NYPORTS

The New York Patient Occurrence Reporting and Tracking System

Annual Report 2000/2001

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Table of Contents
NYPORTS Annual Report 2000/2001

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, "Together we will continue to strengthen New York's health care system by enhancing safeguards and protocols to ensure patient safety."

In keeping with the goal of providing quality, safe healthcare, the Department of Health developed the New York Patient Occurrence Reporting and Tracking System (NYPORTS). For the purpose of NYPORTS reporting, an occurrence is an unintended adverse and undesirable development in an individual patient's condition. Since the issuance of the Institute of Medicine's (IOM) Report, To Err is Human, in late 1999, national attention has been focused on medical errors. 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. The data that is collected in NYPORTS is a tool that facilities may use to assist in internal quality initiatives and medical error prevention.

In this second report on NYPORTS, the Department will provide a compilation of information from the years 2000 and 2001. The report will present information detailing system upgrades, reporting compliance, data analysis of adverse events, future plans, and Department initiatives associated with NYPORTS.

To achieve the goal of improving patient safety, the Department believes that there must be an awareness and recognition of adverse events by facilities. In support of increasing reporting compliance, Commissioner Novello notified hospitals in February 2000 that, while the Department is ready to assist hospitals in meeting statutory reporting requirements, it also "stands ready to enforce requirements, and will publicly sanction those facilities that fail to promptly and accurately report incidents." The Commissioner also directed hospitals in a February 2001 letter to conduct internal reviews to identify any unreported events occurring in 1999 and 2000 and to report them to the Department within 60 days. In response, a significant increase in reporting was noted. Reporting has remained at that elevated level.

Although reporting has risen to a higher level in 2000 and 2001 in response to Commissioner Novello's directive, there are still improvements to be made. Complete reporting is crucial to utilizing NYPORTS data as a tool for quality improvement and adverse event reduction efforts. Although reporting in 2000 and 2001 shows improvement, it is clear that there are still a large number of cases that remain unreported. The monitoring of incident reporting will continue to be a high priority for the Department of Health. It is the intention of the Department to assist facilities in not only meeting their mandatory reporting requirements, but also to exceed the current level of reporting in future years.

Under the direction of Governor George E. Pataki and Department of Health Commissioner Antonia Novello, M.D., M.P.H., Dr. P.H., a panel was convened in May of 2000 to address

serious patient care concerns raised as part of Department of Health surveillance activities. In keeping with the commitment of reducing medical and surgical errors, the panel endeavored to develop a guideline for hospitals and other providers, to ensure quality operative care. Panel members sought to identify definitive practices for ensuring safe patient care outcomes and avoiding surgical errors. The result was the development of the "Pre-Operative Protocols", a list of recommendations designed to reduce the occurrence of wrong side or wrong patient surgeries. These protocols were issued in February of 2001 to all hospitals, and are considered applicable across a variety of health care settings, such as ambulatory surgery and interventional radiology. Facilities are expected to implement these protocols as a baseline, and to expand upon them to make them appropriate for their settings. There is also evidence to suggest the benefit of expanding pre-operative protocols to address specific areas of the system, such as communication. The Department of Health is confident that the use of these protocols will result in a reduction of these types of clearly preventable surgical errors.

As stated above, reporting improved during the year 2000 and 2001. The following is a list of significant improvements:

- **The number of reports submitted to NYPORTS increased from 16,939 cases in 1999, to 24,368 in 2000, and to 28,689 in 2001.**

- **Reporting has increased from 716 reports per 100,000 discharges in 1999, to 1,004 reports per 100,000 discharges in 2000, to 1,159 reports per 100,000 discharges in 2001.**

- **NYPORTS reporting per 100,000 discharges has risen 61.9% from 1999 to 2001.**

- **With the exception of one region, all geographical regions in New York State noted increases in reporting in 2000 and 2001, as compared with 1999. From 1999 to 2001, improvements ranged from an 18.4% increase in the Central New York region to a 109.2% increase in the New York City Region. In 2000 and 2001, the Northeast region had the highest reporting rates, while the New York City Region had the lowest reporting rates. In 2001, Central New York had a 3.4% decrease in reporting as compared with 2000.**

- **For the code 605 (Death occurring after procedure) events, the reporting percentage increased from 16.2% in 1999 to 80% in 2000, and remained at a high level, 73%, in 2001.**

- **Data provided in this report demonstrates that regional variations with reporting, though still evident, are diminishing.**

Introduction and Background

The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is an 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 occurrence is an unintended adverse and undesirable development in an individual patient's condition, such as a patient death or impairments of bodily functions in circumstances other than those related to the natural course of illness, disease or proper treatment, in accordance with generally accepted medical standards. Most occurrences reported are tracked and trended as groups and are reported on a short form. More serious occurrences are investigated individually by the hospital and require the hospital 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.

In this second report on the NYPORTS system, the Department will provide information regarding the upgrading of NYPORTS, as well as, analysis of data collected regarding adverse events that occurred during the years 2000 and 2001. We will also provide information regarding activities undertaken to assure complete reporting by hospitals into this mandatory system and present a description of future plans. Future plans include ongoing improvement of the system, ongoing training and support, and continuing in-depth data analysis by occurrence code, to improve the quality of care and safety of patients in hospitals in New York State. Sanctions will continue to be imposed on those hospitals that repeatedly fail to report as required.

New York State has had a long history of implementing efforts to improve patient safety by mandating hospitals to report and initiate improvement 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 and a consumer representative. The workgroup included a practicing surgeon, a practicing anesthesiologist, a consumer representative, facility medical directors, internal medicine practitioners, and professionals from nursing, quality assurance, and risk management. The workgroup was chaired by the chief quality officer at a major academic medical center. That group continues to meet and oversee the ongoing implementation and continued improvement of NYPORTS. The Department participated with the group and

provided the necessary support to carry out development and implementation activities. The statewide hospital association and its regional affiliates also participated in development and implementation in support of the group's activities. The resulting system is based on objective criteria and information and provides hospitals with clear definitions of what must be reported. It 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 construct. 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.

Significant systems 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 and a revised and improved instructional manual. Additional system improvements were implemented in 2001, including the installation of a new server, a "bulletin board" to post information and documents, a home screen that will display changes in case status, the ability to create RCAs for all 900 code occurrences, and unlimited time to enter data.

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 internal investigations into the system of care. These investigations, known as Root Cause Analyses, must identify root causes for such events, enact systems improvements and build in back-up, "fail-safe" procedures to prevent reoccurrence. Hospitals are then required to monitor the implementation and effectiveness of these system improvements through quality assurance activities to assure that they function as intended. For events of lesser patient consequence, hospitals 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 over time 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.

Based on published reports, 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. NASHP states, "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."[1] By fulfilling and exceeding these criteria set forth by NASHP, NYPORTS has distinguished itself as a model state reporting system.

[1] Lynda Flowers and Trish Riley, "State-based Mandatory Reporting of Medical Errors: An Analysis of the Legal and Policy Issues," March 2001, page 5.

Completeness of Reporting in NYPORTS

As noted in the 1999 NYPORTS Annual Report, completeness of reporting is an important concern when using NYPORTS for quality improvement and adverse event reduction purposes. If data are 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 and regions cannot be accurately computed. Incomplete reporting exacerbates the task of determining which occurrence codes should be scrutinized and makes it difficult to compare adverse event rates among regions and among hospitals.

In addition, it was noted that it is very difficult to assess the completeness of reporting in NYPORTS because, for nearly all of the adverse event codes, a "gold standard" database that includes cases that should be reported, does not exist.

Matching NYPORTS 605 Occurrences with SPARCS Data

The 1999 NYPORTS Annual Report examined the completeness of reporting for one NYPORTS code (code 605) that matches well to data contained in the Statewide Planning and Research Cooperative System (SPARCS). SPARCS is a database containing information on all inpatient stays in New York State acute care hospitals. This database contains up to 15 procedure codes for any inpatient stay, as well as the dates of these procedures and the date of discharge (which is the date of death for inpatients that died in the hospital). The completeness of reporting for code 605 was again examined as part of this report.

It should be noted that the definition of code 605 was modified as of June 1, 2000. There are two components to this change. One occurred in order to define the time frame of the event occurrence. Formerly, a report to NYPORTS for a death within 48 hours of a procedure was required. Since SPARCS collects data by date, the 48-hour time frame could not be precisely determined. The new time frame for code 605 was redefined as “occurring the same day as, or the first or second day after” the date of the procedure. If the adverse event occurs on the day of the procedure or during the next two calendar days, it is reportable in NYPORTS.

The other change relates to the kind of procedure performed. Initially, a 605 report was required for a death that occurred within 48 hours of any procedure performed in an operating room. Procedures done at the bedside, in specialty suites, in radiology or in other such sites were excluded. This resulted in inconsistent reporting since some hospitals do most, if not all, procedures in the operating room, while others have specialty areas where some surgical procedures can be performed. In the 1999 NYPORTS Annual Report, a common set of procedures that are customarily performed in an operating room were identified and chosen as “valid operating room procedures”. These "valid operating room procedures" are consistent with those recognized by volume 3 of *The International Classification of Diseases, 9th Edition, Clinical Modification* (ICD-9-CM), a nationally accepted standardized classification system, which is used to classify procedures in SPARCS. Reporting is now required for ten specific

categories of procedures (appendectomy, non-cardiac anteriography, cholecystectomy, endarterectomy, resection of large intestine, hysterectomy, colonoscopy, prostatectomy, replacement of joint of lower extremity and spinal fusion) regardless of the location where the procedure was performed.

During the analysis of NYPORTS occurrence code 605 during 2000 and 2001, it was found that non-cardiac anteriography and colonoscopy were commonly performed on an outpatient basis, and therefore, were not captured within the SPARCS system. Consequently, the assessment of reporting completeness for the NYPORTS code 605 in year 2000 and 2001 was confined to the other eight procedures (appendectomy, cholecystectomy, endarterectomy, resection of the large intestine, hysterectomy, prostatectomy, replacement of joint of lower extremity and spinal fusion).

Process for Measuring Reporting of 605 Occurrences

1. Use SPARCS data submitted as of December 31st of the following year to identify all patients undergoing any of the following procedures, as either a principal procedure or a secondary procedure: appendectomy, cholecystectomy, endarterectomy, resection of the large intestine, hysterectomy, prostatectomy, replacement of joint of lower extremity and spinal fusion.

2. Use SPARCS to determine which patients, undergoing any of the above 8 procedures, died on the day of the procedure or on either of the 2 days following the day of the procedure.

3. Match all of the patients identified in SPARCS, with the 8 corresponding procedure codes, with patients who were reported for the year 2000 or 2001 in NYPORTS.

4. 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 identified cases for the 8 procedures in SPARCS.

Results of Process

Using the methods described above, 161 SPARCS cases were identified as potentially reportable under NYPORTS occurrence code 605, from June 1, 2000 to December 31, 2000. Of these patients, a total of 128 cases (80%) were reported by hospitals to NYPORTS as of December 31, 2001.

For 2001, there were 363 SPARCS cases identified as potentially reportable under NYPORTS occurrence code 605 for the entire year. Of these patients, a total of 265 cases (73%) were reported by hospitals to NYPORTS as of December 31, 2002.

In 1999, a total of 1,030 cases were judged to be reportable 605 occurrences based on SPARCS (using the 1999 definition of a 605 occurrence). Of these patients, a total of 167 (16.2%) were

reported by hospitals to NYPORTS as of September 9, 2000. Thus, between 1999 and the second half of 2000, the completeness of reporting of code 605 increased from 16.2% to 80%.

When SPARCS was used to identify the 1999 occurrences of code 605 using the definition introduced in June 2000 (limited to the eight procedures mentioned above), there were a total of 320 cases identified in SPARCS. A total of 65 of these cases (20.3%) were reported in the 1999 NYPORTS database as of September 15, 2000. Thus, when the same definition of 605 cases was used in both years, the reporting percentage rose from 20.3% to 79%. When 605 data for 2001 was examined, there continued to be a high level of reporting from hospitals with 73% of the records identified in SPARCS being reported.

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. As an example of these efforts, the Department contacted facilities that were identified as missing SPARCS validated 605 records in 2000. These facilities were provided information to locate and report these occurrences. A total of 49 occurrences among 38 facilities were identified by SPARCS validation. In the process of locating and re-evaluating these occurrences, the facilities were able to assess and make improvements to their own internal identification processes. 92% of these cases were reported into NYPORTS, while the remaining 8% of cases were determined not to match code 605 reporting criteria. A similar effort is being undertaken for 2001 SPARCS validated 605 records. Facilities that exhibit repeated non-compliance with reporting will be closely monitored and fines will be assessed in instances of repetitive non-compliance. Through this, and similar efforts, the Department is confident that reporting rates will continue to increase.

