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Office of Health Systems Management
Division of Primary and Acute Care Services

New York
Patient Occurrence Reporting and Tracking System
Report

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Commissioner of Health

Hon. George E. Pataki
Governor – State of New York

2002-2004

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NYPORTS Report 2002/2003/2004

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-l 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

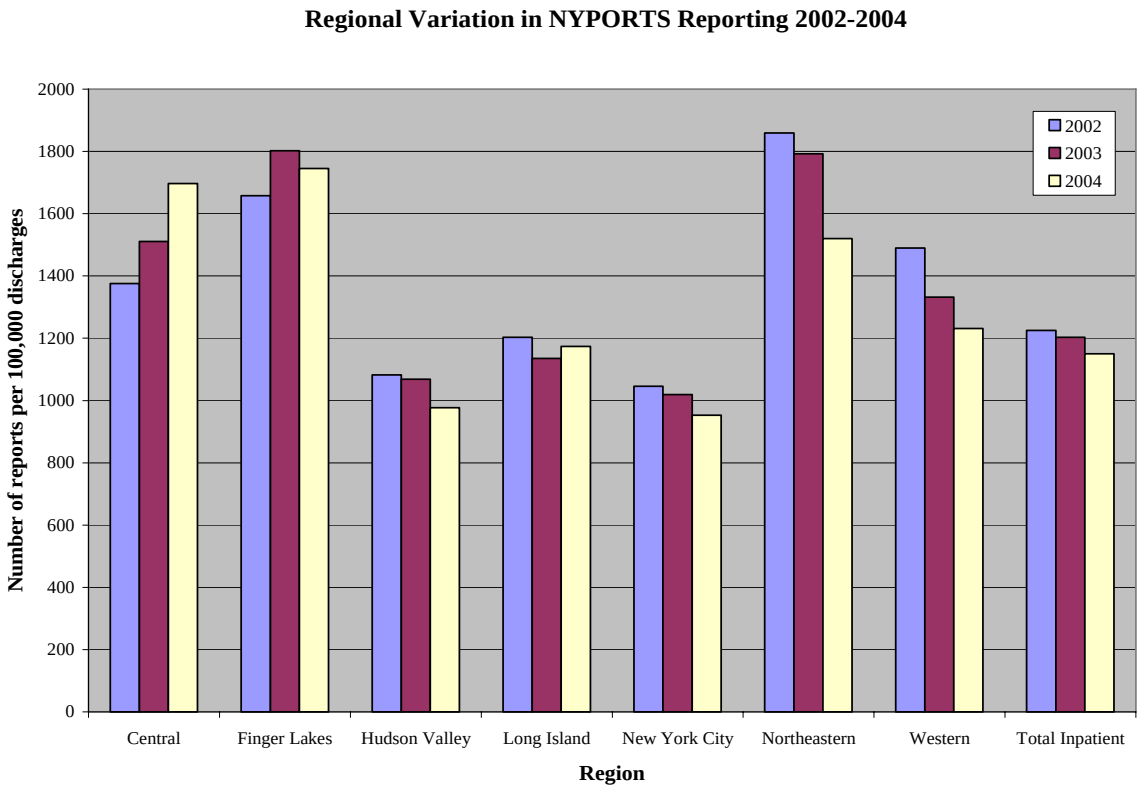
	2002			2003			2004		
Region	NYPORTS	SPARCS	Rate per 100,000	NYPORTS	SPARCS	Rate per 100,000	NYPORTS	SPARCS	Rate per 100,000
Central	2660	193421	1375.2	3012	199363	1510.8	3435	202446	1696.7
Finger Lakes	2464	148605	1658.1	2694	149472	1802.3	2678	153462	1745.1
Hudson Valley	2717	251083	1082.1	2865	268244	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 year2004 (submitted as of December 31, 2005) by region and for the entire state.



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.

