and vaginal	166	129	176
Cesarean section	147	147	165
Other hernia repair	148	121	148
Coronary artery bypass graft (CABG)	121	136	125
Laminectomy; excision intervertebral disc	127	131	104
Arthroplasty knee	128	108	118
Other OR gastrointestinal therapeutic procedures	106	102	141
Spinal fusion	124	117	105
Debridement of wound; infection or burn	115	116	113

Procedures Associated with Code 819: Return to the OR

Description	2002	2003	2004
Colorectal resection	211	174	161
Other OR procedures on vessels other than head and neck	124	115	108
Insertion; revision; replacement; removal of cardiac pacemaker or cardioverter/defibrillator	102	115	108
Other OR gastrointestinal therapeutic procedures	127	98	97
Hip replacement; total and partial	105	93	123
Other OR upper GI therapeutic procedures	99	97	122
Cholecystectomy and common duct exploration	111	82	107
Incision and excision of Central Nervous System	93	86	105
Other OR lower GI therapeutic procedures	91	90	96
Laminectomy; excision intervertebral disc	88	95	93
Coronary artery bypass graft (CABG)	84	87	92

Data Characteristics regarding NYPORTS cases

The events reported to NYPORTS include a variety of demographic information for the patients involved. Examining these demographic factors may help health care providers understand which patients are most at risk for suffering NYPORTS events.

The table below shows the number of patients with NYPORTS occurrences in 2002, 2003 and 2004, by the location in which the incident occurred. NYPORTS incidents listed with a location of " HOME" are associated with patient re-admission to the hospital and findings of an occurrence that meets the timeframe of a reportable occurrence.

Location of NYPORTS Incidents

Location	Total
OPERATING ROOM	30147
PATIENT ROOM	29748
HOME	10309
ICU	3172
RADIOLOGY	2205
DIALYSIS UNIT	1311
CATH LAB	1294
SICU (SURGICAL ICU)	1267
DELIVERY ROOM	1263
PACU - POST ANES. CARE UNIT	1224
ER	1219
ENDOSCOPY SUITE	924
CLINIC	710
RECOVERY ROOM	508
HALL/CORRIDOR/STAIRS	498

The table below shows the number of patients with NYPORTS occurrences in 2002, 2003 and 2004 by clinical service in the hospital where the incident occurred.

Clinical Service within Hospital of NYPORTS Occurrences

Service	Total
SURGERY/GENERAL	22983
MEDICINE	13627
ORTHOPEDICS	9840
GYNECOLOGY	5381
VASCULAR SURGERY	4286
NEUROSURGERY	3960
OBSTETRICS	3897
CARDIOTHORACIC SURGERY	3717
UROLOGY	2503
CARDIOLOGY	2385
OTOLARYNGOLOGY/ENT	1759
OTHER	1474
GASTROENTEROLOGY	1360
REHABILITATION/REHAB MEDICINE	1246
OPHTHALMOLOGY	1111

The number of NYPORTS cases for 2002, 2003 and 2004, plus the number of records reported from SPARCS for inpatient hospitalizations for these three years are presented below. This table also shows the rate of NYPORTS events for each of the age groups. No age group has a rate of NYPORTS events higher than 2%. The age group with the lowest rate is children less than one year old. The age group with the highest rate is 71 – 80 years old.

Age Grouping of Patients for NYPORTS Occurrences

Age Group	NYPORTS (2002-2004)	SPARCS (2002-2004)	Rate
< 1 year	1,859	833,410	0.22%
01-10	1,391	213,093	0.65%
11-20	2,302	315,859	0.73%
21-30	4,847	721,946	0.67%
31-40	8,308	911,187	0.91%
41-50	10,983	862,330	1.27%
51-60	13,606	855,891	1.59%
61-70	15,437	867,222	1.78%
71-80	19,174	1,066,478	1.80%
81-90	11,389	781,227	1.46%
91100	1,739	172,712	1.01%
100+	34	4,187	0.81%

The NYPORTS system requires that the most serious reportable events include a detailed root cause analysis of the reportable event. The table below identifies the top 10 root causes/contributing factors contributing to events for the most serious events reported to NYPORTS.

Top Ten Root Causes/ Contributing Factors for Events

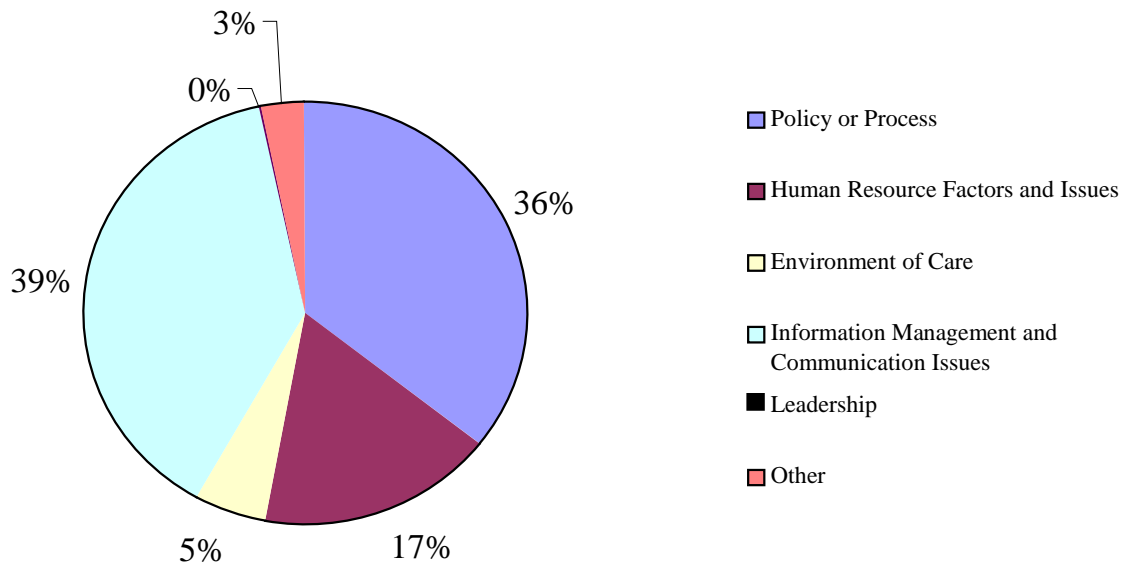
Reason Contributing to Events From Root Cause Analysis	2002	2003	2004
Communication among participants was not effective.	318	365	380
The system in place related to the event was not carried out as intended.	321	350	372
Human error did contribute to the outcome.	286	378	378
The system in place related to the event is not effective.	176	237	245
Necessary information was incomplete.	182	225	195
An effective policy is not in writing.	139	175	165
An effective procedure is not in place.	128	170	178
Necessary information was not available.	141	165	153
Necessary information was not clear and unambiguous.	126	142	146
Necessary information was not accurate.	114	141	125

Reason for Events

An alternate way of looking at the reasons contributing to events is to group the reasons into 6 major categories. For example, the pie chart below shows that “policy or process” is a contributing factor in 36% of all events.

The following reasons are combined into Policy or Process: the system in place related to the event is not effective, the system in place related to the event was not carried out as intended, an effective policy is not in writing, the policy was not effectively communicated, and an effective procedure is not in place. Below find the distribution of causes of events occurring in 2002, 2003 and 2004, grouped into six major categories.

2002-2004 Reasons that contributed to Event



Analysis of Selected NYPORTS Codes Code 911/912 Analysis

In support of its primary focus, improvement of patient care and safety, NYPORTS continues to track and share both facility identified root causes/ contributing factors and risk reduction strategies/corrective actions stemming from the analysis of serious occurrences requiring Root Cause Analysis.

A study of actual occurrences submitted for NYPORTS code 911(wrong patient, wrong site surgical procedure) and Code 912 (incorrect procedure or treatment invasive) has been conducted. The full analysis of Code 911 and Code 912, which consists of 51 adverse occurrences for Code 911 within the time frame of January 1, 2003 to December 31, 2005 and 199 adverse occurrences for Code 912 from January 1, 2004 to December 31, 2005 is presented in Appendix C.

Information from the data highlights adverse events in categories both inside and outside the surgical suite. These categories became apparent after analyzing the data in aggregate form and are in line with national data submitted to JCAHO. As part of the project, a comprehensive literature search was conducted to identify national efforts undertaken by professional organizations, directed at reducing the incidence of these type events. Actual root causes/ contributing factors, risk reduction strategies/actions extracted from analysis of submitted Code 911 and Code 912 reports have been shared statewide, through the "NYPORTS News and Alert" and the Statewide NYPORTS Council. The comprehensive lists of root causes identified as well as the risk reduction strategies are explained in full in Appendix C.

The Department has convened a multidisciplinary panel of experts, the Procedural and Surgical Site Verification Panel (PSSVP), to revise its Protocol for ensuring correct surgery and invasive procedures, based on current literature and lessons learned from the analysis of actual occurrences reported to NYPORTS. The Panel, lead by Chair John Morley, M.D., Medical Director of OHSM, has established the goal of completing the revised protocol for release in the fall of 2006.

Going forward, the new protocol will establish increased awareness of evidenced based findings that ensure the indicated procedure is performed on the correct patient, at the correct site and if applicable with the correct implant/equipment. This Protocol will apply to invasive procedures performed within the operative suite as well as to invasive procedures performed outside the operative suite, such as in Radiology, Interventional Radiology, Emergency Department, newborn nursery, at the bedside, NICU, PICU, SICU, MICU, CCU and all other intensive care units or related specialty areas.

The Pre-Operative Protocols for Hospitals, Ambulatory Surgery Centers and Individual Practitioners issued by Commissioner of Health, Antonia C. Novello M.D., M.P.H., Dr. P.H. and Governor Honorable George E. Pataki in January of 2001, was utilized in the 2006 project. The original protocol served as a base in the development of the new protocol.

Once finalized, the 2006 New York State Protocol to ensure the correct surgical or invasive procedure will be disseminated statewide for implementation at Hospitals, Ambulatory Surgery Centers and for Individual Practitioners.

Code 108, 109, and 110 Analysis

A comprehensive medication analysis was conducted on reportable medication errors submitted between June 2000 through May 2002. The multidisciplinary panel of professionals performed a qualitative and quantitative analysis on the events. The errors analyzed were classified by severity of patient harm utilizing National Coordinating Council Medication Reporting Program (NCC MERP) criteria for category G (resulting in permanent harm- represented as NYPORTS code 108), category H (resulting in a near-death event-represented as NYPORTS code 109) and category I (resulting in patient death-represented as NYPORTS code 110).

The subcommittee analyzed 108 specific medication errors. 89% of the errors were reported and appropriately associated with a NYPORTS medication code, however 11% were reported without an associated medication error code. The categorical breakdown of the 89% of codes associated with NYPORTS medication error codes is as follows: medication errors resulting in permanent harm (NYPORTS code 108) accounted for 18%, near- death errors (NYPORTS code 109) accounted for 49% and errors resulting in death (NYPORTS code 110) accounted for 23% of the cases. The remaining 11% of errors, reported without the associated medication code, were reported as NYPORTS code 915 only (Unexpected death). Today enhanced system functions force appropriate coding.

The Department disseminated this analysis in many different forums. It was first presented to the NYPORTS Statewide Council, then at the 2005 Patient Safety Conference. **Qualitative and Quantitative Analysis of Medication Errors: The New York Experience** was published in the February 2005 publication, *Advances in Patient Safety*. The analysis concluded that mandatory error reporting can provide useful information about systems contributing to errors, strategies for prevention and evidence based information. This information is important for hospitals to consider when analyzing medication errors and implementing system fixes to improve patient safety. **See Appendix E for this article.**

System Enhancements

NYPORTS is an ever-evolving system. Based on various needs including those presented to the Department by hospitals, our own regional offices and those identified by the OSC audit. Change to NYPORTS continues to occur to make the system better able to track and capture adverse event information. Changes included the following:

“Date the Facility Became Aware” Date

Section 405.8 of Title 10 NYCRR requires hospitals to report incidents “within 24 hours of when the incident occurred or when the hospital has reasonable cause to believe that such an incident has occurred.” Although there is a date field in NYPORTS to capture the occurrence date, a date field to capture the date “when the hospital has reasonable cause to believe that such an incident has occurred” or the “date the facility became aware” was not present on the short form.

The OSC audit cited the Department for inadequate monitoring of timeliness of reporting due to the absence of this date on the system, as timeliness could only be measured from the date of occurrence. As a result, this date field was added to the short form. The programming to support the addition of this date field was completed in July 9, 2004.

Since this mandatory date field was added to the NYPORTS short form, facilities must enter the date that the facility became aware of the occurrence. The Department will interpret this to mean the date when the Risk Manager, NYPORTS coordinator, or other person designated as responsible for NYPORTS reporting, is aware that the occurrence meets NYPORTS reporting criteria.

Policy for Reporting 900 Codes Requiring RCA and Extensions for RCA’s

One of the recommendations from the NYPORTS audit was to change the timeframe to report a Root Cause Analysis. In response to this recommendation, the Department has revised its policy with regard to reporting timeframes for all codes requiring a RCA (911-913, 915-923, 938, 961-963).

These codes represent the most serious occurrences and require notification of the Department by submission of a report within “24 hours or one business day of when the incident occurred or when the hospital has reasonable cause to believe that such an incident has occurred” (Title 10 of the Department of Health Rules and Regulation 405.8 Incident Reporting).

Public Health Law 2805-I specifies that incident reports must be made to the department in a manner and within timeframes as specified by regulation of the Department and further mandates the hospital shall conduct an investigation of specified incidents within 30 days of obtaining knowledge of any information which reasonable appears to show that such an incident has occurred.

Through the analysis of submitted reports, it was brought to the Departments attention that in many cases, a 30-day time frame is not an adequate amount of time to complete a thorough and credible RCA.

If a facility requires additional time to produce and report its RCA, a written request must be submitted outlining the justification and estimated date of completion to the appropriate Regional NYPORTS Coordinator. A "Written request" form, entitled "Extension Request Form" must be completed electronically on the NYPORTS system. The Regional NYPORTS Coordinator can grant 30 additional days for a facility to report its RCA into the system. Therefore, with an approved extension, facilities will have a total of 60 days from the date that the facility became aware of the occurrence to report their RCA.

Forcing function for NYPORTS Codes 108,109,110

When a facility reports a Code 108 (medication error resulting in permanent patient harm), Code 109 (medication error resulting in near death), or Code 110 (medication error resulting in death), a facility must report a corresponding Code 915-918 detail code. Code 108-110 events require the facility to conduct an investigation as part of the RCA process. However, in many cases during the past, Code 108-110 cases were reported to NYPORTS without a corresponding 900 code and therefore, without a RCA.

To prevent this from happening, the system was reprogrammed so that it will be impossible to submit a 108-110 Code occurrence without a corresponding 915-918 detail code. This enhancement was implemented on June 9, 2004.

Patient Safety Initiatives

NYPORTS News and Alert

The Department of Health distributes a newsletter, entitled the "NYPORTS News and Alert" to all hospitals in New York State. The "News and Alert" is sent to Hospital Administration and the NYPORTS Coordinator designated by the hospital. This newsletter is designed to give system users information to assist with the reporting process. Additionally, it has been used to publish results of analysis, including root causes and corrective actions.

Historically, the distribution of the "News and Alert" has been a paper process. In 2001, the Department instituted electronic distribution of this newsletter, in addition to paper distribution. Today the newsletter is sent out electronically and posted on the HPN web based NYPORTS bulletin board.

Highlights from key NYPORTS News and Alert articles include but are not limited to:

- The September 2002 NYPORTS News and Alert contains an article titled **Retained Surgical Sponges**. The article found that surgical sponges and lap pads are the most frequently retained foreign bodies following a surgical procedure. These Retained items can result in serious complications and require a return to the OR. Corrective actions derived from submitted NYPORTS Code 913 reports (Unintentionally Retained Foreign body) focuses on prevention of future events and include the Association of Operative Registered Nurses (AORN) recommendations, which are listed in the article **(See Appendix F for the complete article)**.
- **Magnetic Resonance Imaging Safety**, published in the February 2003 NYPORTS News and Alert, found that the number of adverse events attributed to Magnetic Imaging is quite small when compared to the actual number of scans performed annually. However, projectile incidents continue to occur with varying degrees of injury, and in one instance, a fatality. Recommendations for MRI Safety written by ECRI are included **(See Appendix F for the complete article)**.
- **Electrosurgical Burns and Fire Occurrences** from the June 2003 News and Alert, describes occurrences involving second and third degree burns to patients resulting from use of electrocautery instruments. Comprehensive data was shared from analysis of NYPORTS events over a five-year period, as well as ECRI recommended actions to prevent surgical fires and subsequent burns **(See Appendix F for complete article)**.

Lessons Learned from the August 14-15, 2003 Blackout

On August 14, 2003, many hospitals in New York State experienced a power outage, which ranged from minutes to over 24 hours for some facilities. The outage provided an opportunity to test hospital emergency preparedness plans and to refine and improve upon emergency response systems.

The reports submitted to the New York Patient Occurrence Reporting and Tracking System (NYPORTS) provide a unique ability to determine how hospitals and patients were impacted by this major power failure. There were 86 reported occurrences on August 14th, and 40 additional occurrences were reported the following day. Codes 933 (termination of any services vital to the continued safe operation of the hospital, or the health and safety of its patients and personnel) and 932 (external disaster outside the control of the hospital that effects facility operations) were the two codes most frequently reported. There were no reports of unexpected death or serious patient related adverse events attributed to the power outage.

Submissions yielded important lessons that provide an opportunity to positively impact hospital vulnerabilities and to improve emergency communication.

According to reports received, lack of generator power was the most frequent issue identified, which occurred both at onset of the power outage, as well as throughout the blackout. Reportedly, five generators failed or malfunctioned almost immediately and eight failed or malfunctioned at various times throughout the duration of the outage.

Lessons learned include:

1. Know the surge capacity of the facility's generator(s).
2. Test generators during maximal power usage.
3. If a service is moved within the physical structure, ensure it is maintained on back up generator power, if vital to emergency hospital operations or patient care.
4. Have adequate back-up fuel available.
5. Make advance arrangements with local fuel distributors to ensure emergency delivery if needed, eliminating the need to utilize emergency municipal resources.

Contributing causes cited for generator failure at onset included overheating, damage to the switch or insulation, and failure of the charger. Generator failures identified throughout the duration of the outage were attributed to overheating and the negative effects of power surges. The power outage demonstrated that even when generators work, some essential areas of the hospital might not be supplied with emergency power. In fact, many hospitals reported lack of power to critical patient areas, elevators, x-ray and telephone/internet services. In addition, both internal hospital beeper and paging systems, as well as, telephone/cell phone services were reportedly interrupted.

Shortly following the outage, Commissioner Novello outlined recommendations relevant to emergency power in a memo to hospital facilities. The memo recommended that each hospital evaluate its own emergency power system. The recommendations include:

- All hospitals are required to have two independent sources of power.
- Each facility must critically evaluate how their outpatient clinics, especially dialysis centers, are affected by power loss. Many hospitals provide dialysis services in outpatient clinics that are not required to have auxiliary power. Additionally, hospitals may close their outpatient clinic in accordance with their own disaster plan.
- Emergency generators must be tested under maximal power usage at least monthly.
- All emergency systems should be reviewed for capacity.
- Hospitals must have a clear understanding of which services and areas will be maintained by emergency power and which services and areas will not have service. Hospitals must ensure uninterrupted internal and external communication including uninterrupted operation of the Hospital Emergency Response Data System (HERD).

The power outage brought issues relating to the management of patients requiring mechanical ventilation to the forefront. The issues include:

1. Hospital personnel manually ventilated respirator dependant patients at various points of the outage.
2. The location of ventilator dependent units within the hospital became an issue when hospital personnel had to carry a ventilator dependent patient and their equipment down six flights of stairs to access emergency power.

3. Community health providers, such as nursing homes, should establish plans with hospitals to arrange for the transfer of ventilator dependent patients during future power outages. If possible, nursing homes should make arrangements with more than one facility to receive ventilator dependent patients to prevent the overload of any one facility during an emergency. In addition, the nursing home should ensure that a patient's equipment, care plan, medications, other relevant information, and nursing personnel, when appropriate, are sent to the hospital when the patient is transferred.
4. Communities should work with hospital affiliates to set up shelters for those not requiring medical care in an emergent event.

As stated in the Commissioner's August 21, 2003 letter, the lessons learned from the blackout gives New York hospitals the opportunity to "be better prepared to respond to future emergencies."

This example illustrates the importance of information obtained from analysis of NYPORTS data. **See Appendix F for this issue of "NYPORTS News and Alert".**

New York State Safety Improvement Demonstration Project

The Department completed a three-year federal Agency for Healthcare Research and Quality (AHRQ) funded grant totaling \$5.4 million to support its ongoing efforts to improve patient safety. The goals of the New York State Safety Improvement Demonstration Project were accomplished through two initiatives: The first initiative was more complete reporting in NYPORTS so that more meaningful analysis of data can occur. The second initiative was to oversee three demonstration projects involving hospital groups or networks that studied specific types of adverse outcomes and developed and tested interventions to reduce harm and increase physician compliance.

Three NYPORTS reportable adverse events studied were: 1) new acute pulmonary embolism and new documented deep vein thrombosis 2) surgical site infection 3) peri-operative acute myocardial infarction in non-cardiac surgery patients.

The project was developed by three groups of hospitals, each addressing a specific adverse event. It was carried out at these hospitals of various sizes in diverse geographic areas of New York State from August 2002 – August 2004. Interventions were designed and implemented for hospital inpatients.

Each hospital group carried out retrospective and prospective activities to identify adverse events in the study hospitals, using a combination of concurrent reporting, laboratory and diagnostic studies, discharge abstract ICD-9-CM code analysis, and other methods. Additionally each hospital group developed a best practice guideline for risk assessment and prophylaxis of the adverse event of interest and implemented the guideline beginning in April 2003.

The hospital groups then conducted medical record reviews using a standard data collection form and sampling randomly chosen discharges from the baseline year 2001 and intervention years 2003 – 2004. They also obtained standard risk assessment prophylaxis, testing, treatment and outcome data, for all adverse events of interest reportable to NYPORTS during the baseline and intervention periods.

The Westchester Medical Center Group

Westchester Medical Center, Benedictine Hospital and Kingston Hospital developed and implemented antimicrobial prophylaxis (AMP) protocols to reduce surgical site infections. The protocols standardized the use of AMP in association for select clean and clean-contaminated surgical procedures. The rates of patients with prophylaxis, strictly per guideline, which included five criteria, increased significantly from the baseline to the implementation year. Compliance with the postoperative duration of prophylaxis criteria showed the lowest increase, apparently reflecting the pre-implementation experience of the practitioners. This group was able to demonstrate a significant decrease in the surgical site infection event rate.

The Perioperative Utilization of Beta Blockers (PUBB) Project

Columbia Presbyterian, NY Hospital Medical Center Queens, NY Methodist, White Plains Hospital Center and St. Barnabas adopted a system wide evidence based consensus statement recommending the use of peri-operative beta-blocker therapy in appropriately selected patients undergoing non-cardiac surgical procedures. A multi-dimensional educational intervention was implemented aimed at changing clinician behavior and improving the clinical utilization and effectiveness of B-blocker therapy. The findings from the study showed that in the perioperative AMI hospital group, the rates of patients receiving beta blocker prophylaxis strictly per the guideline increased significantly from the baseline to the implementation year. Perioperative beta-blocker was initiated predominately in the outpatient setting by the patient's primary care physician with only infrequent initiation after hospitalization. The AMI hospital group was not able to demonstrate a decrease in AMI event rates from the baseline to intervention due to the sample size.

The Rochester Regional Thromboembolism Collaborative

Strong Memorial Hospital, Highland Hospital, F.F. Thompson, Jones Memorial Hospital and St. James Mercy developed risk assessment and prophylaxis protocols based on evidence based medicine through multidisciplinary committee work. The rates of patients failing to receive prophylaxis in the PE and DVT hospital group decreased in aggregate from the baseline year to the intervention year, and prophylaxis strictly per the guideline increased from the baseline to the implementation year. This project was able to demonstrate there was a significant increase in PE events detected and reported in the intervention year due to increased awareness and improved identification.

This hospital group was able to demonstrate improved methods of detecting and reporting PE's and DVT's to the NYPORTS system.

Recommendations

Use of Consensus Statements in the SSI and AMI projects were effective in establishing buy-in from all key participants and served as a guidepost as the interventions were implemented. The more prescriptive model used by the SSI project appeared to be more useful. One hospital in the AMI study that utilized a pre-admission form which contained information on prophylactic use of beta blockers showed the highest compliance rate of the participating hospitals.

The role of opinion leaders in the three projects was important in establishing a consensus for action in the initial stages and sustaining unified action throughout the intervention period. Each project used physician champions in consensus development and protocol implementation. These leaders were critical in obtaining the necessary physician buy-in, which led to increased compliance with established protocols for the studies.

The use of a concurrent review process to target areas of low compliance and providing feedback directly to the individual physician appeared to be a useful tool in improving compliance with the protocols. This methodology was used in the PE/DVT and SSI projects. Improved compliance for specific services following physician feedback seemed to indicate that this methodology was effective in changing behavior.

The smaller hospitals in all of the projects had more flexibility to modify existing forms and the approval process was much simpler. For example, adding information about beta blocker utilization on a pre-admission form or developing pre-printed order sets for PE/DVT prophylaxis was much easier in the small rural and community hospitals than in the academic medical centers or tertiary facilities. The larger institutions also relied heavily on the use of electronic systems such as CPOE, for protocol implementation.

The process of identifying NYPORTS cases of interest was easier to do at smaller facilities and most cases could be identified in real time. The larger facilities again relied on electronic systems and administrative databases to identify potential cases. Validation occurred through medical record review or clinical information system screening which was a labor-intensive process.

Identifying potential cases of interest through the utilization of administrative databases alone may be the most cost efficient way to identify adverse events. It is not as timely and an administrative database will not identify 100% of the cases, but using the SPARCS administrative database as a safety net is probably the one most effective method of case identification, especially in larger, more complex facilities.

Education in combination with forcing functions and audit and feedback seemed to be the most effective way to change physician behavior. Modalities for education included multidisciplinary grand rounds, divisional lectures, web-based education program, providing supportive materials (i.e. posters, pocket cards), as well as support from local opinion leaders. The SSI study actually obtained consensus that their established protocol for antimicrobial prophylaxis is instituted as a standard of care at each participating facility. This more prescriptive approach appeared to be effective in improving compliance rates with their protocols.

Finally, ongoing communication was a key factor in the success of all three projects. Regular face-to-face meetings and conference calls facilitated frequent communication among the key stakeholders in the projects allowed issues to be discussed and resolved in a timely manner. Ongoing communication also allowed the momentum of the project to continue in a positive way. It also showed the commitment to keep the projects on track.

Patients Safety Awards

The Health Department has created the New York State Patient Safety and Patient/Resident Safety Award Program. To assist in the effort and to reduce medical errors and recognize provider improvement initiatives, New York State established an award program that publicly acknowledges providers that have become leaders in this endeavor. Starting in 2002, the Department granted awards of \$200,000 to two hospitals for their patient safety initiatives.

Based on the initial success by hospitals to improve and recognize patient safety efforts, the Commissioner of Health expanded the awards to include other entities. Awards for two hospitals, two nursing homes, one adult care facility and one federally qualified health center are now available each year based on their accomplishments in promoting patient and resident safety and reducing errors. In addition to receiving the New York State Award, each awardee is provided with a grant of up to \$200,000 to work with the Department of Health in promoting their initiatives for reduction strategies with other health care providers in New York State.

Awards are based on evidence that quality improvement efforts have produced actual reductions in errors. There are two award categories for hospitals based on size; one award for hospitals 200 beds or less and one for those with more than 200 beds. There are two award categories for nursing homes; one award for nursing homes 150 beds or less and one for those with more than 150 beds. There is an award category for adult care facilities and one award category for federally qualified health centers. Award winners are expected to work with the Department and be willing to share their strategies for reducing errors. The selection of award winners is made by a panel including national experts in quality improvement of health care.

In the year 2002, the Department granted awards of \$200,000 to two hospitals that designed and implemented systems to improve patient safety in their facilities.

Ellis Hospital in Schenectady demonstrated a substantial decrease in the incidence of deep vein thrombosis (DVT) in their surgical population.

The Hospital of Special Surgery in Manhattan created a dramatic reduction in medication errors, thereby substantially reducing risk to patients under their care.

In the year 2003, awards of \$200,000 were granted to five facilities for their outstanding efforts in improving the quality of care for their patients.

Children's Hospital of Buffalo developed a comprehensive medication selection system and tutorial with competency exam for their house staff. The system included a requirement to complete an "indication" field (reason the drug is indicated) on the medication order form. This resulted in a significant reduction in medication errors.

