Assessing Hospitals' Use of State-Mandated Adverse Event Reporting Data

Final Report to the National Patient Safety Foundation

Kimberley Fox, M.P.A.
Amy M. Tiedemann, Ph.D.
Denise Davis Dr.P.H., M.P.A.
Joel C. Cantor, Sc.D.

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THE STATE UNIVERSITY OF NEW JERSEY
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EXECUTIVE SUMMARY

State-mandated medical error reporting in hospitals and other health care facilities has become common since the release of the Institute of Medicine's report *To Err is Human* in 2000. In 2002, Rutgers Center for State Health Policy conducted an exploratory study funded by the National Patient Safety Foundation to assess hospitals' use of state-mandated medical error and adverse event data in New York State, which has one of the oldest and largest state-mandated hospital reporting systems in the country. Based on semi-structured telephone interviews with over 100 administrative and clinical leaders from a stratified random sample of 20 hospitals throughout New York State, the study investigates hospital leaders' awareness and perceived purpose of the state-mandated reporting system, the process by which hospitals collect and use this data, the barriers to use, and perceived value by hospital leaders and its impact on patient safety. The study also sought to identify key factors that either facilitated or limited the use of data from the mandatory reporting system within New York State hospitals. This report presents the findings and highlights "best practices" for collecting and utilizing such data as well as barriers that may limit its usefulness.

Key Findings

Awareness and Purpose

- Most hospital administrative and clinical leaders are familiar with NYPORTS to some extent. However, the degree of familiarity varies considerably across position within the hospital hierarchy.
- Chiefs of surgery and pharmacy directors were least familiar with NYPORTS, despite the fact that a large number of NYPORTS-reportable incidents are surgery-related and pharmacy errors are a continuing area of concern.

- Awareness of reporting less serious adverse events to the state was far lower than for major events that trigger a root cause analysis (RCA).

Data Collection and Confidence in Data Reported

- According to administrative and clinical leader respondents, nurses and case managers most commonly report NYPORTS cases. Physicians are much less likely to report due, in part, to fear of concerns about potential punitive actions by NYSDOH.
- Three quarters of respondents were confident that most NYPORTS-reportable cases were being reported at their facility. However, many felt that the NYPORTS system failed to capture some important near-miss events that the hospital could equally learn from. In addition, respondents were less confident in the uniformity and comprehensiveness of reporting by other facilities.

Analysis and Response

- Most respondents indicated that they had participated in at least one root cause analysis (RCA) within the past year and nearly universally found the RCA process beneficial.
- Most commonly, RCAs resulted in modifications to policies and procedures, and in-house training programs to re-educate nursing and resident staff. Only a few hospitals had made monetary investments in response to an RCA.
- While many respondents understood that NYPORTS is intended to provide standardized data to compare performance with other hospitals, most hospital leaders were unaware that comparative reports could be generated from the NYPORTS online system. Those that were aware of them found them difficult to use. Nearly all respondents were familiar with aggregate annual state-level reports but felt that they were of minimal use.
- Few hospitals disseminated information on NYPORTS to all staff at the hospital.

Barriers to Reporting and Use

- Despite efforts by facilities to move towards a non-punitive "systems" approach to addressing medical errors, the primary barrier to reporting cited by nearly all respondents was that reported errors would be used for punitive purposes either within the hospital or by the state. Physicians were identified as most resistant to reporting.

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- The large majority of hospital leaders, especially clinical leaders, were sympathetic to physicians' concerns about external repercussions. The leaders believe that this concern is fueled in part by the mixed messages sent by the state including the requirement that physician license numbers be reported.
- Most respondents felt that the state had made a concerted effort to clearly define what cases should be reported, although some respondents still were unclear about which events should be reported.
- Many interviewees reported that hospitals could use more timely feedback from the state in the form of "best practices" and comparative error data.

Perceived Impact of NYPORTS in Improving Patient Safety

- The state mandate, while not always welcomed by these leaders, was generally credited with increased awareness and 'raising the bar' of accountability, which has helped leaders of quality departments garner resources.
- Some felt that NYPORTS had a chilling effect on error identification due to the close affiliation of this process with the professional oversight by the Department of Health.
- Most respondents found it difficult to identify a causal connection between modifications that may have resulted from a NYPORTS-related investigation and improved patient safety.
- Most respondents felt that RCAs were very helpful in fostering a systems-focused culture to investigate errors. However, most of the changes made as a result of RCAs were changes in policies, procedures and in-service education, which are largely process versus systems modifications.

Conclusion

This study, the first of its kind, suggests that state-mandated hospital adverse event reporting in New York has been successful in raising awareness of patient safety among hospital leadership and promoting investigative processes of serious medical errors that hospitals have found to be useful. However, hospitals do not appear to be utilizing much of NYPORTS adverse event data because of insufficient comparative data feedback and lack of confidence in event reporting across hospitals.

Although we set out to explore how hospital characteristics relate to NYPORTS use, we generally did not observe variations in patterns of use across hospital types. Our primary

findings instead demonstrate the influence that one's position in a hospital's administrative and leadership structure has for perceptions of this adverse event reporting system.

This study suggests that well-designed, state-mandated reporting systems can have positive impacts in raising awareness and accountability within hospitals, but also points to some barriers and burdens that designers of next-generation error reporting systems should address:

- New York's root cause analysis requirement for serious adverse events has been an important component of their state-mandated reporting system and appears to have had a positive impact on internal process improvements within hospitals. States that choose to mandate error reporting should require similar investigative processes.

- Clear distinctions should be made between the state's regulatory oversight function and adverse event reporting for patient safety improvement.

- States need to dedicate more resources to providing timely feedback to hospitals and disseminating "best practices".

- It may not be possible to achieve comprehensive, consistent reporting of adverse events for comparative purposes. States should concentrate on mandating reporting for those events that result in the greatest harm (i.e. where root cause analyses are required).

- Mandatory adverse event reporting may be insufficient to spur hospitals to invest in effective but costly means of error reduction, such as automated systems and greater staff resources. Direct financial incentives to support such interventions may be an important adjunct to mandatory reporting.

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Introduction

State-mandated medical error reporting in hospitals and other health care facilities has proliferated since the release of the Institute of Medicine's report *To Err is Human* in 2000. As of October 2003, 21 states had some form of mandatory reporting for hospitals or health care facilities[1]. Congress has also introduced several bills addressing patient safety and mandatory error reporting[2]. As regulators of medical facilities, state and federal governments have mandated reporting of medical errors and adverse events in order to protect the public's health. By requiring facilities to report errors, policymakers believe that greater attention will be paid to the issue, and facilities will utilize this information to modify internal systems, thereby reducing the prevalence of errors over time. Though mandatory reporting laws have the potential to be useful instruments for improving patient safety, little is known about how hospitals utilize adverse event information internally, and whether mandatory reporting results in system changes that reduce errors or improve patient safety.

In 2002, Rutgers Center for State Health Policy undertook an exploratory study in collaboration with the Healthcare Association of New York State and funded by the National Patient Safety Foundation to assess hospitals' use of data from New York's mandatory adverse event reporting system. The New York Patient Occurrence Reporting and Tracking System (NYPORTS) is one of the oldest and largest state mandated hospital reporting systems in the country. The purpose of the study was to assess hospital clinical and administrative leaders' awareness of this well-established mandatory reporting system and their knowledge of how the data are collected and used internally to improve patient safety. We also sought to identify specific hospital characteristics or leadership attributes that contributed to greater use of the data or to patient safety improvements that resulted directly from increased awareness of errors.

Collecting data alone does not necessarily lead to institutional change. By understanding how clinical leaders and administrators utilize adverse reporting systems, this study seeks to inform the design and development of mandatory error reporting

systems in New York and other states. This report presents the findings of our analysis, highlights 'best practices' for collecting and utilizing such data, and identifies barriers that may limit the usefulness of reporting mandates.

History and Description of NYPORTS

With nearly 30,000 events reported annually, New York's mandatory hospital reporting system is often cited as one of the most comprehensive adverse event reporting systems in the country and a model worthy of replication. Mandatory hospital incident reporting was first introduced in New York State in 1985 in conjunction with tort reform (New York State Public Health Law Section 2805-1, Incident Reporting). The NYPORTS internet-based software system currently used by hospitals was implemented by the New York State Department of Health in 1995 as an offshoot of earlier versions of mandatory paper-based and email reporting. NYPORTS was created in response to criticisms of previous systems that did not allow feedback to hospitals, which limited the use of the data for quality improvement.[3] The new system was designed "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 those patterns with other facilities in the region and the State."[4]

In contrast to most error reporting systems which only require the reporting of incidents that result in serious injury or death, NYPORTS requires hospitals to report both serious medical errors and adverse events to the Department of Health. For the purposes of NYPORTS reporting, an "occurrence" is an unintended adverse and undesirable development in an individual patient's condition, while the patient is in a hospital or health care facility.[5] To develop objective criteria and clear definitions of what should and should not be reported, the state collaborated with the state hospital associations and convened a statewide workgroup of industry and clinical experts and consumer representatives. This iterative process culminated in a detailed list -- known as the includes/excludes list -- which the state has provided to all hospitals to assist them in determining what is NYPORTS-reportable (see Appendix A).

While hospitals are required to report all adverse events that fall within these definitions, they are only required to conduct internal investigations into the systems of care for the most significant adverse events (NYPORTS '900' codes), which include wrong site surgery errors, unexpected deaths, and equipment malfunctions that result in serious injury or death.[6] These investigations, known as root cause analyses (RCAs), must

identify root causes for such events and lead to systems improvements and back-up 'fail-safe' procedures to prevent reoccurrence.[7] Once completed, the hospital is required to monitor the implementation and effectiveness of these improvements through quality assurance activities. Compliance with proposed corrective action is monitored through the state survey process. The Department of Health also directly investigates a portion of the most significant occurrences.

In contrast, for adverse events that are not serious errors or do not result in serious harm, the law is less prescriptive about how hospitals should use this information. For these incidents, for example cases of post-operative wound infections or falls resulting in fractures, hospitals are required to fill out a shorter form and submit the data to the state. According to the first annual NYPORTS report, the collection of adverse event data is intended to be a "tool to reduce medical errors," and, "through proper usage of the NYPORTS system and process, hospitals are aided in improving the safety of patients." To help hospitals identify areas of improvement on which to focus, the NYPORTS software provides hospitals access to a comparative database of similar institutions in the state or region so that they can benchmark their performance against their peers. The identity of reporting hospitals remains confidential and institution names are not mentioned in the comparative reports. According to the state's annual NYPORTS report, the Department also provides alerts to all hospitals in the state regarding areas of significant concern, and shares 'best practices' through a quarterly newsletter to prevent or reduce occurrences in other facilities. The state also convenes regional consortia that meet periodically to share best practices and review aggregate data.

Study Purpose

The purpose of this study is to investigate how hospitals use NYPORTS data and whether they are using it to reduce medical error and/or improve patient safety as intended by the state. The study also seeks to assess why some hospitals may be more likely than others to use the data, by identifying hospital characteristics or existing internal conditions that appear to support meaningful use of NYPORTS. For example, information systems, such as adverse event reporting, however well designed, are not likely to be successful without support from the leadership of the organization and a culture that supports learning from mistakes. Therefore, one factor that we considered was the degree to which hospitals with clear leadership commitment and strong patient safety cultures were more likely to use NYPORTS for patient safety improvement. For

hospitals that are using NYPORTS, we sought to identify lessons learned that might help other facilities use the data more appropriately. For hospitals that do not utilize the data, we sought to understand why, by identifying the barriers that limit the data's usefulness.

Research Questions

This study seeks to answer the following questions:

1. Awareness and Perceived Purpose – To what extent are hospital leaders and staff aware of NYPORTS? What do hospitals believe the purpose of NYPORTS to be?

2. Data Collection and Perceived Quality of Collected Data - How are hospitals collecting the information reported in NYPORTS, and how confident are they that all incidents are being reported?

3. Analysis and Response – How are hospitals using information derived from the mandatory incident reporting system as a basis for patient safety improvements?

4. Barriers to Use and Resource Costs - For those that use the data minimally or not at all, what are the barriers or limitations that prevent using adverse event data to identify areas for system improvement?

