

# Chapter 35. Error Reporting and Disclosure

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## Background

This chapter examines reporting of health care errors (e.g., verbal, written, or other form of communication and/or recording of near miss and patient safety events that generally involves some form of reporting system) and these events' disclosure (e.g., communication of errors to patients and their families), including the ethical aspects of error-reporting mechanisms. The potential benefits of intrainstitutional and Web-based databases might assist nurses and other providers to prevent similar hazards and improve patient safety. Clinicians' fears of lawsuits and their self-perceptions of incompetence could be dispelled by organizational cultures emphasizing safety rather than blame. This chapter focuses on the assertion that reporting errors that result in patient harm as well as seemingly trivial errors and near misses has the potential to strengthen processes of care and improve the quality of care afforded patients.

## Reporting Errors

Reporting errors is fundamental to error prevention. The focus on medical errors that followed the release of the Institute of Medicine's (IOM) report *To Err Is Human: Building a Safer Health System*<sup>1</sup> centered on the suggestion that preventable adverse events in hospital were a leading cause of death in the United States. This report emphasized findings from the Harvard Medical Practice Study that found that more than 70 percent of errors resulting in adverse events were considered to be secondary to negligence, and more than 90 percent were judged to be preventable.<sup>2,3</sup> The IOM report also emphasized the importance of reporting errors, using systems to "hold providers accountable for performance," and "provide information that leads to improved safety." Conceptually these purposes are not incompatible, but in reality they can prove difficult to satisfy simultaneously<sup>1</sup> (p. 156). Nonetheless, reporting potentially harmful errors that were intercepted before harm was done, errors that did not cause harm, and near-miss errors is as important as reporting the ones that do harm patients. Patient safety initiatives target systems-related failures that contribute to errors within the complex environment of health care. Because many errors are never reported voluntarily or captured through other mechanisms, these improvement efforts may fail.

Errors that occur either do or do not harm patients and reflect numerous problems in the system,<sup>4</sup> such as a culture not driven toward safety and the presence of unfavorable working conditions for nurses. To effectively avoid future errors that can cause patient harm, improvements must be made on the underlying, more-common and less-harmful systems problems<sup>5</sup> most often associated with near misses. Systems problems can be detected through reports of errors that harm patients, errors that occur but do not result in patient harm, and errors that could have caused harm but were mitigated in some manner before they ever reached the patient. Reporting near misses (i.e., an event/occurrence where harm to the patient was avoided), which can occur 300 times more frequently than adverse events, can provide invaluable information for proactively reducing errors.<sup>6</sup> Analysis of reported errors have revealed many "hidden dangers" (near misses, dangerous situations, and deviations or variations) that point to

system vulnerabilities, not intentional acts of clinician performance that may eventually cause patients harm.<sup>7</sup>

Opinions and experiences of hospital leaders about State reporting systems were solicited from chief executive and chief operating officers of hospitals in six States with a variety of reporting systems: mandatory, nonconfidential; mandatory, confidential; and voluntary systems.<sup>8</sup> Questionnaires addressed perceptions of the effect of mandatory systems on error reporting, since it was thought that they reduced the frequency of error reports. Items elicited perceptions on the likelihood of lawsuits, overall patient safety, attitudes regarding release of incident reports to the public, and likelihood of reporting incidents to the States or affected patients based on hypothetical clinical vignettes varying in type and severity of patient injury. Safety was a high priority across hospitals. Most hospital leaders reported that a mandatory, nonconfidential reporting system run by the State deterred reporting of patient safety incidents to internal reporting systems. The majority thought that a mandatory, nonconfidential system encouraged lawsuits. Over half indicated that patients should learn details of errors on request by patients or families. They preferred that individual practitioner and hospital names be kept confidential and that incidents involving serious injury be reported to the State. Most indicated that the State should not release information to patients under certain circumstances. Definitions of reportable events varied by State, bringing hospital leaders to call for specific, national definitions of errors.

Just because an error did not result in a serious or potentially serious event does not negate the fact that it was and still is an error. Since reporting both errors and near misses has been key for many industries to improve safety,<sup>6</sup> health care organizations and the patients they serve can benefit from enabling reporting. Reporting sets up a process so that errors and near misses can be communicated to key stakeholders. Once data are compiled, health care agencies can then evaluate causes and revise and create processes to reduce the risk of errors. As such, organizations have implemented strategies, such as staff education, elicitation of staff advice, and budget appropriations, to ease the implementation of patient safety systems and to improve internal (e.g., intrainstitutional) reporting and disclosure to patients and families.

The ramifications of errors that do cause patient harm can provide critical information to inform the modification or creation of policies and procedures for averting similar errors from harming future patients. The position taken by the Joint Commission is that once errors are identified and the underlying factors/problems or “root causes” are identified, similar errors can be reduced and patient safety increased. When both errors and near misses are reported, the information can help organizations better understand exactly what happened, identify the combination of factors that caused the error/near miss to occur, determine its frequency, and predict whether it could happen again. Underreporting and failure to report errors and near misses prevents efforts to avoid future errors and thwarts the organization’s and clinicians’ obligation to inform/disclose to patients about the error.

As patients become more aware of actual and potential errors, they not only want to be informed, they want to know that quality improvement efforts supported by shared learning will prevent similar future errors.<sup>9</sup> Patients and the public support error reporting,<sup>10, 11</sup> particularly mandatory reporting,<sup>12</sup> and want to know that clinicians and organizations acknowledge errors<sup>13</sup> to leaders, managers, and peers, and that errors are reported as soon as they are detected.<sup>14</sup>

## Ethical Implications of Reporting and Disclosure

Health care providers are typically so devastated and embarrassed by their mistakes that they may attempt to conceal them or defend themselves by shifting the blame to someone or something else.<sup>15</sup> Some attribute failure of honestly acknowledging health care mistakes to providers' personal difficulty with admitting mistakes and incriminating other providers.<sup>16-19</sup> Ethical frameworks operate when health care mistakes are made.<sup>20</sup> Respect for patient autonomy is paramount, as is the importance of veracity. Fidelity, beneficence, and nonmaleficence are all principles that orient reporting and disclosure policies. Providers might benefit from accepting responsibility for errors, reporting and discussing errors with colleagues, and disclosing errors to patients and apologizing to them.<sup>21</sup>

When providers tell the truth, practitioners and patients share trust. The fiduciary responsibility of institutions exists in patients' and families' trust that providers will take care of them. If providers cover up errors and mistakes, they do not necessarily stay hidden and often result in compromising the mission of health care organizations. Consistent with their mission, institutions have an ethical obligation to admit clinical mistakes. Professional and organizational policies and procedures, risk management, and performance improvement initiatives demand prompt reporting. When patients, families, and communities do not trust health care agencies, suspicion and adversarial relationships result.<sup>18</sup> Likewise, the breach of the principle of fidelity or truthfulness by deception damages provider-patient relationships.<sup>22</sup> Fidelity and trust, implicit to the provider-patient relationship, do not coexist with deception.<sup>23</sup>

Physicians, nurses, and other health care providers have legal and ethical obligation to report risks, benefits, and alternative treatments through informed consent mandates. Legal self-interest and vulnerability after errors are committed must be tempered by the principle of fidelity (truthfulness and loyalty).<sup>24-26</sup> This ethical principle has been reinforced by practical lessons learned from errors; especially when an adverse event causes serious harm or even death, there is an ethical and moral obligation to disclose information.<sup>27, 28</sup> Candid reports and disclosure of errors by physicians as well as other health care providers (or institutional leadership if the physician refuses to disclose)<sup>19</sup> might result in greater patient trust and less litigation.<sup>29</sup> Furthermore, it is essential to act after errors are reported, with interventions aimed at protecting the welfare of patients by targeting iatrogenic problems and documenting the care given.

Additionally, the ethical principles of beneficence (doing good) and nonmaleficence (preventing harm) are violated when errors are not reported or disclosed. These ethical principles, beneficence and nonmaleficence, shape caring nursing practice, and caring presupposes that nurses act in the best interests of patients. For example, sharing information and preventing harm to patients through truth telling, regardless of good or bad news, build relationships between elder residents and nursing home staff.<sup>30</sup> Putting residents' interests first represents nurse caring and characterizes relationships in which sharing information, rather than hiding it, surrenders nurses' control related to withholding information. Thus, failure to disclose health care mistakes can be viewed from the perspective of provider control over the rights of patients or residents.

## Error-Reporting Mechanisms

Traditional mechanisms have utilized verbal reports and paper-based incident reports to detect and document clinically significant medical errors; yet the correlation with actual errors

has been low.<sup>31</sup> The benefits of these reports are dependent upon the design of the system, how and what information is collected, and whether the information is used to inform a sophisticated investigation of specific errors to understand the nature and magnitude of the problem. Additionally, reports can reflect the clinician's ability to recognize an error and willingness to report it, whether through formal reporting mechanisms or documentation in patient records. A consistent finding in the literature is that nurses and physicians can identify error events, but nurses are more likely to submit written reports or use error-reporting systems than are physicians.

Many types of errors that involve medications, health care acquired infections, and medical devices have been targeted for reporting and dissemination mechanisms.<sup>32</sup> In the case of medication errors, errors made by nurses during the administration of medications to patients are more likely to be reported in incident reports than are errors made by the prescribers (e.g., physicians) or distributors (e.g., pharmacists).<sup>33</sup> That said, it is important to note that physicians do not necessarily use incident-reporting systems.<sup>31</sup>

Error-reporting mechanisms may capture only a fraction of actual errors. Research has approached potential errors using direct observation, which, while expensive and not necessarily practical in all practice settings, generates more accurate error reports.<sup>34</sup> More recent approaches have been focusing on increasing and simplifying error reporting, and automating the detection of errors, including creating Web-based forms or adapted standard spreadsheets to reveal patterns of errors.<sup>35</sup> Many of these efforts have focused on improving physician participation and emphasize voluntary<sup>31</sup> and confidential reporting.<sup>36</sup> Most have encouraged reports of errors and near misses and shared occurrences with risk managers, other agency leaders, and patient safety specialists.<sup>37</sup> Perhaps a combination of reporting mechanisms, both concurrent and retrospective, might improve reporting and ideally result in safer processes.

Some of the challenges in using error-reporting mechanisms are associated with the lack of standard definitions, gaining easy access to databases, and the associated cost of electronic applications.<sup>38</sup> The capability of health care organizations' networks and hardware, the existing policies and reporting processes, including reporting actual errors and near misses, and whether the new system will provide error details to assist quality improvement initiatives must be evaluated.

Patients can also be a source of information for reports about the occurrence of adverse effects associated with medical interventions. In institutional settings, patients can provide information on new symptoms that may not be readily detected by clinician observation or testing. In outpatient settings, it could be argued that when there is no direct communication between patients and their outpatient clinicians, some unplanned emergency department (ED) visits and hospitalizations have been used to determine patients with significant, reportable, and actionable adverse drug reactions (ADRs). Two studies of patients in an outpatient setting found that patients reported more information about ADRs, the majority of which did not warrant an ED visit or hospitalization, when specifically asked, providing clinicians the opportunity to make changes in the patient's medication therapy. Without the patient's report of an ADR, clinicians would not know about the majority of ADRs affecting patients.<sup>39, 40</sup>

## **Voluntary Versus Mandatory Reporting**

The IOM differentiated between mandatory and voluntary reporting of health care errors.<sup>41</sup> Voluntary reports may encourage practitioners to report near misses and errors, thus producing

important information that might reduce future errors. However, there is concern that with voluntary reporting, the true error frequency may be many times greater than what is actually reported.<sup>42</sup> Both of these types of reporting programs can be Web-based and nationally representative. Mandatory and voluntary reporting systems differ in relation to the details required in the information that is reported.