Albany Memorial Hospital created a system whereby nurse case managers coordinated the full spectrum of care for patients with congestive heart failure. This comprehensive approach resulted in an extraordinary reduction in re-admissions for the cardiac patients.

United Health Services, Ideal Senior Living Center, a nursing home in Endicott, received a patient safety award for their detailed process improvement effort to reduce pressure ulcers in their residents. An interdisciplinary team was established to re-evaluate and re-assess all residents on a quarterly basis, resulting in substantial reductions in the incidence of pressure ulcers.

Sunset Park Family Health Center Network was recognized for implementing a number of successful interventions to improve clinical outcomes for their patients. The successful improvement areas included in this award recognition were expedited HIV testing, management of pediatric asthma patients and testing on adult diabetics. Significant improvements were demonstrated in these categories as a result of the creation of a diabetic registry, an interdisciplinary team approach to care the development of clinical guidelines, and case management services for high risk patients.

In the year 2004, the following facilities received awards:

Brookdale Hospital Center for the successful implementation of infection control policies and procedures to reduce patient risk of central venous catheter related blood stream infections. Brookdale was able to demonstrate an 89% reduction in catheter related infections within three years of implementation.

Geneva General Hospital established and refined protocols to require lipid profiles for patients receiving care in the emergency department of acute myocardial infarction. When a patient presents to the emergency department with chest pain, orders for lipid profiles are submitted from a preprinted cardiac admitting form. The compliance rate for patients receiving lipid profiles within 24 hours improved from 43% in 2000 to 80% in 2003.

Bellevue Woman's Hospital created a comprehensive prenatal case management and incentive program to identify and assess women for potential high-risk pregnancies. The case management program promotes healthy lifestyles for women and includes access to educational classes and materials on child bearing, referrals to employment services, access to mental health services, and alcohol and substance abuse counseling. Since the program's inception in 1999, there have been no infant deaths or pregnancy terminations involving participating women.

Morris Heights Health Center developed an Advanced Access Program to ensure patient access to primary care physicians for all visits and tailored the visits to the need of every patient. The program includes strengthened triage and assessment policies that have led to improved patient care.

In the year 2005 the following facilities received awards:

St. Francis Hospital, Poughkeepsie: Implemented and enhanced protocols designed to raise awareness and staff accountability to improve the accuracy of patient identification. The protocols emphasize accurate patient identification through required inter-department review and comparison of patient ID bands with the patient census reports to identify patients who did not have ID bracelets or their bracelets contained incorrect information.

St. Mary's Hospital, Amsterdam: An interdisciplinary Quality Improvement Team was convened to assess the entire medication administration process. Multiple decision points and variations between and among units were identified. Adding unit coordinator positions, expanding pharmacy hours, automated dispensing machines and continuous education and reassessment of patients has improved medication management and related services.

Long Island State Veteran's Home Stony Brook: The nursing home undertook an extensive review to accurately identify and address the root causes of falls. By reassessing the incident process the committee was able to completely overhaul the incident reporting system. A daily log for trending causes, staff education, and a new accident reporting form has been implemented as a result. This successful fall prevention program has resulted in a significant reduction in the number of incidents involving resident falls within the home.

Beechwood Continuing Care, Getzville: By establishing a Building on Excellence for Quality program the facility had experienced documented and sustained improvements in reducing the incidence of falls and pressure ulcers. The four-step program along with consistent leadership and more effective utilization of existing resources have contributed to a major change in current practice. As a result, the quality indicators used to identify and respond to falls and skin ulcers among residents have been refined.

Madison York Assisted Living, Corona: Implemented a multi-directional strategy for improving medication management that focus on substantially improving the documentation of prescription drugs provided to patients and strengthening incident reporting. This adult care facility focused on improving adherence to the medication management systems through training sessions with staff, as well as residents to take medication, pharmacy initiated events and discontinuance of medication instructions from outside physicians.

Hudson Headwaters Health Network, Glen Falls: By undertaking an extensive analysis of the policies in use at each of the networks eleven facilities, the incident reporting process was found to be cumbersome, confusing and inconsistent. Streamlining the reporting process has strengthened the networks ability to track prescription drugs, as well as prevent the potential for drug diversion and the improper use of medications.

As part of the 2005 ceremony, Dr. Novello also presented certificates of recognition to Mount Sinai Medical Center (New York City), Strong Memorial Hospital (Monroe County), Huntington Living Center (Seneca County) and DePaul Adult Care Community (Rochester) for their efforts in the advancement of patient safety initiatives.

The awards represent an important component of New York's comprehensive statewide patient safety initiative to identify adverse incidents involving patients and to promote the development of additional quality assurance measures by hospital's statewide. Since 2000, New York State has dedicated more than \$7 million to this program.

New York State Patient Safety Improvement Corps (PSIC)

New York State DOH sent a delegation to the first Annual three week course in Washington DC sponsored by AHRQ and taught by the VA National Center for Patient Safety (VA-NCPS). After completion of the course in May 2004, NYSDOH staff developed curriculum and held thirteen regional training days, held in seven regional locations to disseminate materials learned at the PSIC.

The newly developed root cause analysis protocol was disseminated at these training forums and implemented by the Department on November 1, 2005. This comprehensive protocol should improve the quality; thoroughness and credibility of all root cause analysis (RCA) submitted into the NYPORTS system. New York State DOH was the first in the country to develop and implement a RCA protocol.

Development and Implementation of Root Cause Analysis Protocol

A collaborative effort involving the Patient Safety Improvement Corps (PSIC) team members, NYSDOH Central Office Administration, the Patient Safety Project Director and Project Managers, NYSDOH Hospital Program Directors and Regional NYPORTS coordinators, led to finalization and implementation of a new RCA Evaluation Protocol.

The need for improving the quality of RCA submissions was first realized during expert analyses of the documents for feedback of trended information and lessons learned across the state. Additionally, the recent NYPORTS audit by the Office of State Comptroller described the need for establishing a standardized method that assures RCA's are submitted on time and are evaluated for thoroughness and credibility. The JCAHO and the VA National Center also noted a wide variation in the quality of RCAs for Patient Safety.

NYSDOH's PSIC project involved the development and implementation of the RCA evaluation protocol. The PSIC provided expert patient safety education, which was utilized in the early drafts of the RCA evaluation protocol.

Effective November 1, 2004, every RCA submitted by facilities into NYPORTS is evaluated to assure it meets standard criteria for thoroughness and credibility. The RCA Evaluation Protocol criteria categories are:

- Coding of occurrence: short form codes, detail 900 series codes
- RCA narrative description
- System and process factors
- Literature search
- Leadership and corporate culture
- Executive summary of the analysis
- RCA participants
- Quality/Standard of care

Under each category, the criteria outlines the expectations of what information is contained within a credible and thorough RCA. For example, in the literature search category, at least three sources should be utilized including books, articles, and websites. The name of the author(s), title of article, date of publication, journal name, volume number, should be listed. The focus of the literature search must be on issues relevant or related to the event(s) that includes established community standards of care.

The RCA Protocol was disseminated statewide between September and November 2004 as part of Patient Safety Training which concentrated on the RCA process and culture of patient safety.

Prior to submission of a RCA, facility NYPORTS coordinators should assure that information contained in the RCA meet all criteria within the protocol. If a RCA does not meet the criteria the facility will be asked by the DOH regional NYPORTS coordinators to add or edit information until all criteria are satisfied.

A copy of the RCA Evaluation Protocol has been placed on the NYPORTS Bulletin Board for convenient access. Elements of the protocol were also placed on the HELP screens on the RCA pages of the electronic RCA in June 2005. **See Appendix E for Root Cause Analysis Protocol.**

Statewide Patient Safety Training

Eleven statewide full day Patient Safety educational sessions were conducted by NYSDOH staff Janet Mannion and Peg Dameron and hosted by respective hospital associations in nine regional sites between September 2004 and March 2005. Over 750 Healthcare professionals, mainly from hospital quality and risk management departments were in attendance. The educational sessions included:

- Culture of Safety. The current views of today's patient safety leaders, What the issues are and how we can begin to effectuate change. Education on human factors engineering and systems approach to reducing adverse events.
- Josie King video and discussion. Josie King was a young child that died of a series of medical errors at John's Hopkins. The video highlights the Josie King Pediatric Patient Safety Center and how Josie's parents partnered with the staff at John's Hopkins staff to inspire caregivers to prevent what happened to Josie from happening to other patients.
- Human Factors Engineering (HFE) Human factors engineering is one of the basic sciences
- Process for Improving Root Cause Analysis (RCA). RCA is a tool for identifying strategies to prevent re-occurrence of an adverse event(s). It is a process that is part of the effort to build a culture of safety and move beyond the culture of blame.
- Root Cause Analysis Evaluation Protocol (see above).
- RCA Practicum. Practice RCA on post-operative patient that had a near fatal Pulmonary Embolus Practicum included: a full description of the event, formation of a problem statement, formation of a flow diagram, formation of a cause and effect diagram, identification of system root causes and contributing factors of the occurrence, risk reduction strategies/actions to prevent reoccurrence, measures of effectiveness, literature search, leadership participation, standard of care, and summary.

These sessions were conducted as a "train the trainer" program. Hospitals were given the powerpoint presentations and could then tailor them for use at their own facility training sessions.

“Working Together: Partnering for Patient Safety” Conference

The Department of Health, in collaboration with the US Health and Human Services' Agency for Healthcare Research and Quality held its second Patient Safety Conference, ***Working Together - Partnering for Patient Safety*** at the Desmond Hotel and Conference Center on March 16 & 17, 2005. Approximately 300 professionals from hospitals, nursing homes, ambulatory surgery centers, health plans, healthcare associations, DOH and other interested parties were in attendance for the one and a half-day conference.

James Bagian, MD, Director of the VA National Center for Patient Safety, keynote speaker, opened the conference. Dr. Bagian's keynote speech focused on the culture of safety in healthcare organizations, defined the issues related to patient safety and quality assurance, and identified ways to help prevent medical errors from occurring. "Patient Safety is the foundation upon which quality health care is built, this conference affords us an outstanding opportunity to share the knowledge we have gathered through years of practical experience," Dr. Bagian said.

The overall goal of the conference was to enhance and promote patient safety for healthcare organizations by sharing lessons learned from national, state and local leaders. It was also a forum to showcase the Department's AHRQ funded demonstration projects in an effort to disseminate information on implementation of evidence based guidelines that can improve the quality of healthcare for New York residents. Four breakout sessions included topics on Consumer Centered Healthcare, Medication Errors, Performance Measures and Quality and Bariatric Surgery as follows:

- **Medication Errors:** The presentations focused on medication safety. Participants examined the role of communication and teamwork in medication safety; described an analysis of medication errors reported through the NYPORTS program; and discussed national efforts to reduce adverse medication outcomes.
- **Performance Measures and Quality:** Panelists promoted ways to strengthen the delivery of quality health care and ways to measure outcomes. Collectively, they shared examples of current initiatives that they were undertaking while providing an overview of performance measurement and quality in health care facilities.

- **Bariatric Surgery:** Obesity is now considered a national epidemic creating a major national health crisis. With more than five million Americans classified as “morbidly obese,” the demand for bariatric surgery is on the rise. The session focused on issues surrounding patient selection criteria; surgeon qualifications and optimum equipment and staffing for facilities offering weight loss surgery.
- **Empowering the Patient/Consumer Centered Health care:** Participants discussed what patients must be aware of to help them make well-informed health care decisions and how patients can help improve their own outcomes by asking questions and effectively communicating with health care providers.

The focus of the second day was how Health Information Technology can improve patient safety. Rex Cowdry, MD, MPH, Senior Consultant, Office of the National Coordinator for HIT, presented the keynote address on the US government’s strategic framework for improving health care through HIT and the role of the public and private sectors in developing standards for electronic health records.

Dr. Cowdry said, “Done well, electronic medical records, decision support and secure information exchange can make patient safety efforts far more comprehensive and effective”. “Done well, health information technology will reach well beyond patient safety, empowering patients and transforming our health care system into a patient-centered, information-rich, provider friendly and integrated system”. His address was followed by a panel presentation on IT initiatives around the state.

The Health Information Technology (HIT) Panel highlighted some of the groundbreaking strides being made in New York State towards incorporating state-of-the-art information technology with clinical practice to further protect patients.

Department of Health Publications

As a national leader in the evolution of reporting systems, it was important for New York State to share the challenges and lessons learned during the evolution and implementation process. **Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems** was published in February 2005 in an AHRQ/DOD publication called Advances in Patient Safety.

Critical elements for success of a mandatory reporting system were shared including: basing the system on statute, collaborative system with clear definitions and objective reporting criteria, providing meaningful data that can be analyzed and disseminated for improving patient safety, and adequate resources to maintain the system. **See Appendix E for this article.**

Qualitative and Quantitative Analysis of Medication Errors: The New York Experience, was also published in the February 2005 publication, Advances in Patient Safety. The analysis concluded that mandatory error reporting can provide useful information about systems contributing to errors, strategies for prevention and evidence based information. This information is important for hospitals to consider when analyzing medication errors and implementing system fixes to improve patient safety. **See Appendix E for this article.**

Work in Progress

The Department of Health is committed to continuously improving the quality of care and increasing patient safety for residents of New York State. NYPORTS plays a critical role in achieving these goals.

After careful analysis of the New York Patient Occurrence Reporting and Tracking System (NYPORTS), the Department of Health initiated a project in 2004, to not only redesign the functionality of the system but to streamline and clarify reporting requirements. The code revisions were implemented on June 1, 2005.

The Department, working in collaboration with facilities and hospital associations, incorporated user feedback into the project plan for the system enhancements.

System Enhancements

"NYPORTS 2005" retained all of the functionality of the previous system but has been reprogrammed to include the following enhancements:

- "NYPORTS 2005" was re-written using .net technology, which allows for improved compatibility with web-based applications into the future.
- Users are able to navigate the system more easily and efficiently. For example, action and navigation buttons have been added to the bottom of key areas of NYPORTS to allow for the desired action with one click.
- A revised report function was designed to allow facilities to generate reports using selected parameters. This function will retain the facility's ability to compare their experience against peer group, regional or statewide data. New reports will assist facilities in tracking their occurrences that require RCA and generate data suitable for use in Quality Assurance activities.
- A search function was added that can locate occurrences in the database based on specific criteria.
- Help pages are now available throughout the application to guide users through the process.

The Department is confident that these changes to NYPORTS will improve the efficiency of use while providing additional features that will assist facilities in meeting their reporting requirements, generate data for internal QA purposes and uncover meaningful root causes, contributing factors and risk reduction strategies.

Code Revisions

Following a detailed analysis of NYPORTS, the Department reduced the number of reportable events, effective June 1, 2005. While each reporting category in NYPORTS represented adverse events that impact patient safety, the Department retained sentinel events mandated in regulation as well as additional events which might yield the most significant risk reduction strategies. These codes relate to patient safety initiatives, such as implementation of evidenced-based protocols. All retained codes lend themselves to meaningful data analysis that can be conducted and lessons learned shared statewide (See Appendix B for new Includes/Excludes list).

Process Measures Project: Codes 401 and 604

The "Using process measures to improve patient safety practices for PE and AMI" project is expanding upon lessons learned from two of the recently completed Agency for Healthcare Research and Quality reporting demonstration projects. The project is aimed at increasing the use of prophylaxis for patients at risk for developing acute myocardial infarction following non-cardiac surgery and pulmonary embolus in hospitalized patients.

The Project requires that each of 12 participating facilities implement and evaluate process measures. The measures were designed to increase the awareness and use of prophylaxis among patients at risk for developing one of these conditions. This project will enable the New York State Department of Health to be a collaborative partner with facilities, in improving patient safety for all patients in New York. An aggressive dissemination program will facilitate the sharing of findings.

Projects completed over the last two years by the New York Presbyterian Healthcare System and the University of Public Health, IPRO, of Rochester, Strong Memorial Hospital showed significant increases in the use of beta-blocker and thromboprophylactic agents respectively for patients at risk. However, there is still much opportunity for improvement in changing practitioner behavior to increase adherence to evidence based guidelines.

The New York State Department of Health is carrying out the proposed project in collaboration with the University of Albany School the New York Presbyterian Healthcare System, and Strong Memorial Hospital. An advisory group consisting of members from the collaborating organizations is reviewing the project and advising on future activities. Should the project be successful, it is anticipated that it will be implement statewide and the collection of process measures data will be incorporated into NYPORTS.

Future NYPORTS Initiatives

The Department is committed to continuous evolvement of its mandatory reporting system in the following areas:

- The Department will continue to improve NYPORTS through further refinement of definitions and improvement in the reporting process. The Refinement subcommittee is responsible for the task of clarifying language in the electronic system and manuals. They will also examine the includes/excludes list to determine whether codes need to be modified, added or deleted.

- The Department will provide ongoing training to hospitals on relevant issues related to NYPORTS including system improvements, changes in definitions to NYPORTS and patient safety.
- The Department will monitor reporting compliance through overall hospital surveillance activities and appropriate enforcement actions will be taken. Sanctions will be imposed for continued failure to report as required. Chart reviews by an independent outside agent will continue to identify non-reported NYPORTS events.
- The Department will continue to identify Root Causes and Risk Reduction Strategies after selective analysis. This information will be shared with hospitals to support improvement in patient care systems.
- The Department will continue to issue the NYPORTS News and Alert on a periodic basis, or as needed, to disseminate reporting up-dates, patient safety related information and data analysis to facilities.
- The Department will continue its collaboration with the University at Albany School of Public Health to analyze and extract patient safety data from NYPORTS.
- NYPORTS subcommittees will remain active in their pursuit of sharing information and making improvements to the system. The Medication Error subcommittee will examine data specific to medication related occurrences. Root causes and corrective actions will be identified by the group and shared with facilities. The RCA subcommittee will focus on changes to the RCA form and process, and suggest improvements to the system.
- The Department will collaborate with Island Peer Review Organization (IPRO), in their medical record review process, to improve the completeness of reporting in NYPORTS.

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Greater New York Hospital Association
Healthcare Association of New York
Iroquois Healthcare Alliance
Nassau Suffolk Hospital Counsel
Northern Metropolitan Hospital Association
Rochester Regional Hospital Association
Western New York Hospital Association

APPENDIX A

Counties by Region

WESTERN NEW YORK

Allegany, Cattaraugus, Chautauqua, Erie, Genesee, Niagara, Orleans, Wyoming

FINGER LAKES

Chemung, Livingston, Monroe, Ontario, Schuyler, Seneca, Steuben, Wayne, Yates

CENTRAL NEW YORK

Broome, Cayuga, Chenango, Cortland, Herkimer, Jefferson, Lewis, Madison, Oneida, Onondaga, Oswego, St. Lawrence, Tompkins, Tioga

NORTHEASTERN NEW YORK

Albany, Clinton, Columbia, Delaware, Essex, Franklin, Fulton, Greene, Hamilton, Montgomery, Otsego, Rensselaer, Saratoga, Schenectady, Schoharie, Warren, Washington

HUDSON VALLEY

Dutchess, Orange, Putnam, Rockland, Sullivan, Ulster, Westchester

LONG ISLAND

Nassau, Suffolk

NEW YORK CITY

Bronx, Kings, New York, Queens, Richmond

**APPENDIX B
NYPORTS INCLUDES AND EXCLUDES LIST**

INCLUDES/EXCLUDES LIST

OCCURRENCE CODE	INCLUDES	EXCLUDES
<p>CODE 401 Thromboembolic Disorder</p> <p>Include Readmission's Within 30 days</p>	<p>New Acute Pulmonary Embolism (PE) confirmed or suspected and treated.</p> <ul style="list-style-type: none"> • PE occurring during a hospital stay or, • Patients readmitted with a PE within 30 days of a discharge. 	<ul style="list-style-type: none"> • Acute pulmonary embolism present on admission (patient would not have had a hospitalization in the past 30 days). • New, acute pulmonary embolism is suspected cause of sudden death but there is no autopsy to confirm (consider for 915 reporting). • End of life care patients who are intentionally not prophylaxed (e.g., comfort care, and hospice).
<p>CODE 402 Thromboembolic Disorder</p> <p>Include Readmission's Within 30 days</p>	<p>New Documented Deep Vein Thrombosis (DVT) at any site.</p> <ul style="list-style-type: none"> • DVT occurring during a hospital stay or, • Patients readmitted with a DVT within 30 days of a discharge regardless of the reason for the previous hospital stay. 	<ul style="list-style-type: none"> • Superficial thrombophlebitis. • New documented DVT present on admission (patient would not have had a hospitalization in the past 30 days). • Patient's who are admitted through the ED with a rule out diagnosis of DVT and receive treatment (medical record must support the R/O DVT diagnoses). <p>NOTE: If DVT were confirmed, it would not be excluded if the patient had a previous hospitalization in the past 30 days.</p> <ul style="list-style-type: none"> • End of life care patients who are intentionally not prophylaxed (e.g., comfort care, and hospice).
<p>CODE 604 Perioperative Or Endoscopic Related AMI</p> <ul style="list-style-type: none"> • Occurring the same day as, or on the 1st or 2nd day after a procedure <p>Include readmission's occurring the same day as, or on the 1st or 2nd day after a procedure</p>	<p>Acute Myocardial Infarction (AMI) unrelated to a cardiac procedure.</p> <ul style="list-style-type: none"> • Operative procedures done in the operating room or ambulatory surgery suite. • Endoscopy procedures. <p>NOTE: Consider codes 915 or 916 when applicable.</p>	<ul style="list-style-type: none"> • Cardiac diagnostic or interventional procedure occurrences (complications) reported to the Cardiac Services Reporting System (CSRS), (e.g., bypass or other structural cardiac repairs such as aortic repair within the thoracic cavity, cardiac catheterization). • Multiple trauma, AAA rupture known at time of surgery. • ESRD (end stage renal disease) patients during and post dialysis treatment.

OCCURRENCE CODE	INCLUDES	EXCLUDES
CODE 701	Burns <ul style="list-style-type: none"> • 2nd and/or 3rd degree burns occurring during inpatient or outpatient service encounters. NOTE: Consider 900 codes when applicable.	<ul style="list-style-type: none"> • Burn present on admission. • 1st degree burns (see definitions).
CODE 751	Falls Resulting in x-ray proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma (e.g., hepatic or splenic injury). NOTE: Consider 900 codes when applicable.	<ul style="list-style-type: none"> • Falls resulting in soft tissue injuries (bruising, reddened areas). • Falls with no harm identified. • Dislocations (consider for code 918)
CODE 808 Surgical Related Infection: <ul style="list-style-type: none"> • Within 30 Days Of Surgical Procedure While Hospitalized. <p>Include Readmission Within 30 Days Of Surgical Procedure.</p>	Post-op surgical wound Infection: Following clean or clean/contaminated case that requires incision and /or drainage or IV antibiotics during the hospitalization. <ul style="list-style-type: none"> • Performed in the operating room or surgical suite only. • ASA class is required to be noted on the NYPORTS short form report • Infections related to the same surgical intervention, which may not be located at the primary surgical wound site (e.g., external drain site, associated internal tissue). • Patients readmitted within 30 days within 30 days of a surgical procedure with a post-op wound infection. 	<ul style="list-style-type: none"> • Contaminated or dirty case procedure. • Wound opening for therapeutic measures to enhance/promote healing process. • Allograft site infection Reported these occurrences to Blood and Tissue Resources Program (BTRP). • Sepsis related to central line insertion (reportable to the DOH Infection Control Program when facility thresholds are exceeded). <p>Exclude cardiac surgery related infections (occurring in approved cardiac surgical centers only) meeting the following definitions:</p> <p>For Adult Cardiac Surgery Reporting System (CSRS)</p> <ul style="list-style-type: none"> • Deep Sternal Wound Infection: (Involvement of bone with drainage of purulent material from the sternotomy wound and instability of the sternum). • Sepsis: (Fever and positive blood cultures related to the procedure). • Endocarditis: (Two or more positive blood cultures without obvious source, demonstrated valvular vegetation or acute valvular dysfunction cause by infection). <p>For Pediatric Cardiac Reporting System (PED CSRS)</p> <ul style="list-style-type: none"> • Any sternal wound infection (drainage of purulent material from the sternotomy wound). <p>Clinical sepsis/positive culture (with temp>101 and increase WBC or temp<98.6 and decreased WBC).</p>

OCCURRENCE CODES	INCLUDES	EXCLUDES
<p>Medication Errors: 108-110 Report Within 24 Hours Of Date Of Awareness.</p> <p>CODES 108-110 Require:</p> <ul style="list-style-type: none"> • Associated 900 Detail Code • Completion Of The Medication Supplement Form • Root Cause Analysis. 	<p>108. A medication error occurred that resulted in permanent patient harm.</p> <p>NOTE: NYPORTS defines permanent harm for code 108, as an impairment meeting codes 916- 918 reporting criteria (See examples).</p> <p>109. A medication error occurred that resulted in a near-death event (e.g., cardiac or respiratory arrest requiring advanced cardiopulmonary life support (ACLS).</p> <p>110. A medication error occurred that resulted in a patient death.</p>	<p>108-110. Any adverse drug reaction that was not the result of a medication error.</p> <p>108. Medication error that resulted in the need for treatment, intervention, initial or prolonged hospitalization and caused temporary harm.</p> <p>109. Medication error results in cardiac or respiratory arrest requiring the need for basic life support only.</p> <p>110. Death that is not the direct result of a medication error (consider code 915).</p>
<p>CODE 911 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Wrong Patient, Wrong Site Surgical Procedure</p> <ul style="list-style-type: none"> • Surgical procedures performed in the operating room or ambulatory surgery suite only. • Surgery that proceeds to surgical incision or beyond. 	<ul style="list-style-type: none"> • Surgery which proceeds with the administration of anesthesia only and is stopped or rescheduled (code as 912). • Procedures usually done outside the O.R (e.g., Endoscopy, Interventional Radiology, Nursery, bedside, E.D.).
<p>CODE 912 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Incorrect Procedure or Treatment - Invasive</p> <p>Some O.R. occurrences that are not wrong patient or site, such as:</p> <ul style="list-style-type: none"> • Inserting the wrong surgical implant (e.g., lens or total knee components). • Surgical procedures that involve the administration of anesthesia only prior to commencement of a surgical incision. • Wrong treatment or procedure performed on a patient related to error of omission, laboratory or radiological findings. 	<ul style="list-style-type: none"> • Venipuncture for Phlebotomy • Diagnostic tests without contrast agents. • Transfusion related occurrences are to be reported to Blood & Tissue Resources Program (BTRP) only.

OCCURRENCE CODES	INCLUDES	EXCLUDES
<p>Code 913 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Unintentionally Retained Foreign Body (e.g., sponges, lap pads, instruments, guidewires from central line insertion, cut intravascular cannulas, needles)</p> <p>Retained foreign body discovered after wound closure while still in O.R.</p>	<ul style="list-style-type: none"> Foreign bodies retained due to equipment malfunction or defective product (report under code 937 or 938). Intentionally leaving a foreign body - must be assessed on a case by case basis (e.g., foreign body left for treatment reasons).
<p>CODE 915 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Unexpected Death (E.g., brain death). In circumstances other than those related to the natural course of illness, disease or proper treatment (e.g., delay in treatment, diagnoses or an omission of care) in accordance with generally accepted medical standards.</p> <ul style="list-style-type: none"> Death of fetus/neonate meeting all the following criteria: <p>For live Or Still Birth</p> <ul style="list-style-type: none"> Greater than or equal to 28 weeks gestation Greater than or equal to 1000 grams of weight Any iatrogenic occurrence resulting in death at any gestation/weight. All maternal deaths 	<ul style="list-style-type: none"> End of life care such as DNR with comfort care only, Hospice Patients. <p>Emergent and unplanned surgical patients with significant mortality category (ASA1V or V) if the occurrence is not related to deviation from the standard of care, medication error, omission, delay, or an iatrogenic event.</p> <p>Patients admitted with severe illness/incapacitating systemic disease that is a constant threat to life or moribund and not expected to survive for 24 hours with or without an operation</p> <p>Death of fetus/neonate with presence of congenital anomalies incompatible with life (e.g., Anencephalus, Trisomy 13,18, Tracheal or Pulmonary Atresia, Multiple life threatening congenital anomalies).</p> <p>Sepsis related to opportunistic infection following required antibiotic therapy (e.g., C. Difficile) resulting in death.</p> <ul style="list-style-type: none"> Transfusion related death, report to Blood and Tissue Resources Program (BTRP) only.
<p>CODE 916 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Cardiac And/Or Respiratory Arrest Requiring ACLS Intervention. In circumstances other than those related to the natural course of illness, disease or proper treatment (e.g., delay in treatment, diagnoses or an omission of care) in accordance with generally accepted medical standards</p>	<ul style="list-style-type: none"> Events not requiring ACLS intervention.

