

Between a Rock and a Hard Place: Disclosing Medical Errors

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Background: Healthcare-related errors cause patient morbidity and mortality. Despite fear of reprimand, laboratory personnel have a professional obligation to rapidly report major medical errors when they are identified. Well-defined protocols regarding how and when to disclose a suspected error by a colleague do not exist.

Patient: We describe a woman with a well documented allergy to sulfamethoxazole who was treated with sulfadiazine that led to toxic epidermal necrolysis. After the patient's death, the laboratory medicine resident was asked by one of the patient's physicians to measure serum sulfadiazine, but only if the results were not reported in the patient's electronic medical record. The case was brought to the attention of a laboratory medicine faculty member and the hospital risk management team.

Issues: Laboratorians are patient fiduciaries and are responsible for reporting errors. Most medical associations have codes of ethics that address disclosure of incompetence and errors, although the AACCP's Guide to Ethics does not. New types of error, risk management, and root-cause analyses help to shift the focus to system errors and away from individuals' errors. This can lead to a healthcare environment that encourages truth and disclosure rather than fear and reprimand.

Disposition: The individuals involved in the presented case fulfilled their fiduciary duty to the patient by reporting this incident. An extensive investigation

showed that, in fact, no medical errors or misconducts had occurred in the care of the patient.

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Prevention of medical errors is a major goal of healthcare. Error prevention and ethical conduct is important for all healthcare workers. However, the role of the laboratory in error reporting is sometimes misunderstood. A recent case highlighted some salient issues regarding the role of laboratorians in identifying and reporting errors.

Case

A 44-year-old woman with HIV/AIDS presented to the emergency department (ED) with a generalized rash. In the 12 years since her disease was diagnosed, her poor compliance with medications had led to several hospital admissions for HIV-related complications. Only a few days before this presentation, she had been discharged with home medications, including sulfadiazine (a sulfonamide antibiotic) for central nervous system toxoplasmosis. Her last CD4 count was 45 cells/mm³.

Her past medical history was considerable for hypertension, gastroesophageal reflux disease, iron deficiency anemia, and alcohol abuse. Her medications included atenolol, azithromycin, dapsone, iron, leucovorin, lisinopril, pyrimethamine, ranitidine, and sulfadiazine. She had a well-documented allergy to sulfamethoxazole (also a sulfonamide antibiotic).

In the ED, the patient was febrile and appeared uncomfortable. A painful, generalized erythematous papular skin rash was present, with several bullous lesions oozing on the upper extremities. Sloughing of the oropharynx mucosal membranes was noted, as was crusting around her eyes and the orifices of her nose and mouth. Her skin was warm to the touch. The consulting dermatology team's impression was toxic epidermal necrolysis, a severe drug-induced reaction with high morbidity and mortality. The patient was admitted to the intensive care unit, where she rapidly declined and subsequently died.

A resident in laboratory medicine was contacted by one of the patient's physicians who inquired about which

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reference laboratory could measure serum sulfadiazine. Attempts to gather information about the patient and the clinical rationale for the testing were resisted by the clinician. The laboratory medicine resident was able to determine that a serum sample had been obtained from the patient just before death, but postmortem examination had not been performed. The purpose of the request appeared to be documentation of perimortem sulfadiazine in a patient with known hypersensitivity to sulfa-based drugs. However, the clinical team asked if the results could remain off the patient's electronic medical record for "legal reasons". When the laboratory medicine resident said that results could not be withheld from the patient's chart, the inquiring physician said, in that case, they did not want the testing performed. The laboratory medicine resident, with feelings of "fear" and "confusion about the right thing to do", brought the case to the attention of a laboratory medicine faculty member. The resident felt "stuck between a rock and a hard place".

Discussion

We use this case to discuss, from the laboratorian's viewpoint, the ethical problems of error disclosure.

