UNDER-REPORTING OF SURGICAL ERRORS: STATE PERCEPTIONS AND RESPONSES

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ABSTRACT

PAUL W. THRONE: Under-Reporting of Surgical Errors: State Perceptions and Responses

(Under the direction of Sandra Greene, DrPH)

Objective: Under-reporting of surgical errors inhibits development of knowledge and strategies that can lead to lower error rates. Mandatory error reporting programs have proliferated among states as one means of reducing the incidence of errors. Evidence suggests that errors are under-reported. Little is known of the perceptions of states regarding the risk of under-reporting, their responses to it and the ways they use reported data to improve patient safety. A qualitative study was conducted to assess the perceptions of state managers regarding the risk of under-reporting and the role of enforcement, analysis and feedback in current and ideal error reporting programs

Methods: 24 state medical error reporting programs were surveyed for characteristics and perceptions of surgical error reporting compliance. A key informant sample of 11 states explored perceptions of barriers and facilitators to reporting, and current and ideal strategies for enforcement and data use. Qualitative data were coded for themes and key findings. A plan for change responds to the conclusions.

Results: 52% of states had discovered surgical errors through means other than required reporting by health care institutions. 76% of states reported that it was impossible to know whether all required reports were made. Some managers did not have adequate resources to enforce reporting, analyze data or engage the health

care industry to improve patient safety. State managers understood most of the same reasons given by the health care industry in the literature for failure to report, except lack of program usefulness and feedback. Most managers valued using error data analysis in collaboration with the health care industry to reduce the incidence of surgical errors, but only 37.5% of states use data this way.

Conclusion: Most state managers do not know whether their programs receive all required surgical error reports, and most do not have the resources to use data the way they would like to. Managers did not understand lack of program value and feedback as an important barrier. A plan for change provides education to states and recommendations that include standardization of reporting requirements, data sharing, and new requirements for error reporting.

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List of Abbreviations

ACA	Affordable Care Act
ACO	Accountable Care Organization
AHA	American Hospital Association
AHRQ	Agency for Health Care Research and Quality
AIMS	Australian Incident Monitoring System
ASA	Anesthesia Society of America
ASC	Ambulatory Surgical Center
CLD	Causal Loop Diagramming
CMS	Centers for Medicare/Medicaid Services
ICD-9	International Classification of Diseases - 9th Revision
IG	Inspector General
IHI	Institute for Healthcare Improvement
IOM	Institute of Medicine
IRB	Institutional Review Board
HHS	Health and Human Services
NASHP	National Academy for State Health Policy
NQF	National Quality Forum
QSM	Qualified Manager
QSA	Qualified State Agency
NYPORTS	New York Patient Occurrence and Tracking System
PSO	Patient Safety Organization
PSQIA	Patient Safety and Quality Improvement Act

TJC (formerly JCAHO)	The Joint Commission (formerly Joint Commission on the Accreditation of Healthcare Organizations)
WSPE	Wrong-side/Wrong-site/Wrong-procedure/Wrong-patient events
WHO	World Health Organization

Chapter 1: Surgical Errors and Error Reporting Systems

Medical errors are a frequent occurrence in acute care. Surgical errors are an important subtype of medical errors and are the focus of this study. Efforts to prevent surgical errors include procedural and systems advances, and internal and external reporting systems. This study examines external reporting systems by exploring the perceptions of regulators regarding compliance with mandatory reporting requirements and the use of the information provided by health care entities.

The perspective of regulators on the strength of the error reporting relationship between state agencies and the health care industry is not well understood. This study develops this knowledge and leads to suggestions that will enhance the effectiveness of mandatory surgical error reporting as one strategy to reduce the incidence of surgical errors.

Medical Errors and System Challenges

The Institute of Medicine (IOM) estimated in 1999 that as many as 98,000 deaths annually may be attributed to inpatient errors (Kohn et al., 2000). The Institute extrapolated this figure from other research that included the landmark Harvard Medical Practice Study, which found that while serious medical errors occurred in only 3.7% of hospitalizations in New York in 1984, more than a quarter of the events were the result of negligence, and some events led to permanent

disability (2.6% of events) or death (13.6% of events) (Brennan et al., 2004). The Harvard study concluded that “There is a substantial amount of injury to patients from medical management, and any injuries are the result of substandard care” (Brennan et al., 2004: 145).

A second study examined by the IOM found a slightly lower rate of adverse events in hospitalized patients in Colorado and Utah (2.9%) (Thomas et al., 1999), but concluded that, even using this lower figure, medical errors were the 7th leading cause of death at the time, exceeding deaths from “motor vehicle accidents, breast cancer or AIDS” (Kohn et al., 2000: 1). April Significantly, in both the Colorado/Utah and New York studies, slightly more than half of all adverse events were attributable to preventable error (Kohn et al., 2000).

Surgical Error: An Important Type of Medical Error

One important type of medical error is surgical error, and surgical errors themselves have subtypes. The definition of “surgical error” varies between states and health care monitoring organizations, but among those errors most commonly referenced are:

1. Surgery on the wrong patient
2. Surgery on the wrong body part
3. Wrong surgical procedure
4. Unintentionally retained foreign bodies after surgery
5. Death of an ASA Class I patient during or immediately after surgery [ASA is the American Society of Anesthesiologists. ASA Class I patients are considered the healthiest patients with the lowest risk for anesthesia-related complications or reactions]

Errors in surgery have been discovered to originate with individuals, systems, and work groups. Among the causes are:

- “Error in diagnosis
    - Misinterpretation of diagnostic test results
    - Failure to diagnose or misdiagnosis
    - Delayed diagnosis
    - Failure to perform diagnostic tests…
- Error in treatment
    - Unnecessary treatment
    - Medication error
    - Delayed treatment
    - Technical error
    - Wrong treatment concept
    - Failure to treat…
- Error in communication
    - Error in written communication
    - Error in verbal communication
    - Error in information handover…
- Error in judgment
    - Inadequate planning of procedure
    - Wrong indication for procedure
    - Violation of guideline or protocol…
- System issue
    - Time-out not performed
    - Environmental safety or security issue
    - Error in credentialing or competency
    - Error in supervision or staffing
    - Inadequate resources…” (Stahel et al., 2010: 981)

Surgical errors, while uncommon, have a significant personal and social impact. They are estimated to cost employers as much as $1.5 billion annually (AHRQ, 2008) and can be fatal. AHRQ estimates that 1 of every 10 patients who died within 90 days of surgery did so because of a preventable error, and Mehtsun, et al., found that “…6.6% of surgical never events result in the death of the patient” (Mehtsun et al., 2012: 5). Seiden and Barach note that, as with medical errors in general, the consequences of surgical errors can range from “…increased hospitalization and pain to serious iatrogenic injury and death,” and that surgical

errors frequently result in permanent patient injury and litigation awards that average $96,032 and have ranged as high as $9 million (Seiden and Barach, 2006: 935).

Variation in the Incidence of Surgical Errors

Estimates of the incidence of surgical errors vary by as much as eleven times (ranging from 0.4/10,000 surgeries to 4.5/10,000 surgeries), partly due to variation in definitions and types of reporting systems (Neily, 2011). Referring to one type of surgical error (wrong site surgery), Michaels, et al., report that "…we lack national estimates of the true incidence of wrong site operations, and little is known about hospital efforts to mitigate these preventable events" (Michaels et al., 2007: 526).

> Until now, there has been an ongoing lack of reliable data about the true incidence of wrong-patient and wrong-site operations because these confidential data—derived from closed claims, sentinel event database, or other types of surveys based on voluntary reporting—may represent just the tip of the iceberg of selected, most severe occurrences (Stahel, 2010: 979).

Some data are available, however, that illustrate the risk of surgical error. The rate for adverse events occurring within the operating room in the Veterans Health Administration system is 0.4 per 10,000 surgeries (Neily, 2011). The American Academy of Orthopaedic Surgeons found that the chance of any given orthopedic surgeon performing wrong-site surgery is 25% over the course of 35 years (Stahel et al., 2010). Looking only at wrong-site and wrong-procedure occurrences, Stahel et al. also examined a prospective physician insurance database in Colorado covering January, 2002 through May, 2008 and identified 132 events during the period. Although such errors are uncommon, "The occurrence of a surgical never event can

be catastrophic for a patient and can also be destructive to a surgeon's career and an institution's reputation" (Mehtsun et al., 2012: 1).

Seiden and Barach examined the National Practitioner Data Bank and found that between 1990 and 2003 there were at least:

- 2217 cases of "wrong body part surgery"
- 3723 cases of "wrong treatment/wrong procedure performed"
- 4295 cases of "retained foreign body"

They state, however, that "the exact incidence and prevalence of WSPEs [wrong-side/wrong-site/wrong-procedure/wrong-patient events] remains unknown" (Seiden and Barach, 2006: 932). Extrapolating from a review of WSPEs at 17 Minnesota hospitals in 2003 – 2004, however, they estimate that as many as 2760 surgical errors occur in the United States annually. This number only includes extrapolating from three of the five common categories of surgical error, since they did not consider wrong patient or death of an ASA I patient.

Efforts to Reduce Surgical Errors

That surgical errors are numerous and devastating has long been recognized (Becher and Chassin, 2001) and has led to multiple efforts to reduce them. Among the most prominent actions taken have been the recommendations of the American College of Surgeons in 2002, which published recommendations to prevent wrong-site, wrong patient, wrong-procedure events, and the Universal Protocol published by the Joint Commission in 2004 (Stahel, 2010). The Joint Commission Universal Protocol includes system interventions such as marking of a patient's surgical site

and a pause before initiating surgery to verify that the correct procedure is being performed on the correct patient (Stahel, 2010).

Perhaps the most celebrated of the prevention efforts has been the adoption of the surgical checklist advanced by the World Health Organization. In trials in eight hospitals in different nations the use of the checklist was found to reduce surgical complications by 36% and deaths by 47% (Gawande, 2009).

In spite of many efforts to reform surgery processes to prevent errors, however, they continue to occur, and "We have few data on how often and why they occur and on why the safety mechanisms in place fail to prevent them" (Seiden and Barach, 2006: 931). Stahel et al. note that "Despite the widespread implementation of the Universal Protocol in recent years, wrong-site surgery continues to pose a significant challenge to patient safety in the United States" (Stahel et al., 2010: 978-979). Seiden and Barach report that "…one third of wrong-site surgery cases occurred even with careful site identification procedures…" (Seiden and Barach, 2006: 937).

It is recognized that the circumstances surrounding surgical errors are not easy to assess. "In complex systems, a single failure rarely leads to harm….When things go wrong, it is usually because a series of failures conspires to produce disaster" (Gawande, 2002). Surgical errors are the result of a "…series of individual errors" that requires an organization to be alert to the multiple factors that combine to create an opportunity for error and to plan for systemic responses that "…will

either prevent or anticipate and compensate for errors that human beings inevitably make" (Becher and Chassin, 2001: 75).

The Center for Transforming Healthcare agrees:

> Since wrong site surgeries are relatively rare events, they are difficult to study. Research has shown that there is usually no one root cause of failure. Instead, such events are frequently the result of a cascade of small errors that are able to penetrate organizational defenses. It is important to examine the failures in an organization's defenses to fully understand the event and reduce the risk of future failures (Joint Commission Center for Transforming Healthcare, 2011: 1).

Ultimately, as with other medical errors, "The current health care system is not culturally or structurally organized for preventing" them (Seiden and Barach, 2006: 935). A major complication in the effort to reduce medical errors is "A widely held view in society of error as indicative of incompetence [that] leads people in organizational hierarchies to systematically suppress mistakes and deny responsibility....Hierarchical structures thus discourage the kind of systematic analysis of mistakes that would allow people to better design systems to prevent them" (Edmondson, 1996: 9). Tucker and Edmondson agree that poor system design prevents learning from error (Tucker and Edmondson, 2003).

Carroll and Edmondson state that health care institutions "…can improve quality and other outcomes by enhancing their capabilities for organizational learning…" a process that they describe as "…increasing the capacity for effective organizational action through knowledge and understanding" (Carroll and Edmondson, 2002: 51). They find that learning does not come naturally to organizations, however. Opportunities for information sharing and learning must be created, since they do not arise naturally within the organization.

Learning from Failure

The complex web of causation behind surgical errors creates an imperative to understand and define the contributing factors that permit errors to occur. Such understanding in turn requires cooperation from the medical profession and hospital administrators. Progress, however, has been slow, at least in part because such cooperation cuts against the traditions of these institutions. Edmondson states that "…the culture of medicine more generally discourages admission of error, thereby greatly diminishing a given hospital's potential to learn from mistakes, both consequential or not" (Edmondson, 2004: ii5). Tucker and Edmondson concur that "…in spite of increased emphasis on these issues, hospitals are not learning from the daily problems and errors encountered by their workers…..process failures are not rare but rather are an integral part of working on the front lines of health care delivery" (Tucker and Edmondson, 2003: 56).

The possibility that hospitals (and by extension other health care institutions where surgery occurs) can learn from failure, however, is also acknowledged by Tucker and Edmondson: "Both errors and problems can be detected and used as launching points for organizational learning and improvements by motivating changes to avoid recurrence" (Tucker and Edmondson, 2003: 69). To accomplish this they argue against reliance on first-order [specific to the occurrence] problem solving alone, because it "…does not address underlying causes, thus not reducing the likelihood of a similar problem in the future...." and "…can preclude improvement by obscuring the existence of problems and errors and preventing operational and structural changes that would prevent the same failures from happening again"

(Tucker and Edmondson, 2003: 60 – 61). Because serious medical errors are rare, "…an individual health care facility cannot improve its performance unless its research goes beyond its own data….Hospitals may have to share data if they are to improve their performances" (West, 2006: 15).

The World Health Organization agrees. The WHO Draft Guidelines for Adverse Event Reporting and Learning Systems state that "Too often neither health-care providers nor health-care organizations advise others when a mishap occurs, nor do they share what they have learned when an investigation has been carried out. As a consequence, the same mistakes occur repeatedly in many settings and patients continue to be harmed by preventable errors" (WHO, 2005: 7).

Reporting of Surgical Errors

One important means by which organizations are thought to learn to prevent errors is through reporting systems, and "…there has recently been increasing recognition of the need for healthcare organizations to monitor and learn from patient safety incidents" (Hutchinson et al., 2009: 5). This opportunity for improvement arises when errors are considered not only in the moment of their occurrence, by those who have intimate knowledge of the error, but when they are reported to authorities who can then assess the scope and severity of the problem, as well as provide greater objectivity and expertise in the appropriate preventive measures needed. As Mehtsun, et al., note:

> It is clear that we need a mandatory reporting system of surgical never events that is not reliant on risk management or voluntary reporting. We also need reporting systems that provide more root-cause information about each

> event so that safe hospital systems can be developed (Mehtsun et al., 2012: 6).

Reporting systems are thought to be important because they "…have the potential to serve two important functions. They can hold providers accountable for performance or, alternatively, they can provide information that leads to improved safety" (Kohn, 2000: 86). Indeed, Chamberlain reports that in New Zealand, "One study showed incident reporting reduced the adverse event rate in hospitals and emergency department to a half and a quarter respectively over an 8-year period" (Chamberlain, 2008: 60). Thus, reporting of serious errors may help reduce future errors by creating an opportunity to investigate and learn from them (Hartnell et al., 2012: 362). In addition, mandatory reporting requirements create a risk of possible public exposure of errors, which in turn is an incentive to reduce their incidence in order to prevent embarrassment.

Many organizations and governments have recognized the need to develop systems for reporting surgical errors. Becher and Chasin note that "State governments can also facilitate the collection, analysis, and public dissemination of key data on health care quality" (Becher and Chasin, 2001: 78). WHO agrees: "At a minimum, reporting can help identify hazards and risks, and provide information as to where the system is breaking down. This can help target improvement efforts and systems changes to reduce the likelihood of injury to future patients" (WHO, 2005: 7).

State Medical Error Reporting Systems

The 1999 IOM report was a catalyst for the growth of state medical error reporting systems. In 2000 15 states had some type of reporting system in place, although they did not all focus on the serious events considered in this study. By 2005, 23 states had some system in place for reporting medical errors, and the Joint Commission, as well as the National Quality Forum, had developed well-defined standardized lists of reportable errors, including surgical errors (Clarke, 2006).

The state error reporting landscape is subject to continuous modification through the addition of new state systems, deletion of other state systems, and adjustment of reportable events and reporting requirements. As of 2007, NASHP reported that four states had added mandatory reporting systems and eleven states extensively revised their systems in the period of 2005 – 2007 (Rosenthal and Takach, 2007).

By 2010, 27 states and the District of Columbia had some system for voluntary or mandatory reporting of medical errors (NASHP, 2011). The growth of mandatory reporting systems is demonstrated in Table 1-1 below.

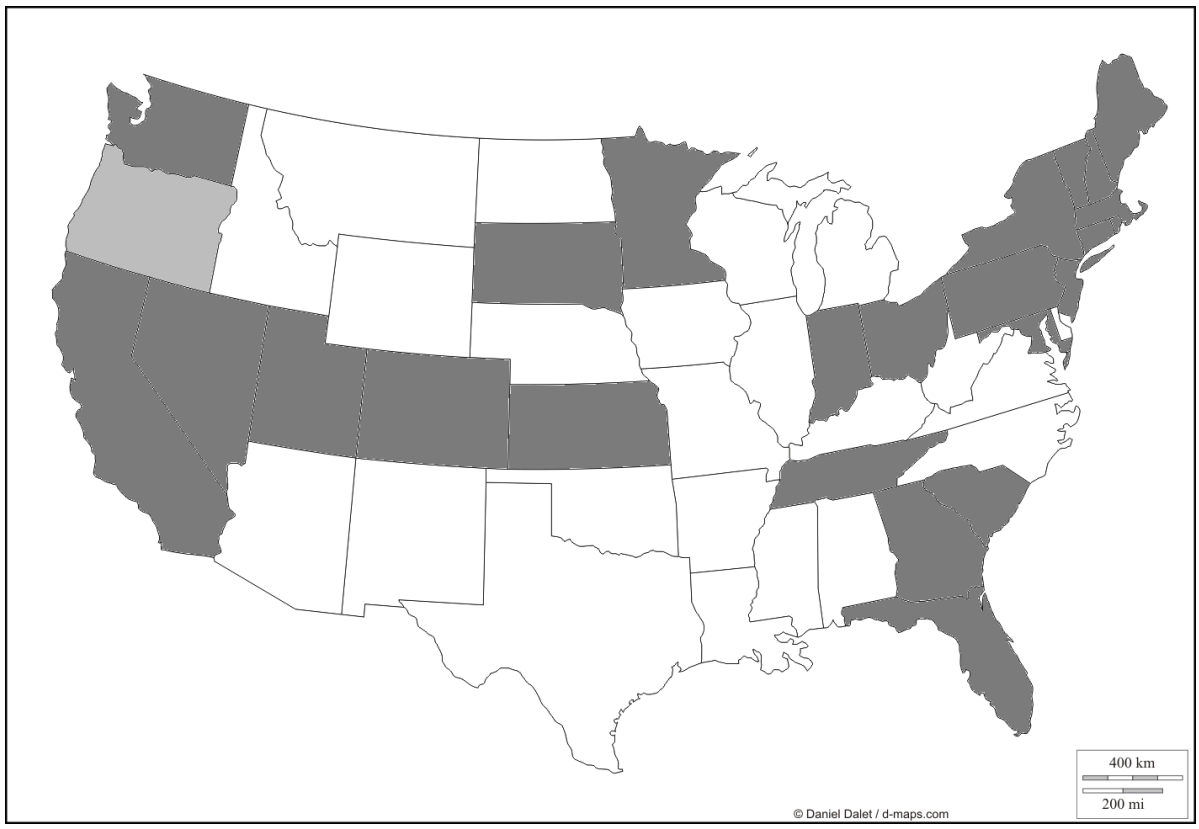
Table 1-1: ADVERSE EVENT REPORTING SYSTEMS IN 2000 AND 2007

15 authorized adverse event reporting systems in 2000 (including several that focused solely on abuse, neglect, or clinical outcomes, not adverse/patient safety events)	**27 authorized adverse event reporting systems in October 2007** (only those systems that focus on adverse events with the intent to improve patient safety)
Colorado, Florida, Kansas, Massachusetts, Nebraska, New Jersey, New York, Ohio, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Washington	California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Illinois, Indiana, Kansas, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New York, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Washington, Wyoming

Source: Rosenthal and Takach (2007)

The current landscape of voluntary and mandatory medical error reporting programs is illustrated by Figure 1-1 below, based on important changes found in the course of this research since Table 1-1 was developed: the state of Wyoming ceased its program in 2010, Illinois' program never functioned, and the state of New Hampshire has implemented a new program:

Figure 1-1: STATES WITH MEDICAL ERROR REPORTING SYSTEMS IN 2012
Source: Rosenthal and Takach (2007) modified by this research
Key: = mandatory reporting = voluntary reporting



Types of reporting systems vary widely between states. The fundamental difference is whether medical error reporting is voluntary or mandatory. Each of these types has a particular purpose. The Institute of Medicine notes that mandatory systems exist mainly to enforce accountability for serious incidents that lead to injury or death. These systems are primarily located within state agencies with investigative and enforcement powers, and:

- "…provide the public with a minimum level of protection by assuring that the most serious errors are reported and investigated and appropriate follow-up action is taken"
- "…provide an incentive to health care organizations to improve patient safety in order to avoid the potential penalties and public exposure" and

- "…require all health care organizations to make some level of investment in patient safety, thus creating a more level playing field." (Kohn, 2000: 86)

In contrast, voluntary reporting systems are intended to permit the review of incidents that result in minor harm or do not actually reach a patient. Such voluntary reports typically do not result in public disclosure or penalties. Their purpose is to "…identify and remedy vulnerabilities in systems before the occurrence of harm" (Kohn, 2000: 87).

Only mandatory medical error reporting systems are considered in this study, because the purpose of this research is to determine state agency perceptions regarding compliance with the reporting requirements.

Fulfilling the Call of the IOM through a Cycle of Reporting and Feedback

If the reporting process functions ideally, the additional knowledge acquired by analysis of the error will generate recognition and learning at the level of the surgical episode, and future errors may be prevented. WHO states that "…if the event is reported and the findings from the investigation are entered into a database, the event can be aggregated with similar incidents to elucidate common underlying causes. A variety of solutions could emerge..." (WHO, 2005: 9). WHO finds that reporting can lead to improvements in several ways:

1. By generating safety alerts
2. Dissemination of lessons learned from errors
3. Analysis can reveal patterns of errors
4. Aggregation of data can lead to recommendations for improved practice (WHO, 2005).

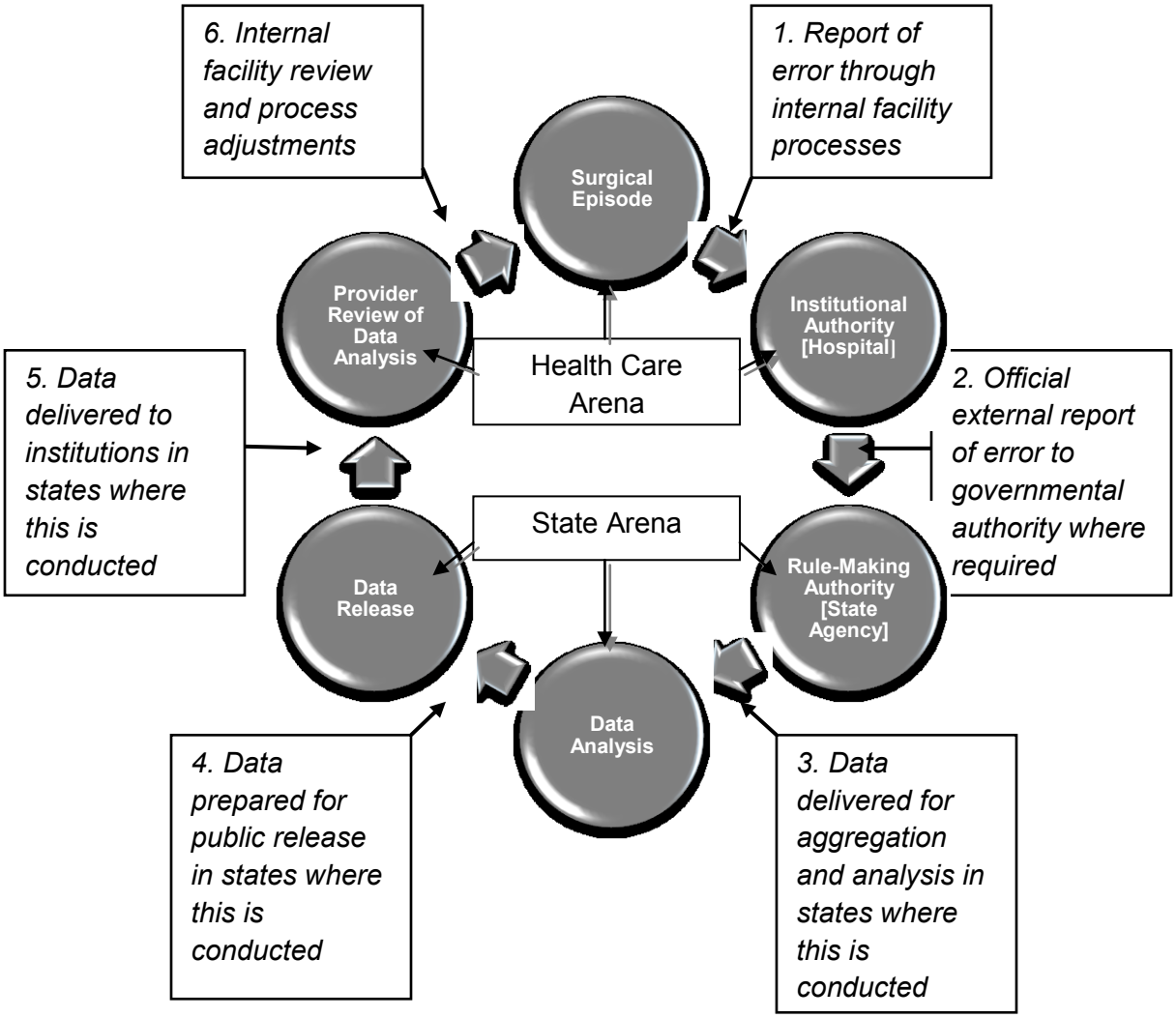
The feedback loop is vital to the efficacy of the reporting process. Clarke notes that "Feedback…motivates reporting….An effective reporting system must not

only capture system errors, it must also use them to drive improvement in the system of healthcare delivery. Effective analysis is the other critical component of a patient safety reporting system" (Clarke, 2006:1089).

In an effective error reporting system, the stakeholders include the medical professions, hospitals, governmental authorities, and the public. Each party requires information in order to make informed judgments regarding the nature and cause of surgical errors. The system relies upon the honest and complete reporting of error data, from operating room to hospital administration, to governmental authority, to the public and back to the providers.

Figure 1-2 illustrates a model error reporting system that returns critical information back to medical providers in order to use learning to prevent future surgical errors. The model was adapted for this study from performance improvement models that emphasize a closed feedback loop, an example of which is the "Plan-Do-Study-Act" strategy (Langley et al., 1996), and from the WHO Guidelines that include the note that "…a reporting system must produce a visible, useful response by the receiver to justify the resources expended in reporting, or, for that matter, to stimulate individuals or institutions to report. The response system is more important than the reporting system" (WHO, 2005: 12).