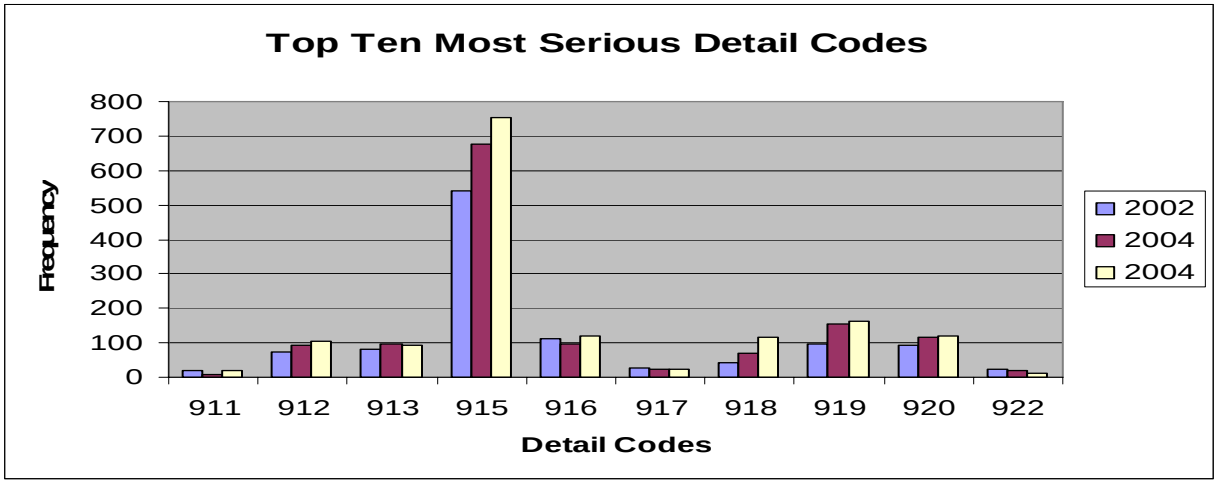
It is likely that accuracy and completeness of reporting is the reason for most of the differences in the table above. Since over-reporting is unlikely, under-reporting in regions with the lowest reporting rates is likely the cause of variation. Although the size of the regions are believed large enough 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%.

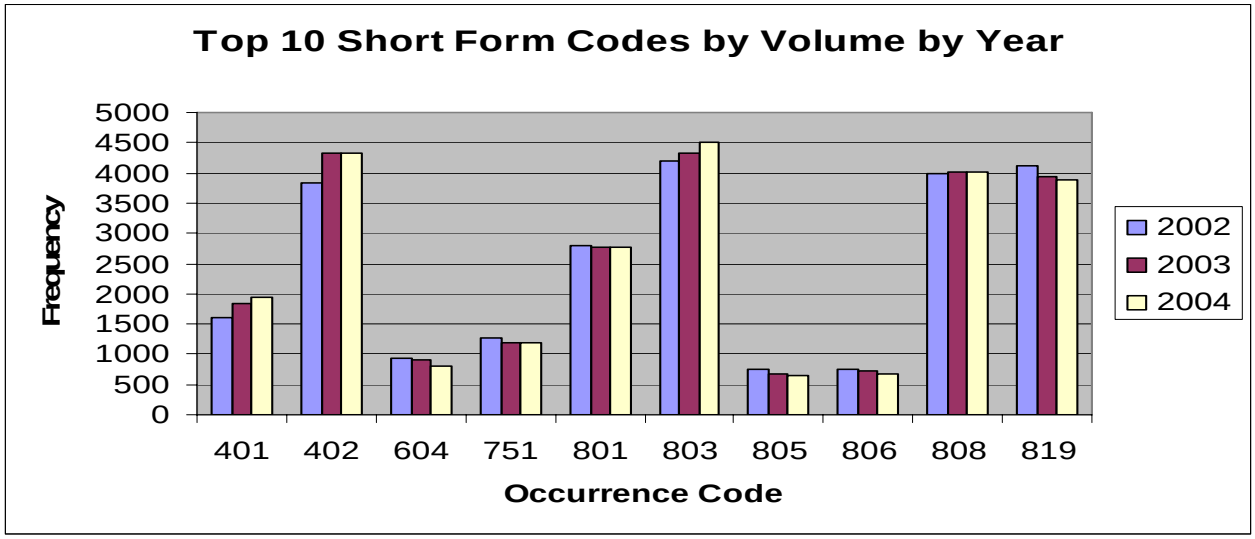
The following bar charts present changes in reporting between 2002 and 2004 for individual NYPORTS codes. The codes have been divided into two groups based on volume. The first group is the top ten most serious codes.