ERRORS IN MEDICINE

An error is something that unintentionally deviates from what is correct or true. In a discussion of medical errors (medical mistakes), it is important to recognize that errors are of several types. Some are preventable, others are not. Some errors are made by instrument malfunction, some are made by individuals, and others reflect system design flaws rather than errors of a single individual or instrument. Furthermore, differentiation must be made between errors caused by unintentional mistakes and those caused by misconduct. Misconduct is considered a deliberate violation of clearly articulated rules and procedures whereas a mistake is unintentional. Individuals should be accountable for misconduct, whereas some mistakes may be unavoidable. There should be constant effort to minimize both misconduct and mistakes.

In 2000, the Institute of Medicine published a report entitled "To Err is Human: Building a Safer Health System" (1). The findings about the magnitude and scope of preventable errors in healthcare came as a surprise to much of the medical profession and captured the public's interest. According to the report, more than one million preventable adverse events occur each year in United States hospitals as a result of healthcare (1). Of these adverse events, an estimated 100 000 caused patients serious harm, and between 44 000 and 98 000 led to death (1). Even conservative estimates indicate that more patients die annually of preventable adverse events related to healthcare than from motor vehicle accidents (43 458), breast cancer (42 297), or AIDS (16 516) (1).

Within healthcare, the field of laboratory medicine has for years recognized quality assurance and error prevention priorities. Scrutiny of preventable analytic errors by

regulatory and accreditation groups has influenced laboratory processes, including automation, quality control, proficiency testing, and programs to define error frequency such as Q-Probes and Q-Tracks from the College of American Pathologists (2, 3). As a result, preanalytic errors, not measurement errors, are now the most common type of error, with poor specimen quality and patient misidentification being the most frequent (4). Published error rates in the clinical chemistry laboratory range from 0.045% to 2.3%, depending on the definition of "error" (for example, whether sample mix-ups are included) (4). Although these low rates are encouraging, the field of medicine continues to tolerate error rates higher than, or equal to, many other nonmedical industries (5, 6). For instance, even airline baggage handling has a comparable error rate (0.5%), despite less life threatening consequences (7). It is likely that the reported clinical chemistry error rates are actually an underestimate of actual error rates. Laboratory professionals have a duty to try to avoid preventable errors and rapidly report identified errors (both preventable and nonpreventable, including those caused by misconduct) for the best interest of patients.

THE LABORATORY PROFESSIONAL ACTING AS A FIDUCIARY

A fiduciary is entrusted with power and responsibility to act with another's rights and interests in mind. The fiduciary relationship is the modern basis for professional ethics, and specifically a model of the modern patient-physician relationship. Fundamental to the fiduciary relationship are these principles: autonomy, beneficence, nonmaleficence, and justice (8).

Autonomy. Autonomy (from the Greek "autonomos" meaning "self rule") is the freedom of individuals to make their own decisions, recognizing their capability for self-control, deliberation, and carrying out their own plans. An autonomous patient is able to give fully informed consent when he has an awareness of all relevant medical concerns. When medical errors are not disclosed, his ability to understand the rationale or risks of an additional or alternative procedure or longer hospital stay is impeded, i.e., he is no longer capable of giving informed consent.

Beneficence. Beneficence (from the Latin, "bene" and "facio," meaning "to do well") is a healthcare provider's obligation to help his patients. Allowing a patient to believe his disease is responsible for an event (a prolonged treatment time or additional testing), when in actuality the event is the result of a medical error, would not be fair or kind. A reassurance including a full explanation by a beneficent physician allows the patient to anticipate and understand what may occur in the future (9).

Nonmaleficence. Nonmaleficence (from the Latin “male” and “ficus,” meaning “to do no harm”) is a passive obligation. It is encapsulated in the motto, *Primum non nocere*, first do no harm. Healthcare providers must prevent patients from making bad decisions based on incomplete information. If an error has harmed a patient, the physician should do whatever is necessary to prevent further harm. Doing otherwise only makes the problem worse (10).

Justice. Justice (from the Latin “jus” meaning “law” or “right”) dictates that patients should receive what they deserve. They may be owed compensation (for increased hospital costs, or lost wages) and an apology. Most studies indicate that nearly all patients demand, at a minimum, an apology (11, 12). Most physicians want to apologize but may not do so in fear that the apology may imply legal liability (10, 13).