Mandatory reporting systems, usually enacted under State law, generally require reporting of sentinel events, such as specific errors, adverse events causing patient harm, and unanticipated outcomes (e.g., serious patient injury or death). It is estimated that less than half the States have some form of mandatory reporting system for adverse events—a number that is expected to grow in the next few years. One such State-mandated system is created by Pennsylvania's Medical Care Availability and Reduction of Error (MCARE) Act of 2002 (on the Web at [www.mcare.state.pa.us/mclf/lib/mclf/hb1802.pdf](http://www.mcare.state.pa.us/mclf/lib/mclf/hb1802.pdf)). Another example is the New York Patient Occurrence Reporting and Tracking System (NYPORTS), a Web-based, external, confidential, mandatory reporting system that has been in existence since 1998. The focus of NYPORTS is on serious complications of acute disease, tests, and treatments. The system has 9 occurrence categories (aspiration, embolic, burns/falls, intravascular catheter related, laparoscopic, medication errors, perioperative/periprocedural, procedure related, and other statutory events) and 54 specific event codes.<sup>43, 44</sup>

Sentinel events, such as serious medication errors resulting in deaths, are incidents that can be voluntarily submitted to the Joint Commission in accordance with their Sentinel Event Policy (accessible at [www.jointcommission.org/SentinelEvents/PolicyandProcedures](http://www.jointcommission.org/SentinelEvents/PolicyandProcedures)), which is based on root-cause analyses. Root-cause analysis is a systematic investigation of the reported event to discover the underlying causes. The Joint Commission's position on mandatory reporting is that providers who are forced to report errors may not describe the details of the event, since they are motivated by a requirement. Nationally, the Joint Commission's Sentinel Alerts provide electronic access to selected sentinel events, identify common underlying causes, and recommend steps to prevent future events. The alerts provide clinicians the opportunity to learn about root causes of errors. Sentinel event statistics are available for clinicians to note error trends and root causes.

An example of voluntary external reporting mechanisms, specifically a Web-based, anonymous/confidential system, is the Medication Errors Reporting Program (MERP) of the United States Pharmacopoeia and the Institute for Safe Medication Practices (assessable at [www.usp.org/hqi/patientSafety/mer](http://www.usp.org/hqi/patientSafety/mer)). Reported errors make up the MEDMARX<sup>®</sup> database, which subscribing hospitals and health care systems can use as part of their quality improvement initiatives. Employees of subscriber organizations enter, review, and release data to a central data repository that is then available for all subscribers to search. Comparisons can be made within institutions of a single health care system and across participating health care systems. The sharing of data allows medication error types, locations in agencies, level of staff involved, products, and facts contributing to errors to be known and serves to alert clinicians to safety hazards. Actual, intercepted, and potential errors are all included. MEDMARX<sup>®</sup> examines the medication use process, systems, and technologies rather than individual blame and emphasizes the Joint Commission's framework for root-cause analysis.

## **Barriers to Error Reporting**

Many errors go unreported by health care workers.<sup>45</sup> The major concern they have is that self-reporting will result in repercussions.<sup>46-48</sup> Providers' emotional responses to errors inhibit reporting, yet some are relieved when they share the events of the error with patients.<sup>49</sup> Health care professionals report feeling worried, guilty, and depressed following serious errors, as well as being concerned for patient safety and fearful of disciplinary actions. They also are aware of their direct responsibility for errors.<sup>16, 50</sup> Many nurses accept responsibility and blame themselves for serious-outcome errors.<sup>51</sup> Similarly, physicians responded to memorable mistakes with self-doubt, self-blame, and shame.<sup>52</sup> The need of clinicians for support may be fulfilled by discussing their mistake with another person. However, many received support most often from spouses rather than colleagues. Instead of bearing the pain of mistakes in silence, clinicians should admit them, share them with peers, and dispel the myth of perfect practice. However, this support might keep disclosure within the disciplinary culture and practice of medicine rather than bringing mistakes to multidisciplinary teams.

Self-reporting errors can be thwarted by several factors. First, clinicians fear career-threatening disciplinary actions and possible malpractice litigation and liability.<sup>22, 24, 53, 54</sup> Health care leaders who do not protect reporters of errors from negative consequences reinforce this fear,<sup>8, 55</sup> as does the criminalization of fatal health care mistakes.<sup>56, 57</sup> Fear of these negative consequences can lead to reporting errors only when a patient is harmed or when the error could not be "covered up";<sup>58</sup> yet more health care providers are vulnerable to legal action if detailed error reports are documented for events that could formerly be concealed.<sup>27, 28</sup> Additionally, the moral residue of previous mistakes may also restrict disclosure of errors.<sup>59</sup> This residue could be replaced in providers' memories by efforts encouraging reporting in a nonpunitive milieu<sup>60</sup> and incorporating the systems improvements that follow. Clinicians do not want to intentionally harm patients; yet when they conceal errors, they place patients at increased risk of some type of harm.

Second, clinicians working in a culture of blame and punishment do not report all errors, primarily because they fear punishment. A long-held tradition in health care is the "name you, blame you, shame you"<sup>61</sup> mantra. Many organizations have been challenged to provide an environment in which it is safe to admit errors and understand why the errors occurred.<sup>41</sup> Fears of reprisal and punishment have led to a norm of silence. But silence kills, and health care professionals need to have conversations about their concerns at work, including errors and dangerous behavior of coworkers.<sup>62</sup> Among health care providers, especially nurses, individual blame has been the predominant reaction for errors.<sup>63</sup> When individuals and organizations are able to move from individual blame toward a culture of safety, where the blame and shame of errors is eliminated and reporting is rewarded, organizations are enabled to institutionalize reporting systems and increase reporting of all types of errors.<sup>64, 65</sup> To do so, clinicians and others must know that safety can be improved by nonpunitive reporting of error and that organizational flaws cause errors.<sup>1</sup> As communication, collaboration, and safety are inextricably linked in the pursuit of quality care, risk managers, safety officers, and other leaders in health care institutions are encouraging the development of a culture of safety. In a culture of safety, open communication facilitates reporting and disclosure among stakeholders and is considered the norm.<sup>20</sup> Yet even in organizations with a culture of safety, creating a nonpunitive environment is a work in progress.<sup>66</sup>

Third, there is significant variation in how errors are defined, what information is reported, and who should be involved in reporting and mitigating the effects of errors. Differing definitions of errors and near misses and significant differences in reporting—among health care providers working in the same institution and across health care systems—make it difficult to act and prevent similar errors. One of the greatest challenges confronting the patient safety movement is agreeing on standard definitions of what constitutes errors.<sup>67</sup> Reporting near misses can facilitate a blame-free approach (a hallmark of a culture of safety) and fewer cultural and psychological barriers. Yet, clinicians who believe that an error or near miss was unimportant or caused no harm, especially if intercepted, might decide that a report of a near miss is not warranted,<sup>68–70</sup> near misses are not frequently reported.<sup>71</sup>

Lastly, error reports are difficult to complete, and feedback about needed system changes to improve safety is not commonly given.<sup>55</sup> The lack of standardization in the information that is reported and collected makes comparisons and trending as well as preventing future errors difficult. Implementing and using standardized reports of error events, such as those available in hospital databases, is just one example of an open communication strategy, benefiting both clinicians and ultimately the patients they serve.<sup>72</sup> However, the process for reviewing events is not consistently applied nor conducted in matter conducive to providing feedback and improving safety.<sup>73</sup>

These and other barriers to reporting and disclosing errors must be breached to accomplish safer health care.<sup>25</sup> Reporting errors and near misses through established systems provides opportunities to prevent future similar, and perhaps even more serious, errors. Failure to report and speak up about errors and near misses is unacceptable because the welfare of patients is at stake. Investigations into the reporting behaviors of clinicians have found that clinicians are more likely to report an error if the patient was not harmed.<sup>74</sup> Clinicians would also be likely to report an error made by a colleague regardless of patient harm.<sup>74</sup>

Several factors are necessary to increase error reporting: having leadership committed to patient safety; eliminating a punitive culture and institutionalizing a culture of safety; increasing reporting of near misses; providing timely feedback and followup actions and improvements to avert future errors; and having a multidisciplinary approach to reporting.<sup>64, 65</sup> Only through reporting errors can nurses and other health care providers learn which system design and operational failures contribute to human fallibilities and subsequently improve the quality of care. Additionally, one study found that physicians, pharmacists, advanced practitioners, and nurses considered the following to be modifiable barriers to reporting: lack of error reporting system or forms, lack of information on how to report an error, and lack of feedback to the reporter.<sup>75</sup>

## **Error Disclosure**

Disclosure of health care errors is not only another type of error reporting, it is also an account of a mistake. It involves an admission that a mistake was made and typically, but not exclusively, refers to a provider telling a patient about mistakes or unanticipated outcomes. Disclosure addresses the needs of the recipient of care (including patients and family members) and is often delivered by attending physicians and chief nurse executives. However, while physicians' willingness to disclose errors may be stimulated by accountability, honesty, trust, and reducing risk of malpractice, physicians may hesitate to disclose because of professional repercussions, humiliation, guilt, and lack of anonymity.<sup>76</sup>

Disclosure also sometimes calls for a formal verbal apology, in some institutions presented in writing by patient safety officers. Often the providers involved in the error apologize. The central element of disclosure is the trust relationship between patients (or residents of long-term care facilities) and health care providers. Agency policies specify the disclosure approach and identify the person—for example, the primary care provider or safety officer—who communicates the error, adverse event, or unanticipated outcome to the patient or resident, or family member. Some institutions make error disclosure mandatory, and some disclose errors on a voluntary basis.

Providers were concerned about disclosure. They felt shame and fear about their mistakes. “Medical missteps” were transformed into clinical mistakes after practice standards were developed; next, malpractice suits followed. As a result, mistakes were subsequently hidden, creating a negative cycle of events.<sup>72</sup> Furthermore, physicians’ anxiety about malpractice litigation and liability and their defensive behavior toward patients have blocked individual and group strategies for preventing and reducing medical errors, thus hindering error reduction attempts.<sup>22</sup> Hiding errors at times resulted in providers being involved in litigation. The association between hiding errors and reducing costs seemed less certain than formerly believed.<sup>29</sup>

When patients’ concerns are not addressed, they are more unwilling to return for future care needs<sup>77</sup> and follow medical advice, and are more likely to seek malpractice lawsuits.<sup>78–80</sup> Several surveys of patients and the general public have found that they believe health care to be only moderately safe and that they are concerned about errors affecting them if they seek care in hospitals.<sup>54, 81–84</sup> Specifically, patients are concerned about misdiagnoses, physician errors,<sup>85</sup> medication errors, nursing errors,<sup>77, 85</sup> wrong test/procedure errors,<sup>85</sup> and problems with medical equipment.<sup>77</sup>

Another dimension of reporting and disclosing errors is the role patients can have. Patients can understand, perceive the risk of, and are concerned about health care errors. As more is learned about errors, patients and clinicians have opportunities to improve health care quality. Patients want full disclosure<sup>86</sup> and to know everything about medical errors that impact them. Disclosure can avert patients seeking another physician and can improve patient satisfaction, trust, and positive emotional response to an error, as well as decrease the likelihood of patients seeking legal advice following the error.<sup>87</sup> Patients have the right to know; patients and the public strongly desire disclosure.<sup>86, 87</sup> Failure to disclose mistakes and unanticipated outcomes limits opportunities for evaluation of systems and processes, and for sharing knowledge gained by publishing safety alerts across organizations, conducting educational sessions, modifying practice, and offering opportunities for improved performance.<sup>88</sup> Disclosure is also an element that contributes to the creation of a culture of safety<sup>89</sup> and as such must be accepted as a strategy in health care institutions interested in becoming high-reliability organizations, “those in which error seldom occurs even in dangerous environments”<sup>90</sup> (p. 121).

A significant barrier to disclosing errors is the clinicians’ willingness to do so. This may in part be due to the lack of clarity as to exactly what should be disclosed, when the discussion should take place, and who (e.g., a hospital administrator, physician, or nurse) should disclose the error. When it comes to what should be disclosed, research has found that physicians and nurses want to disclose only what had happened,<sup>81</sup> but there are no universal rules for doing so.<sup>86</sup> Decisions to disclose or not to disclose are complex and depend on how errors are defined and if they are recognized or detected. Health care providers are heavily influenced by their perceived

professional responsibility, fears, and training, while patients are influenced by their desire for information, their level of health care sophistication, and their rapport with their provider.<sup>91</sup>

Both health care providers and patients seem to agree that errors disclosure should take place when patients are harmed and that corrective action should involve systems improvement.<sup>91</sup> Other research has found that the likelihood of disclosure increased for physicians, nurses, and emergency medical technicians (EMTs) as the severity of the error increased.<sup>92</sup> Somewhat conflicting with this is the assertion that patients would suffer additional harm when “unnecessary” information was shared about a mistake.<sup>30</sup> Unfortunately, this line of reasoning has its roots in the dubious contention that patients might be more harmed when told the truth as compared with disclosing the mistake.