Figure 1-2: MODEL CYCLE OF SURGICAL ERROR REPORTING AND FEEDBACK TO PREVENT FUTURE ERRORS THROUGH LEARNING



Each of these steps is worthy of study to identify vulnerabilities and opportunities to strengthen the system. Step 2 is one of the two intersection points between the institutional and governmental processes in the cycle (the other point being Step 5). This study is concentrated on the role of the governmental authority in the process, and the perceptions and responses of managers to institutional failures

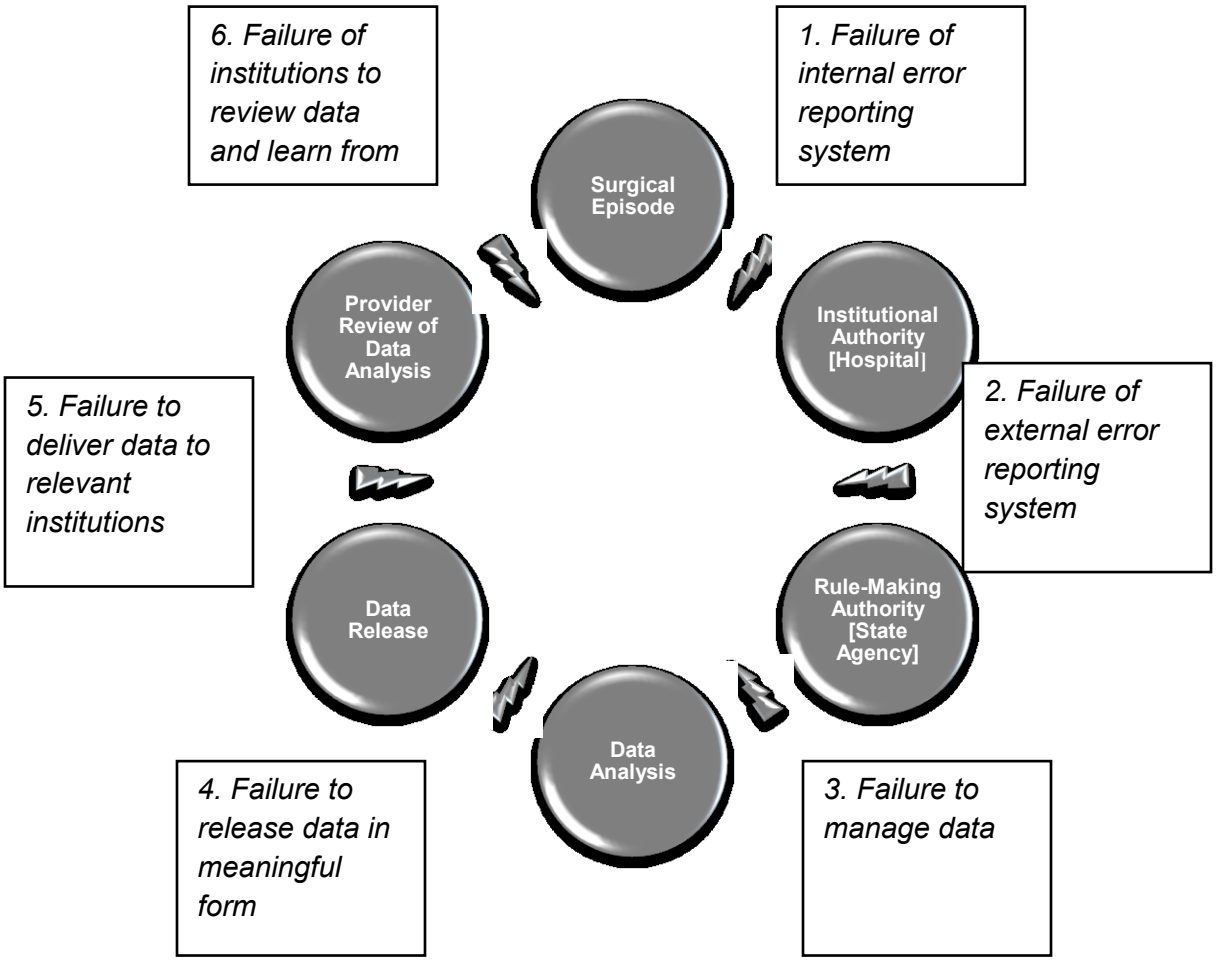
to report errors as required. Therefore, the focus of this study was Step 2, although data were generated that also illuminate processes downstream from Step 2 as well.

Failure Points in the Cycle of Error Reporting and Feedback

The chain of reporting surgical errors is vulnerable. At each step in the process there are multiple players and multiple opportunities to misunderstand or overlook the error itself or the need to report the error, and each of the process steps in this cycle is susceptible to failure through lack of data input. As the cycle progresses the risk of failure increases because each step relies on the data inputs and processes in the previous steps. As a result, the opportunities for learning and performance improvement offered by the system are subject to multiple failure points. When events are not reported, critical opportunities to learn how to prevent future surgical errors may be lost.

Figure 1-3 illustrates points in the Cycle of Surgical Error Reporting and Feedback where the flow of information may be blocked and cause system failure.

Figure 1-3: FAILURE POINTS IN THE CYCLE OF SURGICAL ERROR REPORTING AND FEEDBACK



Examples of failures at each of these process steps include:

Step 1: Report of error through internal facility processes. Institutional personnel who become aware of an error may fail to follow policy to report the error internally.

Step 2: Official external report of error to governmental authority where required. The institutional authority may fail to report the error to the governmental authority for many reasons described in the literature review, including fear of negative consequences, uncertainty regarding reporting requirements, perception of lack of value in reporting, and lack of awareness of the error occurrence.

Step 3: Data delivered for aggregation and analysis in states where this is conducted. States may fail to process data in a meaningful way, including failure to deliver the necessary data to personnel with the skills and awareness of the issues required for effective data analysis and summaries.

Step 4: Data prepared for public release in states where this is conducted. In those states where data are aggregated, analyzed and then publicly released, the release of data may be compromised by lack of resources, lack of appropriate information outlets, or low prioritization of this step.

Step 5: Data delivered to institutions in states where this is conducted. Data may be released in a format that is not useful to institutions, including “summary only” data, data missing causative analysis, or data not reaching specific institutions with an interest in process improvement.

Step 6: Internal facility review and process adjustments. The institutions receiving data may be incapable, unwilling or uninterested in using the data to review and improve internal processes designed to prevent future errors.

Lack of resources and failures of organization structure may also occur at every step.

Each of these steps is worthy of study to identify vulnerabilities and opportunities to strengthen the system. A great investment has been made in discovering the reasons for the failure of Step 1, and as the literature review will show, there has also been some research investigating possible reasons for failure in Step 2, which is the focus of this study. Loss of information at each handoff in the cycle results in further loss of learning downstream. The point at which health care entities must report a surgical error to state authorities is critical to the successful flow of data at all subsequent points in the system.

Research into the Failure of Step 2

As error reporting systems began to proliferate starting in the early 2000s, expectations were high. “As states adopt the serious reportable events list…the data on medical errors will become more and more reliable, with the ability to spot trends and regional problems (American Health Consultants, 2001: 162).

However, some research has found that many reportable medical errors are *not* reported (Gottleib, 2004). Review of medical records in two states found many more reportable errors than actual official error reports. In Washington State, a collaboration between Hearst Newspapers and the Niagara Health Quality Coalition utilized retrospective medical record review to determine that as many as 2200 serious errors should be reported in Washington annually, but only about 200 events were actually reported (Nalder, 2010). A similar discovery was made in Nevada, where billing data showed that:

> 1,363 occurrences statewide that fit the definition of grave, reportable medical errors in 2008 and 2009. But Nevada hospitals reported to state health officials 402 serious errors for those years. A subsequent review by the state found some serious hospital mistakes weren't reported (Mullen, 2011).

Noncompliance with reporting requirements can begin at the surgical episode and extend through the institutional management. The Inspector General of the Department of Health and Human Services reported that “93 percent of serious adverse events in hospitals went undetected by the hospitals’ own internal reporting systems” (Nalder, 2010). Responsibility for maintaining an effective cycle of reporting and improvement also lies with the state agencies that receive error

reports. Governmental authority plays a critical part in the cycle of error reporting, analysis and feedback. This role is under-evaluated, as the literature review will show.

Study Questions and Aims

This study is intended to illuminate questions of what states perceive to be the effectiveness of their medical error reporting programs, the extent and urgency of under-reporting and what approaches they take in using reported data to reduce surgical errors. This study will concentrate on surgical errors because the definition of reportable medical error varies widely between the states, but many states either use the NQF definition of surgical errors or have developed their own definitions that are quite similar. At least at the level of defined reportable error, surgical errors are a fairly consistent category for exploration of medical error reporting systems in various states.

As the literature review will demonstrate, barriers to reporting surgical errors have been reported from the perspective of health care institutions. Little, however, is currently known about the perceptions held by state agencies regarding barriers to surgical error reporting and the risk of under-reporting. Because the error reporting system plays an important role in the prevention of future errors, it is important to understand the beliefs of state agencies regarding potential under-reporting, and the states' perception of their role in managing reporting compliance.

The fundamental research questions in this study are:

1. What are the states' perceptions of compliance with mandatory reporting of surgical errors?

2. What are the perceptions of state agencies regarding barriers to reporting of surgical errors?

3. If states believe under-reporting is occurring, what is their level of concern about it?

4. If states believe under-reporting is occurring, what are they doing about it?

5. What are the states doing with their reported error data to improve healthcare Quality?

6. What feedback do states give to providers regarding reported errors?

7. How do state agencies perceive their role in enforcing reporting requirements?

The unit of analysis and sample size, which will be described more fully in Chapter 3, were the twenty five state government agencies that receive and process reports of surgical errors from health care institutions. The study utilized qualitative methods, which do not require a hypothesis. Instead, the qualitative methodology illuminates perceptions and processes that help to answer the research questions.

Significance of this Study

As the literature review will demonstrate, little is known of the perceptions of state agencies regarding potential under-reporting of surgical errors and their role in the enforcement of error reporting requirements. By locating the state within the error reporting cycle and examining state perceptions of, and responses to, possible error under-reporting, this study contributes to the understanding of the role of the regulatory agency in preventing medical errors and increasing patient safety in several ways. It:

1. Provides previously unknown information about state agency perceptions of the risks of medical error under-reporting

2. Provides previously unknown information about state agency perceptions of barriers to medical error reporting

3. Provides previously unknown information about state agency perceptions of their role in enforcing medical error reporting requirements and using reported data to improve patient safety

4. Results in a plan for change that includes enhancements to the error reporting systems that may increase the data available for review and can broaden and deepen the knowledge available to providers on the causes and prevention of surgical errors.

Because continued improvement in the incidence of surgical errors relies in large part on the learning acquired through study of reported errors, noncompliance with surgical error reporting is a cause for concern. The successful functioning of all of the segments of the reporting system is critical for the completion of the learning cycle as efforts continue to reduce the incidence of medical errors.

Chapter 2: Literature Review

Extensive study, analysis and intervention have been conducted on the health care institution side of the medical error reporting system, where errors actually occur. Researchers have examined the training, competence, teamwork, work and stress levels, communication, human factors issues and many other aspects involved in the actual commission of surgical errors in an effort to reduce their incidence. One of the profound results of this work has been the World Health Organization Safe Surgery Checklist, the use of which has been associated with major reductions in surgical errors around the globe (Gawande, 2009).

The act of reporting errors has received some research attention as well, but it focuses primarily on actions inside health care institutions: the individuals who commit or observe an error, and whether they recognize and report errors to their institutional authorities. Less data are available regarding the regulatory side of the error reporting systems, where institutions report to the governmental authorities, and the governmental authorities analyze and report the data back to the industry and to the public.

Benn found that “Limited research evidence exists concerning the issue of effective forms of safety feedback within healthcare,” but that the establishment of effective feedback mechanisms may permit the diffusion of knowledge that “…may

be usefully employed to promote safety awareness, improve clinical processes and promote future reporting" (Benn, 2009: 11). The issue of potential noncompliance with medical error reporting rules therefore requires an examination of barriers, both real and perceived, in the reporting process. This literature review was conducted to determine what barriers to surgical error reporting are cited by health care institutions and state regulatory agencies.

The published literature on the subject of state perceptions of their own reporting systems is meager. Little is available regarding the state agencies' perceptions of the strength of the reporting relationship, the agencies' enforcement roles, the degree of health care industry non-compliance, and attitudes within the state agencies to their place in the reporting cycle.

The primary source of published information regarding these questions is the National Academy for State Health Policy (NASHP), which has issued 11 reports on the subject since 2000. These reports are valuable for describing the various state systems, their legislative mandates, their approaches to defining reportable events and collecting, managing, analyzing and distributing data. However, almost no research conducted by NASHP or any other individual or agency has been found on the subject of state attitudes toward compliance with their own reporting systems. One relevant NASHP study regarding state perceptions is noted below.

Literature is presented first, however, that describes what is known about barriers and facilitators to reporting as perceived by health care entities, in order to demonstrate the challenges that states face when implementing mandatory reporting

systems and to identify points of potential weakness and leverage in the error reporting relationship.

A crucial aspect of this study is determining whether state agencies recognize these challenges and are actively responding to them. The major themes developed in the literature review appear again in the study results section in a matrix comparing them against the themes arising from the key informant interviews. This comparison permits an evaluation of whether the perceptions of industry and those of the regulatory agencies are congruent.

Institutional Barriers to Reporting in the Literature

Efforts to determine the causes of errors in the surgical environment have been productive, and analysis of barriers to reporting of errors from the surgical environment to the institutional authorities, such as hospital administration, have revealed training, trust and other issues (Hughes, 2008). Relatively little research, however, has been conducted regarding barriers to reporting of surgical errors to governmental authorities by the health care institutions where the errors occurred.

The published literature discussed here reveals some similarities between reluctance of providers and institutions to report errors, primarily around legal and reputational issues. Significant differences are also apparent, however, with individual providers reporting many concerns related to institutional culture and personnel issues while institutional leaders focused more on regulatory uncertainty and relationships between the institutions and governmental authority, as well as stronger concern for exposure to liability as a consequence of disclosure.

As is the case regarding state perceptions of their own reporting systems, literature is scarce on the larger subject of institutional barriers to mandatory surgical error reporting between health care entities and regulators. Therefore, the literature review was broadly designed to capture as many available published articles and studies on the subject as could reasonably be accomplished. Both descriptive and analytical studies were considered for this review, and both qualitative and quantitative data were accepted. No hierarchy of evidence, such as that in which randomized control trials are pre-eminent, was employed.

Many of the retrieved articles, while relevant, did not rely on primary or secondary evidence for their specific conclusions regarding the phenomenon of institutional reporting to governmental authorities. These articles were grouped into the categories “Issues Overviews” and “Editorials and Commentary” in order to emphasize that their perspectives are not explicitly founded in evidence presented or cited in the studies. Their place to this literature review arises through their contribution to a general consensus regarding the nature of barriers and the need for system improvements. Although the conclusions found in the Issues Overviews and Editorials and Commentaries are not grounded in presented data, the consistency of perspective found in these articles is notable.

The broad search strategy employed here over-emphasizes sensitivity at the expense of specificity, but this effect is desirable when so little research is available for examination. Extensive title and abstract review of the captured articles was used to apply more specific inclusion and exclusion criteria. The search was not date-restricted, because study of the reporting of surgical errors, like the reporting itself, is

a fairly recent phenomenon. Results were accepted from research conducted outside the United States, because lessons from the interaction of medical practice and governmental regulation may be illuminating regardless of the country considered. The only search limitation applied was [language = English].

The captured articles were a rich source of additional references, both because references to external error reporting were frequently embedded within an article that had a slightly different primary emphasis, and because the additional articles had not been captured by the original search terms. Including both the original search and the snowballing results, 32 journal articles were reviewed. Each article in the final selection was read twice to capture its type, methods and findings and to ensure that barriers to external reporting were defined or suggested. Tabular analysis was used to categorize the articles by strength of research method and details of processes and findings.

Many of the articles, referred to positive requirements for effective external reporting as well as to negative barriers. These positive statements may *imply* negative barriers (e.g. “effective reporting systems must be confidential” implies that lack of confidentiality can be considered a barrier to reporting), and therefore the positive requirements, which are remarkably consistent between the articles, are presented in addition to explicit negative barriers that were identified.

Analysis of the Literature

The articles that were retrieved were largely descriptive in nature. Many were overviews of the history and types of error reporting systems. Analytical studies and

systematic literature reviews were included, but like the overview articles their insights on external reporting barriers sometimes took the form of assertions or statements that were either not supported by the studies' data, or were supported by research that was actually conducted on a different subject. When this was the case, these analytic studies were included in the Issues Overviews or the Editorials and Commentary category. Likewise, several commentaries were found that made claims to external reporting barriers that were only lightly supported.

This presents questions regarding validity of many of the articles, which will be discussed below. However, some of the cross-sectional studies and retrospective reviews that were identified, as well as several systematic literature reviews, considered the subject of barriers to external reporting in an explicit manner.

A recurring feature of many of these articles is that reporting systems in the USA differ significantly in structure from those in the UK, Australia, and several other countries. In the USA practitioners report errors to their facility administration, which then reports to the government agencies where required. In many other nations the reporting systems permit practitioners to enter errors directly into a government database, eliminating the mediating effect of the institution. Many of the barriers identified in other countries to error reporting actually refer to hesitancy by practitioners, rather than institutions, and therefore correspond to *internal* barriers in the USA. However, there remains some relevance to the question of external barriers since external reports in the USA rely significantly on internal processes. The barriers mentioned in the articles from the UK and Australia are considered, but with awareness of the structural differences in those systems.

The results of the systematic literature review were:

- Descriptive and Analytic studies (n = 8)
- Systematic literature reviews (n = 2)
- Issue overviews (n = 15 (including 2 analytic studies moved to this category))
- Editorials and commentary (n = 7 (including 2 analytic studies moved to this category))

Major Themes in the Literature

Taken as a whole, the barriers identified in all categories of literature reviewed include these major areas and subtopics (number of articles mentioning each theme in parentheses):

1. Policy issues
    a. Mandatory or voluntary reporting systems (4)
    b. Legal and civil liability risks and protections (8)
    c. Legal discovery risks and protections (8)
    d. Negative publicity or consequences of public disclosure (11)
    e. Protection from, or risk of, professional retribution (4)
    f. Confidentiality guarantees or lack of confidentiality (5)
    g. Lack of state enforcement or resources (3)
2. System issues
    a. Degree of clarity of reporting requirements (6)
    b. System ease of use (4)
    c. Control over information (1)
    d. Perceived value in reporting data, including effective analysis and feedback (7)
    e. Stakeholder involvement in system design (3)
    f. Ongoing training in system requirements and use (1)
    g. Inclusion of safety tools as part of the reporting process (1)
3. Internal issues
    a. Institutional culture (safety- or blame-oriented) (5)
    b. Effectiveness of internal error reporting and control systems (1)
    c. Institutional leadership on reporting (1)
    d. Staff turnover (1)
    e. Burden of reporting (1)

The results of the literature review are organized by the themes arising in the stronger of the studies, and by general synopses of the points made in the Issues Overviews and Editorials and Commentary.

Themes Arising in the Descriptive and Analytic Studies

Seven studies were identified that were either conducted explicitly on the subject of external reporting and its barriers, or drew supported conclusions on the subject from the data. The studies are summarized in Table 2-1. In addition, two systematic literature reviews addressed the topic explicitly.

Theme 1: Policy Issues

Policy issues were discussed extensively in most of the relevant literature. Policy issues, for the purposes of this review, include discussion of barriers or benefits inherent in different system types and structures.

Several studies directly questioned institutional users about external reporting of errors. Weissman et al. (2005) interviewed senior management in 203 hospitals, including those from:

1. states with mandatory reporting systems with public disclosure
2. states with mandatory reporting systems without public disclosure
3. states without mandatory reporting systems

They found that most hospital administrators felt that external, mandatory reporting systems would discourage internal reporting of errors within the hospitals, and more than three quarters of the administrators felt that mandatory external

reporting systems encouraged lawsuits. Not surprisingly, then, hospital leaders strongly endorsed confidentiality for both hospitals and practitioners involved.

Direct analysis of reported errors also provided an opportunity for several researchers to examine the barriers inherent in the reporting process. Flink et al. compared voluntary error reports made to JCAHO and mandatory reports entered into the New York error reporting system, NYPORTS. Wrong site surgery had a clear correspondence as a defined reporting category in both JCAHO and NYPORTS. 104 cases of wrong site surgery had been entered in NYPORTS from June 1, 2000 to December 31, 2003, while there were only 300 nationwide reports made to JCAHO between 1995 and 2003. They concluded that "the comparison of the number of reports in a mandatory system (NYPORTS) versus a voluntary system (JCAHO) shows the potential utility of mandatory reporting," implying that the voluntary nature of the JCAHO reporting system is in itself a possible barrier to reporting (Flink et al., 2005: 142).

The question of whether the voluntary or mandatory nature of a system may itself be a barrier to reporting was also examined by Morton et al., (2006) who compared nationwide voluntary and mandatory reporting systems (mandatory claims-based vs. voluntary quality-based) to determine which system recorded more incidents of specific surgical complications in the same population over the same period. Reports of two specific complications were significantly different between the two systems, with the voluntary system showing reports of fewer "other pulmonary" complications and more arrhythmias. Their conclusions are equivocal. Both systems were limited by data accuracy and completeness problems, but the voluntary system

had lower provider participation and was prone to the risk of editing patient outcomes when logging complications into the system.

Russell et al. sought to understand the quality of data on surgical mortality. They examined over 3300 abstracts of studies related to the monitoring of postoperative mortality. Their relevant conclusion for the purposes of this review was that “Reluctance to treat high-risk patients when mortality rates were made public was reported from North America” (Russell et al., 2003: 930). This finding was specific to the literature on cardiac surgery, however, and mortality rates are not the same as error rates. Still, the impact of publication of outcomes data on provider willingness to treat is relevant to the discussion of errors that may be disclosed to the public.

Fassett (2006) examined the research that was the impetus for the passage of the federal Patient Safety and Quality Improvement Act of 2005 (PSQIA). A key feature of this act is the ability of states to create Patient Safety Organizations (PSOs) that can receive voluntary quality data from institutions in return for “legal protections against unauthorized disclosure…” These data are also protected from legal discovery in most civil, criminal and administrative cases. Fassett notes that “The PSQIA is best seen as an attempt to remove an often-cited barrier to provider reporting of errors for use in quality improvement programs (i.e., fear that the information will be used in a lawsuit or disciplinary hearing against the provider)” (Fassett, 2006: 922).

Theme 2: System Issues

System issues were not reported as widely as policy issues, but they did arise in several of the captured studies. System issues, for the purposes of this review, include discussion of barriers or benefits inherent in different system types and structures.

In contrast to fears of liability and a perception of lack of clarity and usefulness in the USA, Spigelman and Swan (2005) administered a satisfaction survey to twelve institutional users of AIMS, the Australian Incident Monitoring System. They found that the major limitations of the system for users were "…frustrations around the limited reporting capabilities and the lack of control over the database to modify reports for individual user needs" (Spigelman and Swan, 2005: 659).

Flink observed that "One of the most critical lessons learned is that information gathered into the system must be meaningful and useful to those who are reporting events," (Flink et al., 2005: 148) while Weissman, et al., found that twenty-three per cent of hospital leaders "…from the mandatory reporting states thought that reporting criteria were not very clear or not at all clear" (Weissman et al., 2005: 1363).

Theme 3: Internal Institutional Issues

Internal institutional issues, for the purposes of this review, include discussion of barriers or benefits inherent in different system types and structures. Internal

institutional issues were not reported as widely as policy issues, but they also arose in several of the studies.

In the UK, where providers enter error data directly into the national database, Hutchinson, et al., (2009) analyzed incident and error reports in 148 hospitals that had reported at least one event into the national system from April 2004 – November 2005. Reporting rates were generated and compared with positive responses on a safety culture survey administered at the same hospitals at approximately the same time as the events were reported. The researchers found that "The significant correlations between reporting rates and staff survey responses over two consecutive years (2004 and 2005) suggest that staff perceptions of the culture of safety and reporting within their hospital influence the actual number of reports being made" (Hutchinson et al., 2009: 8).

Likewise, Tuttle, et al. (2002) reviewed their own hospital's ICD-9 data to determine whether additional state-reportable incidents could be identified beyond those already reported as required. After 560 completed retrospective record reviews, they conclude "Hospitals that code more aggressively (assigning postoperative complications codes) than others could show an artificially high rate of postoperative events" (Tuttle et al., 2002: 357). This suggests that internal processes that intensify a medical outcome might be a factor in reporting. Specific barriers to mandatory reporting were not identified, however.

Flink noted that, in addition to factors noted above, “The turnover of hospital staff affects reporting rates and the quality of the reports submitted” (Flink et al., 2005: 149).

Summary of the Descriptive and Analytic Studies

Policy issues dominated the literature in the studies that included original research. Weissman, et al., conclude that “…most hospital leaders had serious reservations about these systems. On balance, hospital leaders believed that mandatory, nonconfidential state reporting systems as designed discouraged internal reporting of medical errors and led to a greater frequency of lawsuits while failing to provide substantial benefit to patient safety….hospital leaders resoundingly favored confidentiality……..many hospital leaders perceived a lack of clarity…” (Weissman et al., 2005: 1364).

It should be noted that Weissman, et al. surveyed hospital chief executives, chief operating officers and chief medical officers. In some hospitals, these positions may have a direct role to play in the external reporting of medical errors. In many hospitals, however, the reporting of errors is the domain of the risk manager or hospital compliance officer, positions that were not included in this survey.

Flink, who found that a system with mandatory reporting (NYPORTS) was more likely than a voluntary reporting system (JCAHO) to capture events, concluded with lessons learned for the success of such a system, including:

1. “Making the system legally required, with protection from discovery
2. Developing the system collaboratively, including all stakeholders in the system’s design and implementation

3. Clear and objective definitions of reporting criteria as a basis for collecting accurate and consistent data
4. Ongoing training and educational support for system users; and
5. Having a stakeholder advisory group for ongoing assessment and recommendations, ensuring the system's relevance and viability….Ultimately, the success of the system also requires that users received feedback regarding their own performance" (Flink et al., 2005: 149).

By stating these essential elements for system success, they again imply that their opposites may result in system failure.

The conclusions of these studies were largely supported by those of Barach and Small (2000), who interviewed directors of error and incident reporting systems in various non-health care industries. They conclude:

> Examination of successful non-medical domains indicates that the following factors are important in determining the quality of incident reports and the success of incident reporting systems: immunity (as far as practical); confidentiality or data de-identification (making data untraceable to caregivers, patients, institutions, time); independent outsourcing of report collection and analysis by peer experts; rapid meaningful feedback to reporters and all interested parties; ease of reporting and sustained leadership support (Barach and Small, 2000: 761).

Issue Overviews

Thirteen articles were essentially overviews and summaries of the history and issues related to medical error reporting. In addition, two analytical studies are placed in this category because their conclusions about barriers to external reporting are derived from research other than their own. These overviews stated both negative barriers and positive requirements for reporting systems. There was

remarkable consistency in the positive and negative attributes of error reporting systems between the articles and between national systems.

Summaries of reporting systems and issues in the USA identified these positive aspects of successful systems:

- Freedom from retribution (Seiden and Barach, who note "After a near miss in clinical care, clinicians in Florida are at risk of paying significant fines and of performing community service. This practice has had a chilling effect on reporting and patient safety programs in the state" (Seiden and Barach, 2006: 938)).

- "Rapid, nonpunitive, confidential, simple, and demonstrably beneficial" (Spencer, 2000: 417).

- Public dissemination of data (Becher and Chassin, 2001).

- Safe, simple, worthwhile (Leape, 2002).

- Confidential, supportive of a culture of safety, and disseminated knowledge about how to use the system, executive level dedication to reporting, knowledge of reporting requirements, two-way communication between agencies and institutions, awareness of how external reporting is beneficial (Wood and Nash, 2005).

These negative barriers were noted:

- Events are rare and "so devastating they are often not disclosed openly," and (relating to aspergillus arising from a hospital construction project) "…presumably due to litigation and risk to program operations, the phenomenon is not addressed much in a public forum" (Larson, 2002: 997-998).

- No feedback and no trend-tracking. Public disclosure and litigation. Lack of state resources (Leape, 2002).

- "…health care facilities face major deterrents to revealing mistakes. Reporting can result in fines or even loss of accreditation for a health care facility" (Stow, 2006: 411).

- Concern that information will be used in a punitive manner against physicians; uncertainty about requirements, lack of state enforcement, a culture of non-reporting, fear of liability and fear of publicity (Robeznieks, 2004).

Barriers to reporting in Australia were found to include:

- Concerns for job security, the views of other professionals, inhibitive reporting cultures, lack of adequate systems and "patterns of sociologically implicit or explicit discouragement or blaming mores" (Braithwaite et al., 2008: 185).

In New Zealand, the barriers included:

- Fear, medical culture, Individual counterincentives, organizational embarrassment, knowledge of the importance of the issue (Chamberlain, 2008).

The UK was no different. Barriers included:

- Lack of engagement from doctors and lack of knowledge of how to access incident form (Mahajan, 2010).
- "…mandatory systems deter practitioners and hospitals from reporting incidents as they fear public disclosure will lead to possible comeback for the reporting physician or trust" (Panesar, Cleary, and Sheikh, 2009:256). (Note that two issues are collapsed into one in this statement: mandatory systems and public disclosure).
- A system should be developed in the historical, incentive and political context of its country. It should be mandatory and national; it should exist alongside supporting safety tools and incentives to promote a sense of safe reporting; learning and dissemination systems should be parallel; new safety interventions should be developed; front line compliance should be strategized; candor should be encouraged, along with anonymity (Williams and Osborn, 2006).