5. Perceived Effectiveness in Improving Patient Safety - How is use of NYPORTS integrated with other quality assurance activities? How do hospital leaders judge the value of NYPORTS relative to these other sources of data? What impact has NYPORTS had on improving patient safety?

In analyzing the responses to all of these questions, we sought to identify patterns and trends across hospitals and within hospitals to determine what factors predict greater use of mandatory incident reporting systems to improve patient safety.

Methods

This study utilized a two-stage qualitative research design. The first stage involved exploratory case studies of hospitals identified by industry representatives as leaders in patient safety. The second stage, on which the reported findings are based, involved semi-structured telephone interviews with administrative and clinical leaders from a stratified random sample of 20 hospitals across the state.

Case Studies

The purpose of the case studies was to identify promising practices for using NYPORTS in a broad set of hospitals across the state, and to field-test and refine our

interview protocol. The case studies also allowed the research team to identify clinical and administrative leaders within the hospitals that are most likely to benefit from NYPORTS, and to identify hospital characteristics to be used for stratifying the stage two random sample. The case studies were conducted in the spring of 2002 at three hospitals, which varied by size, teaching status, and geographic location. We conducted on-site visits to each of the hospitals and conducted interviews with eight to ten administrative and clinical leaders in each facility.

Based on the findings from the case studies, the research team narrowed the list of leaders to be interviewed in stage two to six department leaders who should be knowledgeable of NYPORTS and were likely to benefit from utilizing NYPORTS data for patient safety improvement. These are the Vice President (VP) or Director of Quality Improvement/ Assurance, Director of Risk Management, Medical Director or VP for Medical Affairs, VP of Nursing, Director of Pharmacy, and Chief of Surgery. Based on the case studies, we chose not to include the CEOs or Board Members in the list of leaders to be interviewed in the second stage. Where we were able to talk with a CEO and/or Board member, we found that these interviews yielded minimal return beyond what we learned from other leaders about CEO and Board involvement in the NYPORTS oversight and analysis process. Thus, we modified the interview protocol to include more questions about CEO and Board involvement, and assessed the involvement of top leaders through the responses of other administrative and clinical leaders.

Hospital Sample and Recruitment

Based on a review of the literature and our case study observations, we identified hospital characteristics that have been associated with variations in error reporting to stratify our sampling frame. As a result, the sample was stratified based on public or non-public, teaching or non-teaching, and geographic location within New York State. Hospitals with fewer than 50 medical or surgical beds and specialty hospitals were excluded from the sample.

The number of randomly selected hospitals within each stratum was determined by the relative size of the stratum and the overall desired sample size of 20 hospitals. New York City public hospitals were oversampled to ensure adequate representation of public hospitals, the majority of which are in New York City. To ensure a sufficient sample frame (assuming that some hospitals might refuse to participate), we contacted a total of 38 hospitals.

Invitational letters were mailed to the CEOs or Executive Directors of sampled hospitals, and follow-up phone calls were made to further explain the study and ask for the hospitals' participation. In the letter and subsequent conversations, the hospitals and individual interview respondents were guaranteed confidentiality. In the event that a hospital in the initial sample of 20 facilities refused to participate, we drew from the backup list of hospitals in its sampling strata. In sum, as shown in Table 1, of the 30 eligible hospitals that were contacted by phone[8], three did not respond, and seven hospitals declined to participate, resulting in a participation rate of 66%. The primary reason for refusal to participate was inadequate time. Some hospitals indicated that they were undergoing financial difficulties or structural reorganizations, while others gave no specific reason. Within strata, refusals were most frequent among hospitals based in New York City.

Table 1: Contacted Facilities and Response Rates

Letters mailed to Main and Back-up Sample Hospitals	38
Hospitals not Called to Participate because Sampling strata filled from Initial List	5
Hospitals Called and Deemed Ineligible	3
Eligible Hospitals Called to Participate	30
No response	3
Declined to participate	7
Participating Hospitals	20
Response Rate of Contacted Eligible Facilities	66%

For each participating facility, a member of the research team worked with an administrative representative to coordinate telephone interviews with the staff. While we attempted to include administrative and clinical leaders with similar responsibilities across hospitals, due to variations in job titles and responsibilities, the number and type of respondents varied somewhat across hospitals. The research team sought to interview four to six respondents per facility resulting in a total of 104 interviews in the 20 hospitals across the state. Table 2 delineates the number of participating facilities by strata, and Table 3 shows the number of respondents within participating facilities by job title.

Table 2: Participating Hospitals by Sample Strata

Hospital Type	Number in Sample
Public	3
NYC Non-Public	3
Other Urban (non-NYC) Teaching	3
Other Urban Non-Teaching	4
Suburban Teaching	2
Suburban Non-Teaching	2
Rural	3
TOTAL HOSPITALS	20

Table 3: Participating Respondents by Job Title

Job Category	Number in Sample
VP or Director of Quality	17
Risk Manager/VP for Regulatory Affairs	17
Medical Director/VP of Medical Affairs	20
Director of Nursing/VP of Patient Care Services	20
Chief of Surgery	13
Director of Pharmacy	17
TOTAL RESPONDENTS	104

Among clinical and administrative leaders, surgeons were the most difficult to reach and had the lowest participation rates primarily due to scheduling difficulties and lack of time. One surgeon, of those who we were able to contact, refused to participate due to concerns about confidentiality.

Interview Protocols and Administration

The interviews were approximately 45 minutes to an hour in length and included questions that reflected the study domains of Purpose and Awareness of NYPORTS;

Quality of Data Collection; Analysis and Response; Barriers, Limitations, and Resource Consumption;, Perceived Effectiveness including integration with other quality and patient safety activities. We also asked questions about leadership and organizational culture related to patient safety. See Appendix A for a full copy of the survey instrument. All phone interviews were audio taped, and notes were transcribed.

Participants were informed that responses would be kept confidential, and that neither participant nor hospital names would be identified in any released results. To encourage candid responses, all respondents were given the opportunity to request that the audio tape be turned off for answers to particular questions or for the entire interview.

Data Analysis

Notes from the 104 telephone interviews were entered into an electronic database and the audio tapes were used to fill in any gaps. The notes were imported into NVivo, a qualitative data analysis program, and respondents were categorized according to job title, as well as structural hospital characteristics, including ownership (public/private), region of the state, teaching status, hospital size, and whether the hospital was part of a hospital system based on self-report.

We then categorized and coded the responses to all questions in the eight domains by common themes and subthemes. The themes were developed by a consensus approach, with three researchers reviewing responses to questions within each domain and developing a typology of themes to be shared and agreed upon. The data were then coded by theme and verified by another member of the research team.

We analyzed the coded data in aggregate and by hospital and respondent characteristics. Information for the hospital level analysis was derived from responses from the various hospital leaders who were interviewed at that facility. Because we interviewed leaders from various departments, some of whom were more likely to be aware of the hospitals' policies and procedures than others, there was not always consensus among respondents in the facility. Therefore, in our presentation of findings we are careful to attribute conclusions to particular administrative leaders or groups and only to the hospital as a whole when consensus existed across respondents.

In addition to structural characteristics, another means for stratifying the sample for analysis was developed. Based on our coding of the interview data, we divided hospitals into three patient safety culture categories – "strong," "in transition," and "weak" -- as measured by consistency of responses within hospitals to specific questions regarding

leadership and organizational culture. We coded all references to the institutional patient safety culture, descriptions of the leadership's commitment to patient safety, and all mentions of punitive/non-punitive hospital atmospheres (primarily from Questions 5,6,7 in interview protocol. See Appendix B.) Three research team members reviewed all references for each hospital until all agreed into which category each hospital should fall. These categorizations are based on our grouping of the qualitative responses of all the administrators and medical leaders interviewed within a hospital, which we did not attempt to verify with written hospital policies and procedures. This perceptional measure reflects the degree to which hospital patient safety policies and procedures are known by key leaders in the facility, are integrated into the hospital culture and are perceived as critical to the functioning of daily practice.

Hospitals categorized as having a strong patient safety culture had an obvious leadership commitment to patient safety that was consistently identified across respondents in that institution. These institutions had a high-ranking individual program champion, a leadership team focusing explicitly on patient safety, evidence of a non-punitive environment (e.g. anonymous reporting, involving staff in developing solutions to errors), and/or specific patient safety committees. The following quotes are from individuals in institutions we categorized as having a strong patient safety focus and are representative of comments from staff in other hospitals in this category.

> I joined the institution at the right time and was able to help promote
> the non-punitive medication error reporting process. I got support from
> Nursing and Medical staff so we started a non-punitive system, which
> was a huge challenge because we had a punitive system in place. It was
> like if you do something bad it goes to your personnel file and it was a
> point system and eventually you get terminated. With that system in
> place, we didn't get any reports, very few, until we started a lot of
> education. We worked with Institute for Safe Medication Practice and
> had speakers come here 3 times. We did a lot of education and
> seminars and then we implemented it. We came along way and on
> average we now get about 150 medication related events reported,
> which is a huge turnaround. This was a big step that we took and I
> believe it's worth it in the long run. We are identifying a lot of problems.

Some of them we have addressed, some we will identify in the future
and invest resources. So the culture has changed.

This is the most thoughtful, intellectual environment that I have ever worked in.
People will go the nth degree in an RCA to figure out what the problem is, much
more so than in other hospitals I've worked in. Patient safety infiltrates the
institution and there are multiple portals for information to flow about safety
issues. Patient safety and reporting are totally institutionalized.

Hospitals categorized as having weak patient safety cultures generally did not have
specific patient safety committees, had punitive systems (e.g. still using negative point
systems for medication errors), and had a distant leadership presence in patient safety
initiatives. The quotations below are from staff in hospitals with a weak patient safety
focus.

I am more systems oriented and see errors as systems related. I have
been educated on this message but I don't see the same attitude from
my hospital or the state.

Our system is NOT non-punitive and the leadership are not on board
with the non-punitive message. They still seem like they are out to get
individuals.

The staff do not have a thorough understanding of the issue of errors. A
cultural change is still needed.

Finally, hospitals categorized as in transition had either made a full commitment to
patient safety practices but only recently, or were in the very early stages of moving from
a punitive culture toward one that was more systems-focused. Again, provided below are
some examples of hospitals in this category.

We are making a concerted effort to develop a blame-free system but
we are not completely there yet. We are a culture in transition.

The staff have not been able to cross-over yet [to trusting that system is blame-free]. They are still afraid of being reprimanded for errors and afraid of repercussions.

The long term staff are slower to change because they are from another culture. But they are coming around. It comes down to a selling job in nursing and pharmacy by the administration. There was a lot of opposition when our variance reporting system was first introduced because people didn't want to deal with more paperwork. The administration had to explain that reporting would save more time in the end due to error prevention. Now the staff are beginning to understand.

As shown in Table 4, based on these criteria, half of our sample hospitals met the conditions of having a strong patient safety focus; one fifth had a weak focus; and the remainder were in a period of transition. Hospitals in our sample with strong patient safety cultures tended to be more likely to be teaching hospitals, located in an urban area, and of medium or large size, while those with weak or transitional patient safety cultures tended to be in small hospitals. Those in transition also tended to be non-teaching hospitals.

Table 4: Sample Hospitals by Patient Safety Focus

Hospitals in Sample	Patient Safety Focus		
	Strong	**Weak**	**In Transition**
Total	10	4	6
Teaching	8	2	1
Non-teaching	2	2	5
Rural	1	2	0
NYC	5	0	0
Other urban	2	1	5
Suburban	2	1	1
Small	1	3	3
Medium	5	1	2
Large	4	0	1

Findings

Awareness

In response to a close-ended question, "How familiar would you say you are with the NYPORTS incident reporting system: very familiar, somewhat familiar, not very familiar, or not at all familiar," most respondents reported they were very or somewhat familiar with NYPORTS, but the degree of familiarity varied by job title. Respondents who were directly responsible for administering NYPORTS (either Director of Quality or Risk Manager/VP of Regulatory Affairs) were most likely to claim to be very familiar with NYPORTS and often demonstrated knowledge of specific reporting codes. Medical Directors or the VPs of Medical Affairs and the VPs of Nursing also tended to be very familiar with NYPORTS although less familiar with the details of what is NYPORTS-

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reportable except in their clinical areas.   In contrast, while most Chiefs of Surgery related that they were aware that a mandatory occurrence reporting system existed in the state, only three claimed to be very familiar with NYPORTS. This lower awareness is somewhat surprising since many NYPORTS-reportable incidents are surgery-related. One notable exception was a Chief of Surgery who had used NYPORTS in an educational course as a platform for teaching residents how to trend surgical adverse event data.