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 epiduralhematoma, 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

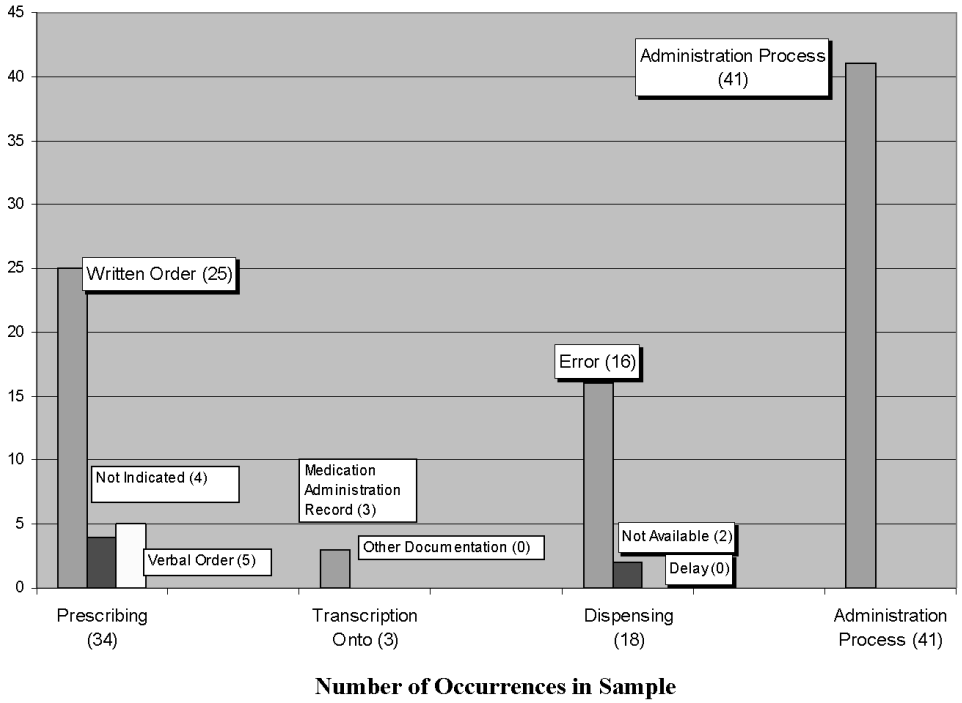
As part of NYPORTS reporting, hospitals are required to enter the ICD-9-CM procedure code most closely associated with the adverse event, if a procedure was associated with the event. In support of its primary focus, improvement of patient care and safety, NYPORTS continues to accumulate and analyze 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).