In the Netherlands the same issues were addressed:

- "We must adopt a system of blame free reporting…Fear of being dragged before a medical disciplinary board must not be an impediment" (Sheldon, 2004, quoting Netherlands Healthcare Inspector General, Herre Kingma).

As they were in Greece:

- "…such events often lead to long lasting internal investigations from the hospital's manager or end up in the press or in the courts, with adverse consequences for a doctor, a hospital or for the Health Care System" (Vozikis, 2009: 21).

Summary of Issue Overviews

Although the issues overviews are so categorized because they do not consist of original research, their assertions and conclusions are consistent with those of the descriptive and analytic studies reviewed above. In particular, there is great emphasis on the risk to institutions and individuals of reporting. Cultures of safety and governmental resources merit a mention, but by far the greater discussion relates to legal and civil liability and to the public embarrassment to which providers and institutions may be exposed as a result of reporting.

Editorials and Commentary

Seven editorials or commentaries ((Dovey, 2004), (Zivin and Pfaff, 2004), (Cohen, 2000), (Bates et al., 2003), (Wheeland, 2005, in (Coldiron et al., 2005)), (Balkrishnan, Gill, Vallee, & Feldman, 2003) and (Flowers and Riley, 2001)) consisted of assertions about what constitutes barriers to error reporting or what aspects of a reporting system will encourage reporting, including two analytic studies that veered into editorial when discussing external reporting barriers. The lack of references or research to support these assertions leaves them with little weight, but their similarity to the issues already described helps paint a picture of the issue as

one that has perhaps neared a point of consensus, and helps determine whether the consensus is well-founded.

The elements of the editorials are not described further, but are included in the summary in Table 2-2.

Studies Specific to State Agency Perceptions and Responses

The reports of the NASHP are the primary reference available regarding the history, structure and mandates of the various state reporting systems. What little is found regarding state perceptions of under-reporting appears in one NASHP report that specifically surveyed state agency perceptions of the causes under-reporting.

The perspective of state error reporting system administrators was examined by Marchev et al. (2003), who studied the question of public disclosure of reported errors by analyzing the data release practices of states with mandatory error reporting. Telephone interviews were conducted with the responsible managers of 19 states. They found that "All states with mandatory systems… recounted a problem with under reporting." Among the barriers to event reporting mentioned by the states were:

1. "A lack of effective internal systems within hospitals to identify incidents
2. Unclear definitions or requirements for what must be reported
3. Reporting burden and a lack of perceived usefulness by facilities
4. Fear of liability and negative publicity creates a culture of non-reporting, and
5. A lack of enforcement at the state level" (Marchev et al., 2003: 20).

They observe, interestingly, that “Many states noted that they provide data protection in the interest of achieving a high level of compliance. However, since all of the states with mandatory reporting systems describe under reporting as a problem, the connection between protection of data and under reporting is not an easy one to draw” (Marchev et al., 2003: 20).

It is notable that Marchev found that state agency managers named many of the same concerns that hospital administrators and researchers working at the institutional level also mentioned. Marchev’s findings suggest that state agencies should acknowledge underreporting and should express an understanding of the health care industry’s perceptions of the causes of underreporting. This study tests this suggestion.

The survey by Marchev comprises the entire published literature located on the subject of state agency perceptions of compliance with medical error reporting requirements.

Discussion

Literature on the cause and prevention of medical errors is enormous, and on the identification and reporting of errors to internal authorities is quite large. The literature addressing barriers to external reporting of medical errors is, by contrast, minimal. Little original research was found specifically addressing barriers to external reporting. That which was located was either fairly narrow (e.g. interviews of hospital administrators regarding their opinions of reporting systems), was specific to

certain state systems, or was founded in the experience of other countries with different reporting systems.

Four studies, however, consisted of retrospective reviews of reported incidents in several contrasting systems, which permitted a comparison of voluntary and involuntary reporting rules and tested the reliability of hospital data. These studies concluded that voluntary systems, and those that rely on spontaneous reporting rather than automated reporting, may lead to underreporting of errors. They also found that internal barriers, such as coding and reporting structures within a hospital and turnover of hospital personnel, may affect external reporting compliance, and a culture of safety within an institution may be associated with increased rates of reported errors, and is thus likely a facilitator of reporting.

Three cross-sectional surveys of hospital and state agency personnel were revealing in their consistency. Those who manage hospitals, those who work at the patient-care level, and those who administer external reporting programs within state governments agreed that major concerns about error reporting related to where the data were going, how it would be used, and whether it was publicly disclosable or legally discoverable. Most hospital administrators felt that reporting requirements would not succeed whether they were mandatory or voluntary, while some state agency administrators thought that internal hospital systems were weak. Both sides agreed that a lack of perceived value or usefulness of the data and a lack of clarity regarding reporting requirements were obstacles to compliance.

The two systematic literature reviews that were located reached few conclusions about barriers to external reporting. They did find that concerns about legal liability, and a consequent recommendation that data be protected from discovery, were important. They also noted that public disclosure could have unanticipated negative effects, such as a reluctance to care for high-risk patients.

By contrast, many overviews of the issue have been published, along with editorials and commentary urging one approach or another. The overviews tend toward a broader, historical perspective, and perhaps as a consequence they discuss a wider range of barriers and recommendations. By far the most common barriers mentioned in the issue overviews were public disclosure and its consequent embarrassment to institutions or individual providers, the related issues of discoverability and confidentiality/anonymity, and internal hospital cultures.

Internal institution issues, which are relevant to this discussion because internal error reporting is the beginning of the external error reporting process, were not mentioned often in the original research. They were discussed in issues overviews and editorials, particularly in terms of institutional cultures of shame and blame or of safety, with a consensus that blame-free cultures and those that support and promote safety and reporting would be more successful.

There was agreement by state agencies with some of these beliefs. The literature specific to state agency perceptions, however, is extremely scarce. The only study located demonstrated that state agencies are aware of under-reporting and believe it is caused by some of the same factors that institutions also report.

However, the methodology and results of the study were not described fully, so a complete analysis of this study is not possible. The interview protocol published in the report reveals that only two of the questions on the survey specifically asked about under-reporting: “Is there a high level of reporting compliance among hospitals or is there a problem with under reporting?” and, “What factors influence compliance?”

Limitations in the Literature

Most of the literature that was captured in this search is limited in some manner. The seven editorials and commentaries are opinion only, at least as far as their references to external reporting barriers or strategies for success, although they may be based on research that has not been referenced in the articles. Similarly, the issues overviews did not present a methodology for searching the literature to reach their conclusions, but instead appeared to collect references that reflected the author’s purposes.

These articles must be considered warily in terms of any contribution they make to the state of knowledge on the subject. They have been included here because they illustrate the degree to which some elements of the question of external error reporting may have reached a consensus that is not necessarily based on data. They may illustrate the phenomenon of strongly held beliefs not supported by evidence. Nevertheless, as Table 2-2 illustrates, there is a great deal of overlap in the issues and concerns raised in these less-substantial articles, as compared with the original studies and systematic literature reviews.

The original studies were of various validity. Weissman et al. interviewed hospital administrators. While leadership is vital to reporting compliance, administrators are not necessarily the hospital personnel who make decisions regarding external reporting. Hospital risk managers and compliance officers would have been appropriate to include in the sample.

Marchev et al. do not quantify their conclusions. They state that “The following were among the reasons cited for under reporting,” (Marchev et al., 2003: 20) but they do not report how many of the 19 states in the sample reported each or all of the five reasons they give. Likewise, Barach and Small reach their conclusions without discussing the specifics of the interview sample and precisely which industries the experts represented.

Spigelman and Swan, and Hutchinson et al., studied error reporting barriers and facilitators, but in countries (Australia and the UK) where providers report directly into the national system. Their conclusions regarding data control concerns and cultures of safety may be transferrable to the USA, but mainly correspond to *internal* reporting processes in this country.

In most of the original studies and literature reviews conclusions about barriers to external reporting were not the primary focus of the research. They appear incidentally or tangentially, and are not necessarily the product of the study designs. Although Weissman et al., Hutchinson et al., and Morton et al. report statistical data specifically regarding external reporting barriers, their data are highly specific to their chosen subject (such as a comparison of two specific databases,

rather than a broader review of the success of several voluntary and mandatory databases), or not limited to surgical error reporting.

Limitations in this Review

Inclusion of studies not specifically referring to surgical error reporting is also a limitation of this literature search. Although the search terms were specific to surgical error, many of the articles that were retrieved were not limited to surgical errors, and frequently did not address them specifically. Instead, the literature tended to discuss reportable medical errors in general, particularly the studies of NYPORTS and in foreign countries, where it appears that many incident reports are entered into government databases that would not meet the more restricted criteria of surgical errors as defined by many state systems in the USA.

Conclusion

The literature on barriers to external reporting of surgical errors is immature. Little work has been published specific to the processes hospitals and other medical institutions engage as they report, or fail to report, as required by many states. There remain questions about whether barriers to internal reporting within hospitals may be analogous to external reporting barriers, perhaps with analogous solutions. It also remains mysterious whether states and institutions are fully aware of the extent of under-reporting, consider this a serious problem, or know what to do about it.

It is clear that there is widespread anxiety regarding the consequences of reporting. Legal liability, confidentiality and public embarrassment are frequently

cited as major factors complicating compliance with reporting. The actual effect of these concerns on reporting has not been quantified.

Although some states have adopted the Patient Safety Organizations permitted under the Patient Safety and Quality Improvement Act, no research was located that studies whether states with PSOs are experiencing improved rates of error reporting, even though the PSO system provides increased protection from discovery and disclosure.

Likewise, no research was discovered that compares rates of error reporting between states with mandatory and voluntary reporting systems, or between states with punitive and nonpunitive approaches to reported errors.

Table 2-1: SYNTHESIS OF STUDIES AND SYSTEMATIC LITERATURE REVIEWS

Authors and Year	Nation	Methodology	Sample	Negative Barriers	Positive Recommendations
Weissman et al. (2005)	USA	Cross-sectional survey	203 hospital senior administrators	*By % asserting:* Mandatory, nonconfidential nature (68%, p=.83) Mandatory, confidential nature (64%, p=.83 Nonmandatory nature (73%, p = .83) Legal liability (79%, p=.01) Unclear reporting criteria (23%, p not stated) Belief systems do not effect patient safety (no effect or negative effect 73%, p=.04)	Confidentiality Clarify definitions Collaborate with hospitals Grant protected access to information Liaison with state hospital and medical associations
Spigelman and Swan (2004)	AUS	Cross-sectional survey	12 users (including multiple hospitals for each user) of national reporting system	Limited reporting capabilities Lack of control over database Monitoring of clinical quality and patient safety strategies would create an incentive for under-reporting	Comparison data readily available
Marchev et al. (2003)	USA	Cross-sectional survey	Responsible managers in 19 states with mandatory reporting systems	Lack of internal systems to identify errors Lack of clarity over reporting requirements Reporting burden	

				Perception of lack of usefulness Lack of state enforcement Fear of legal liability and public embarrassment	
Hutchinson et al. (2007)	UK	Retrospective analysis of reports	Incidents reported from 148 hospitals		Culture of safety and reporting in organization. Higher reporting rates were correlated with encouragement to report (regression coefficient 0.03, CI 0.01 – 0.06, p=.009), with staff having experience reporting errors (regression coefficient 0.04, CI -0.001 – 0.05, p=.058)
Flink et al. (2009)	USA	Retrospective comparison of JCAHO and NYPORTS data	11,028 reports to NYPORTS and 2405 to JCAHO	Spontaneous reporting (non-automatic) Turnover of hospital reporting staff	Mandatory reporting Effective information tech systems Information must be meaningful and useful to reporters Protection from discovery Include stakeholders in design and implementation Clear reporting criteria Ongoing training and support Stakeholder advisory Feedback to reporters
Morton et al. (2004)	USA	Retrospective comparison of reports to NIS and SAGES	99,552 cases in NIS, 579 cases in SAGES	Voluntary system may lead to underreporting	

Tuttle et al. (2002)	USA	Retrospective comparison of NYPORTS reports and hospital records	560 case reviews	Lack of clarity in internal systems	
Barach and Small (2000)	USA	Cross-sectional survey	Unspecified		Debriefing procedures included in reporting Non-punitive systems Protected data Voluntary reporting Balance accountability, transparency, and protection
Russell et al. (2003)	UK, but refers to USA	Systematic Literature Review	3300+ studies	Publicly disclosed mortality may contribute to a reluctance to treat high-risk patients	
Fassett (2006)	USA	Systematic Literature Review	"All relevant publications"	Fear of legal liability	Protection from discovery

Table 2-2: FACTORS AFFECTING ERROR REPORTING BY NUMBER OF ARTICLES IN WHICH THEY APPEAR

FACTOR	Studies	Systematic Literature Reviews	Issue Overviews	Editorials
BARRIERS TO REPORTING				
Policy: Mandatory nature of system	●		●	●
Policy: Voluntary nature of system	●●●			
Policy: Fear of legal and civil liability	●●	●	●●	●●●
Policy: Concern about public disclosure	●●		●●●●●●●	●●
Policy: Fear of professional retribution			●●	●●
Policy: Lack of state enforcement or resources	●		●●	
System: Lack of clarity of reporting requirements	●●●		●●	●
System: Lack of control over information	●			
System: Lack of feedback and perceived usefulness	●●		●	
Internal: Culture of shame and blame			●●●	●
Internal: Lack of effective internal systems to identify errors	●			
Internal: Reporting burden	●			
Internal: Turnover of hospital reporting personnel	●			
FACILITATORS OF REPORTING				
Policy: Voluntary nature of system	●			
Policy: Mandatory nature of system	●		●	●●
Policy: Protection from discovery or negative consequences	●●	●	●●●	●●
Policy: Public Disclosure			●	
Policy: Protection from professional retribution			●	●●
Policy: Confidentiality of reports	●		●●●	●
System: Clear reporting criteria	●●		●	
System: System ease of use			●●●	●
System: Effective analysis and feedback loop	●●●●●		●●	
System: System includes safety tools and incentives			●	
System: Stakeholder involvement in design and implementation	●●●			

System: Ongoing training and education	●		●	
Internal: Culture of safety	●		●●●	●
Internal: Institutional leadership supportive of reporting			●	

Chapter 3: Study Model and Methodology

Study Objectives

The position that the state agency occupies is critical in relation to the other actors in the medical error reporting system. The literature review demonstrated, however, that little is currently known about the perceptions held by state agencies regarding the risk of surgical error under-reporting. The importance of the research questions derive from the vital role of the state surgical error reporting systems in the prevention of future errors. The objective of this study is to illuminate the beliefs of state agencies regarding potential under-reporting, and the states' perception of their role in managing compliance with surgical error reporting requirements.

The study answers these questions:

1. What are the states' perceptions of compliance with mandatory reporting of surgical errors?
2. What are the perceptions of state agencies regarding barriers to reporting of surgical errors?
3. If states believe under-reporting is occurring, what is their level of concern about it?
4. If states believe under-reporting is occurring, what are they doing about it?
5. What are the states doing with their reported error data to improve healthcare Quality?
6. What feedback do states give to providers regarding reported errors?

7. How do state agencies perceive their role in enforcing reporting requirements?

Method and Support

This research consisted of a case study of state attitudes toward compliance with requirements for surgical error reporting, and leads to recommendations for ways that state and federal agencies can modify policies to improve error reporting. A case study model is appropriate because so little is known at this time about the degree of awareness or priority held by state agencies regarding under-reporting. The study is largely descriptive, intended to discover and report the perceptions of state agency leaders. The concept of "case" may include either the entity being studied, or an issue "for which cases are selected to illustrate..." (Creswell, 1998:.63). This study examined an issue (under-reporting of surgical errors) for which cases (key informants in state agencies) were selected. A diverse sample of state agencies was chosen in order to include the variety of state error system types in the study. Table 3-3 displays the sampling frame used to assess the degree of heterogeneity among state reporting systems and to ensure diversity in the sample for key informant interviews.

Because the research questions are open-ended inquiries of the "What, how, why" type, a qualitative approach to the study is appropriate. Qualitative research is a strategy that illuminates phenomena by approaching the inquiry in particular ways, and "…for certain research problems, qualitative methods, which originate from within the tradition of the social sciences, offer a superior or alternative approach"

(Young, 2005: 215). Creswell notes several key characteristics of qualitative inquiry. Those are particularly applicable to this study are:

1. "Natural setting – Qualitative researchers tend to collect data in the field at the site where participants experience the issue or problem under study."

2. "Researcher as key instrument – Qualitative researchers collect data themselves through examining documents, observing behavior, or interviewing participants."

3. "Inductive data analysis – Qualitative researchers build their patterns, categories, and themes from the bottom up, by organizing the data into increasingly more abstract units of information."

4. "Participants' meanings – In the entire qualitative research process, the researcher keeps a focus on learning the meaning that the participants hold about the problem or issue, not the meaning that the researchers bring to the research or writers express in the literature."

5. "Theoretical lens – Qualitative researchers often use lens to view their studies…"

6. "Interpretive – Qualitative research is a form of interpretive inquiry…"

7. "Holistic account – Qualitative researchers try to develop a complex picture of the problem or issue under study. This involves reporting multiple perspectives, identifying the many factors involved in a situation, and generally sketching the larger picture that emerges" (Creswell, 2009: 175 – 176).

This study design is consistent with the selected characteristics of Creswell: it was designed the take place in the natural setting of the key informants, utilizing a sole researcher, and conducted to develop answers to the research questions using the meanings reported by the key informants themselves. The extremity and complexity of responses was respected and sought, in order to serve the interpretive process.

This study is also compatible with characteristics of qualitative studies described by Rubin and Rubin, who find the qualitative method suitable for those seeking:

- "Nuance and subtlety"
- Tracing "…how present situations resulted from prior events"
- A fresh view
- Explanations for the unexpected
- "Layers of discovery" that lead to "alternatives that are then explored in turn" (Rubin and Rubin, 2005: 47 - 48).

This study seeks new explanations for phenomena not previously examined, and answering the research questions required understanding and sensitivity to subtleties in the informants' responses and the pursuit of new explanations.

The samples in a qualitative study "…tend to be purposive, rather than random," and small (Miles and Huberman, 1994: 27). In this study, the universe of state agencies available is 25, and the number of states selected for interviews was 11. The sample was chosen deliberately, based on the high value that was placed on diversity of agency characteristics regarding error reporting.

Environmental Model and Conceptual Framework

State error reporting systems operate within a complex landscape of government, health care institutions, health care providers, law, media and the public. The state agencies may interact with any or all of these stakeholders. The state agencies are subject to competing forces from the governmental side as well as from legal, institutional and public sectors. This study focused on questions

surrounding the ways that states regard the reporting hospitals as compliant or non-compliant with reporting requirements.

The environmental model of the position of the state agency presented in Figure 3-1 was developed by the author to define the arena for the research questions. Because the environment is complex and includes many two-way influences, the conceptual model is a web of relationships and information pathways. It is at the point between the reporting health care institution and the state agency that the error reporting cycle of notifications, data analysis and feedback occurs under ideal circumstances.

FIGURE 3-1: LOCATION OF THE STUDY FOCUS WITHIN THE ENVIRONMENT OF ERROR REPORTING

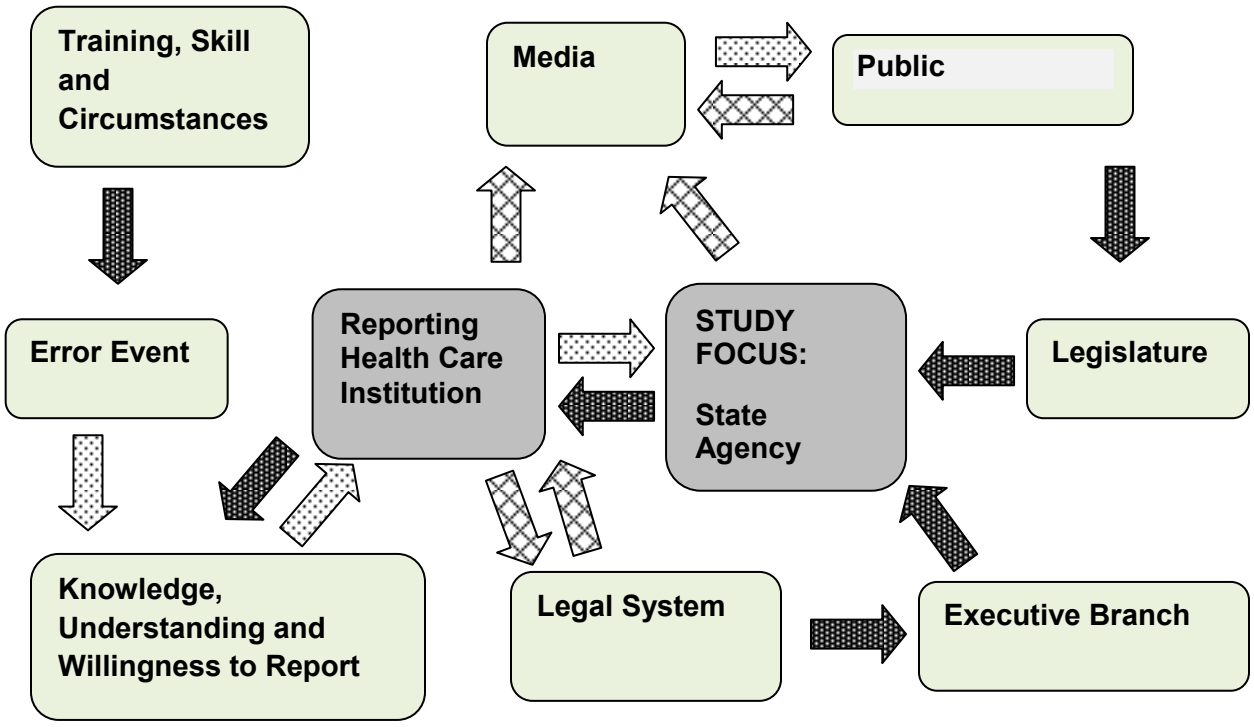
Error reporting and influence may theoretically occur between almost any two or more of these stakeholders, and in any direction. The primary concern of this study is reflected in the direction of the error reports and influence described in this model

Key:

Error Information Flow* (⇨ **)**

Legal, political and social influence (➡ **)**

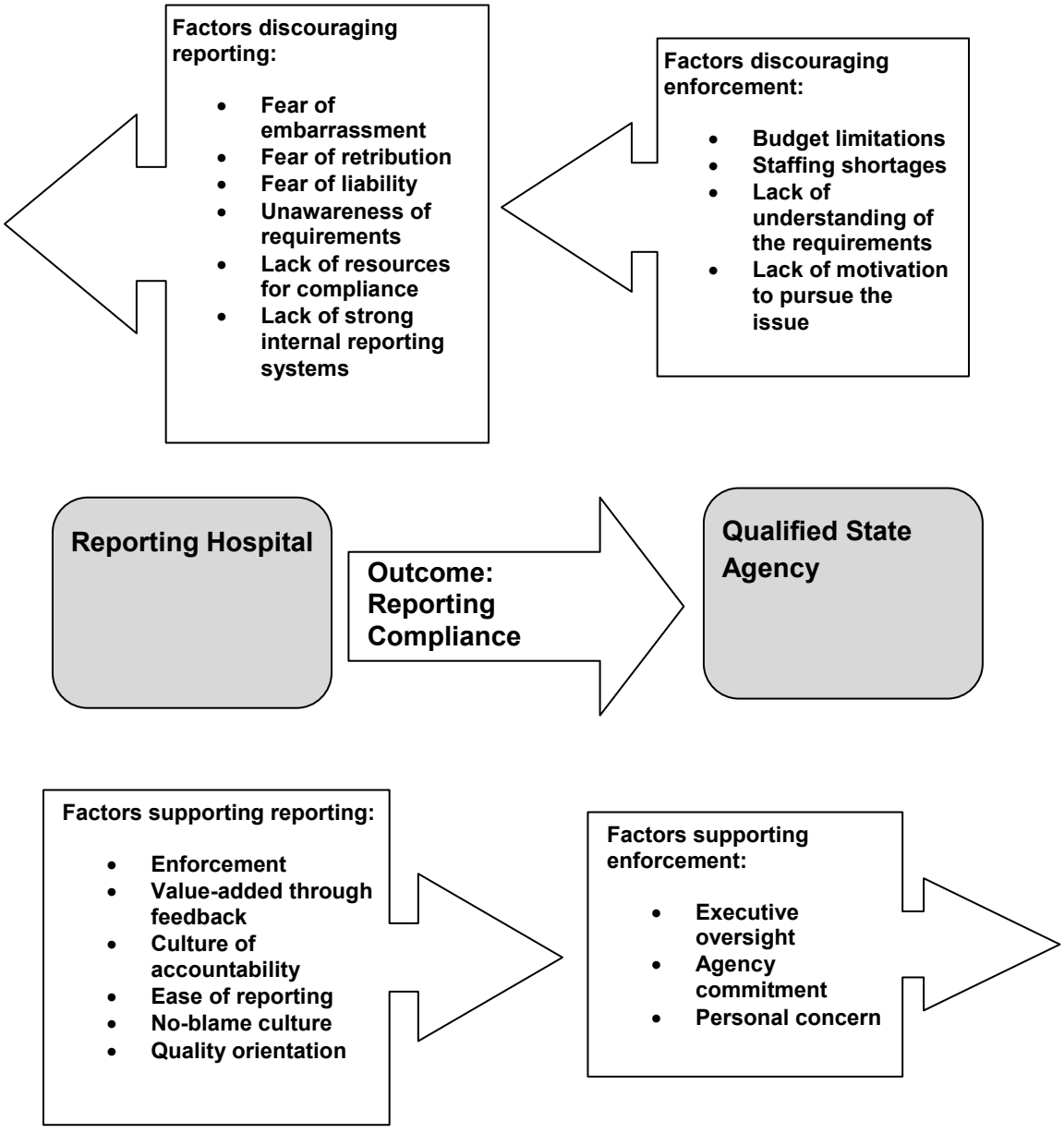
Both (⇨ **)**



The conceptual framework for this study is derived from the central relationship between the reporting health care institution and the state agency in the model. The literature review discovered factors (both negative and positive) affecting error reporting compliance from the perspective of health care institutions. The conceptual framework adopted for this study in Figure 3-2 is conceived as a tug-of-

war between factors that encourage and discourage compliance at the level of the reporting facility, and factors that encourage and discourage enforcement at the level of the state agency.

FIGURE 3-2: CONCEPTUAL FRAMEWORK



The study methodology was crafted in part to respond to this conceptual framework by examining the understanding of the QSAs regarding these factors and the QSAs' efforts to ensure reporting compliance.

Overview of Study Design

This qualitative case study was conducted in two phases: a descriptive pre-survey and a smaller selection of key informants for qualitative interviews. In order to answer the research questions, it was essential to begin by collecting state agency information through a pre-survey that permitted the key informant statements to be placed in context. The interviews with key informants in turn provided most of the data that answered the research questions.

Pre-Survey

The purpose of the pre-interview survey was to differentiate between state agencies on the basis of bureaucratic and legal responses to surgical error reports. This differentiation allowed a diversification of the survey sample in order to ensure that perspectives from states with a variety of policies were included.

The survey also provided updated information on the practices of the agencies. National Academy of State Health Policy reports from 2002 to 2007 report a rapidly evolving environment in which the number of states requiring error reporting has accelerated, the levels of protections extended to reporters have evolved, and the definitions of reportable errors have begun to standardize across the country.

Key Informant Interviews

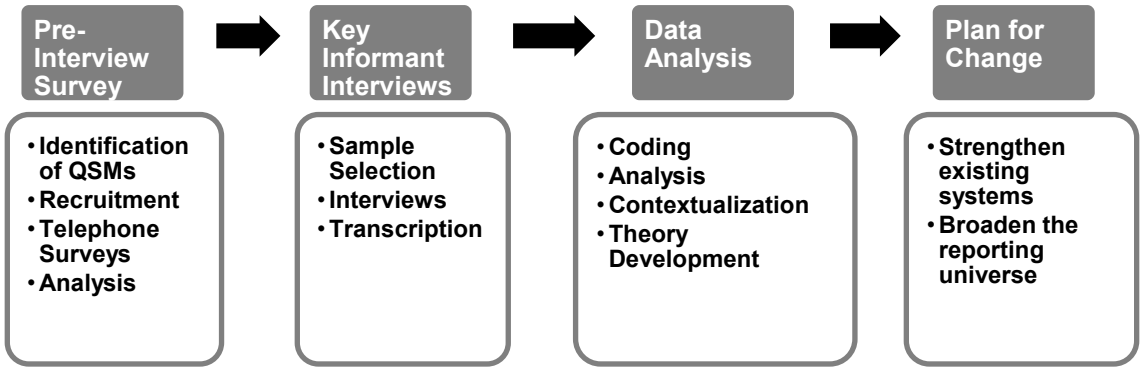
Following the collection of the pre-interview survey results and the selection of the key informant sample, key informant interviews were conducted. Key informant interviews followed accepted practice regarding recruitment, confidentiality, interview conduct and documentation, and protection of data. The data received from the key informant interviews were coded and analyzed in context with the information received from the pre-interview surveys.