Physicians have argued that they should be responsible for disclosing errors to the patient.<sup>93</sup> This is borne out in some research that has shown that in practice, at least among emergency care providers, nurses were less likely (23 percent to 54 percent) to disclose an error than were physicians (71 percent to 74 percent).<sup>92, 94</sup>

Because there are instances when error disclosure has been followed by the “victims” seeking further action, the disclosure of errors in practice may not reflect all errors that have harmed patients,<sup>95-97</sup> nor all those that could or should have been disclosed. In many instances, patients may be less likely to seek legal action if the error is disclosed by the physician<sup>82, 83</sup> and if they do not suspect a cover-up.<sup>78</sup> However, it is not known if there is a causal relationship between disclosure of errors and adverse consequences such as litigation.<sup>87</sup>

**Disclosure policies.** Written policies on disclosing health care mistakes stand to benefit institutions because they can reduce idiosyncratic responses of reporters.<sup>19</sup> Specific policies and systems of error disclosure are preferred over position statements.<sup>98, 99</sup> This is because policies stipulate health care personnel to be notified, patient care to be given following the mistake, and the content of the disclosure notification. Plans to care for the patient are also included. “True informed consent can only be as a result of discussion between a patient and physician”<sup>19</sup> (p. 155). Such a policy fits within a systemwide approach to quality and safety. Underreporting may be addressed by a standardized patient safety event form, integration of databases for event reporting, ongoing education to reinforce the need for providers to report, and patient and family involvement in care delivery processes.<sup>100</sup>

A disclosure policy implemented by the Veterans Affairs (VA) Medical Center in Lexington, Kentucky,<sup>91</sup> resulted in liability payments that were more moderate than such payments at similar facilities. The policy required disclosure to patients of unanticipated outcomes (accidents or medical negligence).<sup>101</sup> This developing, national VA initiative continued its focus on research and policy related to health care error, error-reporting systems and analysis, and feedback methods. Improving systems of care was the target of the ongoing initiative.<sup>102</sup> The VA’s disclosure policy included reporting details of incidents, expressing institutional regret, and identifying corrective actions. Comparable liability payments resulted when contrasted with other VA hospitals. Another solution instituted was the granting of a waiver for practitioners who reported errors. Many voluntary adverse event/health care error-reporting systems created for acute care hospitals have built on the VA reporting system.<sup>44</sup> Nonetheless, many health care organizations may not disclose errors to patients,<sup>53</sup> although virtually all have traditionally reported errors through paper incident reports that remained internal and confidential. Error-communication strategies are changing, since several States have mandated that health care institutions notify patients about unanticipated outcomes.<sup>103</sup>

Policies can be supported by advisories, which have historically relied on relatively few contributions from patients. Patients' responses to drafts of advisories were explored best with Medicare beneficiaries.<sup>104</sup> While not specifying advisory content on disclosure of health care errors, recommendations included the involvement of patients and providers. Discussions on patient roles in safety enhancement and the development of protocols for inclusion in safety advisories were encouraged.

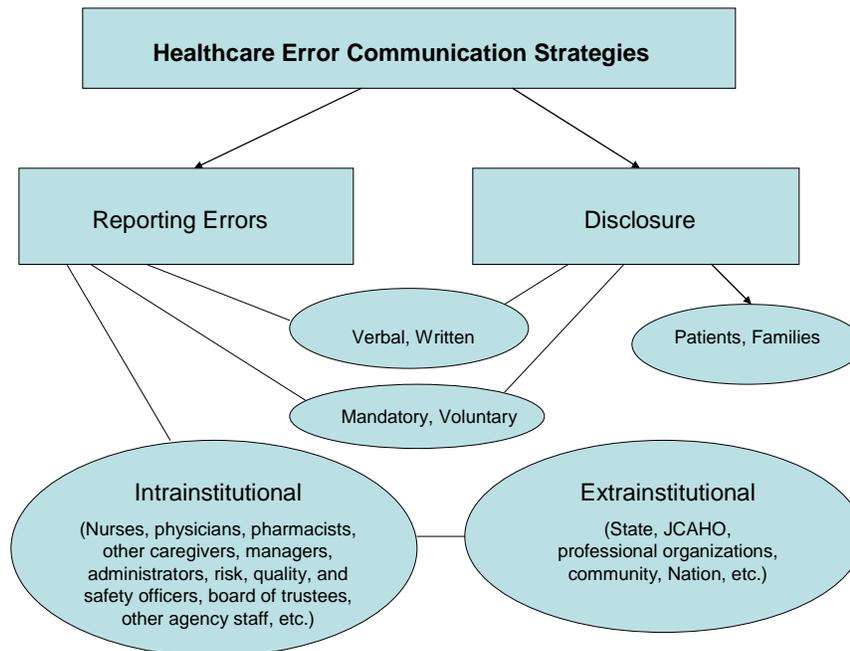
The development and implementation of disclosure policies should be part of an organization-wide effort predicated on cultural change that includes open communication, truth telling, and no blame.<sup>20, 60</sup> Debate regarding the assignment of blame has not negated the importance of counseling some clinicians when policies are intentionally violated—or prosecuted in the case of criminal behavior. Policies on disclosure, including apologies to patients and families, have been justified; respect for patients and their autonomy prevails as a source and support of patients' right to information about health care errors. The aforementioned changes for disclosure policies—for example, open communication, truth telling, and no blame—apply to error-reporting systems as well.

**Differences between reporting and disclosure.** It is important to place health care error-communication strategies, specifically definitions of reporting and disclosure, in context (see Figure 1). The process of reporting errors is sometimes referred to as disclosure of errors, causing confusion. A report of a health care error is defined as an account of the mistake that conveys details of the occurrences, at times implicating health care providers, patients, or family members in error events. Both clinicians and patients can detect and report errors.<sup>105</sup> Each report of a health care error can be communicated through established and informal systems existing in health care agencies (internal) and outside organizations (external), and may be written (e.g., electronic or paper) or verbal, voluntary or mandatory (policy driven). The core value supporting reporting is nonmaleficence, do no harm, or preventing the recurrence of errors.

An error report may be transmitted internally to health care agency administrators, managers, physicians, nurses, pharmacists, laboratory technicians, other caregivers, and agency legal counsel. Reporting is often directly related to risk management activities intended to prevent actual or potential threats of harm. Intrainstitutional or internal reporting examples are incident reports, nurses' notes, safety committee reports, patient care rounds, and change-of-shift reports. Intrainstitutional reports have increased since the initial IOM report and the elimination of the culture of blame in many health care agencies. Of these, the most common means of reporting serious errors for nurses has been through incident reports, a mechanism that has been criticized as being subjective and ineffective in improving patient safety.<sup>106, 107</sup>

Extrainstitutional or external reporting systems include accounts submitted to agencies such as the Medical Event Reporting System for Transfusion Medicine (MERS-TM), MERP, the Joint Commission, and various State departments of health, as well databases such as United States Pharmacopeia's MEDMARX<sup>®</sup> Reporting System (U.S. Pharmacopeial Convention 2006), as illustrated in Figure 1. Additional reporting methods have been called for, such as databases that allow for analysis and communication of alerts to key stakeholders in single agencies and across systems.

Figure 1. Health Care Error-Communication Strategies



Reporting (providing accounts of mistakes) and disclosing (sharing with patients and significant others) actual errors and near misses provide opportunities to reduce the effects of errors and prevent the likelihood of future errors by, in effect, warning others about the potential risk of harm. Reporting reduces the number of future errors, diminishing personal suffering<sup>108</sup> and decreasing financial costs. In contrast, disclosure is thought to benefit patients and providers by supplying them with immediate answers about errors and reducing lengthy litigation.<sup>109</sup> Although clinicians and health care managers and administrators feel uncomfortable with disclosure, disclosure is a duty.

## Error Reporting and Detecting Strategies

Several strategies have been used to improve error reporting. In a literature review of incident-reporting research published between 1990 and 2000, the effectiveness of chart reviews, computer monitoring, and voluntary reporting were compared. The investigators found that the most adverse drug events were identified through chart reviews; the least effective method was voluntary reporting. The most efficient method of understanding errors was computer-based monitoring because more adverse drug events were found than with voluntary reporting and it took less time than chart reviews.<sup>110</sup>

A strategy tested in another project, developed within a hospital, used an electronic, anonymous paper report to increase close call (i.e., near miss) incident reporting. Close call categories included blood/transfusions, diagnostic tests/procedures, falls, medications, other treatments, surgery, and therapeutic procedures. The final template included five main screens and was received very positively by providers. A clinical analyst assisted in communicating feedback and describing the etiology of close call situations, and urgent close calls were rapidly

communicated. The investigators found that improved reporting systems may encourage providers to report near misses. Once identified and shared with front-line providers, errors may be prevented.<sup>111</sup>

Several Web-based systems have also been used in hospitals to improve error reporting. One study investigated reported errors, intercepted errors, and data quality after a Web-based software application was introduced for medication error event internal reporting. The reporting system generated occurrence reports, documented anonymously submitted reports, and allowed for the possibility of real-time reporting and more rapid investigation of contributing factors. The investigators found that error reports increased as well as intercepted error threats (near misses), and intercepted nurse, physician, and pharmacist medication errors increased. The details of cause-of-error reporting also increased as did the participation of hospital leadership.<sup>112</sup> In another study, Wu and colleagues<sup>113</sup> described the use of Web-based internal reporting in the intensive care unit setting. The researchers found that analyzing and disseminating error and near miss data, so that providers are alerted to safety risks, could reduce errors. Additionally, patient safety would most likely improve when providers see the benefits of reporting through systems improvements.<sup>113</sup> One other project occurred when leaders at Baylor Medical Center at Grapevine partnered with DoctorQuality to create a Web-based form for reporting errors.<sup>114</sup> At the same time, they implemented strategies to change the culture of the organization, supported by education on the use of the reporting system, incident reporting, communication, and feedback information about errors. Investigators found that event reporting doubled, suggesting that even with increased reporting, the actual number of errors may not be identified. Proactive risk management allowed for timely followup, the percentage of errors submitted increased after implementation, and the average days from event to submission shortened.<sup>115</sup>

Using a voluntary, regional external reporting database and United States Pharmacopeia's MEDMARX<sup>®</sup> database increased medication error reports across critical access hospitals.<sup>116</sup> Most errors reported to the regional database and MEDMARX<sup>®</sup> did not result in harm to patients. However, significant differences existed in severity, phase, and types of error when comparing the two external reporting systems. More error reports from the critical access hospital database (Nebraska Center for Rural Health Research) reached patients than did MEDMARX<sup>®</sup> errors. Increased reporting of potential and near-miss errors by nursing and pharmacy personnel was associated with easily accessible pharmacist availability.

Another strategy to improve awareness of errors is the assessment of medical records to detect errors that were not otherwise reported. Two prospective, cross-sectional studies compared facilitated incident monitoring to retrospective review of patient medical records in hospitals. The first<sup>117</sup> compared medical record review to physician reporting prompts by daily electronic reminders for 3,146 medical patients in an urban teaching hospital. The investigators found that the physician reporting method identified nearly the same number (2.7 percent) of adverse events as did the retrospective medical record review (2.8 percent), but the electronic reminders detected more preventable adverse events (62.5 percent vs. 32.9 percent), was less costly than the record review (\$15,000 vs. \$54,000), and could be integrated in the daily routine through electronic health information technology. The second, smaller study<sup>118</sup> compared facilitated discussions to medical record review in one 12-bed intensive care unit (ICU) with 164 patients in an Australian hospital with an established incident reporting system. The investigators found that facilitated discussions, in addition to the incident reporting system, identified more preventable incidents than retrospective medical record review and was not as resource intensive

as medical record reviews (50 hours vs. 65 hours). However, medical record review detected some incidents not captured by the incident reporting system.

## Research Evidence

Over the past 11 years, research on the reporting of errors among nurses targeted four key areas: (1) description of who reports errors and what errors are and perceived to be reported; (2) barriers to error reporting; (3) disclosure preferences; and (4) reporting systems and frameworks, including the development of effective reporting systems. The researchers used different methods to assess reporting preferences and what was reported, including surveys, retrospectively assessed error reports,<sup>116, 119–128</sup> a 2-week journal,<sup>129</sup> error scenarios,<sup>81, 92, 130</sup> and focus groups.<sup>91, 131, 132</sup> One study used a mixture of methods.<sup>58</sup> Most of the research included in this analysis involved discussions of reporting involving health care providers using existing systems, while 11 studies assessed the effects of new or revised error-reporting systems.