OCCURRENCES CODES	INCLUDES	EXCLUDES
<p>CODE 917 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Loss Of limb Or Organ. In circumstances other than those related to the natural course of illness, disease or proper treatment (e.g., delay in treatment, diagnoses or an omission of care) in accordance with generally accepted medical standards</p> <ul style="list-style-type: none"> • Impairment must be present at discharge or for at least 2 weeks after occurrence if patient is not discharged <p>Ruptured uterus requiring hysterectomy following VBAC.</p>	<ul style="list-style-type: none"> • Malfunction of equipment resulting in death or loss of limb or organ should be reported under 938. • Procedure related injuries resulting from intended direct operation on an organ or anatomical structure based on disease process or lack of alternative approach to address the surgical condition. • Vascular cases where conservative approach tried first (e.g., thrombectomy or fem-pop bypass), but ultimately fails (below knee amputation done as last resort).
<p>CODE 918 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Impairment Of Limb, Organ or Body Functions. (limb, organ body function unable to function at same level prior to occurrence). In circumstances other than those related to the natural course of illness, disease or proper treatment (e.g., delay in treatment, diagnoses or an omission of care) in accordance with generally accepted medical standards.</p> <ul style="list-style-type: none"> • Impairments present at discharge or for at least 2 weeks after occurrence if patient is not discharged. • Body function (e.g., sensory, motor, communication or physiologic function diminished from level prior to occurrence). 	<ul style="list-style-type: none"> • Procedure related function loss resulting from direct operation on an organ or other anatomical structure based on disease process or lack of an alternative approach to address the present surgical condition. • Limb or body functions at the same level as prior to the occurrence, impairment resolves by discharge or within two weeks if not discharged. • Positioning parathesias. • Any case involving malfunction of equipment resulting in impairment should be reported under 938. • Surgical nick to bladder requiring foley catheter to promote healing.
<p>CODE 938 Root Cause Analysis Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Malfunction Of Equipment during treatment or diagnosis, or a defective product Resulting In Death Or Serious Injury (as described in 915-918) to patient or personnel</p> <p>Please include:</p> <ul style="list-style-type: none"> • equipment/device name • malfunction • model # • serial # 	

OCCURRENCE CODES	INCLUDES	EXCLUDES
<p>CODE 901 Submit Short Form Only</p> <p>Root Cause Analysis May Be Required</p>	<p>Serious occurrence warranting DOH notification (not covered by codes 911-963).</p>	
<p>CODE 902</p> <p>This Code Is Applicable To Article 28, Diagnostic And Treatment Centers (D&TC) In Compliance With Section 751 Of DOH Regulations.</p> <p>Report transfers by ambulance within 24 hours of the Date Of Awareness</p> <p>Report electronically into the NYPORTS system (on the HPN) using the NYPORTS shortform</p> <p>Investigation reports must be submitted within 30 days of The Date Of Awareness.</p>	<p>Specific AMBULANCE Transfers to the hospital from an Article 28 diagnostic and treatment center, in circumstances other than those related to the natural course of illness, disease or proper treatment in accordance with generally accepted medical standards (e.g., delay in treatment, delay in diagnoses, iatrogenic event, severe reaction or complication, omission of care).</p> <p>Including The Following Reasons:</p> <ol style="list-style-type: none"> a. Patient required CPR or other life sustaining effort. b. Adverse occurrence resulting in unexpected impairment of body function. c. Adverse Occurrence during OB/GYN procedure. d. Adverse Occurrence while patient treated in an ambulatory surgical center. 	<ul style="list-style-type: none"> • Occurrences in an extension clinic under a hospital's operating certificate. • Patients transferred to hospital for additional work up or tests in the normal process of follow up. • Patient transferred to hospital for diagnostic tests not available at the D&TC (e.g., MRI). • Patients in dialysis (ESRD) center that require transfer to hospital for shunt repair or treatment of thrombosed shunt sites. • Patients arrive at D&TC with symptomatology or unstable comorbid conditions that warrant immediate ambulance transfer to hospital.

OCCURRENCE CODES	INCLUDES	EXCLUDES
<p>CODE 914</p> <p>Submit Short Form Only</p> <p>Root Cause Analysis Not Required Except as Defined in 16.25 b (2) (ii)</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Misadministration Of Radiation or Radioactive Material (as defined by BERP, Section 16.25, 10NYCRR).</p> <p>Misadministration involving diagnostic or therapeutic use or ionizing radiation (radioactive materials, x-rays and electrons).</p>	
<p>CODE 921</p> <p>Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Crime Resulting In Death Or Serious Injury. As defined in 915-918 (actual death, or near death event requiring ACLS; unexpected loss of limb or organ, impairment of limb, organ or bodily function that exists for two weeks during a hospitalization or at discharge.</p>	<ul style="list-style-type: none"> Crimes that result in other serious events not captured by codes 915-918 may be reported under the voluntary code of 901.
<p>CODE 922</p> <p>Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Suicides And Attempted Suicides Related To An Inpatient Hospitalization, With Serious Injury. As defined in 915-918 (Actual death, or near death event requiring ACLS. Unexpected loss of limb or organ, impairment/ dysfunction of limb or bodily functions that exists for two weeks during a hospitalization or at discharge.</p>	

OCCURRENCE CODE	INCLUDES	EXCLUDES
<p>CODE 931 Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Strike By Hospital/Center Staff.</p>	
<p>CODE 932 Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>External Disaster outside the control of the hospital/Center which effects facility operations.</p> <ul style="list-style-type: none"> • Natural or catastrophic disasters. • Internal facility operations affected directly by a natural or catastrophic disaster. 	<ul style="list-style-type: none"> • Facility operations that are affected by an internal disaster not affiliated with a natural or catastrophic disaster (e.g., septic pipe breaks and leaks toxic gases, patients must be transferred to other units in the facility for continuation of care.) code as 935.
<p>CODE 933 Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p>	<p>Termination Of Any Services Vital To The Continued Safe Operation Of The Hospital Or To The Health And Safety Of Its Patients And Personnel, including but not limited to the anticipated or actual termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food or contract services.</p>	<ul style="list-style-type: none"> • Excludes services maintained by back-up services, planned transitions with seamless continuation of services. (E.g., back up generator to maintain electric for brief period- no change in care or harm, back up O2 supply that its immediately retrieved and no harm or alteration to care occurs, laundry vendor changed over with seamless continued services.) • Termination of services due to the direct result of a natural or catastrophic disaster (code as 932). • Equipment failure related to defect or malfunction (code as 937 or 938)

OCCURRENCE CODES	INCLUDES	EXCLUDES
<p>CODE 934 Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Poisoning Occurring Within The Hospital (water, air, and food).</p>	
<p>CODE 935 Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Hospital/Center Fire or other internal disaster disrupting patient care or causing harm to patients or staff.</p>	
<p>CODE 937 Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Malfunction Of Equipment during treatment or diagnosis or a defective product which has a Potential For Adversely Affecting Patient Or Hospital/Center Personnel <u>or results in a retained foreign body.</u></p> <p>Please include:</p> <ul style="list-style-type: none"> • equipment/device name • manufacturer • model # • serial # 	
<p>CODE 961</p> <p>Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Infant Abduction.</p>	

OCCURRENCE CODES	INCLUDES	EXCLUDES
<p>CODE 962</p> <p>Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Infant Discharged To Wrong Family.</p>	
<p>Code 963</p> <p>Submit Short Form Only</p> <p>Root Cause Analysis Not Required</p> <p>Report Within 24 Hours Of Date Of Awareness.</p>	<p>Rape Of A Patient. (Includes alleged rape with clinical confirmation).</p>	

APPENDIX C
NYPORTS CODE 911 AND 912 ANALYSES

Code 911 and Code 912 Analyses

The following pages describe findings from in-depth review of NYPORTS Code 911 and 912 root cause analyses. The Code 911 information is derived from cases submitted from January 1, 2003 to December 31, 2005 (3 years) and Code 912, from January 1, 2005 to December 31, 2005 (2 years). During these timeframes, 52 adverse occurrences were reported for Code 911 and 202 adverse occurrences were reported for Code 912. A description of these codes with examples, statistics, and actual findings extracted from the respective root cause analyses are shared.

Descriptions and Examples:

Code 911 Wrong Patient, Wrong Site Surgical Procedure

- Surgical procedures performed in the Operating Room or Ambulatory Surgery Suite only.
- Surgery that proceeds to surgical incision or beyond.

Examples of Code 911:

- Patient identified herself as wrong patient (similar names) and was taken to ambulatory surgical suite for eye surgery; surgery completed before it was discovered that it was the wrong patient.
- Bone scan positive for osteomyelitis of left foot; patient taken to OR and biopsy performed on right foot.

Code 912 Incorrect Procedure or Treatment–Invasive

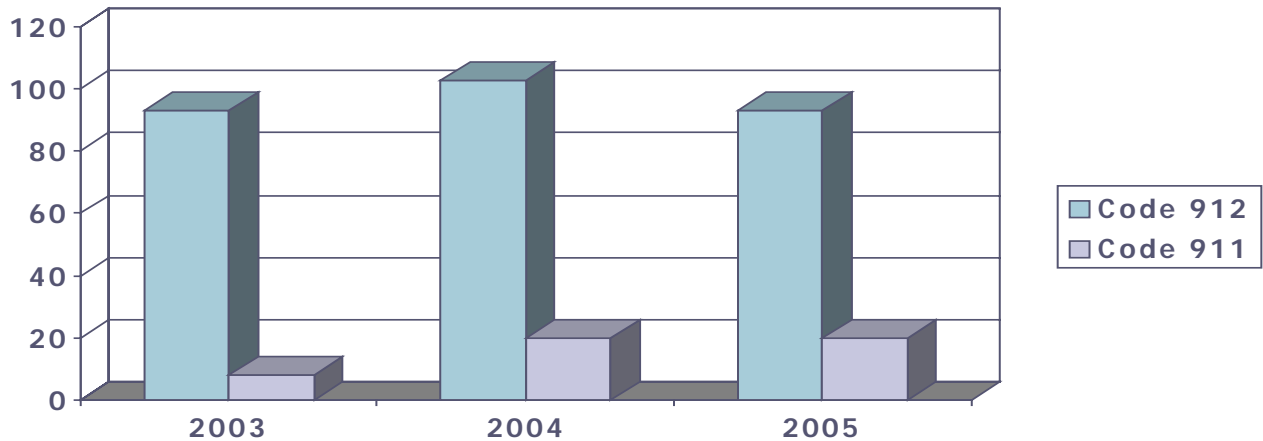
- Includes all wrong patient, wrong site, and wrong invasive procedures outside the Operating **Room or Ambulatory Surgery Suite**.
- In addition, it includes some OR occurrences that are not wrong patient or site, such as:
 - Insertion of the wrong surgical implant (i.e. lens or total knee components)
 - Surgical procedures that involve the administration of anesthesia only prior to commencement of a surgical incision.
 - Wrong treatment or procedure performed on a patient related to an error of omission, laboratory or radiological findings.

Examples of Code 912:

- ED patient with pleural effusion has chest tube insertion on wrong side.
- Patient had the wrong diopter lens implanted in the correct eye.

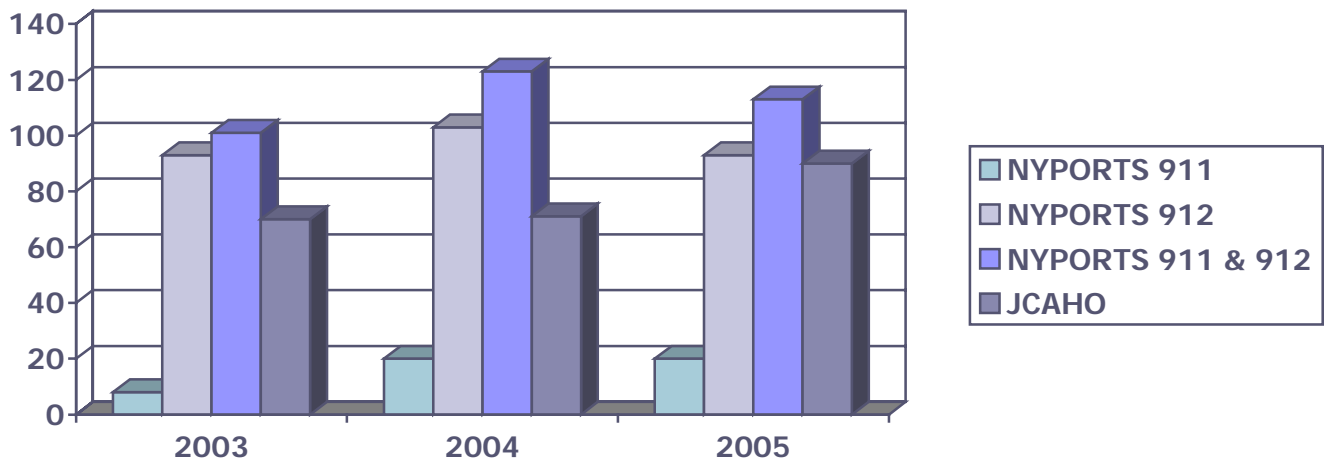
Statistics from our mandatory reporting system show that there is significantly more Code 912 cases than Code 911 cases reported to NYPORTS annually.

Counts of NYPORTS Code 911 & 912 Cases by Year



The following graph shows the yield of mandatory reporting for New York State in comparison to national, voluntary reports, submitted during the same timeframes to the Joint Commission for Accreditation of Hospital Organization (JCAHO).

Counts of NYPORTS and JCAHO Events by Year



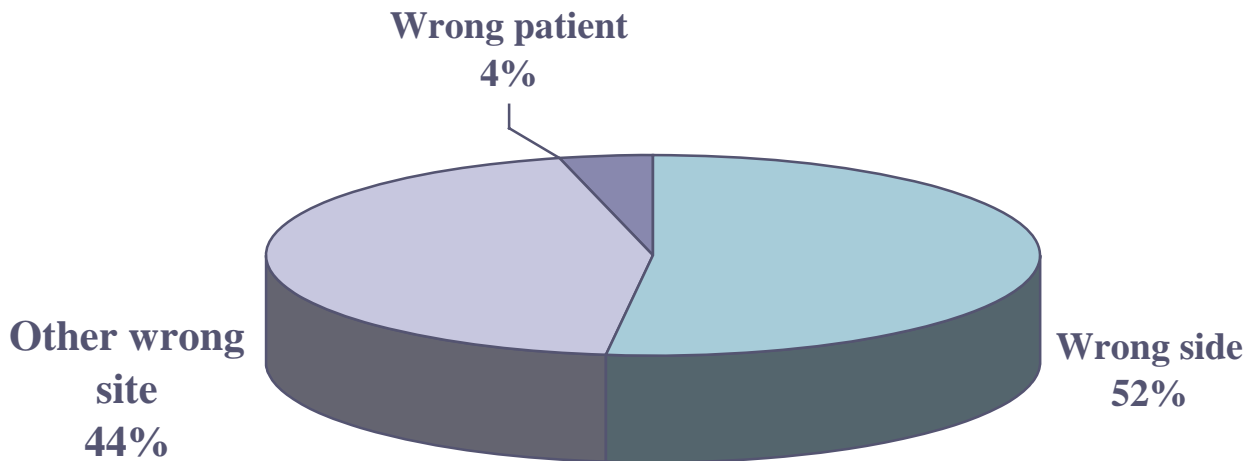
Code 911 and Code 912 categories were further sub-divided by category for analysis.

Below are counts and percentages of Code 911 (Wrong Patient, Wrong Site, operating room or ambulatory surgical suite procedure) by type of event: wrong site, wrong side or wrong patient. Of these cases, wrong site and wrong-sided cases account for 96 % of the total cases submitted.

Code 911 Cases for 2003-2005

Type of Code 911 Event	Count	Actual Event examples
Wrong Site	23	7 finger cases, 7 spinal cases, 1 hernia case
Wrong Side	27	3 hernia cases, 1 spinal case
Wrong Patient	2	1 triple lumen, 1 wrong cataract extraction/implant
Total Code 911 cases	52	

Percentages of Types of 911 Cases for 2003-2005



Counts and percentages of Code 911 cases were also assessed by surgical specialty and anatomical body part affected in the occurrence:

**Code 911 Wrong Site Surgery Cases for 2003-2005
By Specialty**

Specialty # of cases	Percentage
14 Orthopedic surgery cases	27 %
10 General surgery cases	20 %
8 Neurosurgery cases	15 %
7 Urology cases	13 %
6 Cardiovascular-thoracic cases	11 %
1 Otolaryngology case	2 %
1 Vascular surgery case	2 %
1 Obstetrics/gynecology case	2 %
1 Transplant surgery case	2 %
1 Pain Service case	2 %
1 Ophthalmology case	2 %
1 Plastic surgery case	2 %
52 Total cases	100%•

Code 911 Surgery Cases by Anatomical Site for 2003-2005

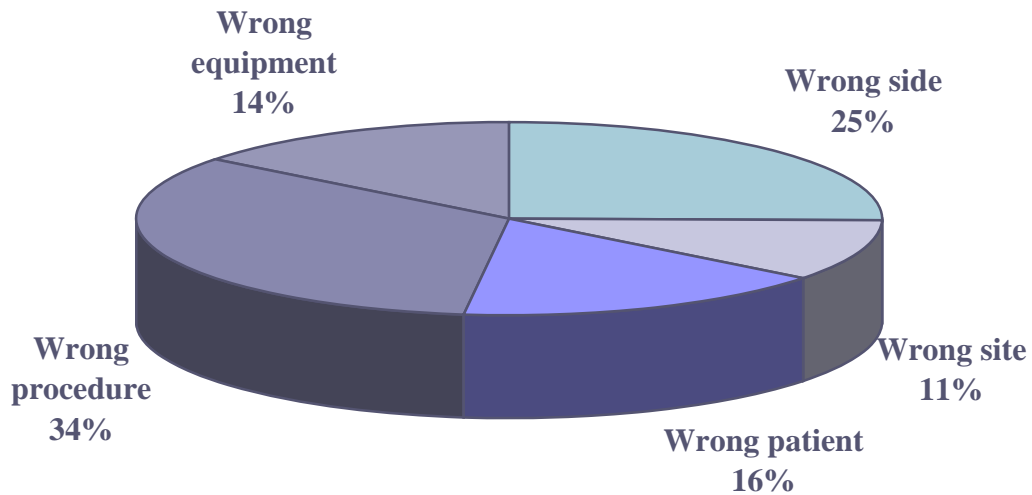
Anatomical Site	#	Anatomical Site	#
Spine	8	Uterus/ovaries/tubes	1
Finger	7	Kidney	1
Chest/rib	6	Heart	1
Ureter	7	Back	1
Hernia	4	Arm	1
Abdominal cavity	3	Ear	1
Leg	2	Hip	1
Foot/ankle	2	Eye	1
Cranium	2	Lip	1
Male genitalia	1		
Arm/forearm	1	Total	52•

Below are counts and percentages of Code 912 (Wrong Treatment or Procedure Invasive) by type of event: wrong site, wrong side, wrong patient or wrong procedure. This code captures OR cases that are not wrong site/ wrong side or wrong patient specific, as well as all other wrong invasive procedures performed outside the OR.

Type of Occurrence Code 912 for 2004-2005

Type of Code 912 Occurrence	#	Percentage
Wrong procedure	68	34%
Wrong side	51	25%
Wrong patient	33	16%
Wrong equipment	29	14%
Wrong site	21	11%
Total	202	100%•

Percentage of Code 912 Cases by Type of Events for 2004-2005



Wrong patient procedures are reported with much greater frequency outside the OR. A large portion of Code 912 cases are OR cases that fall outside the definition of Code 911, including for example wrong procedure or equipment.

Below are counts and percentages of Code 912 cases by the setting where the occurrence happened:

Code 912 Cases by Setting for 2004-2005

Setting of Code 912 Cases	#	%
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, Nursery, ICU ,PACU]	15	7 %
Total	202	100 %•

Of the Seventy-Five, Code 912 OR cases noted above, specific types of events are culled from the reports:

- The wrong procedure is done.
- The wrong side is anesthetized and surgery is stopped before proceeding to the wrong side.
- Wrong equipment is involved in the procedure.

Type of Occurrence Code 912 OR Events for 2004-2005

Type of Code 912 OR event	#	%
Wrong procedure	34	45%
Wrong side (19 Cases are the result of anesthesia given on the wrong side, the case is terminated before surgical incision). The remaining case is a scopic case done in the OR.	20	27%
Wrong equipment	21	28%
Total	75	100%•

Of the twenty wrong side occurrences, nineteen cases involve Anesthesia blocks either done by the Surgeon or Anesthesiologist involved in the case. The table below outlines these cases by count and percentages.

Anesthesia Wrong Side Occurrence Code 912 OR Events for 2004-2005

Type of Wrong Side Case Anesthesia only	#	%
Wrong side shoulder block	5	26%
Wrong eye blocked	5	26%
Wrong side femoral block for knee surgery	4	21%
Wrong side spinal block	2	10.5
Wrong side local for fistula	1	5.5%
Wrong side block for carotid surgery	1	5.5%
Wrong side block for ankle surgery	1	5.5%
Total	19	100 %•

Counts and percentages of wrong equipment used in an OR procedure are shown below. The wrong diopter lens (for eye surgery) accounts for 70 % of wrong equipment OR cases.

OR Wrong Equipment Code 912 Cases for 2004-2005

Type of Wrong Equipment OR Case	#	%
Wrong lens/ eye surgery	15	70 %
Wrong knee components	4	20 %
Wrong breast implant	1	5 %
Wrong catheter	1	5 %
Total	21	100 %•

Samples from wrong procedure reports, listing the intended procedure and actual procedure performed, are shown below:

OR Wrong Procedure Code 912 Cases For 2004-2005

Intended Procedure	Actual Procedure Performed
Appendectomy	Fat removal
Appendectomy	Salpingectomy
Appendectomy	Aborted, appendix already removed
Right Colectomy	Wrong segment of colon connected to colostomy
Right Colectomy	Right Colectomy based on erroneous pathology- surgery not indicated
IVC Filter	Aborted, IVC filter in situ
D&C for positive urine hcg	D&C yielded empty uterus, pregnancy ectopic
Left Partial Mastectomy	Left Partial Mastectomy based on another patient's pathology-surgery not indicated.

Counts and Percentages of Radiology procedures reported into NYPORTS Code 912 are shown below:

Code 912 Radiology Cases 2004-2005

Type of Code 911 Radiology Case	Example Cases	#	%
Wrong procedure	Gallium scan done instead of HIDA scan, MRI of head instead of esophogram, Cat Scan with contrast instead of without contrast.	24	46%
Wrong patient	MRI head with contrast instead of, Cat Scan of head and chest with contrast, Cat Scan of kidney with contrast instead of Cat scan of neck with contrast.	16	31%
Wrong side	Chest tube insertion, Angiogram leg, Cat Scan, MRI breast with agent.	5	10%
Wrong site	Cat Scan of head or chest instead of abdomen.	7	13%
Totals		52	100%•

Code 912 Interventional Radiology Cases 2004-2005

Type of Interventional Radiology case		#	%
Wrong side	Spinal block, PICC line, Lung bx, CT guided abdominal drainage.	6	40%
Wrong site	Wrong Level of spinal block, Wrong Site IVC filter, Abdominal mass biopsies instead of Liver biopsies.	3	20%
Wrong equipment	3 wrong lumen aphresis catheters.	3	20%
Wrong procedure	Pancreatic biopsy instead of liver biopsy done, IVC filter (based on prelim results).	2	13%
Wrong patient	IVC filter.	1	7%
Total		15	100%•

The root cause analyses submitted for Codes 911 and 912 were examined for trends, common root causes/contributing factors and identified actions/risk reduction strategies. This information was shared with a multidisciplinary panel of experts empanelled to revise the 2001 New York State recommendations for ensuring correct surgical and invasive procedures. Findings were similar to those reported nationally to JCAHO.

Facility identified root causes/contributing factors in scheduling and consent processes:

- **Scheduling**
 - Case scheduled with no SIDE/LATERALITY identified
 - Case scheduled with no SITE/LEVEL identified
 - Scheduled for bilateral, intention was for one SIDE
 - Scheduled for bilateral, changed to one SIDE
 - Scheduled without implant/explant device or donor site specified
- **Consent**
 - SITE not written on consent form
 - SIDE not written on consent form
 - Written for wrong side
 - Surgeon added incorrect side after pt. signature
 - Consent did not match scheduled case

Facility identified actions/risk reduction strategies in scheduling and consent processes:

- **Scheduling**
 - No Scheduling Unless:**
 - Exact site: level, digit, is requested
 - Side/laterality is requested
 - Information on implant available
 - Or information on removal of a device
 - Information on harvest/donor sites
- **Scheduling by Phone:**
 - Read back of site/side
 - Follow up by fax
- Do not use OR schedule as official document in time-out

- **Consent Must Include:**
 - Correct patient (first and last name)
 - Name and description of procedure
 - Reason (condition or diagnosis) for surgery or procedure
 - Correct site: side, level, digit
 - Date
 - Patient/family signature
 - Surgeon signature
 - Implant or device to be removed
- Entire word RIGHT and LEFT is written out
- No acronyms/abbreviations
- Pt/family must sign consent again if it is altered
- Consent done over if it is altered

Facility identified root causes/contributing factors with History and Physical processes:

- **History & Physical**
 - Site discrepancy between H & P and consent not communicated/resolved
 - H & P too old
 - H & P did not have change of planned procedure
 - Pre-anesthesia evaluation stated wrong side

Facility identified actions/risk reduction strategies with History and Physical Processes:

- Must be signed and be less than 7 days old
- Must have planned surgical procedure including site, side, level, implants/explants, planned donor sites
- Site discrepancy (H & P and consent) = STOP
- Part of pre-operative protocol checklist
 - Procedure
 - 2 patient identifiers
 - Consent
 - H & P
 - Side/site verification
 - Surgical time-out

Facility identified root causes/contributing factors in patient identification processes:

• **Patient Identification**

- ID band not checked
- Same last name, different first name
- Same last name, same first name
- Identified by name only, second identifier not checked (date of birth or SS#)
- Similar last name
- Same last name, different gender
- Same last name, no hearing aid
- Similar first name (Anna Vs Ann)
- Patient hard of hearing, no hearing aid
- Same first initials, different initials last name
- Language barrier
- Bi-lingual patient did not understand question
- Patient confused, dx of dementia
- Transportation did not ID patient when pt. transported

Facility identified actions/risk reduction strategies in patient identification processes:

• **Patient Identification**

- Use 2-3 identifiers
 - First and last name must be checked
 - Include social security number or medical record number
 - Include date of birth
- Pt. asked to state full name, not confirm their name
- Interpreter provided for patient ID if necessary
- Family/health care proxy can be used
- Check for dementia/alzheimer's/confusion and communicate these conditions anytime a patient is transported
- Staff in all departments must be trained
- Patient that are HOH should have hearing aid in and turned on, confirm that they can hear

Facility identified root causes/contributing factors in site marking processes:

- **Site Marking**

- No site marking:
 - Level
 - Side
 - Digit
 - Both sides of extremity/digit
- No site marking due to splint/cast
- Surgical site marked not at actual site
- Wrong side marked by surgeon
- Marked with an X
- Surgical mark made with a pen (erased during prep)
- Site marked by RN
- Bilateral or multiple sites not marked
- Patient/family not involved in marking process
- Patient/family stated wrong side and it was utilized as basis for marking, consent, surgery

Facility identified actions/risk reduction strategies in site marking processes:

- **Site Marking**

- No Mark = No Surgery**

- Specifics of marking
 - Size of mark/handwriting must be legible
 - Mark bilateral sites, mark multiple sites
 - Mark Site(s) with Surgeon initials as close to planned incision as possible
 - No X for a mark
 - Spinal level and right or left if applicable
 - Include level of limb/digit amputations
 - Use indelible markers (FDA approved) black/purple for light skin
 - Use silver sharpie for patients with dark skin
 - Mark anterior and posterior surfaces of digit, extremity if surgery involves both surfaces
 - Mark site after cast/splint is removed
 - If concern regarding a particular site exists (awkward/problematic such as perineum, internal, midline) a special purpose wristband can substitute for a marked site
 - Patient/family involved in site marking to the extent able
 - Exemptions to marking (i.e., neonates marking may cause a tattoo)

Facility identified root causes/contributing factors in time out processes:

- **Time-Out/Critical Pause**
 - No time out prior to incision
 - CT/x-rays/not present in OR (in radiology or at St. Elsewhere)
 - One CT or x-ray vital to procedure ,missing
 - CT/x-rays in room, not reviewed
 - X-ray displayed wrong in view box
 - Pre-operative photos not in OR
 - Patient not identified, or called by first name only
 - OR schedule, H & P, or consent not reviewed
 - Time-out not documented
 - Site/side/level not confirmed
 - Early time out before pt. transferred to OR table
 - Incomplete team during time out
 - Surgeon out of room
 - RN out of room
 - No second time out after midline incision, change in position or intra-operative film with markers
 - Case based on wrong information on OR schedule

Facility identified actions/risk reduction strategies in time out processes:

- **Comprehensive Time-Out**
 - Correct patient: 2 identifiers: first and last name & a second identifier
 - Correct site including side
 - Patient position
 - Implants/special equipment are available
 - X-rays/imaging studies/pictures confirmed to be from the correct pt. and have been reviewed (surgeon, anesthesia, circulator & scrub)
- No time out without all team members in attendance and attentive
- When: prior to incision, after a change in position, re-draping or after intra-op x-ray or fluoroscopy
- No x-ray, CT, picture = no surgery
- No surgical instruments passed until time out is complete, no discrepancies
- Time out must be documented by all team members
- **Comprehensive Universal Protocol**
 - 2 patient identifiers
 - Consent
 - H & P
 - Site/side verification
 - Surgical time out

Facility identified root causes/contributing factors with team processes:

- **Team Issues**
 - Informal norm allows for deviation from written policy
 - “Work a-rounds”/shortcuts/at risk behaviors of team members
 - Emergent/urgent case can lead to deviation from existing policy (ie. Eliminated steps in site verification)
 - Time pressure
 - Multiple procedures
 - More than one medical record in OR or procedure room
 - Policy not specific enough
 - Deviation from policies by team members/non-compliance

Facility identified actions/risk reduction strategies with team processes:

- Zero tolerance of violations – immediate termination to eliminate informal norms
- “Red Rules” to bring high visibility to Universal Protocol
- Team training for OR teams
- Patient to remain in pre-op area until H & P authenticated, consent signed and site/side marked per protocol
- Education of all staff re: changes in policy
- Work to resolve hierarchical issues to promote equality in accountability of team members
- Ongoing compliance monitoring of Universal Protocol
- Only the medical record of the patient in the OR or procedure room at that time
- **Discrepancy and Escalation policies**
- Universal protocol to apply to surgery and invasive procedures in all departments outside the OR (ED, ICU, CU, NICU, PICU, Cardiac Catheterization, EP lab, Interventional Radiology, MRI, Nuclear Med., Radiology, pt. bedside, L & D, Endoscopy Suite, etc)
- Ongoing facility monitoring to ensure consistent compliance with Universal Protocol and time-out, with goal of 100% compliance (follow up for non-compliance)

Facility identified root causes/contributing factors with Surgical Issues

- Discrepancy between scheduled case and patient complaints and physical findings
- Lack of standardized process to prevent intra-operative loss of landmarks
- Midline incision increased risk of side disorientation
- Microscope increased likelihood side disorientation
- Misinterpretation of anatomy due to adhesions
- Multiple surgeons
- No intra-operative spinal markers used

Facility identified root causes/contributing factors with positioning/prepping/draping/room set up processes:

- **Positioning/Prepping/Draping/Room Set Up**
 - Surgical site marking obliterated by prepping
 - Surgical site marking not visible due to dark marker on dark skin
 - Surgical site not marked after cast/splint removal prior to prep
 - Surgical site mark not visible after repositioning
 - Surgical site not visible after draping
 - Bilateral prepping done when one side was scheduled
 - Wrong extremity prepped/draped
 - Prepping/draping done without reference to surgical mark
 - Room set up for wrong side, surgeon went to side that was set up
 - Head positioned with wrong side up
 - Positioned with wrong hip side up
 - Patient positioned opposite of correct position
 - Room set up opposite of intended procedure
 - Morbid obesity, physical deformity, or swollen digits present

Facility identified actions/risk reduction strategies with positioning/prepping/draping/room set up processes:

- **Prepping/Draping**
 - Use FDA approved indelible markers 100% of time, silver for dark skinned patients, black/purple for light skin
 - Mark site after cast/splint removed
 - Only prep where surgical site is marked
 - Unilateral prepping/draping for one side surgery
- **Positioning/Room Set Up**
 - Set up room for correct side
 - Position patient per surgeon for scheduled procedure
 - Correct position of surgeon, radiologist, or anesthetist in relationship to patient

Facility identified root causes/contributing factors with radiological/pathological processes:

• **Radiology Related**

- No intra-op films to determine level
- Image quality
 - Repeat images of poor quality
- A/P film taken, then pt. positioned in an arched lateral position
- Misinterpretation of intra-operative x-ray
- No side marker on x-ray
- X-ray was not marked correctly
- CT scan report and colonoscopy report are not consistent, discrepancy not identified
- Radiologist transposed sides on dictated report and did not identify error when authentication of report done
- CT report had wrong side/laterality
- No radiological reports in medical record
- Erroneous pathology
- Pathology not available

Facility identified actions/risk reduction strategies with radiological/pathological processes:

- Installation of a PACS (Picture Archiving System) that permits clinicians to review radiology images on-line and call up report so that correlation can take place
- Put sterile marker in the intra-spinal space
- 2 stage marking for spinal surgery
 - Skin marked with general marking
 - Intra-space marking(s) for exact spinal level(s) to be operated on confirmed with x-ray
 - Second time-out after intra-operative marking film
- Radiograph after spinal instrumentation to verify position prior to closure
- New equipment (fluoroscopy)
- 2 person review of radiology films (radiologist/surgeon) with documentation
- No radiological/imaging reports = STOP no surgery or procedure
- No x-rays, CT scans, MRIs, pictures, ultrasounds = STOP no surgery or procedure
- Films must be displayed properly in OR
- Reports and actual imaging must be present/displayed and reviewed by 2 team members as part of time out
- No pathology reports = STOP no surgery or procedure (timing of review, report dates, scheduling)
- Policy for review of internal/external pathology

**SUMMARY: COMMON ROOT CAUSES OF NYPORTS
CODE 911 & 912 CASES**

- **Communication**
- **Inadequate policies & procedures**
- **Non-compliance with existing policies & procedures**
- **Team issues – informal norms, hierarchy**
- **Patient identification & assessment**
- **Orientation/training**
- **Information available (x-rays, reports, labs)**
- **Pathology issues**
- **Production/time pressure**
- **Urgency of case**

APPENDIX D
ROOT CAUSE ANALYSIS PROTOCOL

NYPORTS ROOT CAUSE ANALYSIS EVALUATION PROTOCOL

RCA Item #	STANDARD CRITERIA REQUIRED	Intent Met	Intent Not Met	N/A	COMMENTS FOLLOW-UP	Date Intent Met
1.	Short Form					
1a.	Short form category code(s) accurately reflects occurrence described.					
1b.	Detail code (900 series code) accurately reflects occurrence described.					
2.	RCA Narrative Description					
2a.	Detailed description of the adverse occurrence (sentinel event) must include date, day of the week, time and area/service involved.					
2b.	Identify who by title, what, where and a chronology of event that includes times.					
2c.	When pertinent, include: co-morbid conditions, height, weight, serial lab values, surgical procedures, changes in level of care, diagnostic testing results, vital signs, consults, other clinical data, and/or non-clinical data.					
2d.	Fully explains the event so that a reader unfamiliar with the occurrence understands what happened and why the event happened.					

3-7	Policy or Process in Which Event Occurred (P), Human Resource Factors and Issues (H), Environment of Care (E), Information Management/ Communication Issues (I)				P H E I	COMMENTS FOLLOW-UP	
3a.	Root cause statement #1 is consistent with the 5 rules of causation.						
3b.	Root cause #1: Risk reduction strategies/actions would prevent or minimize future events or close calls.						
3c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #1.						
3d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.						
4a.	Root cause statement #2 is consistent with the 5 rules of causation.						
4b.	Root cause #2: Risk reduction strategies/actions would prevent or minimize future events or close calls.						

RCA Item #	STANDARD CRITERIA REQUIRED	Intent Met	Intent Not Met	N/A		COMMENTS FOLLOW-UP	Date Intent Met
4c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #2.						
4d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.						
5a.	Root cause statement #3 is consistent with the 5 rules of causation.						
5b.	Root cause #3: Risk reduction strategies/actions would prevent or minimize future events or close calls.						
5c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #3.						
5d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.						
6a.	Root cause statement #4 is consistent with the 5 rules of causation.						
6b.	Root cause #4: Risk reduction strategies/actions would prevent or minimize future events or close calls.						
6c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #4.						

RCA Item #	STANDARD CRITERIA REQUIRED	Intent Met	Intent Not Met	N/A	COMMENTS FOLLOW-UP		Date Intent Met
6d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.						
7a.	Root cause statement #5 is consistent with the 5 rules of causation.						
7b.	Root cause #5: Risk reduction strategies/actions would prevent or minimize future events or close calls.						
7c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #5.						
7d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.						

RCA Item #	STANDARD CRITERIA REQUIRED	Intent Met	Intent Not Met	N/A	COMMENTS FOLLOW-UP	Date Intent Met
8.	Hospital policies, clinical practice guidelines, critical pathways, or practice protocols related to event are followed as intended, developed, or revised after review of the occurrence.					
9.	Review identifies all root causes likely to prevent recurrence of event.					
10.	RCA and identified root causes do not leave any obvious unanswered questions.					
11.	RCA is internally consistent and does not contradict itself.					
12.	Literature Search					
12a.	Literature search includes at least 3 sources when available. References can include books, articles, and websites. List the name of author(s), title of article, date of publication, journal name, volume number etc.					
12b.	Focus of literature search is on issues relevant or related to the event (s) that includes established community standards of care.					
13.	Leadership: Corporate Culture					
13a.	Leadership is involved in the evaluation of adverse patient care occurrences. They participate in the RCA process and are identified by title.					
14.	Executive Summary of the Analysis					
14a.	Analysis of clinical findings of review of occurrence is thorough.					

RCA Item #	STANDARD CRITERIA REQUIRED	Intent Met	Intent Not Met	N/A	COMMENTS FOLLOW-UP	Date Intent Met
14b.	Any external expert review findings are included if obtained.					
14c.	Relevant Q/A findings are summarized.					
14d.	Pertinent findings from literature review are included.					
14e.	All elements are tied together to justify root causes, risk reduction strategies, and measures of effectiveness.					
15.	RCA Participants					
15a.	Individuals in roles involved in the processes and systems under review participate in RCA and are identified by title only. (I.e., RN, Pharmacist, Radiological Technician, LPN, Attending Surgeon, Resident, PCA, etc.)					
16.	Quality/Standard of Care					
16a.	RCA findings support the facility's standard of care determination.					
16b.	Facility's determination of standard of care is consistent with current practice.					
16c.	If standard of care not met and is directly linked to an individual practitioner, the full name and license number or certification number is entered.					

RCA item Additional root causes

17 a.	Root cause statement #6 is consistent with the 5 rules of causation.
17 b.	Root cause #6: Risk reduction strategies/actions would prevent or minimize future events or close calls.
17 c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #6.
17 d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.
18 a.	Root cause statement #7 is consistent with the 5 rules of causation.
18 b.	Root cause #7: Risk reduction strategies/actions would prevent or minimize future events or close calls.
18 c.	Measures of effectiveness directly apply to risk reduction strategy for root cause #7.
18 d.	Measures of effectiveness must have defined timeframes, numerators for audits, thresholds in percentages for compliance, and follow-up for non-compliance. They must measure impact of root cause or risk reduction strategies.
19 a-d.	Apply to root cause statement #8.
20 a-d.	Apply to root cause statement #9.

Any required follow-up with a facility on RCA protocol criteria will be documented on NYSDOH NYPORTS Review Screen.

APPENDIX E
PUBLISHED ARTICLES

Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems

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Frederick J. Heigel, Ruth Leslie, Janet Mannion, Robert J. Panzer

Abstract

New York State has had a mandatory incident reporting system in place since 1985. The current system, the New York Patient Occurrence Reporting and Tracking System (NYPORTS), was implemented in 1998 pursuant to New York State Public Health Law Section 2805-l, Incident Reporting. NYPORTS is a secure Web-based system that simplifies reporting, coordinates with other reporting systems, and allows hospitals to obtain feedback on their own reporting patterns. The authors review the evolution and implementation of NYPORTS and its predecessors, the Hospital Incident Reporting System and the Patient Event Tracking System. Discussion and data comparisons are made between the Joint Commission on Accreditation of Healthcare Organizations' voluntary sentinel event reporting system and NYPORTS. Critical elements for success of a mandatory incident reporting system include collaborative system design; basing the system on statute, with clear definitions and objective reporting criteria; providing meaningful data that can be analyzed and disseminated for improving patient safety; and adequate resources to maintain the system. Innovative program features may be of interest to other States implementing reporting systems.

Introduction

The evolution of an adverse event reporting system is complex, creates many challenges, and provides several lessons learned. This paper focuses on the New York State Patient Occurrence Reporting and Tracking System (NYPORTS), describing the history, evolution, and implementation of the system over a 19-year time span and three distinct system iterations. Critical characteristics of NYPORTS and its use in quality improvement will be described. Lessons learned from the system's evolution and implementation will be shared.

Background

In 1985, The New York State Department of Health (NYSDOH) developed its first mandatory adverse event reporting system. The program required reporting of preventable adverse events and a description of steps taken to address underlying deficiencies in hospital systems and/or practitioner training and capabilities. Incident reporting in New York State emerged statutorily in 1986 as part of the Malpractice Prevention Program.¹ This program was created by the legislature to capture preventable events caused by human or mechanical error resulting in patient harm. The statute requires hospitals to collect and report

information on negative health outcomes and incidents, placing the already-existing reporting system into the context of malpractice prevention. Incident reporting expanded to include patient responses to illness and treatment, clouding the issue of “preventability.” This led to the initial development and standardization of definitions to clarify which events were reportable and to minimize variation in the events reported.

There were several redesigns of the system, culminating in the current NYPORTS system. The evolution of incident reporting in New York State led to the inclusion of several critical characteristics and lessons learned that can be shared with other States developing or revising their own incident reporting systems.

The pervasive focus on medical errors in the U.S. health care system gained momentum in 1991, when a landmark study documented the type and extent of medical errors in 30,000 hospital discharges in New York State.² This momentum continued to build through the 1990s with several published reports on medical error fatalities. The Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*,³ brought widespread public attention to medical errors and was an impetus in making patient safety a national priority. The report also highlighted the importance of creating mandatory adverse event reporting systems as a mechanism to learn from these events and prevent similar events in the future. NYPORTS was implemented prior to the IOM report, illustrating the seriousness with which NYSDOH approaches improving patient safety.

As a result of the IOM report, several actions occurred to bring adverse event/medical error reporting systems into the forefront of public policy. President Clinton ordered the development of the Quality Interagency Coordination Task Force (QuIC) to recommend strategies for improving patient safety and health care quality. The QuIC report in 2000⁴ detailed many strategies, including the establishment of mandatory reporting systems in all 50 States. The Agency for Healthcare Research and Quality (AHRQ) was designated as the lead Federal agency for improving health care quality and funded demonstration projects to study adverse event/medical error reporting in 2001. The National Academy for State Health Policy (NASHP) analyzed legal and policy issues of State mandatory reporting systems, concluding that mandatory and voluntary systems can work together to help reduce death and serious injury in the health care system.⁵

The Healthcare Financing Administration (now the Centers for Medicare and Medicaid Services [CMS]) began using its peer review organizations to reduce errors of omission among its beneficiaries. Information on adverse events related to treatment, such as nosocomial infections and unintended effects of drugs and medical devices, is collected by the Centers for Disease Control (CDC) and the Food and Drug Administration (FDA), respectively. The Department of Veterans Affairs (VA) has both mandatory and voluntary reporting systems, capturing both adverse events and near misses. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) implemented its sentinel event policy in 1996 to evaluate sentinel events in JCAHO-accredited hospitals. This policy

emphasizes the gathering and analysis of error-related information.⁶ The IOM released a report in November 2003 calling for development of a standardized report format to support the full range of existing reporting systems in all settings.⁷ The report notes that the electronic medical record will make these systems useful, ensuring that information is transferred back to the point of care and analyzed for lessons learned. The 2003 IOM report recommends that near misses also be included in reporting, as they represent most of the events that occur.

Mandatory versus voluntary reporting of adverse events and medical errors is a current issue being addressed in Congress and in the medical community. Both the House and the Senate have bills (S. 720; H.R. 663)^{8,9} to establish a national voluntary reporting system. Many believe that a voluntary system is the most effective way of encouraging reporting in a nonpunitive culture (e.g., JCAHO; the aviation safety reporting system; the Medication Errors Reporting Program [MER]; MEDMARxSM, a national database for medication errors). The Anesthesia Patient Safety Foundation (APSF), a pioneer in reporting adverse events/medical errors, strongly supports voluntary efforts and feels that the call for a national mandatory reporting system is premature.¹⁰ Others believe that the system should be mandatory, while opponents fear this would actually discourage reporting and create liability issues for providers.¹¹

IOM's 2003 report discusses Scherkenbach's "cycle of fear" as a model of how using performance data can instill fear and provoke defensive behavior on the part of providers.⁷ The NYPORTS system is an example of a mandatory system that successfully uses data at both the State and facility levels, perhaps due to the fact that the focus is on systems improvement. Also, information gathered from the root-cause analysis (RCA) process and the RCA itself is protected from discovery.

History and development of NYPORTS

New York State has a long history of implementing efforts to improve the quality of hospital care. New York State Public Health Law 2805-1¹² requires hospitals to report and investigate incidents of deaths and other serious injuries in circumstances other than those related to the natural course of illness, disease, or proper treatment. Public Health Law 2805-m¹³ protects the confidentiality of the reports and prevents disclosure of incident reports under the Freedom of Information Law.¹⁴ Regulations requiring adverse event reporting became effective in October 1985. The objective of the public health law and the regulations is to ensure that incidents are identified and reported promptly and that a thorough investigation is completed, assessing the causes of the incident and developing corrective actions to mitigate reoccurrence. The first mandatory adverse event reporting system, the Hospital Incident Reporting System (HIRS), was a paper-based system that relied on telephone and mail communication. Reports were entered into the HIRS database by NYSDOH staff. Data collection became burdensome and there was no routine feedback mechanism for hospitals.

In 1993, the mandatory incident reporting system was redesigned and renamed the Patient Event Tracking System (PETS). PETS was an e-mail system based on a decision algorithm of patient harm and therapeutic treatment. It involved subjective judgment regarding incidents through a peer review process, which led to inconsistent data.

In 1995, as part of Governor Pataki's regulatory reform effort, a statewide workgroup of industry experts and a consumer representative was convened to develop, test, implement, and oversee a new mandatory reporting system. The group brainstormed to determine the purpose of the system (Table 1). Building on a collaborative model with the workgroup, the NYSDOH and hospital association representatives aimed to produce a system that was simple, clear, and outcomes-driven, providing useful information for hospitals to improve their own care. The New York Patient Occurrence Reporting and Tracking System¹⁵ was created to focus on quality improvement in conjunction with simplifying reporting, streamlining occurrence coding, and coordinating with other existing systems. The intent of NYPORTS is to allow hospitals to obtain feedback on their own reporting patterns and compare their experience with similar hospitals regionally and statewide (Table 2). Hospital-generated reports allow comparison of experiences with regional, statewide, or peer group aggregate data to enhance quality improvement activities. The most serious occurrences require facilities to conduct a root-cause analysis and develop risk-reduction strategies with corresponding measures of effectiveness to prevent similar future occurrences.

NYPORTS, a secure Web-based system, is based on an "includes/excludes" list¹⁶ of clearly defined reportable occurrences, which was developed and extensively field tested during 1996 and 1997 (Appendix A).^{*} After comprehensive regional training, statewide implementation was completed in April 1998 for 250 hospitals. Major revisions to the includes/excludes list and implementation of system enhancements took place in June 2000. Training included a standardized format for root-cause analyses consistent with the JCAHO model for sentinel event analysis.¹⁷ Annual statewide, regional, and ad hoc education and training sessions are ongoing. NYPORTS remains a dynamic system that will continually evolve over time.

Key characteristics of NYPORTS

The success of NYPORTS as a mandatory incident reporting system is dependent upon many factors that are integrated to enhance and support the system. The following elements are considered to be integral to the success of NYPORTS.

^{*} Appendix A is available electronically at http://www.health.state.ny.us/nysdoh/hospital/nyports/annual_report/2000-2001/appendixb.htm.

Table 1. NYPORTS brainstorming exercise

What is our purpose?
Improve the health of New Yorkers
Valuable system <ul style="list-style-type: none"> - Increase confidence of public in hospitals - Reduce liability for M.D.s and hospitals - Improve the accountability of the State
Identify and release relevant information to the public <ul style="list-style-type: none"> - Produce meaningful outcomes - Increase safety of patient care - Address the bad 2% - Shared vision of hospital and State
Demonstrate utility of collaboration between regulator and regulated <ul style="list-style-type: none"> - System where labor does not become overwhelming - Look for trends that lead to improvement - Stimulate quality assurance (QA) efforts - Promote collaboration among organizations - Understand limits of system - Define goals of the reporting process - Determine if incident reporting works with QA - Improve the models of incidents - How do we weave education into the process - User-friendly system - Shared success - Do not violate legislative mandate - If it doesn't work, stop - Consistent definitions - System where there is no fear of reporting
Evaluate cost of system vs. poor quality <ul style="list-style-type: none"> - Improve accuracy of data reported - Reduce input, increase output - Data for benchmarking - Coordination of data collection efforts - Increase utility of data collection - Database accessible to all

Secure, Internet-based, user-friendly system

Facilities access NYPORTS through a secure Internet site. The data is protected by dual firewalls within the NYSDOH. Facility staff members who request access to NYPORTS must sign a confidentiality attestation to further ensure data protection.

Statutory basis for NYPORTS

Public Health Law §2805-1, Incident Reporting,¹² mandates incident reporting by “hospitals,” defined as “a facility or institution engaged principally in providing services by or under the supervision of a physician...for the prevention, diagnosis, or treatment of human disease, pain, injury, deformity, or physical condition...” This definition applies to general hospitals and diagnostic and treatment centers.

Table 2. New York State reporting system evolution

Name	Hospital Incident Reporting System (HIRS) (1985–1993)	Patient Safety Event Tracking System (PETS) (1993–1998)	New York State Patient Occurrence Reporting Tracking System (NYPORTS) (1998–present)
System type	Reporting system	Reporting and tracking system	Reporting and tracking system
System focus	“Serious event”-driven	“Harm”-driven	“Outcomes”-driven
Foundation of system	No focused definitions, open-ended indicators, general categories of reportable events	Decision algorithms based on patient treatment, harm, and hospital peer review process	Includes/excludes lists of clearly defined reportable occurrences
Method of data collection	Manual system of data collection and submission	Electronic and manual system of data collection and submission	Electronic system of data collection, submission, and feedback
System design	Quality Assurance Model	Quality Management Model	Continuous Quality Improvement Best Practices Model
Data utility	Nonspecific data collection	Too much variation in reporting due to widespread interpretation of definitions and algorithms	Uniform, consistent data with limited variability due to clear and comprehensive includes/excludes lists
Types of events captured	<ul style="list-style-type: none"> • Treatment/procedure-related incidents resulting in death or major permanent loss of function, not related to the patient’s natural course of illness or underlying disease • Events specified in Public Health Law 2805-1 <ul style="list-style-type: none"> - Fires - Strikes - External disasters - Equipment malfunction - Termination of services 	<ul style="list-style-type: none"> • Nontreatment-related events (such as criminal acts, specified statutory events, and nosocomial infection outbreaks) • Treatment and procedure-related events (trackable events and reportable incidents) 	<p>Short form (trackable) occurrences:</p> <ul style="list-style-type: none"> • Medication errors • Aspirations • IV-related • Embolic and related disorders • Laparoscopic complications • Perioperative injuries • Burns • Falls • Procedure-related complications • Facility and other statutory occurrences <p>(Reportable and trackable) Occurrences requiring a root-cause analysis:</p> <ul style="list-style-type: none"> • Treatment-related • Other patient occurrences (crimes, suicides, and elopements)

Certain incidents (e.g., patient deaths or impairments, fires, equipment malfunctions, poisonings, strikes, disasters, and termination of vital hospital services) are specified in the statute, comprising the foundation of NYPORTS reporting. The statute further requires an investigation of a subset of these incidents to discern their root causes. The NYSDOH has expanded the required list of events to include a total of 54 distinct reporting codes.

Public Health Law §2805-m, Confidentiality,¹³ guarantees the protection of adverse event data submitted to NYPORTS from disclosure. Further protection exists in the State Education Law, section 6527.¹⁸

Accountability for NYPORTS reporting/case identification

Facilities within New York State have designated coordinators who report occurrences. Facilitywide support for NYPORTS is a vital part of quality/process improvement. Leadership support is critical in creating a culture of patient safety, where there is a nonpunitive approach to occurrence/event investigations, reporting, and the root-cause analysis process. NYPORTS case identification is accomplished either on a concurrent or retrospective basis. Case managers, nurse managers, and/or other professional staff are able to identify a high volume of specific NYPORTS occurrences, as they are “hands on” in the medical records on a daily basis. Using administrative ICD-9CM codes and clinical databases such as radiology as a safety net to identify potential NYPORTS reportable cases that were not captured by the concurrent methodology are examples of a retrospective case finding method.¹⁹

Resources

The development and ongoing support of a mandatory reporting system requires allocation of finances and dedicated NYSDOH professional and support staff. Professional staff, such as registered nurses, pharmacists, and physicians, are essential to the success of all phases of operation, including data analysis and dissemination.

NYPORTS Statewide Council

The NYPORTS Statewide Council, an advisory group to the NYSDOH, meets on a quarterly basis to discuss issues of significance to NYPORTS. The group consists of approximately 50 facility representatives, provider association representatives, and NYSDOH staff. Six of the original 10 workgroup members continue to be active members of the Council. NYPORTS subcommittees were formed to focus on specific aspects of the system, such as the codes and definitions, data analysis, root-cause analysis, education, and dissemination. Progress reports of subcommittee work and recommendations regarding system improvements are presented at the quarterly Council meetings.

NYPORTS includes and excludes list

The NYPORTS includes/excludes list¹⁶ is designed to specifically define reportable occurrences. This list is part of the *NYPORTS User's Manual*,¹⁶ which also outlines policies, procedures, definitions, examples, and operational guidance. The manual is revised periodically to reflect changes in definitions and policy, provide clearer examples, and explain system enhancements.

Data utilization and comparisons

A review of statistics of JCAHO's sentinel events from its national voluntary reporting system indicate that 2,405 events were reported from January 1995 through December 2003.²⁰ JCAHO received these reports of sentinel events from multiple health care settings. The majority (1,556) of these sentinel events were reported from general hospitals. Of interest is the low number of self-reported sentinel events (106) from 1,326 New York State JCAHO-accredited facilities and an additional 70 unreported sentinel events from other sources (such as media reports, complaints, CMS or State reports), bringing the total to 176 events.^{21, 22} In comparison, NYPORTS collected 11,028 reports of similar types of occurrences (NYPORTS codes 911–963), from 1998 to December 2003, from 250 New York State hospitals. In addition, a total of 149,697 occurrences have been reported to the NYPORTS system since 1998. The number of reports increased annually from 11,266 in 1998 to 28,972 in 2003.¹⁵ An analysis of the sentinel event types reported to JCAHO²⁰ indicates that two of the events, wrong-site surgery and infant abduction, correlate closely with two NYPORTS codes—911 (wrong-patient/wrong-site surgical procedure) and 961 (infant abduction). A review of these NYPORTS codes indicates that from June 1, 2000, to December 31, 2003, there were 104 cases of wrong-patient/wrong-site surgery (code 911) for New York alone,¹⁵ as compared to 300 cases reported to JCAHO²⁰ from 1995 to 2003 for the entire country. Code 961 (infant abduction) shows 7 cases reported to NYPORTS¹⁵ from June 1, 2000, to December 31, 2003, as compared to 18 cases reported to JCAHO²⁰ from 1995 to 2003. The comparison of the number of reports in a mandatory system (NYPORTS) versus a voluntary system (JCAHO) shows the potential utility of mandatory reporting (Tables 3 and 4).

The analysis of NYPORTS data can have a significant positive impact on patient safety. The challenge for any data collection system is to provide system users with an easy and efficient way to extract data for meaningful analysis. NYPORTS allows analysis to occur at both the facility and NYSDOH levels for use in quality assurance activities or statewide analysis of individual reporting codes.