Examination of Regional Variation in Reporting NYPORTS Data

Another 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 result 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. 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: 1999, 2000 and 2001

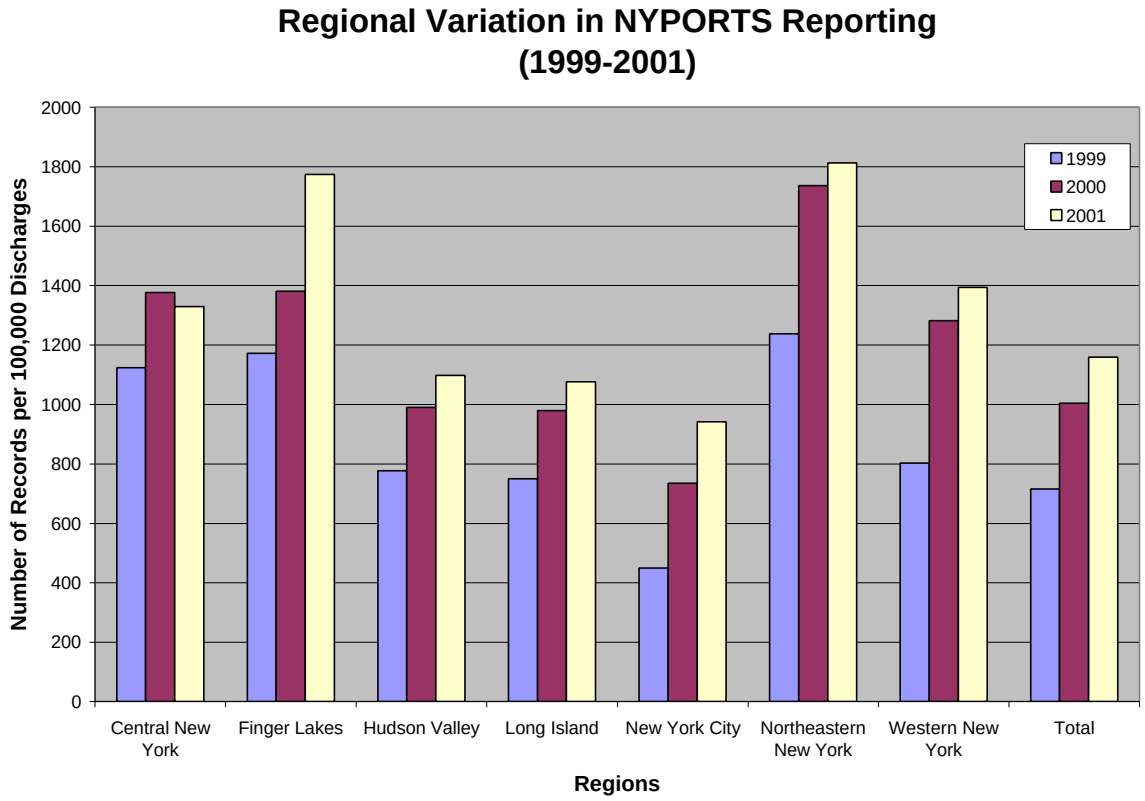
Region	NYPORTS Cases			Acute Care Discharges			NYPORTS Cases per 100,000 Discharges		
	Year 1999	Year 2000	Year 2001	Year 1999	Year 2000	Year 2001	Year 1999	Year 2000	Year 2001
Central New York	2,235	2,760	2,695	198,910	200,449	202,668	1,124	1,377	1,330
Finger Lakes	1,616	1,967	2,514	137,811	142,431	141,700	1,173	1,381	1,774
Hudson Valley	1,877	2,474	2,834	241,609	249,829	258,156	777	990	1,098
Long Island	2,632	3,576	3,945	350,753	365,165	366,706	750	979	1,076
New York City	4,849	8,267	10,814	1,077,136	1,124,189	1,148,175	450	735	942
Northeastern New York	2,051	2,701	3,042	165,706	155,525	167,780	1,238	1,737	1,813
Western New York	1,547	2,434	2,654	192,688	189,804	190,295	803	1,282	1,395
Outpatient Facilities	132	189	191	744	-----	-----	-----	-----	-----
Total	16,939	24,368	28,689	2,365,357	2,427,392	2,475,480	716	1,004	1,159

For the year 1999, there were 16,939 NYPORTS cases reported for all of the various occurrence codes and 2,365,357 SPARCS cases submitted by December 31, 2000. The number of NYPORTS cases submitted per 100,000 discharges for 1999 in New York State was 716. This differs from the rate reported in the 1999 NYPORTS Annual Report (625 NYPORTS reports per 100,000 discharges) due to the use of updated data. The 1999 Annual Report used cases that were submitted by the hospitals as of September 15, 2000, while this report uses year 1999 data that was submitted by the hospitals as of December 31, 2000.

As indicated in the table above, a total of 24,368 NYPORTS cases for 2000 were submitted by December 31, 2001 for all of the various occurrence codes in NYPORTS, and a total of 2,427,392 patients were discharged from New York State acute care hospitals in 2000, based on data submitted by December 31, 2001. The number of NYPORTS cases submitted per 100,000 discharges for 2000 in New York State was 1,004.

Also indicated in the table above, a total of 28,689 NYPORTS cases for 2001 were submitted by December 31, 2002 for all of the various occurrence codes in NYPORTS, and a total of 2,475,480 patients were discharged from New York State acute care hospitals in 2001, based on data submitted by December 31, 2002. The number of NYPORTS cases submitted per 100,000 discharges for 2001 in New York State was 1,159.

The following bar chart compares the reporting for year 1999 (reported as of December 31, 2000), year 2000 (reported as of December 31, 2001) and year 2001 (reported as of December 31, 2002) by region, and for the entire state.



Increased Reporting Statewide

The statewide number of NYPORTS cases reported per 100,000 discharges in 1999 was 716. Consequently, the NYPORTS reporting rate per 100,000 discharges has risen by 61.9% between 1999 and 2001. It should be noted that definitions for several of the NYPORTS codes changed between 1999 and 2001. On inspection of the definitional changes, the codes subject to reporting changes based on definitional modifications are Code 401 (new acute pulmonary embolism), Code 402 (new documented deep vein thrombosis), both of which included for the first time re-admissions as of June 1, 2000, and the aforementioned Code 605. In addition, codes 911 and 912 changed in order to be more in line with Joint Commission on Accreditation of Heathcare Organizations (JCAHO) sentinel event definition.

These analyses of the number of NYPORTS events reported each year, which are based on the total number of records reported after similar periods of time had elapsed following the close of each year, demonstrate the impact of the Department of Health's efforts to improve reporting. Among these efforts were a press release on February 12, 2001 and a letter from the Commissioner, sent to all hospitals on February 22, 2001, advising all facilities to increase their reporting efforts. An indication of the effects of these efforts is that the total number of NYPORTS records for 1999 increased from 15,127 cases to 19,551 cases by November 7, 2001.

Increased Reporting by Region

The regional percentage increase in NYPORTS cases reported per 100,000 discharges between 1999 (reported as of December 31, 2000) and 2001 (reported as of December 31, 2002) ranged from 18.4% (from 1,124 to 1,330) in the Central New York region to 109.2% (from 450 to 942) in New York City.

For the year 2000, the number of NYPORTS cases submitted per 100,000 discharges per region varied by a factor of 2.4, whereas in 1999 the number of NYPORTS cases submitted per 100,000 discharges varied by a factor of 2.75. This regional reporting gap continues to decrease in 2001 where the number of NYPORTS cases submitted per 100,000 discharges per region varied by a factor of 1.9.

For the year 2000, three regions (Western New York, Finger Lakes, and Central New York) had similar reporting rates (ranging from 1,282 reported occurrences per 100,000 discharges in Western New York to 1,381 reported occurrences per 100,000 discharges in the Finger Lakes). Two other regions, Hudson Valley and Long Island had very similar reporting rates (990 and 979 occurrences per 100,000 discharges respectively). Northeastern New York had the highest reporting rate (1,737 occurrences per 100,000 discharges). New York City again reported the fewest occurrences per 100,000 discharges (735).

For the year 2001, Central New York and Western New York continued to have similar reporting rates (1,330 and 1,395 reported occurrences per 100,000 discharges respectively). Hudson Valley and Long Island also had very similar reporting rates (1,098 and 1,076 occurrences per 100,000 discharges respectively). Finger Lakes and Northeastern New York had the highest reporting rates (1,774 and 1,813 occurrences per 100,000 discharges respectively). New York City again reported the fewest occurrences per 100,000 discharges (942).

All regions except for New York City, Hudson Valley and Long Island Regions, are above the statewide average for reporting for years 2000 and 2001. As mentioned in the 1999 report, these variations in reporting frequencies could be a result of a variety of factors, including quality of care, types of hospital admissions, procedures performed, and accuracy and completeness of reporting. The precise contribution of each of these factors could not be estimated without a thorough medical record audit in each region. It is the Department of Health's view, however, that differences in types of patients and treatments performed should have a minor impact on the variations, because the size of the regions used to calculate rates were large enough to compensate for major differences in types of patients and treatments. Furthermore, it seems unlikely that there would be large differences among regions in the overall quality of care provided. It is likely that accuracy and completeness of reporting is the reason for most of the differences in the table above. In addition, since it is doubtful that there is widespread over-reporting of occurrences, under-reporting in the regions with the lowest reporting rates is the likely cause of variation.

In addition to the issuance of the 1999 NYPORTS Annual Report, the Department has taken several other steps to promote complete reporting. Ten days after the annual report was issued,

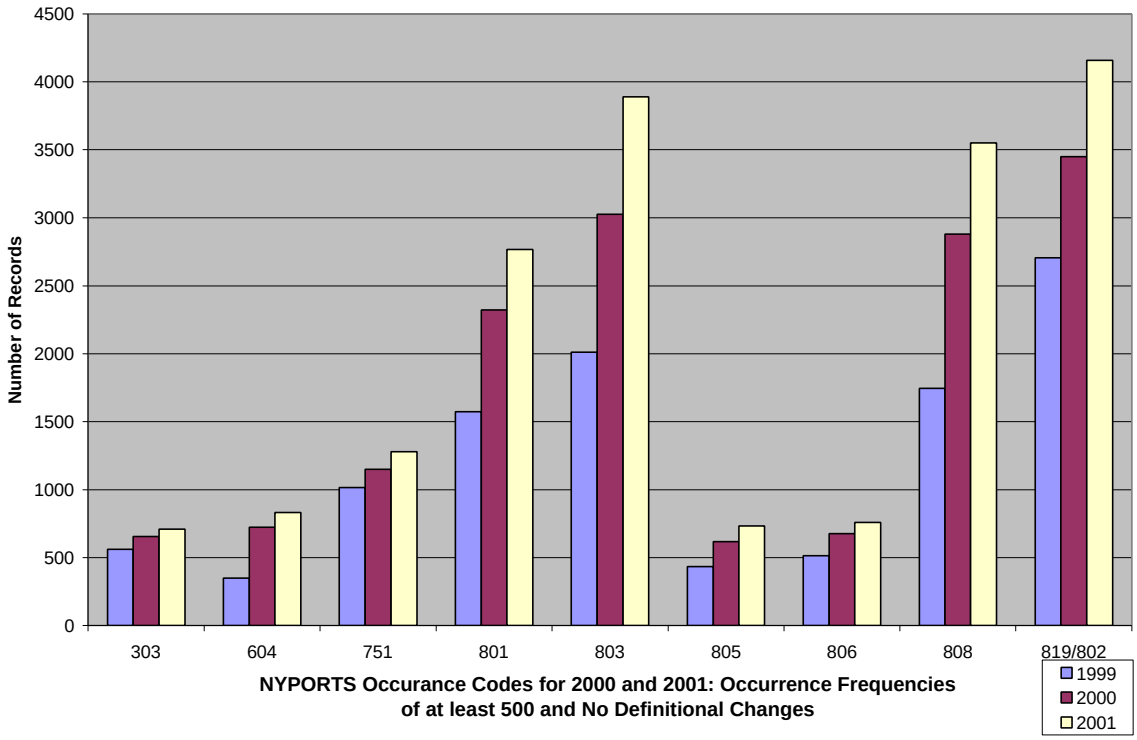
Commissioner Novello called for all hospitals to conduct an internal review of records for 1999 and 2000 for the purposes of identifying occurrences that had been missed. Prior to completing this report, the Department has already been in contact with the lowest reporting hospitals, detailing their 2000 rates and regional comparisons. The Department strongly encouraged a re-evaluation of their internal NYPORTS identification process. Additionally, the Department encourages identification of NYPORTS occurrences by using an outside review agent to conduct medical record review. NYPORTS reportability will be evaluated and shared with the hospital with the intent that knowledge of unreported occurrences will lead to improvement in the facility's occurrence identification process. Finally, the Department, in its role as regulator of hospitals, will continue to identify non-compliance with the regulations and statutes regarding NYPORTS reporting, and will assess fines and mandate corrective measures where warranted.