### Who Is Reporting

Verbal, paper-based, electronic, and Web-based error-reporting mechanisms have been used to capture, record, and communicate errors. Nurses were found to report the majority of errors. The proportion of error report submitted by nurses ranged from 67.1 percent<sup>133</sup> to 93.3 percent.<sup>124</sup> Nurses reported 27 percent more errors than did physicians.<sup>134</sup> Physicians submitted 2 percent<sup>135</sup> to 23.1 percent, and 9.5 percent were submitted by others.<sup>133</sup> Considering the 11 surveys included in this analysis that investigated who submitted error reports, all found that nurses reported the majority of incident reports.<sup>36, 46, 106, 120, 123, 124, 133–137</sup>

Factors that have influenced the submission of error reports included believing it was beneficial to do so<sup>131</sup> and having quality management processes in place.<sup>138</sup> Feeling comfortable reporting, working in a climate of patient-centered care, job satisfaction, and the serious nature of the error enabled error reporting.<sup>131</sup> In terms of characteristics associated with those likely to report errors, nurses with more than 5 years of experience were more likely to believe there was no value in reporting near misses.<sup>106</sup> This contradicts findings from another survey where the frequency of error reporting was found to be higher among nurses with 5 to 10 years of experience.<sup>139</sup> Another finding that complicates this notion is that in one survey, nurse managers reported more errors than did staff nurses,<sup>139</sup> but this could have been associated with organizational structure rather than ability of staff nurses. Additional characteristics were that nurses providing direct patient care were more likely to report,<sup>140</sup> and that pediatric nurses reported medication errors more frequently than adult nurses.<sup>141</sup>

Compared to physicians, nurses seemed to have more knowledge/awareness of the reporting process/system,<sup>106, 132</sup> know what should be reported,<sup>69, 142</sup> know when the error should be reported,<sup>142</sup> be more likely to have submitted an error/incident report, know how to use an incident report form, and know where to submit the report.<sup>106</sup> One survey found that while 98.3 percent of physicians and nurses knew about incident reporting systems within their organizations, nurses were more likely to know how to submit an error report, have experience with submitting an error report, and know where to submit the report.<sup>106</sup> Another survey found that 54 percent of residents and 97 percent of nurses knew about their hospital's error-reporting system, and 13 percent of residents and 72 percent of nurses were likely to use the reporting system.<sup>143</sup> Conversely, another survey found that less than 10 percent of physicians and nurses

were aware of their State's mandatory reporting system, and only a small subset of the ones familiar with the system (less than 50 percent of nurses and 20 percent of physicians) had actually submitted a report using the mandatory system.<sup>144</sup>

Who reported was also be associated with their understanding of what should be reported. One survey of medication administration errors found that nurses acknowledged differences in how reportable errors were defined among staff.<sup>145</sup> Similar findings were found in another survey of nurses in Korea, where nurses were not clear as to what should be reported.<sup>139</sup>

Nurses tended to be more likely to report errors, considering it a professional obligation. One survey of nurses in rural hospitals found that nurses believed they were responsible for reporting errors, getting needed education, recommending changes in policies and procedures to prevent future errors, and participating in investigations of the causes of errors.<sup>58</sup> Another found that physicians believed that nurses were responsible for reporting errors.<sup>144</sup> Similar findings were found using error scenarios, where nurses believed that error reporting was a professional responsibility and that nurses should report the errors made by other nurses if they did not do so themselves.<sup>130</sup> However, another survey found that nurses were more comfortable reporting their own errors than they were of those of colleagues.<sup>146</sup> Another found that 54 percent of residents and 91 percent of nurses believed that they would report their own error or someone else's, and 25 percent of residents and 1 percent of nurses would report the errors of others if they did not like the person who caused the error.<sup>143</sup>

## **What Is Reported**

What is reported could depend upon the understanding of nurses as to what should be reported, which is associated with how reportable errors and near misses are defined. If nurses, nurse managers, and physicians question the value of reporting because they did not see improved patient safety in practice and policies,<sup>132</sup> few errors may be reported. If nurses did not understand the definition of errors and near misses, they were not able to identify or differentiate errors and near misses when they occurred. For example, one very small study gave four error scenarios to 13 perioperative nurses to assess whether they could detect errors and their reporting preferences. The investigators found that 58 percent of the theoretical errors were identified as errors, but only 26.7 percent of them would have been reported.<sup>130</sup> However, when nurses were given definitions of errors and near misses, one study indicated that nurses reported 58 percent of errors and 59 percent of near misses.<sup>129</sup> Among the respondents, 61 percent reported one error and 38 percent reported making between two and five errors during a 2-week period.

The severity of errors and who is doing the reporting influence which errors are reported. One survey found that 58 percent of nurses did not report minor medication errors.<sup>69</sup> Another survey found that while nurses reported 27 percent more errors than physicians, physicians reported more major events and nurses reported more minor events because they had a more "inclusive view." Both physicians and nurses reported near misses.<sup>134</sup> Analysis of error reports in Japan found similar differences in error reporting among different types of clinicians. One study found that nurses and pharmacists submitted more reports of events that were considered minor, while physicians submitted reports when errors were detected and prevented by nurses or pharmacists.<sup>123</sup> The other study of error reports submitted by physicians and nurses in a hospital found that 99.5 percent of the reports—the majority of which were submitted by nurses—were for what were considered minor incidents. Additionally, the lag time for reporting major events

was 18 percent shorter than it was for minor reports, but 75 percent longer when physicians submitted the error report.<sup>124</sup>

Several surveys assessed whether errors that resulted in harm to patients were reported. One survey of physicians and nurses in England found that error reporting was more likely if the error harmed a patient, yet physicians were less likely to report errors than were nurses or midwives. Clinicians were less likely to report errors made by senior colleagues, and physicians in particular were unlikely to report violations of clinical protocols, whereas nurses and midwives would.<sup>46</sup> A review of error reports found that when an error harmed a patient, 34 percent of the reports were submitted by physicians and 27 percent of the reports were submitted by nurses. When errors did not harm patients, 31 percent of the reports were submitted by nurses and 17 percent were submitted by physicians.<sup>133</sup> One survey found that nurses would report errors whether they harmed the patient or not.<sup>140</sup> A survey in Korea found that 67 percent of nurses believed they always reported errors that harmed patients.<sup>139</sup> A very small study found that reporting errors that harmed patients was a secondary concern for nurses; nurses believed that errors that fell outside the scope of the nurse's practice should be reported by the responsible individual (i.e., not the nurse).<sup>130</sup> A related study found that errors resulting in either patient harm or worker injury were underreported.<sup>138</sup> Thus, events that may harm patients are at risk for not being reported.

What is reported may also be associated with whether the reports are confidential or anonymous. Informal reporting mechanisms were used by both nurses and physicians. One survey found that nurses also informally reported to physicians when a dose was withheld or omitted, but they were less likely to formally report the missed dose as an error.<sup>142</sup> Nurses also had a greater tendency to informally report errors to nurse colleagues.<sup>130</sup> Reviewers found that confidential reports were more complete than anonymous ones, but the types of patient harm did not vary between anonymous and confidential reports.<sup>121</sup> Since voluntary reporting depends on health care professionals to report medication errors so that the more realistic frequency and type of errors that happened can be known, several surveys encouraged anonymous responses to identify the barriers to reporting medication administration errors.<sup>58, 69, 142, 147-149</sup> While only brief descriptions of the survey instruments were discussed in each of the studies, the surveys did capture error reports that may not have been communicated or known otherwise.

## **Type of Errors Reported**

An analysis of error reports found that the most serious reports involved rule violations, management practices, and nonstandardized nursing practices.<sup>125</sup> One study found that the majority of error reports involved delays or omissions of medications, diagnostic tests, or necessary/planned procedures; medication errors, and malfunctioning equipment. Ten percent of the reported errors required life-sustaining interventions (61 percent of which resulted from delays/omissions of prescribed nonmedication treatments and necessary planned procedures), and 3 percent might have caused the patient's death.<sup>137</sup>

In a study of surgical ICUs, the type of events reported were related to medications, tests, treatments, or procedures.<sup>136</sup> Researchers in another study found that 47 percent of reported errors were associated with diagnostic tests, 35 percent with medications, and 14 percent with both diagnostic tests and medications. The investigators believed that 71 percent of these errors were associated with communication breakdowns.<sup>121</sup> One study found that nurses generally were more likely to report patient falls than pressure ulcers or near-miss medication errors, and nurses

with fewer than 5 years experience were more likely to report deep vein thrombosis.<sup>106</sup> Another retrospective analysis of error reports in six Japanese hospitals found that reported error rates were high for prevention of problematic behavior, patient suicide, patient falls, and subcutaneous injections of insulin. A high number of error reports in some hospitals were associated with maintenance of dialysis, endoscopy preparation and assistance, administration of preoperative treatments, and blood transfusions. There were more reported errors in the elderly, hemodialysis patients, and those with problematic types of behavior.<sup>125</sup> Another study found that the major types of errors reported were for unsafe conditions or near misses, adverse events that harmed patients, medication/infusion errors, and patient falls.<sup>135</sup> In yet another study, researchers found that the majority of reports involved medication errors, surgical errors, falls, and problems with procedures.<sup>127</sup>

Additionally, the type of errors reported can be associated with characteristics of the patient population. For example, the findings from one survey indicated that medication error rates, which were computed from actual occurrence reports, were higher on pediatric units than adult units.<sup>141</sup> Children's vulnerability to adverse outcomes from medication errors was attributed to weight-based drug dosing, dilution of stock solutions, and immature physiological buffering systems, situations that are unique to children.

## **Estimations and Perceptions of Error Reporting**

Several surveys asked nurses to estimate how many and what types of errors were reported by colleagues and themselves. There was significant variation when nurses were asked to estimate how many errors were reported. Respondents in one survey estimated that an average of 45.6 percent of errors were reported.<sup>142</sup> Nurses may not easily estimate how many errors are reported, as indicated in one study where staff nurses were not consistent estimators of medication administration errors.<sup>145</sup> Another study of medication errors in 29 rural hospitals in nine States found that less than half of nurses believed that all medication errors were reported,<sup>58</sup> while another study found that 44 percent of nurses estimated that 25 percent of medication errors were reported.<sup>69</sup> Another survey found that nurses estimated that less than half of all medication administration errors were reported,<sup>138</sup> an estimate that is lower than those in other surveys.<sup>70, 150-152</sup>

Estimation may also reflect where one works as well as one's experience. In terms of where nurses work, one survey found that nurses working in neonatal ICUs perceived higher reported errors than did those working in medical/surgical units. The mean perceived percentage of reported errors was 46 percent.<sup>142</sup> Another survey found that pediatric nurses estimated that 67 percent of medication errors were reported, while adult nurses estimated 56 percent. The stronger the agreement with management-related and individual/personal reasons for not reporting errors, the lower the estimates of errors reported by pediatric nurses.<sup>141</sup> In terms of experience, one survey found that staff nurses relied on personal experience to estimate medication administration errors on their unit.<sup>145</sup>

Other surveys investigated what nurses thought should be reported. One study divided nurses into high- and low-reporting rates; groups differed by definition of what makes up a reportable error, by personal experience when estimating unit error reporting, and by willingness to share occurrence data with other nurses. Also, nurses were surveyed on the perspectives of types of errors that should be reported, the proportion of errors reported, worker safety, and opinions about the work environment and job satisfaction.<sup>138</sup> Although nurses indicated that all errors

except near misses should be reported, less than half of medication administration errors were reported. Intravenous medication errors were the highest percentage reported events; patient falls were associated with major injuries. Not reporting medication errors was attributed to nurses' concerns about administrative responses and personal fears such as imagining the poor opinion of their coworkers. Sharps injuries, exposure to body fluids, and back injuries threatened nurse safety. Some questioned hospitals' quality management processes.

The perceived rates of error reporting may be associated with organizational characteristics. For example, the perceived rates of medication administration error reporting were compared by organizational cultures of hospitals and extent of applied continuous quality improvement (CQI) philosophy and principles.<sup>151</sup> As bed size increased, perceived rate of medication administration error reporting decreased. Larger hospitals tended to be more hierarchical in nature. Group-oriented hospital culture (norms and values associated with affiliation and trust, flexibility, a people-oriented culture with concerned and supportive leadership) and higher levels of CQI implementation were positively associated with the estimated overall percentage of medication administration errors reported.