NYPORTS reporting and the resultant access to comparative data have prompted individual facilities to conduct internal studies, targeting areas of concern through analysis of patterns and trends. The results of these studies have been significant in improving patient care and safety, as well as reducing hospital costs. For example, one facility reduced the risk of patients developing deep vein

Table 3. NYPORTS serious events requiring a root-cause analysis, April 1998–April 2004

Event*	Code	#	%
Wrong patient/site—surgical procedure	911	163	2.4
Incorrect procedure/treatment invasive	912	538	7.9
Retained foreign body	913	527	7.8
Unexpected death	915	2,866	42.3
Unexpected cardiac arrest (BLS/ACLS intervention)	916	643	9.5
Unexpected removal of organ	917	191	2.8
Unexpected loss/impairment of limb	918	458	6.8
Unexpected loss/impairment of bodily function	919	634	9.4
Error of omission/delay leading to death/serious injury	920	357	5.3
Crime leading to death/serious injury	921	20	0.3
Suicide/attempted suicide	922	278	4.1
Elopement from hospital leading to death/serious injury	923	44	0.6
Equipment malfunction leading to death/serious injury	938	22	0.3
Infant abduction	961	8	0.1
Infant discharged to wrong family	962	2	0.2
Rape by another patient/staff	963	25	0.4

* N = 6,776

thrombosis and pulmonary embolus. This area of focus was identified through the system's comparative reporting function. A comprehensive risk-factor assessment and prophylaxis protocol was established. This identifies patients at risk upon admission and ensures that they receive appropriate prophylaxis, decreasing the number of hospital-acquired thromboembolic events.

Impact of reporting systems on patient safety

Quality improvement opportunities

NYPORTS provides data for statewide performance improvement efforts and individual hospitals to identify trends or patterns of occurrences over time. New systems or processes can be implemented and measured to determine their effectiveness for reducing specific occurrence codes. Hospitals can export their own NYPORTS data into a Microsoft® Access database to create customized reports. The system allows creation of reports comparing individual hospital data to regional, statewide, and peer groups. NYPORTS is well integrated into many hospital and systemwide quality management systems. Hospitals can share data on several levels, including individually by practitioner or service. Hospital networks use NYPORTS data to identify trends within their systems, promoting performance improvement at the individual practitioner, facility, or system level.

Table 4. JCAHO sentinel events statistics, as of January 2004

Type of sentinel event*	#	%
Patient suicide	374	15.2
Op/post-op complication	315	12.8
Wrong-site surgery	300	12.2
Medication error	282	11.5
Delay in treatment	161	6.6
Patient death/injury in restraints	112	4.6
Patient fall	110	4.5
Assault/rape/homicide	84	3.4
Transfusion error	69	2.8
Perinatal death/loss of function	67	2.7
Patient elopement	48	2.0
Fire	45	1.8
Ventilator death/injury	38	1.5
Anesthesia-related event	35	1.4
Infection-related event	34	1.4
Medical equipment-related	32	1.3
Maternal death	28	1.1
Infant abduction	18	0.7
Utility systems-related event	18	0.7
Other less frequent types	285	11.6

* N = 2,455 since 1995

In a presentation at an AHRQ conference in August 2003, Robert Panzer, M.D., chief quality officer at the University of Rochester Medical Center, discussed his overall approach to patient safety using NYPORTS data at Strong Memorial Hospital.²³ Reporting and tracking of less serious but common adverse events may encourage clinical leaders to implement preventive measures, while reporting more serious events leads to root-cause analysis and systems improvement driven by senior leadership. This supports the use of NYPORTS as an integral part of promoting a culture of patient safety.

Reduction in certain types of events

NYPORTS captures data on 54 specifically defined reportable occurrences. Analysis of NYPORTS data allows the NYSDOH and facilities to identify those areas where errors can occur and to implement interventions to reduce the likelihood of these errors occurring in the future. An analysis of wrong-patient/wrong-site surgical errors led to the development of the New York preoperative protocols final report in January 2001, which focused on strategies to reduce or prevent wrong-patient/wrong-site surgery, wrong procedures, and

procedures conducted on the wrong patient.²⁴ Hospitals and other health care facilities were expected to develop and implement procedures to ensure that at least three independent verifications of surgical site location and correct patient identification occur. The report stresses the importance of the surgeon seeing and talking to the patient in the perioperative area and the importance of communication among members of the surgical team and the patient. It strongly recommended delaying any procedure where discrepancies of information exist. As a result of the adoption of the protocols and NYPORTS analysis, the number of wrong-patient/wrong-site events decreased in 2002 (25 events) and 2003 (17 events).¹⁵ Findings and recommendations remain applicable to hospitals, ambulatory surgery centers, and office-based surgery settings and will complement the JCAHO Universal Protocols effective July 1, 2004.²⁵

Evolution of NYPORTS— Continuous Quality Improvement

NYPORTS is a dynamic system that continues to evolve and improve over time. Since its inception, several multidisciplinary subcommittees have played critical roles in creating and maintaining the current quality system. The refinement subcommittee reviews the includes/excludes list to determine whether occurrence codes need to be added, deleted, or modified and to provide clarification to the definitions manual. The training and education subcommittee coordinates and schedules regional and statewide training sessions and disseminates information. The medication error subcommittee develops medication error reporting categories and the medication error supplemental form.¹⁶ This committee has analyzed 108 medication errors and associated root-cause analysis submissions for a 2-year period and has presented findings at a statewide NYPORTS Council meeting and multiple professional conferences. A data analysis panel has reviewed approximately 300 NYPORTS occurrences and associated root-cause analyses of unexpected deaths over an 18-month period. Experts reviewed and trended the root causes and risk-reduction strategies identified by facilities and reviewed evidence-based practices to support additional facility system fixes. The Root Cause Analysis Subcommittee is responsible for modifying the RCA form and providing training on the RCA process. An RCA evaluation tool, designed by the NYSDOH, is used by DOH regional coordinators to ensure information contained in RCAs is thorough and credible.

The NYSDOH works with a computer firm to enhance NYPORTS and implement changes/upgrades annually. The University at Albany School of Public Health contracts with the NYSDOH to analyze NYPORTS occurrence codes and report findings at quarterly statewide Council meetings. Links between NYPORTS and New York State's administrative database, the Statewide Planning and Research Cooperative System (SPARCS), have been established to identify and carry out projects to improve NYPORTS reporting. The School of Public Health is studying AHRQ's Patient Safety Indicators and comparing them

to the NYPORTS occurrence codes that are similar to determine potential ways to streamline the reportable occurrences in NYPORTS.

Dissemination of information and analysis

The NYSDOH disseminates data analysis results using various methods in order to achieve system and patient safety improvements that impact quality of care. Key dissemination activities include sharing lessons learned, educational programs, presentations, the *NYPORTS News and Alert* newsletter,²⁶ the NYPORTS bulletin board,²⁶ publicly publishing comprehensive reports,^{27, 28} and the New York State Patient Safety Award program (Table 5).

Table 5. NYPORTS information dissemination activities

Methods	Description	Example
Statewide Council meetings	The NYPORTS Statewide Council is an advisory group to the NYSDOH in matters concerning NYPORTS. The Council consists of facility representatives, provider association representatives, original workgroup members, and NYSDOH staff.	Code 915—Unexpected Death Analysis presented at January and May 2003 meetings. Deaths in the following specialties were analyzed: <ul style="list-style-type: none"> ● Neurology ● Pharmacology ● Pulmonary ● Surgery ● Cardiology ● Neonatal/maternal
Regional forums	Regional hospital associations disseminate information from Statewide Council meetings and address NYPORTS-related issues at periodic meetings.	Regional forums have presented system enhancements, analysis, and general NYPORTS information to hospital personnel.
Professional organizations	Department of Health staff presents results of NYPORTS analysis and operational topics at conferences hosted by professional organizations.	NYSDOH staff presented Medication Analysis results at the NYS Council of Hospital Pharmacists and St. Elizabeth's Hospital.
<i>NYPORTS News & Alert</i>	The <i>NYPORTS News & Alert</i> is a newsletter periodically issued to educate facilities about analysis, interpretations, and system use.	Issue #13 provided guidance to facilities regarding prevention of surgical fires and burns.
NYPORTS bulletin board	The NYPORTS bulletin board is accessed on the secure Web-based system, providing an opportunity for the NYSDOH to post relevant information for system users.	Postings include, but are not limited to, the <i>User's Manual</i> , <i>News & Alert</i> issues, and system enhancement information.

Table 5. NYPORTS information dissemination activities, cont.

Methods	Description	Example
Dear Chief Executive Officer letters	Letters are issued to the CEO/administrators of facilities to share advisories, policy clarifications, and other information.	Topics include NYPORTS, as well as a variety of other topics relative to hospital administration and regulatory compliance.
Patient Safety Conference	The NYSDOH will hold a statewide Patient Safety Conference to disseminate analysis and promote patient safety awareness in New York State.	Proposed presentations include Patient Safety Award recipients and results of DOH-sponsored analysis.
Hospital Association/ Department of Health training	The NYSDOH, in conjunction with hospital associations, gives periodic education sessions to hospital personnel. The sessions are often videoconferenced to multiple sites, and CD-ROMs are made and distributed for future use.	The Hospital Association of New York State (HANYNS) and the DOH have conducted multiple NYPORTS educational sessions which are available statewide. The latest session took place 11/3/04.
NYPORTS annual reports	The NYSDOH publishes a comprehensive NYPORTS annual report that includes statewide reporting and analysis data and provides a resource for patient safety information in New York State.	The DOH has issued two NYPORTS annual reports, one for 1999 and one for 2000/2001. Both reports may be accessed on the public Web site.
New York Patient Safety Awards	Hospitals, nursing homes, and Federally Qualified Health Care Centers (FQHC) are eligible to receive an award and a grant of up to \$200,000 to promote their patient safety strategy that has shown measurable decreases in adverse patient outcomes.	Annual award recognizes facilities for successful patient safety initiatives. The DOH assists the award recipients to disseminate their patient safety strategies statewide.

Discussion

Current proposals for voluntary adverse event/medical error reporting systems build on elements from existing systems such as the Aviation Safety Reporting System (ASRS) and the VA's National Center for Patient Safety's Patient Safety Reporting System. These systems are public and nonpunitive. Events are reported to a national nonregulatory agency. Near misses are a vital part of voluntary reporting systems.^{29, 30} The VA also operates the Patient Safety Information System,³⁰ a voluntary confidential reporting system for adverse events. Recommendations for developing a national mandatory system include focusing on errors related to licensing and other regulatory issues in a confidential system. There is nearly universal consensus that information technology needs to play a role for any system to be effective in detecting adverse events. Systems that rely on spontaneous reporting are ineffective and contribute to current underreporting issues.³¹

The APSF¹⁰ believes that creating a mandatory reporting system is very complex and there is no evidence to show that it results in meaningful improvement in practice. The American Medical Association (AMA) and the American Hospital Association (AHA) oppose mandatory reporting and believe that any reporting that is tied to punitive action or public disclosure will encourage making the reporting system a “numbers game” and drive reporting underground by perpetuating a culture of blame.³² However, the volume of reports in the NYPORTS system and its use of the root-cause analysis framework demonstrate that mandatory reporting can result in important systems improvement. The NYPORTS system incorporates elements of a mandatory reporting system as recommended by the IOM and NASHP, including—

- operation by a state regulatory agency;
- collection of standardized information;
- inclusion of serious adverse events and medical errors;
- ongoing statewide analysis of patterns and systemic issues;
- external data validation; and
- required followup.

NYPORTS is in compliance with JCAHO’s sentinel event reporting system.

There is a central conflict underlying the development of mandatory reporting systems that creates a significant barrier. The public desires accountability from physicians and other providers, while physicians and hospitals fear malpractice liability and damage to their reputations. Physicians and hospitals support voluntary reporting and sharing of the information to improve patient safety, which is desirable when the primary goal is to learn from prior mistakes and experience. However, the public feels that mandatory reporting improves accountability.³³ The NYPORTS system integrates these elements providing accountability within a learning environment.

Lessons learned

The experience of developing adverse event incident reporting systems in New York State resulted in several lessons learned that might help shape the design of future systems. One of the most critical lessons learned is that information gathered into the system must be meaningful and useful to those who are reporting events. This is more likely to occur if key stakeholders help develop the system, as they will help build the consensus needed regarding the importance and utility of the system. Designing a Web-based system where facilities can access their own data and create comparative reports is the foundation upon which NYPORTS was built. Without this ability, facilities would be dependent upon the NYSDOH to create reports. In our earlier reporting systems, data were not timely, delaying knowledge learned from the reports.

The initial NYPORTS system was designed using a “short form/long form” concept. The short form, containing demographic data and a narrative description

of the event, must be submitted for every occurrence. The long form was a narrative-free text investigative report submitted on the most serious events. In June 2000, the RCA framework replaced the long form. This added structure to the reports and allowed more meaningful analysis to occur. RCA analysis revealed that the quality of the information submitted was variable, despite ongoing educational efforts. A tool was designed and implemented to evaluate submitted RCAs against specific criteria expected in a thorough and credible RCA and to assure more consistency.

The turnover of hospital staff affects reporting rates and the quality of the reports submitted. A standard NYPORTS tutorial ensures that new staff members are consistently trained. Educational forums include NYPORTS statewide and regional Councils. Memberships of these advisory groups were initially structured with 3-year cycles, which never happened. Instead, the meetings have steadily grown in attendance. It is difficult to limit the involvement of people who see the value of the system and want to be active participants.

An incident reporting system must remain open for continual improvement. The NYPORTS system's three phases of field testing in 1996 and 1997 led to initial meaningful changes and improvements. NYPORTS and other incident reporting systems need a process to ensure that regular reviews, updating, and system enhancements occur that can be balanced with the desire to track longitudinal data. Definitions are improved and clarified on an ongoing basis, often as a result of scenarios presented by facilities. Although NYPORTS has been in place for 6 years, gray areas still exist.

Conclusion

Based on NYSDOH's experiences with the development and evolution of our mandatory reporting system, we have found that certain critical elements are necessary for its success. These critical elements include making the system legally required, with protection from discovery; developing the system collaboratively, including all stakeholders in the system's design and implementation; clear and objective definitions of reporting criteria as a basis for collecting accurate and consistent data; ongoing training and educational support for system users; and having a stakeholder advisory group for ongoing assessment and recommendations, ensuring the system's relevance and viability. Other elements vital to the success of NYPORTS include having a secure Web-based system and ensuring that adequate resources and supports are dedicated to operating and maintaining the system. Ultimately, the success of the system also requires that users receive feedback regarding their own performance. It must be possible to analyze data at both the facility and statewide levels, incorporating dissemination of lessons learned. Collectively, these elements are the basis of performance improvement efforts that will positively impact patient safety and move quality and patient safety to the next level.

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References

1. Public Health Law §2805-j, Medical, dental and podiatric malpractice prevention program (Added L. 1986, c.266).
2. Brennan TA, Leape LL, Laird NM, et al. Incidence of adverse events and negligence in hospitalized patients. Results of the Harvard Medical Practice Study I. *NEJM*, 1991 Feb7;324(6):370–6.
3. Kohn LT, Corrigan JM, Donaldson, MS, editors. *To err is human: building a safer health system. A report of the Committee on Quality of Health Care in America*, Institute of Medicine. Washington, DC: National Academy Press; 2000.
4. Quality Interagency Coordination Task Force to the President. *Federal Actions to reduce medical errors and their impact*; 2000 Feb.
5. Flowers L, Riley T. *State-based mandatory reporting of medical errors*. National Academy for State Health Policy; 2001 Mar.
6. Joint Commission on Accreditation of Healthcare Organizations. *A journey through the history of the Joint Commission*; 2004. Available at: <http://www.jcaho.org/about+us/history/index.htm>.
7. Institute of Medicine. *Patient safety: achieving a new standard of care*. Washington, DC: National Academy Press; 2003.
8. Amendment to Title IX of the Public Health Service Act, S.720, 108th Congress. Library of Congress. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_bills&docid=f:s720rs.txt.pdf.
9. Amendment to Title IX of the Public Health Service Act, H.R.663, 108th Congress. Library of Congress. http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_bills&docid=f:h663rh.txt.pdf.
10. Stoelting R. APSF response to the IOM report. Comments from the Anesthesia Patient Safety Foundation; 2000. http://www.gasnet.org/societies/apsf/safety/iom_response3.php.
11. Brennan, T. The Institute of Medicine report on medical errors: could it do harm? *NEJM* 2000 Apr 13;342(15):1123–5.
12. Public Health Law §2805-1, Incident Reporting (Added L. 1986, c.266).
13. Public Health Law §2805-m, Confidentiality (Added L. 1986, c.266).
14. Public Officer's Law, Article 6, §87 (Added L. 1977, c.933).
15. New York Patient Occurrence Reporting and Tracking System Database. Secure database for authorized users. Data retrieved on 2004 Apr 14.
16. New York State Department of Health. *NYPORIS user's manual*. Version 2.2. New York State Department of Health; 2002.
17. Joint Commission on Accreditation of Healthcare Organizations. *Sentinel events: evaluating cause and planning improvement*. Oakbrook Terrace, IL: JCAHO; 1998.
18. New York Education Law, sec. 6527(3); 2000.

19. Tuttle D, Panzer R, Baird T. Using administrative data to improve compliance with mandatory State event reporting. *Jt Comm J Qual Improv* 2002 June;28(6):349–58.
20. Joint Commission on Accreditation of Healthcare Organizations. Sentinel event statistics. Available at: http://www.jcaho.org/accredited+organizations/office+based+surgery/sentinel+events/se_stats_9_04.pdf. (Accessed 2004, Apr 14.)
21. Joint Commission on Accreditation of Healthcare Organizations. Self-reported events by State, January 1995 through December 2003. Available at: <http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/set+self-reported.htm>. (Accessed 2004, Jul 8.)
22. Joint Commission on Accreditation of Healthcare Organizations. Total reviewed events by State, January 1995 through December 2003. <http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/set+total+reviewed.htm>. (Accessed 2004, Jul 8.)
23. Panzer RJ. Facility Patient Safety Practices; Strong Memorial Hospital. AHRQ Conference: Making New Jersey a Model for Patient Safety; 2003 Aug 20.
24. New York State Department of Health. Homepage on the Internet. <http://www.health.state.ny.us/press/releases/2001/preopletter.htm> (Accessed 2004, Apr 14.)
25. Joint Commission on Accreditation of Healthcare Organizations. Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery.™ December 2003. <http://www.jcaho.org/accredited+organizations/patient+safety/universal+protocol/universal+protocol.pdf>.
26. NYPORTS. On-line New York Patient Occurrence Reporting and Tracking System. Albany, NY: New York State Department of Health. c1998–2004 (Updated Apr 9, 2004.) <https://commerce.health.state.ny.us/hpn/nyports/intro.html>. (Log in required; accessed 2004, Apr 14.)
27. New York State Department of Health. NYPORTS—The New York Patient Occurrence Reporting and Tracking System Annual Report. New York State Department of Health; 1999. <http://www.health.state.ny.us/nysdoh/hospital/nyports/index.htm>
28. New York State Department of Health. NYPORTS—The New York Patient Occurrence Reporting and Tracking System Annual Report. New York State Department of Health; 2001–2002. <http://www.health.state.ny.us/nysdoh/hospital/nyports/index.htm>
29. Aviation Safety Reporting System. <http://www.asrs.arc.nasa.gov>.
30. Department of Veterans Affairs, National Center for Patient Safety. Patient Safety Reporting System. Program Overview. http://psrs.arc.nasa.gov/program_briefing.htm.
31. Bates D, Evans S, Murff, H, et.al. Detecting adverse events using information technology. *J Am Med Assoc* 2003 Mar/Apr;10(2):115–28.
32. Kaufman M. Clinton seeks medical error reports: proposal to reduce mistakes includes mandatory disclosure, lawsuit, shield. *The Washington Post*; 2000 Feb 22. p. A–2.
33. Leape L. Reporting on adverse events. *NEJM* 2002 Nov20;347(20):1633–8.

Quantitative and Qualitative Analysis of Medication Errors: The New York Experience

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Abstract

Objectives: In June 2000, the New York State Department of Health (NYSDOH) expanded its New York Patient Occurrence Reporting and Tracking System (NYPORTS) mandatory adverse event reporting system to include the reporting of medication errors. The errors included were those that resulted in a severity of patient harm that met the National Coordinating Council Medication Error Reporting Program (NCC MERP) criteria for categories G (resulting in permanent patient harm), H (resulting in a near-death event) and I (resulting in patient death). Root cause analyses (RCA) that examine systems issues and identify mechanisms for future prevention of these events were studied. **Methods:** A panel of 11 multidisciplinary professionals performed a quantitative and qualitative analysis of 24 months of medication errors reports submitted to the NYPORTS system. NYPORTS requires that the 249 hospitals in New York State (NYS) electronically notify the NYSDOH of reportable errors within 24 hours of occurrence detection and that a RCA for that occurrence be submitted within 30 days. **Results:** Qualitative analysis of the RCAs included findings related to lessons learned, emergent themes, and use of system fixes instead of punitive fixes or inappropriate/incomplete system fixes. The quantitative analysis examined several variables. These included where in the process the error occurred, what disciplines were involved, the error distribution, the occurrence type, the medication or medication classes involved, and the breakdown by patient outcome. **Conclusions:** Mandatory medication error reporting can provide useful information about systems contributing to errors, strategies for prevention, and evidence-based information about patient safety concepts. This information is important for hospitals to consider both when analyzing medication errors and when implementing systems to improve safety. This report is intended to help guide public policy and provide guidance to other states interested in establishing mandatory reporting systems.

Introduction

During a statewide meeting of the New York Patient Occurrence Reporting and Tracking System (NYPORTS) Council, held on September 18, 1998, there was a consensus that a special subcommittee should be formed to address the reporting of medication errors. The first meeting of the multidisciplinary committee took place in October 1998. Nurses, pharmacists, and New York State Department of Health (NYSDOH) administrators were recruited to join the

subcommittee. The medication subcommittee was charged with developing reporting criteria and a mechanism by which this data would be reported, and with analyzing submitted reports. When the Institute of Medicine (IOM) report on medical errors¹ was issued, the subcommittee reviewed the report to incorporate applicable recommendations into the proposed reporting process. In preparation for data analysis, the subcommittee was expanded to include more individuals with practical expertise needed to make meaningful data interpretations. Physicians with expertise in error and systems analysis, and experience with the poison control center, were recruited to join the panel. Organizational and geographic balance was sought by recruiting clinicians from the private and public sector, different regions of the state, large urban academic medical centers, and small community hospitals. Wide panel diversification was sought to ensure that proposed system fixes would be applicable across a broad spectrum of care settings.

Implementation

Issues discussed by the medication subcommittee included the following:

- What do we want to learn from this system?
- What information will we need in order to draw valid conclusions?
- What definitions will be used?
- Which errors will be reportable?
- Do we want to incorporate national standards?

The goal of data collection on medication errors was to provide useful, practical data to hospitals, not only regarding errors themselves, but regarding methods used to reduce their incidence. Subcommittee consensus determined that only medication errors would be included, with a focus on system approaches and not individual practitioners. In determining the medication error criteria, the subcommittee considered the American Society of Health Systems Pharmacists (ASHP) severity index,² the ASHP guidelines,³ the medical event reporting system for transfusion medicine (MERS-TM)⁴ and the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) definition for outcome based event categories,⁵ as well as criteria developed by local medical centers with strong, successful medication error reporting programs. The subcommittee determined that the NCC MERP outcome severity index and definition of a medication error were nationally recognized standards already in use in many hospitals, and thus would lend themselves to benchmarking of data and provide clear, understandable categories for reporting of errors. The subcommittee felt using the NCC MERP information would provide the best potential for meeting the IOM recommendation of standardized data collection using a defined list of adverse events.¹

The subcommittee adopted the NCC MERP definition of a medication error:⁵

A medication error is any preventable event that may cause or lead to inappropriate use or patient harm while the medication is in control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures and systems including prescribing; order communication; administration; education; monitoring and use.*

The NCC MERP definitions for outcome categories—G (resulting in permanent harm), H (resulting in near death), and I (resulting in death)—were incorporated into the NYPORTS database (Table 1).⁶ Focusing on these errors followed the IOM mandate that mandatory error reporting programs gather data on errors associated with fatal outcomes or serious injuries.¹ A supplemental form for medication was developed to capture error-specific data. The form was pilot tested, revised on the basis of the pilot test results, and finalized by the Statewide NYPORTS Council for adoption and implementation statewide in June 2000.

Table 1. Medication errors resulting in death, near death experience, or permanent patient harm—New York Patient Occurrence Reporting and Tracking System (NYPORTS)

NYPORTS occurrence code	NYPORTS definition	Corresponding NCC MERP medication error category and definition
108	A medication error occurred that resulted in permanent patient harm.	-G- An error occurred that may have contributed to or resulted in permanent patient harm.
109	A medication error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac arrest).	-H- An error occurred that required an intervention necessary to sustain life.
110	A medication error occurred that resulted in a patient death.	-I- An error occurred that may have contributed to or resulted in the patient's death.

NOTE: All medication errors require a corresponding 900 code and submission of a root cause analysis.

NCC MERP = National Coordinating Council Medication Error Reporting Program

Methods

NYPORTS provides both an epidemiological data source that has historically been relied upon to assess trends or potential vulnerabilities that can impact patient safety, and a database of serious events that require retrospective root cause analysis (RCA).⁶

* Because the committee decided to start with reporting of medication errors resulting in harm, the word “or” in the above definition was changed to “and.”

The methodology used to assess these occurrences utilized the taxonomy for human error that is based on the work of James Reason.⁷ Evaluation of the submitted RCAs took place only if there was representation from each professional discipline (pharmacy, medicine, nursing, and NYSDOH administration). A total of 108 reports were reviewed by the Medication Committee, 53 of which were submitted with RCAs (June 2000 through May 2002).

Medication data was extracted directly from the NYPORTS database and exported in Microsoft™ Access 2000 format. Microsoft Access was also utilized to extract those medication error cases submitted without a medication error code. A quantitative analysis was performed to examine where in the medication use process the error occurred (prescribing, transcribing, dispensing, administering, monitoring), the disciplines involved (physicians, pharmacists, nurses, respiratory therapists), the breakdown by occurrence type (wrong dose, wrong route, etc.), which medications or medication classes were involved in the errors, the breakdown by patient outcome, patient age, and occurrence data by facility.

Qualitative data analysis relied on the expertise of the medication panel and reference to the current literature. The medication panel used the Agency for Healthcare Research and Quality (AHRQ) model employed in the Evidence Report on patient safety practices⁸ for their review. The AHRQ model includes practice description, evidence, potential for harm (unintended outcomes), opportunities for impact, cost, and implementation when determining the strength of the proposed system fixes. The medication panel felt that the AHRQ model carried the greatest potential for identifying best practices, incorporating evidence-based medicine, bringing methodological rigor to systems improvements, and allowing scalability to other institutions. The panel used human factors engineering⁹ and error theory⁷ to suggest corrections for inappropriate system fixes and to build better systems.

Results

Quantitative analysis

A total of 108 NYPORTS reports were analyzed for the review period. The categories of reportable medication errors used in this analysis are defined in Table 1. Of the medication errors reviewed, errors resulting in permanent harm accounted for 18 percent, near-death errors accounted for 48 percent, and errors resulting in death accounted for 23 percent of the reports. Unexpected deaths (code 915 only) related to medication errors accounted for 11 percent (Figure 1).

All medication errors require the submission of an RCA and corresponding 900 code. The 900 code series (901 to 920) is utilized with the 100 code series and generally indicates a serious outcome to the patient and requires that the facility perform a detailed RCA. There was an initial lack of compliance with this mandate (Table 2). Reeducation of hospitals and redesign of the electronic system has corrected this problem.