Analysis and Plan for Change

The research questions were answered using the information from both data sources, and discussed in the context of relevant organizational theory. A plan for change is proposed using the results of the research as support for public policies that will encourage greater awareness of the need to ensure that all reportable surgical errors are in fact reported, and that reports lead to improvements in patient safety.

The study components were structured and sequenced as described in Figure 3-3:

FIGURE 3-3: STUDY COMPONENTS AND SEQUENCE



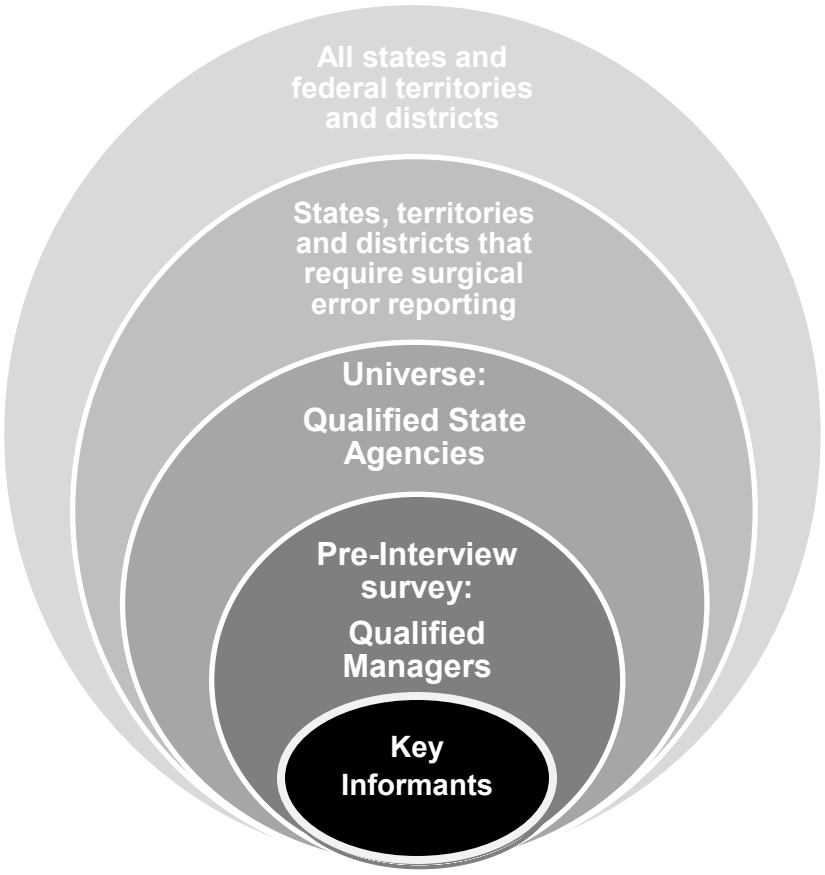
Study Design and Research Strategy in Detail

Study Subjects

The study was multi-sited, focused upon an issue of interest. The human subjects of this study were Qualified State Managers (QSMs) located within the Qualified State Agencies (QSAs) that receive reports of surgical errors. QSAs are typically units or divisions within the state health department or its equivalent. In some states QSAs have multiple responsibilities including licensing of health care entities and error reporting, while other states have separated the two functions into distinct units. In states with such separation, the QSA was the unit that manages error reporting. The QSMs had responsibility for receiving or managing, or supervising the receiving or managing, of incoming medical error reports.

The selection of study subjects and the key informant sample in this research followed a funneling strategy as described in Figure 3-1:

FIGURE 3-4: SELECTION OF STUDY SUBJECTS



Inclusion

Subjects were included in the pre-interview sample selection and key informant sample selection if they were QSMs.

Exclusion

No exclusions were necessary from the QSM sample selection.

Study Setting

The research was conducted by telephone at the subjects' workplaces. Additional information was exchanged by email. Published reports of state medical error programs and the laws that established them also provided necessary data.

Definitions

Several challenging terms required careful definition in this study. Among the most critical are "reportable error" and "surgical error." Additionally, this study considered "punitive" and "non-punitive" responses to error reporting. These and other terms required clear definition.

Qualified State Agency: An organization was considered "qualified" for sample selection for this study if it met al.l of the following criteria:

1. It is located within the executive branch of a state, territorial or federal district government
2. The state, territory or federal district in which it is located requires surgical errors to be reported to the state by health care entities
3. It is designated as the entity within the state, territory or federal district government that receives reports of surgical errors from medical facilities

Qualified State Manager: A manager was qualified for participation in this study if he/she met al.l of the following criteria:

1. He/she works within a Qualified State Agency
2. He/she is responsible for managing the receipt of reports of surgical errors from medical facilities OR
3. He/she is responsible for supervising those who manage the receipt of reports of surgical errors from medical facilities

Reportable Medical Error: "Reportable Medical Errors" were defined in this study as any medical error that is required to be reported to the state. If a state required an error to be reported, it was considered a "Reportable Medical Error." This simple term was be used

consistently in survey and interview stages and was defined for the survey and interview participants.

Reportable Surgical Error: "Reportable Surgical Errors" were defined in this study as any surgical error that is required to be reported to the state. The commonality of the NQF definitions used by many states is a strength of error reporting systems, but it was also valuable to examine the experiences and insights of states that define their own surgical errors. It is the nature of reporting, under-reporting and enforcement that concerned this study, so the insights of states that developed their own definitions of surgical errors were as useful as those that follow the NQF definitions.

Punitive: States were considered to take a "Punitive" approach to reported surgical errors when they may take any of these actions in response to errors reported in compliance with state law:

1. Open an investigation into the incident
2. Expose the reporting facility to the potential of a Statement of Deficiencies
3. Expose the reporting facility to the potential of a required Plan of Correction
4. Expose the reporting facility to the potential of fines
5. Expose the reporting facility to the potential of suspension or loss of license

"Punitive" did not include requiring facilities to submit documentation related directly to the event, including reports, case records, root cause analyses (including associated plans for correction), or any other quality improvement record as a normal part of the process of receiving the error report. Submission of these types of documents was considered routine. "Punitive" also did not include release of aggregated, facility-specific or incident-specific data to the public when this was a normal part of the state practice in response to reported errors. Such data release was also considered routine, unless the power to release such data was used selectively in response to some reported errors and not others.

Nonpunitive: States were considered to take a non-punitive approach to reported surgical errors when they did not take any of the "Punitive" actions defined above.

Recruitment

Study participants were selected from the twenty-five "Qualified State Agencies" in the USA. Within each QSA the most appropriate QSM was identified through email and telephone inquiries, considering the advice of the NASHP and the NQF, which have frequent contact with many QSAs. When the most appropriate QSM was identified, a series of timed contacts was employed to encourage participation for each of the two projects (pre-interview survey and key informant interviews):

1. Email to QSMs thanking them for agreeing to participate and describing the coming pre-interview telephone survey and its purposes and confidentiality provisions (standard form attached as Appendix A)

2. QSMs were contacted by telephone or email to confirm a mutually-acceptable time for completion of the pre-interview survey

3. After the sample selection was completed for key informant interviews, the selected subjects were contacted again by email and a mutually-acceptable time was decided for completion of the interview

4. When key informants were not present or available at the scheduled interview time, an additional contact by telephone or email was made to reschedule and to express the value of the subject's participation in the study

Pre-Interview Survey

QSMs in the twenty-five states that actively require reporting of medical errors were contacted and requested to complete a short telephone pre-interview survey. The pre-interview survey is attached as Appendix B. The survey consisted of fifteen questions, two of which give permission for further contact.

Two key areas of the pre-survey asked the QSMs' opinions regarding compliance by health care entities with reporting requirements, and awareness of unreported errors discovered through other channels. Critical additional information in the pre-interview survey included types of facilities that were required to report surgical errors, definitions of surgical errors used in the state, and potential consequences under state policy to providers who comply with reporting requirements. This last component was used to ensure that the key informants include states with both punitive and non-punitive approaches to reported errors.

In addition, legal protections for reporters and details of state data analysis and data release were collected in order to generate a current context for the interviews.

Content validity of the pre-interview survey was established through a pretest of the survey instrument by four employees and two managers performing regulatory compliance in a state agency outside the QSA selection, following which the instrument was revised and refined. Survey categories were rewritten for clarity and restructured for logical flow.

Because responses to the pre-survey were used to diversify the key informant sample, it was valuable that many of the questions in the pre-survey updated information that was not published since 2007. These items are identified below by (*). Questions that reveal information not currently available from any other identified source are identified below by (**):

- What facilities must report errors in the state (*)
- What are the potential regulatory consequences of error reporting (*)
- What types of disclosure of reports are made to the public and press (*)
- What legal protections may result from reporting by facilities to the state (*)
- What definitions are used in requiring error reporting (*)
- What does the state estimate as the level of compliance with error reporting (**)
- What is done with reported error information? (*)
- What role does the agency receiving reports have in enforcement of reporting requirements (**)

The survey questions were written with attention to ease of reading and comprehension and clarity of response options. Because QSMs were anticipated to be college graduates, questions were written to approximately a 12th grade reading level.

Selection of Key Informants for Interviews

The results of the pre-interview survey were used in the selection of key informants for interviews. The selection was guided by the principle of diversification of the sample, which is important in order to ensure that a variety of perspectives and opinions are included in the data. Although the universe of QSAs is not large, efforts were made to include QSMs from states that fall into each of the categories described in Table 3-3: Low and High Perceived Under-Reporting; Low and High Punitive Response to Error Reports; and Low and High Role in Enforcement of Reporting Requirements. The intention of this study was to perform key informant interviews with 35% - 45% of QSMs, for a total of between 9 and 11 interviews, and with sufficient sample size to include at least one QSM in each of the categories in Table 3-3:

TABLE 3-1: SAMPLING FRAME FOR KEY INFORMANT INTERVIEWS SAMPLE TO INCLUDE QUALIFIED STATE AGENCIES WITH:

Dimension I: Perceived Under-Reporting	LOW	HIGH
Dimension II: Punitive Response to Reported Errors	LOW	HIGH
Dimension III: Role in Enforcement of Reporting Requirements	LOW	HIGH

A score for each QSA on each dimension was calculated from the pre-survey responses or from recoding of some variables on the pre-survey. Each QSA was placed in either the “LOW” or “HIGH” category for each dimension.

Key Informant Interviews

The major component of the study consisted of semi-structured, open-ended key informant interviews with QSMs. The interviews were conducted by telephone as in-person interviews were impractical due to the nationwide scope of the sample. The interviews followed a constructed interview protocol to ensure that identical topics were raised in each interview. The interview guide is attached as Appendix C. Each interview concentrated on questions surrounding under-reporting: the QSMs’ perceptions of their state agency’s role in enforcement, the possible causes of under-reporting, uses of reported data and whether the key informants believe that improving under-reporting is an issue worth investing in and is supported by their state agency, executive or legislative body.

The interview guide progressed through major topic areas that reflect the primary research questions. Each topic area included several questions designed to

illuminate the general topic. The topic areas correspond to the research questions in this way:

TABLE 3-2: INTERVIEW TOPICS KEYED TO RESEARCH QUESTIONS

Interview Topic Area	Research Questions Addressed
Extent of concern regarding possible noncompliance	What are the states' perceptions of compliance with mandatory reporting of surgical errors?
Perceptions of potential causes of underreporting	What are the perceptions of state agencies regarding barriers to reporting of surgical errors?
Perceptions of the Agency's role in enforcement	If states believe under-reporting is occurring, what is their level of concern about it? If states believe under-reporting is occurring, what are they doing about it? How do state agencies perceive their role regarding enforcement of reporting requirements
Perceptions of the Agency's role in analysis of error reporting data	Are the state agencies using their reported error data to improve healthcare quality? What feedback do state agencies give to providers regarding reported errors?

Interviews were digitally recorded with the key informants' permission, and were transcribed and analyzed as described below.

Reliability and Validity

Both the pre-interview survey guide and the key informant interview guide were subjected to processes intended to ensure reliability and validity.

Reliability: Pre-interview survey coding and key informant interview transcripts were double-checked for errors. Code drift was controlled through careful memo writing regarding the meaning of the codes, and through continual checking of data against codes. This is consistent with the guidance of Creswell, who notes "Make sure that there is not a drift in the definition of codes, a shift in the meaning of the codes during the process of coding. This can be accomplished by constantly comparing data with the codes and by writing memos about the codes and their definitions" (Creswell, 2009: 190).

Validity: Content validity of the pre-interview survey and key informant interview guide was achieved through field-testing by employees and managers performing regulatory compliance in a state agency outside sample selection. Feedback was solicited for clarity, ease of use, relevance and other factors that may have influenced results. The survey instrument and interview guide were modified in response to this feedback.

Both the pre-interview survey and key informant interviews were subjected to peer debriefing, in which a person not involved in the study reviewed the data. This process adds an "interpretation beyond the researcher and invested in another person" and "adds validity to an account" (Creswell, 2009: 192). The two peer debriefers both responded that the conclusions appeared reasonable and logically followed from the findings.

The process of member checking was employed to clarify or verify the themes arising from the data. Member checking was conducted through follow-up

emails. Two key informants were asked to review the study findings and conclusions for validity. One key informant disagreed with one conclusion. The conclusion was reviewed in light of the key informant's comments and was modified to clarify that effective use of data does not necessarily require complete reporting, and deletion of a statement that enforcement must be used to be of value.

Finally, triangulation resulting from multiple viewpoints contributed to study validity. "If themes are established based on converging several sources of data or perspectives from participants, then this process can be claimed as adding to the validity of the study" (Creswell, 2009: 191). Triangulation was achieved through multiple interviews with a state agency, and through comparison of interview data with published laws and state agency reports.

Risks and Benefits: IRB and Confidentiality

It was anticipated that only a rare risk of harm to the study subjects existed. A request for an exemption from full review was granted by the Institutional Review Board (IRB). The minimal risk to the subjects was based on possible lapses in confidentiality of the data resulting from key informant interviews. Rigorous segregation and protection of interview subject identifying information was employed to protect against this risk. Final analysis and publication of the interview data does not include personal or state identifiers.

The pre-interview survey was not handled in the same confidential manner because the information sought through the survey was mostly publicly available and reveals policy, rather than opinion. In those areas where the pre-survey includes

potentially embarrassing information, such as opinions regarding error reporting compliance, the same dual protections of personal and state identifiers were employed.

Verbal consent for the pre-interview survey included an explanation that completing the survey constituted consent to participate in only that portion of the study. Consent for participation in the key informant interviews was obtained verbally before the interviews commenced and confidentiality provisions were reviewed at that time.

The benefits of the study outweigh the minimal risk to participants. The study yielded descriptive data regarding state agencies that are novel or have not been updated since 2007. More importantly, the qualitative component illuminates the perceptions of state agencies regarding potential under-reporting of surgical errors and their role in the enforcement of error reporting requirements. This in turn may lead to increases in patient safety through awareness of the importance of the success of the error reporting process.

Study Delimitations

This study was bounded in several ways. It was limited to only those states where surgical errors are reported to a state agency by law or regulation. As of 2012, this included 26 agencies (25 states and the District of Columbia). One state (Oregon) has a system of voluntary error reporting, and was not included for that reason. A total of 25 states and federal districts were included in the study universe.

The remaining states and territories had no requirements for surgical error reporting and were not included in the study.

As described in Figure 3-1, the environment in which surgical errors occur and are reported and analyzed is complex. The role of the state agency touches many other institutions and stakeholders. Because the research questions focus on the state agencies' perceptions of error reporting compliance, the study was bounded by examining only the perceptions of the state agencies, rather than the perceptions of the other actors in the error reporting system. Although many important players, including legislators, executive branch officials, hospital administrators and the public are excluded from the study in this manner, the requirement for reporting emanates from the state executive branches, and thus the examination of the designated state agencies' opinions was of most importance in answering the study questions.

Study Limitations

Several limitations of this study must be acknowledged:

1. The key informants may not have been the most knowledgeable or effective personnel within the state agencies on the subject of the agencies' perceptions of the potential for under-reporting and the agencies' role in enforcing reporting. The selection of key informants included inquiries into the position, role and responsibilities of the individuals, but it is possible that others within the same or adjacent agencies may have had greater

knowledge of the states' positions on the subject. It is possible that several individuals had responsibilities for different aspects of the reporting cycle, and may have had different perspectives that may not all have been captured.

2. The key informants may have been reluctant to portray their states or their agencies in a perceived negative light. They may have been inclined to minimize the potential for under-reporting of surgical errors in their states, and to over-emphasize the effectiveness of their states in ensuring compliance with the laws and regulations. They may also have been inclined to minimize any perceived deficiencies in the quality activities of their agencies after data had been submitted.

3. The key informants, even if the most qualified subjects for the study, may not have been completely aware of their respective agencies' policies and institutional approaches to the topic of under-reporting of surgical errors. The key informants may, in such cases, have provided information they believed will please the interviewer rather than truthfully stating that they did not have information.

Researcher Bias

Creswell notes that the researcher in a qualitative study is engaged in interpretive research, which presents a range of ethical issues. The researcher should, therefore, "…explicitly identify reflexively their biases, values, and personal

background…that may shape their interpretations formed during a study" (Creswell, 2009: 177).

I have worked in the field of hospital licensing in the state of Washington for thirteen years. At times I have been responsible for enforcing the state law that hospitals report certain medical errors to the Department in which I work. I have also reviewed the reports hospitals have made, their investigations of their errors, and their plans for improvement to prevent future errors.

In the course of my work I became aware that at least some reportable errors were not reported as required in my state, and I cited several hospitals for failing to do so. My perception is that there is no reason to assume that Washington is different in this respect than any other state where error reports are required.

I must acknowledge my perception that under-reporting is a real phenomenon, and that it is unlikely to be corrected without active intervention by state agencies. However, upon beginning this study I had limited understanding of the nature of the work performed in other states where error reporting is mandatory. I had no knowledge of the techniques that other states have tried to improve reporting compliance, or whether their strategies to implement their laws and rules were more effective than I have observed in Washington. In this study it was necessary to maintain a position of openness to the unique characteristics and experiences of each state in the sample, and to particularly note the perceptions and experiences of those states that challenged my experience in Washington.

Limitation Management:

1. Initial recruitment of the Qualified Managers included the advice of researchers at the National Academy for State Health Policy, which produced numerous reports on the subject of state agencies and reportable medical errors over more than a decade. NASHP has accumulated the largest available published data collection regarding the characteristics of the Qualified State Agencies, so the advice of NASHP regarding key contacts within these agencies was valuable. The guidance of the National Quality forum was also sought regarding identification of QSMs and was extremely helpful when combined with that of the NASHP.

2. The pre-survey and interview included assurances of confidentiality and encouragements to respond frankly. Respondents were informed that they were making a contribution to research seeking answers that will make reporting systems more effective. They were encouraged to conduct the interview in private, so that they might speak freely. This was intended to encourage veracity and completeness of responses, and to overcome possible temptation on the part of respondents to portray their agencies in what the respondent may believe to be the best light.

3. Researcher bias was mitigated by crafting a survey instrument and interview guide that reflected objectivity and openness to the unique experiences and

perspectives of the various states. Particular attention was paid when state responses contradicted or challenged my own experiences and expectations.

4. Emphasis was placed on recognizing and considering discrepant information. Contradictory evidence widens and validates the account of a theme in the data (Creswell, 2009).

Chapter 4: Pre-Survey Results

The pre-survey and key informant interviews followed the guides in Appendices B and C. These instruments were designed so that topic areas corresponded to the research questions as described in Table 4-1. Each topic area was developed and analyzed to reveal descriptive and qualitative data that lead to answers to the research questions. The topics, corresponding research questions and data sources were:

TABLE 4-1: STUDY TOPICS KEYED TO RESEARCH QUESTIONS AND DATA SOURCES

Study Topic	Research Questions	Data Source
1. Extent of concern regarding possible noncompliance	What are the states' perceptions of compliance with mandatory reporting of surgical errors?	Pre-survey
2. Perceptions of potential causes of underreporting	What are the perceptions of state agencies regarding barriers to reporting of surgical errors?	Key Informant Interview
3. Perceptions of the Agency's role in enforcement	If states believe under-reporting is occurring, what is their level of concern about it? If states believe under-reporting is occurring, what are they doing about it? How do state agencies perceive their role regarding enforcement of reporting	Key Informant Interview Pre-survey and Key Informant Interview

	requirements?	Key Informant Interview
4. Perceptions of the Agency's role in analysis of error reporting data	Are the state agencies using their reported error data to improve healthcare quality? What feedback do state agencies give to providers regarding reported errors?	Key Informant Interview Pre-survey and Key Informant Interview

For each topic area, the data resulted in key findings that are presented here, followed by the data that supported the findings. Topic 1 is addressed in the pre-survey results presented in this chapter. Chapter 5 includes results of Topics 2 – 4.

Twenty-seven Qualified State Agencies (QSAs) were contacted by email and telephone during September – December, 2012. During the course of these contacts it was found that one state (Wyoming) had ceased its medical error reporting program. Another state (Illinois) had never implemented its program due to lack of funding. The universe of QSAs was reduced to 25.

Telephone pre-surveys were conducted with 22 of 25 QSAs (88.0%). QSM responses were documented on the pre-survey instrument. Verbatim notes were taken by hand for the open-ended questions. All identified QSMs in the 22 contacted states agreed to be interviewed by telephone or provided substantially complete information by email. The refusal rate for the 22 states was 0.0%

Three QSAs could not be contacted for interviews. However, two of these three QSAs publish annual reports of their medical error reporting programs that provided significant data. Thus, the pre-survey was substantially completed for 24 of 25 QSAs (96.0%). One QSA (South Carolina) could not be contacted by telephone or email, and no published medical error report could be found.

Complete results of the pre-survey are found in Appendix D. Descriptive data are presented here, followed by transitional qualitative data included in the pre-survey. The descriptive data illustrate the variety of program approaches to surgical error reporting. Note that the *n* varies between data presentations because not all states responded to every question on the pre-survey.

Topic 1: Extent of concern regarding possible noncompliance

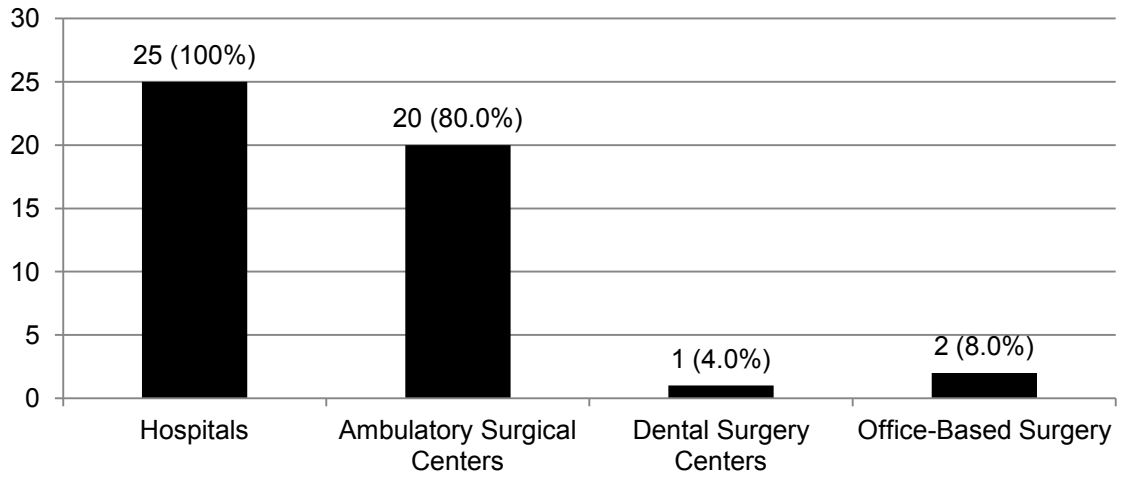
Pre-Survey Descriptive Data:

KEY FINDING #1: There is great consistency between the states in terms of the types of health care entities that must report surgical errors and the response of the QSA to a report. (Reference Figures 4-1 and 4-2)

States with error reporting programs universally require hospitals to report surgical errors to the QSA. Most also require ambulatory surgical centers (ASCs) to report surgical errors, although in several states the specific categories of errors that must be reported differed between hospitals and ASCs. Requiring error reports from dental surgery centers and physician office-based surgery was unusual.

FIGURE 4-1: FACILITIES REQUIRED TO REPORT SURGICAL ERRORS BY NUMBER OF STATES WITH THIS REQUIREMENT

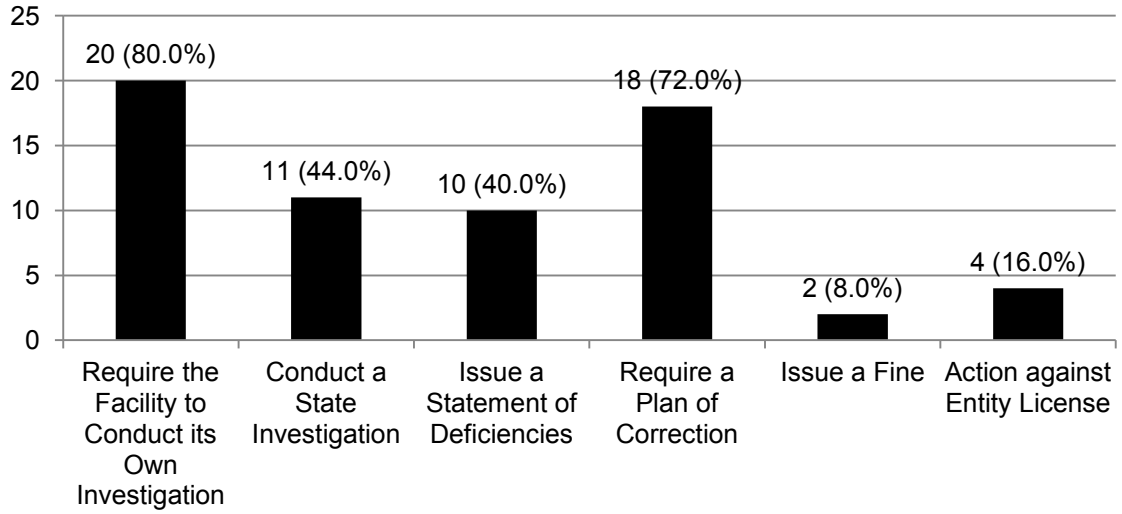
n=25 (State agencies may have multiple responses to this question)



Most QSAs required the reporting health care entity to complete an internal investigation in the form of a root cause analysis (RCA), and submit the RCA to the QSA. As part of the RCA, most states also required the reporting entity to generate a plan of correction and submit this as well. Some QSAs reported that the state might also conduct its own investigation of a reported event, and that investigation could result in a statement of deficiencies issued to the entity. Highly punitive actions such as fines, action against the entity's license or action against a practitioner were not common features of the programs.