From the application of these principles comes veracity (truth telling) and fidelity (promise keeping) (8). It is implied that a fiduciary will not deceive his or her patients. Without this premise, the privilege of being a patient’s healthcare provider would likely not have been entrusted to the healthcare provider.

ERROR DISCLOSURE

As a fiduciary, a healthcare professional strives to maintain a reputation of honesty, integrity, and reliability, i.e., the fiduciary relationship in medicine is based on trust. Therefore, when medical errors are discovered, they should be disclosed. Ethicists, patient safety experts, and patients agree that once serious errors occur they should be disclosed to the patient as soon as possible (13). Although most physicians agree, citing their responsibilities as the patient’s healthcare fiduciary (Table 1), the literature suggests they carry out this practice in less than half of instances when a serious error has occurred (11). In fact, many physicians admit that they have used deception when forced to make a difficult ethical decision (14). Interestingly, one third of polled physicians report they

(or a family member) have been a victim of medical error, and in those cases they desire full disclosure of errors (15).

When and how to disclose a colleague’s error is even more poorly defined. Medical tradition tends to emphasize the loyal brotherhood of physicians (16). Medical training reinforces respect for teachers and colleagues and thus discourages whistle blowing (17). Moreover, in the real world, whistleblowers face discrimination (18). Although error disclosure is difficult to approach, it is an essential component of our profession. It is not a surprise that errors occur in medicine. How we choose to respond to them defines us, ethically, as professionals.

The medical profession generally supports the disclosure of error, even when the error is not one’s own. No definitive procedure or document outlines how a health professional should disclose the errors of another health professional, because vastly different circumstances can exist. In general, once the facts are known, the person who committed an error should be given the opportunity to disclose it. If that person is unwilling, another person who is aware of the error must act on his or her primary responsibility to the patient and disclose the error. Appropriate hospital patient safety mechanisms must then be followed.

Many medical associations have adopted codes of ethics that address the issue of disclosing incompetence and errors. For instance, the American Medical Association’s *Principles of Medical Ethics* states:

A physician shall uphold the standards of the profession, be honest in all professional interactions, and strive to report physicians deficient in character or competence, or engaging in fraud or deception, to appropriate entities (19).

The American College of Physicians’ *Ethics Manual* states

... physicians should disclose to patients information about procedural or judgment errors made in the course of care if such information is material to the patient’s well being. Errors do not

Table 1. Comparison of patient and physician attitudes about medical error disclosure.

Focus Group Themes	Patient Attitudes	Physician Attitudes
Definition of error	Broad; includes deviations from standard care, some nonpreventable adverse events, poor service quality, and practitioner’s deficient interpersonal skills	Narrow; deviations from accepted standard care only
What errors to disclose	All errors that cause harm	Errors that cause harm, except when harm is trivial, patient cannot understand error, or patient does not want to know about error
Disclose near misses?	Mixed	No
What information to disclose about error?	Tell everything	Choose words carefully
How to disclose error	Truthfully and compassionately	Truthfully, objectively, and professionally
Role of apology	Desirable	Concerned that apology creates a legal liability
Emotional impact of error	Upset, angry, scared	Upset that patient was harmed and about how error could impact career

necessarily constitute improper, negligent, or unethical behavior, but failure to disclose them may (20).

The American Society for Clinical Laboratory Science's *Code of Ethics* states that clinical laboratory professionals have a duty to the patient in "... striving to safeguard the patient from incompetent or illegal practice by others." and a duty to society to "... comply with relevant laws and regulations pertaining to the practice of clinical laboratory science and actively seek, within the dictates of their consciences, to change those which do not meet the high standards of care and practice to which the profession is committed" (21).

The College of American Pathologists' *Principles of Ethical and Professional Conduct* states that "A pathologist shall strive to report any physician or healthcare professional who engages in fraud or deception or whose deficiency in character or competence jeopardizes patient care or other personnel" (22).