Figure 1. Percentage breakdown of reported medication errors included in project (N = 108)

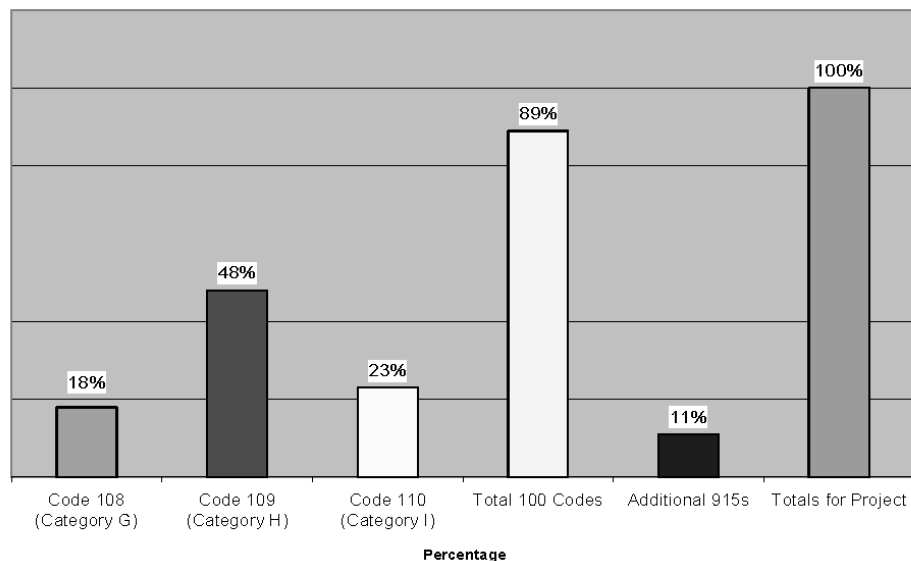


Table 2. Breakdown of 100 code medication errors by associated 900-series codes (N = 96)

Code #	Description of code	Number of reports with a 100 code medication error n (%)
901	Serious occurrence warranting Department of Health notification, not covered by codes 911-963.	6 (6)
915	Any unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in death.	25 (26)
916	Any unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in cardiac and/or respiratory arrest requiring basic life support/advanced cardiac life support intervention.	11 (11)
918	Any unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in impairment of limb.	2 (2)
919	Any unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in loss or impairment of bodily functions.	4 (4)
920	Errors of omission resulting in death or serious injury related to the patient's underlying condition.	6 (6)
Not assigned a 900 code and root cause analysis not submitted		42 (44)

The NYPORTS program also collects as part of submitted medication errors the type of occurrence of the medication error. Analysis of the data by type of occurrence (Figure 2) identified the most commonly occurring error as wrong dose, followed by wrong drug. When analyzing where in the medication use process the error occurred, it was found that the administration process accounted for the greatest number of errors (Figure 3). This finding is not unexpected, as 90 percent of the errors involved administration of a drug (errors of commission). A further drill-down into the data indicated that in prescribing, verbal orders accounted for 15 percent of the prescribing errors, while written orders accounted for 74 percent of the errors. In the dispensing error category, the drug not being available accounted for 11 percent of the errors. Of note, NYPORTS collects monitoring errors only as a “type of occurrence” and not as part of the “medication use process.” A review of the categories of staff involved in the medication occurrences indicated that a registered nurse was involved in 77 percent of the cases, physicians were involved in 58 percent of the cases, and a registered pharmacist was involved in 18 percent of the cases. A breakdown by patient age revealed that the medication errors were more prevalent in patients above 65 years old (46 percent). Further breakdown showed 40 percent of errors occurred in the 18–65 year-old range, and 14 percent in patients younger than 18 years old.

A review of the facility occurrence rates indicates that several facilities reported higher numbers of errors. One facility accounted for 5.5 percent of the medication errors, while a second facility accounted for 4.6 percent. Four facilities each had a reporting percentage of 3.7, and three facilities had a reporting percentage of 2.7. A review of medication classes involved revealed the most common classes to be cardiovascular drugs and narcotic analgesics, both at 14 percent; anticoagulants at 11 percent; followed by central nervous system (CNS) medications and antibiotics, both at 8 percent.

Figure 2. Percentage breakdown of data by type of occurrence (N = 96)

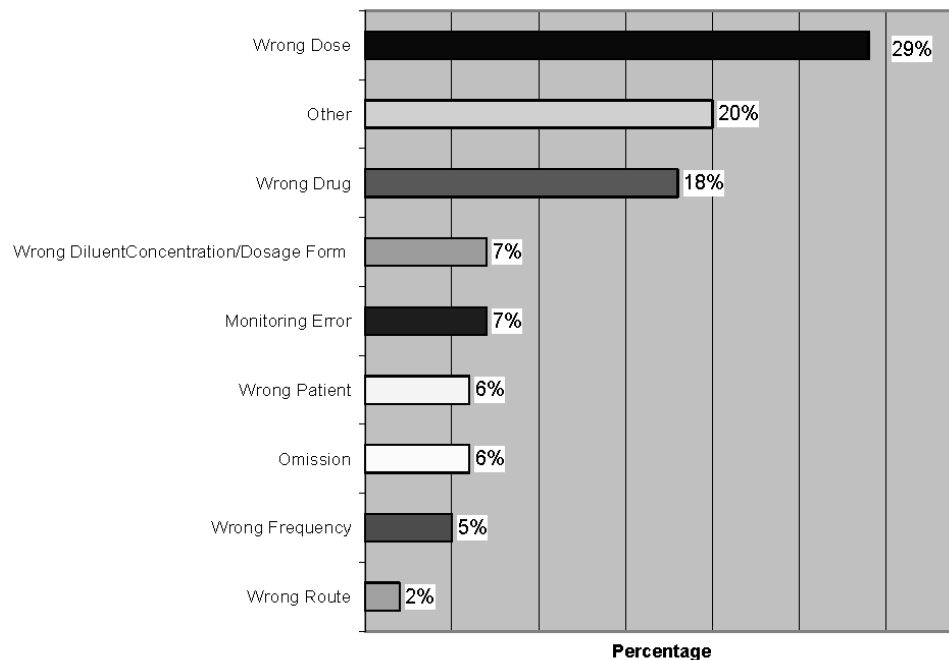
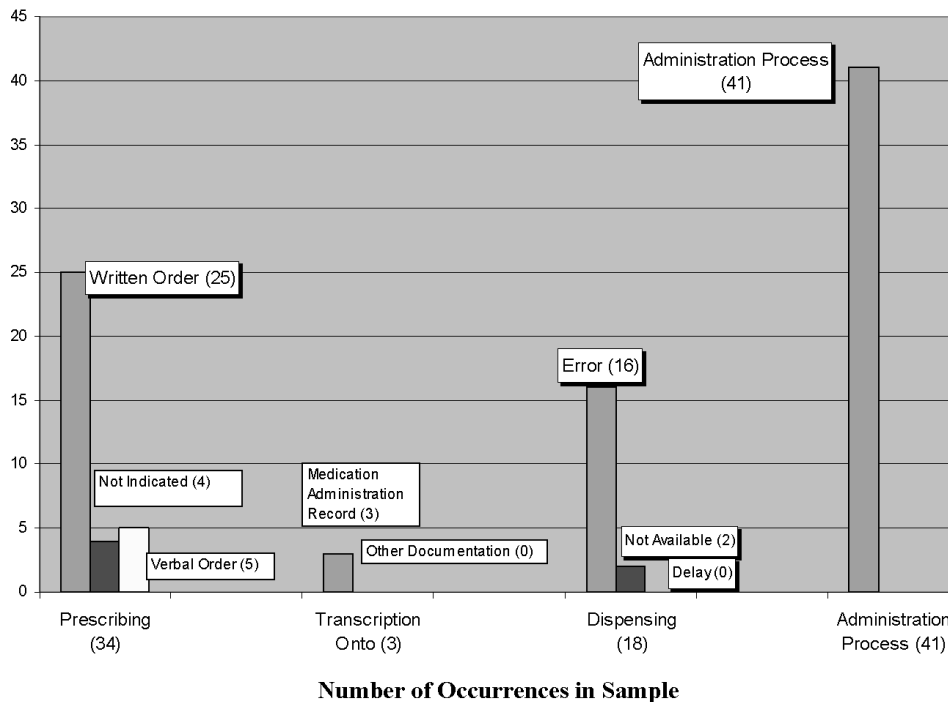


Figure 3. Where in the medication use process the error occurred (N = 96)



Discussion

Quantitative findings

The finding that nursing is the number one discipline involved in the errors is not surprising, given that the nurse administers most medications and is the final individual in the process. The pharmacist or nurse may intercept prescribing errors and the nurse may catch dispensing errors. In the absence of technological support, there is little or no opportunity for errors of administration to be intercepted or caught prior to completion. This information is consistent with voluntary reporting programs, where 2 percent of the errors of administration were trapped prior to completion.¹⁰

The population above age 65 sustained more injuries than did the pediatric population; this is consistent with the findings of a voluntary medication error reporting program.¹¹ This may be explained by an increased number of medications used in the elderly and the resilience of younger patients, who respond better to intervention and thus would not sustain an injury likely to meet the NYPORTS reporting threshold. The medication classes involved in the errors in this review are consistent with those reported to the Institute of Safe Medication Practices (ISMP).¹² Several of the root causes of the errors reviewed closely resemble those in the ISMP medication alerts.

Nine facilities accounted for 33 percent of the errors in the NYPORTS database. The findings raised the issue about whether these facilities are more

error-prone or more skilled at detecting errors. To answer this question, more data about the hospitals and medication processes would be needed. This is currently outside of the scope of the NYPORTS program. Historical data from NYPORTS nonmedication reporting suggests that the higher-reporting institutions are more safety vigilant and more likely to identify reportable errors.

Qualitative findings

While the quantitative data identifies processes for targeted improvements, it is the narrative data that provides the richest source for system fixes. The medication panel reviewed the 53 RCAs submitted for lessons that could be shared with the larger community to enhance safety. Emergent themes that presented threats to patient safety, weaknesses in system fixes, and failure-to-rescue type events where earlier intervention may have prevented patient injury were identified. Space limitations require examples from each of these areas be used to illustrate the concepts rather than a comprehensive overview of the entire dataset.

Emerging themes in patient safety threats

The medication panel noted common factors or themes that appeared as significant safety threats. The most significant potential for injury occurred in the transition of a patient across and between levels of care, with medications requiring complex dosing regimens, and in tightly coupled systems where staff faced unusual or uncommon situations. The transition between levels of care within the acute care setting or across the continuum of care resulted in opportunities for communication gaps that led to adverse outcomes. Inaccurate or incomplete data about medication regimens, when undetected, caused patient injuries. An example of such a case included a patient who gave the correct concentration and name of the product for glaucoma control upon admission, but the formulation was not correctly identified. The patient had been taking a long-acting (once-a-day) gel, but had the short-acting product ordered once a day when it was intended for twice-a-day dosing. The patient was given a discharge prescription for the short-acting drops and continued to follow this regimen at home. The patient's ophthalmologist discovered the error 6 weeks postdischarge, at a followup visit. At the time of error discovery, the patient had sustained irreversible eye damage. In other cases, providers omitted drugs that patients were already taking in the transition across levels of care, and the lack of redundant safety checks prevented detection prior to onset of an adverse effect. One example of this is when prescribers omitted chronic steroids in the transfer orders for a patient moving from an intensive care unit (ICU) to a lower level of care, resulting in Addisonian crisis and subsequent death.

Complex medication dosing regimens or overlap between multiple drug formulations created serious threats to patient safety. Correctly dosing patients with low molecular weight heparin (LMWH) for the proper indication, the patient's renal function, therapeutic substitutions, and bridge therapy between short- and long-term anticoagulation creates a level of complexity that requires

careful oversight, which was frequently lacking. RCA teams identified a lack of evidence-based information as a barrier to establishing protocols for care. Cost justification of LMWH usage may include the elimination of lab values for monitoring. In the absence of a lab value, the indicator of therapeutic adjustment was the resulting adverse patient outcome. Unfortunately, the outcomes may be the occurrence of catastrophic bleeds or embolic events that result in irreversible injury or death. Allowing inadequate time between dosing with LMWH and initiating unfractionated heparin or inadvertent use of several regimens concurrently went undetected until an adverse event occurred.

Liposomal amphotericin preparations can have a dosing regimen up to 10-fold higher than for conventional amphotericin formulations.¹³ Ordering conventional amphotericin at the liposomal dose resulted in fatal overdoses. The lack of 24-hour pharmacy oversight and the emergent need for prompt initiation of therapy compounded the potential for an error to go undetected until signs of toxicity presented. Intervention was unsuccessful in reversing the effects of the drug for patients with symptoms of amphotericin overdose.

Tightly coupled systems are those in which an action is taken that directly affects the outcome. There is little buffer or slack in the system.¹⁴ Tightly coupled systems pose a great threat of harm because the time from action to response is so narrow that detection of the error is often lacking. The areas identified in the NYPORTS system where tightly coupled systems played a role in adverse patient outcomes were ICUs, emergency departments (EDs), and diagnostic/interventional areas.

Rare or unfamiliar circumstances compounded the potential that an adverse event would occur. For example, ketamine is the drug of choice for rapid sequence induction in patients with status asthmaticus. It is rarely used in EDs except for this purpose. Patients presenting in status asthmaticus are critically ill and require prompt intervention and rapid estimation of their weight to dose them appropriately. In the absence of prepared dosing guidelines, the risk of an error in dose calculation is significant. System fixes included affixing laminated dosing guidelines to patient clipboards and having the guidelines available to practitioners in the medication rooms.

Physicians assuming roles that they are unaccustomed to, especially in tightly coupled systems, creates a risky environment for patients. One such case involved an ED patient being evaluated for change in mental status in the middle of the night, who was sent to radiology accompanied by a medical resident. The attending physician instructed the resident about the sedative agent to be administered, but the resident was told in radiology that the agent was unavailable. Time pressures—due to limited CT scanner availability; the critical nature of the patient's condition; lack of immediate access to the attending physician; and the need for the resident to order, procure, and administer the drug without nursing or pharmacy support—contributed to the patient receiving a paralyzing agent instead of a sedative agent. Intubation was necessary and saved the patient from a fatal outcome. The reporting hospital changed its practice to staff the radiology suite around-the-clock with a registered nurse (RN) to provide

the necessary skill set in this situation. The aforementioned fixes provide safety nets that focus on the system, but not all of the reporting hospitals displayed the skills required to attain better outcomes, as described in the next section.

Weaknesses of system fixes

The most common pitfalls in the RCAs were solutions that fixed the situation and not the system. Several times, nurses administered incorrect doses from multidose oral solution bottles. RCA analysis identified a “cognitive flip” in which the RN administered the *milligram* dose as a dose in *milliliters*. In one situation, the physician ordered 20 mg of a drug, and the RN administered 20 mL. This same type of error was reported several times in the NYPORTS database. Organizations with expertise in systems analysis produced solutions that looked at all oral liquids in their formularies and dispensed these oral solutions to the nursing units in unit-dose form. Facilities with less expertise frequently proposed less effective solutions, ranging from unit-dose dispensing only for the drug involved in the actual error to affixing a “check strength/concentration” sticker to the product. Unit-dose dispensing of the drug involved in the error will prevent an error with that drug, but not prevent occurrences with other drugs. The sticker will not prevent cognitive flips and is an ineffective solution to the problem. Affixing a label that tells the nurse the dose in milliliters is more likely to reduce a cognitive flip but requires more time on the part of the pharmacy during dispensing.

Another commonly identified weakness of system fixes was to propose educational fixes in the absence of a knowledge deficit. One physician was required to attend a class after a memory lapse that resulted in administration of a contraindicated thrombolytic agent, resulting in a subsequent fatal bleed. The literature tells us that education will not prevent memory lapses.⁷ A stronger systems fix would be developing a preprinted anticoagulation order sheet. This sheet would require the prescriber to verify all data has been checked and provides prompts about contraindications at the time of ordering (just-in-time education that reduces the potential that critical information will be overlooked).

Lessons learned

A limitation of the NYPORTS data is that the system fixes proposed often are those that RCA teams plan to implement. Consequently, there is a lack of evidence to measure the impact of the changes made at the time of submission. In addition, with rare events, the absence of injury is not necessarily the best indication that the system fixes have corrected the latent errors. The lessons learned that had the strongest potential for contributing to safety were those extrapolated from other areas within health care or from the literature.

Fatal dosing errors occurred when concentrated narcotics were stored on nursing units so that nurses could mix narcotic infusions. Removal of concentrated narcotics from these areas was recommended, utilizing the same processes applied for reducing deaths from concentrated electrolytes. The medication panel felt that, in addition to removing the concentrated narcotics,

supplying the nursing units with premixed narcotic infusions or having the pharmacy mix the narcotic infusions would avoid delays in treating patients who were in pain and prevent inadvertent reintroduction of concentrated narcotics onto the nursing units.

Organizations that do not have 24-hour pharmacy services need to develop procedural barriers to prevent high-risk drugs from being obtained without pharmacy review. One example is a fatal overdose from conventional amphotericin that was ordered at the liposomal dose. The usual dose of conventional amphotericin is not to exceed 1.5 mg/kg/day, and dosing at 3 mg/kg/day can be fatal.¹³ Normal dosing for liposomal amphotericin is 2.5–5 mg/kg/day. The order for 5mg/kg/day of conventional amphotericin was placed after the pharmacy closed and the urgent nature of initiating therapy required access to this medication. The drug was accessed from the automated drug-dispensing unit designated for off-hour use by the nursing supervisor. As result of the error, the hospital focused on eliminating the need for after-hours access. The panel recommended that the unpredictable need for the drug should be anticipated, with the drug carrying a message on the outside of the vial that dose verification was required by a pharmacist on-call prior to release of this medication to the nursing unit. Limiting the amount of available drug to the maximum recommended adult dose would create a barrier that would force the nursing supervisor to call for the location of additional vials. Each organization would need to identify all high-risk drugs contained in the off-hour cabinet/supply and develop similar barriers.

Hospitals relied on education and physician specialists (e.g., hematologists) to avoid errors with sound-alike names or medications with multiple dosing regimens. The panel felt a more effective system fix would be to require the prescriber to include an indication as part of the order, to assist in error detection. Methotrexate is given weekly for rheumatoid arthritis, but an incident where the prescriber ordered it on a daily basis—which is the oncology regimen—was described. The error was detected when bone marrow suppression occurred and the patient developed an episode of fatal sepsis. Lack of ready access to the patient's full medical history prevents the pharmacy from being able to validate the appropriate use of some agents and allow timely dispensing of drugs. A New York State (NYS) hospital demonstrated significant improvement in patient safety when it implemented the requirement that orders for drugs with multiple indications designate the specific use for which the agent is being ordered. Orders for drugs with only one indication or dosing regimen would not need to carry the indication to keep the prescribing burden low and reduce the risk of clinician noncompliance.

Failure-to-rescue events

Failure-to-rescue is defined as a situation in which a patient develops a complication and the providers fail to intervene, resulting in avoidable patient injury.¹⁵ While the majority of errors were discovered with the onset of adverse effects, there were instances in which the error was discovered within the window

of opportunity for intervention. The options proposed by the medication panel to be considered when dealing with unintended medication administration were—

- Administer charcoal to block the absorption of the agents.
- Consult with the poison control center.
- Use reversal agents (naloxone–narcan; sodium polysterene-kayexlate, etc.).
- Administer diphenhydramine (Benadryl™) and steroids.
- Establish intravenous access for rapid intervention if an adverse effect occurs.
- Move the patient to a higher level of care for more careful monitoring.
- Institute watchful waiting.

Unless a clear reversal agent was indicated (e.g., naloxone for narcotics or glucose for insulin), the most common response reported was watchful waiting. In some situations, once there was onset of symptoms, the adverse effects could not be reversed and supportive treatment was unsuccessful. This was especially evident in cases where the patient had a significant medical history with poor cardiac reserve and inadvertently received myocardial suppressants. The RCAs reflected a lack of assessment of the risks to the patient and infrequent use of proactive interventions to offset potential adverse events. Reactive or supportive treatment was the most common response. It should be noted that if proactive intervention was taken and the patient did not experience a serious adverse event, this would preclude the event from being reported in the NYPORTS database.⁶

Intervention carries risks as well. Use of naloxone in the narcotic-dependent patient carries the risk of complete narcotic withdrawal with fatal, noncardiogenic pulmonary edema. One end-of-life patient apparently self-adjusted the infusion pump and received a large dose of morphine. The RCA describes acute shortness of breath, accompanied by severe pain, immediately following the administration of the naloxone. The clinicians continued to administer naloxone despite worsening symptoms. The patient died shortly after the naloxone was administered, but the RCA never discussed the potential of acute narcotic withdrawal to explain the symptoms. Titrating the naloxone to patient symptoms, rather than administering a predetermined amount, will help prevent patient injury associated with complete narcotic reversal. Balancing the need to intervene against potential risks of intervention requires expert knowledge of drugs that anticipates the impact on the patient's condition relative to his or her diagnosis and comorbidities. The poison control center has expertise that is available for clinical consultation to support patient safety, but few RCAs cited this as a strategy for minimizing injury.

Qualitative data analysis and information sharing

System fixes and RCAs are relatively new within health care, and the NYPORTS qualitative data analysis provides information that should help

hospitals increase their expertise in these areas. Sharing information among hospitals will facilitate learning about patient safety initiatives. Identifying weak system fixes and providing information about how to strengthen them will facilitate progress on the patient safety learning curve. Describing the options to eliminate failure-to-rescue type events may help hospitals to undertake proactive steps so that, when an error does occur, patient injury will be avoided.

Limitations of data

The data obtained from the NYPORTS program is from the hospitals' own analyses of medication errors and determination that events meet the NYPORTS criteria for reportability. The data includes only those errors that result in the most serious harm. Further research is needed to establish the generalizability of the data beyond the NYPORTS criteria, and readers are cautioned about drawing conclusions.

Conclusion

NYPORTS mandatory reporting of medication errors has successfully met the IOM mandate for a program that uses the lessons learned from fatal or near-fatal errors for patient safety improvements and information sharing. Next steps include educational initiatives to address identified weaknesses in the RCAs and to measure the impact of the educational initiatives. The qualitative data analysis process is being reviewed and streamlined for timelier data sharing. The panel is examining the potential for including other NCC MERP categories.⁵ It is anticipated that each of these initiatives will provide hospitals with the knowledge and skills to proactively implement safer systems and reactively analyze systems to achieve better outcomes.

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References

1. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. A report of the Committee on Quality of Health Care in America, Institute of Medicine. Washington, DC: National Academy Press; 2000.
2. Hartwig SC, Denger SD, Schneider PJ. Severity-indexed, incident report-based medication error-reporting program. *Amer J Hosp Pharm* 1991;48(12):2611–6.
3. American Society of Health Systems Pharmacists. ASHP guidelines on preventing medication errors in hospitals. *Amer J Hosp Pharm* 1993;50(2):305–14.
4. Kaplan Hs, Battles JB, Van der Schaaf TW, et al. Identification and classification of the causes of events in transfusion medicine. *Transfusion* 1998 Nov–Dec;38 (11–12):1071–81.
5. NCCMERP.org. National Coordinating Council for Medication Error Reporting and Prevention. (Accessed 2004 Apr 14.)
6. NYPORTS Database. Albany (NY): New York Patient Occurrence Reporting and Tracking System. c2000–2002. (Accessed 2004 Apr 14.)
7. Reason J. Human error. Cambridge, UK: Cambridge University Press; 1990.
8. Shojania KG, Duncan BW, McDonald KM, et al., eds. Making health care safer: a critical analysis of patient safety practices. Evidence Report/Technology Assessment No. 43 (Prepared by the University of California at San Francisco–Stanford Evidence-based Practice Center under Contract No. 290-97-0013), AHRQ Publication No. 01-E058, Rockville, MD: Agency for Healthcare Research and Quality. July 2001.
9. Reason, J. Managing the risks of organizational accidents. 1st ed. Brookfield, VT: Ashgate Publishing Company; 1997. p. 252.
10. Leape LL, Bates DW, Cullen DJ, et al., Systems analysis of adverse drug events. ADE Prevention Study Group. *JAMA* 1995 Jul 5;274(1):35–43.
11. Cousins DD, Kotzin JR. MEDMARXSM U.S. Pharmacopeia. Summary of information submitted to MEDMARXSM in the year 2002: the quest for quality. Webcast (PowerPoint presentation dated Nov 18, 2003) available in the News Releases section at www.onlinepressroom.net/uspharm.
12. ISMP.org. Institute for Safe Medication Practices. (Accessed 2004 Apr 14.)
13. Wickersham RM, Novak KK, managing eds. Drug facts and comparisons. St. Louis, MO: Wolters Kluwer Health, Inc.; 2004. pp. 1358–64.
14. Perrow C. Normal accidents: living with high risk technologies. Princeton, NJ: Princeton University Press.,1984/1999.
15. Clarke SP, Aiken LH. Failure to rescue. *AJN* 2003;103(1):42–7.

APPENDIX F
NYPORTS NEWS AND ALERTS
#11-14

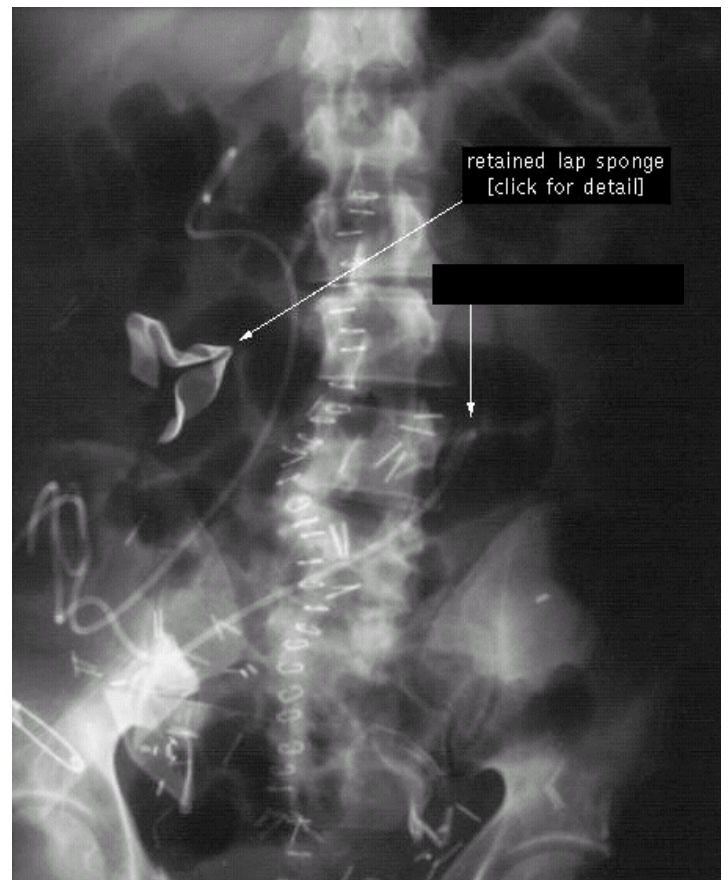
NYPORTS News & Alert

Department of Health, Issue 11

September 2002

Retained Surgical Sponges

The retained surgical sponge/lap pad occurrence is less likely to garner public notoriety typical of a wrong site surgery. However, a NYPORTS analysis completed in 1999 (News and Alert #3) and updated in July, 2001 (News And Alert #9) found that surgical sponges and lap pads are the most frequently retained foreign objects after the surgical procedure. Retained sponges/lap pads can result in serious conditions including sepsis, intestinal obstruction, fistula or abscess formation and adhesions. A secondary surgical procedure is often required for removal of the retained foreign item. The NYPORTS findings have prompted an interest in retrospective analysis of the Root Cause Analysis (RCA's) submitted for code 913 (Unintentionally retained foreign body due to inaccurate surgical count or break in surgical technique). The purpose of the analysis is to identify methods and suggestions presented in the RCA's that might improve the accuracy of the surgical count and decrease the occurrence of a retained surgical sponge or lap pad.



Looking at Prophylaxis for Thromboembolic Disease

Proper prophylaxis plays a major role in the prevention of unexpected adverse occurrences due to PE or DVT. However, despite the most ardent efforts, it is not effective in every case. The process for identifying risk factor categories for thromboembolism and the resulting prophylaxis varies from facility to facility. Some facilities have developed a thromboembolism risk factor assessment tool, which assigns a designated number or score to a variety of risk factors to determine whether a patient is at low, moderate or high risk for a developing a PE/DVT. An assessment of several thromboembolism risk factor assessment tools, which were shared with the NYSDOH, revealed that facilities assign different scores and weights to the same risk factor, and that the number of risk factors used varies. For example, at one facility the risk factor score for prior DVT is assigned a score of 1. At another facility, the same risk factor is given a score of 3. Since the risk categories are determined by the sum of these scores, the same patient could be potentially considered a moderate risk at one facility and at high risk at another, changing the agent and modalities for prophylaxis accordingly.

Continued on page 2

Looking at Prophylaxis for Thromboembolic Disease, continued from page 1

A recent research study at Brigham and Woman's Hospital (Goldhaber, Dunn, and MacDougal, 2000) calculated percentages of the patients in the study who developed venous thromboembolism (VTE) with 0-4+ risk factors. The study also found that most patients who developed secondary VTE had multiple risk factors. For example, 101 cases had two risk factors, 113 had 3 risk factors and 104 cases had 4+ risk factors. The research study also found that most deaths due to PE in this study population were related to failed versus omitted prophylaxis. The study suggests that quality improvement committees consider more intensive prophylaxis of high-risk patients and conduct meticulous follow-up of these patients to ensure successful outcomes. Based on this study, hospitals should consider examining their thromboembolism risk factor assessment tools to assure proper patient risk categories are in place and proper prophylaxis occurs in all risk categories.