## Perceived Barriers to Reporting Medication Errors

There were 15 identified studies that surveyed nurses about their perceptions of what factors (e.g., organizational, process, individual) precluded them from reporting errors. Fourteen of these studies used cross-sectional surveys of nurses,<sup>69, 70, 106, 120, 131, 138, 141, 142, 147–151, 153</sup> and all but one of the surveys<sup>131</sup> were in hospitals. Of the two studies that used focus groups, one interviewed clinicians in 20 community hospitals,<sup>132</sup> the other in ambulatory care settings.<sup>131</sup> Several themes emerged from these studies, as illustrated in Table 1. The types of responses given by nurses may have depended upon the questions asked, but that is not known. In all, research findings seem to indicate that, as Wakefield and colleagues<sup>151</sup> found, the greater the number of barriers, the lower the reporting of errors.

One survey of nurses in the Midwest found that nurses were able to recognize errors and events associated with intentional wrongdoing related to questionable behavior. Nurses were more apt to report serious errors but not unintentional errors.<sup>153</sup>

Other clinicians are concerned about reporting barriers as well. In one survey of physicians and nurses, physicians identified twice as many barriers to reporting than did nurses; both identified time and extra work involved in documenting an error. However, nurses were more concerned about anonymity, "telling" on someone else, fear of lawsuits, and the necessity of reporting errors that did not result in patient harm.<sup>149</sup>

Additional barriers were identified as well. One survey in a State with mandatory reporting found that both physicians (40 percent) and nurses (30 percent) were concerned about the lack of anonymity of reports and that the reports would be used punitively against the individual who submitted the report.<sup>144</sup> Another survey of nurses in Korea found that 32 percent were worried that their errors were kept in files; 66 percent felt that their suggestions to improve patient safety were ignored; 83 percent felt that it was by chance that more errors did not happen; 52 percent believed their units had serious patient safety problems; and 56 percent reported problems talking with physicians.<sup>139</sup>

**Table 1. Reasons why clinicians do not report and disclose errors and near misses**

<b>Reporting Barriers</b>
<b>Fear</b>
Fear <sup>69, 138, 148, 150, 151</sup>
Fear of being blamed for negative patient outcome <sup>70, 147</sup>
Fear other providers will consider provider who made the error incompetent <sup>70, 138, 141, 142, 147</sup>
Fear of reprimand from physician(s) <sup>70, 147, 148</sup>
Fear patients will develop negative attitudes <sup>70, 147</sup>
Fear of legal liability, belief that disclosure of errors to patients results in lawsuits <sup>149</sup>
Fear of “telling” on someone else <sup>149</sup>
Fear of adverse consequences from reporting <sup>70, 141, 147, 148</sup>
Fear of reporting that is not anonymous <sup>149</sup>
<b>Understanding</b>
Confusion over definition of errors and near misses <sup>70</sup>
Disagreement with the organizations’ definition of error <sup>70, 148, 151</sup>
Providers unaware that errors occurred <sup>70, 142, 147</sup>
Providers’ bias about which incidents should be reported <sup>70, 149, 153</sup>
Some incidents, i.e., near misses, thought too trivial/unimportant to report <sup>106</sup>
No perceived benefit <sup>131, 149</sup>
<b>Administrative/Management/Organizational</b>
Administrative response <sup>138, 142, 148, 150, 151</sup>
Lack of feedback on reported errors <sup>70, 120, 147, 148</sup>
Persistence of the culture of blame/shame, blaming the individual <sup>70</sup>
Excessive emphasis on medication error rates as quality measure of care <sup>70, 147</sup>
Poor match of administrative response to errors with severity of errors <sup>70, 148</sup>
<b>Burden of Effort</b> <sup>148</sup>
Incident reports take too long to complete <sup>70, 131, 147, 149, 151</sup>
Verbal reports to physicians take too long or contacting the doctor takes too much time <sup>70</sup>
Providers forget to make a report, too busy <sup>106, 131</sup>
Extra work involved in reporting <sup>149</sup>

Five studies provided additional information about reporting barriers for nurses. In a survey of nurses in Taiwan, nurses did not vary in their concerns about the effects of reporting barriers based on factors such as the age of the nurse, type of education, length of experiences, and length of employment. Yet nurses who perceived more error reporting barriers also believed that errors were over- or underreported, compared to nurses who reported that the error reporting rates were accurate. In this study, factors that could thwart error reporting were positively correlated with the power hierarchy and face-saving concern. On the other hand, the better the work environment, quality management, and relationships with peers, the fewer the perceived barriers for error reporting.<sup>147</sup>

Factors about the organization’s culture may be barriers to error reporting. In one survey of clinicians in rural hospitals, the majority agreed that hospital administrators did not punish error reporters. Most agreed that the hospital culture recognized that mistakes could be made (64 percent) and that error reporting could be done by all employees (86 percent). The majority felt comfortable (65 percent) or somewhat comfortable (32 percent) discussing medical errors, and

have learned and would like to continue to learn from the mistakes of others. Attempts to maintain collegiality and their belief about lacking authority prevented nurses from questioning physicians. Nonphysicians attributed many errors to nursing practices. In fact, if an error occurred, 96 percent of nurses and more than 90 percent of physicians, administrators, and pharmacists would have assigned patient safety responsibility to nurses. Only 22 percent of respondents believed that clinicians and administrators shared equal responsibility for patient safety.<sup>58</sup>

Three studies by Wakefield and colleagues<sup>70, 150, 151</sup> asked nurses about organizational and leadership/management factors that could thwart error reporting. Staff nurses believed that having an organizational culture that did not support error reporting<sup>70</sup> and management practices and beliefs (e.g., supervisors not viewing fear of an administrative response as a barrier to error reporting)<sup>150</sup> thwarted error reporting. Wakefield and colleagues<sup>151</sup> found in another survey that hospital culture types varied; smaller institutions tended to have group-oriented cultures while larger institutions tended to be more hierarchal (which was negatively associated with error reporting). They also found that the extent of CQI implementation increased with bed size of the hospital, and perceived rate of medication administration error reporting decreased. Considered together, the presence of a group-oriented culture and higher levels of CQI implementation were positively but not significantly associated with reporting errors.

One study surveyed physicians and nurses about barriers that could be modified to enable error reporting. The modifiable barriers they identified were the structure and processes for reporting errors and the lack of education about errors. The least modifiable barriers they reported were fear of lawsuits, fear of being blamed, and motivational issues.<sup>149</sup>

## Error-Reporting Strategies

Thirteen studies investigated the effects of new and revised error-reporting systems on error reporting. Investigators examined a clinical pharmacist on units;<sup>119</sup> education, a revised reporting system, and a call center;<sup>120</sup> a voluntary reporting system;<sup>121, 122</sup> a voluntary system for near misses;<sup>154</sup> a voluntary, paper-based reporting system;<sup>133, 136, 137</sup> a confidential, electronic-based reporting system;<sup>135</sup> education enhanced by error report summaries;<sup>115</sup> education of nurse case managers;<sup>126</sup> a Web-based anonymous reporting system;<sup>112</sup> and confidential peer interviews.<sup>36</sup> Only one study assessed the impact of mandatory error reporting.<sup>144</sup>

Three of the studies introduced an “expert” to assist providers in detecting errors. In one, a clinical pharmacist was introduced on units to improve medication safety and increase medication error reporting as well as error reporting generally. Error reports remained relatively constant, yet error reports from physicians decreased. The severity of errors decreased over time, and the reporting of near misses increased from 9 percent to 51 percent.<sup>119</sup> Another study introduced an “expert peer” to prompt assessment of patients, using confidential peer interviews during morning rounds or via e-mail. Verbal reports of errors were confirmed with the patient medical records, but only one incident report was submitted by a house officer for a patient fall. Nurses submitted the majority of incident reports for errors involving patient slips and falls, medication errors, and other events.<sup>36</sup> In the third study, a hospital introduced nurse case managers to review patient medications, detect adverse drug events (ADEs), and report detected ADEs. Once the nurse case managers began reviewing medications and submitting ADE reports, the majority of which were for serious ADEs and possible ADEs, the reports of ADEs nearly doubled.<sup>126</sup>

Researchers in one study provided error reporting education to staff, revised their current reporting system, and introduced a call center. As a result, reporting increased throughout the hospital—more physicians in the emergency department and more nurses in medical units submitted error reports—and there were more anonymous reports compared to the hospital used as a control. More reports were submitted using the one-page form than through the call center. Nurses continued to submit the majority of reports.<sup>120</sup>

One study aimed to improve error reporting through educational initiatives in 10 critical access hospitals. The investigators conducted several education workshops about the nature of errors, the design of safety systems, and best practices in medication safety. Then they collected error reports from all the hospitals and provided quarterly reports from the error reports to each of the hospitals, including the results and averages from the group of hospitals. The investigators found that most of the errors were not harmful and were associated with medication administration, mostly for dose omissions. The reports helped hospitals identify and address systems factors that were conducive to errors.<sup>116</sup>

Five studies tested the effects of new, voluntary error-reporting systems. One study assessed the impact of introducing an error-reporting system in community, primary care research networks. Investigators found that the number of reports increased, but the confidential reports were more complete than the anonymous ones.<sup>121</sup> Another study also found that error reports increased after the introduction of a voluntary reporting system, that nurses submitted the majority of the errors reports, followed by pharmacists, and physicians submitted an error report only if the error was detected and prevented by the nurse.<sup>122</sup> A teaching hospital in New York implemented a new confidential, electronic-based error-reporting system along with an educational program. Investigators found that error reporting increased, but reporting remained low among physicians.<sup>135</sup> Another study assessed the effects of introducing a new Web-based anonymous reporting system. Investigators found that error reports, including those for intercepted errors, increased, and errors attributed to physicians increased while those attributed to nurses and pharmacists decreased.<sup>112</sup> The last of these five studies assessed the impact of using a voluntary reporting that called near misses, “close calls” and frequent feedback reports. The investigators found that after six months, the number of error reports increased by 1,468 percent.<sup>154</sup>

The association between voluntary error reporting and the number of error reports submitted was tested in two prospective, interrelated studies, using paper-based SAFE (Safety, Actions, Focus, Everyone) cards. One tested these cards in the medical ICU,<sup>137</sup> the other in the surgical ICU.<sup>136</sup> The SAFE report card was used over a period of 6 months to document types of events, including errors in tests, treatments, and procedures; medication; equipment; blood products; intravenous complications; behavioral/psychiatric; laboratory; surgery; and falls. This new reporting system resulted in more reported events (232 events) than what was captured by the existing hospitalwide database used to register errors and high-risk events (29 events before and 26 events during the intervention). The investigators believed that the system fostered reporting by unit team members and could reduce events proactively through improved practice.<sup>136</sup> The second study used similar methodology and added an additional step: the cards were withdrawn then reintroduced. The cards were reintroduced once the investigators assessed the significant drop in error reporting. The initial use of the cards increased nurse and physician reporting. After the cards were withdrawn, there was a decrease in reports by both nurses and physicians; instead, there were an increased number of reports submitted to the hospital electronic reporting system by nurses. The investigators found that a higher proportion of events reported by physicians were

for events that resulted in patient harm, whereas the higher proportion for nurses was for events that did not result in patient harm.<sup>136</sup> In both studies, nurses submitted the majority of reports and physician reporting increased.