Table 5: Familiarity with NYPORTS by Administrative/Clinical Position

	Very Familiar		Somewhat Familiar		Not Very/ Not at All Familiar	
Job Title	**#**	**%**	**#**	**%**	**#**	**%**
Director of Quality	12	71	5	29	0	0
Risk Manager	13	76	2	12	2	12
Director of Nursing	11	55	8	40	1	5
Medical Director	11	55	9	45	0	0
Director of Surgery	3	23	9	69	1	8
Director of Pharmacy	1	6	11	65	5	29
TOTAL	51		44		9	

As a group, the Directors of Pharmacy were the most likely to say they were not aware of the existence of NYPORTS and had very little exposure to specific information about the system. Those who said they were familiar with the system indicated that NYPORTS had limited usefulness, because it only requires medication errors to be reported if they result in permanent patient harm (a patient death or near-death event), which are rare occurrences. Most pharmacists said they are much more interested in tracking more common, less serious medication errors and adverse drug reaction events for internal quality improvement. Thus, many had developed their own data systems, which provide them with more detailed information on medication-related adverse events than NYPORTS. In fact, we found that the Directors of Pharmacy are among the most data savvy of the administrative and clinical leaders with whom we spoke, and regularly track and trend data to identify potential problems. Many of the pharmacists also

participate in the Institute for Safe Medication Practices, a national, voluntary pharmacy error reporting system.

Overall, among respondents who are familiar with NYPORTS, the degree of familiarity varies. Many more respondents reported that they are familiar with the serious adverse events that trigger an RCA, and far fewer are aware of the less serious events that require no specific investigation but are reported for trending purposes.

In addition to asking respondents about their own knowledge of NYPORTS, we asked them to speculate about familiarity among the broader hospital staff. The vast majority of respondents reported that they believe the "rank and file" are probably not very familiar with the term "NYPORTS" as distinct from their hospitals' existing occurrence reporting systems or departmental data. The exceptions are nurses and case managers who are specifically responsible for capturing NYPORTS data and have received NYPORTS-specific training.

Not surprisingly, participation in an RCA increased awareness of NYPORTS. Respondents reporting the greatest familiarity had all participated in an RCA in the last year. RCA meetings provide a means for staff with marginal exposure to NYPORTS to learn more about its purpose. While most hospitals usually limit participation to staff directly involved with the incident or managers/directors of those divisions, some hospitals, try to pull as many staff as possible into the RCA process or have an open-invitation policy that allows any interested staff member to attend the meetings. One Director of Quality told us:

> We try to include as many staff in RCAs as possible. For example, nurses aides, board clerks, anyone remotely involved is invited, so they can see that we are looking at ways to improve the system. Also, people who do the work know how to fix it and have great ideas so their presence in RCAs is important.

In addition to increasing awareness of mandated reporting requirements, the hospitals have found that RCAs increase cooperation among departments and decrease resistance to reporting, because staff can see the non-punitive, systems approach applied in the process. These findings will be discussed in more detail in the section on use of NYPORTS data.

Data Collection and Perceived Quality of Data Collected

Empirical research indicates that medical practitioners' perceived usefulness of error reporting is strongly associated with the level and accuracy of reporting.[9] Thus, we asked respondents about the quality of reporting as an indicator of usefulness.

As shown in Table 5, responsibility for collecting and reporting NYPORTS data falls to either the quality or risk management divisions in the facilities included in our study, with more than half assigning it to quality activities.

Table 6: Methods of Identifying NYPORTS-reportable Incidents

	# of Hospitals	%
Department Responsible		
Quality Department	12	60
Risk Management	8	40
Primary Identification Method		
Occurrence Tracking	11	55
Concurrent Chart Review	5	25
Phone Call in Combination with Occurrence Tracking	3	15
Chart Review with Review of Discharge/ Other Data	1	5
Identification Methods – Any Use		
Occurrence Tracking	20	100
Chart Review	20	70
Phone Call	14	70
Discharge or Other Data	15	75

While the state provides no standard mechanism or guidance to hospitals for identification of NYPORTS-reportable cases, we found that hospitals primarily reported using one of four methods to identify incidents that are reportable to the state. As shown in Table 5, 70% of hospitals either rely solely on their pre-existing occurrence reporting

systems to identify NYPORTS cases, or they use these systems in combination with telephone trees.

Prior to the introduction of NYPORTS, all hospitals had some form of internal occurrence tracking or incident reporting system, many of which require both a paper report as well as entry into an electronic database for sorting and analysis. The definition of what is reported through internal occurrence tracking systems varies. Some hospitals only require staff to report serious deviations from "standard of care." Others encourage staff to report any incident perceived as involving a mistake or staff misconduct. In both cases, hospitals are actually using a broader definition of "reportable" events for their internal occurrence reporting than is proscribed by NYPORTS. Thus, hospitals have used this broader set of incidents to identify those that meet the more narrow definitions of what is NYPORTS reportable.

A few hospitals indicated that they rely equally on their occurrence tracking systems and phone calls to their Quality or Risk Management staffs. One hospital had actually developed an anonymous automated phone prompt system that acts as its occurrence tracking system. Staff can call the occurrence tracking phone number at any time to report an incident, which is recorded in an electronic database by the Quality Improvement office. Respondents in this hospital reported great success with the anonymous call-in system, and universally felt that it had resulted in increased reporting.

Many fewer hospitals (6) reported using concurrent medical chart reviews as their sole method of identifying NYPORTS incidents or in combination with a retrospective review of discharge data. Some of these hospitals specifically assign a staff person the function of reviewing charts specifically to identify NYPORTS-reportable incidents on an ongoing basis. Others fold this responsibility into the job descriptions of existing case managers who regularly review charts for other purposes. Some hospitals implemented innovative ways of using medical records to find NYPORTS cases and to gain better knowledge of procedures occurring at the facility. For example, one hospital began a "surgery of the month" chart review, where each month all the charts of patients who have a specific surgery are pulled for quality improvement purposes and examined to identify NYPORTS cases that may have been missed.

Medical chart review is very resource intensive. All but one of the hospitals that reported using chart review as a primary mechanism for capturing NYPORTS cases are small or medium sized facilities that have fewer cases to review. However, administrators in these hospitals are confident in its accuracy. As one Quality Director said:

> With the system that we have in place, with our concurrent review
> process, where we are daily reviewing our admissions and our charts, it
> almost becomes a safety net to identifying a NYPORT, because 99.9% of
> the time, we've already identified it before I see the incident report.

Other hospitals, several of which had been identified as "low reporters" by the New York State Department of Health, have conducted retrospective chart reviews as a secondary method for identifying incidents that may have been missed through the occurrence reporting method. A few hospitals, after discovering many more cases through retrospective chart review, opted to move to concurrent chart review as their primary method for identifying NYPORTS rather than continuing to rely on occurrence tracking. Hospitals have also used discharge data and other hospital records as back-up sources to identify NYPORTS cases. In addition to reviewing ICD-9 codes in discharge data, some hospitals inspect the operating room logs, examine all charts for any returns to surgery, and analyze all mortality/morbidity and infection control reports. Respondents in many hospitals said that they have instructed medical records staff to search for NYPORTS cases during the course of routine coding and examination of hospital records and reports. Several respondents suggested that reviewing medical records separately, solely for the purpose of capturing NYPORTS-reportable events, would be inefficient and excessively time-consuming, as many of the cases would have already been identified by other means.

All of the hospitals in our sample used at least two, if not all, of the above methods to capture state reportable events. Hospitals characterized as having a strong patient safety focus were the most likely to be using all of these case identification methods in some capacity. Of the hospitals that only used two methods, both had a weak patient safety focus according to our categorizations. No hospital that we examined, however, appears to put equal emphasis on the methods that they use. That is, every facility appears to rely heavily on one or two of these methods.

Who Reports NYPORTS Cases?

Theoretically, according to respondents in all the hospitals in our sample, anyone within these organizations can identify and report NYPORTS events to the appropriate departments. In reality, nurses, either staff or nurse managers, most frequently report cases through their incident reporting systems, and case managers/medical records staff

find cases in the charts or other records. In all instances, staff who identify adverse events, whether state-reportable or not, are required to call or notify their designated superiors or department heads, or fill out incident reports, depending on the particular hospital's system. Once an event is reported, the responsible department often conducts follow-up with staff involved in the event to gather more information and to complete both internal and state-mandated reports.

According to respondents, physicians are the least likely of all staff to report adverse events. This is mainly because, within most hospital quality improvement processes, physicians are not expected to be the primary reporters of adverse events; this responsibility most frequently lies with nurses. Physicians are encouraged by administrators to report any events that they are involved in or aware of, but the ultimate responsibility for reporting is rarely theirs. Most respondents also attribute low reporting among physicians to fear of a punitive response from the hospital or state, or the belief that reporting is unnecessary and ineffective. Physician perspectives on reporting will be discussed in more detail in the Barriers section of this report.

Training

While every hospital indicated that it had both formal and informal mechanisms for training staff about NYPORTS, the level of training varies considerably by type of staff. Staff members directly responsible for reporting adverse events within the hospital receive the most training. Formal training includes training exclusively on NYPORTS from the New York Department of Health, which is usually limited to supervisors or individuals within the departments responsible for NYPORTS reporting in Quality Management or Risk Management/ Office of Regulatory Affairs. Hospitals have also developed internal training to educate staff responsible for identifying NYPORTS cases in patient charts, primarily nurses, case managers, and/or medical records staff. In addition, many hospitals provide some NYPORTS training to management personnel so that they can recognize cases reported to them, oversee reporting by their departments, and assist other managers in reviewing and deciding on the reportability of events.

Formal training of hospital-wide staff not directly responsible for NYPORTS is usually limited to new-hire job orientation sessions and annual in-service quality education courses. A few respondents also mentioned that they reviewed NYPORTS in continuing medical education courses. For example, one hospital includes a question on NYPORTS on its annual nurse exam.

Staff nurses are commonly trained on what and how to report into their hospital occurrence tracking systems, but not necessarily to identify which cases are NYPORTS. The perspective of the individuals in our sample is that most staff nurses know that NYPORTS exists, or, even if they do not know the name "NYPORTS," they at least know that a state mandated adverse event system exists. However, they do not tend to know any more detailed information about its workings. The primary concerns of hospital management seem to be that staff understand and comply with their responsibility to report internally any adverse events that they witness or hear about, regardless of whether those events fall within the narrow definitions of incidents that are reportable to the state.

Hospitals are much less likely to provide NYPORTS-specific training to physicians, although some hospitals did indicate that some NYPORTS information is included in new-hire orientation and annual in-service materials. Pharmacists are the least likely of all hospital staff in the sample to receive formal or informal training in NYPORTS. In general, the Directors of Pharmacy were the individuals in our sample most likely to say that they and their departmental staff had received no training and were not exposed to NYPORTS information on a routine basis. Although, as stated earlier, in spite of this lack of exposure, many Directors of Pharmacy have developed their own systems to track medication data and errors.

Confidence in Data Reported

The majority of respondents (77 or 74%) were very confident that most NYPORTS-reportable events are being reported in their facilities. Respondents from small, non-urban hospitals indicated that medical errors are relatively rare, and, when they occur, all staff would be aware of them, and they would be reported. A few respondents in hospitals that had previously been identified by the state as under-reporters felt that they were now overcompensating and potentially even over-reporting to err on the safe side.

Several leaders indicated that recent audits conducted for the state by the Peer Review Organization had yielded very few cases that their hospitals had failed to report, suggesting that their methods of identifying NYPORTS-reportable cases are fairly thorough. The high level of confidence in reporting may be the result of heightened efforts to improve reporting; many facilities indicated that, in the past year, they had developed more complex in-house verification systems to increase the frequency of reporting. The confidence that we detected could also be related to the fact that many of these respondents are accountable for hospital reporting systems in their facility and thus

they may have a desire to convey that their hospitals are meeting regulatory requirements.