Changes in Reporting by Individual NYPORTS Code

As indicated above, the total number of NYPORTS records reported increased from 716 per 100,000 discharges in 1999 to 1,004 per 100,000 discharges in 2000, to 1,159 in 2001 resulting in an overall increase from 1999 to 2001 of 61.9%.

The following bar chart presents changes in reporting between 1999 and 2001 for individual NYPORTS codes. In particular, codes with frequencies of at least 500 cases that did not undergo any major changes in definition are represented in the following bar chart. The percentage increase between 1999 and 2000 in these codes ranged from 24.9% for code 751 (falls resulting in x-ray proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma) to 137.9% for code 604 (AMI-Acute Myocardial Infarction).

Reporting of Individual NYPORTS Codes: 1999, 2000 and 2001



Code 303: Pneumothorax, regardless of size or treatment
Code 604: Acute Myocardial Infarction, unrelated to a cardiac procedure
Code 751: Falls resulting in x-ray proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and\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 819/802: 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. 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 frequent in the NYPORTS data.

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. nonoperating room). Examples of CCS procedure categories are: heart valve procedures, coronary artery bypass graft (CABG), bone marrow biopsy and procedures on the spleen.

In order for CCS to be used effectively, hospitals must report in NYPORTS the most specific ICD-9-CM procedure code allowable. In 2000, there were 20,095 NYPORTS records that contained an ICD-9-CM procedure code. Of these records, 885 did not match to a CCS group due to the procedure code being invalid. For the year 2001, there were 23,694 records that contained an ICD-9-CM procedure code, of which 372 did not match to a CCS group due to an invalid procedure code.

The next table lists the procedure groups that represent the largest proportion of all NYPORTS cases for the years 2000 and 2001. 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 2000 and 2001, 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 2,003 cases in this group, or 4.8% of the total cases in NYPORTS (2,003/ 42,532 = 4.8).

Procedure Groups Reported Most Frequently in NYPORTS in 2000/2001

CCS Group	2000/2001 Count	% of All NYPORTS Cases in CCS Groups in 2000 and 2001
Colorectal Resection	2,033	4.78
Hysterectomy, abdominal and vaginal	1,547	3.64
Peripheral vascular bypass	1,313	3.09
Hip Replacement, total and partial	1,287	3.03
Cholecystectomy and common duct exploration	1,117	2.63
Treatment, fracture or dislocation of hip and femur	948	2.23
Cesarean section	941	2.21
Other Vascular catheterization, not heart	876	2.06
Arthroplasty knee	789	1.86
Insertion, revision, replacement, or removal of a cardiac pacemaker or cardioverter	748	1.76

An alternative way of using NYPORTS data to describe the frequency of adverse events by procedure involves using both NYPORTS and SPARCS data to describe the percentage of the time that particular procedure groups are reported to NYPORTS. Using this approach, SPARCS data provides an estimate of the total number of procedures that are being performed each year. NYPORTS data are used to estimate the percentage of these procedures that result in a reported event. The following table presents the procedure groups that occur most frequently compared to all cases that are reported in SPARCS. This comparison uses all NYPORTS records within a given group of procedure codes in the numerator and all SPARCS cases with the same group of procedure codes in the denominator. For example, there were 1,698 kidney transplants recorded in SPARCS for 2000 and 2001. Of these cases, 126 (7.4%) involved events which were reported to NYPORTS.

The distribution of cases in the CCS categories in the following table was similar for the years 2000 and 2001, with the notable exception of ‘Other organ transplant, not kidney’. For 2000, there were 563 SPARCS records in this CCS category, and 67 of these cases (11.9%) involved events that were reported in NYPORTS. For 2001, there were 654 SPARCS records in this CCS category, and 179 of these cases (27.4%) were reported in NYPORTS. The increase in NYPORTS cases involving events in 2001 was due largely to more liver transplants being reported.

Procedure Groups with the Highest Reporting Percentage in NYPORTS in 2000/2001

CCS Group	Number of Occurrences in NYPORTS for 2000/2001	Number of Occurrences in SPARCS for 2000/2001	Relative Frequency (NYPORTS/ SPARCS)*100
Organ transplantation, not kidney	246	1,217	20.21
Kidney transplant	126	1,698	7.42
Peripheral vascular bypass	1,313	17,381	7.55
Exploratory Laparotomy	424	6,821	6.22
Gastrectomy, partial and total	256	4,180	6.12
Small bowel resection	554	9,840	5.63
Aortic resection, replacement or anastomosis	321	5,778	5.56
Colorectal resection	2,033	41,311	4.92
Incision and excision of CNS	658	15,478	4.25
Embolectomy and endarterectomy of lower limbs	218	5,240	4.16
Insertion, replacement, or removal of extracranial ventricular shunt	234	5,817	4.02

Developing relative frequencies for specific procedures can identify adverse event trends for special interest areas. For example, the following table shows analysis of specific ICD-9-CM codes within the CCS Grouping of Gastrectomy, partial and total. Since this type of surgery has a relatively high complication rate, this grouping provides an opportunity for further analysis to identify trends among specific ICD-9-CM codes.

Procedure Code	Occurrences in NYPORTS 2001	Occurrences in SPARCS 2001	Frequency (NYPORTS/ SPARCS)*100
44.31-High Gastric Bypass	70	1281	5.5%
44.39-Other Gastroenterostomy	143	2296	6.2%
Total	213	3577	6.0%

Analysis of Selected NYPORTS Codes

912 Analysis

In support of its primary focus-improvement of patient care and safety-NYPORTS continues to accumulate and disclose a wealth of corrective actions and risk reduction strategies, stemming from the tracking, trending, and sharing of serious occurrences requiring Root Cause Analysis. Risk reduction strategies from each NYPORTS occurrence code will be shared as analysis is completed. This important information is being used by facilities to modify their current systems to enhance patient safety and ensure desired outcomes.

The first in-depth analysis of root cause findings and corrective actions for code 912 (Incorrect treatment or procedure, invasive) has been completed. This information has been shared with facilities through the "NYPORTS News and Alert" and by the Department providing copies of the analysis to individual facilities.

The analysis supports the development by facilities of pre-procedure protocols to include invasive procedures done in areas outside the operative suite, such as the bedside, radiology, emergency department, or other specialty areas.

The results of the analysis of NYPORTS code 912 (Incorrect Procedure or Treatment, invasive) are located in Appendix C. This appendix is an excerpt from the full analysis of code 912, which consists of 80 adverse occurrences within the time frame of June 2000 to August 2001.

Appendix C yields three specific areas of identified adverse event categories, both inside and outside the surgical suite. These categories became apparent after analyzing the data in aggregate form. The number column of the table reflects the frequency of occurrence of each particular category. Root causes have been identified from scrutiny of hospital-submitted Root Cause Analysis. Risk Reduction Strategies have been developed from both hospital identified solutions and commonly accepted standards of practice. The root causes identified, as well as the risk reduction strategies, are given and correlate by number (i.e., Risk Reduction Strategy #1 was identified as a method to reduce or eliminate the occurrence of Root Cause #1). The root causes and risk reduction strategies appearing in boldface type were the result of the statewide analysis of aggregate data, and those appearing in normal type were identified by the hospitals as part of their RCA process.

915 Analysis

In 2002, the Department assembled a Data Analysis Panel, consisting of a multidisciplinary team of experts including physicians, a pharmacist, and registered nurses to review Code 915 (Unexpected death not directly related to the natural course of illness or underlying condition) events. The panel members reviewed occurrences that were submitted from June 1, 2000 to December 31, 2001. These occurrences have been divided into seven categories: Medication-

related, Neurological, Cardiac, Pulmonary, Maternal, Neonatal, and Surgical/Procedural. The preliminary results of the Pulmonary and Pharmacological-related analysis are available in Appendix D. The Department's goal is to extract root causes and risk reduction strategies identified by individual hospitals in their own RCAs, as well as common themes that became apparent only when the data were examined on a statewide level. The panel has added risk reduction strategies based upon standards of medical practice and evidence-based medicine. The goal of the data analysis is to share the identified risk reduction strategies so that every facility in New York State may have the benefit of this information to improve patient safety.

NYPORTS News and Alert

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

Historically, the distribution of the "News and Alert" has been a paper process. In 2001, the Department has instituted electronic distribution of this newsletter, in addition to paper distribution.

The following is an example of a "News and Alert" article that was published in the September 2002 issue.

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.

Many corrective actions from RCA's suggest utilization of x-ray to identify retained foreign bodies. The use of sponges containing a radiopaque marker substantially improves the ability to locate them in a x-ray. While this is a widely used practice, it does not prevent the retention of surgical sponges. Although the use of x-ray is a standard

diagnostic tool in locating a retained sponge or lap pad, there can be great variability in their appearance, leading to diagnostic misinterpretations. It may be helpful for facilities to maintain a collection of examples of the x-ray appearance of retained surgical sponges to assist the Radiologists/Surgeons with identification.

The Association of Operative Registered Nurses (AORN Journal Dec 1999) recommends that sponges be counted:

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

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

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

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

This example illustrates the importance of information obtained from analysis of NYPORTS data. This issue of "NYPORTS News and Alert" is available to view at the end of this report.

Agency for Healthcare Research and Quality Patient Safety Grant

The Department has been awarded a three year federal grant totaling $5.4 million from the Agency for Healthcare Research and Quality (AHRQ) to support its ongoing efforts to improve patient safety. The goals of the New York State Safety Improvement Demonstration Project are to improve the completeness of reporting in NYPORTS, to identify the causes of preventable errors and patient injury in health care using the root cause analysis process, and to develop, demonstrate and evaluate strategies for reducing adverse events and improving patient safety through hospital interventions. The goals will be accomplished through two initiatives: assuring more complete reporting in NYPORTS so that more meaningful analysis of data can occur and overseeing three demonstration projects involving hospital groups or networks that will study specific types of adverse outcomes and will develop and test interventions to reduce their occurrence.

The goal of improving NYPORTS reporting has been accomplished in several ways. Interviews were conducted for a sample of hospitals across New York State to determine the key characteristics of an effective concurrent detection system. A survey will be developed and sent to all hospitals to determine whether those hospitals having these key characteristics do in fact have an effective concurrent NYPORTS reporting process. Additionally, linking NYPORTS and SPARCS to identify potential missed events has proven effective in improving reporting. Training medical record coders about NYPORTS is another initiative being carried out to improve the quality of the SPARCS database and also identify potential NYPORTS cases. Having more effective systems will lead to better quality data, which in turn will lead to improved patient safety practices.

In fulfilling the second initiative, awards were made to three hospital groups in June, 2002 totaling $1.7 million, to reduce the occurrence of three common and preventable occurrences reported in NYPORTS. The projects are funded through August 14, 2004. Summaries of the three projects are as follows:

· **The Westchester Medical Center group** (Westchester Medical Center, Westchester Medical Center White Plains Pavilion, Benedictine Hospital, Kingston Hospital and Ellenville Regional Hospital) analyzed current use of antimicrobials and found that antibiotics that are considered broad spectrum and should be reserved for treatment of infections were being used for surgical prophylaxis and then continued to be administered after the surgery was completed. This is contrary to published recommendations and can lead to increased antibiotic resistance and significantly increased costs to the facilities. In addition, antibiotics were not administered at the optimum time before surgery to achieve optimal serum and tissue levels.

As a result, standardized surgical antimicrobial prophylaxis protocols for the administration of antimicrobial prophylaxis (AMP) were developed using evidenced based medical literature. The protocols are designed to standardize the use of prophylactic antimicrobial agents in association with select clean and clean-contaminated surgical procedures. The development of these protocols involved active participation from the surgical staff and the anesthesia departments. These protocols were approved by the appropriate surgical related committees in each of the participating hospitals. A consensus statement was developed indicating that compliance with these protocols is consistent with the standard of practice in each of the participating hospitals. Compliance with these protocols will be monitored through the study period. The intervention was implemented on January 1, 2003 and data collection for the analysis of the intervention was initiated on February 1, 2003. The demonstration project will be completed on August 15, 2004 and the results will be disseminated throughout NYS.