## **Disclosure Preferences**

Five studies investigated factors associated with disclosure preferences of nurses. Two studies investigated disclosure preferences of patients and clinicians. In one of these studies, which used surveys with error scenarios, patients reported wanting full disclosure of errors, yet physicians and nurses wanted to disclose only what happened.<sup>81</sup> In the other study, which used focus groups, patients and clinicians agreed that errors should be disclosed when the patient was harmed. The degree of harm caused by errors and whether patients and others were aware of errors were related to disclosure preferences. Institutional culture (perceived tolerance for error and supportive infrastructure) was important to the disclosure decision. Relevant patient factors were health care sophistication, desire for information, and rapport with provider. Provider factors included fears of malpractice, reputation, job threat, and change in rapport with the patient, as well as perceived professional responsibility, medical training, lack of confidence in disclosure skills, and personal discomfort.<sup>91</sup>

Three studies used surveys to investigate disclosure preferences of EMTs, physicians, and nurses. In one study that specifically asked only nurses, nurses reported that they were less likely than physicians to want to disclose errors.<sup>81</sup> Another survey found that 74 percent of physicians, 23 percent of nurses, and 19 percent of EMTs had disclosed errors.<sup>95</sup> Physicians were also more likely to disclose (71 percent) an error than were nurses (59 percent), but nurses (68 percent) were more likely to report an error than were physicians (54 percent).<sup>92</sup>

Another survey found that 29 percent of physicians and 64 percent of nurses reported feeling comfortable discussing mistakes. Also, 42 percent of physicians and 44 percent of nurses reported feeling uncomfortable discussing errors with patients.<sup>143</sup>

## **Evidence-Based Practice Implications**

Given the history of error reporting and the role nurses have in patient care, it is important to emphasize that nurses are pivotal in improving patient safety via error reporting. Patient safety will improve when systems effectively assure and improve safety, predicated on a culture in which the reporting of errors or near misses is considered valuable, and positive actions lead to study and change for improvement, not blame.<sup>155</sup> To avert underreporting of errors and to effectively learn from errors, administrators in health care agencies need to develop policies that support the routine reporting of errors, so that increased numbers of reports of actual errors and near misses are rewarded on an individual or unit basis. By easing the transition of an institution to a culture of safety, eliminating blame and the pressure of a punitive environment, error reporting will most likely increase. Additionally, it is evident that caregivers and patients profit from detailed accounts and increased reports, specifically in hospitals that act on unsafe practices identified through analysis of error reports. Systems improvements need to be communicated with all stakeholders so that they benefit from seeing the feedback loop in action.

Ethical principles—including beneficence, fiduciary responsibility, respect for autonomy, justice, and honesty—guide clinical practice and mandate reporting and disclosure.<sup>156</sup> These principles guide safety efforts and must be espoused by administrators and providers. Improved

safety practices begin with policy and procedure development and continue with the allocation of resources for developing reporting systems and databases as well as educating caregivers.

New systems of reporting errors are generally developed in-house or purchased by health care agencies. Electronic systems that are Web-based—that include easy reporting and standard definitions of errors, near misses, and potential root causes as well as personnel responsible for analyzing and sharing safety hazards—provide opportunities for data management and pattern identification of unsafe practices. They also save time for providers as reports are entered into databases and help to shorten the time from incident to report. Developing new systems of reporting requires administrators to budget accordingly so that additional personnel and electronic reporting systems as well as complementary software are financed. Periodic training of personnel and upgrading reporting databases are necessary, as are systems improvements that depend on error-report analysis.

Patients and families desire disclosure of health care errors by health care providers. Providers have an ethical responsibility to disclose. Generally, organizations use verbal reports, followed by written reports offered by patient safety officers, in consultation with agency attorneys, in accord with institutional reporting and disclosure policies. Refusing to disclose suggests fear and a need for provider control rather than patients' and families' need for honesty about their care. Disclosure policies must be created with honesty and respect for patient autonomy in mind; apologies must be required.

The emotional responses and perceptions of caregivers about errors are important barriers to reporting. Providers consider themselves at risk when they report errors because many providers carry the residue from previous experiences with mistakes. Anger from coworkers, shame, lack of confidence, and the like combine with guilt about the suffering of patients and fear of potential litigation to hinder reporting and disclosure. Nurses respond similarly to errors as physicians. They feel vulnerable to disciplinary action and legal repercussions; thus errors go underreported. Providers must experience changes in institutional culture, where systems improvements are targeted rather than individual blame.

Teamwork training improves error reporting and reduces clinical errors. Teamwork principles include increased communication among health care providers. One element of a teamwork training program, cross-monitoring, might result in decreased errors as providers observe each other, identify unsafe behaviors, and act to correct each others' mistakes. Status barriers must be penetrated. Cross-monitoring involves interdisciplinary/caregiver observations, identifying unsafe behaviors, and acting to correct unsafe behaviors. The challenge is how this team training element might be successfully initiated and consistently reinforced in acute care hospitals, critical access hospitals, nursing homes, long-term care facilities, and other agencies. Along these lines, nurse educators are challenged to include teamwork strategies and exercises aimed at increasing safety practices in health care agencies in undergraduate and graduate nursing courses, taking into account content on existing status issues among health care providers.

## **Research Implications**

The majority of the research on error reporting has occurred within the past 10 years. While the studies included in this analysis provide important insight into what is being reported, they were primarily descriptive and none were nonrandomized or randomized controlled trials. Thus, additional well-designed studies are called for. Teamwork training holds promise as an

intervention that might affect frequency and severity of reported errors. Emphasizing cross-monitoring and increased communication as team training strategies might also affect outcomes. Teamwork training could include scenarios that challenge clinicians to determine how and what to report. Multisite team training programs should be investigated. The benefit of team training is in the development of expertise in reporting and disclosure among front-line providers. However, additional research is needed on the effect of team training on error frequency and reporting and disclosure skills, especially among nurses. Examples of research questions might be, Are there differences in patient and family member satisfaction when disclosure of errors is provided by team-trained versus usual-approach health care providers? Does team training affect error and near-miss reporting rates?

Additional studies could be conducted in which disclosure of errors to patients and families is linked to differences in outcomes, for example, claims reports and monetary awards. More research is needed on the impact of Web-based reporting systems on time used for reporting via data entry, time from incident to report, time to systems improvement, as well as a classification of systems improvement strategies and the effect of strategies on error outcomes. Examples of research questions might be, Are there differences in severity scores following errors when Web-based versus incident-report methods of reporting are used by health care providers? Are there differences in frequency of error reports when Web-based versus incident reporting systems are used? Comparisons also might be made between physician and administrator methods of disclosure to patients and families in which simplicity or complexity of disclosure events are examined. Examples of research questions might be, Are there differences in patient and family satisfaction when physician/administrator disclosers are trained using standard, simple script versus unscripted (usual) disclosure communication approaches? Are there differences in the number of liability claims and monetary awards when mandatory versus voluntary disclosure policies are used?

Notable in the reviewed literature was the dearth of studies on reporting and disclosure regarding the variety of adverse events, for example, blood transfusion errors, device malfunctions, health care acquired infections, and others. Most addressed were medication errors. Data are needed across all settings; most research on reporting is hospital-based. Community settings, nursing homes, free-standing short-procedure units, and primary care offices also require additional study regarding error reporting and disclosure. Consequently, there are many research opportunities for nurse investigators. Research is needed describing initial patterns of errors across various settings and focusing on other events, including blood transfusions, surgical incidents, device malfunctions, etc. Comparisons might also be made in liability lawsuit statistics between institutions that have disseminated and acted on the no-blame cultural approach versus those that have initially instituted this approach.

## **Conclusions**

Sustained and collaborative efforts to reduce the occurrence and severity of health care errors are required so that safer, higher quality care results. To improve safety, error-reporting strategies should include identifying errors, admitting mistakes, correcting unsafe conditions, and reporting systems improvements to stakeholders. The greater the number of actual errors and near misses reported, the more reliable a health care organization or system could be, from a safety viewpoint, when systems improvements are consistent with error patterns.

Clinicians appreciate seeing the results of the reports they submitted transformed into systems improvements. Understanding and communicating the root causes of errors and near misses can decrease the risk of future errors, and support the concept that health care errors are often systemic and multifactorial. Reporting errors and near misses may increase through voluntary reporting systems, because voluntary systems provide additional evidence that the blame/shame patterns are being eliminated in health care organizations and systems.

Electronic error-reporting systems can possibly make the time required to report shorter, shorten the time for correcting unsafe conditions, and alert providers to emerging unsafe patterns. Some systems can also facilitate quality improvement initiatives through enhanced error-reporting systems. The benefits of Web-based health care reporting systems that clinicians find easy to use and see the effects of their reporting in changes to systems might ultimately reduce the incidence of serious errors, and significantly improve the safety and quality of health care afforded patients.

## **Search Strategy**

Various databases were searched to locate studies and related literature on reporting and disclosing health care errors, including CINAHL<sup>®</sup>, PubMed<sup>®</sup>, and Psycharticles. Search terms included “medical errors” and “medical error reports.” Published results in a non-English language, expert opinions, case reports, and letters were excluded. Studies specifically assessing rates, types, and causes of reported medication administration errors were excluded as well. To be included in the analysis, each article had to involve nursing and report findings specific to nurses. Most of the articles identified in the literature search were primarily descriptive.

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**Evidence Table. Error Reporting and Disclosure**

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Balas 2004 <sup>129</sup>	Error reporting Reporting near errors	Cross-sectional study	Qualitative, voluntary, anonymous, self-reported recording of 14-days of shift work, sleep, and errors using a journal (Level 4)	119 full-time hospital registered nurses (RNs). Note: subset of the larger study with 393 full-time RNs described in other articles.	None	58% of reported errors and 59% of near misses were medication related. 73 nurses reported 1 error, while 45 reported making between 2 and 5 errors during the study period.
Blegen 2004 <sup>138</sup>	Barriers to reporting medication administration errors (MAEs) and near misses	Cross-sectional study	Survey, including falls and MAEs, near misses, staff injury, and reporting barriers (Level 4)	1,105 RN respondents in 25 acute care hospitals nationally	None	Reporting rates varied, with 47% errors reported overall; intravenous MAEs highest rate overall. Reporting inhibited by fear of being blamed, peer reactions, patients becoming negative, reprimands by physicians, losing license, and public reporting. Reporting of MAEs was higher in units with quality management processes. Errors resulting in patient and staff injuries were underreported.
Chiang 2006 <sup>147</sup>	Barriers to error reporting	Cross-sectional study	Self-administered survey of barriers to reporting MAEs (Level 4)	597 nurses in 1 hospital in Taiwan	None	Fear was the main barrier to reporting MAEs, significantly associated with organizational power hierarchy and face-saving concerns.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Cook 2004 <sup>58</sup>	Responsibility for errors Defining medical errors	Cross-sectional study	Assessed hospital data and administered the "Close Call Pilot Culture Assessment," error reports, staff patient safety instrument, e-mailed questionnaires, staff patient-safety survey, case studies, and telephone interviews (Level 4)	485 clinicians (305 nurses, 49 physicians, and others) in 29 hospitals in 9 States	None	<p>Majority agreed that hospital administrators did not punish error reporters. Staff have learned and would like to continue to learn from mistakes of others. Most agreed that the hospital culture recognized that mistakes could be made (64%) and that error reporting could be done by all employees (86%). Majority felt comfortable (65%) or somewhat comfortable (32%) discussing medical errors.</p> <p>Attempts to maintain collegiality and their belief about lacking authority prevented nurses from questioning physicians. Pharmacists were more confident in their ability to recognize errors.</p> <p>Nurses reported most frequent problem was unclear or confusing patient orders. Nonphysicians attributed many errors to nursing practices.</p> <p>96% of nurses and more than 90% of physicians, administrators, and pharmacists assigned patient safety responsibility to nurses. 22% of respondents believed that clinicians and administrators shared equal responsibility for patient safety.</p> <p>Nurses reported that they were responsible for reporting errors (99%), educating themselves (98%), recommending changes in procedures (88%) and policy (86%), reviewing reported events (79%), and participating in investigations of errors (72%). However fewer than half had participated in investigating, reviewing, or analyzing errors.</p>