The 25% of respondents who reported being "somewhat.", "not very," or "not at all" confident that all NYPORTS events are being reported attributed their doubts to a continuing culture of fear and resistance to reporting, despite efforts by their hospitals to promote non-blaming cultures. Others are very confident in the accuracy of reporting major events, but are also concerned that less serious events or near-misses are often overlooked or not reported. As one Medical Director put it:

> I am very confident that errors are reported, but there are a lot of bad things that happen in hospitals that are not reportable because they are near-misses, and there is no reason to report those, even though you can learn a lot from them. And since the system is so punitive, I don't think there is anyone that would go out of their way to report those…but we talk about them internally through word of mouth.

Risk managers, medical directors, and pharmacy directors, in particular, were more likely to lack confidence in the data, because they had access to other data sources such as discharge records, patient charts, or operating room logs that allow them to check what events are being reported. As one medical director stated:

> I never feel really confident…you're always afraid that something is passing by or you're missing it. What makes me lose confidence is from time to time, we hear about something we didn't know about and that's upsetting.

Respondents who are less confident that all adverse events are being reported tend to be concentrated in five or six hospitals, primarily in those that were categorized as having a weak patient safety culture or those under relatively new leadership and still in transition.

Analysis and Response – How Hospitals Use NYPORTS Data

Hospitals vary in how they utilize the NYPORTS data. For many hospitals, their efforts seem to concentrate primarily on getting the number of adverse events reported to

a level that meets state requirements. In 1999, the state issued letters of reprimand to hospitals that had lower than expected errors reported. In response, many hospitals focused on averting potential financial penalty by increasing case reviews to identify more incidents that should have been reported to NYPORTS, rather than determining how best to utilize the data within their organizations. With the exception of performing RCAs, deciding how data can be used internally for patient safety improvement is often a secondary consideration to maximizing reporting.

Perceived Purpose

Since users' perceptions of the goals and purposes of collecting and analyzing data have an impact on whether and how they utilize the data, we asked hospital leaders to describe the purpose of NYPORTS collection and use within their organizations. While many respondents cited more than one purpose, the purpose most commonly mentioned was: to meet the state mandate. More than half of all respondents identified fulfilling the regulatory requirements of the state as the primary purpose for collecting NYPORTS data. Within this group, two thirds also identified some additional, beneficial internal purpose. These benefits fell into the following categories: 1) to conduct systematic RCAs to identify why errors occur and correct them, and/or 2) as an additional source of data to track trends for performance improvement.

For example one Vice President of Nursing at a public hospital said:

> When we have a NYPORTS report where we think that we have some
> issues that we need to look at, we do a root cause analysis, and we look
> to see if it was a system problem versus a person problem, and if so,
> what can we do to prevent this event from occurring again. We do it
> not only because it's a requirement by the state, but because it's good
> practice.

Others saw NYPORTS as another source of data that their hospitals could utilize with their existing occurrence tracking and other data systems to track trends. Said one respondent:

> We try to look at it as not just an oversight mechanism by the state, but
> as a way of trending occurrences within the hospital, and we have

actually been using some of the data to [identify trends] and then
focusing in on those areas to start performance improvement
initiatives.

Nonetheless, approximately one fifth of all respondents said that they see the state mandate as the only purpose, and indicated that NYPORTS offers no additional value to their existing internal data collection for quality improvement. Overall, at least one person from each hospital said that the purpose of their hospital's collection of NYPORTS data was only to meet state requirements. Somewhat surprisingly, these respondents and those who said NYPORTS offered no additional value, were as likely to be from hospitals with strong patient safety cultures with fairly sophisticated internal data systems as from those with weak or transitional cultures. In general, these respondents felt they already had strong internal tracking and monitoring mechanisms in place prior to NYPORTS. For example the following are quotes from two Chiefs of Surgery, the first from a strong patient safety culture hospital and the second from a one with a weak patient safety focus.

Our hospital has been collecting this data for years and all NYPORTS
does is add another classification scheme for complications. Nothing
beyond that.

There is not a great deal of difference from the existence of NYPORTS.
Our own [occurrence tracking] system is more detailed. Physicians just
get annoyed from NYPORTS.

Cited purposes also varied somewhat by administrative leaders. As we found with the general awareness of NYPORTS, pharmacy directors were generally less clear on the purpose of NYPORTS, in part because they utilize other data sources. Risk managers also were more likely to indicate that NYPORTS serves no purpose beyond the state mandate, as they often said that their existing systems provide sufficient data to track and trend internally.

The half of respondents that did not explicitly mention the regulatory requirement in describing the main purpose for NYPORTS focused instead on the opportunity that the system affords to investigate system problems. Most of these respondents were identifying the theoretical purpose behind the development of NYPORTS more than its actual use in practice. For example, approximately one quarter of respondents identified

the desired purpose of comparing their performance with other hospitals. Although they see great potential value in having the state standardize the way errors are reported, so that hospitals can benchmark themselves with other hospitals, most indicated that they have not seen any data from the state.

Internal Process Improvement through Root Cause Analyses

When hospitals report serious adverse events, they are required by the state to conduct RCAs. Until recently and at the time of our interviews, New York State's form and procedure for RCAs differed from those required by the Joint Commission for Accreditation of Healthcare Organizations (JCAHO),[10] but were similarly designed to replicate the series of steps and decisions that led to the occurrence of an error in order to identify system failures. Most respondents said they are familiar with this process, and most had participated in at least one RCA. For those who are familiar with them, nearly all feel that the RCAs are a very useful mechanism for uncovering system problems for patient safety improvement.

Many leaders indicated that the RCAs, more than the reporting of errors themselves, promote a non-punitive, problem-solving systems approach, which increases trust by staff that the focus is on systems improvement, not individual blame. Some hospital leaders also suggested that the extent of staff involvement in developing system changes for patient safety influences compliance with new procedures and willingness to report adverse events. When staff feel that they have input into potential organizational changes, they become more committed to patient safety practices in general. As one Vice President for Regulatory Affairs explained:

> I believe we have successfully shifted the culture. Am I satisfied? No, I'll never be completely satisfied, but when I first started people were afraid to report the errors. But now they know that I am really on their side because I oversee the Root Cause Analyses and the whole quality program. They see that I'm really looking to improve care and mitigate any mistakes before they affect patients.

In fact, leaders in nearly every hospital indicated that they found the RCA process so beneficial that the hospital had elected to conduct RCAs for some events even when they were not mandated by the state. The process for determining which non-mandated events merit RCAs is usually left to a senior management team. Most hospitals elect to

conduct RCAs for near-misses that have occurred within their hospitals, cases that were similar to incidents reported in the press or identified through JCAHO Sentinel Event Alerts at other hospitals, or at a department head's request. Several hospitals also indicated that they use RCAs for events that involve multiple departments. Others conduct RCAs much more liberally, even for minor staffing issues and medication variances in order to get staff involved and to change the culture from one of blame to systems improvement.

Participation in and leadership of RCAs differs across hospitals. For the vast majority of hospitals, RCAs are led by a member of the senior leadership team, most commonly the Vice President or Director of Quality, Regulatory Affairs, or Risk Management, but often also by the relevant department chair. The RCA process varies in terms of who participates. Some hospitals limit participation to those directly involved in the incident. Others interview the staff directly involved but have other senior members of the department conduct the RCA. Still others try to invite all staff who could potentially contribute to the RCA meetings, even if they did not directly witness or were not otherwise related to the incident, particularly for RCAs on non-serious events. For example, one Director of Quality said:

> We do root cause analyses for small events too, and because of this I
> think that the staff are beginning to see the 'process' focus and the lack
> of punishment that comes out of it. We try to include as many staff in
> the RCAs as possible. We invite nurse's aides, board clerks, anyone
> remotely involved, so that they can see we are looking at ways to
> improve the system. Also, the people that do the work know how to
> fix it. They have great ideas so their presence in RCA meetings
> is important.

To assess how RCAs have resulted in system changes, we asked respondents about the three most significant RCAs that had occurred in the last year and what system changes had been made as a result. The significant adverse events that hospital leaders identified varied considerably across hospitals, but primarily fell within the groupings of deaths or near-miss events related to medication errors, patient identification errors (including wrong site, wrong procedure, and wrong specimen), errors related to delays in treatment either in the emergency department or in delivering blood or lab results, or

unexpected events such as maternity complications or psychiatric-related incidents. Within hospitals, the different department leaders interviewed tended to cite the same events as the most significant. Interestingly, many of the RCAs deemed most significant by leaders were for events that were not NYPORTS-reportable, but the hospitals decided to conduct investigations independently.

The most commonly reported changes that occurred, due to RCAs conducted for either NYPORTS or other events, were changes to policies and procedures. These included changes in medication records, storage and dispensing; clinical pathways and treatment protocols; communication between departments; supervision of residents; and documentation such as multiple sign-offs and double checking to ensure appropriate patient identification. More than half of the hospitals have also instituted in-service or other training programs to re-educate nurses or residents. Far fewer hospitals made monetary investments to purchase new equipment -- most commonly automated medication dispensing systems – or to increase staffing. For example, one hospital had been considering computerizing its medication management system, and, after an adverse drug event, it was able to garner the resources to automate.

Table 7: Selected Examples of Internal Procedural Changes Resulting from Root Cause Analyses

Wrong medication to wrong patient	• Revised procedures so two nurses check that medications are in the correct drawers • Piloting a one-day cart fill rather than two • Pharmacy notifying nurse managers when reconciliation not received from the floors
Interdepartmental Communication Breakdown	• Piloting multidisciplinary progress note
Wrong Site Surgery	• Three persons must verify the site • Revised check sheet for verification of site • Medical staff leadership met with surgeons to comply with new verification procedures
Missing Medications	• Moved to non-cart system with Pyxis machines
Blood clots resulting in death or other complications	• Implemented web-based DVT risk assessment upon admission

Comparing Performance with Peers

While New York State officials repeatedly stress the importance of NYPORTS in providing standardized data by which to compare hospitals' performance with their peers, hospital leaders were largely unaware that such data were available. While the NYPORTS software has the capacity to generate comparative reports for hospitals, only a few respondents were aware that these online reports exist, and even those who are aware of the reports have rarely used them due to difficulties in accessing them. All leaders interviewed lack familiarity with these reports, even those who are directly responsible for gathering and reporting NYPORTS to the state.

Most respondents had only seen aggregate state-level reports that focus on reporting prevalence and under-reporting by hospitals, which most respondents feel has minimal usefulness, except to confirm that reporting varies widely by hospital. In fact, given reporting disparities across hospitals, many of the more data-oriented respondents questioned the value of external comparisons with their peers. Because data standards vary among institutions, they are not confident that peers are reporting at the same level as themselves. Others indicated that there are too many differences among hospitals to make comparisons, particularly since the data are not risk-adjusted. A few hospital leaders were particularly concerned about the state using NYPORTS data for publicly released hospital report cards given the unevenness of reporting and lack of comparability. For the most serious errors, many respondents also noted that the infrequency of these events makes it difficult to use this data for comparison or for tracking and spotting patterns. As one Medical Director stated, "Until you can ensure uniform reporting, benchmarking is ludicrous."

Of the few hospitals that reported using comparative data, most are located within networks or systems. These hospitals share data at network meetings, and do not rely on comparative reports available through the NYPORTS reporting system. Even comparison within networks varies widely. Highly centralized networks uniformly share data, and utilize NYPORTS with other data available for quality improvement and comparing best practices. Other more decentralized hospital systems that are loosely affiliated or newly formed, do not share data but occasionally share 'best practices' based on the experience of one hospital within the network.

Tracking and Trending Adverse Events through NYPORTS

As indicated above, all hospitals had pre-existing occurrence reporting systems that many had already been using for quality improvement efforts and to track adverse events. For many of these hospitals, particularly those that have strong patient safety cultures, the use of NYPORTS adverse event data only provides marginal additional value. Risk/Quality Managers have mostly relied on this data to verify/double-check other systems that are already in place or as another supplemental source of data.

Staff Education – Dissemination of NYPORTS

While some hospitals do disseminate information on errors to their staffs, few, if any, specifically identify them as NYPORTS. The most frequently mentioned method for disseminating information on NYPORTS across hospitals is through regularly scheduled staff or committee meetings, for example, Quality Improvement, Patient Safety, or individual departmental meetings. The specificity of information distributed depends on staff responsibilities in relation to NYPORTS. For example, non-management staff may only be told the purpose of the system as an impetus to report, while management may review and discuss the number of NYPORTS cases in monthly meetings.