· **The Rochester Regional Thromboembolism Collaborative** (Strong Memorial Hospital, Highland Hospital, F.F. Thompson Hospital, St. James Mercy Hospital and Jones Memorial Hospital) has developed the risk assessment and prophylaxis protocols based on evidenced based medicine via collaborative multidisciplinary committee work. The protocols were piloted at all five hospitals and revised based on the piloting. The

Data Collection Tools and corresponding Data Dictionary were developed to be utilized for a sample of cases in the 2001 baseline period and the study period to assess compliance with the risk assessment and proper use of thromboembolic prophylaxis. The risk assessment tool and prophylaxis intervention was implemented across the study hospitals in April 2003.

The School of Public Health in Albany, as part of a qualitative analysis project, conducted site visits at all participating hospitals in November 2002. Individuals at all levels were interviewed; physicians, registered nurses, nurse practitioners, etc and preliminary feedback was provided via conference call in February 2003.

A web site was developed for the DVT/PE NYPORTS project. Information regarding the project is now at the fingertips of all participants and gives them the ability to stay informed up to the minute through the distribution of materials through the web site.

- **The New York Presbyterian-Healthcare System** project (New York Presbyterian Hospital-Columbia, New York Methodist, New York Medical Center Queens, St. Barnabas and White Plains Hospital Center) is completing the development of the 2001 baseline of perioperative MI cases meeting study criteria by electronically matching surgical DRG codes matched with a laboratory database of elevated enzymes. Medical Directors have reviewed all AMI cases and a 10% sample of ineligible cases.

The Medical Directors Committee of the New York Presbyterian Healthcare System adopted a system wide evidence-based consensus statement recommending the use of perioperative B-blocker therapy in appropriately selected patients undergoing non-cardiac surgical procedures. This statement includes perioperative risk stratification and guidelines for the appropriate use of B-blocker prophylaxis. Current data indicates an underutilization of perioperative B-blockers within the system. A multi-dimensional educational intervention was implemented in January, 2003 aimed at changing clinician behavior and improving the clinical utilization and effectiveness of B-blocker therapy. Modalities include multidisciplinary grand rounds and divisional lectures, improved coordination of care among preoperative medical staff, utilizing a web-based education program, providing supportive materials (i.e.- posters, pocket cards) and support of local opinion leaders. Compliance to these protocols will be measured throughout the study period.

The intervention began on April 1, 2003. All research personnel have been trained to work on the project. Communication among all participants is important and is enhanced by a secured program web site. Weekly telephone conferences occur among all Medical Directors and key project personnel.

NYPORTS Information Prompts Hospital Studies

NYPORTS reporting and the resultant access to comparative data have prompted individual facilities to conduct their own system studies. Using the information gained through the NYPORTS system, facilities can target areas of concern and perform focus studies. The results of these studies have been significant in improving patient care and safety, as well as reducing hospital costs.

As a direct result of NYPORTS initiatives, the Department has created the "New York State Hospital Patient Safety Award" program. This award recognizes 2 hospitals based upon their accomplishments in promoting patient safety and reducing medical errors. Each hospital will receive the award and a grant of up to $ 200,000 to work with the Department in promoting their patient safety strategies for other hospitals and care providers in New York State.

The recipients of the First Annual New York State Hospital Patient Safety Awards were announced at a conference, jointly sponsored by the Agency of Healthcare Research and Quality (AHRQ) and the Department of Health, “Working Together: How Hospitals Can Ensure Patient Safety" in January of 2002. The recipient of the award for hospitals with over 200 beds was Ellis Hospital, Schenectady, and the winner for hospitals under 200 beds was The Hospital for Special Surgery, Manhattan.

Ellis Hospital was recognized for its efforts to reduce the risk of dangerous clots forming in hospitalized patients. A comprehensive risk factor assessment and treatment protocol was established to identify and treat patients at risk for this complication. This assessment is now part of the hospital's admission process and is recorded in each patient's chart and care plan during their hospital stay. Since instituting this new screening process, there has been a significant decrease in the number of hospital-acquired deep vein thrombosis (blood clots) and pulmonary embolus.

The Hospital for Special Surgery was recognized by the Department for its innovative program leading to improvement in the medication use process. This initiative established hospital protocols to ensure legibility of medication orders, which resulted in a 97.6% decline in the number of illegible orders from November 2000 to December 2001. This short term error reduction strategy focused on the 'process of process improvement', helping to meet the Hospital's short-term goal of enhancing current systems and processes, while working towards the long term goal of Computerized Physician Order Entry (CPOE).

In addition to the award-winning hospitals, seven other New York hospitals received Honorable Mention awards and were recognized for their work to establish patient safety programs, including:

- Albany Medical Center, Albany- Developed a comprehensive automated data collection system to identify, monitor and track the distribution of medications to patients. The database helps pharmacists cross check the possibility of adverse reaction in patients prescribed multiple drugs at once;

- Mercy Medical Center, Rockville Center- Enhanced policies to prevent medication errors from occurring, including the development of a universal flow chart to track drug distribution to patients;

- New York Presbyterian Hospital, New York City- Strengthened policies related to the assessment of patients admitted to the emergency department for acute myocardial infarction (heart attack);

- North Shore University Hospital, Forest Hills- Enhanced protocols for administering antibiotics to prevent infection in patients immediately following surgical procedures;

- Park Ridge Hospital, Rochester- Strengthened policies related to the tracking and dispensing of medications to patients to prevent errors from occurring, implemented interventions for reducing the incidence of central line related blood stream infections in ICU patients, and improved patient safety related to safety hazards due to wheelchairs in disrepair;

- The Hospital for Joint Diseases, New York City- Developed comprehensive policies to identify the correct area of surgery on patients to help prevent wrong-site surgeries from occurring; and

- Wyckoff Medical Center, Brooklyn- Strengthened policies related to identification and prevention of medication errors that may result from relying on written orders.

The Second Annual Patient Safety Awards were expanded to not only to acknowledge the effort of hospitals in improving patient safety, but also to recognize the efforts of nursing homes and Federally Qualified Health Care Centers (FQHC). The 2002 Patient Safety Award recipients are Children's Hospital, Buffalo (hospitals over 200 beds), and Albany Memorial Hospital, Albany (hospitals under 200 beds). The Nursing Home award recipient is United Health Services. Ideal Senior Living Center, Endicott, and the FQHC award recipient is Sunset Park Family Healthcare Center Network of Lutheran Medical Center, Brooklyn.

Children's Hospital, Buffalo, was acknowledged for their efforts to improve and ultimately, eliminate errors of medication prescription. The program was implemented in 1998, with a review of 21,000 medical records, which identified specific focus areas. In response to this exercise, the facility developed order forms that promote improved completeness and accuracy through a forced function format. In addition, the program included a plan to reduce the frequency of incorrect orders. Personal digital assistants (PDA) were given to house staff to assist in this effort. The facility noted a 48% reduction in incorrect drug selection, dose and frequency during a one year observation period. Children's Hospital has also developed a website tutorial and competency exam for medication prescription. This website tutorial is a requirement for all new residents to the facility.

Albany Memorial Hospital, Albany, has been recognized for their efforts in coordinating care management for patients with heart failure. This program utilizes a professional nurse case

manager to facilitate care for patients with complex medication regimens and high risk for hospitalization across the continuum of care. This effort includes successful strategies for an integrated information system, a full spectrum of services from primary care through long term care, dedicated resources and system wide commitment to this program, seamless transition across the continuum, and empowerment of patients with self care management. The result of this program has been a 75% reduction in hospitalizations and a 100% reduction in Emergency Department visits for patients utilizing this program.

United Health Services-Ideal Senior Living Center, Endicott, received the Patient Safety Award for efforts in developing a prevalence study of residents with pressure ulcers. The program was initiated in April 2000 and the prevalence rate was found to be at 22%. An interdisciplinary team was structured and all residents were re evaluated. It was determined that all residents would continue to be reassessed quarterly and annually, with episodic charting of skin integrity changes, lab chemistry changes, and weight changes. Any residents with status changes would be discussed at morning report and immediate follow-up would occur. This effort to reduce pressure ulcers resulted in a rate decrease from 22% in June 2000 to 9% in June of 2001, and to 5% in June of 2002.

Sunset Park Family Healthcare Center Network of Lutheran Medical Center, Brooklyn, has been instrumental in providing services to under served neighborhoods of southwest and central Brooklyn since 1967. Their Patient Safety proposal included a number of improvement areas such as patient satisfaction, expedited HIV testing, management of pediatric asthma patients and testing in adult diabetics. Significant improvements were demonstrated in these categories as a result of quality improvement interventions. For example, prior to the implementation of the Diabetes Management Program, 80% of adult diabetics had evidence of an annual test in 1999. This percentage has increased to 95% in 2002 through several effective interventions, such as the creation of a diabetic registry, the use of an interdisciplinary team approach to care, the development of clinical guidelines, the use of a self management education program for adults, and the use of case management services for high risk patients. In addition, Sunset Park instituted a program of pre registering and tracking of all prenatal patients to ensure that expedited testing was not needed at the time of delivery. The program reduced the rate of expedited testing at birth from 44% in 2001 to 3% in March 2002.

Work in Progress

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

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

- The Department will provide ongoing training to hospitals regarding proper implementation, system improvements, and changes in definitions to NYPORTS.

- The Department will monitor reporting compliance through overall hospital surveillance activities and appropriate enforcement actions and sanctions will be taken for continued failure to report as required. Chart reviews by an independent outside agent will continue to identify missed NYPORTS events.

- The Department will continue to identify Root Causes and Risk Reduction Strategies. This information will be shared with hospitals to support improvement in patient care systems.

- The Department will continue to issue NYPORTS News and Alert on a quarterly basis, or as needed, to disseminate patient safety related information to facilities.

- The Department will continue its collaboration with the University at Albany School of Public Health to analyze and extract patient safety data from NYPORTS.

- NYPORTS subcommittees will remain active in their pursuit of improvements to the system. The Medication Error subcommittee will examine data specific to medication related occurrences. Root causes and corrective actions will be identified by the group and shared with facilities. The RCA subcommittee will focus on changes to the RCA form and process, and suggest improvements to the system.

- The Department will continue its work on the New York State Safety Improvement Demonstration Project in order to reach its goals to improve the completeness of reporting in NYPORTS, to identify the causes of preventable errors and patient injury in health care using the Root Cause Analysis process, and to develop, demonstrate and evaluate strategies for reducing adverse events and improving patient safety through hospital interventions.

- The Department will continue to work with Island Peer Review Organization (IPRO), in their medical record review process, to verify hospital reporting compliance. IPRO will identify those hospitals that have high reporting rates and will examine their systems to extract meaningful strategies. These strategies will be shared with hospitals that are identified as low reporters, in order to bolster improvement activities with respect to occurrence reporting.

APPENDIX A

WESTERN NEW YORK

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

FINGER LAKES

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

CENTRAL NEW YORK

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

NORTHEASTERN NEW YORK

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

HUDSON VALLEY

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

LONG ISLAND

Nassau, Suffolk

NEW YORK CITY

Bronx, Kings, New York, Queens, Richmond

APPENDIX B
Includes/Excludes List

OCCURRENCE CODE	INCLUDES	EXCLUDES
Medication Errors: **Topical, Injectables, IV, PO** **Treatment Medications, Contrasts, Chemotherapy** **915-920 codes and Root Cause Analysis Required.**	108. **A medication error occurred that resulted in permanent patient harm**. (Permanent harm is harm that is enduring and cannot be rectified by treatment) Refer to definition manual pages 7-8 109. **A medication error occurred that resulted in a near-death event** (e.g., cardiac or respiratory arrest requiring BLS or ACLS). Refer to definition manual pages 7-8 110. **A medication error occurred that resulted in a patient death**. Refer to definition manual pages 7-8	108-110. Any adverse drug reaction that was not the result of a medication error. 109. A medication error that resulted in the need for treatment, intervention, initial or prolonged hospitalization and caused **temporary** patient harm. Examples: A medication error where a patient is given glucose to counteract a low blood sugar from an overdose of insulin; or a patient is given naloxone (narcan) to counteract an overdose of narcotic
Aspiration	201. **Aspiration pneumonitis/pneumonia in a non-intubated patient related to conscious sedation.** Refer to definition manual page 9	201. Patients intubated on ventilation, or with known history of chronic aspiration.
Intravascular Catheter Related	**301. Necrosis or infection requiring repair incision and drainage (I&D), debridement, or other surgical intervention), regardless of the location for the repair** (e.g., at the bedside, in a treatment room, in the OR). Refer to definition manual page 10 302. **Volume overload leading to pulmonary edema**. Refer to definition manual page 11	301. Any infiltration or infection treated exclusively with cold or warm packs, wound irrigation, IV change, and/or medication use (e.g., IV, PO, topical). 302. Pulmonary edema clearly secondary to acute myocardial infarction. Pulmonary edema occurring in patients with previously known, predisposing conditions such as CHF, cardiac disease, renal failure, renal insufficiency or hemodynamic instability in critically ill patients. Volume overload occurrences related to blood transfusion are reported to Blood and Tissue Resources Program only.