Goldhaber, S., Dunn, K., and MacDougal, R. (2000).

New onset of thromboembolism among hospitalized patients at Brigham and Woman's Hospital is caused more often by prophylaxis failure than withholding treatment. **Chest, 118:1680-1684.**

Reporting an unexpected death related to PE/DVT (even when prophylaxis was given) allows trends to be identified by the retrospective analysis of statewide RCA submissions that may not be detectable by an individual facility. The 915 definition does not include language regarding preventability or prophylaxis. Current analysis of high-risk populations in the 915-study sample does not support modifying the reporting criteria. A Data Analysis Panel (Clinical Specialists) has recently begun to study the qualitative and quantitative information from the RCA submissions and will be providing feedback to hospitals.

Top 5 NYPORTS Procedures Associated with DVT:

1. Total Knee Replacement
2. Total Hip Replacement
3. Venous Catheterization
4. Open Reduction/Internal Fixation of Femur
5. Partial Resection of Small Intestine

Top 5 NYPORTS Procedures Associated with PE:

1. Total Knee Replacement
2. Incision/Excision and Occlusion of Abdominal veins
3. Open Reduction/Internal Fixation of Femur
4. Total Hip Replacement
5. Total Abdominal Hysterectomy

JM

A Matter of Laterality

The NYSDOH evaluated Root Cause Analysis submissions for wrong surgical components in total knee replacement systems, and concluded that the femoral component of this system is the only part that requires laterality verification. Wrong knee component occurrences are a continued problem identified by NYPORTS code 912 (Incorrect procedure or treatment-invasive). Although not on the list of Specific Pre-op Protocols, implant device verification and the communication to effectuate this process is recommended in the Pre-Operative Protocols Final Report (Available on the DOH website at health.state.ny.us).

Below are some of the corrective actions compiled from the evaluation of RCA's submitted for this occurrence:

- Evaluate the packaging of knee component parts, and consult your component vendor regarding packaging issues, (Root causes regarding laterality describe exceptionally small font for the words "left" and "right" on the component packaging).
- Facilitate education through vendor workshops.
- Develop a Device/Implant confirmation form, for selecting and signing for component parts. This tool might detail a 3-4-step verification process initiated by the surgeon. The circulating nurse would verify the device/implant and state size and laterality of the component. The nurse will show components to the surgeon prior to opening them and place them on the sterile field.
- It may be helpful to separate components on supply carts and storage areas by laterality, as well as size.

JM



Complicated Cases-Which One Would You Report?

Read each of the following cases studies to determine which case should be reported to NYPORTS.

Case #1

A patient underwent an urgent tricuspid valve replacement, during which vegetations from endocarditis were well noted. The patient developed an acute abdomen and after evaluation was taken to the OR for a colectomy and end ileostomy due to gangrenous colon. The patient subsequently expired. The patient's pre-existing condition was Candida Endocarditis, with resulting tricuspid insufficiency, renal failure, and sepsis.

Case #2

A patient underwent surgical intervention for a large tumor removal, developed a pulmonary embolism and expired. SCD boots were used immediately postoperatively. Anti-coagulant therapy was contraindicated. The patient was at high risk for Diabetes Incipitius related to tumor location, and required the use of the drug, DDAVP (a known platelet activator). Pharmacy literature states that there have been rare reports of thrombotic events following administration of DDAVP in patients predisposed to thrombus formation.

Find the answer and explanation on page 4.

Many corrective actions from RCA's suggest utilization of x-ray to identify retained foreign bodies. The use of sponges containing a radiopaque marker substantially improves the ability to locate them in a x-ray. While this is a widely used practice, it does not prevent the retention of surgical sponges. Although the use of x-ray is a standard diagnostic tool in locating a retained sponge or lap pad, there can be great variability in their appearance, leading to diagnostic misinterpretations. It may be helpful for facilities to maintain a collection of examples of the x-ray appearance of retained surgical sponges to assist the Radiologists/Surgeons with identification. The Association of Operative Registered Nurses (AORN Journal Dec 1999) recommends that sponges be counted:

1. Before the procedure to establish a baseline,
2. Before closure of a cavity within a cavity,
3. Before wound closure begins,
4. At skin closure or end of procedure, and
5. At the time of permanent relief of either the scrub person or the circulating nurse.

Also, sponges should be counted and recorded when added to the field.

RCA's note that even with this meticulous care, inaccurate counts can occur when surgical sponges stick together or when situations interrupt the counting process (common root causes). Additional suggestions compiled from NYPORTS RCA's include:

- Using two individuals to perform the surgical count, instead of one.
- Consulting the attending radiologist to determine which radiographic pictures would be most beneficial in locating a retained sponge or lap pad.
- Developing protocols for extended situations that may warrant x-ray examination in addition to surgical counts, such as when surgical sponge count is impacted by emergent situations.
- Considering a protocol to account for the use of an unusual or different type of sponge/lap pad, other than what was planned for procedure.

Janet Mannion R.N.

Reportable?

Answer #1- Not reportable

It was concluded that the patient in case #1 had complications related to underlying fungal endocarditis that likely precipitated this unfortunate event. The gangrenous bowel was likely related to the effects of hemodynamic deterioration resulting from embolized fragments of vegetative growths from the heart and its effect on mesenteric perfusion. In addition, it was concluded that the septic condition and surgical stress contributed to the death.

Answer #2-Reportable

The patient in case #2 did not suffer a PE as a result of underlying disease, but related to the known risk factors. Risk factors alone do not exclude an occurrence from NYPORTS 915 code reportability. This case should be reported as a 401 and 915.

NYPORTS Statewide Council Meeting

The NYPORTS Statewide Council will meet on September 27, 2002 at the School of Public Health, Rensselaer, from 10:00 a.m.- 3:30 p.m.

DOH/ HANYS NYPORTS Training

Through a joint effort, the NYSDOH and HANYS will present videoconference training on November 4, 2002. Proposed topics include comparative reports, RCA quality initiatives, enhancements of the NYPORTS I/E list and definitions manual, and NYPORTS data/lessons learned related to unexpected deaths. If you are interested in attending, please contact HANYS at (518) 431-7600.

Reminder

For all medication error submissions (108-110), please include the corresponding Detail Code (915-920) and RCA.

AHRQ GRANT UPDATE

The NYSDOH, in conjunction with the University of Albany School of Public Health (SPH), was awarded a patient safety grant by The Federal Agency for Healthcare Research and Quality (AHRQ). The funding period is 09/30/01 through 08/31/04. Updates will be regularly provided.

The patient safety Project encompasses two initiatives:

1. An effort to improve the quality and completeness of reporting under NYPORTS, and
2. Efforts to reduce the occurrence of adverse outcomes through sponsorship of three demonstration projects involving networks or groups of hospitals that study a common and preventable adverse outcome and develop and test initiatives to reduce that outcome.

Awards were made for three Patient Safety Demonstration Projects during June 2002 for the study period 8/15/02-8/14/04. Hospital groups participating are:

- **Code 401/402-** (new documented PE, New documented DVT)
Lead organization- Strong Memorial Hospital. Participating hospitals: Highland Hospital, FF Thompson Hospital, St. James Mercy Hospital, and Jones Memorial Hospital.
- **Code 604-** (Acute Myocardial Infarction unrelated to a cardiac procedure)
Lead organization- New York Presbyterian Hospital, Columbia Presbyterian Center. Participating hospitals-New York Methodist Hospital, St. Barnabas Hospital, White Plains Hospital Center and NY Hospital Center-Queens
- **Code 808-** (Post-op wound infection following clean or clean/contaminated case requiring drainage or hospital admission within 30 days).
Lead Organization- Westchester Medical Center. Participating hospitals- Benedictine Hospital, St. Agnes Hospital, and Ellenville Regional Hospital.

NYPORTS News & Alert

Department of Health, Issue 12

February 2003

Magnetic Resonance Imaging Safety

The number of adverse events attributed to Magnetic Resonance Imaging (MRI) is quite small when compared with the total number of scans performed annually. However, projectile incidents continue to occur resulting in varying degrees of injury, and in one instance, a fatality.

The static magnetic force of a MRI will attract ferromagnetic objects into its core with significant force. Oxygen tanks, IV poles, chairs, ladders, scissors, and a host of other metal objects have become projectiles due to the attraction of the magnetic force. Even objects that may appear safe can become projectiles. For example, sandbags are assumed to contain only sand, but some contain ferromagnetic pieces, making them potential projectiles in a MRI environment. In addition, facilities should not assume oxygen cylinders are ferromagnetic or not based solely on their outward appearance. In a recent event, staff assumed that an oxygen cylinder was non-ferromagnetic based on the color pattern of the tank. This assumption resulted in the cylinder being drawn into the MRI core, because the tank was actually ferromagnetic despite having the usual coloration of a non-ferromagnetic tank. To date there is no standardized color combination to indicate a ferromagnetic vs. non-ferromagnetic tank. Although some oxygen suppliers label their tanks with wording or stickers, others do not, or the labeling has proven to be inconsistent.

The following recommendations for MRI safety have been excerpted from "Patient Death Illustrates the Importance of Adhering to Safety Precautions in Magnetic Resonance Environments". written by ECRI in August 2001.



The complete document is available at www.ecri.org.

1. Appoint a safety officer responsible for ensuring that procedures are in effect and enforced to ensure safety in the MRI environment.
2. Establish and routinely review MR policies and procedures, and assess the level of compliance by staff.
3. Provide all MR staff, along with other personnel who would have an opportunity to enter the MR environment (e.g., transport, security, housekeeping, and maintenance), with formal training on safety considerations in the MR environment.
4. Always assume that the MR system's static magnetic field is present, and treat the system accordingly.
5. Identify zones in the MR suite and surrounding rooms (including adjacent floors) where the magnetic field strength exceed 5 gauss (G). Define this area as the MR environment, and restrict access to this area.
6. Don't allow equipment and devices containing magnetic (especially ferromagnetic) components past the 5G line, unless they have been tested by the device manufacturer and have been labeled "MR safe" for your specific MR environment.

Also, adhere to any restrictions provided by suppliers regarding the use of "MR-safe" and "MR-compatible" equipment and devices in your MR environment.

MR safe=the device when used in the MR environment has been demonstrated to present no additional risk to the patient or other individuals but may effect the quality of diagnostic information

MR compatible=MR safe and can be used in the MR environment with no significant effect on its operation or on the quality of diagnostic information

7. Don't make assumptions about devices or equipment (e.g., sandbags) being safe. Unless a device has been proven to be MR safe, do not bring it into the MR environment.
8. Maintain a list of MR-safe and MR-compatible equipment, including restrictions for use. This list should be kept in every MR center by the MR safety officer. It is critical that the safety officer knows which equipment has been determined to be safe or compatible for which particular MR environments. Further, if MR systems are upgraded or new MR systems are purchased, the safety officer must determine whether the equipment is still MR safe or MR compatible with the new or upgraded system.
9. Test equipment or devices with a powerful handheld magnet to determine their potential to be attracted by the MR system before allowing them into the MR environment. This is important even for MR-safe and MR-compatible equipment. Keep in mind that this test will not catch all magnetic materials (e.g., sandbags). However, the test will generally detect sizable magnetic objects.
10. Be extremely careful if you must use equipment containing ferromagnetic components in the MR environment:
 - A. To prevent the equipment from being moved too close to the MR system, the equipment should be physically secured a safe distance from the MR system throughout non-magnetic means. It is important that the method used to secure the equipment is adequately tested before it is used. In addition, the equipment should be properly labeled.
 - B. Any small, ferromagnetic components of devices, such as caps and covers, should be firmly attached to the device (by nonmagnetic means), since ferromagnetic components can work loose over time.
11. Bring non-ambulatory patients into the MR environment using a nonmagnetic wheelchair or wheeled stretcher. Ensure that no oxygen bottles, sandbags, or any other magnetic objects are concealed under blankets or stowed away on the transport equipment.
12. Ensure that IV poles accompanying the patient for the MR procedure are not magnetic.
13. Carefully screen all people entering the MR environment for magnetic objects in their bodies, on their bodies, or attached to their bodies. Magnetic objects on or attached to patients', family members', or staff members' bodies should be removed if feasible (dental fillings are an example of a non-removable item) before such individuals enter the MR scan room. Patients with ferromagnetic materials in their bodies may not be candidates for MR imaging, unless the physician has reviewed the case and approved scanning.
14. Have patients wear hospital gowns-those without metallic fasteners-for MR procedures if possible.

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Other sites with information pertaining to MRI safety:

www.fda.gov Food and Drug Administration

www.acr.org "American College of Radiology White Paper on Safety", June 2002.

Ruth Leslie.

605 OVER REPORTING

Recent analysis of NYPORTS code 605(Death occurring after procedure) show that procedures other than the ICD-9 codes specifically listed for inclusion (see Includes/Excludes list) are being erroneously entered. Please review the appropriate ICD-9 codes and do not report if the procedure is not listed. If multiple surgeries are performed, please report the surgery that is found in the includes list.

CODING CORRECTLY

After looking at code 805 (wound dehiscence requiring repair), we discovered that many facilities are listing the ICD-9 procedure that was done to ameliorate the occurrence, rather than the ICD-9 primary procedure that led to the actual occurrence. For example: "repair of post-op wound dehiscence" or "reclosure of post-op disruption" are the "fix", not the occurrence procedure. Please be sure to input the appropriate ICD-9 procedure.

NYPORTS ENHANCEMENTS

On November 4th, 2002 a statewide videoconference/training session was held at HANYS to introduce enhancements to the NYPORTS definitions document and Includes/Excludes list. Immediately following the session the enhancements were placed into effect. The enhancements consist primarily of clarifying language, narrowing the focus of a few codes, and adding additional examples and references to pages of significance. One fundamental change was the expansion of code 915 (unexpected death). It was expanded to include both live and still birth that meets specific criteria:

- a. greater than or equal to 32 weeks gestation
- b. greater than or equal to 1500 grams of weight
- c. Absence of life threatening congenital anomalies.

Neonatologists involved in the enhancements and Data Analysis project strongly suggested scaling back to 28 weeks gestation and 1000 grams to more appropriately reflect today's expectation for good outcome, and offered more clarifying detail. These proposals were brought to the NYPORTS council on January 31,2003, discussed in detail and approved.

The revised criteria for 915 will be:

- a. greater than or equal to 28 weeks gestation
 - b. greater than or equal to 1000 grams of weight
- Exclusions will include congenital anomalies incompatible with life (e.g., Trisomy 13, 18, Anencephalus, Tracheal or Pulmonary Atresia, Multiple life threatening congenital anomalies).
 - **ANY** iatrogenic occurrence no matter what gestation/weight, etc. would be included in reporting.
 - Still birth occurrences will be limited to:
 - Mom is admitted to the hospital with a viable fetus meeting the above criteria and has fetal demise/stillbirth during the hospital stay.
 - Stillbirth on admission, when the mother has been seen at an Article 28 facility or any service listed on the operating certificate (Article 28 hospital clinic, Article 28 hospital

Continued on page 4

STATUS OF DATA ANALYSIS

The Data Analysis Panel has been analyzing Unexpected Death Occurrences (Code 915), that were submitted from June 1, 2000 to December 31, 2001. The occurrences have been divided into seven categories: Pharmacological-related, Neurological, Cardiac, Pulmonary, Maternal, Neonatal, and Surgical/Procedural.

At the Statewide Council meeting on January 31, 2003, three members of the panel presented their preliminary findings. Dr. Brad Truax presented his analysis of Neurological events and falls with injury. Dr. Jean-Paul Hafner presented Pulmonary cases and Angelo Ruperto, PharmD, MBA, presented findings from Pharmacological-related analysis. Preliminary analysis of the other categories is expected to be shared at the next NYPORTS Statewide Council meeting in May.

The following is an excerpt from the analysis of Pharmacological-related events, specifically of events involving anticoagulants.

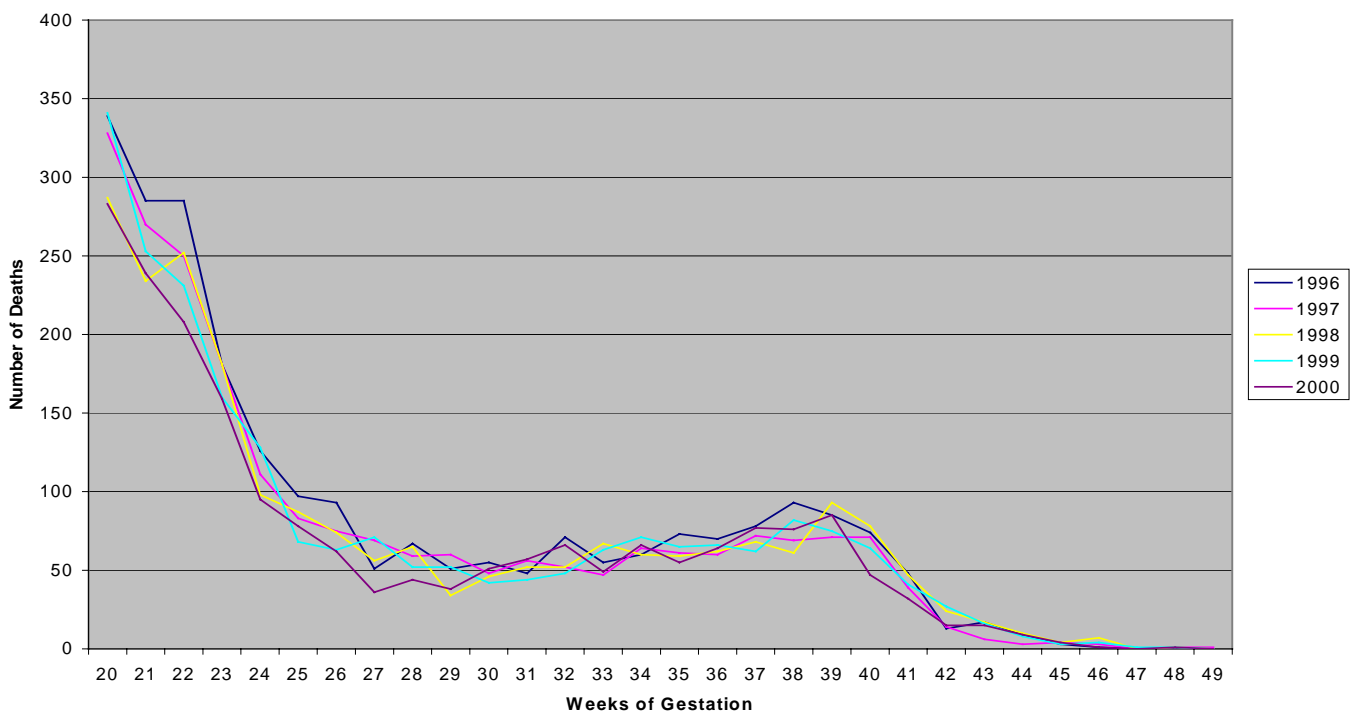
- Pharmacy computer system should flag anticoagulant orders for parameters such as weight and renal function.
- Avoid stocking of heparin premixed bags on nursing units.
- Review policy addressing notification of panic values from laboratory.
- Post an INR reference chart on nursing units.
- Protocols, guidelines, and standard order forms should prominently remind practitioners to assess all drug therapy (including in the ED) and avoid concomitant use of heparin products.
- Establish an escalation Policy & Procedure to guide staff when faced with improper or unsafe drug use.
- Education of staff of the concomitant

*Continued on
page 5*

Fetal Death Statistics

There were many requests for the NYS fetal death statistics used in validating gestation criteria at the November 4, 2002 HANYS /NYPORTS videoconference. The information on the graph below, provided by the Statewide Perinatal Data System (SPDS), shows that there were actually fewer deaths at gestational ages 28-32 weeks than 36-40 weeks. Choosing the gestational age of 28 weeks to define the collection criteria for 915 is appropriate based on the data below. In addition, it is important to develop consistencies between DOH systems that support quality improvement efforts and analysis.

New York State Fetal Deaths by Weeks Gestation



Enhancements continued

imaging department, free standing clinic, free standing medical imaging center) within the past 72 hours, and deemed to have a viable fetus.

It was decided that a formal letter will be sent to all facilities prior to the implementation of the additional revisions. Those who wish to continue to report on the enhancements disclosed on Nov 4th, 2002, may certainly do so (excluding 915 those enhancements are still in effect) but no facility will be held accountable for the enhancements until receipt of a formal letter from the DOH. We will be sending the NYPORTS manual out in its entirety immediately following the letter.

NYPORTS STATISTICS 2001

NYPORTS received a total of 28,706 records for 2001.

The top 5 codes reported to NYPORTS in 2001 are as follows:

1. **Code 819:** Unplanned operation or return to the OR-35% of total records
2. **Code 803:** Hemorrhage /hematoma requiring drainage-14% of total records
3. **Code 808:** Post-op wound infection-13% of total records
4. **Code 402:** New documented DVT -11% of total records
5. **Code 801:** Procedure related injury requiring repair -9% of total records

The top five procedures for each of the top five codes and the number of each procedure, except for 402, are found below. The top five procedures reported under 402 are found in News and Alert #11.

Code 819-10,097 reports

1. Other (Peripheral) Vascular Shunt or Bypass-323
2. Total Abdominal Hysterectomy-149
3. Lap Chole-136
4. Partial Resection of Small Intestine-128
5. Liver Transplant-127

Code 803-4,126 reports

1. Tonsillectomy with Adenoidectomy-127
2. Tonsillectomy without Adenoidectomy-114
3. Other (Peripheral) Vascular Shunt or Bypass-100
4. Low Cervical C-Section-91
5. Total Abdominal Hysterectomy-88

Code 808-3,729 reports-

1. Other (Peripheral) Shunt or Bypass-127
2. Appendectomy-102
3. Low Cervical C-Section-101
4. Total Abdominal Hysterectomy-91
5. Total Knee Replacement-67

Code 801-2,848 reports

1. Total Abdominal Hysterectomy-141
2. Laparoscopic Cholecystectomy-77
3. Low Cervical C-Section-77
4. Colonoscopy-67
5. Phacoemulsification/Aspiration of Cataract-53

Code 402 (found in News and Alert #11)-3,066 reports

Data Analysis continued

use of anticoagulants including the dissemination of the Institute for Safe Medication Practices (ISMP) alert on 2/21/2001.

- Institute policy that requires formal referral for any patient prescribed less commonly used anticoagulant medications such as Recludan (lepirudin).
- Develop policy to require frequent monitoring of PT/INR.
- Patients should be advised to fill prescriptions at one pharmacy to address drug interaction issues.
- High caution should when applied to any therapeutic substitutions of anticoagulants such as the substitution of Fragmin (dalteparin) for Lovenox (enoxaparin).

INFORMATION REGARDING YOUR NYPORTS COORDINATOR AND HOW THEY CAN BE OF ASSISTANCE

- Contact them when you have a question about reporting criteria, DOH requirements for brief clear descriptions in a short form summary (REMEMBER this is no longer limited to 50 words or less but not intended to be a mini RCA) or what constitutes a thorough and credible RCA.
- Contact them when you have trouble getting information submitted within reporting timeframes. You can make arrangements with your regional NYPORTS coordinator to get an occurrence submitted on time, and enter additional clarifying text within a reasonable timeframe. For example, if you are awaiting the results of consultants, review teams, autopsy etc, that would make the information complete and thorough, but delay your submission, your coordinator will be able to help you meet your reporting requirements.
- Work out solutions to facilitate getting additional information regarding RCA's entered into the electronic report. Without complete information, data analysis/feedback is severely restricted.

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E-Mail Marcia at mah12@health.state.ny.us

INCLUDES COUNTIES: Niagara, Orleans, Genesee, Erie, Wyoming, Allegany, Chautauqua, and Cattaraugus.

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NYPORTS News & Alert

Department of Health, Issue 13

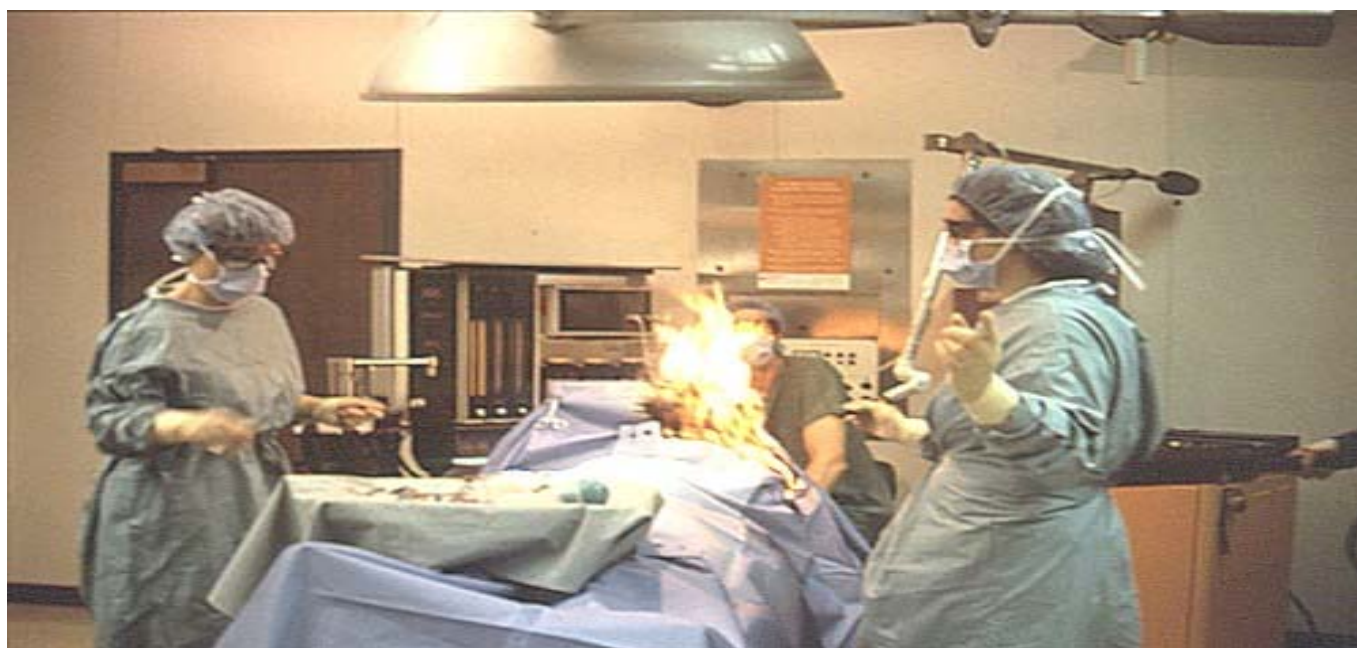
June 2003

Electrosurgical Burns and Fire Occurrences

When two significant occurrences involving 2nd-3rd degree burns to patients with the use of electrosurgical instruments were recently reported in NYPORTS, the Bureau of Hospital & Primary Care Services conducted a retrospective review of all NYPORTS occurrences involving electrosurgery. The findings of this review underscored the need for this alert to hospitals, which discusses electrosurgical occurrences and assesses current research in support of recommendations that can raise the standard, augment systems set in place to increase patient safety and decrease the incidence of patient harm while using this equipment.

Since the inception of NYPORTS in April of 1998 through April of 2003, there were ninety- five NYPORTS occurrence reports associated with electrosurgery. This News & Alert reviews the surgical fire, tissue burn and equipment malfunction occurrences addressed in those reports.

Electrosurgery was first practiced in the early 1920's and involves the use of a tool that is designed for the cutting or coagulation (electrocautery) of tissues by means of a high frequency current, which is passed through targeted tissue. It allows for relatively bloodless surgery and is commonly used with excellent results. However, there are inherent risks in the use of electrosurgery, such as burns to the skin or non- target tissues, and surgical fires. Although advancing medical technology has had a positive impact on the safety of electrosurgical equipment, adverse events resulting in patient injury continue to



Surgical Fire Occurrences

For a fire to begin, the right combination of elements must be present: an ignition mechanism (such as the electrosurgical tool used by the surgeon), a fuel (runs the gamut of OR supplies- dressings, linens, tubing and antiseptic preps etc., including patient's hair), and an oxidizer enriched atmosphere (gas such as oxygen or nitrous oxide) provided by the anesthetist. Three key individuals (Surgeon, Anesthetist, and Nurse) in the O.R. play a primary role in planning, interacting and facilitating a safe surgical experience using electrosurgery/cautery tools.

Of the thousands of surgeries performed in New York State over the past five years, an electrosurgical tool has been associated in ninety-five NYPORTS occurrences, primarily code 701- Burns (2-3rd degree), code 801- Injury requiring repair, and code 937/938 Equipment malfunctions with/without serious injury. One occurrence can be reported into NYPORTS using more than one code, indicating for example, that there was an equipment malfunction (937/938) and a burn (701).