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Costello 2007 <sup>119</sup>	Error reporting	Pretest and post-test	Retrospectively assessed error reports, then again assessed error reports after several interventions (Level 4)	Physicians and nurses in a pediatric critical care center	Introduction of clinical pharmacists to raise awareness of medication safety and encourage reporting of all errors	Medication error reporting increased overall, but reports from nurses remained relatively constant and the reports from physicians decreased. The pharmacist did not change the error reporting culture.
Day 2004 <sup>134</sup>	Reporting adverse events	Cross-sectional study	Administered a retrospective questionnaire about experience in reporting errors (Level 4)	32 physicians, 175 nurses, and 44 others (a 43% response rate) in 1 hospital in Utah	None	Physicians and nurses reported similar reporting experiences, but nurses reported 27% more. 34% of ICU staff reported errors. Physicians reported more major events while nurses reported more minor events; nurses had a more "inclusive view." Physicians and nurses reported more near misses. 47% reported time and 27% reported fear of punitive actions as the major barriers to reporting.
Elder 2007 <sup>131</sup>	Barriers to error reporting Reasons to report errors	Cross-sectional study	Conducted focus groups on errors related to testing, issues involved in error reporting, and the effects of error reporting on office systems (Level 4)	Physicians, nurse practitioners, physician assistants, office staff, and nurses in 8 family physicians offices	None	Majority of reporting barriers were a lack of time, forgetfulness, and confusion about what to and who should report. Most common reported reason for reporting errors was a perceived benefit.
Espin 2006 <sup>81</sup>	Error disclosure and reporting	Cross-sectional study	Questionnaire using 4 scenarios	9 surgeons, 9 nurses, 10 anesthesiologists in operating rooms at 2 teaching hospitals	None	Patients want full disclosure, while physicians and nurses want to disclose only what happened. Nurses (the only clinician type asked) were less likely to want to report errors than patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Espin 2007 <sup>130</sup>	Error reporting	Cross-sectional study	Administered 4 error scenarios to nurses	13 perioperative nurses at 1 hospital in Canada	None	58% of theoretical errors were identified as errors, only 26.7% of which would have been reported by the nurses. Nurses perceived error reporting as a profession-specific responsibility; nurses should report errors made by nurses. The presence of a negative outcome appeared to be a secondary consideration for nurse error reporting. Nurses had a greater tendency to report errors informally with a nurse colleague or nurse manager.
Evans 2006 <sup>106</sup>	Barriers to error reporting	Cross-sectional study	Anonymous survey of physicians and nurses about their knowledge of their organizations' reporting system, how often they reported errors, and reasons why errors were not reported (Level 4)	70.7 response rate for physicians and 73.6% for nurses in hospitals in southern Australia	None	98.3% of physicians and nurses were aware of the incident reporting system. Nurses were more likely to know how to submit an error report (88.3%), to have completed an error report (89.2%), and to know where to submit an error report (81.9%).
Evans 2007 <sup>120</sup>	Error reporting	Nonrandomized trial	Comparison of incident reporting rates between 1 control and 1 intervention hospital (Level 3)	2 hospitals in Australia	Educational intervention was combined with a revised reporting system, with an option for a call center.	Reporting increased throughout the hospitals. More reports were initiated by physicians in EDs and were anonymous. Nurses generated 84% of error reports.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Fein 2005 <sup>91</sup>	Error disclosure	Case control study	Focus group interviews, on ethical perceptions and details of error disclosure (Level 4)	Hospital personnel and former patients (n = 240), 25 focus groups: separate stakeholder groups of attending physicians, residents, nurses, administrators, former patients	None	All agreed that errors should be disclosed when patients are harmed. Degree of harm caused by error and whether patients and others were aware of errors were characteristics related to disclosure. Institutional culture (perceived tolerance for error and supportive infrastructure) was important to disclosure decision. Patient factors were health care sophistication, desire for information, and rapport with provider. Provider factors included fears of malpractice, reputation, job threat, and change in rapport with the patient, as well as perceived professional responsibility, medical training, lack of confidence in disclosure skills, and personal discomfort.
Fernald 2004 <sup>121</sup>	Error reporting in ambulatory settings	Cross-sectional study	Collected and analyzed error reports from clinicians and staff, using a voluntary reporting system (Level 4)	2 practice-based research networks	Implemented a voluntary reporting system	47% of reported errors were associated with diagnostic tests, 35.4% with medications, and 13.6% with both medication and a diagnostic test; 70.8% of error reports were associated with communication errors. Confidential reports were more complete than anonymous reports. Reporting different types of patient harm did not vary between anonymous and confidential reports.
France 2003 <sup>122</sup>	Reporting system	Quality improvement	Assessed utilization of a voluntary reporting system and provider-initiated improvements (Level 4)	1 hospital in Tennessee	Implemented a voluntary reporting system	Nurse reporting significantly decreased after implementation, while pharmacy reporting significantly increased.
Furukawa 2003 <sup>123</sup>	Reporting medication errors	Cross-sectional study	Errors reported using a Web-based system during a 2-year period (Level 4)	Physicians, nurses, pharmacists, technologists, and others in 1 hospital in Japan	None	Nurses reported 78% of errors, an average of 2.2 reports per nurse. The majority of error reports submitted by nurses and pharmacists were considered minor. Physicians were found to report errors only when detected and prevented by nurses or pharmacists.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Harper 2005 <sup>144</sup>	Barriers to error reporting	Cross-sectional study	Self-report survey (Reporting Culture Survey) on mandatory reporting system in hospitals transitioning to close-call reporting system: scaled and open-ended items (Level 4)	858 nurses and physicians (a 41% response rate) at 2 hospitals in Texas	None	Less than 10% of respondents had knowledge of the mandatory reporting system, but less than half of nurses and 20% of physicians reported using the system. Physicians and nurses were not positive about the effectiveness of a hospital-based reporting system. Physicians reported that nurses were responsible for reporting errors. 40% of physicians and 30% of nurses were concerned about the anonymity of reporters, yet 86% of nurses and 81% of physicians favored feedback on corrective action taken in response to the report. 40% of physicians and 30% of nurses were concerned that the reporting system would be used punitively.
Harris 2007 <sup>133</sup>	Error reporting	Prospective cohort study	Assessment of error reports once a new reporting system had been put in place (Level 4)	3 ICUs in a 1,371-bed urban teaching hospital	A new, card-based reporting program to encourage anonymous reporting of errors	Nurses submitted 67.1% of error reports, followed by 23.1% by physicians and 9.5% by other reporters. Of the reports where errors did not reach the patient, 31.1% were from nurses, 36.2% from other staff, and 17% from physicians. Of the reports where errors harmed patients, 33.9% were from physicians, 27.2% from nurses, and 13% from other staff.
Hirose 2007 <sup>124</sup>	Error reporting	Cross-sectional study	Evaluation of lag time of submission of 6,880 reports filed by nurses and physicians during a 3-year period (Level 3)	Reports submitted by nurses and physicians in 1 hospital in central Japan	None	Nurses filed 93.3% of the reports, 99.5% of which were categorized as minor incidents. Physicians submitted 32 reports (an annual reporting rate of 0.26 per physician), while nurses submitted 31 reports (an annual reporting rate of 3.43 per nurse) for major errors. Lag time was 18% shorter for major events than minor, and 75% longer for physicians.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Hobgood 2004 <sup>100</sup>	Error disclosure Error reporting	Cross-sectional study	Retrospective survey of health care providers' experiences with disclosing medical errors (Level 4)	41 EMTs, 33 RNs, and 42 physicians in 1 tertiary care academic medical center	None	Disclosure to patients was associated with provider type (19% EMTs, 23% RNs, and 74% physicians). 59% of physicians reported observing another provider disclose an error.
Hobgood 2006 <sup>92</sup>	Error disclosure Error reporting	Cross-sectional study	Survey using 10 clinical vignettes (Level 4)	40 physicians, 26 nurses, and 35 EMTs in 1 tertiary care academic emergency department	None	Physicians were more likely (71%) to disclose an error than were nurses (59%), but nurses were more likely (68%) to report the error than were physicians (54%).
Inoue 2004 <sup>125</sup>	Types of error reports	Cross-sectional study	Retrospective analysis of errors reported through incident reports (Level 4)	Incident reports submitted by nurses in 6 urban hospitals in Japan	None	Error rates were high for prevention of problematic behavior, prevention of suicide, safeguarding against falls, and subcutaneous injections of insulin. Error rates that were high in some hospitals, but not all, were maintenance of dialysis, endoscopy preparation and assistance, administration of preoperative treatments, and blood transfusions. Error rates were higher in hemodialysis patients, those with problematic types of behavior, and the elderly. Incidence of errors was associated with rule violations, management practices, and nonstandardized nursing practices.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Jeffe 2004 <sup>132</sup>	Perceptions of error reporting Barriers to error reporting	Cross-sectional study	Verbatim transcribed focus groups, recommendations for systems change to improve reporting, including awareness of provider status, benefits of feedback, and culture change (Level 4)	9 focus groups with 49 nurses, 10 nurse managers, and 30 physicians in 20 community and academic hospitals	None	Culture change might be accomplished as providers' concern and responses were considered in systems changes to improve reporting and policy revisions; how best to improve error reporting and disseminate information about errors might benefit when considering perceived barriers to reporting and including front-line providers' perspectives on clear guidelines on what to report, education on reporting mechanisms, anonymous reporting mechanisms, personnel, and routine followup of error reports for education and hospital action. Nurses were more knowledgeable about how to report errors. All mentioned barriers—fear of reprisals, lack of confidentiality, time, and feedback after an error—are reported. Both physicians and nurses agreed that reporting was intended to change practice and policy to promote patient safety.
Jones 2004 <sup>116</sup>	Error reporting	Quality improvement	Standardized voluntary medication reporting form and database, compared with MEDMARX; NCC MERP severity index was used to categorize severity of harm to the patient (Level 4)	10 critical access hospitals	Conducted education workshops about nature of errors, the design of safety systems, and best practices in medication safety; provided quarterly reports from the error reports the hospitals	Most errors were not harmful; greater availability of pharmacists associated with reporting greater proportions of Category A errors (circumstances have the capacity to cause error) and Category B errors (an error occurred, but the error did not reach the patient). Nurses submitted 97% of error reports.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Kim 2006 <sup>157</sup>	Electronic error reporting	Cross-sectional study	Structured interview (Level 4)	Chairs of nursing departments (a 35% response rate) throughout Korea	None	Only 3% of hospitals used health information technology (HIT); HIT mainly used for medication administration, order entry, and radiology.
Kim 2007 <sup>139</sup>	Error reporting Barriers to error reporting	Cross-sectional study	AHRQ's patient safety culture survey (Level 4)	886 nurses (a 92.3% response rate) in 8 teaching hospitals in Korea	None	67% of nurses reported always reporting errors resulting in patient harm. About half were unclear about what should be reported. 32% worried that their errors were kept in files. 52% reported having been given feedback and informed about errors made. 48% reported speaking out if they saw something negative, and 38% would voice opinions that differed from those in authority. 66% felt that their suggestions to improve patient safety were ignored. 83% felt that more errors should have happened than did, and 52% reported their units had serious patient safety problems. 56% reported problems talking with physicians. Frequency of reporting errors was higher among nurses with 5 to 10 years experience. Head nurses reported errors more frequently than did staff.
King 2001 <sup>153</sup>	Error reporting	Cross-sectional study	Mailed surveys of error scenarios to RNs to elicit error reporting behaviors (Level 4)	372 nurses in the Midwest	None	Nurses were able to differentiate between intentional wrongdoing, which was related to questionable behavior. The perception of severity determined whether the error was reported. Unintentional errors would not be reported.
Lata 2004 <sup>126</sup>	Improving adverse drug event (ADE) reporting	Cross-sectional study	Determine whether nurse case managers and pharmacists increase reporting of serious ADEs (Level 4)	1 community hospital in rural Wisconsin	Nurse case managers were educated that they were expected to report ADEs.	Nurse case managers reported 62% of ADEs, compared to 17% by pharmacists, and 75% of serious adverse drug reactions.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Lawton 2002 <sup>46</sup>	Barriers to error reporting	Cross-sectional study	Questionnaire about willingness to report errors of others; included error scenarios (Level 4)	73 physicians, 145 nurses, and 92 midwives (a 53% response rate) in 3 NHS trusts in England	None	Reporting was more likely if there was a bad outcome. Physicians were less likely to make a report than were nurses or midwives. Health care professionals were less likely to report errors of senior colleagues. Physicians were unlikely to report violations of clinical protocols, whereas nurses and midwives were more likely.
Mayo 2004 <sup>142</sup>	Error reporting	Cross-sectional study	Random sample of RNs surveyed about perceived causes of medication errors, percentage of medication errors reported to nurse managers, types of reportable incidents, and reporting behaviors, including medication errors scenarios (Level 4)	983 RNs (20% response rate) in the United Nurses Association of California/ Union of Health Care Professionals	None	When the dose was withheld or omitted, the majority would report the event to the physician, but few would have completed an incident report for the withheld medication, compared to about half for the omitted dose. Nurses working in neonatal intensive care units perceived higher reported errors (52.5%) than did those working in medical/surgical units (35.3%). The mean perceived percentage of reported errors was 45.6%. 92.6% reported knowing what a medication error was, and 91.3% reported knowing when to use an incident report. Reporting barriers were fear of manager reactions (76.9%), fear of coworker reactions (61.4%), and considering error was not serious enough to warrant reporting (52.9%).
Mick 2007 <sup>154</sup>	Reporting Errors	Cross-sectional study	Assessed error reports	300 employees (out of a possible 800) in 5 inpatient units	New close call error reporting program, called the Good Catch Program with periodic feedback to staff.	The new program resulted in a 1,468% increase (from 175 before to 2,744 afterwards) in the number of reports. Reports facilitated the targeting of interventions to improve patient safety.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Nuckols 2007 <sup>127</sup>	Reporting errors	Cross-sectional study	Analyzed 3,875 reports from 2 hospitals (Level 4)	1 academic tertiary referral hospital and 1 affiliated community hospital in Southern California	None	The majority of reports were for errors involving medications, operations, falls, and procedures. 89% of incident reports were from nurses. 48% of incidents occurred on general floors, 21% in ICUs, and 14% in operating rooms. Nurses were involved in 43% of the potentially preventable events, while physicians were involved in 16%.
Osborne 1999 <sup>69</sup>	Perceptions of errors Reporting medication errors Barriers to error reporting	Cross-sectional study	Survey to RNs about perceived causes of medication errors (Level 4)	57 RNs (61.9% response rate) on medical-surgical units in a 700-bed community hospital in South Florida	None	43.9% of respondents reported that only 25% of medication errors were reported. 84.2% of respondents indicated that they knew what defined an error, and 86% that medication errors were not reported because of fear. 57.9% reported that they did not report a medication error when they did not consider it serious. There was no difference in perceptions associated with age, years of experience, or level of education.
Osmon 2004 <sup>137</sup>	Reporting errors	Cross-sectional study	Prospective analysis following implementation of a new error reporting process, specific to the hospital (Level 4)	1 urban teaching hospital in Missouri	Implementation of new hospital-based error reporting system using the SAFE reporting cards	Reporting rate for medical events was 31.9 per 100 ICU patient admissions. Nurses reported the majority of events (59.1%), followed by medical students (27.2%) and ICU attending physicians (2.6%). Most reports involved delays or omissions (e.g., medications, diagnostic tests, or necessary/planned procedures (36.5%)), medication errors (20.2%), and malfunctioning equipment (7.9%). 9.9% of events required life-sustaining interventions, and 3% may have led to the patient's death. 60.9% of life-sustaining interventions were a result of delays/omission of prescribed nonmedication treatments and necessary planned procedures.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Rathert 2007 <sup>146</sup>	Reporting errors	Cross-sectional study	Survey measuring patient-centered climate, perceived medication error frequency, job satisfaction, comfort reporting own errors and pointing out the errors of others (Level 4)	307 nurses (a 57% response rate) in 3 acute care hospitals in the eastern United States	None	Nurses are more comfortable reporting their own errors in a patient-centered care climate than they are pointing out the errors made by others.
Rudman 2005 <sup>112</sup>	Error reporting systems	Cross-sectional study	Comparative description of baseline paper-based medication errors with postintervention Web-based reports; increased medication error reports, increased intercepted medication error threats, and staff access to post error interventions (Level 3)	Hospital reported errors: pre (average = 434.5/mo.) vs. post (average = 79.9/mo.)	Web-based, anonymous medication error reporting system on all personal computers and work stations	Staff accessed reports, noting immediate actions taken. Error reports and intercepted error threats increased. Intercepted nurse, physician, and pharmacist medication errors increased. Errors attributed to physicians increased as nurses' and pharmacists' decreased. Details of cause-of-error reporting.
Schuerer 2006 <sup>136</sup>	Error reporting systems	Prospective cohort study	Assessment of error reporting using a prospective analysis following implementation, withdrawal, and then reintroduction of a new error reporting process, specific to the hospital (Level 4)	Nurses, physicians and other health care workers in 1 24-bed surgical ICU	A card-based reporting system (SAFE)	Physician reporting increased from 0.3 to 5.8 reports per 1,000 patient days, and nurses from 18 to 39 reports per 1,000 patient days. When reporting cards were removed, physician reporting decreased to 0 per 1,000 patient days, then increased to 8.1 reports when the cards were reintroduced. A higher proportion of events reported by physicians were for events that caused harm, while the higher proportion of events reported by nurses were for events that did not cause harm to patients.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Stratton 2004 <sup>141</sup>	Perceptions on error reporting	Cross-sectional study	Survey of pediatric and adult hospital nurses on their perceptions of the proportion of reported medication errors and why errors are not reported (Level 4)	57 pediatric and 227 adult nurses (a 40% response rate) in 33 acute care units in 11 hospitals (in rural Midwestern States, urban areas in the Rocky Mountain region of the United States)	None	<p>Pediatric nurses estimated that 67% of medication errors were reported; adult nurses estimated 56%. Error rates per 1,000 patient-days were 14.80 in pediatric units and 5.66 in adult units.</p> <p>Medication errors are underreported by pediatric and adult nurses, with more reported on pediatric units.</p> <p>The more strongly nurses on pediatric units agreed with management-related and individual/personal reasons for not reporting errors, the lower the estimates of errors reported.</p> <p>Pediatric nurses agreed that nurses fear consequences from reporting and believe peers will think of the reporters as incompetent.</p>
Throckmorton 2007 <sup>140</sup>	Error reporting	Cross-sectional study	Survey about the environment and reasons why nurses do not report errors (Level 4)	435 nurses (a 10% response rate) licensed to practice in Texas	None	<p>Knowledge of the nurse practice act was not associated with intent to report.</p> <p>Nurses providing direct care to patients were more likely to report.</p> <p>Nurses would report both errors that harmed patients and those that did not.</p>
Tuttle 2004 <sup>135</sup>	Error reporting system	Prospective cohort study	Implementation of a voluntary, electronic reporting system (ERS) for safety events involving patients or visitors (Level 4)	1 teaching hospital in New York	Implemented new confidential ERS for safety events and provided multifaceted education program to promote safety awareness and how to use the ERS.	<p>Nurses reported 73% of the 2,843 safety events; physicians reported 2%.</p> <p>Of the events reported:</p> <ul style="list-style-type: none"> <li>- 16% were unsafe conditions or near misses; 22% were adverse events where patient was harmed; and 39% were not reported correctly.</li> <li>- 40% were medication/infusion events, 30% were adverse clinical events, and 24% were falls.</li> </ul>