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 meets 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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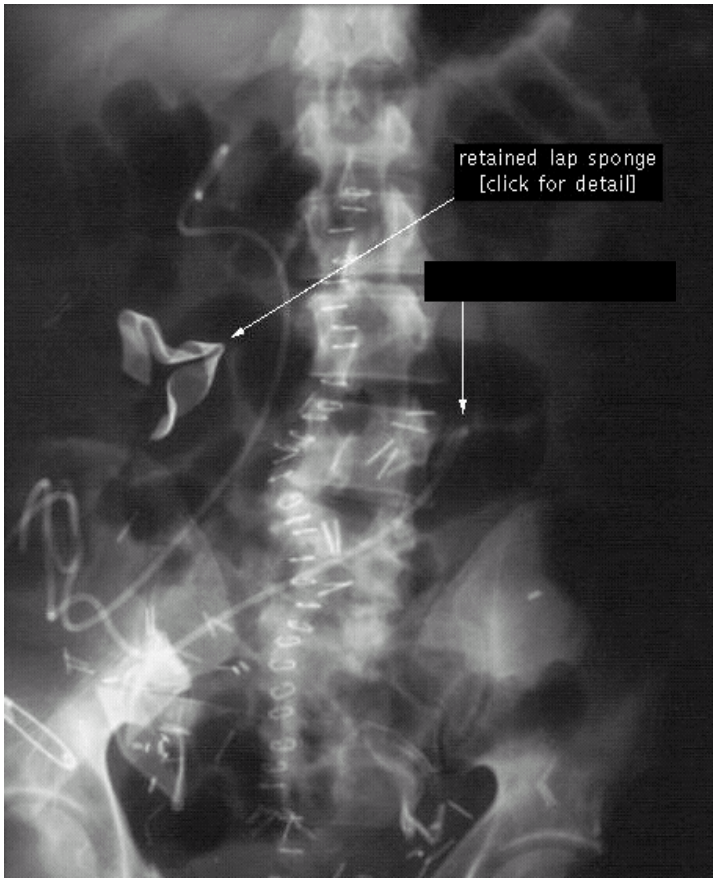
APPENDIX F
NYPORTS NEWS AND ALERTS
#11-14

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 t 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 MacDougall, 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 Inciptius 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:

- Á Using two individuals to perform the surgical count, instead of one.
- Á Consulting the attending radiologist to determine which radiographic pictures would be most beneficial in locating a retained sponge or lap pad.
- Á 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.
- Á 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.

Continued on page 2

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 June1, 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 Pharmocological-related analysis. Preliminary analysis of the other categories is expected to be shared at the next NYPORTS Statewide Council meeting in May.