	303. **Pneumothorax, regardless of size or treatment** (including pneumothoraces resulting from a procedure performed through an intravascular catheter, e.g., temporary pacemaker insertion). Refer to definition manual page 12	303. Non-intravascular catheter related pneumothoraces such as those resulting from lung biopsy, thoracentesis, permanent pacemaker insertion, etc.
Embolic and Related Disorders • **include readmissions within 30 days**	401. **New, acute pulmonary embolism, confirmed, or suspected and treated.** Refer to definition manual page 13 402. **New documented DVT** (deep vein thrombosis) Refer to definition manual page 14	401. New, acute pulmonary embolism is suspected cause of sudden death but there is no autopsy to confirm (consider code 915). Acute pulmonary embolism present on admission and not associated with previous hospitalization within the past 30 days. 402. Superficial thrombophlebitis. New documented DVT present on admission and not associated with previous hospitalization within the past 30 days.
Laparoscopic	501. **All unplanned conversions to an open procedure because of an injury and/or bleeding during the laparoscopic procedure**. Refer to definition manual page 15	501. Diagnostic laparoscopy with a planned conversion or conversion based on a diagnosis made during the laparoscopic procedure. Conversions due to difficulty in identifying anatomy.
Perioperative/ Periprocedural Related • **Occurring the same day as, or on the 1st or 2nd day after procedure** • **regardless of setting of operation or procedure** • **include readmissions.**	600's category 601. **Any new central neurological deficit** (e.g., TIA, stroke, hypoxic/anoxic encephalopathy). Refer to definition manual pages 16-18	601-604 Cardiac related occurrences complications) reported in the cardiac reporting systems (refer to definition manual pages 77-82). 603-604 Multiple trauma**,** AAA rupture known at time of surgery ESRD (End Stage Renal Disease) patients post dialysis treatment. (Include only if occurs while patient is in dialysis area.) NOTE:Consider the 911-963 codes when applicable 601. Central neurological deficits due to direct procedures on the central nervous system (e.g., tumor dissection or removal). Transient metabolic encephalopathy. Birth related neonatal events reported to Perinatal Data System (page 86). 601-604 Cardiac related occurrences

		complications) reported in the cardiac reporting systems (refer to definition manual pages 77-82). 603-604 Multiple trauma**,** AAA rupture known at time of surgery. ESRD (End Stage Renal Disease) patients post dialysis treatment. (Include only if occurs while patient is in dialysis area.) NOTE:Consider the 911-963 codes when applicable
	602. Any new peripheral neurological deficit (e.g., palsy, paresis) with motor weakness. Refer to definition manual pages 16, 19, 20	602. Deficits due to operative or other procedure on a specific nerve (e.g., procedures involving neurofibroma, acoustic neuroma). Sensory symptoms or deficits without motor weakness (e.g., numbness or tingling, alone). Deficits due to central neurological insults (such as hemiparesis) are submitted as a 601. Birth related neonatal events reported to Perinatal Data System (page 86). Intentional arrest during cardiopulmonary procedures. Cardiac arrest with unsuccessful resuscitation (consider code 915).
	603. **Cardiac arrest with successful resuscitation.** Refer to definition manual pages 16, 21	603-604 Multiple trauma**,** AAA rupture known at time of surgery. NOTE:Consider the 911-963 codes when applicable
	604**. AMI** (Acute Myocardial Infarction) – **unrelated to a cardiac** procedure. Refer to definition manual pages 16, 22	
	605. **Death occurring after procedure See attached list** (include ASA class if the procedure involves general anesthesia or conscious sedation) Refer to definition manual pages 16, 23-24	

Burns/Falls	701 **2nd and/or 3rd degree burns.** Refer to definition manual page 25 751. **Falls resulting in x-ray proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma** (e.g., hepatic or splenic injury). Refer to definition manual page 26	701. 1st degree burns. 751. Falls resulting in soft tissue injuries. NOTE:Consider the 911-963 codes, when applicable
Procedure Related • **Regardless of setting*** *** Excludes code 808** • **Within 30 days of the procedure** • **Include readmission**	800's category 801. **Procedure related injury requiring repair, removal of an organ, or other procedural intervention**. **Any** procedural injury to liver or spleen, including injury associated with lysis of adhesions or manipulation of the organ. Refer to definition manual pages 27-31	801-819. Cardiac related occurrences (complications) reported in the Cardiac Reporting Systems (refer to pages 80-85 of the definition manual). Maternal and Neonatal related occurrences reported in the Statewide Perinatal Data System (refer to pages 86-87 of the definition manual). NOTE:Consider the 911-963 codes, when applicable. 801. Procedure related injuries which do not penetrate, perforate or enter a lumen, require only a suture(s) to serosal/muscular layers to repair, and which do not require removal of an organ. Procedure related injuries resulting from intended, direct operation on an organ or other anatomical structure based on disease process or lack of an alternative approach available to address the presenting surgical condition. Perineal lacerations from childbirth.

Procedure Related • **Regardless of setting *** *** Excludes code 808** • **Within 30 days of the procedure** • **Include readmissions .**		801-819. Cardiac related occurrences (complications) reported in the Cardiac Reporting Systems (refer to pages 80-85 of the definition manual). Maternal and Neonatal related occurrences reported in the Statewide Perinatal Data System (refer to pages 86-87 of the definition manual). NOTE:Consider the 911-963 codes, when applicable.
	803. **Hemorrhage or hematoma requiring drainage, evacuation or other procedural intervention.** Refer to definition manual pages 27-28, 32-33	803. Vaginal packing intervention and routine blood transfusion given during or after initial procedure for procedure related blood loss. Postpartum hemorrhage requiring removal of retained Placenta only.
	804. **Anastomatic leakage requiring repair.** Refer to definition manual pages 27-28, 34	
	805. **Wound dehiscence requiring repair.** Refer to definition manual pages 27-28, 35	
	806. **Displacement, migration or breakage of an implant, device, graft, or drain, whether repaired, intentionally left in place or removed.** Refer to definition manual pages 27-28, 36	806. Occurrences reported in 913 (retained foreign body) or occurrences due to equipment malfunction or defective product reported in 937 or 938. Patient initiated occurrences (e.g., patient removes G.T.) NOTE: If caused by hemorrhage report as code 803, if caused by post-op wound infection report as code 808.
	807. **Thrombosed distal bypass graftrequiring repair.** Refer to definition manual pages 27-28, 37	807. AV grafts and fistulas used for dialysis.
	808. ***Post-op surgical wound infection following clean or clean/contaminated case (performed in the O.R. or Surgical suite only) requiring drainage during the hospital stay or INPATIENT hospital admission within 30 days.** ASA class is required to be noted.	808. Contaminated or dirty case procedure. Allograft occurrences (tissue transplant) report to Tissue Resources Program only (see page 75 of the definition manual).

Procedure Related • **Regardless of setting *** *** Excludes code 808** • **Within 30 days of the procedure** • **Include readmissions**	Refer to definition manual pages 27-28, 38-41. 819- **Any unplanned operation or reoperation (RTOR) related to the primary procedure, regardless of setting of primary procedure**. (If occurrence involves 801 or 803-808, enter 801 or 803-808 in the 1st occurrence code field, followed by 819 in the 2nd occurrence code field.) Refer to definition manual pages 27-28, 42-43 851. **Post partum hysterectomy** Refer to definition manual pages 27-28, 44 852. **Inverted uterus** Refer to definition manual pages 27-28, 45 853. **Ruptured uterus** Refer to definition manual pages 27-28, 46 854. **Circumcision requiring repair** Refer to definition manual pages 27-28, 47	819. Non-anesthesia procedural interventions (e.g., ERCP) usually performed in special procedure rooms in larger hospitals but which are performed in the OR in a smaller hospital simply due to lack of specialized facilities. Procedures that are commonly sequential or repeated (skin flaps, colostomy closure, 2nd look trauma, biopsy follow-up, documented planned 2nd look for ischemia after bowel resection or whenever intestinal ischemia is expected). Also lap 2nd look post oncologic procedure when post-op adjuvant therapy was given (ovarian cancer, Hodgkin's and non-Hodgkins lymphoma). Excludes debridement, vascular cases where conservative approach tried first (thrombectomy, fem-pop bypass) but ultimately fails (BKA done as last resort). Postpartum hemorrhage requiring removal of retained Placenta only. 854. Planned suture during procedure

Root Cause Analysis Required	900's category Serious events such as unexpected deaths are reportable as 900 codes even if the surgery was a CABG.	
	911. **Wrong Patient, Wrong Site-Surgical Procedure** Refer to definition manual pages 48-49, 52	911. Occurrence with the administration of anesthesia only-code as 912. Endoscopy- code as 912
	912. **Incorrect Procedure or Treatment - Invasive** Refer to definition manual pages 48-49, 53	912 Venipuncture for phlebotomy, diagnostic tests without contrast agents. Transfusion related occurrences (report to Blood and tissue resources program only).
	913. **Unintentionally retained foreign body due to inaccurate surgical count or break in procedural technique** (sponges, lap pads, instruments, guidewires from central line insertion, cut intravascular cannulas, needles, etc.) Refer to definition manual pages 48-49, 54	913. Foreign bodies retained due to equipment malfunction or defective product (report under 937 or 938) or those reported under 806.
	915-919. <u>Any unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in</u>**<u>:</u>**	915-919. Any unexpected adverse occurrence directly related to the natural course of the patient's illness or underlying condition (e.g., terminal or severe illness present on admission).
	915. Death (e.g., brain death). **Report Death of fetus/neonate meeting the following criteria:** **For live or still birth** a. Greater than or equal to 28 weeks gestation. b. Greater than or equal to 1000 grams of weight NOTE: Include any Iatrogenic occurrence resulting in death at any gestation/weight Refer to definition manual pages 48-49, 58-59	Exclude deaths of fetus/neonate with presence of congenital anomalies incompatible with life (e.g., Anencephalus, Trisomy 13,18, Trachael or Pulmonary Atresia, Multiple life threatening Anomalies). Exclude Transfusion related death (Report to Blood and Tissue Resources Program only) See definition manual page 79. NOTE: Any cases involving malfunction of equipment resulting in death or serious injury should be reported under 938.

Root Cause Analysis Required	915-919 Any unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in**:**	915-919 Any unexpected adverse occurrence directly related to the natural course of the patient's illness or underlying condition (e.g., terminal or severe illness present on admission).
	916. **Cardiac and/or respiratory arrest requiring BLS/ACLS intervention**. Refer to definition manual pages 48-49, 60	916. Events not requiring BLS/ACLS intervention.
	917. **Loss of limb or organ**. Refer to definition manual pages 48-49, 61	916-919. Birth related neonatal events reported in the Statewide Perinatal System. See page 86.
	918. **Impairment of limb** (limb unable to function at same level prior to occurrence) **and impairment present at discharge or for at least 2 weeks after occurrence if patient is not discharged.** Refer to definition manual pages 48-49, 62	918. Limb functions at the same level as prior to the occurrence, impairment resolves by discharge or within two weeks if not discharged. Excludes positioning parathesias.
	919. **Loss or impairment of bodily functions** (sensory, motor, communication or physiologic function diminished from level prior to occurrence) **and present at discharge or for at least 2 weeks after occurrence if patient is not discharged.** Refer to definition manual pages 48-49, 63	919. Bodily function at the same level as prior to the occurrence, impairment resolves by discharge or within two weeks if not discharged. Excludes positioning parathesias.
	920. Errors of OMISSION/DELAY resulting in death or serious injury RELATED to the patient's underlying condition. Refer to definition manual pages 48-49, 64	
	921. **Crime resulting in death or serious injury, as defined in 915- 919.** Refer to definition manual pages 48-49, 65	
	922. **Suicides and attempted suicides related to an inpatient hospitalization, with serious injury as defined in 915-919.**	

Root Cause Analysis Required	Refer to definition manual pages 48-49, 66 923. **Elopement from the hospital resulting in death or serious injury as defined in 915-919.** Refer to definition manual pages 48-49, 67 938. **Malfunction of equipment during treatment or diagnosis or a defective product which resulted in death or serious injury as described in 915-919.** Please include: a. equipment/device name b. manufacturer c. model # d. serial # Refer to definition manual pages 48-49, 74 961. **Infant Abduction**. Refer to definition manual pages 48-49, 75 962. **Infant discharged to wrong family**. Refer to definition manual pages 48-49, 76 963. **Rape by another patient or staff**. (Includes alleged rape with clinical confirmation) Refer to definition manual pages 48-49, 77	923. Cases in which the patient outcome would have been the same whether or not the elopement occurred (cancer death, etc.).