Interestingly, the American Association for Clinical Chemistry's *Guide to Ethics* (1990 revision) states that "... I, as a clinical chemist, shall strive to conduct myself with integrity and honesty" and "avoid scientific and professional misconduct..." (23).

The general guide makes no specific statement about disclosing errors or incompetence.

Because clinical chemists participate in the care of a very large number of patients on a daily basis, they are likely to become aware of errors. Most of the errors clinical chemists detect are laboratory generated, but clinical chemists are also in a position to detect errors occurring outside the laboratory. Yet, unlike physicians and other healthcare workers with direct patient care, clinical chemists are often working with limited clinical information. Therefore, when the errors of nonlaboratory personnel are suspected, laboratorians should proceed with caution until all the facts have been gathered.

TRAINEES, NONPHYSICIANS AND ERROR DISCLOSURE

Error disclosure is difficult for laboratory physicians, who may feel they are jeopardizing their clinical colleagues. This difficulty is intensified for those lower on the hierarchy (fellows, residents, technologists), who feel they cannot or should not challenge their superiors. Trainees and technologists should be encouraged to come forward when errors or incompetent practices are suspected (both within and outside the laboratory) (24). To disclose another's error, trainees and technologists should be directed to their supervisor (not the patient), who should clarify the facts with the mistake maker. If disclosure does not occur by the mistake maker, the supervisor should then report the error to another supervisor, the department chief, or the chief of staff's office (25).

MODELS OF MISTAKES

Healthcare workers, in general, have traits of personal social responsibility and accountability. These are not

people who want to make mistakes (26). This alone does not prevent the large number of medical errors documented each year. People traditionally respond to medical errors by blaming and disciplining the individual most immediately connected to the event. This person is deemed careless or inattentive and is made a negative example. Rooting out and punishing an individual is emotionally satisfying, say psychologists. However, this perpetuates the notion that humans should be error-free and that only "bad" humans make mistakes.

Several authors have indicated the need for a paradigm shift in the analysis of error causation, particularly within the culture of healthcare (27,28). Cognitive theorists suggest that, even in medicine, all humans should be expected eventually to err. The "swiss cheese" model of system accidents proposed by James Reason assumes that errors happen (27). This model suggests that all systems, including healthcare, have many defenses or safeguards that protect against errors (like a nursing station alarm and a light above the patient's room). However, each defense has a weakness (nursing station alarms ring constantly and are sometimes ignored). These weaknesses are arranged like the holes in a block of swiss cheese. In practice, the holes are constantly opening or closing (maybe the night nurse is attentive to the alarm) and moving from place to place. Inevitably, at random, the holes in the swiss cheese will align (the nursing station alarm is ignored and the light above the patient's room is burned out), and the tunnel through the cheese allows an opportunistic accident to harm a patient (a patient's call for help goes unanswered and the patient dies).

Aviation maintenance which, like medicine, is a risky and decision-dense profession like medicine, conducts evaluations of all accidents. In 90% of cases, a poorly structured system (not an individual error) is ultimately found to be the cause of errors (27). As a result, the aviation industry as a whole takes responsibility for streamlining and correcting vulnerabilities likely to lead to error. Adoption of these ideas has already begun in medicine. In 2005, an unusual but highly informative discussion of medical error (a case of a patient with fetal loss and hysterectomy) was published in *JAMA* (29). Discussants noted not a single negligent physician, but 10 contributing errors, each of which could be addressed in a systems approach. Modern hospital risk management is responsible for much of this change as well as the increased focus on organizational ethics.

RISK MANAGEMENT

Risk is the probability of an undesirable event occurring. From a hospital's perspective, risk depends on features specific to each facility such as size, teaching status, mission statement, patient population, etc. For instance, risk of error is increased in teaching hospitals, where more individuals participate in patient care (30). The role of a hospital risk manager is to promote patient safety through the identification and reduction of risk.

To identify and reduce risk, the first step is to recognize a sentinel event, which, as defined by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), is "an unexpected occurrence involving death, serious physical or psychological injury, or the risk thereof" (31). Once a sentinel event is identified, an investigation can be initiated by the risk management team. One risk management approach is to investigate all the factors that contribute to an event through a root cause analysis involving a group of specialists in patient safety, risk management, medication errors, infection control, and regulatory compliance who investigate the circumstances surrounding the incident. They examine medical records and build a timeline of events. All the involved parties are interviewed, and all factors that contributed to the error are documented (30). As a result, changes can be made to eliminate or minimize the system's flaws that lead to the sentinel event. This type of root cause analysis shifts the focus from individuals to systems. Risk managers believe that disciplining the individual will not fix the system and, as a result, if the only action is discipline, the error will recur (1, 28, 32).

Although the model of system error has gained recognition in many industrial and military fields, and even among some healthcare accrediting bodies, healthcare workers themselves haven't yet accepted it, and neither has the public (15). Lucian Leape, an expert in healthcare policy and patient safety, has long noted that without acceptance, it will be "unlikely that any substantial progress will be made in reducing medical errors" (28). The barrier to acceptance lies in the philosophy of healthcare education and thus in the culture of healthcare professionals. Trainees are conditioned, in professional and legal circles, to believe that error is unacceptable. When they ultimately and inevitably do err, they are afraid to come forward to admit or analyze an error, or even a near miss, without feeling solely responsible. Healthcare education should include training regarding system error analysis and system reconfiguration. Several excellent sources of material on this topic are currently available (33, 34).

SUMMARY OF DISCUSSION

Healthcare-related errors cause a considerable patient morbidity and mortality each year. Laboratory personnel, serving as patient fiduciaries, have a professional obligation to disclose medical errors. New models of system error may lead to a healthcare environment that encourages truth and disclosure rather than fear and reprimand.

CASE FOLLOW-UP

The laboratory medicine resident, when unable to elicit history from the clinician, suspected misconduct and was justifiably concerned. Clearly, the attempt to order serum sulfadiazine concentration "off the record" was inappropriate. After consulting with a laboratory medicine faculty member, the laboratory medicine resident contacted

a member of the hospital's risk management team. A risk management investigation was already ongoing, as a pharmacist had noted the drug allergy in this patient's record. During the investigation, personnel in laboratory medicine were interviewed regarding their knowledge of the case.

Ultimately, the investigation showed the administration of sulfadiazine to this patient (despite a known history of sulfa-drug allergy) was not a mistake but rather a nonpreventable adverse outcome. The clinical team knew the patient's allergy to this drug class. As experts in HIV treatment, they also knew the increased incidence of allergic reactions (including toxic epidermal necrolysis) to sulfa-based drugs in this patient population. However, this patient's life threatening cerebral toxoplasmosis left the clinical team few therapeutic alternatives (32). In addition, this poorly compliant patient had "doubled up" her sulfadiazine medication dose for several days before presenting to the ED with toxic epidermal necrolysis. The cause of death was presumed sepsis secondary to toxic epidermal necrolysis. In this case, no systems failure, nor breach of standard of care, occurred.

It remains unclear why the clinician requested an off-record test. It seems plausible that there may not have been a team consensus regarding the use of sulfadiazine in this patient. Perhaps the prescriber worried about legal liability. Maybe this patient's family, frustrated by the patient's decline because of overwhelming infections, threatened legal action. Although no error occurred, the laboratory medicine resident appropriately informed her supervisor, and an appropriate investigation was conducted.

Because of the status of this case as a nonpreventable adverse outcome, this case was not deemed a sentinel event under JCAHO definitions, and a root cause analysis was therefore not performed. An optional internal review (through Patient Safety and Quality) was not pursued because the poor medication compliance (9-day overdose) occurred when the patient was an outpatient. A formal hospital incident report was generated, based on the classification of the adverse event as "prescribing medication error". The case was closed.

This case illustrates how healthcare professionals can work together to ensure quality patient care. These types of scenarios play out every day in laboratories everywhere. The details of this case are understood because several individuals (the laboratory medicine resident and a pharmacist) had the courage to come forward and report findings that they felt might have been caused by error or misconduct. These individuals fulfilled their fiduciary duty to the patient.

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