Exhibit 1 gives a breakdown of the NYPORTS occurrences involving Electrosurgery.

Of the 11 fires reported to NYPORTS, five resulted in 2nd or 3rd degree burns (Exhibit 2) to the patient. Four of the five fires caused burns to the patient's face and/or neck area. Three of the five burns cite that the surgical drapes caught fire during surgery while using an electrosurgical tool in an oxidizer enriched environment. The remaining two of the five fires cite a flash fire to the hairline of a patient during electrosurgery and an alcohol preparation ignited during electrosurgery respectively.

Exhibit 1

Events Reported to NYPORTS (95 Occurrences)		
NYPORTS code	Code Description	Number of times indicated in NYPORTS
801	Injury requiring repair	26
937/938	Equipment malfunctions with/without serious injury	26
701	Burns	65

It is pertinent that clinicians become very familiar with the hazards of enriched atmospheres, ignition sources and combustible substances likely to be encountered in the O.R. Many products/items/body parts that are typically non flammable under normal circumstances, can become highly flammable in what is referred to as an oxidizer enriched atmosphere (OEA). Oxidizers are gases that support combustion. For example, the soft downy hair that covers our bodies (referred to as "vellus") can become highly flammable in an oxidizer enriched atmosphere (greater than 50% oxygen). Typically the air we breathe is 21% oxygen, and would not cause the hair on our bodies to ignite and rapidly burn in the face of an ignition source, but rather shrivel.

Exhibit 2

Burn Classification	
Second degree burn	Reddened skin with blisters and/or superficial open weeping lesions
Third degree burns	Stiff ischemic (deficient of blood supply) or necrotic tissue (death of tissue) which is black or white, depending on the etiology of the burn

The recommendations that follow in this advisory are provided by ECRI (formerly known as Emergency Care Research Institute), an independent, non-profit health service research agency. While the Department of Health can not officially endorse any specific organization, it recognizes the evidence-based healthcare technology research relative to electrosurgical occurrences, performed and published by ECRI. It is the expectation of the Department that facilities will use these, and recommendations from other sources, to ensure the safety of patients and healthcare workers during the use of electrosurgical equipment.

For more on ECRI, and links to electrosurgical safety information, see page 6 of this newsletter.

Recommended actions include:

1. If open oxygen is being administered during head and neck surgery (e.g., via nasal cannula or O2 mask), make hair near the operative site (e.g., eyebrows, mustaches, beards) nonflammable by coating with water soluble lubricating jelly.
2. Inflate endotracheal tube cuffs properly, (there is one reported NYPORTS occurrence of fire involving a cuff; luckily there was no patient harm) and check for leaks with a stethoscope before and during the procedure. Use wetted gauze or sponges with uncuffed tracheal tubes to minimize leakage of O2 into the oropharynx and keep them wet.
3. If the procedure and patient condition permit (as head and neck surgery frequently does) anticipate the use of the electrocautery by at least one minute and discontinue O2 administration to the patient. Oxygen may be re-administered following the use of electrosurgery or cautery unit.
4. When open oxygen sources are used, as is common during head and neck surgery, the use of bipolar electrosurgery is recommended, when possible and clinically appropriate. Bipolar electrocautery creates little or no sparking or arcing, and has not been associated with any known surgical fires.

One particular danger for propagating a fire is the accumulation of operative gases under surgical drapes, as well as in the oropharynx. There are recommended draping techniques that facilitate dissipation of gases away from the patient during electrosurgical surgeries.

Recommended actions include:

1. Make every effort to minimize the build up of oxygen and nitrous oxide beneath drapes and the oropharynx.
2. For ophthalmic and head and neck procedures, tent the operative and full-length body drapes from the end of the nose to facilitate dissipation of gases. The use of auxiliary support (such as the Mayo stand) may be necessary to achieve adequate tenting. With an outlet, gravity will assist in pulling oxygen to the floor and away from the patient.
3. Be aware of methods available to minimize oxygen build up beneath the drapes and oropharyngeal cavity. Allow high concentrations of oxygen to dissipate before activating heat producing surgical units.
4. Scavenge the oropharynx with separate suction.



Eight occurrences reported to NYPORTS indicated sparking with the use of Electrosurgery tools. Two occurrences resulted in 2nd or 3rd degree burns to the patient, while 6 indicate that the electrical cord for the cautery unit emitted sparks. Routine maintenance and monitoring of the electrical cord is critical of course, although fraying of the cord's internal wires may not be visible from the outside. Electrosurgical cords should be detached from the unit or the wall using the plug, not the cord. Educate staff (clinical, maintenance or housekeeping staff) who may have contact with the unit to handle the cords properly and notify your Clinical Engineering Department when issues arise.

Recommended actions include:

1. Use the lowest possible Electrosurgical unit power settings as appropriate for the surgery, as well as the lowest possible oxygen supply that will maintain adequate oxygen saturation for the patient. Reducing the level of oxygen in the surgical environment under the drapes during electrosurgery is extremely important to decrease the risk of sparking and nearby fuel ignition igniting in the oxidizer-enriched atmosphere.
2. Adhere to recommendations for the life expectancy of the cord.

Burn Occurrences

Of the ninety-five reported electrosurgery occurrences, sixty-five involve second to third degree burns incurred by a patient. Fifteen of these burns occurred at the site of the dispersive or return electrode pad site. More than one of these submitted reports implicates buckling of the pad under the patient, and suggest that return electrode pads only be applied with complete visualization of the area used for grounding. According to ECRI, burns at the dispersive or return electrode have been shown to primarily involve inadequate preparation of the dispersive electrode site, placement of the electrode, or malfunction related to the electrode's conductive surface.

The following procedures are recommended to reduce a hospital's risk of dispersive pad burns:

1. Choose a flat or relatively flat muscular area fairly close to the surgical site that will not bear the patient's weight during surgery for dispersive electrode placement.
2. Before placing the electrode, thoroughly clean and dry the site. It is safer to assume that you should shave the site than not shave it.
3. Place the electrode in a location where it is not likely to come into contact with fluids.
4. Before placing the electrode, check it for defects such as dried-out or insufficient amounts of conductive gel or adhesive.
5. After applying the electrode, the operator should run a hand over the dispersive pad to confirm uniform placement. While smoothing, the operator's hand should move only from the outside to the inside of the pad so that no gel is forced out from underneath the pad.
6. OR staff should be aware that inadequate surgical effect at the operative electrode site could be a warning sign of poor return electrode contact. Alarming of the electrosurgical unit's return electrode monitor is another warning sign. The staff should immediately check the dispersive electrode for placement and obvious defects. If no problems are apparent, the pad should be removed and checked for dried out gel or adhesive, and the skin underneath the pad should be examined for signs of high electrode to skin impedance (i.e. pad over a improperly cleaned or shaved area)
7. Fatty tissue or tissue directly over bone can impede electrosurgical return current flow, and dispersive pads placed over these areas should be replaced with a new pad over a muscular area as mentioned above. Obese patients may require a second parallel dispersive electrode to increase the overall dispersive pad surface area, decrease the electrode to skin impedance, and reduce the current density.

Of the remaining 50 burns to non-targeted tissue, the most frequently cited burn area is the thigh, followed by the abdomen and breast area. Short-form summaries describe some of the causes of accidental burns as failure to rest the cautery tool in its holder when not in use, to accidental contact with a live tool.

Recommended actions include:

1. Activate electrosurgical and cautery units (ECU) only when the tip is in view, and always place the ECU active electrodes in a safety holster when not in active use.
2. If using a holster is inconvenient or awkward (e.g., when using endoscopic electrosurgical electrodes), place the electrode away from the patient and surgical drapes on an instrument tray or Mayo stand; if this is not possible, disconnect the active electrode cable.

Trended Analysis of Electrosurgical Occurrences

Many other variables were evaluated for trends from the reports on these occurrences. Exhibit 3 displays the top four surgical services that had patients effected, a breakdown by NYPORTS code and the most common procedure associated with the service.

Exhibit 3

Electrocautery Information Reported to NYPORTS by Service				
Service	NYPORTS code	Number of occurrences	Total Patients	Most Common ICD-9 Procedure Associated with Service
General Surgery (service code 18)	Injury requiring repair (801)	10	31	Laparoscopic Cholecystectomy (51.23) 6 occurrences
	Equipment malfunctions with or without injury (937/938)	7		
	Burns(701)	15		
Gynecology (service code 22)	Injury requiring repair (801)	2	11	Total Abdominal Hysterectomy (68.4) 3 occurrences Vaginal Hysterectomy (68.5) 2 occurrences
	Equipment malfunctions with or without injury (937/938)	2		
	Burns(701)	9		
Orthopedics (service code 11)	Injury requiring repair (801)	1	11	Revision of Hip replacement (81.53) 3 occurrences Revision of arthroplasty of shoulder (81.83) 3 occurrences
	Equipment malfunctions with or without injury (937/938)	1		
	Burns(701)	9		
Otolaryngology/ENT (service code 12)	Injury requiring repair (801)	1	8	Tonsillectomy and Adenoidectomy (28.3) 4 occurrences
	Equipment malfunctions with or without injury (937/938)	3		
	Burns(701)	7		

NYPORTS occurrence data is useful to analyze and trend electrosurgical occurrences. Across the state, 20 facilities had more than one NYPORTS related electrosurgical occurrence. All were scrutinized retrospectively for common factors, and only one facility had 2 similar occurrences within close proximity.

The DOH regional NYPORTS coordinator was aware of these occurrences, and through further analysis, determined that the cases did not have the same practitioner or procedure. In addition, these occurrences were related to a change in the O.R. equipment set up. This change was immediately corrected, and there have been no subsequent instances at that facility. Lessons learned cite “always place the electrosurgical pencil away from the patient and operative site, and in its holder when not in use”.

Coding Concerns/Clarification

All electrosurgical events were analyzed for the accuracy of NYPORTS coding. The majority of cases were coded accurately; however, the following coding issues were identified:

- 11 cases were submitted under code 701 (2nd and 3rd degree burns) and should have included a secondary code of 801 (procedure related injury requiring repair, removal of an organ or other procedural intervention) to indicate a greater degree of patient consequence. In cases that involve 2nd degree burns to a significant portion of the body or 3rd degree burns that require excision/debridement and/or suturing, the secondary code 801 should be used to indicate procedural intervention to an organ (the skin). 1st degree burns or small 2nd degree burns that require superficial treatment only, utilizing a topical ointment/cream such as neosporin/silvadene and a dressing, would be coded as a 701 and would not require the use of secondary 801 coding.
- 4 cases involving electrosurgical burns were submitted as a 937 (malfunction of equipment during treatment or diagnosis or a defective product, which has potential for adversely affecting patient or hospital personnel or resulting in a retained foreign body). Since these cases involved a burn to a patient, they should have had a primary code of 701 and a detail code of 937.
- In 1 case, multiple reports were submitted for two occurrences. Please submit only one report per occurrence.

ECRI (www.ecri.org)

ECRI produces and publishes the monthly journal “Health Devices” and the “Health Devices Alerts”, among others. ECRI’s free clinical information Web site called Medical Device Safety Reports (www.mdsr.ecri.org) contains ECRI published reports on medical device hazards, including information on electrosurgical fires and burns. The agency also offers membership as well as an accident and forensic investigation group. **Contact Mark Bruley or Al de Richmond at 1-610-825-6000 ext 5223 or 5187 respectively or email to accidents@ecri.org.**

- At the ECRI MDSR website enter the word “fires” on the “search terms” line to view their published reports on the causes and prevention of surgical fires.
- Of particular use is a poster titled “only you can prevent surgical fires”. The direct link to that poster is www.mdsr.ecri.org/asp/dynadoc.asp?id=195&nbr=413558.
- An ECRI poster on electrosurgery safety and injury prevention is available at: www.mdsr.ecri.org/asp/dynadoc.asp?id=207&nbr=413570.

On behalf of the New York Patient Occurrence Reporting and Tracking System, we would like to thank Mark E. Bruley, Vice President, Accident and Forensic Investigation, ECRI for sharing his expertise in the production of this newsletter and his kind offer of future participation in electrosurgical fire/burn initiatives.

Janet Mannion R.N.

References:

"A clinician's guide to surgical fires: how they occur, how to prevent them, how to put them out (guidance article)", *Health Devices*, 32 (1), 2003, p. 5-24.

"ESU burns from poor dispersive electrode site preparation (hazard update)", *Health Devices*, 22 (8-9), Aug-Sep 1993, p. 422-3. Web link: www.mdsr.ecri.org/asp/dynadoc.asp?id=80&nbr=409667

"Fires from oxygen use during head and neck surgery", *Health Devices*, 24(4), Apr 1995, p. 155-6. Web link: www.mdsr.ecri.org/asp/dynadoc.asp?id=95&nbr=409722

NYPORTS News & Alert

Department of Health, Issue #14

January 2004

Wrong Patient, Wrong Site Surgery Progress Report

On January 24th, 2002, New York State Health Commissioner Antonia Novello accepted the Institute of Medicine's challenge to reduce medical error by 50% by the year 2005, during a public forum on quality improvement in New York City. In support of this goal, Commissioner Novello endorsed the New York Pre-Operative Protocols Final Report issued in January 2001. The report is available at

<http://www.health.state.ny.us/nysdoh/commish/2001/preopletter.htm>

The purpose for these protocols is "to work towards a system for reducing medical and surgical errors by establishing a safe and protected patient care environment." Based on key recommendations in the report, hospitals and other health care facilities were expected to develop and implement procedures to ensure that at least 3 independent verifications of surgical site location and correct patient identification occur. The Panel noted the critical importance of communication among members of the surgical team and the patient, and strongly recommended delaying any procedure where discrepancies of information exist. Facilities were "strongly encouraged to build upon these guidelines and make them appropriate to the setting in which they are used."

Experts in the patient safety arena consider surgical errors involving the wrong patient or wrong site to be completely preventable. Subsequent to the release of the New York Pre-Operative Protocols, several national organizations have published protocols addressing this subject. For example, the Joint Commission on Accreditation of Health Care Organizations (JCAHO) has released their report, entitled "Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery", available at www.jcaho.com. Similarly, the VA National Center for Patient Safety (NCPS) has issued a pre-operative/pre-procedural checklist, which focuses on ensuring correct surgery outside of the operating room. This checklist may be accessed at http://www.va.gov/ncps/ncps/TIPS_Jul03.pdf in the June/July 2003 edition of *Topics in Patient Safety (TIPS)*.

In keeping with the increasing trend of surgical procedures performed outside of the OR, these protocols should be expanded to include all invasive procedures conducted in sites other than the OR. Root Cause Analysis (RCA) reports, both statewide and nationally, support this recommendation. Additionally, recent national reports recommend that facilities should institute a "time out" prior to commencing a procedure or surgery to allow for final verification of the correct patient, procedure, site and applicable implants.

Continued on page 3

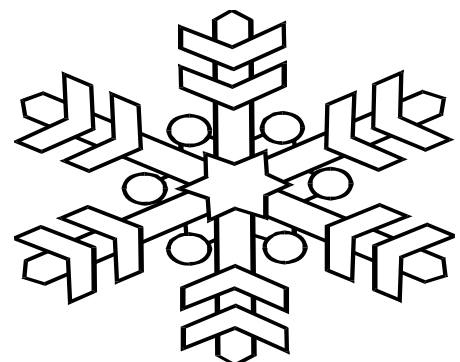
MRI Safety Alert

Issue #12 of the NYPORTS News & Alert (February 2003) focused on Magnetic Resonance Imaging (MRI) safety. In accordance with promoting patient safety during MRI, the Department would like to alert facilities to the following information:

NYPORTS recently received a report describing the occurrence of a burn to a patient's arm during a MRI scan. The patient was wearing a Nicotine patch, which was not visualized by the MRI staff. When the patient complained of pain during the scan, it was discontinued, the patient was removed from the scanner and the staff determined that the patient had received a small burn underneath the Nicotine patch. The hospital reported this event not only to DOH, but also to the FDA and the manufacturer of the MRI equipment. In addition, they contacted an independent contractor to review the circumstances of this event. The independent contractor subcontracted with ECRI, who completed the review of this case. ECRI previously provided DOH with recommendations on MRI safety for the News & Alert Issue 12.

Although the ECRI report

Continued on page 2



Lessons Learned from the August 14-15, 2003 Blackout

On August 14, 2003, many hospitals in New York State experienced a power outage ranging from just a few minutes to over 24 hours. The outage provided an opportunity to test hospital emergency preparedness plans and to refine and improve upon emergency response systems.

The reports submitted to the New York Patient Occurrence Tracking System (NYPORTS) provide a unique ability to determine how hospitals and patients were impacted by this major power failure. There were 86 reported occurrences on August 14th, and 40 additional occurrences were reported the following day. Codes 933 (termination of any services vital to the continued safe operation of the hospital, or the health and safety of its patients and personnel) and 932 (external disaster outside the control of the hospital that effects facility operations) were the two codes most frequently reported. There were no reports of unexpected death or serious patient related adverse events attributed to the power outage.

Submissions yielded important lessons that provide an opportunity to positively impact hospital vulnerabilities and to improve emergency communication.

According to reports received, lack of generator power was the most frequent issue identified, which occurred both at onset of the power outage, as well as throughout the blackout. Reportedly, five generators failed or malfunctioned almost immediately and eight failed or malfunctioned at various times throughout the duration of the outage.

Lessons learned include:

1. Know the surge capacity of the facility's generator(s).
2. Test generators during maximal power usage.
3. If a service is moved within the physical structure, ensure it is maintained on back up generator power, if vital to emergency hospital operations or patient care.
4. Have adequate back-up fuel available.
5. Make advance arrangements with local fuel distributors to ensure emergency delivery if needed, eliminating the need to utilize emergency municipal resources.

Continued on page 5

MRI Alert continued

indicates the need for additional information to definitively determine the cause of the burn, the most likely cause is that the Nicotine patch contained a conductive material, most likely aluminum. If the patch contained conductive material, was located in the bore of the magnet and was in contact with the patient, the MRI could create localized heating, which could have led to the burn experienced by the patient. The Nicotine patch involved in this incident may contain a conductive material; however, the supplier has not yet verified this information.

ECRI indicates that there are no other reports of burns caused by Nicotine patches in their database. However, Nicotine patches are specifically listed on a screening form among other conductive or potentially conductive materials that should not be introduced into the magnetic field. This screening form can be located at http://www.mrisafety.com/screening_form/prescrnf.pdf.

New DOH NYPORTS Staff

We would like to extend a warm welcome to three regional office members, recently assigned to NYPORTS. Judy Foster Stuart (jaf23@health.state.ny.us) is the new Regional NYPORTS Coordinator for the New York City Regional Office. Yvonne Tullock Hunter (jmg01@health.state.ny.us) is working with Rhonda Askinazi in the New Rochelle Regional Office, while Sharon Austin (sma05@health.state.ny.us), together with Sandra Rotunno, is handling NYPORTS responsibilities in the Central New York Regional Office. Please welcome our newest staff!

NYPORTS Statewide Council Meeting

The next Statewide Council meeting will be held January 23, 2004 at the School of Public Health in Rennselaer, New York.

911/912 Update continued

NYPORTS data

Close scrutiny of NYPORTS codes 911 (wrong patient or site surgical) and 912 (wrong treatment or procedure invasive) for 2002 indicates that focusing on the elimination of these errors has yielded positive results. As shown in Figure 1, the number of code 911 occurrences was markedly decreased for 2002. In addition, the number of coding issues between 911 and 912 has continued to decrease, although still exists. Figure 2 demonstrates the regional variation noted in Code 911 and 912 reporting.

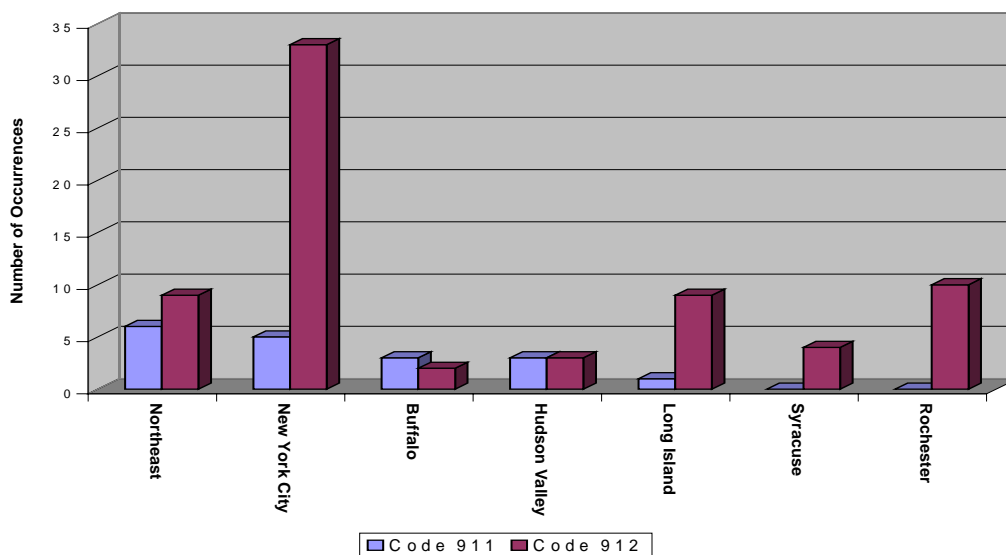
Figure 1

911 NYPORTS Occurrences 1998-2002

Year	Number of Occurrences
1998	16
1999	27
2000	23
2001	35
2002	18

Figure 2

Regional Distribution of Code 911 and 912 Occurrences in 2002



The definition of code 911 is a surgical procedure performed on the wrong patient or site **in the operating room or surgical suite only**. The definition of code 912 is wrong treatment or procedure, invasive, taking place **in the OR or outside of the surgical suite**. Examples of Code 912 events taking place in the OR would be placement of incorrect implants, orthopedic components, etc. The following are examples of events coded as 911 in NYPORTS, but should have been coded 912:

- Wrong infant circumcised in the nursery
- Child admitted to ED for cast to upper extremity, wrong extremity casted
- Wrong patient taken to GYN clinic for unscheduled procedure in lieu of scheduled procedure in endoscopy unit
- Two patients had pleural tap on the wrong side, one in the ED and one in the patient's room

To further clarify code 911 and 912, incision of the skin is used as a determining factor in coding for surgical procedures. For example, in a case where anesthesia has been administered, a wrong patient or site is identified, and the case is either rescheduled or continued at the correct site, the event would be coded as a 912. If the skin was incised, and then the error identified, this would qualify as a 911.

Analysis of 911

Eighteen cases were identified as Code 911's in NYPORTS for 2002. Three were wrong patient cases, 10 involved surgery to the wrong side of the body, and 5 cases involved surgery to the wrong site. The following are examples of Code 911 cases from the year 2002.

Wrong Patient

- A patient's lab was erroneously misplaced with another patient's resulting in additional excision of a benign mass. There was a guideline but not an official policy in writing for specimen verification.
- An individual consented to the wrong treatment. Staff bypassed the Pre-op checklist and the patient ended up with a radioactive implant.
- A patient was mistakenly taken back for additional laser surgery intended for another individual. The policy for verification of patient identification immediately before surgery was not followed.

Wrong Site

- Two patients had procedures in which the site was not marked (hernia repair and facial surgery)
- One patient had an anomaly of their coronary arteries and the wrong vessel was bypassed. Recommendations include tracking the coronary artery to its termination to confirm its identity in cases of anomaly.
- The wrong portion of the colon was resected, prompting a return to the OR for the patient.

Wrong Side

- Subclavian Mediport inserted on the wrong side. Surgeon did not mark the site, or verify laterality during "time out" immediately before surgery.
- Fluoroscopic lung biopsy on the wrong side in the OR. Policy did not include laterality for bronchoscopy, or cystoscopy. Additionally, X-rays not available for the procedure.
- Two arthroscopies.
 - Surgery team relied on correct marking, by-passing other checks and balances. The verification of correct site/side should emphasize following all established procedures.
 - All sites in multiple site procedures should be included on the consent.
- Two cases involved inadvertent incision to the wrong side. Policy and procedures did not require a "time out" immediately prior to incision.
- Wrong side laminectomy took place without proper surgical site marking. Recommendations taken from this case include writing out words right or left on the consent form and using an intra-operative x-ray to identify the exact vertebral level (although the use of x-ray markers that do not move is essential).
- Wrong side stent removal with no site verification. Patient had bilateral kidney stents and required removal of right-sided stent due to pain. Surgeon removed Left stent.

Figure 3
912 Occurrence Locations 2002

Location	Number of Occurrences
OR	18
Patient Room	15
Radiology	13
Dialysis	7
Clinic	5
Emergency Department	4
Endoscopy	3
Delivery Room	1
SICU	1
Hallway	1
Catheterization Lab	1
Nursery	1

Analysis of 912

Seventy Code 912 reports were submitted to NYPORTS in 2002. Figure 3 shows the distribution of cases by location of the occurrence. The larger number of 912 cases (70) compared with the number of 911 cases (18) illustrates the need to expand Pre-Operative Protocols to other settings. While the definition of code 912 largely excludes occurrences in the OR, cases that involve placement of incorrect orthopedic components or other implants that take place in the OR would be included in 912.



Blackout continued from page 2

Contributing causes cited for generator failure at onset included overheating, damage to the switch or insulation, and failure of the charger. Generator failures identified throughout the duration of the outage were attributed to overheating and the negative effects of power surges. The power outage demonstrated that even when generators work, some essential areas of the hospital might not be supplied with emergency power. In fact, many hospitals reported lack of power to critical patient areas, elevators, x-ray and telephone/internet services. In addition, both internal hospital beeper and paging systems, as well as, telephone/cell phone services were reportedly interrupted.

Shortly following the outage, Commissioner Novello outlined recommendations relevant to emergency power in a memo to hospital facilities. The memo recommended that each hospital evaluate its own emergency power system. The recommendations include:

- All hospitals are required to have two independent sources of power.
- Each facility must critically evaluate how their outpatient clinics, especially dialysis centers, are affected by power loss. Many hospitals provide dialysis services in outpatient clinics that are not required to have auxiliary power. Additionally, hospitals may close their outpatient clinic in accordance with their own disaster plan.
- Emergency generators must be tested under maximal power usage at least monthly.
- All emergency systems should be reviewed for capacity.
- Hospitals must have a clear understanding of which services and areas will be maintained by emergency power and which services and areas will not have service.
- Hospitals must ensure uninterrupted internal and external communication including uninterrupted operation of the Hospital Emergency Response Data System (HERDS).

The power outage brought issues relating to the management of patients requiring mechanical ventilation to the forefront. The issues include:

1. Hospital personnel manually ventilated respirator dependant patients at various points of the outage.
2. The location of ventilator dependent units within the hospital became an issue when hospital personnel had to carry a ventilator dependent patient and their equipment down six flights of stairs to access emergency power.
3. Community health providers, such as nursing homes, should establish plans with hospitals to arrange for the transfer of ventilator dependent patients during future power outages. If possible, nursing homes should make arrangements with more than one facility to receive ventilator dependent patients to prevent the overload of any one facility during an emergency. In addition, the nursing home should ensure that a patient's equipment, care plan, medications, other relevant information, and nursing personnel, when appropriate, are sent to the hospital when the patient is transferred.
4. Communities should work with hospital affiliates to set up shelters for those not requiring medical care in an emergent event.

As stated in the Commissioner's August 21, 2003 letter, the lessons learned from the blackout gives New York hospitals the opportunity to "be better prepared to respond to future emergencies."

Janet Mannion and Ruth Leslie



Entering "Old" Cases into NYPORTS

In conjunction with Utilization Review activities, IPRO is identifying NYPORTS reportable events through retrospective medical record review, often with a substantial lag between the review date and the occurrence date. Cases can either be previously "closed" cases in the system or newly identified cases. Although the Department recognizes the difficulty and limitations of performing a RCA on these "old" events, the facility must conduct an investigation and submit a thorough and credible RCA into NYPORTS if required.

Since it is impossible for a facility or anyone else to enter data into a RCA for a closed case, a new process has been instituted. It is now possible for Area Office or Central Office staff to "unclose" a case. Once the case is unclosed, the report will revert to a previous status (reported, reported with RCA, SOD issued, etc.). This will allow the facility to make changes to an existing report or to create a new RCA. Facilities need to work in coordination with Area Office staff to ensure that they are aware of the changes/entries being made. These reports can then be manually re-closed on the system.

The time frame for auto-closure has been extended from 90 to 180 days to allow a longer period for facilities to edit reports and to permit review by Area Office staff. Until system changes can be made, when these "old" cases are entered into the system, the facility should indicate the reason the report is late in the Short Form summary. For example, if the case was identified by IPRO, this should be noted in the Short Form summary.