FIGURE 4-2: RESPONSES OF STATES TO REPORTS OF SURGICAL ERRORS

n=25 (State agencies may have multiple responses to this question)

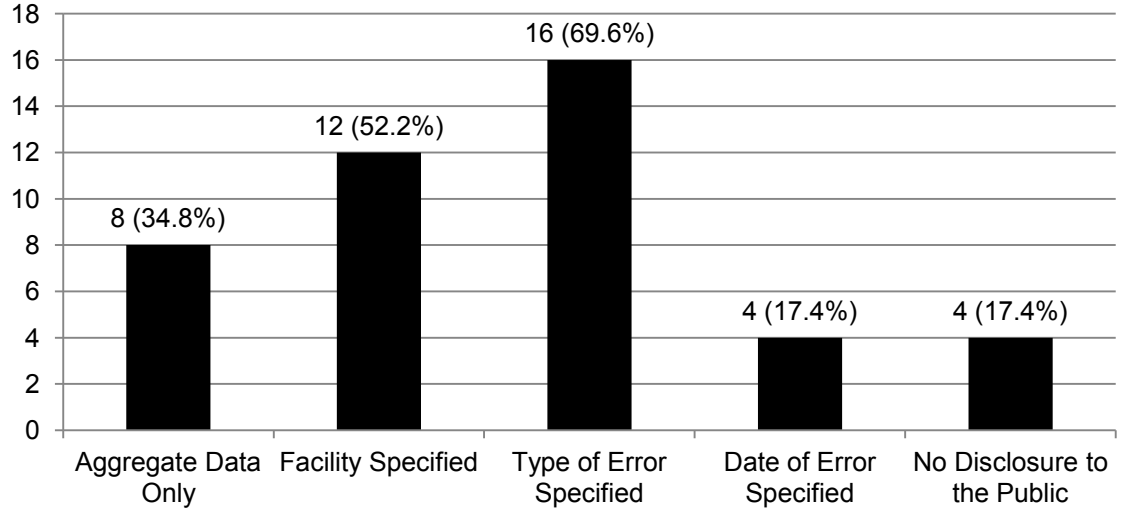


KEY FINDING #2: There is great variety between the states in the definitions of surgical errors, disclosure practices, legal protections offered to reporting entities, enforcement strategies and internal use of the data by the QSAs. (Reference Figures 4-3, 4-4, 4-5, 4-6 and 4-7)

Error reports received by QSAs were released to the public by a majority of the QSAs, but the amount of detail available to the public varied. Some states reported only aggregate data (e.g., “x number of events were reported in the state this year”) while others revealed the number of events by type, by date, and by naming the health care entity where the error occurred. A few did not disclose any reported surgical error data to the public.

FIGURE 4-3: DISCLOSURE OF REPORTED ERRORS BY STATE AGENCIES

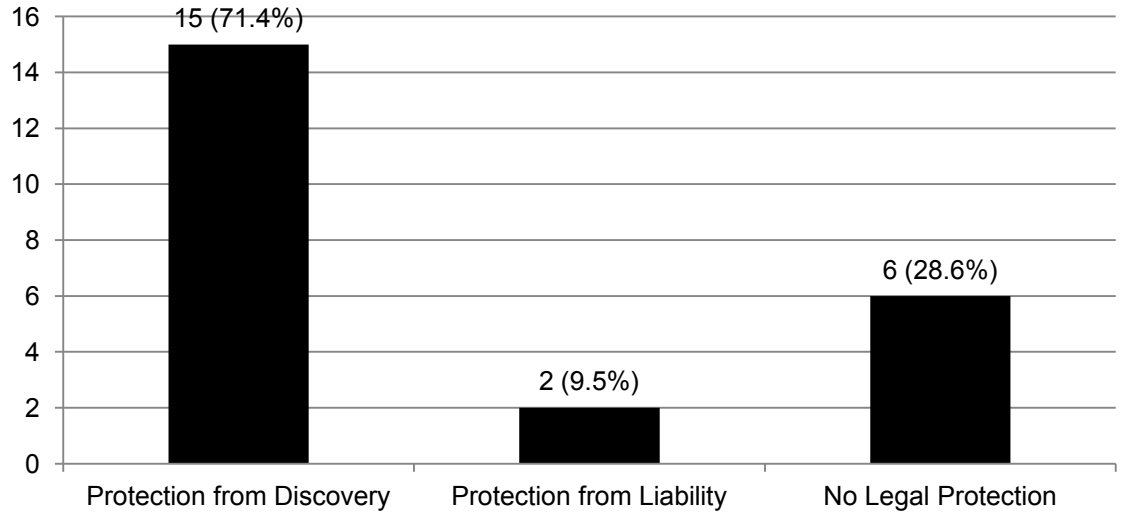
n=23 (State agencies may have multiple responses to this question)



Most states assured the reporting health care entities that the data submitted were protected from legal discovery. A few stated that entities were offered protection from liability for the data submitted, while others provided no legal guarantees to the entities that report.

FIGURE 4-4: PROTECTION OFFERED BY STATES TO REPORTING HEALTH CARE ENTITIES

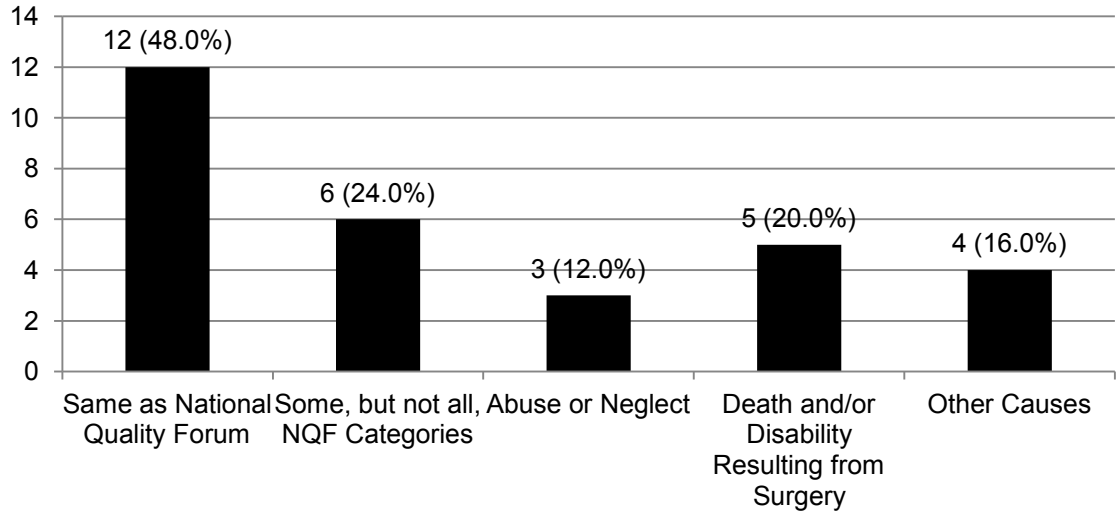
n=21 (State agencies may have multiple responses to this question)



Nearly half of the states that require medical errors to be reported have chosen the definitions of reportable surgical error published by the National Quality Forum (NQF). Among those states that did not adopt the NQF definitions in full, many had definitions that mirrored one or more of the five NQF categories. Several states, however, used a broad requirement to report death or disability caused by abuse or neglect, or death or disability resulting from surgery, rather than specific surgical errors.

FIGURE 4-5: DEFINITION OF SURGICAL ERROR USED BY STATES

n=25 (State agencies may have multiple responses to this question)

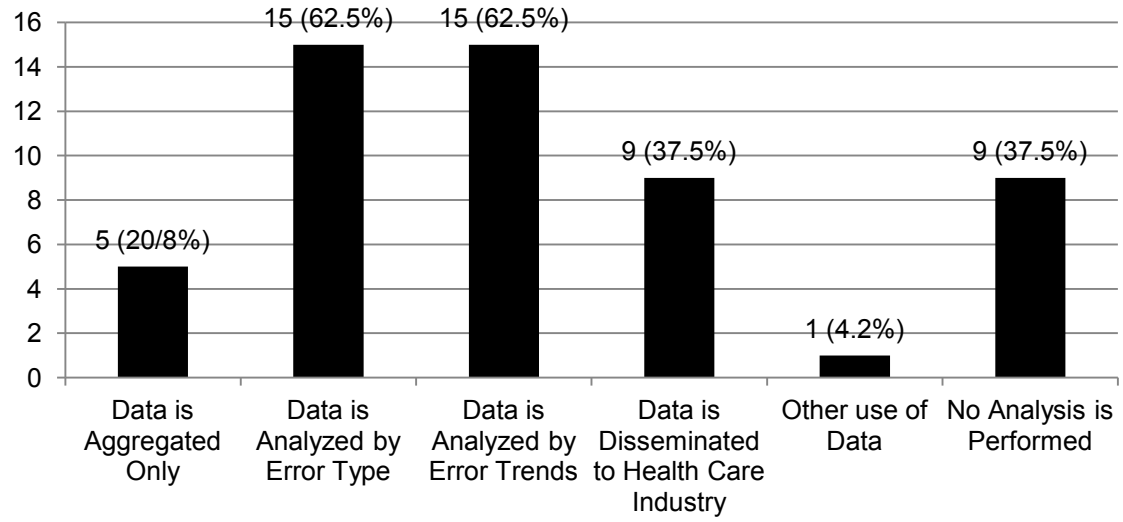


Use of reported surgical error data by QSAs varied widely. Some QSAs used reported data to discovery year-over-year trends in error reports, and to analyze events by type of error. As part of the analysis many states also disseminated information to the health care industry, providing a feedback loop to the entities that reported the errors to the QSA. Other states, however, used the data only in

aggregate form (tracking total numbers of events reported) while some did nothing at all with the data that was submitted.

FIGURE 4-6: ANALYSIS OF REPORTED SURGICAL ERRORS BY STATES

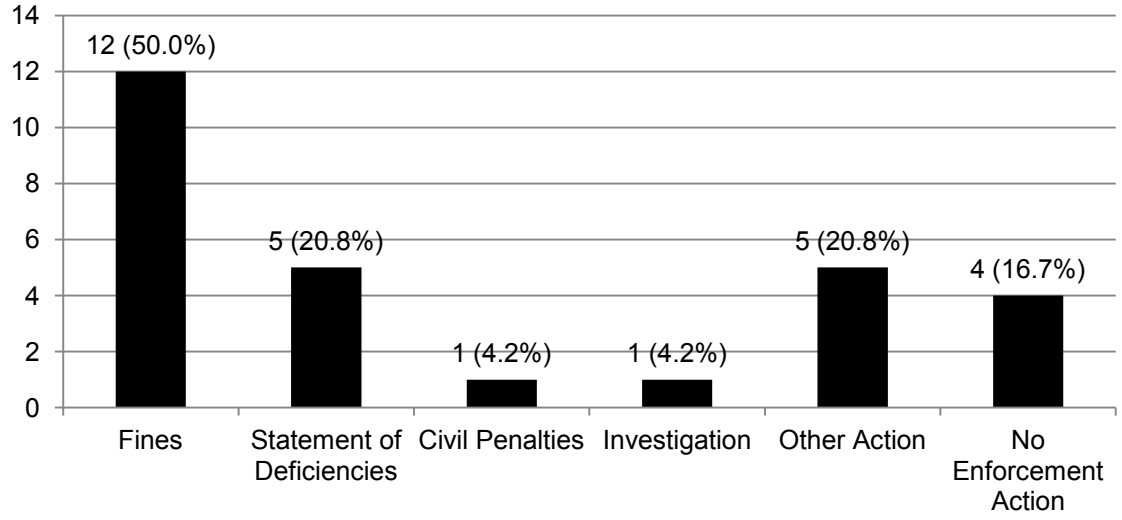
n=24 (State agencies may have multiple responses to this question)



It was common for QSAs to engage in enforcement of the reporting requirements. Penalties for failure to report a surgical error were common, with fines being the most frequently mentioned sanction. Few states took no punitive action when a health care entity failed to report a surgical error as required.

FIGURE 4-7: ENFORCEMENT OF ERROR REPORTING REQUIREMENTS BY STATES

n=24 (State agencies may have multiple responses to this question)



These descriptive results have two applications in this study: they are vital for diversification of the key informant interview sample (ensuring that minority viewpoints on this key question are represented) and they establish the context for the additional data generated from the key informant interviews.

Before presenting the results of the key informant interviews in the next chapter, however, there is was a set of qualitative data included in the pre-survey that is critical for the understanding of the perceptions of the states regarding under-reporting of surgical errors.

Pre-Survey Qualitative Data:

The telephone pre-survey contained several open-ended questions that provided both descriptive and qualitative data. Qualified State Managers (QSMs) were asked three questions:

1. Have you ever become aware of surgical errors that should have been reported to your agency, but were not?
2. If so, how did you become aware of these unreported errors?
3. Of the surgical errors that occur in your state, and are required to be reported to your agency, what % do you think are actually reported?

KEY FINDING #3: About half of the states discover unreported surgical errors. The discoveries are made through patient and family complaints, media reports, and medical audits. (Reference Figures 4-8 and 4-9)

Over half of responding QSMs stated that their agency had become aware of unreported surgical errors. The route by which the QSA became aware of these errors varied widely, with discovery in the course of a routine licensing survey or a complaint from a patient or family member being the most common ways that a QSA became aware of these events.

FIGURE 4-8: QSA AWARENESS OF UNREPORTED ERRORS
n=23

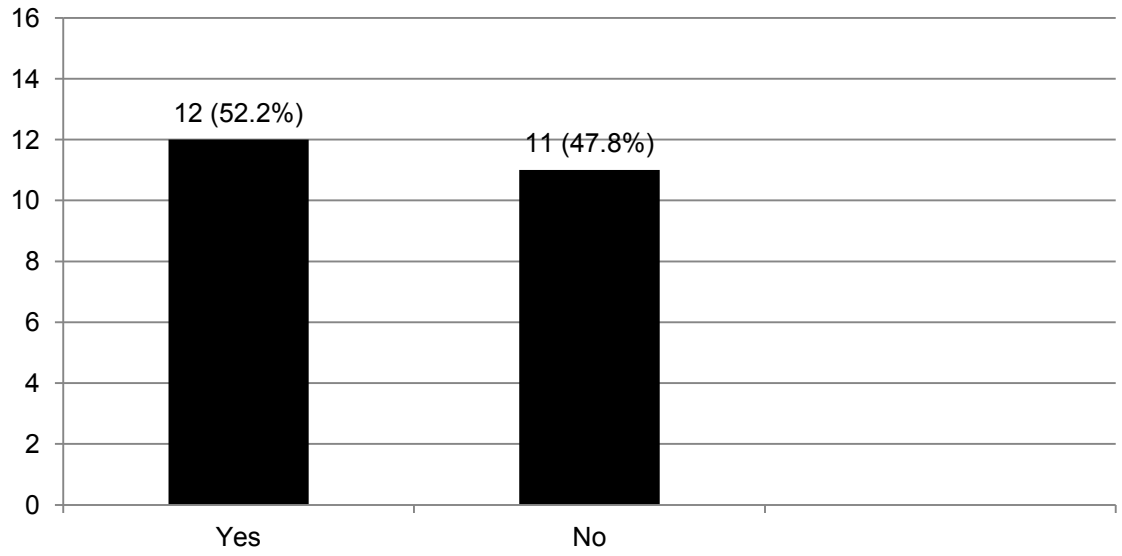
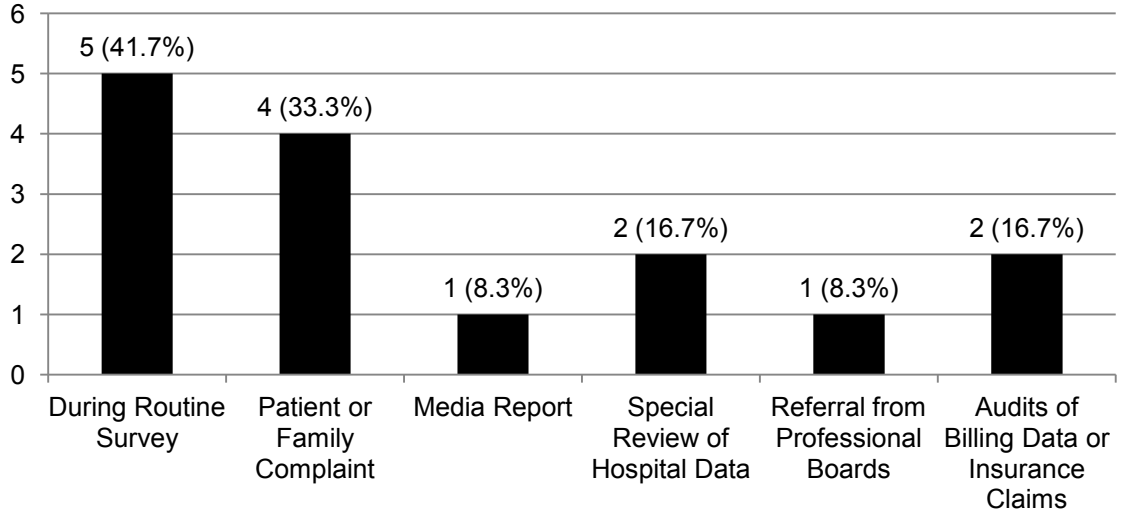


FIGURE 4-9: MEANS BY WHICH QSA BECAME AWARE OF UNREPORTED ERRORS
n=12 (State agencies may have multiple responses to this question)



One QSM stated that:

> *Sometimes we do find out through other means. For example, the media. There can be a news story about a patient who went to the hospital and found out that she had a retained foreign object. Also our office has a collection of certain data on retained foreign objects that facilities have to enter in. Once a year we go through the data of coding for retained foreign objects and then we compare to our database. Pretty much once a year we find something that should have been reported but wasn't.*

Another QSM considered failure to report to be a serious violation of the rules:

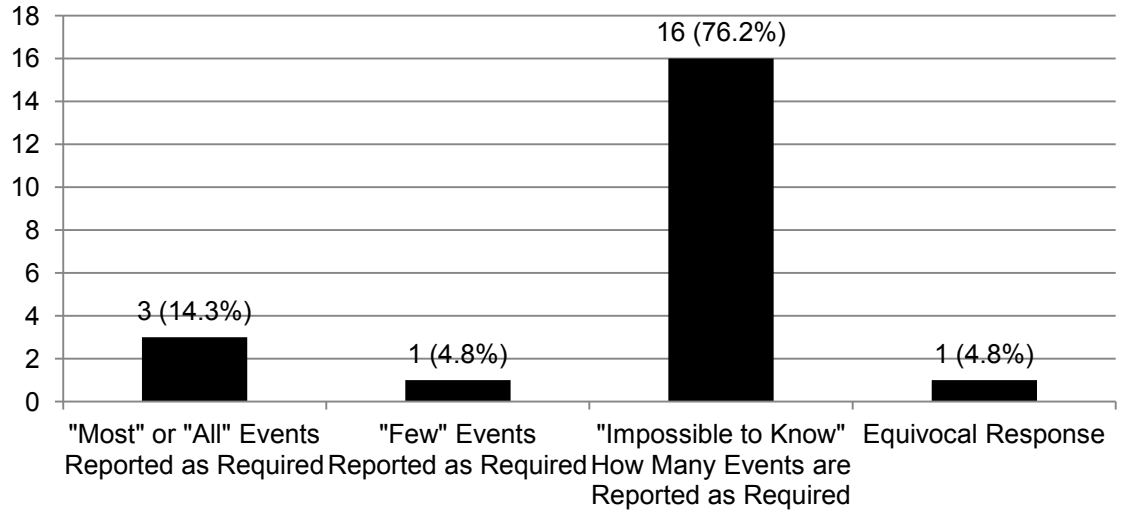
> *When the hospital team doing complaints and incident reports are out, they have been citing for failure to report. Failure to report is bigger than reported late.*

KEY FINDING #4: A large majority of QSMs believe that there is no way of determining whether all surgical errors are being reported as required. (Reference Figure 4-10)

The research questions in this study relate to state perceptions of under-reporting, both in terms of risk and reality, and the state's responses to these perceptions. The question *"Of the surgical errors that occur in your state, and are required to be reported to your agency, what % do you think are actually reported?"* is the key question that leads to development and contextualization of the qualitative results for this study.

Of those QSMs that responded to this question, a large majority responded that they have no way of knowing how many events that should be reported to them actually are reported. A far fewer number of QSMs expressed confidence that their agency receives most or all of the events that must be reported.

FIGURE 4-10: QSA PERCEPTION OF COMPLIANCE WITH REPORTING REQUIREMENTS
n=21



Themes arising from QSM responses to this question included:

- The true number of reportable events is unknown
- Legal risk inhibits reporting
- The reporting systems are vulnerable to health care entity choice to report
- Lack of resources inhibits knowledge of the true number of events
- States have confidence that a good relationship with entities ensures reporting
- Under-reporting is suspected or established by data

When asked to estimate the percentage of reportable errors that were actually reported, most declined to guess, and instead responded that the question was impossible to answer. The uncertainty was frequently accompanied by a suspicion that under-reporting was a risk:

> *That is really a tough question because I feel I don't know how many aren't reported. I couldn't answer that. To be honest I don't believe probably a very significant number.*

I wouldn't honestly be able to put a number to that. All of us here in the office would agree there's under-reporting. To the degree and level we don't know.

One reason for the uncertainty was that the QSA did not have the resources to pursue the question:

We don't go out to do site visits, so we're not out there going through medical records. The OIG has published a recent report about adverse event reporting and their statistics were appalling and alarming. The number of errors that they found that hadn't been reported internally, and then of course only a certain number of states require external reporting. It's sad, the number. I wouldn't be able to even hazard a guess, but I think we're probably on line with what the OIG reported.

Another QSM noted that awareness of the reporting requirements could be an obstacle to compliance:

All you can do it do everything you can to educate people about what is required to be reported. I don't have any sense about how complete it is. Every year we learn of situations where someone wasn't aware of what was required under the law.

Some QSMs expressed confidence that their systems captured most or all reportable surgical errors. Still, they acknowledged some uncertainty about how the truth could be known:

We've tried to trust. Of the ones that are known, I would say the majority are reported.

I would say it's pretty good since there's no…nothing has really come of it since they had to start reporting in '06. There haven't been any specific investigations because of the data they've reported.

I'm not aware of anything that we didn't find out about. The built in catch is that it is that it's protected. It behooves them to report to us.

QSMs that believe their state receives a low percentage of required reports also couched their opinions in uncertainty:

> *I could imagine that we're getting a low number. I can't tell you why, but I can imagine that is what happens.*

Because this is the key question for contextualization of the qualitative data, a representative sample of the various responses is presented in Appendix E.

Chapter 5: Key Informant Interview Results

Key informants were selected from the respondents to the telephone pre-survey. Data from the pre-survey were used to diversify the key informant sample according to the sampling frame presented in Chapter 3. Selected key informants were contacted by email, and telephone interviews were conducted November 2012 – January 2013.

Twelve key informants from ten states completed a telephone interview. In the eleventh state the QSM declined an interview but provided detailed email responses to the interview questions. Published reports from three states provided triangulation that confirmed the accounts of the key informants and contributed additional evidence relevant to the topic areas. The refusal rate for the 11 QSMs was 0.0%

Key informant interviews were recorded for accuracy and transcribed by a professional medical transcriptionist. Transcripts were validated and corrected by comparison with the recordings. Transcripts were imported into MaxQDA v10 software for management of the qualitative data set. One key informant participated in a telephone interview but declined to be recorded. His/her responses to key questions were recorded verbatim by hand during the interview. A second key informant declined a telephone interview but responded by email to the interview

questions. Transcriptions of these two key informant contacts were also entered into the software, along with published annual reports of error reporting programs in three states.

Key informants were assured confidentiality of both their own identity and the identity of their states. This assurance was made in order to encourage openness during the interviews. State identities are masked for this phase of data analysis.

The key informant sample was diversified using data from the pre-survey. Characteristics of the key informant sample were:

Table 5-1: CHARACTERISTICS OF THE KEY INFORMANT SAMPLE

STATE	Degree of Compliance	Punitive Response to Errors	QSA Role in Enforcement	Year Program Established*	Region of USA
1	Unknown	High	Yes	1980s	Northeast
2	Unknown	High	Yes	2010	Northeast
3	High	Low	No	1995	Central
4	Unknown	High	Yes	2006	West
5	High	Low	Yes	1994	Northeast
6	Unknown	High	Yes	1987	Central
7	Unknown	Low	Yes	2003	West
8	High	High	Yes	2002	Northeast
9	Low	Low	Yes	1995	West
10	Unknown	Low	Yes	1985	South
11	Unknown	Low	Yes	2003	Central

*Source: Rosenthal and Takach (2007) except State 2 = personal communication

Data related to Research Topic 1 were acquired during the pre-survey and were addressed in Chapter 4. This chapter applies the results of the key informant interviews to Research Topics 2 – 4. As in Chapter 4, the key findings for each topic are followed by the data supporting the finding.

Topic 2: Perceptions of potential causes of underreporting

KEY FINDING #5: QSMs perceive a wide range of facilitators and barriers to compliance by the health care industry with mandatory surgical error reporting, and these perceptions match well with the facilitators and barriers that the health care industry reports. (ReferenceTables 5-3 (facilitators) and 5-4 (barriers))

Literature review presented in Chapter 2 revealed the perspectives of health care providers regarding facilitators and barriers to compliance with external reporting requirements. This research considered to what degree QSMs perceived similar facilitators and barriers, and whether there was congruence between the opinions of the regulators and the industry that they regulate. If health care entities believe that obstacles exist to compliance with reporting requirements, do the regulatory authorities understand this and acknowledge these same obstacles as a step toward overcoming them?

Individual QSMs frequently recognized one or more facilitators or barriers. All three theme dimensions identified in the literature review (internal, system and policy) were included for both facilitators and barriers. Of the list of themes identified by the health care industry as facilitators and barriers in the literature review, 8 of 9 facilitator themes and 10 of 13 barrier themes were spontaneously referenced by state agencies.

TABLE 5-2: CONGRUENCE BETWEEN QSMs AND HEALTH CARE ENTITIES REGARDING FACILITATORS TO COMPLIANCE FOUND IN THE LITERATURE REVIEW

Theme n= number of states reporting this facilitator	**Representative QSM Statement**
Internal: Culture of Safety n=1	The greatest factor we have working in our favor is that the people who work as risk managers in these positions really do care about patient safety, care that their hospitals are not harming people, and often recognize that reporting these events increases awareness of the events….
System: Stakeholder Involvement n=6	When we wanted to have a discussion we do it with the full awareness of the provider industry. You know, what are our objectives? How do we want to move forward? And we want to include them as part of those discussions and I think that's always fostered a good relationship. We work really, really closely with the hospital association on this. They were one of the organizations that helped to get the law passed ten years ago. And so they have always been very collaborative with us.
System: Effective Analysis and Feedback Loop n=7	People have an incentive to report events when they see those reports used to improve patient safety. The health care delivery system as a whole benefits from the aggregate data collected through NYPORTS. With these data, the Department can identify and disseminate trends in patient safety, error-prone activities and successful strategies to reduce to the risk of those activities.
System: Clear Reporting Criteria n=3	We hear that they appreciate clarity whenever we can make these errors, the definitions, extremely clear.
System: Ongoing Training and Education n=2	To maximize the utility of NYPORTS data and the validity of the RCAs produced by facilities, the Department provided training for hospitals and D&TC staff.

Policy: Confidentiality of Reports n=1	To promote complete and accurate reporting, Public Health Law prohibits public disclosure of NYPORTS reports.
Policy: Protection from Discovery or Negative Consequences n=4	I think it's just very counterproductive to ask somebody to report themselves so that you can hammer them. This report is not intended to place blame or focus attention on specific facilities or individuals. Such an approach would be counterproductive...
Policy: Mandatory Nature of System n=6	…If they knowingly didn't report and we found out about it, the consequences would be more serious to them than anything that would come about from their reporting. Well, it's a law. I think that encourages some of the compliance

TABLE 5-3: CONGRUENCE BETWEEN QSMs AND HEALTH CARE ENTITIES REGARDING BARRIERS TO COMPLIANCE FOUND IN THE LITERATURE REVIEW

Theme n= number of states reporting this barrier	**Representative QSM Statement**
Internal: **Turnover of Personnel** n=2	I just can't believe how many key people are leaving facilities… every time you make those changes…you're kind of taking several steps backward before you can move forward again.
Internal: **Reporting Burden** n=4	Risk managers do a lot more than report directly to the department. They have tons of responsibilities…it's not always somebody's top priority to be on top of the definitions and understanding them and actively developing systems to catch them.
Internal: **Lack of Effective Internal Systems to Identify Errors** n=6	Oftentimes the risk managers or the other facility staff who are responsible for reporting to us aren't aware that the events are occurring… It's really obvious that they're not counting the right thing just from looking at the data. I don't think it's intentional, I think that they don't have a good understanding.
System: **Lack of Control** n=1	They wanted control over it, and because they didn't get control over it they lost that battle so they don't want it at all.
System: **Lack of Clarity of Reporting Requirements** n=4	I think something else that contributes to underreporting is that we don't yet have full definitions of what the events are that hospitals are required to report…how would we know if it was a retained foreign object after surgery if we don't have a definition of "surgery" and we don't have a definition of when surgery ends?
System: **Exposure to Punitive Action** n=1	One of the concerns of facilities was that a reportable event could be used to instigate a health survey of a health care facility.