Hospitals also rely on bulletin board postings, newsletters, email messages, memos, and websites to disseminate quality improvement news, including general NYPORTS facts. Some hospitals post the includes/excludes list on all unit bulletin boards for reference, or distribute copies of newsletters received from the Department of Health to each department. As mentioned above, hospitals also rely on in-services as forums to periodically educate or update staff about NYPORTS.

The release and discussion of specific details on the most serious NYPORTS cases at hospitals are commonly limited to RCA meetings and management level patient safety or quality control meetings. However, there is some variation in how openly management shares RCA details with staff. Several hospitals define RCA information as confidential data that cannot be shared even with other hospital employees, while others distribute specific RCA examples to justify and support system changes. Hospitals are most likely to disseminate details about the occurrence and causes of sentinel events to all staff, if widespread system level changes result from the cases. A theme voiced by many leaders was that staff are more receptive to change in routines if they know why changes are being made and can associate them with particular adverse events.

Keeping Leadership Informed

While NYPORTS dissemination to hospital staff varies significantly across hospitals, most hospitals regularly share NYPORTS data along with other data sources with their Boards or through their Quality or Performance Improvement Committees. Many hospitals indicated that results from all RCAs are shared with their Boards and that discussion of these events is a standing item on their Board agendas.   While the Boards are informed of all significant errors, they are less likely to be directly involved in the decisions to implement system changes, which are more commonly decided by Vice Presidents. Leaders at the CEO and Board level do not appear to participate regularly in RCAs, except at a few of the smaller hospitals.

Barriers to NYPORTS Reporting and Use

To assess whether there are barriers to reporting NYPORTS data, we asked a series of questions related to potential barriers. Specifically, we asked about how reporting errors and adverse events are perceived by leadership compared to clinicians and staff. We also asked distinct questions about potential barriers for reporting and using the data to improve patient safety.

Continuing Culture of Fear

The primary barrier to reporting is a continued fear on the part of staff that reporting errors would be used for punitive purposes either within the hospital or by the state. Despite reported efforts by most facilities to move away from cultures of individual blame, most leaders feel that staff still perceive reporting as punitive in nature. Physicians, in particular, are perceived by hospital leadership as resistant to reporting due to concerns about losing their medical licenses, facing other sanctions or fines by the state, or being reprimanded, fired, or severely penalized by their hospitals. In addition, physicians fear litigation associated with errors, are embarrassed by admission of mistakes, and are worried about potential negative effects on their professional advancement or loss of peer respect. Generally, many leaders believe that physicians are unconvinced of the "systems approach" model. The following quotes from various respondents demonstrate reasons for reluctance to report among hospital staff:

> I think the main barrier is the physician fear of reprisal and malpractice.
> I think the same barrier might be within the division of nursing, fear of

reprisal. But as I said to you we never do any of this in a punitive manner. But it's still a perception; it's a hard perception to overcome.

Physicians get defensive. They don't see errors as an opportunity [for improvement]. It is a great challenge to get physicians to see the forest through the trees.

Although in many instances, leadership describes the NYPORTS process as non-punitive (promoting a systems approach culture as opposed to one focusing on individual error), many administrative and clinical leaders acknowledged that cultural change takes time and that they are still in a period of transition.   This perception was equally evident in hospitals categorized as having strong patient safety cultures and those categorized as having weak patient safety cultures. Discussions with hospital leadership uncovered a common struggle in achieving and maintaining cultures that are blame-free. One leader said, "The [non-punitive] words are in place from the administration but the staff doesn't believe it. I believe we have underreporting of errors because of fear." Another risk manager from a hospital we defined as in transition to a strong patient safety culture stated that "staff are still concerned with the issue of what is being reported and where it is going." Changing physician and staff perceptions about the punitive nature of their systems, as well as providing confidence (encouragement) to report, is an ongoing process of education and re-education within institutions.

While physicians were most commonly identified as resisting reporting due to potential negative ramifications, nurses and pharmacists also share some of these concerns as reported by leadership. Nurses vary in their level of incident reporting based on the philosophy, training, and emphasis placed on this issue by hospital administration. Many hospital administrators indicated that resources for ongoing staff training are limited, and additional efforts to market the concept of reporting as a system advantage are required to ensure staff participation in the process.

Despite these concerns about reporting, most respondents (as indicated above) seemed fairly confident that most incidents are being reported. If this perception is correct, it raises the question of whether physician buy-in is needed if other staff are reporting. In fact, as noted above, the vast majority of events are reported by nurses.

State Perceived as Punitive

The vast majority of hospital leaders, and clinical leaders in particular, were sympathetic to physicians' concerns about external repercussions, and believe that this concern is fueled in part by the mixed messages sent by the state. At the same time that the state markets NYPORTS as non-punitive, the state Department of Health requires facilities to report license numbers of individual physicians responsible and sometimes forwards this information to the New York State Office of Professional Medical Conduct (OPMC) for disciplinary action. As stated by one Assistant Director of Quality:

> The state is sending mixed messages and this requires Risk
> Management to counsel people to be cautious. This also feeds into staff
> reluctance to report.

A Pharmacy Director who was more familiar with the non-punitive voluntary medication errors reporting systems concurred that the threat of disciplinary action has a chilling effect on reporting:

> I think in New York State, the fact that those incidents can still be used
> against those professionals on a punitive basis is part of the dichotomy
> here. We still have to report to the office of professional discipline
> when there is an error which gets into punitive issues. That's a bad part
> of the mandatory reporting in New York.

Given that the state had publicly released information profiling physicians and their malpractice rates at the time of our study, there was heightened concern that the information reported in NYPORTS may later be used in physician profiles.[11] In addition to the recent release of physician report cards on the web and the sharing of data with OPMC, respondents cited several other significant barriers to reporting including union contracts within New York hospitals specifying progressive disciplinary systems and malpractice litigation.

Lack of Clarity on What Should be Reported

In an effort to standardize the types of cases to be reported in the NYPORTS system, the New York State Department of Health has provided definitions for cases to be included in the 900 coded (serious) events as well as the short form (non-serious) events. For added clarification, examples of cases to be excluded from each list are also provided. In June 2000, the Department made further system improvements including improved definitions of reportable events, increased reporting requirements regarding medication errors, and a revised, more detailed definition manual.[12]

To assess whether definitions of NYPORTS-reportable cases are clear, we asked clinical and administrative leaders whether they believe that the state's includes/excludes list clearly defines which cases should be reported for serious and non-serious events. Responses were mixed. Approximately half of the respondents reported that the state has clearly defined expectations of what cases should be reported. Many of these respondents indicated that this clarity had not been true in the past, but that the state was making a concerted, ongoing effort to improve and refine the definitions. However, several respondents felt that, while definitions are clearly defined, they are also unrealistic. One surgeon described NYPORTS as "using a shotgun approach ….collecting everything under the sun without appropriate usefulness of each."

Approximately one quarter of respondents indicated that definitions are still unclear, difficult to use, repetitive, and time consuming. In particular, many respondents feel that the state leaves a lot to interpretation, particularly for the events that result in serious harm (900 codes) for which facilities are required to conduct RCAs. Respondents believe the lack of clear definitions may have resulted in both over-reporting and under-reporting. The remaining quarter of respondents did not know the definitions well enough to comment on their clarity.

For non-serious events, many of the study respondents indicated that definitions are even less clear, leaving much to individual interpretation. Although the state has recently revised the includes/excludes list in an effort to be more specific, administrative managers as well as executive medical personnel continue to find issue with the codes, and have recommended that the Department of Health improve its manual by more clearly addressing ambiguous areas. As one medical director articulated:

> It is less clear for the non-900 codes as to what actually constitutes an
> occurrence. As you know, the Commissioner was concerned that not

enough was being reported so we increased our sweep at that point
and are now probably counting things that we previously did not
consider occurrences.

Table 8: Examples of NYPORTS Events Identified as Requiring Greater Definition

SERIOUS MEDICAL ERRORS (900 CODES)

➢ Unexpected adverse occurrence not directly related to the natural course of the patient's illness or underlying condition resulting in: death, cardiac and/or respiratory arrest, loss of limb or organ, impairment of limb or loss or impairment of bodily functions (915).
➢ Cardiac and respiratory arrest requiring intervention (916)
➢ Loss of impairment of bodily functions present at discharge or for at least two weeks after occurrence if patient is not discharged (919)
➢ Error of Omission resulting in death or serious injury related to the patient's underlying condition (920)
➢ 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 actually termination of telephone, electric, gas, fuel, water, heat, air conditioning, rodent or pest control, laundry services, food or contract services. (933)

ADVERSE EVENTS (000-800 CODES)

➢ Fluid overload leading to pulmonary edema (302).
➢ Cardiac arrest with successful resuscitation within 48 hours (603)
➢ Death (include ASA class if the procedure involves general anesthesia or conscious sedation).(605)
➢ Procedure-related readmissions including those related to injury repair, organ removal, or organ manipulation, hemorrhage or hematoma requiring drainage; wound repair; post-op would infection repair; unplanned operation or return to the OR (800s)

There was also some confusion about whether hospitals need to report incidents into NYPORTS that they had reported to another state surveillance system, such as the cardiac reporting system or the state perinatal database. A few respondents also felt that it was difficult to translate NYPORTS into ICD-9 codes. If the state would provide a list of comparable ICD-9 codes, considerable time could be saved and more could be drawn

from medical records. Overall, many respondents felt that the codes could be streamlined and that a shorter but clearer code list might be more effective. For example, one interviewee told us:

> There are too many codes in NYPORTS. The state should narrow list to 5 or 10 events, this would be more effective to track and trend and then after a few years change the set of codes. This would create a strong focus for patient safety initiatives

Lack of Timely and Meaningful Feedback from State

Respondents also indicated that timeliness is another barrier to using NYPORTS data. The need for real-time data and a synopsis of the types of incidents being reported are examples of information being requested by hospital personnel. Respondents also complained of "not much feedback from the state" once the NYPORTS data were collected and reported to the Department of Health.   Further, a variety of respondents indicated that consistently sharing more information in a timely fashion, in the form of safety bulletins or a quarterly newsletter, would prove more useful to hospitals than just prevalence rates. As indicated above, many respondents were not very familiar with the comparative reports, and thus did not use them to compare their performance with their peers.

Resource Costs

To assess the potential costs of reporting, we asked respondents to estimate the costs that hospitals incur to maintain the NYPORTS system. In addition to the cost of the software and hardware, most hospitals felt that the NYPORTS system had increased costs by increasing the number of full time employees needed for data entry and case finding, particularly case managers and nurses, who are already in short supply. Others mentioned the increased paperwork, training time, administrative meetings, and management hours devoted to deciding whether cases are reportable events. The system also creates the need for re-training when there is position turnover, or when new medical residents are established.

In short, many respondents described NYPORTS as an unfunded mandate that is a drain on overstretched hospital resources. Some hospitals have invested in software to support electronic medical records, computerized physician order entry systems,

medication barcoding, and automated unit dose systems to promote quality improvement and to ease reporting burden associated with NYPORTS. One respondent explains:

> No one is under the assumption that does save us anything. It costs
> money. Mandated programs are unfunded but they cost personnel and
> other costs.

Our respondents also identified the time costs associated with RCAs as particularly high. While leaders support the RCA process, they also acknowledge that it is costly given the amount of time required and the number of clinicians and hospital leaders involved. On average, hospitals estimate that RCAs require a minimum of 6 to 8 hours. Most respondents indicated that they regularly, if not always, participate in RCAs, as did many other high level clinicians and administrative managers. Thus, their estimates under-represent the actual time invested in RCAs, since participation on other committees or task forces are frequently required as part of the process.

Another theme emerging from our discussion of resources and costs of NYPORTS with hospital leaders is that NYPORTS can act as a drain on system resources during a period of staff shortage and declining reimbursement. As a Chief of Surgery stated:

> To generate this data, it requires more staff and that staff requires a
> salary, so that's a nonproductive investment in the health care system. I
> would rather have 2 nurses than 2 people looking at data.

In addition, no respondents were able to identify any cost savings achieved from specific interventions changed as a result of NYPORTS.

Many hospital respondents also noted duplication of reporting as a continuous drain on institutional resources. Due to reporting requirements, hospitals often find that they are reporting the same events to both the JCAHO and the New York State Department of Health (NYSDOH), which places additional strain on already limited resources.