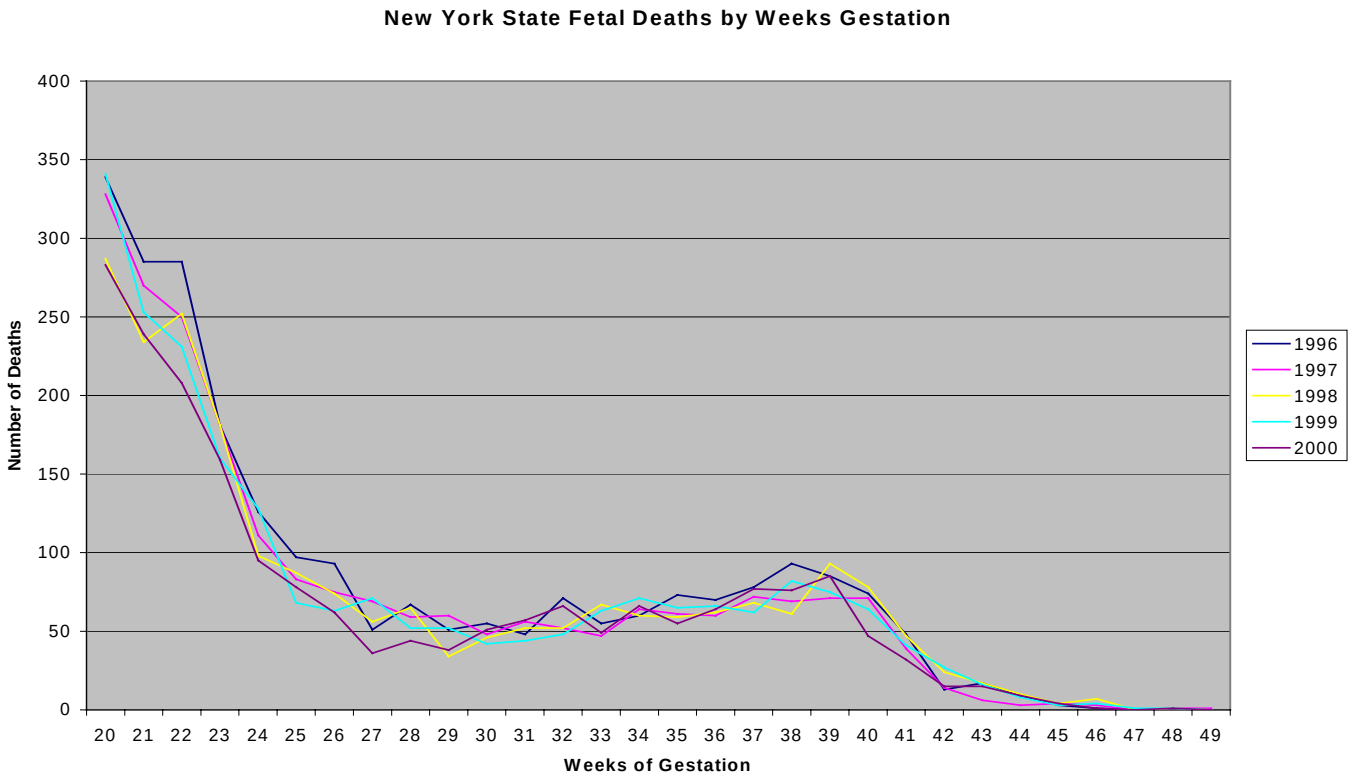
The following is an excerpt from the analysis of Pharmacological-related events, specifically of events involving anticoagulants.

- 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.



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 2001are 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 Refludan (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 Cattauraugus.

ROCHESTER (Western Region): MICHAEL ULINSKI AND LYNNE DEY- (585) 423-8082

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NYPORTS News & Alert

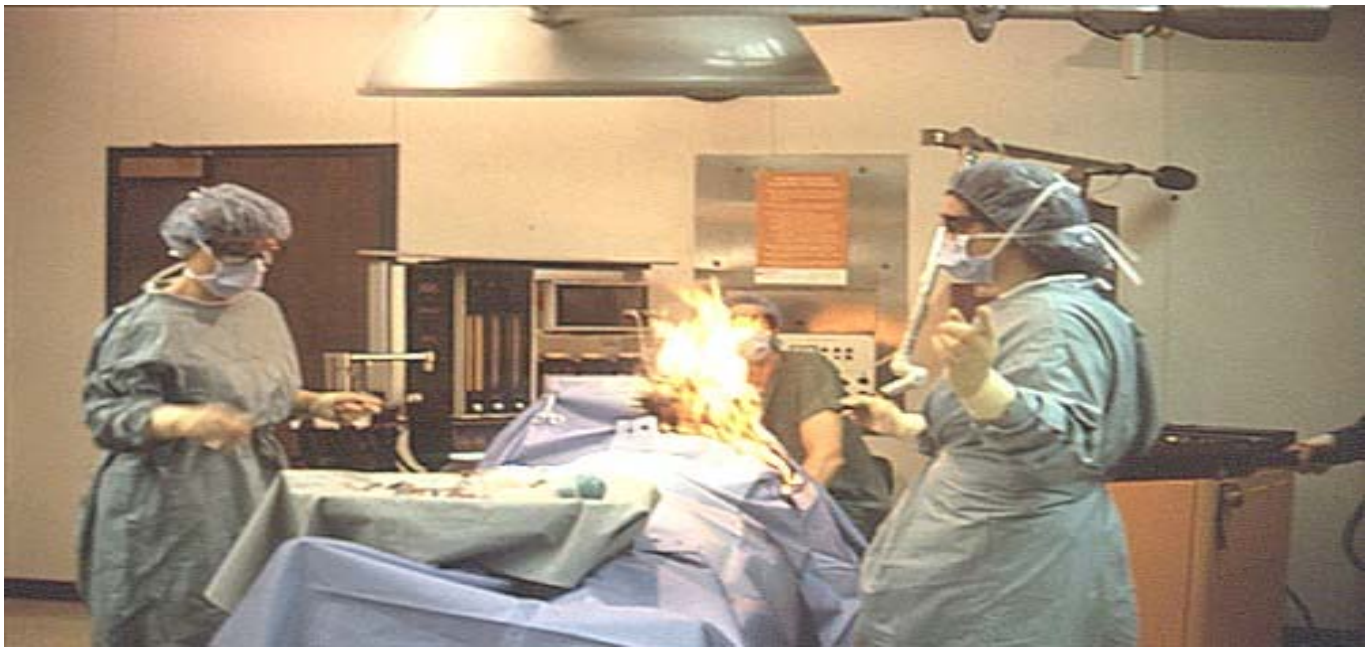
Department of Health, Issue 13 June 2003