Policy: Lack of State Resources n=2	It's tough to make sure you're doing everything you can to hold facilities to that level when you don't have the staff or the resources.
Policy: Concern about Public Disclosure n=4	I wouldn't be surprised if there were attempts on the parts of facilities to reclassify events as not serious reportable events when they can because obviously our data here are publicly reported and attached to the facility name…
Policy: Fear of Legal and Civil Liability n=4	I have heard hospitals say we're supposed to report and then there's a chance that we're going to get $100,000 fine…. I think some facilities would say it's a disincentive for them to report because there's a chance that they would end up with an administrative penalty. The facilities always have an attorney on the line and they are very reluctant to pass on much information when we have those discussions. I think they're just trying from a liability perspective…I think they look at that to probably not necessarily complete those self reports as they should.

The QSM interviews provided excellent coverage of the industry-reported facilitators and barriers found in the literature review. However, some industry-reported themes were not noted by the QSMs:

Facilitators not mentioned:

- Policy: Voluntary nature of a system (Barach and Small, 2000)

Barriers not mentioned:

- System: Lack of feedback and perceived usefulness (Weissman et al., 2005; Marchev et al., 2003)
- Policy: Voluntary nature of a system (Weissman et al., 2005; Morton et al., 2004)
- Policy: Mandatory nature of a system (Weissman et al., 2005)

Reference to a voluntary system as a barrier was not considered relevant to the discussion of mandatory systems, so the absence of comments in this one area is not particularly noteworthy. The three other industry-identified barriers that no QSM mentioned were the issue of lack of feedback and perceived usefulness of the systems, and the mandatory nature of the systems. The sole industry-identified facilitator that no QSM mentioned was a voluntary system. The absence of references to these barriers may indicate that the regulatory authorities do not sense a powerful deterrent to compliance in these areas. However, the fact that the health care industry identified them as barriers indicates that there is an opportunity to improve understanding of compliance at the regulatory level.

Topic 3: Perceptions of the Agency's role in enforcement

Enforcement is the act of ensuring that required error reports are submitted by health care entities. It takes the form of the threat of punitive action if a required report is not submitted in a timely manner. QSMs reported in the pre-survey that they typically use fines and written statements of deficiency to enforce reporting requirements. Of 24 QSMs that completed a pre-survey, all but 4 use some type of punitive pressure to encourage compliance.

KEY FINDING #6: QSMs reported varied amounts of support for the concept of pursuing compliance with reporting rules.

Theme 3-1: Enforcement is a priority.

In some states enforcement was made an explicit priority, in both interviews and in published reports. In some cases the priority is couched in terms of the obvious need to comply with the law:

It's a statutory requirement so I'd say it's high priority.

In other cases states emphasized that enforcement had a practical effect on the success of the program, by ensuring accuracy of data and fairness when reporting statewide error numbers to the public. This idea was expressed in published reports:

> *The completeness of reporting is an important concern....If data are not complete and accurate, the occurrence frequency or the occurrence rate...for hospitals or for a region cannot be accurately computed.*

It was also brought up during interview:

> *I think it's important to enforce the rules as fairly as we can so that when we publicly report at the end of the year, the picture is as accurate as we can make it and no facility looks better or worse because they're more or less compliant with our regulations.*

One key informant placed the view that enforcement was important within the context of knowledge that under-reporting is a reality:

> *I was just recently at an organization focused on…events that sort of relate to patients or employees in a facility….one of them is related to physical assaults, and when I showed them the numbers of physical assaults that have been reported over the years, I mean, it's a very small number, this one person said, "Well, shoot, I know in my facility alone that that happens a lot, more often than that."*

In another state, the QSM felt that enforcement was an integral part of the program's success, so even though resources were not explicitly dedicated to enforcement, she ensured that it remained a priority:

So we do see that as certainly part of our role. There's not an explicit line item in the budget for it, it's just something that is part of the health department's responsibility in administering the law, to make sure that all facilities that are required to report understand what the requirements are and follow it.

Theme 3-2: Enforcement is not a priority.

Conversely, several states mentioned that enforcement of reporting requirements was not a priority. This view was supported by the QSMs either because of confidence in the reporting histories in their state:

We assume as long as each hospital has reported, that they are compliant. …. we do not look at individual cases so we don't have anything in place where we could say, "While your facility reported, we're not sure that your numbers are truthful or accurate". We don't do that part.

Or because they perceived that a positive relationship with the health care industry was associated with compliance:

We have a very, very good working relationship with the hospitals.…I'm not aware of anything that we didn't find out about.

The QSM in one state was willing to consider the number of reports that were made to be the correct number, unless a different number of actual errors was brought to the state's attention, which was a circumstance that had not occurred:

Compliance is only at the facility level that they actually did report, so they could report one case and somebody could argue that they had ten cases, but we don't, we've not had that happen and we don't investigate it.

Theme 3-3: Enforcement is vulnerable to pressure from politicians and industry.

In several states the key informant mentioned stresses placed on the error reporting program that inhibit enforcement of requirements. These stresses have the

effect of preventing the pursuit of potential missing data and thus contribute to possible data starvation in the error reporting program. In one case the stresses were the result of a movement in the state legislature to eliminate the program:

> *Actually, we've been told that…there will be some legislation passed by summer that will eliminate the reporting, so I'm not sure that the current administration is willing to put any more resources toward it.*

In another instance, the health care industry was a factor in the legislature's reluctance to establish a more comprehensive program. This state had only a general reporting requirement but was considering the same kind of specific event reports that many other states use:

> *I know a few years ago there were some attempts within the state legislature to see if we could get mandatory reporting of adverse events, I think that was in 2008, and that didn't get very far within the legislature....There was I think a bill drafted but it wasn't presented to the committee.*
>
> *Researcher: Was the industry a player in that process?*
>
> *Yes. Yes.*

Theme 3-4: Enforcement is vulnerable to resource starvation.

In addition to political pressure on enforcement activities, the state programs are vulnerable to resource shortages. In many of the states, particularly those with newer programs, substantial budgets did not accompany the establishment of the reporting programs. Thus, as one QSM stated, they are forced to choose how to use their resources among multiple program activities, including enforcement:

> *So, we have very few mechanisms in our state to ensure that compliance is high. We are not given funding specific for this program. It's part of our general funding, so any of the work that we do in the area of compliance has to be from within our regular pool of resources*

In another state, the QSM went even further:

> *We really don't have any mechanism beyond the ever looming threat of an onsite investigation to ensure compliance.*

One QSM expressed anxiety regarding compliance because he/she already had suspicions regarding reporting from surgical centers. In this case, frustration about compliance was not merely academic, but arose from concern about data that he/she felt might be missing:

> *We've had a big problem in the past with having ambulatory surgical centers comply with our regulations…We get much, much fewer events reported by them and I don't think there's any reason to suspect that their numbers are actually that much lower, but we know we have a compliance issue there….It's tough to make sure you're doing everything you can to hold facilities to that level when you don't have the staff or the resources.*

Theme 3-5: Lack of recourse inhibits enforcement.

Several QSMs noted that there is actually little their state can do if a facility fails to report. In some cases this inability was based not on resource constraints but on a lack of enforcement options:

> *All we say is, "In review of your data it appears that your numbers may be small, here are the requirements, please review and resubmit." That's all we can do.*

> *We assume as long as each hospital has reported, that they are compliant. We do not look at individual cases so we don't have anything in place where we could say…we're not sure that your numbers are truthful or accurate. We don't do that part.*

In one state, enforcement was not even an option for the state agency. The inability to enforce the requirements was rooted in complete lack of authority over hospitals:

> *Because we don't license hospitals we don't have any regulatory authority over them.*
>
> *Researcher: So, would it even be possible to be an enforcer of this requirement?*
>
> *We cannot, not without new legislation, no.*

KEY FINDING #7: Working within the reality of resource scarcity, states make strategic decisions regarding the best approach to enforcement.

Theme 3-6: Enforcement decisions are made based on value to the state and public.

Faced with limited resources and multiple program tasks, the decision to dedicate resources to enforcement of the reporting requirements is based in many states on an assessment of the potential return on investment. The published report of one state makes this explicit:

> *The decision to launch an investigation is influenced by how often the type of event has been investigated previously and whether DPH is satisfied with the Corrective Action Plan submitted by the facility.*

In another state, the QSM chose not to use one potential avenue for discovery of unreported events because of technical concerns:

> *We do have another method of knowing events…but we've never used those reports from that other insurance division of the state to drive any type of determination of compliance with our regulation. A lot of times, they lag a lot, several years normally before everything is done from an insurance*

perspective, and again we've never said, okay because we get this tool, we're going to use that to find compliance with our regulations.

QSMs struggled with the question of whether aggressive enforcement was counterproductive, or whether it was in fact necessary even if the health care industry objected:

If you go out aggressively after every adverse incident report you perceive, but you do not back it up with a powerful monitoring system, [do you actually encourage adverse incident reports]?

We also need to be accountable to the public and so have sometimes made decisions that the industry wasn't completely happy with because we thought it was in the consumer's best interest.

Theme 3-7: States are interested in improving compliance.

Despite the political and resource challenges faced by state programs, many the QSMs remained enthusiastic about improving reporting compliance. In some states this took the form of “nonpunitive” approaches like education to facilities regarding reporting requirements:

I think it would be great if we could improve enforcement, and I think the right way to do that would not be through fines or threats, but going facility to facility, taking a look at a random sample of their charts, and determining what it looks like, whether or not they're in compliance with the regulations, and if they're not, doing a little bit of education to help explain where they're not quite meeting the regulations.

Another QSM was concerned that knowledge deficits in one branch of the industry may be a factor in inhibiting reporting, and could be addressed through education:

With the ambulatory surgical centers, they might not be as sophisticated with respect to the reporting requirements, which is why we've done some outreach with them and some additional education.

Such approaches have already borne fruit in one state:

> *We just felt there was inconsistent reporting between the facilities and in some cases there were incidents that occurred that made their way to the media's eye…so that prompted us to be proactive and look into it deeper, and part of that was to make sure that report completion was high. We've done various auditing and because the word gets out and we engage with provider associations and the providers directly, that really stimulated them to start reporting more comprehensively and to take it more seriously in some cases.*

In published reports of other states, "punitive" approaches like fines were under consideration:

> *While ongoing education of providers and clarification of reportable event definitions are critical to compliance, stronger penalties for violations of the reporting requirements may be needed to induce more consistent compliance.*

One QSM who considered enforcement integral to the reporting program felt that supporting health care entities to understand the rules was an important aspect of enforcement practices. This statement expressed the opinions of many QSMs:

> *Part of her role is to make sure that hospitals and surgical centers know what the reporting requirements are, and that we're educating them throughout the year, and if she learns of something or if I learn of something that should have been reported we'll follow up.*

Topic 4: Agency Role in Data Analysis

The final topic area is the issue of the state agency's role in data analysis. This area is important because it generates data trends and facility error histories that can be used to "close the loop" by returning knowledge to the public and the health care industry. The increased understanding of surgical errors, their causes and potential solutions depends on effective use of complete data. The role of state

agencies in enforcement relates to the completeness of the data available. The role of state agencies in data analysis relates to the effective use of the data that are received.

KEY FINDING #8: QSMs reported varied amounts of support for the concept of utilizing data analysis to improve surgical safety.

Theme 4-1: Feedback to the health care industry is a priority.

Several QSMs emphasized that the surgical error data they receive from the health care industry should be reflected back to the industry to improve care. This represents an understanding and appreciation of the complete reporting cycle described in Chapter 1. These QSMs go even farther than this, however. They view their agencies' data analysis as only the beginning of the process of improving safety. They seek an active, ongoing communication with health care entities on the subject of patient safety, with reported surgical error data playing a part in informing the dialogue:

> *We don't just collect the data and put out the public report. We do work very, very closely with the hospital association and other entities to do a lot of education, doing trainings, putting out resources, safety alerts, emails, phone calls, conference calls, things like that, about the trends that we're seeing, the things that are happening, the learnings that we're finding, so that other facilities can really learn from those things.*

In several states a similar commitment was included in the published annual program reports:

> *Through these efforts and others, the Department seeks to engage hospitals and D&TCs statewide in effective, evidence based strategies to minimize adverse events and assure significant improvements in patient safety.*

The goal of the Indiana State Department of Health is that this data will increase focus on these issues and promote the development of evidence-based initiatives designed to improve patient safety.

Theme 4-2: Feedback to the health care industry is not a priority.

As with enforcement efforts, QSMs expressed varying degrees of priority and concern regarding the use of reported surgical error data to provide feedback to the health care industry in their states. While some QSMs were enthusiastic about their own use of data feedback, there was an acknowledgement by other QSMs that although feedback was potentially important, because it was not prioritized it did not happen:

Researcher: I'm wondering, inside your agency, how important is it considered to do this kind of analysis on surgical errors?

Um, it's an interesting question…how important is it considered? I think probably not. I think everyone theoretically thinks it's very important. When it gets involved in the shuffle of all the other things that we have to do, the importance level decreases.

In other state, the QSM stated that the delivery of feedback to the industry was outside the mandate of the agency:

It's not our role specifically as the survey function to develop the best practices or even to encourage best practices because our role as the survey agency is, "Did this facility meet the standard in the state or the federal requirement?"

In another state, the program's reporting requirements played a structural role in inhibiting data analysis, because details of events were not shared with the state. The responsibility for learning from the event was placed on the reporting facility

itself. This left other health care entities unaware of the incident and potential preventive measures that could have been discovered through analysis:

> *The facility does not provide the Indiana State Department of Health with a description of the event. The agency therefore does not have the ability to analyze each event. Each event must be reviewed by the facility's Quality Improvement and Assessment Program.*

Theme 4-3: Some QSAs would require additional resources to perform data analysis.

Several of the QSMs noted that, as with enforcement, data analysis requires financial or staffing resources that have not been allocated to their programs. Thus, even though they may value data analysis, in practice they feel it is beyond their capabilities at this time. In several states the program was never fully funded to include data analysis and industry feedback:

> *Our law had originally called for a more comprehensive quality improvement program that would have really looked at adverse events across the system and that part of the law was really never funded.*

In another state, the QSM stated that there was no practical analysis of the reported data, and even that there was no real ability to verify the accuracy of the data:

> *Researcher: Is it still true that you really don't have the resources to do very much analysis of that data?*
>
> *That's true. We don't do any analysis of the data. We barely validate the data.*

As another QSM noted, resource scarcity also includes a lack of sufficient time for qualified personnel to perform the analysis:

We're so taxed and understaffed and overworked so we don't get around to it, but one thing we'd like to do is look more at some of the individual events that come in that are very exemplary of a specific problem, and then to kind of do a write-up on that and then offer preventative guidance for similar events to share with the community, to say "Here's a best practice and here's what could happen if it's not done," and see that on a regular if not routine basis. That would be one effort that we are envisioning but just haven't been able to put that much time behind.

In another state, the issue was data shortage itself. The system was relatively new, and the QSM felt that sufficient error reports had not been received to provide meaningful analysis yet:

I don't think we even know yet and until we have some more data. I don't think we know quite what we're going to do with that.

Theme 4-4: Political pressure influences whether data analysis is made a priority.

Ultimately, as in so many matters of public safety, the pressure upon the bureaucracy by legislatures, industry, media and the public play a major part in determining how much of a priority a particular public safety initiative will be. In the case of reportable surgical error programs, this prioritization can determine whether resources are dedicated to analyzing and using the reported surgical error data for patient safety improvement campaigns.

The state legislature obviously is a key factor in determining the scope of an error reporting program:

I mean basically what we've been told to do by the legislature, well first of all, they passed a law that requires hospitals and ambulatory surgical centers to report, and then we have a requirement to do an annual report of all the adverse events we received for that calendar year.

In several states it was mentioned that the health care industry plays a powerful role in setting the expectations for the relative strength, or even the existence, of the error reporting programs. The role can be either negative or positive from the perspective of the QSM. In one state, the QSM was concerned that the entire error reporting system was in jeopardy due, partly, to dissatisfaction with the program by the health care industry:

> *Researcher: How serious do you think that threat is to eliminate the system?*
>
> *Oh I think it's very. I think that the political strength in our state is such that it probably—we're being told that it's going to go away. There's 99% chance that it'll go away.*
>
> *Researcher: Is the hospital association driving that?*
>
> *Yes, yes… they've had a lot of political pull in our state.*

In another state, however, the health care industry played a major role in establishing and supporting the program:

> *In [our state] the law was passed with the hospital association as part of it. They were one of the organizations pushing for it, rather than having it be something that was imposed on them. That's a huge difference.*

The media's role was also acknowledged. By requesting data from the state agency, the media can provoke analysis by the agency that may not have been planned previously:

> *We did recently have a public records request for all of the statements of deficiency associated with surgical events for the last three years, which if that gets blown up in the papers, I think it was a paper that requested it, if that leads to a lot of public outcry it will certainly become more important to us very quickly.*

Key Finding #9: QSMs would like to use data more extensively and effectively than they currently do.

Theme 4-5: QSMs envision better analysis and feedback processes.

When asked what their ideal use of reported surgical error data would be, and how they would like to use this data to improve surgical safety in their states, many QSMs had an immediate list of improvements they would like to see in their programs. In some cases the improvements involve better statistical analysis of the data:

> *I would like to…start to also kind of like create a denominator and numerator so that these hospitals…actually know based on x-number of surgeries, this is the percentile of times this happened…it would give a much better indicator of what the frequency of these adverse events are.*

This improvement was envisioned by the QSM without any prompting or references to other states that already create error reporting rates, which suggests that improving the comparability of data through standardization is a desire that is shared among some QSMs.

In other states, the QSM was unsure whether the reported data were accurate and complete, and ideally would like to use additional resources to validate the data to create an environment in which analysis would be meaningful:

> *I think that if we had unlimited resources, it would be useful to do far more validation analysis, and we had a validation toolkit that we put together…where we would actually go into the hospital and pull charts and do some onsite validation. That was our plan, sort of to move that across our entire set of measures that we collect from hospitals, so that would have been our next step and where we would go with it, if we actually had resources to put in place.*

In one state an improvement in the reporting method was anticipated to bring an associated ability to manipulate data more easily and productively:

> *I think when the new portal becomes available to us in January, I think that's going to be an opportunity for us to be able to do more analysis where we'll have to spend much less resource actually collecting and compiling the data because the computer system will do it for us.*

Theme 4-6: QSMs consider education to be a necessary component of data analysis.

By far the most frequent comment from QSMs on the ideal use of reported data was to use them to engage the health care industry to reduce future errors through educational opportunities. This was expressed as an interest of the industry as well:

> *In terms of the data that we have that we're sitting on in these root-cause analyses, nothing has been compiled yet, and yes, I think there would be a real interest in the facilities being able to have access to summary reports.*

QSMs spontaneously described multiple approaches to sharing their potential analyses with the health care industry. These approaches included efforts to clarify the reporting requirements as well as application of reported data to improving surgical safety:

> *We would put in place more education around the specific measures and how to report them, actually working with the quality folks within the hospitals, the patient safety people within the hospitals, and all that, and then once we got those things in place, then we could actually do some true analysis.*

The possibilities went beyond merely passively distributing data back to the industry. QSMs visualized an active partnership with health care entities to cooperatively discover safety improvements:

Off the top of my head there could also be other ways that we would interact with hospitals, maybe through patient safety collaboratives, or there might be other ways that we could use that information...

Published reports of state error programs also expressed the need for actively engaging the health care industry as part of the cycle of error reporting and feedback:

[The QSA's data analysis consultant] asserts that the highest priorities for incident reporting systems should be ensuring that those people reporting adverse events know that reporting has led to improvements in safety, making the best possible use of the information that is reported, involving physicians in reporting, and leveraging the advantages of Patient Safety Organizations.

Theme 4-7: QSMs perceive resistance from the health care industry as an obstacle to data analysis and feedback.

Although several states felt that a close agency-industry relationship was mutually beneficial and supported effective use of data, other QSMs were more pessimistic about the possibility of effective data analysis, because reporting was not considered complete in the first place:

Researcher: If you were given resources to do so, is there some way that you would like to use this data to improve health care?

Well, I think we'd all like to do that. I think the thing is, just compiling all the data, and I guess… you'd have to get compliance from the industry to make it have some value, and then how do we get that?

In another state, the QSM reported that the Patient Safety Organizations in the state were not providing sufficient information to permit the state agency to report positive results from PSO-generated reports and data:

I hope to encourage the PSOs to share with DPH and the public what improvements to patient safety have resulted, but you will see from the

annual Quality of Health Care reports that the PSOs document activities, but few results.

Chapter 6: Conclusions and Opportunities

The research questions described in Chapter 1 and expanded in Chapter 2 were organized by topic areas for the composition of the pre-survey and key informant interview guides. Key findings were generated from the descriptive data and themes developed from key informant interviews. In this chapter, key findings are reflected back to the original research questions to provide the groundwork for answering those questions and revealing opportunities for improvement in mandatory surgical error reporting systems. In Chapter 7, the opportunities for improvement will be developed into the Plan for Change.

The key findings are first mapped to the study topic areas and themes developed in the data analysis. The findings are then applied to the research questions to generate conclusions.

TABLE 6-1: KEY FINDINGS MAPPED TO TOPIC AREAS AND THEMES

Topic Area	Theme	Key Finding
Topic 1: Extent of concern regarding possible noncompliance	Findings based on Figures 4-1 and 4-2	Key Finding #1: There is great consistency between the states in terms of the types of health care entities that must report surgical errors and the response of the QSA to a report.
	Findings based on Figures 4-3, 4-4, 4-5, 4-6 and 4-7	Key Finding #2: There is great variety between the states in the definitions of surgical errors, disclosure practices, legal

		protections offered to reporting entities, enforcement strategies and internal use of the data by the QSAs.
	Findings based on Figures 4-8 and 4-9	Key Finding #3: About half of the states discover unreported surgical errors. The discoveries are made through patient and family complaints, media reports, and medical audits.
	Findings based on Figure 4-10	Key Finding #4: A large majority of QSMs believe that there is no way of determining whether all surgical errors are being reported as required.
Topic 2: Perceptions of potential causes of underreporting	Findings based on Tables 5-3 and 5-4	Key Finding #5: QSMs perceive a wide range of facilitators and barriers to compliance by the health care industry with mandatory surgical error reporting, and these perceptions match well with the facilitators and barriers that the health care industry reports.
Topic 3: Perceptions of the Agency's role in enforcement	Theme 3-1: Enforcement is a priority Theme 3-2: Enforcement is not a priority Theme 3-3: Enforcement is vulnerable to pressure from politicians and industry Theme 3-4: Enforcement is vulnerable to resource starvation Theme 3-5: Lack of recourse inhibits enforcement	Key Finding #6: QSMs reported varied amounts of support for the concept of pursuing compliance with reporting rules.

	Theme 3-6: Enforcement decisions are made based on value to the state and public Theme 3-7: States are interested in improving compliance	Key Finding #7: Working within the reality of resource scarcity, states make strategic decisions regarding the best approach to enforcement.
Topic 4: Agency Role in Data Analysis	Theme 4-1: Feedback to the health care industry is a priority Theme 4-2: Feedback to the health care industry is not a priority Theme 4-3: Some QSAs would require additional resources to perform data analysis. Theme 4-4: Political pressure influences whether data analysis is made a priority.	Key Finding #8: QSMs reported varied amounts of support for the concept of utilizing data analysis to improve surgical safety.
	Theme 4-5: QSMs envision better analysis and feedback processes. Theme 4-6: QSMs consider education to be a necessary component of data analysis. Theme 4-7: QSMs	Key Finding #9: QSMs would like to use data more extensively and effectively than they currently do.

	perceive resistance from the health care industry as an obstacle to data analysis and feedback	

Conclusions

Research Question #1: What are the states' perceptions of compliance with mandatory reporting of surgical errors?

Relevant key findings:

- Many states discover unreported surgical errors through patient and family complaints, media reports, and medical audits
- Most QSMs believe that there is no way of determining whether all surgical errors are being reported as required

Pre-survey qualitative analysis shows that in twelve of twenty-three responding states with mandatory surgical error reporting, the QSM was aware of specific surgical errors that should have been reported, but were not. These errors came to the QSMs' attention by many means, such as media, patient complaints and data audits. The most frequent routes by which unreported errors came to the state agency's attention were discovery during routine inspections, or through patient or family complaints.

In an even larger proportion of states (sixteen of twenty-one) the QSM believed that it was impossible to determine the degree of compliance or noncompliance with reporting requirements. Even in four of the eleven states where the QSM was not personally aware of specific unreported errors, QSMs still were not

certain that all required reports were filed. Among the QSMs that did believe that most or all required reports were made, there was also recognition that there was no way to know, or that the belief was founded partly on confidence of a strong relationship with health care entities.

Conclusion:

- **A majority of QSMs felt that it is impossible to know whether their state receives all reports of surgical errors that should be reported.**

Research Question #2: What are the perceptions of state agencies regarding barriers to reporting of surgical errors?

Relevant key finding:

- QSMs perceive a wide range of facilitators and barriers to compliance by the health care industry with mandatory surgical error reporting, and these perceptions match well with the facilitators and barriers that the health care industry reports

As the literature review demonstrated, the health care industry offered multiple, diverse incentives and disincentives to compliance with mandatory reporting requirements. These reported barriers and facilitators were categorized on the three dimensions of policy, internal and system issues. Of these twenty-two themes the QSMs spontaneously identified eighteen that they also believed were incentives or disincentives to industry compliance. There was excellent congruence between the industry and the QSMs on the subject of barriers and facilitators.

The opinions of the health care industry discovered in the literature review revolved significantly around concerns about legal and civil liability (8 of 32 journal articles mentioned these concerns) and public disclosure and embarrassment (11 of 32 journal articles mentioned these concerns). When QSMs were asked what they

considered to be barriers to reporting, legal and civil liability and public disclosure and embarrassment were among the factors cited most often (4 of the 11 key informants cited these issues, with only “Lack of effective internal systems” receiving more frequent mention).

However, the QSMs did not mention several areas that the industry did mention, and they are significant. The QSMs did not raise as issues that a voluntary system could be a positive influence on reporting, or that a mandatory system in itself could have a negative influence. These opinions are essentially two sides of the same idea. The health care industry did volunteer these two factors in the published literature. Perhaps, because the QSMs all function in states with mandatory reporting laws, the mandatory nature of the system may carry a powerful presumption as the “normal” condition, and thus did not arise in the view of the QSMs as a potential variable.

The QSMs also did not identify an industry perception that lack of feedback and perceived usefulness of the system could be a barrier to compliance. This seems very important as well, because in several states the QSM noted both that the health care industry played a powerful role in the shaping of the error reporting program, and that the program was jeopardized by current or pending resource shortages.

Conclusion:

- **QSMs understand most of the reasons that the health care industry reports for compliance and non-compliance.**

Research Question #3: If states believe under-reporting is occurring, what is their level of concern about it?

In this study, management of under-reporting is the realm of enforcement. Twenty of the twenty-four QSMs that responded to this question on the pre-survey reported that their agency does have a responsibility for enforcing the mandatory reporting rules. In half of the responding states enforcement consisted of fines for failure to report. In addition to fines, some states also conducted investigations following the discovery of unreported errors, while others issues statements of deficiency for failure to report.

Key informants stated that in the absence of complete error reporting, it was impossible to assess the degree of risk to patients in their states. Several QSMs also expressed their belief that enforcement is necessary to pursue missing data.

This perception, and the responsibility to enforce and actions taken implies official concern about under-reporting.

Conclusion:

- **QSMs are concerned about under-reporting.**

Research Question #4: If states believe under-reporting is occurring, what are they doing about it?

Relevant key findings:

- QSMs reported varied amounts of support for the concept of pursuing compliance with reporting rules
- Working within the reality of resource scarcity, states make strategic decisions regarding the best approach to enforcement

Even in states where enforcement occurs, QSMs do not always receive support from their agencies to make enforcement a priority. Instead, it must be balanced against other responsibilities for managing the programs. This places the agencies in the position of deciding how best to use limited resources.

In some states resource availability permits active error surveillance, including onsite medical record audits and review of proxy data such as insurance claims. In other states, however, there was no dedicated budget or staff for enforcement of reporting requirements, and enforcement did not occur, was not made a priority, or had to be accomplished outside of formal resource allocation.

There was an interesting association between states with a belief in reporting compliance and states without active enforcement activities. Four states perceived high compliance with reporting rules. Two of these were among the three states with no active enforcement activity. The other two were among twenty states that did have active enforcement programs. Although the numbers are quite small, 2/3 of the states without active enforcement perceived high compliance, while only 1/10 of the states with active enforcement perceived high compliance.

Conclusions:

- **Enforcement can reveal unreported errors, but not all states have resources for effective enforcement.**

- **States with active enforcement programs are more likely to perceive a risk of under-reporting.**

Research Questions #5 and #6: What are states doing with their reported error data to improve health care quality? What feedback do state agencies give to providers regarding reported errors?