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Perceived Impact of NYPORTS in Improving Patient Safety

Respondents were divided on the value of NYPORTS and its impact on patient safety. Approximately half of respondents indicated that the state mandate had increased accountability and thereby increased the level of awareness and attention. Many of these respondents acknowledged that, without NYPORTS, fewer people were likely to report voluntarily:

> You need a system that requires you to report to a regulatory body. If you don't have that, then staff get lax. It definitely helps our department [risk management] to get reports from staff. It gives them an incentive because it is state reportable.

Although some respondents credit NYPORTS with motivating clinicians to report, others, as mentioned above, feel that it has had an opposite affect due to the close affiliation between NYPORTS and the professional oversight bureau of the Department of Health. As one risk manager described:

> The mandate is a double edged sword. Maybe hospitals wouldn't report, so in that way it is good for things to be mandated. But the way it is handled is the issue. If there is always a stick out there, are we doing it because of the stick or because it is the right thing to do?

In terms of the effect on reducing errors, most leaders feel that there is no way to measure the effect, nor is there likely to be over time, given the dilemma of inconsistent reporting across facilities and reporting inflation in order to meet state targets. As one Vice President of Medicine indicated:

> I don't think we've seen the results to actually say that errors are going down because of NYPORTS. I don't think we have enough data to actually suggest this has happened yet. As a matter of fact, if anything, the numbers have gone up because we're looking for more of them, reporting is improving. You can't correlate that with NYPORTS

reducing errors. We can't make a judgment now what effect it has had
in medical error prevention.

As indicated above, hospital leaders who had participated in RCAs nearly universally found this process to be helpful both in identifying potential solutions to avert these events in the future and in creating a culture of systems improvement.

To identify whether RCA-related changes have reduced errors over time, we asked hospital leaders how they measured the impact of those changes and whether they had seen any reduction in errors. Since all hospitals are required by the New York Department of Health to monitor corrective actions for one year after implementation, many leaders – particularly those responsible for quality assurance -- indicated that they had conducted compliance audits to monitor process changes. However, many leaders acknowledged that measuring compliance is not synonymous with measuring impact, which many feel is difficult to do given the infrequency of these occurrences. While many leaders monitor whether there are repeat cases, they recognize that it is difficult to attribute non-reoccurrence to process improvements. As one risk manager explained:

We evaluate if the process changes have taken place but not their
impact on patient safety. This is too hard given the small number of
cases. We're taking a leap that by changing the process you minimize
the risk of that event.

A few leaders said that sustained monitoring over time is also limited due to resource constraints. As one quality director explained, "The problem with limited resources is that too much is spent on the front-end."

Even fewer leaders indicated that they had measured the impact of changes resulting from analyzing adverse event data. As indicated above, many hospitals do not use the NYPORTS data for this purpose, relying more heavily on other data systems such as pharmacy-specific data or occurrence reports.

There were a few cases where leaders saw measurable changes, but many were the result of tracking pharmacy incidents in the hospitals' occurrence reporting or pharmacy-specific data systems, not necessarily those reported through NYPORTS. Many of these changes were in hospitals that had strong patient safety cultures. One medical director said that her hospital saw significant results from increased education on use of insulin

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and insulin derivatives, reducing the number of hypoglycemia cases from a higher than average level (compared to what they had identified in the literature) to none for a six month period. A pharmacy director in another hospital that had gone to a cartless medication dispensing system tracked the changes in missing dosages over time, and saw a decline from 65-70 missing dosages per month to fewer than 10.

Nonetheless, most leaders were hard-pressed to identify a causal connection between changes resulting from either RCAs or from internal tracking and trending of adverse events and error reduction. In contrast, one medical director in a hospital that has a strong patient safety culture and had implemented bar-coding and automated medication dispensing independent of any NYPORTS event felt that these moves had significantly reduced error rates, but they cost a significant amount of money to implement. As he explained:

> We love the bar coding and the Pyxis system, but it costs a lot of money to do those things. When you find a wonderful system like that there should be a state incentive to support hospitals upgrading their technology, so you can improve care without having a disaster first.

Value of NYPORTS Relative to Other Data Sources

Most respondents indicated that NYPORTS is one of many data sources used by their hospitals for patient safety or performance improvement. Many of the hospitals are involved in national data collection efforts, such as the Maryland Indicators project, which allow them to track and trend their performance relative to their peers nationally. While these data sources do not focus on errors, they are seen as a valuable source of information to prevent error by improving quality of care.

The perceived value of NYPORTS relative to these other data sources varied. As the primary people responsible for data collection and reporting, Quality Directors and Risk Managers appear to use NYPORTS the most. In contrast, pharmacy directors rely on other sources of information that help them identify near-misses in order to avert problems in the future.

For the less serious errors, most respondents reported a preference for using their internal occurrence tracking systems as opposed to NYPORTS, because they tend to be more comprehensive and include much more near-miss information. Most leaders estimated that NYPORTS events represent less than 5% of the incidents that their

hospitals report on their own occurrence tracking systems. However, many leaders do concede that NYPORTS has improved reporting on their occurrence tracking systems by increasing awareness toward patient safety.

Potential Improvements

Dissemination of Best Practices and Coordination with JCAHO

Many respondents suggested that the Department of Health and the JCAHO join forces to devise a common reporting system.[10] However, many respondents acknowledged that this would be difficult to achieve without agreement on the intent, which many indicated was more punitive on the part of the state. Many respondents found JCAHO more cognizant of what is going on within hospitals and mindful of where the big problems exist, as evidenced by the sentinel event alerts that JCAHO produces and disseminates.   In general, study respondents find these JCAHO Sentinel Event Alerts very helpful, underscoring the interest in best practice information to improve organizational performance. As one quality director noted

> JCAHO alerts are valuable because they put together a panel of experts
> who ask hospitals for risk reduction strategies and review the literature
> for other strategies and then distribute this information to hospitals.
> This is very helpful and I believe this was the original intent of
> NYPORTS but I haven't seen anything like this yet. You read about best
> practices in the paper before you hear about them from NYPORTS.
> There would certainly be more of a benefit of this system if the state
> shared best practices from the repository of information available
> to them.

While NYSDOH has published several NYPORTS newsletters, very few of the study respondents had seen them. Those that had seen them felt that they should be more timely. One risk manager indicated

> When the state gets information on a serious case they should
> immediately send out a prevention strategy to all hospitals in the state.
> The newsletter alerts are not as good as they can be and are often slow

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to be released. In a case of chemotherapy overdose that happened in 1995, the state did not issue an alert until 2001. That is pathetic.

The IPRO model of provision of standards of practice is also viewed as helpful in highlighting best practices in clinical systems and outcomes, promoting self-improvement, and establishing a standard of care that is evidence-based.

Others also suggested that the state provide more education to facilities through conferences and other convening functions to inform facilities of trends and patterns they are finding across the state and to develop some standards of care that is evidence-based for how to address these incidents proactively. As one respondent indicated:

We need more information directly from the state to say this is what we are seeing, this is what we think will work, so that we will have less guess work.

Another said:

The state should provide education to hospitals, share solutions, and promote more education in improving rather than just collecting numbers. Right now we are just collecting data and not getting anything back.

Less Punitive Approach by State

In addition to taking an evidence-based approach by disseminating best practices and more standards of care, many respondents urged the state to reconsider its punitive stance to reporting, which many felt was not the original intent of NYPORTS and runs counter to the non-punitive, non-blaming systems approach recommended by the Institute of Medicine report and most medical error research. As one Vice President of Nursing stated:

If I thought there were efforts to look at patterns of errors and to provide assistance to individual hospitals in improving that would be great. But my experience with virtually everything so far is that it's almost always punitive. It's always a way to catch you, or to report you,

or to fine you, or to come in to scrutinize you. If it were used proactively to improve clinical systems or outcomes, that would be wonderful. And you'd be able to tap into experts, without having to absorb all the consultation fees yourself. I think they are trying to move in that direction with some of the work they've done on developing standards of care for myocardial infarction and community acquired pneumonia. That is more related to IPRO, but it has been helpful.

Another respondent noted:

The disappointment with DOH is they are really old-school concentrating on regulation and placing blame rather than fostering an environment of collegiality.

Some also suggested greater use of failure mode event analysis (FMEA) which has been used in other industries, instead of RCAs. Proponents of the FMEA approach purported that RCAs, while useful, can make people defensive because it occurs after an event has already happened. FMEA is a preventative analysis which allows the institution to assess potential systems failures before they occur.

Financial Support for Effective Medical Error Reduction

Many respondents advocated that the state provide greater financial incentives to encourage patient safety and quality improvements including providing grant funds or other incentive systems, such as enhanced reimbursement for hospitals pursuing quality initiatives that have proven to be effective. Most hospital leaders acknowledged that the most proven techniques for reducing errors, such as physician order entry systems, are far too costly for most hospitals to afford and that more resources were required from the state to support these technological patient safety advancements.

The general perception of most respondents was that, if reimbursement levels are not increased or additional funding is not provided for NYPORTS, it will become increasingly difficult for hospitals to improve quality, produce timely reports to the state, and demonstrate increasing commitment to patient safety measures.   As one study respondent noted:

[The state should] put some money into clinical care and focus on hospitals that have zero reports. It's bad to paint everyone with the same brush… We need to support 'best practices' and put money into them. There needs to be incentives not just disincentives. Those engaged in best practices need to be rewarded. There should be some way for the state to provide grants or some other means of support for best practices, not just a website where you can look up where the bad docs are.

Respondents noted that mandates should be backed with resources, and some implied that mandated reporting can actually interfere with patient care, because the state continues to regulate, but does not provide funding. As one respondent noted, unless funding is increased or Medicaid reimbursement is increased, the facility would be hard-pressed to do "a lot of things."

Discussion

NYPORTS was envisioned as a system that would enable hospitals to report adverse events as required by law while facilitating greater comparison to like facilities within the state. Findings from this study suggest that the state has been successful in raising awareness among leaders and in promoting an investigative process that hospitals have found to be useful. However, the state has been less successful in encouraging and helping hospitals to utilize and interpret the much larger set of adverse event data that they are required to collect and compile.

The results of this study demonstrate that mandatory adverse event reporting in New York State has heightened awareness of patient safety issues in hospitals across the state. While many hospitals previously had data systems to track potentially problematic incidents, nearly all leaders with whom we spoke acknowledged that the mandate from the state has resulted in greater attention on the part of leadership and a greater willingness to commit resources to the task. A state mandate, while not always welcomed by these leaders, was generally credited with 'raising the bar' of accountability, which has helped leaders of quality departments garner resources that they might not have been dedicated for this purpose without a state mandate. Interestingly, this greater awareness is tied to hospitals' fear of penalties or other repercussions for failing to report. Despite the rhetoric around the need to develop non-punitive systems, it is in part

the state's role as an oversight (and therefore potentially punitive) entity that has resulted in greater awareness on the part of hospital leadership.

On the other hand, the state's continuing punitive posture in collecting these data has inhibited hospitals from shifting from cultures of blame to cultures that foster systems change. The mandate by the state has had a negative effect on reporting by providers, particularly physicians, especially when the department and bureau overseeing the analysis and review of adverse event data is the same agency that monitors regulatory compliance and professional conduct. Hospitals appear to have been somewhat successful, at least based on the self-report of key leaders, at allaying the concerns of nursing staff in this regard. However, there is still considerable reluctance on the part of physicians to report adverse events to the state due to fear of reprisal both by the state and by the hospitals in which they work. While this fear may not raise issues for reporting per se, since most documentation is largely the responsibility of nurses, it does suggest that shifting to cultures that promote openness to change is still far from being achieved.

In order for any system change or reporting system to be effective, the cooperation and support of the hospital medical staff are essential. As the NYPORTS system is considered a punitive process by most physicians interviewed in this study, the tool may continue to be underutilized. Data from this study suggest that the state may need to make some modifications to its current process to encourage the full participation of physicians. These modifications may include providing physician incentives, removing the current requirement to report licensure numbers, or some other assurance by the state that the purpose of collecting adverse events is not to assign blame but to encourage internal examination and systems improvements.