Submit Short Form Only **Root Cause Analysis Not Required**	901. **Serious occurrence warranting DOH notification, not covered by codes 911-963.** Refer to definition manual page 50	
	902. **Patients transferred to the hospital from a diagnostic and treatment center.** **FOR INTERNAL DOH USE ONLY** Refer to definition manual page 51	902. Planned hospital admission from a diagnostic and treatment center.
	914. **Misadministration of radioactive material** (as defined by BERP, Section 16.25, 10NYCRR). Refer to definition manual page 55-57	
	931. **Strike by hospital staff.** Refer to definition manual page 68	
	932. **External disaster outside the control of the hospital which affects facility operations**. Refer to definition manual page 69	932. Situations that are related to termination of service should be reported under 933.
	933. **Termination of any services vital to the continued safe operation of the hospital or to the health and safety of its patients and personnel, including but not limited to the anticipated or actual termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food or contract services.** Refer to definition manual page 70	933. Excludes services maintained by back up services (e.g., back up generator or O2 supply), have no impact on the safe operation of the hospital, or on the health and safety of its patients or staff.
	934. **Poisoning occurring within the hospital** (water, air, food). Refer to definition manual page 71	
	935. **Hospital fire disrupting patient care or causing harm to patients or staff**. Refer to definition manual page 72	

Submit Short Form Only **Root Cause Analysis Not Required**	937. **Malfunction of equipment during treatment or diagnosis or a defective product which has a potential for adversely affecting patient or hospital personnel or a resulting in a retained foreign body.** Please include: a. equipment/device name b. manufacturer c. model # d. serial # Refer to definition manual page 73	

SPECIFIC PROCEDURES FOR CODE 605

NOTE: Consider code 915 in addition to 605 if death is unexpected and not directly related to the natural course of the patient's illness or underlying disease process (even if the procedure is not included in the specific list below).

Procedures	ICD-9 Code Range	Examples
Appendectomy	**47.0-47.19**	Laparoscopic A. Incidental A.
Non-Cardiac Arteriography (Angiography)	**88.4-88.49**	Aortography
Cholecystecomy	**51.2-51.24**	Laparoscopic C.
Endarterectomy	**38.10-38.19**	of Vessels of Arteries of Veins
Resection Of Large Intestine	**45.7-45.8**	Cecectomy Right Hemicolectomy Resection of Transverse Colon Left Hemicolectomy Sigmoidectomy Total Colectomy
Hysterectomy	**68.3-68.7, 68.9**	Subtotal Abdominal Vaginal Laparoscopic Total Radical
Large Bowel Endoscopy	**45.23-45.24**	Colonoscopy Sigmoidoscopy
Prostatectomy	**60.2-60.69**	Transmurethral Suprapubic Retropubic Radical Perineal
Replacement of Joint of Lower Extremity	**81.5-81.59**	Total Hip Partial Hip Revision of Hip Total Knee Revision of Knee Total Ankle Replacement in Toe or Foot
Spinal Fusion	**81.0-81.09**	Atlas-axis Anterior technique Posterior technique Dorsal/Dorsolumbar Lumbar/Lumbosacral, Revision

Appendix C

Excerpts from code 912 analysis: (Incorrect Procedure or Treatment: Invasive)

Category of Adverse Outcomes	Subtype	#	Root Causes	Risk Reduction Strategies
Wrong site procedures	Anesthesia related	7	1. No indication of site for procedure on the consent.	1. Develop specific procedures for what to do in the event the consent is not completed. 1a. Establish a nursing policy that includes the statement that patient will not be released to the O.R. until appropriate physician comes to the nursing unit to complete consent form. 1b. Establish pre-admission policies giving staff more time to obtain a completed consent. i.e. Submit consent 48 hours before the date of surgery.
			2. The process in place did not prevent misidentification of the patient.	2. Develop a step when confirming laterality prior to surgery, which gives the name of the patient, as well as the site for surgery, to assist the surgeon in identifying the patient.
			3. Time lapse between confirmation of laterality and administrating anesthesia.	3. Institute additional step in the laterality confirmation, which includes verbalization of intent to proceed to the surgical team, immediately prior to doing so. This would provide a final safety net. 3a. The syringe for blocking will no longer be placed on the Mayo stand, but will now be placed on the Pre-op table, and given only after the final verification.
			4. Failure to confirm anesthetic was being injected into proper site, before administering the medication.	4. See 3 and 3a.

			5. Thinking of one site, but blocking another. 6. Lack of formal procedure for invasive procedure done outside the surgical suite, in two cases.	5. See 3 and 3a. 6. Consent for anesthesia will be obtained by the anesthesiologist prior to performing any anesthetic procedure, or administration of anesthetic drug. 6a. Confirmation of this pre-operative check will be acknowledged on the consent form by the anesthetist's signature in the area confirming site/side prior to entering the O.R. 6b. Pre-op verification policy should be followed regardless of setting of procedure. 6c. No procedure shall be exempt from the normal process to confirm laterality.
Unnecessary treatment or procedure	Unnecessary Surgery	9	1. General process of dictating normal studies. 2. Radiological log error. 3. Necessary information was omitted on the treatment plan reviewed prior to procedure. 4. Failure to collect	1. Assure "normal" CT report dictation, includes mention of organs that are absent. 2. Institute safeguards and mechanisms to improve communication, in addition to consistency in what is written on log information. 2a. Include clarification of test ordered, and rule-out diagnoses on all radiological logs; separating this information in columns. 3. Consolidate records to minimize duplicative recording of the same information 3a. Revise policies and procedures to include at least three independent verifications of site location and patient identification. 4. See 3a.

			adequate information. 5. Procedure was based on a previous report, not present condition. 6. Mismatch in pre-op and post-op pathology 7. Incorrect pathological findings. 8. Erroneous lab results 9. Failure to adhere to general practice.	5. Stress importance of confirming dates on dated material, addressing clinical discrepancies; and verification of current documented assessments in relation to radiological findings that may not yet be posted on the admission based hospital computer system. 6. RCA and literature review recognize treatment of choice is left up to Surgeon in some instances. 7. Have preceptor guidelines for all Locum Tenens appointees (two peers should review pathological findings) **8. Examine existing procedures for specimen rejection and labeling**. **Consult The Clinical Laboratory Evaluation Program CLEP, Directed by Dr Dick Jenny, at The Wadsworth Center in Albany, for clinical guidelines on laboratory issues @ 518-485-5378** 9. Assure policy for adherence to complete evaluation of patient, prior to arrival in the O.R. suite.
Wrong Surgical device	Knee components	3	1. Lack of implant verification policy in all cases. **2. Lack of established protocol for each staff members' responsibility in a procedure**.	1. Establish policy for implant verification, **which establishes verification process, take place at a time that would allow for correction or replacement if warranted**. **2. Revise policy to include protocol for each staff members' responsibility in a procedure: i.e. confirmation appropriating equipment and supplies (component parts).** **2a. Institute use of a check sheet that confirms surgical components and responsibilities in the process**.

			3. Poor packaging for implant, in two of the three cases.	3. Contact manufacturer, to increase the size of the font in packaging that delineates laterality, or colors of packaging. **3a. Separate component parts on supply cart, and in storage rooms by laterality not size**. **3b. Schedule specific sided procedures on alternate days, or times of day.**
			4. Incomplete verification of correct surgical component	4. Assure orthopedic implant training modules are intact, and expand to include: selection of implant, verification of size, type, name, and laterality; have vendor workshops with testable objectives. See also 1, 2, and 2a.
			5. Lack of policy for dispute resolution.	**5. Include a policy that addresses proper procedure in the event of a dispute.**

Summary of Pulmonary Related Cases-Code 915 (Unexpected Death)

Category of Adverse Outcome	Subtype	#	Root Causes	Risk Reduction Strategies	Expert Comments Additional root causes risk, reduction strategies, and evidence-based literature support.
Thrombo-embolic events (22 cases)	Air embolism	1	1. CVL removed while seated 2. Pt was post surgery and RT to neck; compression difficult	1. Follow protocol which requires pts supine	This is a rare event but underscores the need to have patients supine when removing a CVL.
	Failure of prophylaxis	5	Not identified	Not identified	Perhaps SCDs alone are inadequate to prevent VTE in cases of pelvic surgery or when there is a pelvic inflammatory process. In some cases, despite what would be fully adequate prophylactic measures, several patients had fatal events.
	Failure of therapy	1	1. PE developed despite heparin for DVT 2. PTT never therapeutic; overweight patient	1. More timely application of heparin protocol	Most heparin policies don't adequately deal with the problem of dose adjustment for patients far in excess of ideal body weight. Perhaps that should have been examined for adequacy in this RCA.
	Failure to diagnose	9	1. Atypical presentation / vague sx 2. Overcrowding / patients left in ER for extended time 3. Not an expected diagnosis – i.e., low risk patient	1. Protocol to determine who is responsible for patients boarding in ER	The symptoms described are vague and the patients were truly low-risk. Most of the events were sudden and catastrophic. The real "Root cause" is that VTE can be elusive and a masquerader. This is really not a systems issue, although analysis of these cases identified things that could be improved in general, they were not relevant to the cases and would not have changed the outcomes.
	Failure to give prophylaxis	6	Not identified	Not identified	In all cases some sort of prophylaxis was indicated. The hospitals were unanimous in their unwillingness to apply current guidelines in determining the appropriateness

					of patients for VTE prophylaxis.
Aspiration (10 cases)	While feeding	2	1. Family fed patient; not observed	1. Family members may not feed patients w/o supervision	Lack of speech pathology evaluation / assessment for safe feeding / swallowing
	Undertreated ilieus / obstruction	3	1. Early signs of ilieus not recognized / treated. 2. Lack of communication of findings (obstruction) on XR to clinical staff 3. NGT had been removed in a patient with obstruction and not replaced after diagnosis was made	1. More aggressive management of early signs of ilieus 2. Improve communication between rads and clinical staff 3. Better communication among staff re: need for NGT	Difficult balance between patient comfort (no NGTs) and safety (NGTs help prevent vomiting). However in 2 of these cases there was clearly evidence that NGT was indicated.
	Post conscious sedation	2	1. Patient had history of problems with CS not known to staff 2. Different staff took history pre-CS (and may have known about potential problems) than did the procedure	1. Change pre-CS worksheet to ask more direct questions re: previous problems with CS 2. Schedule same OR staff for repeat cases	
	Feeding tube related	3	1. NGT inserted in lung; X-ray not reviewed (although it was THOUGHT that this happened) 2. Patient receiving TFs left ward with TFs running; not monitored	1. Review p/p for preliminary radiology reports 2. Hold TFs or send RN with patient when they leave unit	The cases of the NGT in the lung are grossly negligent. NGT inserted by RN, but no physician saw the Xray even though physicians were there while patients deteriorating. In one case they were assuming radiology would read the film for them; in another case it was "signed out." If you put in an NGT you must read the film (or find MD to do it for you if an RN).
Lab / Tests (3 cases)	Failure to communicate abnormal values	1	1. Wrong physician name on requisition 2. Primary care provider given inaccurate verbal report	Not clearly identified	Primary care MD name must be attached to all inpatients as backup. Positive cultures from a normally sterile body cavity should be a "panic value" and necessitate a telephone call to pt's MD
	Incorrectly interpreted tests	1	1. CXR misread as pleural effusion; patient died of CHF	Not clearly identified	

	Tests not ordered	1	1. Platelet count too low for procedure; had been OK 2 weeks prior	1. P/P change requiring tests within one week of procedure	
Monitoring (17 cases)	Asthma	3	1. Failure to recognize significance of hypercapnia on ABG in an acute asthma exacerbation. 2. Undertreatment of patient with asthma exacerbation / premature discharge by MD despite objection of RN (justified given lack of improvement shown by patient) 3. Failure to obtain ABG in ill patient with asthma exacerbation 4. Failure to give adequate discharge instructions (patient left w/o - ?if secondary to long wait)	1. Education of staff; suspension of treating MD 2. Reinforcement of backup policy and availability of ER director 24/7 to resolve differences 3. Education of staff re: need for earlier ABG and safe intubation technique 4. Not clearly identified – referred to committee	Education of staff important here. The case of undertreatment / premature discharge apparently was an example of the treating MD forcing RN staff to do what they didn't believe was correct and they either didn't have adequate backup or didn't know about it / use it. The patient who left while waiting for discharge instructions is an issue but unlikely related to the outcome (died at home within hours). There is some overlap here with the "oximetry" category in that in 2 cases the treating providers were misled by normal saturations.
	Disconnect from monitor or equipment	4	1. Patient disconnected from oximeter for transport; expired while in unit awaiting transport. 2. Oxygen ran out during transport; developed respiratory distress leading to death 3. Ventilated patient not adequately assessed when agitated; paralytic given instead – patient had self-extubated and died 4. Patient intubated and ventilated on floor	1. Change in policy that pulse oximeter is not to be disconnected until patient physically leaves the unit 2. Train transport staff in oxygen tank management and the emergency procedures if tank runs out, involve respiratory in all transports with oxygen 3. Education of staff on management of ventilated patients 4. Evaluate transfer process, evaluate ways to make ICU beds more available, education of nurses on ventilator management outside of critical care units	Patient transport from critical care units to testing areas is always a difficult issue. Transporters are not particularly skilled in patient care and the availability of nursing staff / respiratory staff to accompany patients is something that should be examined closely.

			waiting for ICU bed became disconnected and died while not being closely monitored		
	Intubation / difficult airway	3	1. Patient with difficult airway self-extubated; could not be reintubated (after three previous episodes) 2. Patient with epiglottitis deteriorated suddenly and could not be intubated 3. Patient with difficult airway could not be intubated when needed	1. Earlier consideration of tracheostomy given history of self-extubation; review of policy for securing ET tubes 2. Policy for patients with upper airway obstruction – need immediate eval by anesthesia in controlled environment 3. Focused on interpretation of ABGs and evaluation of respiratory distress rather than management of difficult airway	Hospitals should have policy for management of difficult airway including availability of emergency tracheostomy / cricothyroidotomy capability. Adult epiglottitis is truly an emergency; when the diagnosis is made the airway must be closely monitored much in the way the #2 identifies.
	Sleep apnea	2	1. Administration of benzodiazepines to patients who have OSA led to worsening of nighttime hypoxemia and death	1. More aggressive screening of hospitalized patients for OSA and caution with use of respiratory depressants in this population	This seemed to be an issue with psychiatry units / detox units where medical assistance / consultation may be less readily available. In both cases the need for benzodiazepines was real.
	Oximetry	6	1. False reliance on normal pulse oximetry resulting in delayed recognition of severity of illness 2. Patient weaning from ventilator, oximetry alarms not adequate, patient died without alarms sounding 3. Inadequate monitoring of ventilation during anesthesia (i.e., false reassurance by normal oximetry; fatal hypercapnea) 4. Inappropriate response to low saturation in patient with COPD and CO2	1. Education 2. Education on equipment, protocol for monitoring while weaning, how to effectively use alarms on current equipment 3. Education of staff re: oxygen requirements in different populations; changes in hospital oxygen policy especially concerning rapidity of adjustments 4. Education, enforcement of current restraint policy that mandated more frequent assessments of the patient. Some of this may have related to staff shortage	Pulse oximetry only measures oxygenation; patients can be in big trouble with normal saturations. The oximeter does not eliminate the need for ABGs in some instances. Hopefully the ability to measure pCO2 transcutaneously is not far away.

			retention; oxygen changed from 3L to 100% and patient died of CO2 narcosis 5. Agitated patient becoming hypoxic restrained and not reassessed frequently enough; found dead		
Unclassified (7 cases)	Death for unknown reasons	7	The lack of information given in the RCAs here precluded any root causes from being identified.	None identified	There were cases in which further information should have yielded root causes. The information contained in the RCAs was very poor quality and incomplete.

Summary of Medication Related Cases Code 915 (Unexpected Death)

Category of Adverse Outcome	Subtype	#	Root Causes	Risk Reduction Strategies	Expert Comments Additional root causes, risk reduction strategies, and evidence-based literature support
Anticoagulant and Thrombolytic agents	Excessive Dosage administered	4	1. Overdose of Lovenox in a small patient. Patient weighed 52Kg. Dosage of Lovenox is 1mg/kg of body weight. Patient was post-cardiac catheterization. 2. One patient received an excessive dose of Fragmin (dalteparin) after therapeutic substitution for Lovenox (enoxaparin) in OR. 3. One patient received excessive dosage of Refludan (lepirudin), a less commonly used medication. The patient had sensitivity to Heparin. Patient had reduced renal function. Lepirudin dosage not adjusted. 4. One patient on coumadin with sub-therapeutic INR reported. Coumadin 10mg administered and repeated 17 hours later. Patient became lethargic. Intracerebral bleed noted on CT scan. Patient became unresponsive and pronounced brain dead in 24 hours.	1. The pharmacy computer system has been adjusted to flag anticoagulant medications with the patient's weight. 2. Pharmacy computer system should have dosage parameters programmed. 3. Guidelines for the use and proper dosing of anticoagulants post catheterization to be developed. 4. Fragmin removed from OR pharmacy to prevent use. 5. Formal referral required for any patient prescribed Lepirudin. This will be indicated in the pharmacy computer. 6. Education program instituted. 7. Coumadin policy being revised to include more frequent assessment of PT/INR. 8. INR reference chart posted.	1. Dissemination of information on dosage adjustments for Lovenox (enoxaparin) to staff through pharmacy newsletter or formal education process. 2. High caution must be practiced to any therapeutic substitutions of anticoagulants such as the substitution of Fragmin (dalteparin) for Lovenox (enoxaparin). 3. Pharmacy system should be programmed to flag renal function when Lepirudin is ordered. 4. Revise policy addressing notification of panic values from laboratory. 5. Establish guidelines for anticoagulation induction including daily values for INR/PT. <u>Standard of Care</u>*: No. Preventable errors*
	Concurrent use of anticoagulants	2	1. Patient received Heparin and Lovenox concurrently for 2 days while also on Coumadin. Heparin solution borrowed to	1. All heparin premixed bags removed from floor. 2. New policy addressing notification of panic values instituted. 3. Nursing staff education	1. Protocols, guidelines, and standard order forms should prominently remind practitioners to assess all drug therapy (including ED) and avoid concomitant use of

			initiate infusion thus missing pharmacy review. Physicians not queried by nursing staff on triple anticoagulant therapy. Excessive loading dose of Coumadin given. Elevated INR of 6+ not communicated 2. Orders not sent to pharmacy due to this being a ED admission. Education to staff on concomitant use of anticoagulants not distributed.	4. INR reference chart posted. 5. Education on the concomitant use of anticoagulants. 6. Correction of the faxing of orders process to the pharmacy from the ED for patients admitted.	heparin products. 2. Establish an escalation P&P to guide staff when faced with improper or unsafe drug use. 3. Be sure that computer alerts for duplicate therapy have not been suppressed. **4.** Educate nursing on risks inherent in borrowing high alert medications from other patient's supplies. **5.** Education of staff of the concomitant use of anticoagulants should include the dissemination of the Institute for Safe Medication Practices (ISMP) alert (2/21/2001). *<u>Standard of Care</u>: No. Preventable errors*
	Drug Interaction	1	1. Patient on coumadin developed bronchitis and prescribed Bactrim through clinic. Significant drug – drug interaction with significant increase in INR. PT/INR not monitored for 3-5 days.	1. Coumadin policy being revised to include more frequent assessment of PT/INR.	1. Patients should be advised to fill prescriptions at one pharmacy to address drug interaction issues. *<u>Standard of Care</u>: No. Preventable error*
	Inappropriate use of thrombolytic	1	1. Activase (tPA) administered with elevated INR One patient presented to ED with left-sided weakness and atrial fibrillation. Patient was on coumadin. Patient had protime of 17.2 seconds and INR of 2.13. TPA administered with knowledge of levels. Patient also placed on Lovenox. Intracerebral hemorrhage within 48 hours. Staff questioned use of these agents but did not escalate situation.	1. Guidelines developed for use of TPA.	1. Establish an escalation P&P to guide staff when faced with improper or unsafe drug use. **2.** Communication of drug therapy administered in the emergency department must be accomplished and indicated as part of patient's therapy. 2. Be sure that computer alerts for drug interactions have not been suppressed. 3. Use protocols, guidelines and standard order forms to assure that current and recent drug therapy is considered before ordering, dispensing, and administering thrombolytic products. *<u>Standard of Care</u>: No. Preventable error*

Sedative/Hypnotics	Illegible Handwriting	2	1. Librium 100mg given versus 5 mg intended 2. Librium 25 mg given X 7 instead of Lopressor 25mg	1. Pharmacy computer interface for Pyxis system. 2. Pharmacy follow-up with physician on illegible handwriting.	1. Follow the 5 "R"s of medication administration: Right patient, right drug, right dose, right route, right time. 2. Formal policy on illegible handwriting should be implemented. *<u>Standard of Care</u>: No. Preventable errors*
Cardiac Medications	Excessive Dosage-Incorrect medication administered	4	1. Excessive dosage of two cardiac medications (Lisinopril and Carvedilol) administered to an acutely ill dehydrated elderly patient. Lisinopril given at an excessive starting dosage for condition of patient. Carvedilol dosage escalation in excess of manufacturers guidelines. Carvedilol prescribed BID. Patient received 2 doses of Carvedilol in less than 10 hrs. 2. Patient on Cardizem IV drip and Timentin. Pump intended to be adjusted to infuse Timentin. Instead 50mg of diltiazem infused in 30 minutes due to programming error. Pump alert indicating empty bag of Cardizem. Nurse hung new bag. Family of patient alerted nurse. Patient family alerted staff patient was dead 15 minutes later. 3. Patient on Cardizem IV drip and antibiotic. Pump intended to be adjusted to infuse Timentin. Instead 60 - 100mg of diltiazem	1. Pharmacy system to create a flag for Carvedilol orders. 2. Revise medication administration policy to reflect 10 hrs. between bid dosing. 3. Encourage use of specific pathways with dosing guidelines. 4. Triple channel pump will only be used in ED/CCU/ICU. 5. High-risk medication list to be created. They will be labeled as such on IV bags near where it enters the pump. 6. Exploring other multichannel pump manufacturers. 7. Implement medication pass procedure including flow chart that addresses process to ensure meds are secured in an emergent situation. 8. Plastic see through cups should be used instead of soufflé cup utilized during this med error. 9. Use technology- Pyxis system to assist nursing and pharmacy in reducing errors	**1. Follow the 5 "R"s of medication administration: Right patient, right drug, right dose, right route, right time.** 2. Standardize and control drug reference standards. 3. Establish an escalation P&P to guide staff when faced with improper or unsafe drug use. 4. Develop high risk medication list and label IVs as such. 5. Label lines or color code to distinguish medications. 6. Use technology such as Pyxis system to assist nursing and pharmacy in reducing errors. *<u>Standard of Care</u>: No. Preventable errors*

			infused. Pump alerted to empty bag. Patient assessed, asystole in 15-30 min. Triple channel pump used on unauthorized floor. Staff not educated on use. 4. Patient received Catapres 0.1mg that was not ordered. Nurse was distracted by urgent situation. Patient had history of HTN, CHF, DM, PVD, s/p pacer insertion. 45 minutes later BP dropped, fluid challenged transferred to ICU. Dopamine, narcan, and ACLS code without response. Patient also had recent change in cardiac medication to SR formulation		
General Anesthetics	Questionable use of medication	1	1. Use if Diprivan in an non-intubated patient for central line placement. Nursing staff and pharmacy questioned usage. Resident performing procedure did not have adequate training with central lines.	1. Sedation-analgesia and escalation policies have been revised to prohibit use of Diprivan in non-intubated patients. Education programs implemented.	**1.** Establish an escalation P&P to guide staff when faced with improper or unsafe drug use. *<u>Standard of Care</u>: No. Preventable error*
Liposomal Medication	Incorrect drug/dosage administered	1	1. Amphotericin B administered instead of Amphotericin B Liposomal. Resident ordered incorrect dose of Amphotericn B. Drug was obtained after hours of pharmacy operation with lack of familiarity of the medication. Two nurses did not notice the alert sign and warning sign that dosage is based on	1. The nursing administrator must consult with on-call pharmacist 2. Revision of existing P&P on medication administration with education programs and newsletters. 3. Utilize pharmacy warning stickers to alert professionals to look alike/sound alike drugs.	1. Do not store the two Amphotericin B products side by side. 2. Utilize pharmacy warning stickers to alert professionals to look alike/sound alike drugs. 3. Encourage prescribing of liposomal products using brand name. 4. “If you need more than three call the pharmacy” guideline should be an integral part of a hospital’s culture. 5. In order to preserve a

			body weight.		redundant check system, these products are best restricted to dispensing by a pharmacist after required preparation and labeling. Storage in patient care areas or automated dispensing equipment is discouraged. 6. Lipid-based products may be seen as "milky" rather than as a clear solution. Verify that the correct medication is Being used if staff, patients or family members notice a change in the solution's appearance from previous infusions. 7. Disseminate ISMP warning alerts such as 8/18/98 issue concerning lipid-based products. Medication errors have also resulted from confusion between liposomal doxorubicin (Doxil) and the conventional form of doxorubicin (Adriamycin, Rubex). This has also occurred with the liposomal form of daunorubicin (DaunoXome), daunorubicin citrate liposomal) and the conventional daunorubicin hydrochloride (Cerubidine). 8. Establish an escalation P&P to guide staff when faced with improper, unfamiliar, or unsafe drug use. <u>Standard of Care</u>*: No. Preventable error*
Electrolytes	Supplementation without monitoring	4	1. Elderly patient with hypokalemia receiving KCL supplementation for 5 days without monitoring. Verbal orders given for renewal of orders. Patient not seen by physician during 5 days. Peak K+ level of 8.9 reached. 2. Elderly patient with	1. Existing policy in effect requiring acute care patients be seen daily to be enforced. 2. Institute clear guidelines for the adequate coverage in a provider's absence. 3. Identified lapses in patient coverage will be reported to VP of Medical affairs. 4. Medical director for physician group to review policy for physician	1. Increase communication between Lab and pharmacy. with development of a safety net mechanism. 2. Concentrated KCL should be removed from nursing units. <u>Standard of Care</u>*: No. Preventable errors*

			hypokalemia receiving KCL supplementation without daily monitoring. No K+ values for 3 days. Patient experienced renal failure. Peak K+ reached 6.6 3. Elderly patient received KCL supplementation before level known. Patient had a K+ of 5.7 before supplementation. K+ level reached 7.9 4. Elderly patient given K+ Supplementation when level in normal range. Standard of care post op CABG required K+ supplementation for level below 4.0. Verbal order confirmed administration. K+ level reached 7.5	coverage 5. Establish guidelines for potassium supplementation including daily values for K+ to be ordered especially for patients with reduced renal function. 6. Review lab policy on reporting panic values (present panic value is 6.5) 7. Guidelines for ordering and administering potassium in the CTICU being reviewed. 8. Removal of concentrated solution from floor.	
	Communication failure	1	1. One patient received KCL supplementation after the wrong K+ value was reported. Value reported (2.7) was for a patient with a similar name.	1. Policy of communication to unit to be changed. Complete patient identification to be supplied including full name, unit, room etc. 2. Critical lab values policy to be revised. 3. Floor unit will coordinate phone results with computer printout before taking treatment action.	1. Increase communication between lab and pharmacy with the implementation of a safety net mechanism. <u>*Standard of Care*</u>*: No. Preventable error*
	Excessive dosage administered	1	1. K+ administered in a 10X overdose Infant given excessive dosage due to decimal point error. NP did not place decimal point correctly. Calculation error not identified in pharmacy or by nursing. Policy for preparation of KCL not followed. Pharmacy assistant	1. Pharmacy system programmed for maximum single doses by weight for several medications. 2. New pharmacy system to be installed and will interact with the electronic patient record and will have CPOE 3. Pediatric order sheet developed 4. KCL policies throughout institution consolidated and reconciled.	1. Establish an escalation P&P to guide staff when faced with improper or unsafe drug use. 2. Consider using color identification for pediatric order sheet. 3. Require all orders for high alert medications be doubled checked when ordered, dispensed, and administered. 4. Consider implementation of computerized physician order entry (CPOE).

			working beyond scope of practice when IV prepared. Pharmacy short staffing.	5. Pharmacy assistant policies to be enforced. 6. Additional pharmacy staff to be hired. 7. New policy requires all high alert weight based IVPBs to be doubled checked when ordered and again when administered.	*<u>Standard of Care</u>: No. Preventable error*
	Drug Interaction	1	1. K+ increased due to use of ACE inhibitor K+ level elevated 5.9 not treated. Patient discharged on Vasotec 5mg. Patient complaint of N&V just prior to discharge. Patient transported next day to ED from rehab with K+ of 7.6	1. Critical lab values policy to be revised. Review lab policy on reporting panic values. 2. Increase communication between Lab and pharmacy. with development of a safety net mechanism. 3. Establish guidelines for potassium supplementation including daily values for K+ to be ordered especially for patients with reduced renal function.	1. Pharmacy computer alerts should be active and attention should be paid to all alerts. 2. Ambulatory patients should be advised to fill prescriptions at one pharmacy to address drug interaction issues. *<u>Standard of Care</u>: No. Preventable error*
Narcotics	Excessive dosage administered	5	1. Morphine drip ordered at 2mg/hr. Patient received 86mg in one hour. Lock out function of pump not activated. Archived memory indicted Settings were changed 4 times in a two minute period. Patient was a cancer patient in severe pain with possible suicidal tendencies 2. Morphine ordered at 10mg/100cc @ 10cc/hr. Patient received 250mg/100cc @10cc/hr. Patient expired 3 hours later. Availability of multidose narcotic vial. Potential language/communication barrier. Nursing	1. Lock out function to be used on all pumps using controlled substances. 2. Process improvement related to identification of suicide risk. 3. Double check of settings on pumps utilized in oncology. 4. Removal of high potency multidose narcotic vials from patient floors. 5. Standardize dilutions of narcotic infusions. 6. MAR revised. 7. Pharmacy follow-up with physician on illegible handwriting. 8. Revision of existing P&P on medication administration with education programs and newsletters. 9. Encourage use of specific pathways with dosing guidelines.	1. Consider limiting preparation of narcotic infusions to the pharmacy department 2. Develop formal policy for pharmacy follow-up with all prescriber illegible handwriting. This policy should include escalation provision. 3. Encourage specific pathways with dosing guidelines. 4. Consider performing baseline blood level of Methadone upon admission. *<u>Standard of Care</u>: No. Preventable errors*

			shift to shift report inadequate. Faxed orders to pharmacy not verified. 3. Demerol 100mg/Vistaril 25mg ordered for a 75 y.o. given q2h vs. q4h. Patient medicated at 0600 and 0805. Found expired at 0915.Failure to follow P&P. Change of shift report did not include info on last dose. Medication orders not clearly written. Format on MAR had minimal spacing for meds given more than 4X per day. 4. Excessive dosage of Fentanyl utilized due to history of sleep apnea. 49 y.o. suffered hypoxia and cardiac arrest during surgery. 5. IVDA on methadone admitted for PCP pneumonia. Methadone program was called and stated patient received 6-day supply the previous day of which he stated he lost. Patient requested dosage of methadone and received 80mg methadone. Three hours later patient found unresponsive and no vital signs, coded and resuscitated. Narcan eventually administered. Patient died despite emergency treatment		
Antibiotics	Error of omission	1	1. 79yo with aspiration pneumonia prescribed Unasyn stat and Q6hrs. Doses not	1. Enforcement of pneumonia protocol. 2. Increase Communication between units.	<u>*Standard of Care*</u>*: No. Preventable error*

			given for 24 hours. Pneumonia protocol not followed. Nurse to nurse report or communication between ED and floor not accomplished.		
Chemotherapy	Incorrect dosage administered.	2	1. Methotrexate (MTX) ordered weekly and given daily for 9 days. Order incorrectly entered in progress note by attending physician. Methotrexate was not a restricted order drug when used daily. Patient also on prednisone for several days. Patient seen by several physicians including a pulmonologist during error period. Patient experienced respiratory failure on 9th day, intubated and transferred to ICU. Patient expired 3 days later with pancytopenia related to methotrexate toxicity. Methotrexate was not a restricted order drug when used daily. 2. Patient received Procarbazine earlier than delineated in protocol. In addition, patient did not receive adequate rescue for high dose methotrexate (MTX) administration. Inadequate documentation in patient's treatment protocol. Blood levels not drawn; test canceled by lab tech without proper notification. Patient	1. Policy to state that Methotrexate can only be ordered by hematology or oncology on a daily regimen. 2. Pharmacy computer system will flag methotrexate daily dosing.	1. Make sure to configure pharmacy systems to avoid defaulting to a daily dosing schedule. 2. Have a pharmacist conduct a prospective drug utilization review before dispensing oral methotrexate to determine its indication for use, verify proper dosing, confirm the correct dosing schedule on medication administration records and prescription labels, ensure staff and patient education, and promote appropriate monitoring of the patient. 3. Use preventive measures when dispensing methotrexate on an ambulatory basis. Perform mandatory counseling, including advising patients to contact their physician if they miss taking a dose. 4. Consider implementing automatic stop orders on methotrexate. *<u>Standard of Care</u>: No. Preventable errors*

			was transferred between rehab unit and oncology and treatment protocols not sent with patient. Oncologist did not seek out MTX levels prior to continuing administration of chemotherapy.		

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NYPORTS News & Alert

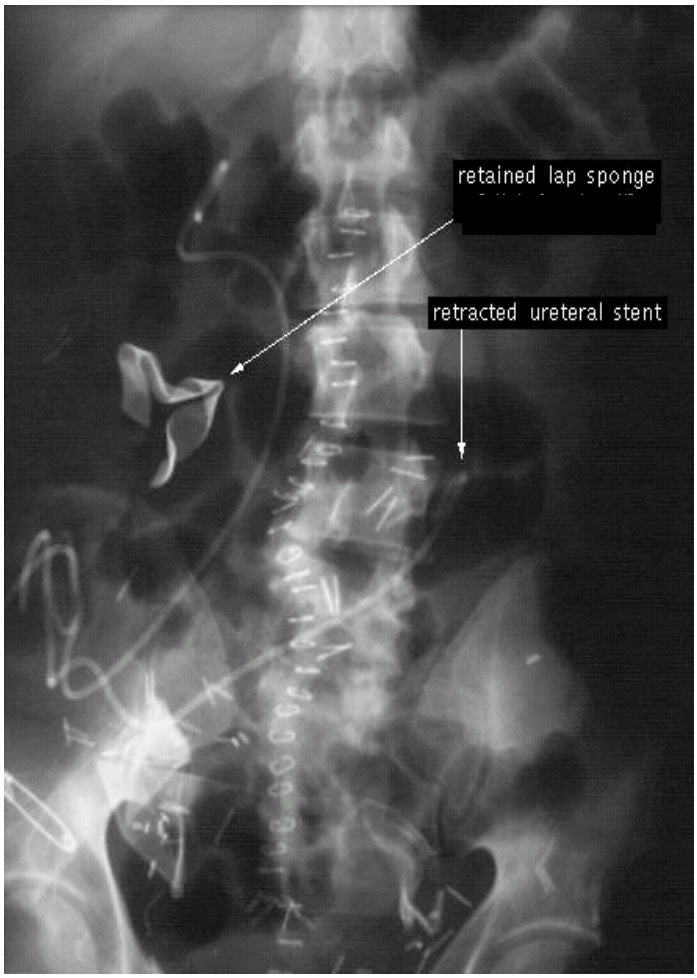
Department of Health, Issue 11 September 2002

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.

Continued page 3



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 assesssment 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

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.

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.

Retained sponge continued

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 an x-ray. While this is a widely used practice, it does not prevent the retention of surgical sponges. Although the use of x-ray is a standard diagnostic tool in locating a retained sponge or lap pad, there can be great variability in their appearance, leading to diagnostic misinterpretations. It may be helpful for facilities to maintain a collection of examples of the x-ray appearance of retained surgical sponges to assist the Radiologists/Surgeons with identification.

The Association of Operative Registered Nurses (AORN Journal Dec 1999) recommends that sponges be counted:

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

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

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

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

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.

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.

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.

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.