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.

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

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 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

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.

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.

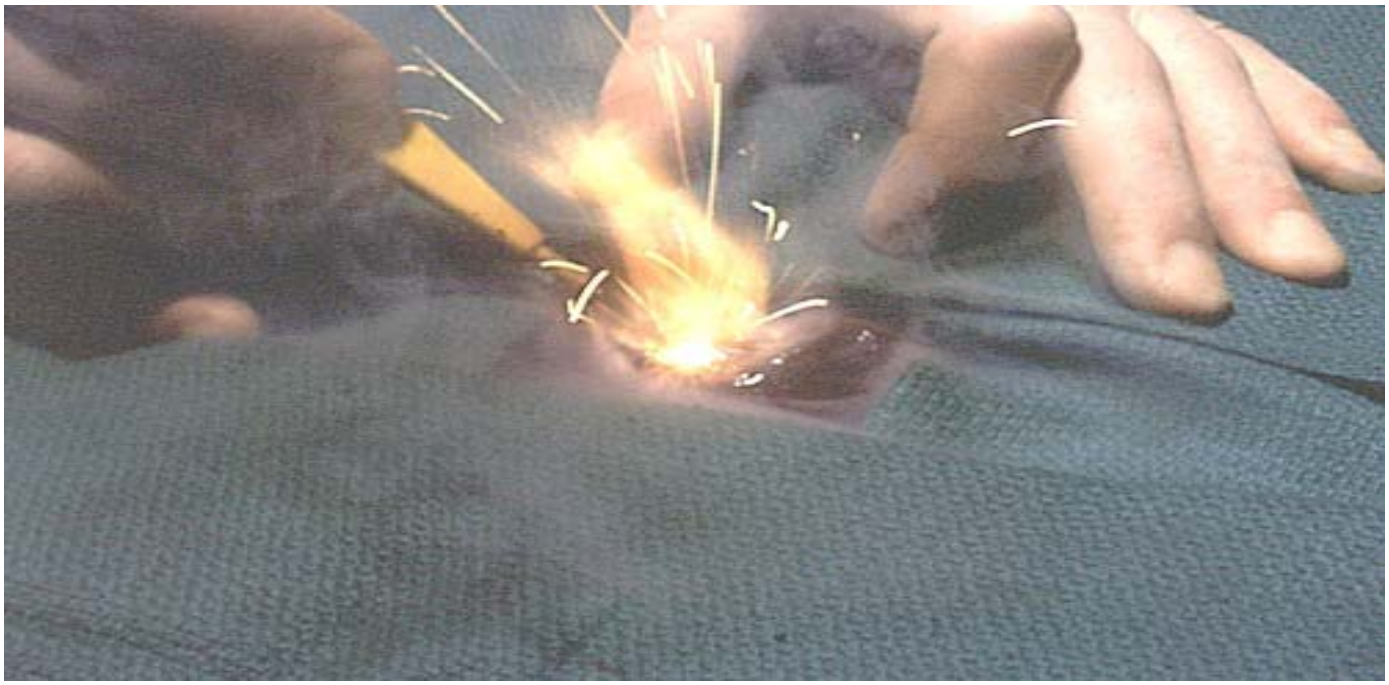
Recommended actions include:

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 opthalmic 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 701and 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.