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Uribe 2002 <sup>149</sup>	Barriers to reporting errors	Cross-sectional study	Survey on perceived barriers to reporting and likelihood they could be modified (Level 4)	56 physicians and 66 nurses (17.3% response rate) in a Midwest academic hospital	None	Major barriers to error reporting were time and work involved in documenting an error; not being able to report anonymously; thinking that errors with no negative outcomes should not be reported; fear of legal actions; and hesitancy to "tell" on someone else. Modifiable barriers were identified as the structure and processes for reporting errors and education. Least modifiable barriers were fear of lawsuits, fear of being blamed, and motivational issues. Physicians identified twice as many barriers to reporting than did nurses; both identified time and extra work involved in documenting an error. Nurses were more concerned about anonymity, "telling" on someone else, fear of lawsuits, and the necessity of reporting errors that did not result in patient harm.
Vojir 2003 <sup>145</sup>	Error reporting	Cross-sectional study	Surveyed nurses about their estimates of reported medication administration errors (Level 4)	1,214 nurses in 205 adult patient care units in 26 hospitals	None	Differences in staff definitions of reportable error, occurrence data not widely shared with staff nurses, staff nurses rely on personal experience to estimate unit medication administration errors.
Wakefield 1996 <sup>70</sup>	Barriers to reporting medication errors	Cross-sectional study	Survey of medication administration errors and reasons nurses do not report errors, oriented to reporting process (Level 4)	RNs (n = 1,384) in 24 acute care hospitals; nonrandomly selected convenience sample	None	Fear, disagreement over whether an error occurred, administrative responses to medication errors, and effort required to report MAE are reasons nurses may not report errors. Fear inhibits reporting; organizational culture change needed to support reliable, valid, complete error reporting; too much emphasis placed on medication errors as measure of quality nursing care.

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Wakefield 1999 <sup>150</sup>	Barriers to reporting MAEs Perceived causes of MAEs Estimated MAEs reported	Cross-sectional study	Survey assessing perceived reasons for not reporting MAEs (Level 4)	Staff nurses and supervisors in 29 acute care hospitals in Iowa	None	There was some agreement on fear and administrative response as barriers to error reporting, but the barriers are associated with individual characteristics and management practices. The degree of agreement between staff and their supervisors about why errors are not reported varied considerably. Supervisors were more likely to view fear of administrative response as a barrier to error reporting, whereas staff nurses did view fear as a barrier.
Wakefield 2001 <sup>151</sup>	Barriers to reporting MAEs	Cross-sectional study	Questionnaire on organizational culture, implementation of clinical quality improvement (CQI), and nurses' perceptions of MAE reporting (Level 4)	292 nurses from 6 Midwest hospitals	None	Hospital culture types varied: smaller institutions tended to have group-oriented cultures, larger institutions tended to be more hierarchal in nature. The extent of CQI implementation increased with bed size of the hospital, and perceived rate of MAE reporting decreased. The greater the number of barriers, the lower the reporting of errors. The presence of a group-oriented culture and higher levels of CQI implementation were positively but not significantly associated with reporting errors. Hierarchical or rational-type cultures were negatively associated with reporting errors.
Wakefield 2005 <sup>148</sup> (Note: This includes findings of Wakefield 1996, 1999, 2001 <sup>70, 150, 151</sup> )	Barriers to reporting medication errors	Cross-sectional study	Scale development, content validity (face), construct validity (factorial), concurrent validity; internal consistency, and test-retest reliability (Level 4)	RNs (n =1,384 in 1994, 1,428 in 1996, 862 in 1998, and 295 in 2001) in hospitals (n = 24 in 1994, 29 in 1996, 21 in 1998, and 16 in 2001)	None	The reported reasons why MAEs were not reported were due to disagreement with the definitions, the burden of the reporting effort, fear (e.g., judgment from peers, patients, and their families, physician reprimand, adverse consequences, and being blamed for patient harm), and administrative response (e.g., no positive feedback, individual blame, and response not matching the severity of the error).

Source	Safety Issue Related to Clinical Practice	Design Type	Study Design, Study Outcome Measure(s)	Study Setting & Study Population	Study Intervention	Key Finding(s)
Weingart 2000 <sup>36</sup>	Error reporting	Cross-sectional study	Compared house officer reports with incident reports and patients' medical records, using confidential peer interviews to identify errors and substandard quality care (Level 3)	Medical house officers, nurses, social workers, physical therapists, and case managers in 1 hospital in Boston	None	Of the errors verbally reported by the house officer and confirmed in the patient's medical record, only one was recorded in the hospitals' incident reporting system. Nurses recorded the majority of incident reports, whereas only 1 incident report was submitted by a house officer.
Wild 2005 <sup>143</sup>	Perceptions and attitudes about error reporting Knowledge and use of error reporting systems	Cross-sectional study	Self-administered survey on the knowledge and use of the hospital error reporting system and attitudes and perceptions about hospital culture regarding error reporting (Level 4).	24 resident physicians (a 96% response rate) and 36 nurses (a 60% response rate) in 1 community hospital in Connecticut	None	54% of residents and 97% of nurses knew of the hospital's error reporting system; 13% of residents and 72% of nurses were likely to use it. Residents were more likely to perceive the culture as more threatening and nonsupportive; 29% of residents and 64% of nurses reported being comfortable discussing mistakes. 42% of residents and 44% of nurses were uncomfortable discussing errors with patients. 64% of nurses were comfortable discussing mistakes with supervisors. 54% of residents and 91% of nurses reported being more likely to report an error, either their own or someone else's. 25% of residents and 1% of nurses were more likely to report an error if they did not like the person who caused the error.
Yamagishi 2003 <sup>128</sup>	Reporting adverse events Reporting method	Cross-sectional study	Adverse event data obtained from incident reports, logs, checklists, nurse interviews, medication error questionnaires, urine leucocyte tests, patient interviews, and medical records. Patients were interviewed about the events (Level 3).	Event reports by 115 staff nurses in 6 wards in 1 hospital in Tokyo, Japan	None	Actual events and reported events were similar when using incident reports, checklists, nurse interviews, urine leucocyte tests, and questionnaires of medication errors. Falls were not always reported, depending on whether patients were independent with activities of daily living or under standardized care protocols. Restraint use was usually not documented in patient record.