

Please read this bit first

The HPCSA and the Med Tech Society have confirmed that this clinical case study, plus your routine review of your EQA reports from Thistle QA, should be documented as a "Journal Club" activity. This means that you must record those attending for CEU purposes. Thistle will **not** issue a certificate to cover these activities, nor send out "correct" answers to the CEU questions at the end of this case study.

The Thistle QA CEU No is: **MT00025**.

Each attendee should claim **THREE** CEU points for completing this Quality Control Journal Club exercise, and retain a copy of the relevant Thistle QA Participation Certificate as proof of registration on a Thistle QA EQA.

January 2007

Quality Laboratory Practice

American Society for Clinical Pathology

Policy Statement (Year Initially Approved, 2006; Date of Next Review, 2009)

The American Society for Clinical Pathology (ASCP) supports the development and maintenance of high-quality standards for laboratory testing to ensure patient safety and to reduce medical errors.

Background and Rationale

Introduction: Anatomic and clinical pathology laboratories directly affect the vast majority of all medical diagnoses in the United States. The topic of patient safety has taken a front seat in the continuing debate on the reform of the American health system. With over 100 million Americans being affected by a medical mistake at a cost of \$200 billion a year, patient safety and quality issues need to be addressed. Most incidents are preventable, and most have little to do with the work done in the laboratory. However, because of the importance placed on accurate test results, those who work in the laboratory bear the ultimate responsibility for patient safety and should therefore follow established best practices.

Laboratory quality management plans, with preanalytic, analytic, and postanalytic components, are key elements in ensuring patient safety. Although all 3 components are important for ensuring patient safety, the greatest impact for overall improvement would be to focus on pre- and postanalytic services in which most errors occur.

S A N A S



PROFICIENCY
TESTING SANAS Accredited to ISO Guide 43 / ILAC G13

Current Initiatives to Ensure Patient Safety in the Laboratory

Clinical Laboratory Improvement Act of 1967 and 1988. These standards include quality control, quality assurance, personnel standards, and proficiency testing. Meant to ensure patient safety and reduce errors in laboratory work, CLIA regulations have become the baseline for all laboratory patient safety initiatives. CLIA of 1988 strengthened and extended quality requirements for laboratories that perform tests to diagnose or treat disease.

Personnel Standards. Without proper laboratory staff training, the likelihood of erroneous laboratory test results increases substantially. Research estimates that more than 25% of these problems affect patient care. These effects include delays in receiving appropriate care and the provision of inappropriate or harmful diagnoses or treatments.

Erroneous test results caused by personnel error can lead to improper diagnoses and treatment, which may ultimately cause injury or death. "False-positive" and "false-negative" laboratory results also produce higher costs, both for the patient and the healthcare system as a whole. Laboratory employees should report all medical errors. Through the practices of reporting and tracking errors, laboratories become more knowledgeable about where errors are occurring and can work with laboratory personnel to rectify these situations.

Proficiency Testing. The pathology community has long held the belief that the quality of the testing result produced by a laboratory is one of the most critical measures for ensuring public safety. Because of this, the laboratory community has embraced proficiency testing at the laboratory level. Laboratories are required to complete proficiency testing to document quality as a part of the accreditation process. Proficiency testing is an important educational and quality assessment tool used "to assist laboratories to identify and solve problems, evaluate personnel, and improve test results."

Laboratory Accreditation and Regulatory Compliance. The goal of laboratory accreditation is to continuously improve the quality of laboratory practice. Accreditation includes professional peer review, education, and compliance with established laboratory standards.

College of American Pathologists Accreditation and Laboratory Improvement. CAP provides a variety of accreditation, inspection, and quality assurance programs to ensure that laboratories provide the highest quality of patient care. CAP's programs, such as Q-PROBES, Q-TRACKS, and Inspection Checklists, are designed to ensure that laboratories operate in accordance with state and federal regulations to achieve optimal patient safety. These programs contribute to patient safety in a variety of ways, including providing comprehensive assessments of key laboratory processes and monitoring beyond the testing phase to evaluate processes that affect test results and patient outcomes.

Legislative and Regulatory Initiatives to Protect Patient Safety

Pathology societies and federal/state government(s) have taken steps to block unethical practices that can distort rational medical decisions and adversely affect patient safety and care, including:

- Passage of legislation to prevent providers from billing for services that they do not perform. Many state pathology societies have advocated passage of legislation requiring direct billing for pathology services. The Center for Health Policy Studies found that in states lacking direct billing laws, per beneficiary laboratory charges were 41% higher than in states protected by direct billing requirements.

S A N A S



PROFICIENCY TESTING SANAS Accredited to ISO Guide 43 / ILAC G13

- Steps to address ethical practices and improper financial incentives, such as antireferral and antikickback requirements that prohibit providers from referring patients for services in which the provider has a financial incentive or receives other forms of compensation. A US Department of Health & Human Services Inspector General report found that providers with a financial interest in the volume of testing services performed 45% more tests.

Recommendations

To ensure the highest quality of patient health and safety, ASCP recommends:

- Patient safety initiatives be designed to reduce errors in all clinical environments, including the laboratory.
- Laboratory professionals recognize and identify all potential problems and vulnerabilities in laboratory settings, including specimen labeling errors, lack of sufficient training for personnel, and data-transferring issues when information is moving to electronic medical records.
- The establishment of electronic health records for all Americans.
- The laboratory/hospital accreditation process as well as standard operating procedures be used to help maximize patient safety goals.
- Continuing medical education for physicians and allied healthcare professionals to promote patient health and safety.
- Certification and licensure of laboratory personnel as a means to ensure laboratory safety.
- Laboratory industry should hold meetings between laboratory and nonlaboratory health professionals to discuss patient safety strategies.
- Collaboration within the laboratory community to optimize the value of laboratory services.
- States adopt direct billing requirements for pathology services.
- The federal government take additional steps to prevent fee splitting and other similar practices.

Conclusion

ASCP recognizes the critical role that the laboratory and its employees play in protecting patient safety. ASCP is committed to working with governmental and other accrediting organizations, laboratories, and individuals to continuously improve the quality of laboratory practice and safety of our patients.

CPD Questions:

1. What do you understand by the term “perverse incentives” as used in South Africa? What aspects in this article are relevant to “perverse incentives” and do you think they apply here?
2. Do you think that SANAS accreditation contributes to patient safety? Create a flow-chart showing how the various clauses of ISO 17025/ 15189 apply to “patient safety” in its broadest definition.
3. The article states that “25% of erroneous laboratory test results affect patient care”. Were do the errors occur in your laboratory; what percentage of errors happen in your lab; and what percentage do you think will directly affect patient care?