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"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

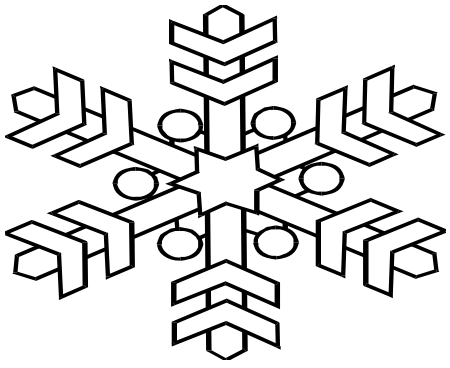
MRI Safety Alert

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.

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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 Rennsselaer, New York.

911/912 Update continued

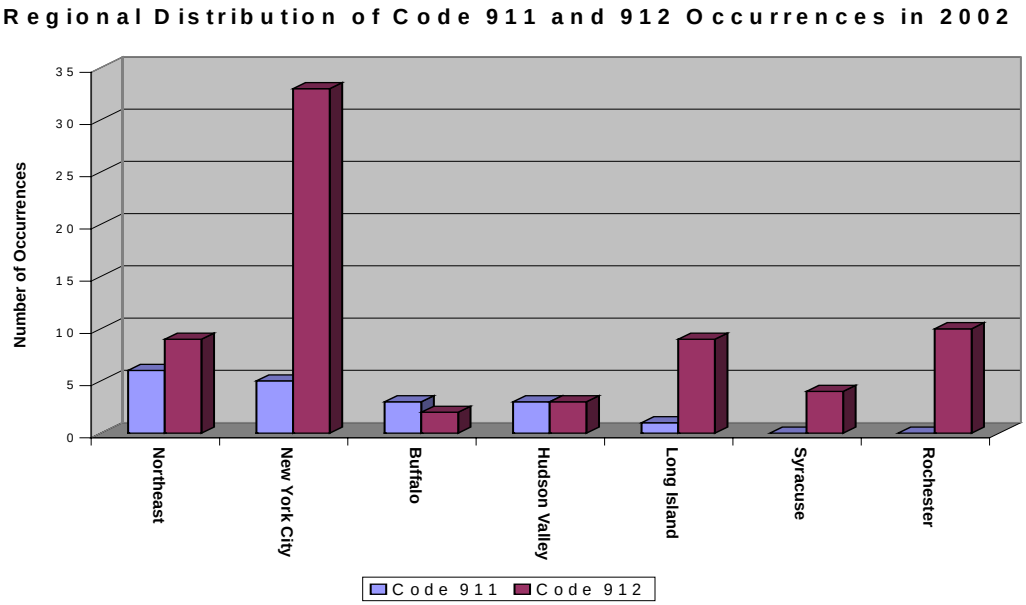
NYPORTS data

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



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.

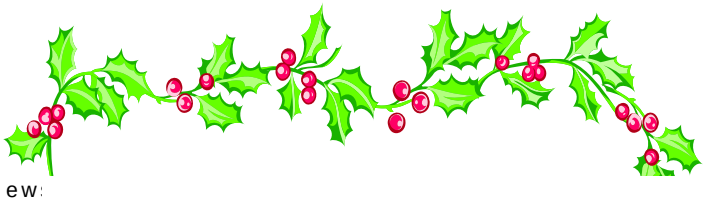
Figure 3

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.