Another shortcoming of the NYPORTS system is its lack of focus on medication errors, which constitute the largest number of errors in hospitals[13]. Effective June 2000, the state increased reporting requirements for medication errors to include errors that do not result in patient death, but do result in permanent harm or near-death events. While we conducted the field work for this study after those changes had been implemented, most pharmacy directors were still relatively unfamiliar with the NYPORTS system, instead relying on their own internal sources of data, national databases such as MedMarks, or voluntary reporting to the Institute for Safe Medication Practices. Given that pharmacy departments appear to rely on other sources of data, NYPORTS may not be the ideal vehicle for addressing less serious medication errors. In fact, hospitals' use

of the less serious NYPORTS adverse event data has been minimal and fraught with complications, given the lack of comparative data and the lack of confidence in uniformity and comprehensiveness of reporting.

Although many leaders question the usefulness of NYPORTS data for internal tracking or external comparison, the vast majority believe that requiring an RCA process for the most serious events has an impact on improving patient care. The fact that many hospitals conduct these analyses, which consume a tremendous amount of staff time and resources, even for events that hospitals are not mandated to analyze, is a testament to the perceived value of the process. Since many hospitals were already doing RCAs prior to NYPORTS, not all of their positive effects can be attributed to the NYPORTS state mandate. However, the state mandate may have pushed hospitals with weaker patient safety agendas to conduct RCAs that they may not have otherwise conducted, which in the opinion of most respondents would be beneficial to patient safety. For example, a Director of Pharmacy explained his view on NYPORTS' impact:

> NYPORTS forced all the institutions to think about their whole process in order to identify the problems. [In an RCA] you have to go through the whole workflow related to the event, analyze the system. And that's really the outcome from NYPORTS, it's more structured.

Whether RCA analysis was implemented due to NYPORTS or not, all hospitals found it worthwhile. This is an important finding, given that many mandated error-reporting systems do not include this component. In most other states requiring reporting of medical errors, reportable information typically includes data on the event itself, a corrective action plan, and confirmation that corrective actions were taken. RCAs are not uniformly required.[14]

While RCAs have resulted in changes in policies and procedures and greater in-service education for nurses and other staff, hospitals have little evidence as to whether these changes will have long-term sustainable impacts on reducing errors over time. Since a number of the RCAs noted by leaders revealed lack of compliance with or knowledge of existing policies and procedures, it is not clear whether process modifications alone will lead to long-term system change. Unfortunately, more systemic changes, such as computerized physician order entry, come at a considerable price, and

only a few hospitals indicated that they are in the process of identifying resources to develop these systems.

While most respondents were not able to quantify the additional resources required to collect, clean, analyze, and respond to NYPORTS-reportable incidents above and beyond their existing quality assurance functions, administrators universally felt that NYPORTS increases the burdens on their staffs without providing the requisite resources. The NYPORTS-related activity that appears to consume the most hospital resources is the RCA, which most hospitals see as providing sufficient benefit, to conduct even for incidents not required by the state. This finding suggests that, at least for the component of NYPORTS that requires reporting of serious adverse events or errors, the benefits may outweigh the costs. In contrast, given the lack of timely, comparative data from the state most hospitals do not appear to be using the broader adverse event data. Even if this comparative data were made available by the state on a more timely basis, many respondents voiced considerable concerns about inter-institutional reliability and risk adjustment, suggesting that this information still would not be used. Thus, the costs of collecting and compiling that data may outweigh the benefits.

This exploratory study has several limitations. The small sample size limited our ability to test differences across subgroups of hospitals. We examined each of our data codes for differences by our sample strata but did not discern any clear patterns, most likely due to the small number of hospitals in each strata. Also, the large number of hospitals that met our definition of having a strong patient safety focus may suggest some self-selection bias in hospital participation. While this bias should have skewed the results toward greater perceived value and use of NYPORTS, we did not generally find this to be the case. Patient safety focus did seem to have a relationship to how comprehensive a system hospitals had for capturing and analyzing internal adverse events but not to any extensive or innovative uses of NYPORTS data in particular. In fact, because NYPORTS was often duplicative of or less comprehensive or meaningful than hospital internal data collection systems, many of the hospitals with a strong patient safety focus tended to primarily use their own internal data, rather than NYPORTS.

Another limitation of this study is the qualitative and cross-sectional nature of the data. Without pre- and post-NYPORTS interviews, we cannot determine changes in perceptions about the impact of error reporting on hospitals' quality and patient safety systems. Our interviews did involved staff members who have worked through earlier versions of NYPORTS, and therefore could offer views on changes in the system over

time. Nonetheless, because our study is based on self-reports we do not have a way to verify actual influence on hospital system change.

Because NYPORTS has many unique features, our findings can not be broadly generalized to other reporting systems or states. However, we believe that the perspectives of hospital administrators, which have not been thoroughly researched prior to this study, help to identify strengths and weaknesses that can assist in the development of similar reporting systems in other settings. Further research is needed to determine if these responses are generalizable or specific to the New York environment.

Although we set out to explore how hospital characteristics relate to NYPORTS use, we generally did not see patterns of use by hospital type. Our primary findings instead demonstrate the influence that one's position in a hospital's administrative and leadership structure has for perceptions of this adverse event reporting system. Job title was related to awareness of NYPORTS, willingness to report adverse events, and the level of fear of a punitive response from the hospital or state. Those crafting other reporting systems, should be aware that different hospital staff are likely to have varied responses to the system and perhaps development of distinct educational and compliance strategies would be beneficial to encourage participation among different types of staff.

This study, the first of its kind, suggests that well-designed, state-mandated reporting systems can have positive impacts in raising awareness and accountability within hospitals, but also points to some barriers and burdens that designers of next-generation error reporting systems should address. In particular, based on the New York experience, if states opt to mandate that hospitals report serious adverse events and medical errors, they should develop programs that include features to promote root cause analysis or similar processes to investigate why errors occur. Only requiring hospitals to report serious medical errors is unlikely to produce system changes.

Secondly, any state putting in this type of system needs to think carefully about the resources required to report out this information. States might want to consider dedicating more resources to the oversight agency to review RCA results statewide to identify incidents where other hospitals might benefit from their findings and summarize them for broader distribution of 'best practices'. Any such reporting would need to be carefully crafted so as to provide sufficient case history for other hospitals to understand the incident that had occurred without providing enough information to be discoverable. Since the time of our interviews, New York State has issued a newsletter on retained surgical sponges and a medication safety toolkit that summarize RCA findings in this

manner, which may address the need for 'best practice' information identified by respondents to the degree that these materials were adequately disseminated.[15]

For adverse events, it is less clear whether mandating reporting has any effect on patient safety. Based on the New York experience, the reliability of these data, given institutional variation in reporting levels and differences in understanding of what is to be reported, is very much in question even if the state had made the data available in a timely or useable fashion.

Finally, as the most effective strategies proven to reduce error involve costly automated systems and greater staff resources, states should consider developing financial incentives to support such interventions either through grant programs or through quality-based contracting and reimbursement as has been pursued in the private sector.

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Endnotes

1   Marchev M, Rosenthal J, Booth M. How States Report Medical Errors to the Public: Issues and Barrires. Portland, ME: National Academy for State Health Policy; 2003.

2   Boodman, Sandra G., "No End to Errors; Three Years After a Landmark Report Found Pervasive Medical Mistakes in American Hospitals, Little has Been Done to Reduce Death and Injury". Washington Post, December 3, 2002.

3   Pataki, G, Novello, A. NYPORTS The New York Patient Occurrence and Tracking System Annual Report 1999. New York State Department of Health, Albany, New York, February 2001, p2.

4   Ibid

5   Pataki, 2001, p2

6   Defined as events that have significant negative or lasting impact on the patient including patient deaths or impairments of bodily functions that are not due to the natural course of illness.

7   Pataki, 2001, p4.

8   Three hospitals were excluded because when we called we discovered they had less than 50 med/surg beds. Five other hospitals were sent letters but not called to participate because their sampling strata had been filled.

9   Katz RI, Lagasse, RS. Factors influencing the reporting of adverse perioperative outcomes to a quality management program. Anesth Analg. 2000; 90:344-50. and Elnitsky, C, Nichols, B, Palmer, K., Are hospital incidents being reported? Journal of Nursing Administration. 1997; 27:40-46.

10 In 2003, JCAHO began consistently accepting the NYPORTS RCA reporting form so that hospitals can complete one form for both New York's and JCAHO's reporting requirements. Hospitals must still file the form separately to each organization, however, because one or both parties were unwilling to share reported data.

11 New York Public Health Law, Section 2805-m prevents disclosure of incident reports under the Freedom of Information Law

12 Pataki, G, Novello, A. NYPORTS The New York Patient Occurrence and Tracking System Annual Report 2000/2001. New York State Department of Health, Albany, New York, July 2003.

13 Boodman, Sandra G., "No End to Errors; Three Years After a Landmark Report Found Pervasive Medical Mistakes in American Hospitals, Little has Been Done to Reduce Death and Injury". Washington Post, December 3, 2002.

14 Presentation by Charles Mowll, Executive Vice President, Joint Commission on Accreditation of Healthcare Organizations at AHRQ User Liaison Program "Reducing Medical Errors: Tracking Errors" based on JCAHO 32 state survey and NASHP 50 state survey.

15 "Retained Surgical Sponges," *NYPORTS News & Alert Issue 11*, New York Department of Health, September 2002, p1.

APPENDIX A
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	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. **New documented DVT** (deep vein thrombosis) Refer to definition manual page 14	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.
	604**. AMI** (Acute Myocardial Infarction) – **unrelated to a cardiac** procedure. Refer to definition manual pages 16, 22	NOTE:Consider the 911-963 codes when applicable
	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	701. 1ˢᵗ degree burns.
	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	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	801-819. 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 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. 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

912. **Incorrect Procedure or Treatment - Invasive**
Refer to definition manual pages 48-49, 53

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

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>**:**

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 | 911. Occurrence with the administration of anesthesia only-code as 912. Endoscopy- code as 912

912   Venipuncture for phlebotomy, diagnostic tests without contrast agents.
 Transfusion related occurrences (report to Blood and tissue resources program only).
913.   Foreign bodies retained due to equipment malfunction or defective product (report under 937 or 938) or those reported under 806.

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).

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	923. Cases in which the patient outcome would have been the same whether or not the elopement occurred (cancer death, etc.).

	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	

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 B

Hospital Interview Protocol

Hospital:_____

Position/Title:_____

Introduction

Please describe your position in the hospital and how long you have held that position.

Awareness and Purpose

1. How familiar would you say you are with the NYPORTS incident reporting system?
   - ___ Very familiar
   - ___ Somewhat familiar
   - ___ Not very familiar
   - ___ Not at all familiar

2. How would you describe the purpose of NYPORTS collection and use within your organization? (Don't read responses, code accordingly)
   - ___ To track errors to compare experience with other hospitals
   - ___ To identify errors in order to take disciplinary action against practitioners
   - ___ To meet state requirements
   - ___ To conduct systematic root cause analysis for serious errors and identify why errors occur and correct them
   - ___ To avoid punitive fines/negative publicity from the state
   - ___ Other, specify_____

3. How familiar are you with the comparative reports available to hospitals to compare their level of reporting with their peer groups?
   - ___ Very familiar
   - ___ Somewhat familiar
   - ___ Not very familiar
   - ___ Not at all familiar

4. (IF # 3= 1-3) How have you used this NYPORTS comparative data and for what purpose?
   - ___ For the non-900 codes only, to compare with other hospitals
   - ___ For a few specific areas that clinical leaders have suggested are higher than average
   - ___ Have not used this data (why not?)_____
   - ___ Other (specify) _____

Leadership and Organizational Culture (Explain these questions relate to organizational culture in general, not just about NYPORTS)

5. How are errors or adverse events perceived by leadership?
   - ___ Non-punitive, opportunity to identify systemic problems and fix them
   - ___ Mostly non-punitive, but punitive when standard of care is not met
   - ___ Primarily Punitive
   - ___ Other, specify_____

6. How are errors or adverse events perceived by clinicians and staff?
   - ___ Non-punitive, opportunity to identify systemic problems and fix them
   - ___ Mostly non-punitive, but punitive when standard of care is not met
   - ___ Primarily Punitive
   - ___ Other, specify_____

7. In what ways does leadership demonstrate its commitment to error reduction to staff throughout the organization? (Don't read responses, code accordingly. Probe: CEO and Board involvement?)
   - ___ Established a Quality Committee w/ participation by Board Members
   - ___ Quality Committee includes multi-departmental participation
   - ___ A senior leader reporting directly to CEO responsible for patient safety/CQI
   - ___ Assigns a specific quality team member/ case manager to specific depts
   - ___ Hospital provides CME course on patient safety
   - ___ CEO /top leadership meets with different departments to identify ways to improve patient safety
   - ___ All levels of staff invited to participate in Root Cause Analysis
   - ___ Systemic changes have been instituted as a result of an error
   - ___ Resources have been invested to improve safety
   - ___ Other, specify_____

8. **(QM/RM ONLY)** How does risk management occurrence reporting relate to NYPORTS if at all? (code by response categories, don't read)
   - ___ Internal procedure dictates that upon a NYPORTS event identification, risk management is immediately contacted
   - ___ Risk management is only contacted if there is a suspected NYPORTS 900 event
   - ___ Risk management is contacted only if the quality officer, chief medical officer or lead administrator identifies the need related to a NYPORTS event
   - ___ Risk management is rarely contacted as no definitive process is in place that ties them to the internal reporting system that would first capture an event
   - ___ Other, specify_____

9. **(QM/VP Med Affairs ONLY)**Please describe the process by which hospital executive staff are involved in reviewing NYPORTS reports and revising patient safety practices? _____

10. **(QM/VP Med Affairs ONLY)** How frequently does this review occur?

