Legal Implications of Laboratory Errors

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The recent national focus on patient safety, including freedom from preventable errors, provides a renewed impetus to emphasize the importance of focusing on laboratory errors as contributing factors to patient harm. Errors are defined by Webster to be “variances from that which is acceptable” and in professional jargon as “deviations from standard operating procedures (SOP), from expected action or performance or from expected outcome.” For laboratory professionals, the definition of “that which is acceptable” comes from standards such as the CAP Standards of Laboratory Services, the AABB Standards for Blood Banks and Transfusion Services and the JCAHO Standards, among others. In addition, there are a number of federal laws and their accompanying regulations that provide information about expectations (e.g., CLIA, OSHA, EPA, HIPAA, etc.) as well as spelling out the consequences of violations. The SOP in each facility indicates the expected action or performance and outcomes in that institution.

It is not the fact that errors will happen that dictate whether legal action will ensue. It is, rather, how the laboratory responds to such errors that will predictably influence both whether a suit will be filed and what the outcome will be.

When a laboratory professional fails to adhere to ‘that which is acceptable,’ errors may occur that lead to adverse consequences for patients. In general, laboratories are more likely to be liable for regulatory violations than to be sued for negligence (medical malpractice) or other legal reasons. However, litigation can occur and individual laboratory technical personnel can be held liable for harm if the patient can show that the laboratory person acted negligently.

The greatest vulnerability for negligence in laboratory practice occurs during the sample collection interaction with the patient. Numerous publications have highlighted the importance of absolute objective patient identification for all medical and laboratory procedures. When the admitting clerk and then the phlebotomist fail to properly identify the inpatient, reliable laboratory information cannot be created. For most laboratories, this is the weakest link in the chain of events that lead from patient sample to generation of laboratory data and then back to the treating physician for subsequent patient treatment or other intervention. Focused efforts to ensure that the right sample is taken from the right patient, appropriately labeled and timely delivered for analysis, will likely eliminate more than half of the errors occurring in laboratories.

Where do laboratory errors occur? The opportunity for errors lies in every step along the path of workflow: from the preanalytic phase (including ordering errors, wrong patient, wrong sample taken, etc.) through the analytical phase (testing the wrong sample, not testing but recording results anyway, recording the results for wrong patient, misidentifying tissue/blocks/slides, equipment or reagent failures, QC failures, inadequate training of personnel, insufficient staffing, etc.) and in the postanalytic phase (wrong interpretation of test data, lack of timeliness of reporting, unintelligible data, mistranscription of oral information, etc.).

The solutions to addressing these errors include increasing automation, introducing simplification, enhancing communications, improving systems (including information systems) and encouraging better performance. Modern laboratory practice should include routine auditing of performance throughout the path of workflow as well as the supporting systems. The gap between what is expected and what is actually happening provides a rich resource for improvements and for avoiding legal involvement. For regulatory compliance, the United States government has provided useful guidance and a recommendation for creating a compliance officer to ensure that CLIA and Medicare regulations are met. There have been well-publicized cases in which the laboratory’s practices have been demonstrated to violate CLIA regulations. Such cases have frequently arisen due to a ‘whistleblower’ suit (known as qui tam actions in legalese). Such suits can (and probably will) be filed in a number of other areas, including personnel safety, shipment of diagnostic samples, record keeping, HIPAA violations, etc.

The best defense against a lawsuit is demonstration of knowledge of the standards and regulations and compliance with them, as documented in routine reviews, audits, external assessments, and regular reports. Humans will err as frequently as 1/350 times when performing the same task. It is not the fact that errors will happen that dictate whether legal action will ensue. It is, rather, how the laboratory responds to such errors that will predictably influence both whether a suit will be filed and, in many instances, what the outcome will be. When errors occur, having a routine method of documenting the error, prompt follow-up to minimize harm, and appropriate interactions with patients to ensure them of an open disclosure and acceptance of responsibility for any injury sustained, will provide the strongest possible defense.

Web Resources

- CLIA – http://www.cms.hhs.gov/clia/
- OSHA – http://www.osha.gov/
- EPA – http://www.epa.gov/epahome/
- JCAHO – http://www.jcaho.org
- AABB – http://www.aabb.org
- CAP – http://www.cap.org