Relevant key finding:

- QSMs reported varied amounts of support for the concept of utilizing data analysis to improve surgical safety
- QSMs would like to use data more extensively and effectively than they currently do

Some states have active data analysis and feedback programs, including ongoing educational programs and frequent collaboration with health care entities. In fifteen of twenty-four responding states, data were analyzed by type of errors and trends. An additional five states at least aggregated their reported data. States with active analysis and feedback programs have the ability to provide health care entities with data that include trends, detailed causation and correction reports from root cause analyses, and related research from other patient safety organizations and agencies.

Nine of twenty four states do not analyze their data, and fifteen of the twenty-four responding states do not report their analysis back to health care entities. This represents a lost potential for partnership with health care providers, and for enhancing the perceived usefulness of the programs in those states.

In almost all cases, however, QSMs expressed a recognition that reported error data could be used to generate problem-solving activities and awareness in the health care industry that could reduce the incidence of future errors. Many of the QSMs had either active plans in place or visions of an ideal to improve their data receipt, validation, analysis and feedback. These plans generally involved

partnerships with the health care industry to use the data to stimulate performance improvement efforts.

In other states, however, there was little or no perceived support for the use of the reported surgical error data. Some states did not even have the resources to validate the data for accuracy when they were received. Even if there was a desire in these states to partner with the health care industry using the reported data for improvement, it would be impossible to do so without data to use or means of converting the data into generalizable learning.

The ability to perform analysis and provide feedback was dependent on resource allocation. Resource allocation, in turn, is a political decision. Several QSMs reported political influence, either legislatively or by the health care industry, that influenced the establishment and support of the error reporting programs in both positive and negative ways.

Conclusions:

- **States value analysis and feedback as part of the effort to improve patient safety but not all states have resources necessary to carry out these activities.**
- **More than half of the states apply some analysis to the reported error data.**
- **A smaller number of states that perform analysis also provide feedback to the health care industry.**
- **Some states are unable to perform even basic tasks like data validation, much less extensive analysis and feedback.**

Research Question #7: How do state agencies perceive their role in enforcing reporting requirements?

Relevant key findings:

- QSMs reported varied amounts of support for the concept of pursuing compliance with reporting rules
- Working within the reality of resource scarcity, states make strategic decisions regarding the best approach to enforcement

Twenty of twenty-four responding states have enforcement power to compel error reporting. In half of states with enforcement power, fines are used when facilities fail to report as required. Other actions, such as issuing a statement of deficiencies, are publicly disclosable reports of failure. A statement of deficiencies typically also compels a facility to respond with a plan for correction of the fault.

In many states, key informant data showed that practical use of enforcement power was constrained by resource limitations, by strategic choice, and by uncertainty regarding whether there were unreported errors.

Conclusions:

- **Most states have the authority to enforce their medical error reporting rules.**
- **Use of enforcement power varies between states depending on resource availability and the QSAs perception of need.**

Further Research Opportunities

This was a case study of current attitudes and practices among states with mandatory surgical error reporting programs. The study revealed perceptions of managers of state programs. It did not provide a means of comparing the effectiveness of error reporting programs among states. This is a rich area for additional research. States have many definitions of reportable errors, degrees of enforcement, and differences in response to the error reports, use of the data and relationship with the health care industry. All of these factors and more may influence reporting rates. Some states do calculate and report error report rates, but may use different denominators (discharges, admissions, inpatient days, surgical events) that make comparison difficult. Calculation of error reporting rates nationally would permit analysis of the different approaches taken in the various states in their error reporting rules and processes, and may reveal which approaches are more effective at encouraging reporting.

Some states have pioneering systems that have been in place for many years, using their own definitions long before the NQF definitions were published. These states, like New York and Pennsylvania, sometimes have bureaucracies dedicated to use and dissemination of error data and to patient safety improvement. Other states have adopted error reporting systems only recently. Some may have little accompanying infrastructure. In such states, requiring reporting may be the full extent of the program. It would be productive to examine the political foundations of the more established programs, the legislative intent of the various programs, and how these programs are fulfilling the mission given to them by their states. It may be

possible that newer programs were adopted without a full recognition of the resources and staffing necessary to have an impact on patient safety.

Finally, it would be useful to understand the political attitudes and forces in states that have not adopted any error reporting programs. The health care industry's role would be particularly interesting to examine in these states.

Limitations of this Study

The study's design and data successfully answered the research questions. However, several limitations should be considered when evaluating the results.

The study is cross-sectional, and causal links cannot be established. It is not possible, for example, to know from this study whether states with low levels of enforcement also tend to have high confidence in reporting compliance because low enforcement results in higher compliance, because low enforcement obscures awareness of missing reports, or merely by coincidence. Likewise, much of the data are descriptive and intended only to provide a picture of the current error reporting landscape, rather than to draw correlations between features of systems and results.

The pre-survey was subject to selection bias in the choice of which state agency representative would be determined to be the QSM. Choices of convenience were a risk to objectivity. Convenience choices were mitigated by consulting with three other organizations (NASHP, NQF and the State of Oregon (which had recently conducted their own studies on the subject)) for advice regarding the most qualified contact at state agencies.

Likewise, the key informant sample was subject to selection bias as well. Some QSMs were enthusiastic during pre-survey interviews and elaborated at length on their programs. There was a temptation to choose these QSMs for the further key informant interviews. This selection bias was mitigated by strictly using the sampling frame to ensure that a diverse key informant sample was chosen based on predetermined attributes.

In both pre-survey and key informant interviews, the QSMs were the primary source of most of the data. The data depend upon their opinions and recollections regarding their respective state systems. Recall bias suggests that more flattering responses may be given, depending upon what the respondent believes the researcher is interested in hearing. Efforts to compensate for this included actively encouraging and expressing an interest in the opinions of QSMs whose perspectives were minority opinions, or differed from the researcher's experience or opinion.

The literature review was limited to only one of the four main topic areas. Literature relevant to the other three topic areas was not available. For the one topic area where literature was available, a majority of the articles reviewed were not founded in original research, but were editorial or overview articles. This limitation is described more fully in Chapter 2. This limitation was managed by use of the literature only for the topic area to which it applied, and by recognizing generalizability issues in the articles themselves as explained in Chapter 2.

Summary

This study provides descriptive data on the features and activities of state medical error reporting programs that has not been updated since 2007, and in the case of state perceptions of compliance with reporting requirements and state agency role in enforcing reporting requirements, have not been previously published.

Pre-survey and key informant interview data reveal a reporting landscape in which many states doubt the completeness of surgical error reporting, and do not believe there is any way to know for certain how many errors are reported as required.

States recognize most of the reasons that the health care industry gives for failure to report as required, with the exception of low perceived value in reporting. Because nine of twenty-four states do not analyze their data, and fifteen of twenty-four states do not report their analysis back to health care entities, there may be a relationship between the states' behaviors (a tendency to not provide feedback to the health care industry) and the states' perceptions (not recognizing that lack of perceived value is a barrier to reporting).

States have varied degrees of enforcement of their reporting rules and varied enforcement strategies and practices. Although many states believe that enforcement is useful, not all states have the ability to enforce their reporting rules as they would like.

Most states analyze the data they receive, but most states do not share their analysis with the health care industry. Most states see a value in such sharing, and

would like to engage in greater efforts to use reported data in partnership with the health care industry to improve patient safety.

Chapter 7: Plan for Change

There are multiple opportunities for improvement in the current system of mandatory surgical error reporting. This Plan for Change includes recommendations addressing many of these opportunities at both state and federal levels. It also describes a specific course of action that the researcher will take to influence policy and approach in the states.

Opportunities for System Improvements

The current system can be summarized, and opportunities for improvement proposed, based on the literature and this study:

TABLE 7-1: CURRENT SYSTEM AND OPPORTUNITIES

SYSTEM ATTRIBUTE	POTENTIAL FOR IMPROVEMENT
Slightly less than half of the states and federal districts currently require reporting of surgical errors	Expansion of state- and federal district-level reporting Initiation of nationwide reporting through CMS
The states that do require reporting of surgical errors have many different definitions that preclude state-to-state comparisons	Standardization of error reporting requirements between states
Most states that do require surgical error reports do not know whether they are receiving all of the reports	Increased awareness of the risk of under-reporting

that that should, and do not have any way of knowing	Increased research on the incidence of surgical errors
The industry and some states understand that fears of liability and embarrassment are powerful inhibitors to reporting surgical errors	Increased protections for reporting health care entities Increased awareness of protections for health care entities that report as required
States did not recognize that a lack of feedback or perceived usefulness by the health care industry was an inhibitor to reporting surgical errors	Increased awareness by the states of the importance of perceived usefulness of the system by health care industry
States are concerned about under-reporting, but not all states have resources for effective enforcement	Increased resources for enforcement
States recognized the value of data analysis and feedback in contributing to improvements in patient safety, but do not always have the resources to carry out these activities	Increased resources for analysis and feedback Increased state-to-state comparison capability

All of the above issues are possible to change, given sufficient resources. For the purposes of this study, change opportunities will be viewed through the lens of leverage points as described by Meadows. Causal Loop Diagramming will illustrate a key opportunity for improvement to addresses a knowledge deficit among the QSAs.

Leverage Points

When prioritizing change, the work of Donella Meadows is very helpful. She describes leverage points as “points of power” where “a small shift in one thing can

produce big changes in everything" (Meadows, 1999: 1). She proposes a hierarchy of leverage points in which the ability to create major changes increases as the points become more abstract. The applicable points are compared here against the opportunities for change identified in Chapter 6:

TABLE 7-2: LEVERAGE POINTS AND CHANGE OPPORTUNITIES

Places to Intervene in a System (in increasing order of effectiveness) (Meadows, 1999: 3)	**Opportunity for Change**	**Arena of Change**
8. The strength of negative feedback loops, relative to the impacts they are trying to correct against	Increased resources for enforcement	Legislation
7. The gain around driving positive feedback loops	Increased resources for analysis and feedback	Legislation
5. The rules of the system (such as incentives, punishments, constraints)	Increased protections for reporting health care entities	Legislation
4. The power to add, change, evolve, or self-organize system structure	Standardization of error reporting requirements between states Increased state-to-state comparison capability	Legislation Administrative
3. The goals of the system	Expansion of state-level reporting Initiation of federal-level reporting Increased research on the incidence of surgical errors	Legislation Legislation Academic
2. The mindset or paradigm out of which the system—it's goals, structure, rules, delays, parameters—arises	Increased awareness of the risk of under-reporting Increased awareness of	Education to states Education by states

	protections for health care entities that report as required Increased awareness by the states of the importance of perceived usefulness of the system by health care industry	to health care industry Education to states

As this comparison shows, many of the opportunities for change identified in Chapter 6 correspond to leverage points that are closer to the more effective end of Meadows' spectrum. Meadows describes leverage points as counter-intuitive, and this comparison seems to reflect this. The assumption that increased resources are a fundamental necessity for improvement in bureaucracy is challenged here by the higher placement of issues of awareness over issues of system resources. While opportunities for change that correspond to leverage points 3, 4, 5, 7 and 8 require legislative and administrative action, the more powerful leverage point 2 contains several opportunities that involve awareness efforts. While the other opportunities will not be ignored, it is particularly the opportunities at leverage point 2 for which this plan for change presents a specific action program.

Causal Loop Diagram

Causal Loop Diagramming reveals opportunities to influence the dynamics in a system. The findings from both the pre-survey and key informant interviews point to a phenomenon that is well-illustrated by causal loop diagramming. This phenomenon—the cyclical effect of weak programs, weak data, weak feedback and

weak perceived usefulness—is shown by the data to be a reality for some states, and a risk for others.

Causal loop diagramming displays this cycle using variables revealed by the data. The resulting loop is an alternative to the ideal cycle of error reporting—a possible cycle that may become the reality in some states.

The variables of interest in the causal loop are derived from these findings in the research:

Pre-Survey

15 of 24 states do not share their analysis of surgical error reports with reporting health care entities

Literature Review

Lack of feedback and perceived usefulness was reported as a barrier to compliance in two studies and one issue overview

Key Informant Interviews

Key informants in some states reported that the health care industry could play both a positive and negative role in the shape and support of the error reporting system

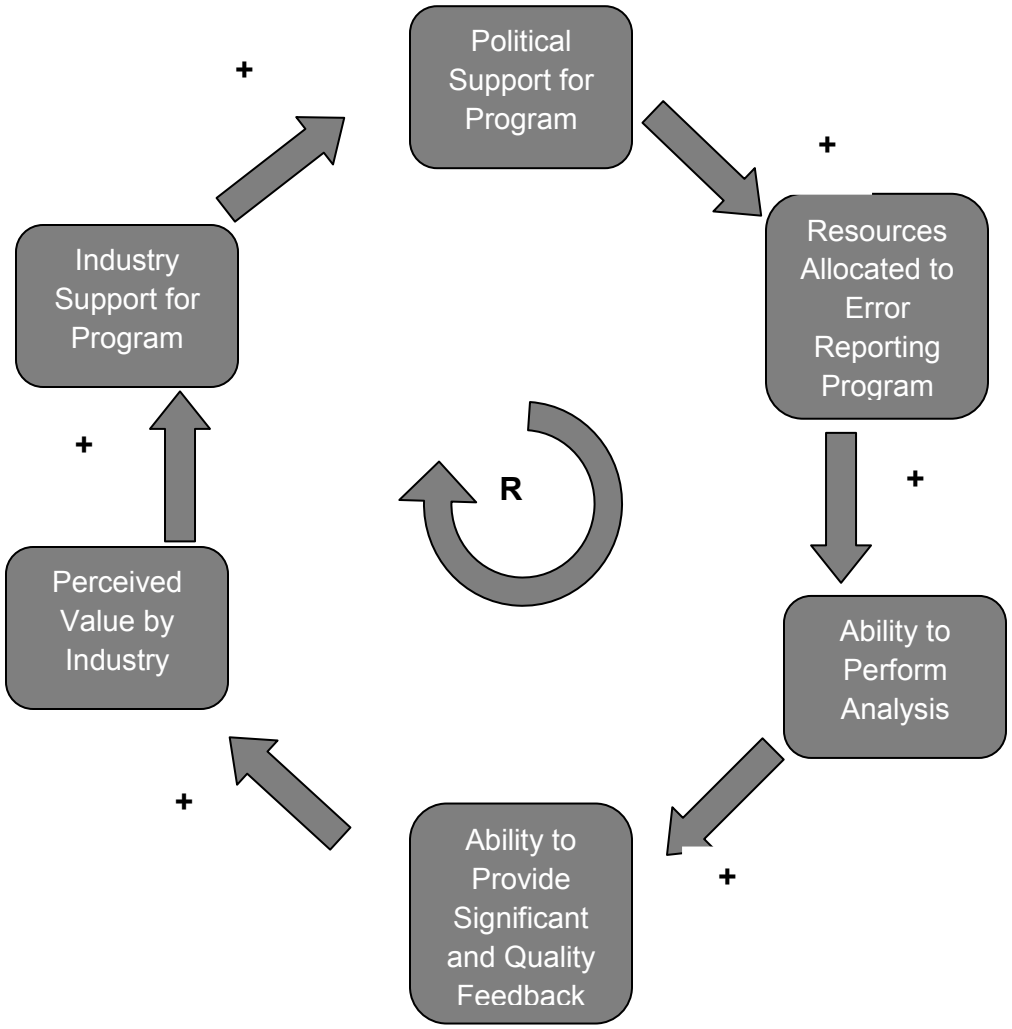
Based on these variables, the following causal loop diagram was developed. The diagram describes the vulnerability of the error reporting programs to the perception of their usefulness by the health care industry. The cycle is a reinforcing one (growing in strength, unless and intervention is made), and may operate either in a negative or positive way.

When negative, the cycle functions in this manner: When programs fail to analyze data and then share their analysis with the health care industry, either through lack of resources, lack of interest or lack of awareness of the importance of

the feedback loop, the industry in turn perceives less usefulness in the program. This may convert to less industry support for a program that has a cost to the industry (time and effort to comply with error reporting, as well as the risk-cost of liability and embarrassment if reports are made). Lower industry support may translate into lower political support, which cuts further into the resources available for the program to analyze data and share feedback.

In a positive iteration, the cycle would result in a stronger program through industry support. The health care industry would value the program because the feedback received is useful for preventing future errors. In turn, the industry's support would translate into political support, additional resources, and further strength in data analysis and feedback.

FIGURE 7-1: FEEDBACK TO THE HEALTH CARE INDUSTRY AFFECTS THE STRENGTH OF THE CURRENT ERROR REPORTING SYSTEM



This causal loop focuses on one of the opportunities for change:

- Increased awareness by the states of the importance of perceived usefulness of the system by health care industry

It also relates to two other opportunities, because they are connected to the idea of effective data collection and industry confidence in the system:

- Increased awareness of the risk of under-reporting
- Increased awareness of protections for health care entities that report as required

The causal loop indicates a powerful opportunity to create change in the current system. The opportunity relates to a high level of effectiveness in Meadows' hierarchy. This opportunity will be the focus of this plan for change.

Plan for Change

The plan for change has two components: responding to the educational needs portrayed in the causal loop diagram and found on the Meadows hierarchy at level 2, and providing recommendations for program improvements found on the Meadows hierarchy at levels 3, 4, 5, 7 and 8.

Meadows Level 2 component:

1. The plan for change will begin with dissemination of the study findings. The results will be shared via executive summary with all QSAs. QSAs will be informed that they have the option to request an electronic copy of the complete study results. The complete study will also be shared with the NASHP, the NQF and the AHA.
2. All QSAs and key national organizations will be invited to participate in a webinar hosted by the researcher. The webinar will focus on the Meadows Level 2 issues:
    a. Increasing awareness of the QSAs to the issue of perceived usefulness of their programs by the health care industry

b. Increasing awareness of the QSAs of the risk of under-reporting
c. Encouraging QSAs to increase health care industry awareness of protections offered to reporting entities

This aspect of the plan for change reflects the leadership descriptions of Kotter, particularly in the distinctions between leadership and management. Several of the leadership functions in Kotter guide this plan. Kotter explains that, while "Management is about coping with complexity….Leadership, by contrast, is about coping with change" (Kotter, 2001: 26). The responsibility for dealing with complex reporting systems lies with the QSMs and their executive branch leaderships. Guiding change in the overall reporting systems is a leadership process that many people, including the researcher, can join.

The contrast between management and leadership is extended by Kotter to several key functions, each of which describes the place of this study in influencing change at the governmental level:

Planning and budgeting vs. Setting a direction: The tasks of implementing program work, including resource allocation, are located at the managerial level in the state agencies. The researcher's role in this plan is to generate a vision: "What's crucial about a vision is not its originality but how well it serves the interests of important constituencies—customers, stockholders, employees—and how easily it can be translated into a realistic competitive strategy" (Kotter, 2001: 28). This plan presents a vision of awareness of the risk of under-reporting, clarity of protections offered, and recognition of the importance of the perception of value by the health

care industry. The plan will communicate this vision to attempt to generate enthusiasm for a higher level of awareness of these factors at the state agency level.

Aligning people vs. Organizing and staffing: Staffing, like budgeting, is an administrative and managerial function. The state agencies will have to make their own decisions about staffing and organizing their programs. This plan seeks to align key state agency managers with a particular perspective. Kotter states that this is "…more of a communications challenge than a design problem….Anyone who can help implement the vision and strategies or who can block implementation is relevant" (Kotter, 2001: 29). This plan seeks alignment of stakeholders through broad distribution of the findings of this study, and open invitation to the educational webinar.

Motivating people vs. controlling and problem solving: Ultimately, the changes envisioned in this plan require enthusiastic buy-in from multiple stakeholders: state and federal agencies, health care entities, and even the general public. This plan is a first step toward changing the status quo in an effort to strengthen and broaden medical error reporting systems. Kotter states that effective motivation requires recognition of the values of the audience, involvement in implementation of the vision, ongoing support and recognition and reward (Kotter, 2001: 30). This plan will include the first of these qualities: recognition of the values of the audience. The data showed that QSMs value error reporting, question its completeness and wish to use their data effectively. The dissemination of the study's findings will emphasize an understanding of these shared values.

Meadows Levels 3 – 8 component:

The plan for change for these elements consists of recommendations to be shared with key stakeholders. These recommendations all involve legislative action and budget decisions. The influence of this study in these arenas is dependent upon the decisions of the stakeholders and their political choices. Dissemination of the study results will provide stakeholders with information and support for decisions to strengthen and broaden the health care error reporting systems nationwide.

In addition to the QSAs and national organizations mentioned above, study recommendations will be shared with the Centers for Medicare and Medicaid Services (CMS), because the most radical suggestion in the Plan for Change is a federal requirement for reporting of surgical errors. Existing relationships with personnel in CMS Region X (Seattle) will be leveraged for dissemination of the findings to CMS.

Recommendations in this stage include:

Strengthening Existing Systems

Efforts to improve compliance with state reporting requirements should address systemic barriers identified by the reporting health care entities as well as those described by state agencies, and thus should concentrate on strengthening the awareness of states about potential problems in compliance with error reporting, removing systemic barriers to reporting where possible, and supporting the meaningful use of data.

Existing state reporting systems display great variability regarding types of errors that must be reported, types of institutions that must report, protections from

disclosure and liability, and data analysis and release. The variation between state systems makes state-by-state comparisons of the efficacy of reporting systems difficult. More importantly, the actions taken in some states to encourage and enforce compliance are not applied uniformly across the nation, creating a likelihood of variation in reporting rates that makes assessment of relative patient safety between states impossible. Under a uniform and effective reporting system it should be possible to determine whether some states are more successful than others at reducing surgical errors, and to learn from these successes.

Recommendations for strengthening existing state systems include the following points:

1. **Enhanced awareness of reporting lapses and barriers.** States should consider the evidence provided by investigative reports and internal inquiries that demonstrate failure of institutions to submit all required reports.

2. **Removing barriers to compliance with mandatory reporting.** Reports from the health care industry clearly and consistently identified causes of potential under-reporting. States should be aware of those areas identified by the health care industry that were not recognized by the states. States should be encouraged to engage in system reform, which should include improved enforcement of reporting requirements and meaningful assurances to the health care industry regarding liability and discoverability protections. In states with weak protection for reported errors, legislation should establish or increase protection.

3. **Support meaningful use of data.** Data that do not pass through effective state agency analysis and public dissemination are not available for industry to use as a knowledge base to support patient safety improvement efforts. Data that are handled differently in different states are not available for effective comparative analysis nationally. As Mehtsun, et al., note: “A centralized mandatory reporting mechanism that would require uniform reporting criteria across states would minimize the surveillance bias inherent in current estimates” (Mehtsun et al., 2012: 6).

   Each of these factors must be addressed:

a. **Standardized definitions and requirements:** Standard definitions of medical errors between states will permit comparative analysis of state reports, reporting rates, and possibly error rates. States should, at a minimum, use a consistent set of definitions for reportable errors, even if they choose to add other medical errors to their own internal list of reportable events. NQF definitions are the most commonly used among the various systems currently established. Unless another system becomes prominently consistent among the states, the NQF definitions should become the minimum required reportable events in states.

b. **Interstate sharing:** Databases and dissemination of analyses should be standardized to the extent possible among states, so that data may be shared in a consistent manner nationally. Sharing data and analysis between states is essential for learning about reporting system effectiveness at the governmental level. The ability to share information between state systems will require compatible technology and interstate centers for data aggregation. The example of the University of Michigan, which collects and transmits quality outcomes for dialysis centers nationwide, is a model for such an error aggregating resource.

Widening the Reporting Universe

Because knowledge of the means of preventing errors requires, in part, awareness of the types and prevalence of errors, efforts should also be directed toward increasing the number of governmental agencies that require reporting of surgical and other medical errors, both at the state and national level.

The above steps will strengthen medical error reporting systems in those states that have adopted such systems by law or regulation. At least 26 states, however, have either ended their error reporting program or have not adopted any mandatory medical error reporting system at this time. Furthermore, federal healthcare systems such as the Veterans Administration are not included in state-level reporting because they are not subject to state authority. Widening the

reporting universe will require two efforts, both of which involve federal power: Incentives for the expansion of state reporting, and a new role for the federal government in the error reporting process:

1. **Encouragement for all states to institute mandatory reporting systems.** The federal government has the ability, through the tremendous power it wields through health care financing, to incentivize adoption of error reporting systems in the states that do not currently have such systems. These incentives could come through programs that direct federal funds to state governments for provision of health care. Medicare, Medicaid and the Affordable Care Act are three possible avenues for incentivization. The incentives could take the form of either positive or negative pressure: Additional funding for states that do implement reporting systems, or decreased funding for states that do not.

2. **Institute mandatory reporting systems through CMS.** CMS would be a unifying factor in the national patchwork of error reporting systems. Almost all hospitals in the United States are certified by CMS as providers of care under the Medicare system. These hospitals must be in compliance with Medicare Conditions of Participation. The implementation of a mandatory medical error reporting system through the CMS rules would immediately cover 81.55% of hospitals in the United States (4726 Medicare-certified hospitals out of 5795 total hospitals (CMS, 2011 and AHA, 2011)), as well as all Medicare-certified ambulatory surgical centers. The Medicare Conditions of Participation for hospitals and Conditions for Coverage for ambulatory surgical centers should be amended to include a requirement for reporting of medical errors to either the state agencies with which CMS contracts for survey and certification processes, or directly to a CMS system that would be established for the purpose. A centralized, CMS-based system would be preferable, because of the consistency of data management that would be available as well as the ability to immediately enforce reporting requirements through the CMS enforcement system. Such a system would go further than the recommendations of the Inspector General for the Department of Health and Human Services, which urged CMS to ensure that state agencies do a better job of monitoring hospital corrective action plans following errors, that error-related Medicare complaint surveys include analysis of the Condition of Participation for Quality Assurance and Performance Improvement, that hospitals receive more specific information about complaints being investigated, and that CMS communicate error reports with accrediting organizations such as the Joint Commission (Department of Health and Human Services, 2011).

3. **Institute mandatory federal hospital reporting system.** The federal government operates approximately 211 hospitals (AHA, 2011) that are outside the authority of state agencies. Some of these hospitals are Veterans Administration health care centers. The appropriate federal agencies managing these hospitals should initiate a mandatory error reporting system consistent with that operated by the states and, ideally, by CMS.

Timeline for Plan for Change

Dissertation completed and approved by committee	March, 2013
Executive Summary written	March, 2013
Executive Summary distributed to all QSAs and key national organizations	April, 2013
Webinar prepared	April, 2013
Webinar delivered	April, 2013
Recommendations delivered to QSAs and CMS	April, 2013

Impact of the Plan for Change

It is unknown at this time how many surgical errors actually occur annually in the United States. This lack of knowledge means that systems for learning and prevention of future errors lack accurate information about the incidence and causes of surgical errors in the USA. Strengthening the cycle of error reporting would stimulate analysis of errors, permit accurate assessments of the risk and severity of error incidence, and support planning and resource allocation to reduce the incidence of error and increase patient safety.

Implementation of the Plan for Change would result in several major improvements in the inconsistent national patchwork of error reporting systems:

1. States would recognize the risk of under-reporting

2. States would recognize the importance of feedback to the health care industry

3. States would support and encourage compliance with mandatory error reporting by enhancing enforcement and extending liability and discoverability protections

4. States would use uniform basic reporting requirements and definitions and would have uniform basic data management programs that would permit state-to-state comparison of error reporting data, possibly including error reporting rates and potentially even including actual error rates

5. All states would be supported by the federal government to establish mandatory error reporting systems

6. CMS would require error reporting as part of the requirement for Medicare certification for health care institutions

7. The federal government would establish mandatory error reporting systems to cover the hospitals within its control

Appendix A: Study Purpose and Confidentiality

Dear _____,

Thank you for agreeing to participate in this study, which is will become part of my dissertation for my doctoral degree in public health at the University of North Carolina at Chapel Hill. This research is conducted under the supervision of my dissertation committee chair.

The topic of the study is the role of state agencies in receiving reports of medical errors from health care entities. Your participation in this study will lead to greater understanding of the way states respond to reports of medical errors.

The study will consist of two parts:

A voluntary brief telephone survey and, for those who agree to participate, a voluntary second telephone interview.

Your completion of the initial survey will be extremely helpful in creating a picture of the various state reporting systems that currently exist in the United States. Your participation in the initial survey does not obligate you to participate in the second interview.

If you agree at the end of the initial survey to further participation in this research, you may be contacted for a second telephone interview. This interview will give an opportunity for participants to describe their state systems more fully and express their opinions regarding medical error reporting.

The second interview is confidential. Your name, and the name of your state, will not be used in the interview results that are written as part of this research. All surveys, transcripts and other data will be destroyed when the research project is completed.

I welcome any questions you may have about this research project. You may contact me at: throne@live.unc.edu

Thank you,

Paul Throne, MSW, MPH

Appendix B: Pre-Interview Survey Guide

Thank you for taking the time to complete this brief survey. This survey is part of my research for my doctoral degree in public health at the University of North Carolina at Chapel Hill. Completing this survey is voluntary and should take no longer than 15 minutes.

Your participation in this survey will lead to greater understanding of the way states respond to reports of medical errors. For the purposes of this survey, a reportable medical error is defined as any medical error that your state requires to be reported to you by a state-licensed facility.

This survey consists mostly of information that is publicly available. Although your state may be specified in data that are reported from this survey, your name will not be used in the results that are written as part of this research. Data will be stored on a secure server at the University of North Carolina. All surveys and other data will be destroyed when the research project is completed.

All surveys and recordings will be destroyed when the research project is completed.

Do you have any questions about this interview or this study?

May I have your permission to record this interview?

<u>Opening</u>

1. Does your agency receive reports of surgical errors from facilities where surgery takes place?

2. Are you personally responsible for receiving or managing reports of surgical errors?

<u>Facilities</u>

3. Which of the following surgical facilities are required to report errors to your agency?

    - Hospitals
    - Ambulatory surgical centers
    - Dental surgery centers
    - Office-based surgery

4. When facilities have reported a surgical error to your agency, does or has your state take any of the following actions?

- Required the facility to conduct its own internal investigation
- Conducted a state investigation of the reported incident
- Issued a statement of deficiencies
- Required a plan of correction
- Issued a fine
- Revoked a facility's license
- Conducted an investigation of the practitioner(s) involved
- Other

5. Has your agency ever become aware of surgical errors that should have been reported by the facility, but were not?

6. How did you become aware of the errors in those cases?

Disposition of Reports

7. Are reported surgical errors disclosable to the public or media in any of these ways in your state?

    - Yes, as aggregate data only
    - Yes, with disclosure of:
        - Facility name
        - Type of error
        - Date of error
    - No, errors are not disclosable

8. Are facilities that report surgical errors to our agency protected legally in any of these ways?

    - Yes:
        - Protection from discovery
        - Protection from liability
        - Other legal protection
    - No, there is no legal protection given to facilities that report

Reporting

9. What definitions does your state use for reportable surgical errors?

    - The Joint Commission Sentinel Events
    - National Quality Forum 29 Reportable Events
    - We developed our own definitions

10. If you developed your own definitions, which of the following are included in the definition of reportable surgical error in your state?

- Surgery on the wrong patient
- Surgery on the wrong body part
- Wrong surgical procedure performed
- Foreign body left unintentionally
- Death of an ASA class I patient during or immediately after surgery
- Other _____

11. In your opinion, what % of reportable surgical errors in your state are actually reported to your agency?

Process

12. When surgical errors are reported to your state agency, which of the following is done with the information?

    - Data are aggregated
    - Data are analyzed for types of errors
    - Data are analyzed over time for trends
    - Data are disseminated to the health care industry
    - Other
    - Nothing is done with the data

13. Does your state agency have a role in enforcing the law that surgical errors must be reported to you?

    - Yes
    - If yes, what does the state do to enforce the law?
    - No

14. May I contact you if I have any questions about your state's policies on reportable surgical errors?

15. Would you be willing to participate in a second interview on this topic?

Thank you for participating in this survey.

Appendix C: Key Informant Interview Guide

[NOTE: Primary questions are in **bold**; potential follow-up or extending questions are in *italics*]

Thank you for taking the time to talk with me today about your agency's role in medical error reporting. This interview is part of my research for my doctoral degree in public health at the University of North Carolina at Chapel Hill. The interview should take about 30 minutes.

The purpose of this interview is to learn more about how your state receives medical error reports from facilities that are required to report medical errors to you. Specifically, I am interested in how your state receives and manages reports of surgical errors. For the purpose of this interview, a reportable surgical error is defined as any surgical error that your state requires to be reported to you by a facility.

This interview is confidential. Your name, and the name of your state, will not be used in the results of the interviews that are written as part of this research. All surveys and recordings will be destroyed when the research project is completed.

Do you have any questions about this interview or this study?

May I have your permission to record this interview?

Topic Area: Extent of concern regarding possible noncompliance

What priority are you asked to give to the issue of compliance with reporting requirements?

How are compliance and noncompliance discussed within your agency?

How does your agency assess compliance with reporting requirements?

Thinking about the specific category of surgical errors, to what extent do you think your state is receiving all of the reports that it should?

Topic Area: Causes of Underreporting

If you were not receiving all of the reports that you should, what do you think may be some of the reasons for that?

Has your agency received any feedback from the industry about your reporting requirements?

If so, what feedback have you received?

Topic Area: Enforcement

Is it your agency's role to be involved in enforcing the requirements for surgical error reporting?

How important do you think it is for your agency to be involved in enforcement?

How effective do you think your agency is at enforcing compliance?

Do you think there are any specific factors that encourage compliance?

Do you think there are any specific factors that discourage compliance?

Topic Area: Analysis

What does your agency do with the data it receives when facilities report surgical errors to you?

How important is it in your agency to analyze the information you receive on surgical errors?

How does your agency use the reporting process to make surgery safer?

How would your agency use this data in an ideal world?

Conclusion

Is there anything else you would want me to know about your agency's role in receiving reports of surgical errors?

Do you have any questions for me about this research?

Thank you for taking the time to talk with me today about your agency.

Appendix D: Results of the Pre-Survey

HEALTH CARE ENTITIES REQUIRE TO REPORT SURGICAL ERRORS BY STATE

STATE	HOSPITALS	AMBULATORY SURGICAL CENTERS	DENTAL SURGERY CENTERS	OFFICE-BASED SURGERY
CA	●	●		
CO	●	●		
CT	●	●		
DC	●	●		●
FL	●	●		
GA	●			
IN	●	●		
KS	●	●		
ME	●	●		
MD	●			
MA	●	●		
MN	●	●		
NH	●	●		
NJ	●	●		
NY	●			●
NV	●	●		
OH	●			
PA	●	●		
RI	●	●		
SC	●	●		
SD	●	●		
TN	●	●	●	
UT	●	●		
VT	●			
WA	●	●		

RESPONSE BY THE STATE TO REPORTED SURGICAL ERRORS

STATE	REQUIRE INTERNAL INVESTIGATION	STATE INVESTIGATION	SOD	POC	FINE	ACTION AGAINST ENTITY LICENSE	INVESTIGATE PRACTITIONER
CA	●	●	●	●	●	●	
CO		●	●	●			
CT	●	●	●	●			
DC	●			●			
FL	●			●			
GA	●	●	●	●	●		
IN	●			●			
KS	●	●	●	●			
ME	●						
MD	●	●	●	●			
MA	●	●	●	●			
MN	●						
NH	●	●	●	●		●	
NJ	●			●			
NY	●			●			
NV	●			●			
OH							
PA							
RI	●	●		●			
SC							
SD	●	●	●	●		●	
TN		●	●	●			
UT	●			●			
VT	●						
WA	●						

DISCLOSURE OF REPORTED SURGICAL ERROR DATA BY THE STATE

STATE	AGGREGATE ONLY	FACILITY IDENTIFIED	BY TYPE OF EVENT	BY DATE OF EVENT	NO DISCLOSURE
CA		●	●	●	
CO		●	●	●	
CT	●	●	●		
DC	●				
FL			●		
GA					●
IN	●	●	●		
KS	●		●		
ME			●		
MD	●		●		
MA		●	●	●	
MN		●	●		
NH		●	●		
NJ		●	●		
NY	●	●	●		
NV		●	●		
OH		●	●		
PA					
RI					
SC					
SD					
TN	●				
UT	●				
VT					
WA		●	●	●	

PROTECTIONS OFFERED TO REPORTING ENTITIES

STATE	PROTECTION FROM DISCOVERY	PROTECTION FROM LIABLITY	OTHER PROTECTIONS	NO PROTECTION
CA				●
CO	●			
CT				
DC	●	●		
FL	●			
GA	●			
IN				
KS	●			
ME	●	●		
MD	●			
MA				●
MN	●			
NH	●			
NJ	●			
NY	●			
NV	●			
OH				●
PA				●
RI	●			
SC				
SD				
TN	●			
UT	●			
VT				●
WA				●

DEFINITION OF SURGICAL ERROR

STATE	SAME AS NQF	OWN DEFINITION IN ADDITION TO OR INSTEAD OF NQF
CA	●	
CO		death, neglect
CT	●	patient death or serious disability as a result of surgery
DC	●	
FL		wrong patient, wrong body part, wrong procedure, foreign body, wrong diagnosis, injury not a known risk
GA		wrong patient, wrong body part, wrong procedure, unanticipated death
IN	●	
KS		all occurrences when the standard of care was not met and injury occurred or was probable
ME	●	
MD		death or serious disability
MA	●	
MN	●	
NH		Extensive list of events in state statute RSA 151
NJ		wrong patient, wrong body part, foreign body, ASAI, other adverse preventable events
NY		Same as NQF but delete ASA I death and add unexpected death
NV		death or serious injury
OH		retained foreign body
PA	●	
RI		wrong patient, wrong procedure, other specified in law
SC		Incidents resulting in death or serious injury
SD		death resulting from abuse/neglect
TN		abuse/neglect
UT	●	
VT	●	
WA	●	

ANALYSIS OF DATA BY STATE

STATE	AGGREGATE ONLY	ANALYZED BY TYPE	ANALYZED BY TRENDS	DISSEMINATED TO HEALTH CARE INDUSTRY	OTHER USE	NO DATA ANALYSIS
CA		●	●	●		
CO						●
CT	●	●	●	●		
DC	●	●	●	●		
FL						●
GA		●	●			
IN	●	●	●			
KS	●	●	●	●		
ME		●	●			
MD		●	●	●		
MA						●
MN		●	●	●		
NH						●
NJ	●	●	●			
NY		●	●	●		
NV		●	●			
OH						●
PA		●	●	●		
RI		●	●			
SC						
SD						●
TN						●
UT		●	●	●	●	
VT						●
WA						●

ENFORCEMENT OPTIONS BY STATE

STATE	FINE	STATEMENT OF DEFICIENCIES	INVESTIGATION	LICENSURE ACTION	OTHER	NO ENFORCEMENT ACTION
CA	●					
CO						●
CT	●	●				
DC	●					
FL	●					
GA		●				
IN	●	●				
KS						●
ME	●					
MD	●					
MA			●			
MN					●	
NH	●					
NJ	●				●	
NY	●				●	
NV	●					
OH						●
PA					●	
RI	●	●				
SC						
SD				●		
TN		●				
UT						●
VT					●	
WA					●	

Appendix E: Pre-Survey Responses to the Question:

"Of the surgical errors that occur in your state, and are required to be reported to your agency, what % do you think are actually reported?"

Category of Response	QSM Perspective	Theme
Impossible to know if all events are reported	Can I say exactly what percentage is actually reported? I don't know that.	*True number of reportable events is unknown*
	That is impossible to answer.	*True number of reportable events is unknown*
	It's impossible to know what's actually reported.	*True number of reportable events is unknown*
	I would have no way of knowing how accurate our reports are. Everybody knows they're not getting the reports they should be.	*True number of reportable events is unknown*
	We don't really have a way of gauging it at this time….	*True number of reportable events is unknown*
	We wouldn't know. Given the perverse incentive the hospitals have to not file the report and the style of litigatory system we have--being the worse the error, the greater exposure, the greater the incentive to shield it--who knows what's going on?	*True number of reportable events is unknown* *Legal risk inhibits reporting*
	You know, I couldn't even begin to tell you but I would hazard…I don't know, it's really hard to say.	*True number of reportable events is unknown*
	That's a hard one. We're currently doing a report on underreporting. We don't know what we don't know.	*True number of reportable events is unknown*
	…It makes it next to impossible to know how many events we really have occurring out there in the state if the facility doesn't self-report and we don't get those calls in.	*True number of reportable events is unknown* *Vulnerable to entity*

		choice whether to report
	We don't have authority to go out and scour through medical records and interview people to find out if really all events are being reported or not but I think there is, I would say a general sense that there's underreporting.	*Lack of resources inhibits knowledge of true number of events*
	There's that huge discrepancy between what you hear from national experts about all these reports, it just sounds like thousands of people are being killed every year but that's just not the experience that we're seeing here through our reporting program, so I don't know how you fill that gap, or what's the truth. Where does the truth lie?	*True number of reportable events is unknown*
	You can't really know for sure, you have to put different cross-checks in place to make sure you got things.	*True number of reportable events is unknown*
Most or all events are reported	I don't have any way to be able to determine that. We operate on good faith here. I'm guessing a majority of those that are required to be reported [are reported].	*True number of reportable events is unknown* *Confidence in relationship with entities*
	I think every one. We have a very, very good working relationship with the hospitals. I'm not aware because usually what happens, if there was something that they were a little late in reporting to us, usually one of the employees will leak it out.	*Confidence in relationship with entities*
	I would say it's fairly accurate….We don't do any kind of audit. The reporting is pretty low in most states but I couldn't really say although there's no negative outcome to reporting. That doesn't mean they want to report them.	*Confidence in relationship with entities* *Vulnerable to entity choice whether to report*

Few events are reported	The numbers are still big numbers but we're just not seeing that volume in our state system, and I don't think it's because we're so much safer. I think it's just because there's just underreporting.	*Suspicion of under-reporting*
	If we look at ICD-9 for object left in, and surgery for object left in, it would look like our reporting is somewhat like 40%….I'd say we're getting under 50% in two years.	*Data reveal under-reporting*
	Hospitals and ASCs are our poorest performers in following that rule. I don't know why. Potentially legal gets involved. They are reluctant to report neglect on staff's part, to make an official document that's reported to the state.	*Suspicion of under-reporting* *Vulnerable to entity choice whether to report*

Appendix F: Regrouping Guide

Some data regrouping was conducted. The purpose of the regrouping was to create categories of difference between states based on the characteristics reported by the state agencies. Several survey questions required regrouping, while others were already sufficiently categorized. The regrouped data were managed according to this guide:

Survey Question	Responses Available	Regrouping:
When a facility reports a medical error to your agency, what responses may your state take? Please select all answers that apply.	○ REQUIRE THE FACILITY TO CONDUCT AN INTERNAL INVESTIGATION ○ CONDUCT A STATE INVESTIGATION OF THE REPORTED INCIDENT ○ ISSUE A STATEMENT OF DEFICIENCIES ○ REQUIRE A PLAN OF CORRECTION ○ ISSUE A FINE ○ REVOKE A FACILITY'S LICENSE ○ CONDUCT AN INVESTIGATION OF THE PRACTITIONER(S) INVOLVED ○ NONE OF THE ABOVE	**1, 2 or 3 positive responses = Punitive Score 1 – 3** **4, 5, or 6 positive responses = Punitive Score 4 – 6** **0 positive responses = Non-Punitive**
Are reported medical errors disclosable to the public or media in your state?	○ YES, AS AGGREGATE DATA ONLY ○ YES, WITH ONLY FACILITIES DISCLOSED ○ YES, WITH FACILITIES AND SPECIFIC ERROR TYPES DISCLOSED ○ YES, WITH FACILITIES AND SPECIFIC ERROR DATES DISCLOSED ○ NO, ERRORS ARE NOT DISCLOSABLE	**0 positive responses = No disclosure** **Positive response to Aggregate Data Only = Aggregate Only** **Positive response to any other option = Facility Identified, with or without type and date**
When surgical errors are reported to your state agency, what is done	○ DATA ARE AGGREGATED ○ DATA ARE ANALYZED FOR TYPES OF ERRORS ○ DATA ARE ANALYZED	**0 positive responses = No Analysis** **Positive response to**

with the information?	OVER TIME FOR TRENDS ○ DATA ARE DISSEMINATED TO INDUSTRY ○ NOTHING IS DONE WITH THE DATA	**aggregated only = data aggregated only** **Positive response to "Data are analyzed for types of errors", or positive response to "Data are analyzed over time for trends" = data analyzed for types and/or trends**

References

Agency for Healthcare Research and Quality. New AHRQ study finds surgical errors cost nearly $1.5 billion annually. Press Release Date: July 28, 2008 http://www.ahrq.gov/news/press/pr2008/surgerrpr.htm, accessed 01/28/2011

American Health Consultants. State systems for “serious reportable events” will require reporting, analysis. Hospital Peer Review, December 2001, 26(2): 161-176.

American Hospital Association. Fast Facts on US Hospitals. http://www.aha.org/research/rc/stat-studies/101207fastfacts.pdf accessed 12/04/2011.

Balkrishnan R; Gill IK, Vallee JA; Feldman SR. No smoking gun: Findings from a national survey of office-based cosmetic surgery adverse event reporting. Dermatol Surg. 2003 Nov; 29(11):1093-9; discussion 1099.

Barach P; Small SD. Reporting and preventing medical mishaps: Lessons from non-medical near miss reporting systems. BMJ. 2000 Mar 18; 320(7237):759-63.

Bates DW; Evans RS; Murff H; Stetson PD; Pizziferri L; Hripcsak G. Policy and the future of adverse event detection using information technology. J Am Med Inform Assoc. 2003 Mar-Apr; 10(2):226-8.

Becher, EC; Chassin, MR. Improving quality, minimizing error: making it happen. Health Affairs 20, 2001; 3:68 – 81.

Benn, J; Koutantji, M; Wallace, L; Spurgeon, P; Rejman, M; Healey, A; Vincent, C. Feedback from incident reporting: information and action to improve patient safety. Qual Saf Health Care 2009; 18:11–21

Braithwaite JJ. Attitudes toward the large-scale implementation of an incident reporting system. International journal for quality in health care. 2008; 20(3):184-91.

Brennan, TA; Leape LL; Laird, NM; Hebert, L; Localio, AR; Lawthers, AG; Newhouse, JP; Weiler, PC; Hiatt, HH. Incidence of adverse events and negligence in hospitalized patients: Results of the Harvard Medical Practice Study I. Qual Saf Health Care 2004; 13:145–152.

Carroll, J; Edmondson, A. Leading organizational learning in health care. Qual Saf Health Care 2002; 11: 51-56.

Centers for Medicare and Medicaid Services. Hospital General Information. http://data.medicare.gov/dataset/Hospital-General-Information/v287-28n3 accessed 12/04/2011.

Chamberlain N. The folly of rewarding silence while hoping for open reporting of adverse medical events—how to realign the rewards. N Z Med J. 2008 Sep 22; 121(1282):58-66.

Clarke, JR. How a system for reporting medical errors can and cannot improve patient safety. The American Surgeon, 2006; 72:1088 – 1091.

Cohen MR. Why error reporting systems should be voluntary. BMJ. 2000 Mar 18; 320(7237):728-9.

Coldiron, B; Fisher, AH; Adelman, E; Yelverton, CB; Balkrishnan, R; Feldman, MA, et al. Adverse event reporting: Lessons learned from 4 years of Florida office data. Dermatol Surg. 2005 Sep; 31(9 Pt 1):1079-92; discussion 1093.

Creswell, JW. Five qualitative traditions of inquiry. In *Qualitative Inquiry and Research Design: Choosing Among Five Traditions*, pp. 47 – 72. Thousand Oaks, CA: Sage Publications (1998).

Creswell, JW *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*. Thousand Oaks, California: Sage Publications (2009).

Department of Health and Human Services. Adverse events in hospitals: Medicare's responses to alleged serious events. OEI-01-08-00590. October, 2011.

Dovey, SSM. What should we report to medical error reporting systems? Qual Saf Health Care 2004; 13(5):322-3.

Edmondson, AC. Learning from mistakes is easier said than done: Group and organizational influences on the detection and correction of human error. The Journal of Applied Behavioral Science. March 1996; 32:5-28.

Edmonson, A C. Learning from failure in health care: frequent opportunities, pervasive barriers. Qual Saf Health Care 2004; 13 (Suppl II): ii3 – ii9.

Fama, EF; Jensen, MC. Separation of ownership and control. Journal of Law & Economics, June 1983; XXVI: 301-325.

Fassett, WE. Patient safety and quality improvement act of 2005. Ann Pharmacother. 2006 May; 40(5):917-24.

Flink, E; Chevalier, CL; Ruperto, A; Dameron, P; Heigel, FJ; Leslie, R; Panzer, RJ; Lessons learned from the evolution of mandatory adverse event reporting systems (2005). In Henriksen, K; Battles, JB; Marks, ES; Flowers, RTL. State-

based mandatory reporting of medical errors: An analysis of the legal and policy issues. Portland, ME: National Academy for State Health Policy, 2001.

Gawande, A. *Complications: A Surgeon's Notes on an Imperfect Science.* New York: Picador, 2002

Gawande, A. *The Checklist Manifesto.* New York: Metropolitan Books, 2009.

Gottlieb, S. United States brings in new rules to prevent surgical errors. BMJ, 2004; 329(7456), 13.

Hartnell, N.; MacKinnon, N.; Sketris, I.; Fleming, M. Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study. BMJ Qual Saf 2012; 21: 361-368.

Hughes, RG, editor. *Patient Safety and Quality: An Evidence-Based Handbook for Nurses.* Rockville (MD): Agency for Healthcare Research and Quality (US), 2008.

Hutchinson, A; Young, T A; Cooper, K L. Trends in healthcare incident reporting and relationship to safety and quality data in acute hospitals: Results from the National Reporting and Learning System. Qual Saf Health Care, 2009; 18: 5-10.

Joint Commission Center for Transforming Healthcare. The Wrong Site Surgery Project. http://www.centerfortransforminghealthcare.org/UserFiles/file/CTH_Wrong_Site Surgery_Project_6_24_11.pdf, accessed 08/12/2011.

Kohn, LT; Corrigan, JM; Donaldson, MS, editors. *To Err Is Human: Building a Safer Health System.* Committee on Quality of Health Care in America, Institute of Medicine, National Academy Press, Washington, D.C., 2000.

Kotter, JP. What leaders really do. HBR's 10 Must Reads on Leadership. Harvard Business Review 1998, reprint R0111F.

Langley, GL; Nolan, KM; Nolan, TW; Norman, CL; Provost, LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. San Francisco: Jossey-Bass Publishers; 1996.

Larson, EB. Measuring, monitoring, and reducing medical harm from a systems perspective: A medical director's personal reflections. Acad Med. 2002 Oct; 77 (10):993-1000.

Leape, LL. Reporting of adverse events. N Engl J Med. 2002 Nov 14; 347(20):1633-8.

Mahajan, RR. Critical incident reporting and learning. British Journal of Anaesthesia 2010; 105(1):69-75.

Marchev, M; Rosenthal, J; Booth, M. How states report medical errors to the public: Issues and barriers. Portland, ME: National Academy for State Health Policy; 2003.

Meadows, D H. Leverage points: Places to intervene in a system. Hartland, VT: The Sustainability Institute; 1999.

Mehtsun, WT; Ibrahim, AM; Diener-West, M; Pronovost, PJ; Makary, MA. Surgical never events in the United States. Surgery 2012; in press: http://dx.doi.org/10.1016/j.surg.2012.10.005

Michaels, RK; Makary, MA; Dahab, Y; Frassica, FJ; Heitmiller, E; Rowen, LC; Crotreau, R; Brem, H; Pronovost, PJ. Achieving the National Quality Forum's "Never Events": Prevention of wrong site, worng procedure, and wrong patient operations. Annals of Surgery, 2007; 245(4): 526-532.

Miles, MB; Huberman, MA. Focusing and bounding the collection of data: The substantive start. In *Qualitative Data Analysis: An Expanded Sourcebook*, pp. 16–38. Thousand Oaks, CA: Sage Publications, Inc. (1994).

Morton, M; Galanko, JA; Soper, NJ; Low, DE; Hunter, J; Traverso, LW. NIS vs SAGES: A comparison of national and voluntary databases. Surgical Endoscopy, 2006; 20(7): 1124-1128.

Mullen, FX. RGJ investigates: No one knows extent of serious hospital errors. http://www.rgj.com/article/20110621/NEWS/106190367/RGJ-investigates-No-one-knows-extent-serious-hospital-errors accessed 08/13/2011.

Nalder, E. Despite law, medical errors likely go unreported. http://www.seattlepi.com/default/article/Despite-law-medical-errors-likely-go-unreported-889076.php accessed 01/28/2011.

National Academy for State Health Policy. Adverse Event Reporting Tools by State. http://www.nashp.org/pst-state-list. Accessed 01/28/2011

Neily, J; Mills, P; Eldridge, N; Carney, B; Pfeffer, D; Turner, J; Young-Xu, Y; Gunnar, W; Bagian, J. Incorrect surgical procedures within and outside of the operating room. Arch Surg. 2011; 146(11): 1235-1239.

Panesar, SS; Cleary, K; Sheikh, A. Reflections on the national patient safety agency's database of medical errors. J R Soc Med, 2009 Jul; 102(7):256-8.

Robeznieks, A. States moving ahead on patient safety front. American Medical News, July 26, 2004. http://www.ama-assn.org.libproxy.lib.unc.edu/amednews/2004/07/26/prsb0726.htm , accessed 04/01/2011.

Rosenthal, J; Booth, M. Defining reportable adverse events: A guide for states tracking medical errors. Portland, ME: National Academy for State Health Policy (2003).

Rosenthal, J; Takach, M. Guide to state adverse event reporting systems. State health policy survey report, Vol. 1, No. 1 (Portland, ME: National Academy for State Health Policy, December 2007), Publication No. 2007-301.

Rubin, HJ; Rubin, IS. *The Art of Hearing Data.* Thousand Oaks, California: Sage Publications (2005).

Russell, EM; Bruce, J; Krukowski, ZH. Systematic review of the quality of surgical mortality monitoring. Br J Surg. 2003 May; 90(5):527-32.

Seiden, SC; Barach, P. Wrong-side/wrong-site, wrong-procedure, and wrong-patient adverse events: Are they preventable? Archives of Surgery, 2006; 141(9), 931-939.

Sheldon, T. Netherlands plans system for reporting errors. BMJ. 2004 Jul 10; 329(7457): 68.

Spencer, FC. Human error in hospitals and industrial accidents: Current concepts. J Am Coll Surg. 2000 Oct; 191(4):410-8.

Spigelman AD; Swan J. Review of the Australian incident monitoring system. ANZ J Surg. 2005 Aug; 75(8):657-61.

Stahel, P; Sable, A; Victoroff, M; Varnell, J; Lembitz, A; Boyle, D; Clarke, T; Smith, W; and Mehler, P. Wrong-site and wrong-patient procedures in the universal protocol era: Analysis of a prospective database of physician self-reported occurrences. Arch Surg. 2010; 145(10): 978-984.

Stow, J. Using medical-error reporting to drive patient safety efforts. AORN J. 2006 Sep; 84(3):406,8, 411-4, 417-20; quiz 421-4.

Thomas, EJ; Studdert, DM; Newhouse, JP, et al. Costs of medical injuries in Utah and Colorado. Inquiry, 1999; 36:255–264.

Tucker, AL; Edmondson, AC. Why hospitals don't learn from failures: Organizational and psychological dynamics that inhibit system change. California Management Review, 2003; 45(2): 55-72.

Tuttle, D; Panzer, RJ; Baird, T. Using administrative data to improve compliance with mandatory state event reporting. Jt Comm J Qual Improv, 2002 Jun; 28(6):349-58.

Vozikis, AA. Information management of medical errors in Greece: The MERIS proposal. Int J Inf Manage. 2009; 29(1):15-26.

Weissman, JS; Annas, CL; Epstein, AM; Schneider, EC; Clarridge, B; Kirle, L; Ridley, N. Error reporting and disclosure systems: Views from hospital leaders. JAMA, 2005; 293(11), 1359-1366. doi:10.1001/jama.293.11.1359.

West, JC. Surgical “never events”: how common are adverse occurrences? ASHRM Journal 2006; 26(1): 15-21.

Williams, SK; Osborn, SS. The development of the national reporting and learning system in England and Wales, 2001-2005. Med J Aust, 2006 May 15;184(10 Suppl):S65-8.

Wood KE, Nash DB. Mandatory state-based error-reporting systems: Current and future prospects. Am J Med Qual 2005 Nov-Dec; 20(6):297-303.

World Health Organization, World Alliance for Patient Safety. *WHO draft guidelines for adverse event reporting and learning systems.* Geneva: WHO Document Production Services (2005).

Young, TK. *Population Health: Concepts and Methods*. New York: Oxford University Press, 2005.

Zivin JG, Pfaff AS. To err on humans is not benign: Incentives for adoption of medical error-reporting systems. J Health Econ. 2004 Sep; 23(5):935-49.