    ____ Monthly
    ____ Quarterly
    ____ Bi-Annually
    ____ Annually
    ____ As incidents come up, no regular review
    ____ Other, specify_____

FOR HOSPITALS IN NETWORKS/SYSTEMS:

11. Do you share any NYPORTS information with the hospital system that you participate in/ other hospitals in the network? If yes, how? YES/NO

12. **(?)** What role, if any, does the network/system play in improving patient safety? (Probe: through using NYPORTS)?_____

Quality of Data Collection/Training

13. Who is responsible for identifying NYPORTS cases within the hospital? How many staff in each category?

YES	# Involved	
___	____	Case managers
___	____	Staff from quality department
___	____	Medical records staff
___	____	Nursing staff in each department
___	____	Nursing supervisors
___	____	Director of Quality
___	____	Risk manager
___	____	Staff Physicians
___	____	Attending Physicians
___	____	Pharmacists
___	____	Other, specify_____

14. Describe the process for identifying NYPORTS cases?

    ___ Departmental meetings
    ___ Chart review
    ___ Review of occurrence reports to identify those that qualify as NYPORTS
    ___ Chart review of E-codes reported on discharge data
    ___ Other, specify_____

15. **(QM ONLY)** Do you have procedures in place to verify the accuracy of the NYPORTS data reported to the DOH? YES/NO

        21a. (If YES) Please describe._____

16. Has DOH clearly defined expectations for which cases should be included in each of the 900 codes? YES/NO

>   16a. (If NO) Do you have a uniform way of categorizing what cases
>   should and should not be included for the 900 codes? YES/NO

17. Has DOH clearly defined expectations for which cases should be included on the short form? YES/NO

>   17a. (If NO) Do you have a uniform way of categorizing what cases
>   should and should not be included for the non-900 short-form codes?
>   YES/NO

18. **(QM/RM ONLY)**Did the hospital have an occurrence reporting system before NYPORTS? YES/NO

19. **(QM/RM ONLY)**How has this system changed as a result of NYPORTS?
    _____ Has not changed, operates separately
    _____ Integrated with NYPORTS reporting
    _____ NYPORTS replaced existing system
    _____ Other, specify_____

20. **(Ask if necessary to QM/RM ONLY)** Do you still have two separate systems in place? YES/NO

21. **(QM/RM ONLY)** What is your estimate of the percent of occurrence reports that are entered into NYPORTS? ___

22. How has the introduction of NYPORTS affected the value of the occurrence reporting system?
    _____ Improved the value, why?_____
    _____ Reduced the value, why?_____
    _____ No impact, why?_____
    _____ Other, specify_____

23. How would you compare the value of the occurrence reporting system to NYPORTS in reducing medical errors in the hospital?_____

24. Who is trained about the NYPORTS system?
    _____ Nurses
    _____ Physicians
    _____ Case Managers
    _____ Other, specify_____

25. How frequently are they trained?
    _____ At Orientation Only
    _____ Monthly
    _____ Quarterly
    _____ Annually
    _____ Other, please specify_____

26. What type of training is provided to inform staff of how the NYPORTS data is to be collected, what the purpose is, and what the information is used for? **(READ each)**
  _____ Literature in hiring packet (indicate which staff for each identified)
  _____ Training at job orientation
  _____ On-going on the job training
  _____ CME Course
  _____ Supervisory oversight meetings
  _____ Other, specify_____

27. How confident are you that most reportable events are being reported in NYPORTS?
  _____ Very confident
  _____ Somewhat confident
  _____ Not very confident
  _____ Not confident at all

28. Do you think there are any barriers to reporting and if yes what are they? (don't read, probe if needed)
  _____ Fear of being fired/penalized by hospital
  _____ Not anonymous
  _____ Shame/embarrassment of admitting mistake
  _____ Fear of losing license or getting fined by state
  _____ Administrative hassle with no clear purpose
  _____ Lack of clear definitions
  _____ Lack of good sources of event information
  _____ Not meaningful data (e.g. medication errors not captured)
  _____ Other, please specify_____

29. **(QM/VP Med Affairs/VP Nursing ONLY)** How does concern about the identification of licensure numbers on adverse event reports affect how individual practitioners report?_____

Analysis and Response

30. **(QM/RM/VP Med Affairs ONLY)**How many root cause analyses for NYPORTS 900 codes have been conducted in the past year at your facility? _____

31. **(QM/RM/VP Med Affairs ONLY)**How many staff have participated in these RCAs?_____

32. **(QM/RM/VP Med Affairs ONLY)**Do you conduct RCAs for events other than required for NYPORTS 900 codes?   YES/NO

  32a. (If YES) How does the hospital prioritize non-900 code events that should get an RCA?
    _____ Department head requests
    _____ Incident at other hospital
    _____ Near-miss with serious ramifications
    _____ Other, specify_____

33. Have you participated in a root cause analysis resulting from a NYPORTS 900 code? YES/NO

34. How many root cause analyses have you been involved in? _____ Number of RCAs

35. For Root Cause Analyses:

        Who attends these meetings?
- _____ CEO
- _____ Board Members
- _____ VP of Medical Care
- _____ VP of Patient Care Services, Nursing
- _____ Director of Quality
- _____ Department Chairs
- _____ Attending Physicians
- _____ Risk Manager
- _____ Staff involved in case
- _____ Pharmacy Department
- _____ Other, specify_____

        Who leads the meetings?
- _____ CEO
- _____ Board Members
- _____ VP of Medical Care
- _____ VP of Patient Care Services, Nursing
- _____ Director of Quality/Quality Department
- _____ Department Chairs
- _____ Attending Physicians
- _____ Risk Manager
- _____ Staff involved in case
- _____ Pharmacy Department
- _____ Other, specify_____

36. For the last root cause analysis conducted at your hospital, which leaders of the organization were engaged in implementing system changes/ plans of correction in response to identified adverse events?
- _____ CEO
- _____ Board Members
- _____ VP of Medical Care
- _____ VP of Patient Care Services, Nursing
- _____ Director of Quality/Quality Department
- _____ Department Chairs
- _____ Information Systems
- _____ Pharmacy
- _____ Other, specify_____

37. In your opinion, what are the three most significant RCAs that have occurred at the hospital.

37a. Please describe the system changes that resulted from these RCAs.
    ____ more nurse training on a particular subject
    ____ bar-coding to reduce medication error
    ____ revised medication storage procedures
    ____ revised policies and procedures - Describe
    ____ new equipment purchased
    ____ faulty equipment returned
    ____ Other, specify_____

38. Has the hospital measured the impact of these changes on reducing error or other outcomes? YES/NO

39. For the non-900 codes, is there a process for prioritizing which adverse events the hospital will look into for further system changes? YES/NO

    39a. (If YES) What criteria are used?
        ____ Frequency of occurrence
        ____ Hospital has higher rates than their peers
        ____ Potential for significant harm
        ____ Other, specify_____

    39b. (If YES) What is the process and who is involved?
        ____ Specific committee - Staff Involved_____
        _____
        ____ Departmental level
        ____ Team-based approach
        ____ Other, specify_____

40. Other than in the RCAs mentioned above, have any system-level improvements been made in response to adverse events *identified by NYPORTS* short-form data in the last year? YES/NO

    40a. (If YES) What types of improvements and for what problems?
        ____ more nurse training on a particular subject
        ____ bar-coding for medication
        ____ revised medication storage procedures
        ____ revised policies and procedures - Describe
        ____ new equipment purchased
        ____ faulty equipment returned
        ____ Other, specify_____

41. Has the hospital measured the impact of these changes on reducing error or other outcomes? YES/NO

42. Does the hospital disseminate and distribute information on errors, or solutions for improving patient safety in general and if so how? YES/NO

    ____ Does not disseminate/distribute info
    ____ Data distributed/reviewed at regular staff/ departmental meetings
    ____ Root Cause Analysis meetings only
    ____ Newsletters to staff
    ____ Broadcast fax
    ____ CME Training
    ____ Memos/ letters
    ____ Web-site
    ____ Other, specify_____

43. **(Ask only if necessary)**Does the hospital disseminate and distribute information specifically on NYPORTS and if so, how? YES/NO

    ____ Does not disseminate NYPORTS to all staff
    ____ Data distributed/reviewed at regular staff/ departmental meetings
    ____ To staff in Root Cause Analysis meetings only
    ____ Newsletters to staff
    ____ Broadcast fax
    ____ CME Training
    ____ Memos/ letters
    ____ Web-site
    ____ Other, please describe_____

44. **(QM/VP Med Affairs ONLY)**Has the hospital evaluated if there have been costs or savings achieved from specific interventions that were changed as a result of NYPORTS? YES/NO

    44a. (If YES) Please describe._____

    44b. (If NO) Can you identify any cost savings achieved as a result of specific interventions that were implemented due to NYPORTS?_____

45. What barriers are there, if any, for **using** the NYPORTS data to improve patient safety?

    ____ Lack of information to compare with other hospitals
    ____ Timeliness of data/ Information too old
    ____ Lack of 'best practice' information on how to improve
    ____ Lack of standard definitions/ apples to oranges
    ____ Lack of leadership commitment to invest sufficient resources
    ____ Insufficient funds to implement changes
    ____ Other, please specify_____

Resource Consumption

46. **(QM/VP Med Affairs ONLY)** What costs does the hospital incur to maintain the NYPORTS system? (probe)
_____ Number of hours spent per RCA
_____ # of Senior staff involved
_____ Budget for quality initiatives
_____ # of quality staff working on NYPORTS
_____ # of staff involved in data entry/case finding
_____ software modifications
_____ Other, specify_____

47. **(QM/VP Med Affairs ONLY)** Has the hospital sought external funds for analyzing NYPORTS data? YES/NO.

47a. (If YES) How much and from whom?_____

Integration with Other Quality & Patient Safety Activities

48. **(QM/RM/VP Med Affairs ONLY)** What other data sources does the hospital rely on (or relied on prior to NYPORTS) to improve patient safety and quality of care?
_____ Occurrence Tracking
_____ Departmental data
_____ Other state required data (e.g. CABG)
_____ Other, specify_____

Perceived Effectiveness

49. What additional value, if any, does NYPORTS provide, above and beyond other information sources? (Probe: short form versus long form)_____

50. What is the value of mandated reporting by the state, if any?
_____ No value/ not beneficial
_____ Added accountability to state, allows quality staff to compete for resources internally
_____ Enables higher resource allocation for systems improvements
_____ Brings attention to important patient safety issues
_____ Other, specify_____

51. Finally, are there other approaches to addressing patient safety issues that you feel are more likely to result in reduction in errors than mandated reporting? YES/NO

            51a. (If YES) What are they?
- _____ Newsletters sharing of information across facilities re: best practices/JCAHO Alerts
- _____ Grant funding to support interventions
- _____ Convening hospitals to discuss best practices (e.g. insurance groups)
- _____ Mechanized system improvements (e.g. physician order entry)
- _____ Near-miss information that allows more preventive interventions
- _____ Other, specify_____

NOTES: