



American Society for Clinical Pathology

THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
POLICY STATEMENT

Quality Laboratory Practice and its Role in Patient Safety (POLICY NUMBER 06-01)

POLICY STATEMENT:

ASCP supports the development and maintenance of high quality practice standards for laboratory testing to assure patient safety and reduce medical errors associated with laboratory medicine.

BACKGROUND AND RATIONALE:

I. Introduction

With anatomic and clinical pathology laboratories (i.e., laboratory medicine) directly impacting the vast majority of all medical diagnoses in the United States,¹ ASCP recognizes that laboratory employees and the work they perform play a crucial role in protecting and preserving patient safety. The topic of patient safety has taken a front seat in the continuing debate on the reform of the American health system. The new attention to the topic is not unwarranted. With estimates of over 100 million Americans being affected by a medical mistake at a cost of \$200 billion a year,² patient safety and quality issues need to be addressed system wide.

Attention brought to this important public health issue has not decreased incidents of medical error. Since the Institute of Medicine (IOM) released its report “To Err Is Human: Building a Safer Health System” in 1999, many of the wide-ranging causes of medical error have been identified.³ 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 pre-analytic, analytic, and post-analytic components, are key elements in ensuring patient safety. While all three components are important for ensuring patient safety, the greatest impact for overall improvement would be to focus on pre- and post-analytic services where most errors occur. At the same time, laboratories need to

continue to improve quality and safety by focusing on control of the analytic phase. Laboratory professionals must be leaders in ensuring patient safety both within, and outside of, the walls of the laboratory. This leadership in the medical community begins with developing a culture within the laboratory that empowers laboratory employees to report errors in their own areas.⁴

II. Current Initiatives to Ensure Patient Safety in the Laboratory

Initiatives have been established and implemented by the federal government and organizational entities so that laboratories can use standard operating procedures and maximize patient safety.

A. Clinical Laboratory Improvements Act of 1967 and 1988

Minimum standards for clinical laboratory testing have been in place since the passage of the Clinical Laboratory Improvements Act in 1967 (CLIA). These standards include quality control, quality assurance, personnel standards, and proficiency testing.⁵ Meant to assure patient safety and reduce errors in laboratory work, CLIA regulations have become the baseline for all laboratory patient safety initiatives. The Clinical Laboratory Improvements Act of 1988 strengthened and extended quality requirements for laboratories that perform tests to diagnose or treat disease. The General Accountability Office recently released a report entitled *Clinical Lab Quality -- CMS and Survey Organization Oversight Should Be Strengthened* that outlines a number of recommendations for improvements in the oversight process.⁶

B. Personnel Standards

Without proper laboratorian training, the likelihood of erroneous laboratory test results increases substantially.⁷ With medical diagnosis highly dependent on laboratory test results, erroneous test results can have a significant impact on patient care.⁸ Research estimates that more than 25 percent of these problems affect patient care.⁹ These effects include delays in receiving appropriate care and the provision of inappropriate or harmful diagnoses or treatments. ASCP provides mechanisms to improve personnel standards including certification, maintenance of certification, continuing education programs for pathologists and laboratory professionals, and supports licensure of laboratory personnel.

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’ lab results also produce higher costs, both for the patient and the health care system as a whole.¹⁰ 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.

C. 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.¹¹ Because of this, the laboratory community has embraced proficiency testing at the laboratory level. Laboratories and laboratorians 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.”¹²

D. Laboratory Accreditation and Regulatory Compliance

ASCP supports the accreditation of our nation's laboratories and hospitals. 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.¹³ In order to maintain the high standards associated with laboratory accreditation, a state of continual excellence is essential; therefore ASCP supports unannounced laboratory accreditation inspections. ASCP also supports the establishment of mechanisms, such as hotlines and whistleblower protections, as a means for laboratory personnel to report patient safety issues without fear of reprisal.

1. JCAHO National Patient Safety Goals

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) sets the standard by which healthcare quality is measured in the United States and around the world.¹⁴ Each year JCAHO revises the National Patient Safety Goals, a set of standards used to evaluate and accredit healthcare organizations.¹⁵ Accreditation is awarded to organizations that meet the standards of the Joint Commission.

ASCP supports the development and annual review of JCAHO's National Patient Safety Goals. These goals cover important aspects of healthcare services. JCAHO's laboratory service related goals should be implemented in a fashion that is conducive to standard operating procedure.¹⁶

In addition, ASCP supports JCAHO's tracking of sentinel events. “A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.”¹⁷ By carefully tracking and understanding these events, JCAHO is able to get a clearer understanding of exactly where these barriers to patient protection are occurring and work towards implementing better systems to protect patient health.

2. COLA

ASCP supports COLA, a physician-directed organization whose purpose is to promote excellence in laboratory medicine and patient care through a program of voluntary education, consultation, and accreditation.¹⁸ ASCP recognizes that COLA is a provider of clinical laboratory accreditation and their services have a positive impact on clinical laboratories.

3. College of American Pathologists (CAP) Accreditation and Laboratory Improvement

ASCP recognizes the importance of the College of American Pathologists (CAP) Accreditation and Laboratory Improvement programs. CAP provides a variety of accreditation, inspection and quality assurance programs to ensure that laboratories provide the highest quality of patient care.¹⁹ 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 also monitoring beyond the testing phase to evaluate processes that impact test results and patient outcomes.

4. National Quality Forum

ASCP supports the development of consensus-based national standards for the measurement and public reporting of healthcare performance data. The National Quality Forum (NQF) mission is to improve American healthcare through endorsement of the development of such standards.²⁰ The NQF convened a workshop in 2006 to define quality in laboratory medicine. Based upon this workshop NQF will release a publication that reviews laboratory medicine quality measures and will recommend implementation strategies for our nation's clinical laboratories.

E. Health Information Technology

The laboratory is an important leader in the realm of patient safety because of its advancements in standardizing processes and validating measurements in everyday activities. The laboratory, unlike other areas of healthcare, has been at the forefront of using technology to implement standardizations that allow for error reduction and better patient safety measures.

1. Electronic Health Records

ASCP supports the establishment of electronic health records for all Americans. According to the Institute of Medicine (IOM) Committee on Data Standards for Patient Safety,²¹ there are five core functionalities of an effective electronic health record system:

- Improve patient safety.
- Support the delivery of effective patient care.
- Facilitate management of chronic conditions.
- Improve efficiency.
- Feasibility of implementation.

The IOM stresses that the establishment of electronic health records would improve patient safety through the delivery of services as well as through patient care support and management.

In 2005, President Bush signed Public Law (P.L.) 109-41, the Patient Safety and Quality Improvement Act.²² Following passage of the law, President Bush established a federal advisory committee under the Secretary of Health and Human Services, the "American Health Information Community" (AHIC), to help advance efforts for the establishment of electronic health records for all Americans in the next ten years.²³

2. Patient Safety Organizations

The recent passage of P.L. 109-41 establishes a network of patient safety organizations that have databases that "shall have the capacity to accept, aggregate across the network, and analyze non-

identifiable patient safety work product voluntarily reported by patient safety organizations, providers, or other entities." These databases will be used to track patterns of healthcare errors, providing the public with annual quality reports. ASCP supports the intent of this legislation to provide a vehicle whereby organizations can learn from adverse experiences of others to avoid similar unanticipated events.

F. Pay for Performance

Pay for Performance (P4P), is an emerging concept in the healthcare field that, in theory, could be designed to ensure patients receive the highest quality healthcare services possible. P4P programs reimburse healthcare providers for their services based on clinical performance criteria including quality, efficiency and improved patient outcome. Clinical laboratories collect large amounts of patient related data that could be used to measure clinical performance and quality of care.

The Federal government is currently exploring the implementation of P4P programs for Medicare reimbursement and as a means of encouraging competition within the ever-burgeoning healthcare system. While P4P has the potential to result in more effective patient care, there is also the risk that these programs could value "cost savings" over "quality" resulting in diminished quality of care. In some situations, providers may have incentives to not accept patients with co-morbidities or discount patient preferences when providing care. ASCP will be active in scrutinizing P4P proposals to ensure that patient safety and quality laboratory practice are not compromised.

III. 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,²⁴ including:

- Passage of direct billing legislation at the state level to prevent providers from billing for services 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 percent higher than in states protected by direct billing requirements.²⁵
- Steps to address ethical practices and improper financial incentives such as anti-referral and anti-kickback requirements which prohibit providers from referring patients for services in which the provider has a financial incentive or receives other forms of compensation. A U.S. Department of Health and Human Services Inspector General report found that providers with a financial interest in the volume of testing services performed 45 percent more tests.²⁶

IV. 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;
 - Data transferring issues when information is moving to Electronic Medical Records.
- The establishment of electronic health records for all Americans.
- Laboratories closely follow the JCAHO Patient Safety Goals as they apply to pathology and laboratory medicine. The laboratory community should comment on the JCAHO yearly goals as they are proposed and revised to maximize their effectiveness.
- The laboratory/hospital accreditation process as well as standard operating procedures be utilized to help maximize patient safety goals.
- The establishment of patient safety organizations as outlined in the new patient safety law, Patient Safety and Quality Improvement Act of 2005 (P.L.109-41).
- 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 non-laboratory health professionals to discuss patient safety strategies.
- The examination of appropriate pay for performance measures as a means to improve patient safety.
- 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.

V. *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.

REFERENCES:

- ¹ AdvaMed. (2005). *The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care*. The Lewin Group, Inc. Washington, DC.
- ² National Patient Safety Foundation. (1997, October 9). *Nationwide Poll on Patient Safety 100 Million Americans See Medical Mistakes Directly Touching Them*. Retrieved May 26, 2005, from <http://www.npsf.org>.
- ³ Kohn, L.T., Corrigan, J.M., and Donaldson, M.S. Eds. (1999). *To Err is Human: Building a Safer Healthcare System*. National Academy Press, Washington, DC.
- ⁴ Marx, David. The Just Culture. *Laboratory Errors and Patient Safety*. May-June 2005. v. 1 n. 6 p. 2-4.

- ⁵ Department of Health and Human Services. (1998). Clinical Laboratory Improvements of 1998. Retrieved July 12, 2004 from <http://www.cms.hhs.gov/clia/>.
- ⁶ <http://www.gao.gov/cgi-bin/getrpt?GAO-06-416>
- ⁷ Stull, Tina M.; Hearn, Thomas L.; Hancock, John S.; Handsfield, James H., and Collins, Carlyn L. Variation in Proficiency Testing Performance by Testing Site. *Journal of the American Medical Association*. February 11, 1998. v279, n6. pp 465.
- ⁸ Foubister, Vida, Bench Press: The Technologist/Technicians Shortfall is Putting the Squeeze on Laboratories Nationwide. CAP Today. September 2000. pp 84.
- ⁹ Nutting, Paul A.; Main, Deborah S.; Fischer, Paul M.; Stull, Tina M.; Pontious, Mike; Boone, D. Joe; Holcomb, Sherry. Problems in Laboratory Testing in Primary Care. The Journal of the American Medical Association, February 28, 1996. v275 n8 p638.
- ¹⁰ *Surveys Show Improvement in Physician Office Labs*. Press Release, U.S. Health Care Financing Administration. September 7, 1995.
- ¹¹ American Society for Clinical Pathology. Letter to Secretary Leavitt. http://www.ascp.org/511live/Timssnet/News/TNT_news.cfm?action=long&PRIMARY_ID=CYTO-LETTER
- ¹² Schoonmaker, M. Memo on Follow up to the Hearing on “Ensuring Accuracy and Accountability in Laboratory Testing” held May 18, 2004. Library of Congress Congressional Research Service. Washington, DC.
- ¹³ http://www.cap.org/apps/cap.portal?_nfbt=true&_pageLabel=lab_accred_book
- ¹⁴ <http://www.jcaho.org/general+public/who+jc/index.htm>
- ¹⁵ Joint Commission Perspectives 26 (7): July 2006.
- ¹⁶ http://www.jcaho.org/general+public/patient+safety/06_npsg_lab.htm
- ¹⁷ http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/se_pp.htm
- ¹⁸ <http://www.cola.org/mission.html>
- ¹⁹ http://www.cap.org/apps/cap.portal?_nfbp=true&_pageLabel=accreditation
- ²⁰ <http://www.qualityforum.org/mission/home.htm>
- ²¹ Institute of Medicine Committee on Data Standards for Patient Safety. (2003). *Key Capabilities of an Electronic Health Record System*. National Academy Press, Washington, DC.
- ²² <http://www.hhs.gov/healthit/ahic.html>
- ²³ Public Law 109-41, Patient Safety and Quality Improvement Act of 2005, July 29, 2005.
- ²⁴ ASCP Policy Statement: Fee Splitting, Markups, and Related Practices. ASCP Policy Statement 04-03. 2004.
- ²⁵ Dyckman, Z. Impact of Direct Billing Requirements For Laboratory Tests on Laboratory Charges, Utilization and Costs. Center for Health Policy Studies. March 1993. p. 15.
- ²⁵ Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989.

¹ AdvaMed. (2005). *The Value of Diagnostics Innovation, Adoption and Diffusion into Health Care*. The Lewin Group, Inc. Washington, DC.

² National Patient Safety Foundation. (1997, October 9). *Nationwide Poll on Patient Safety 100 Million Americans See Medical Mistakes Directly Touching Them*. Retrieved May 26, 2005, from <http://www.npsf.org>.

³ Kohn, L.T., Corrigan, J.M., and Donaldson, M.S. Eds. (1999). *To Err is Human: Building a Safer Healthcare System*. National Academy Press, Washington, DC.

⁴ Marx, David. The Just Culture. *Laboratory Errors and Patient Safety*. May-June 2005. v. 1 n. 6 p. 2-4.

⁵ Department of Health and Human Services. (1998). Clinical Laboratory Improvements of 1998. Retrieved July 12, 2004 from <http://www.cms.hhs.gov/clia/>.

⁶ Stull, Tina M.; Hearn, Thomas L.; Hancock, John S.; Handsfield, James H., and Collins, Carlyn L. Variation in Proficiency Testing Performance by Testing Site. *Journal of the American Medical Association*. February 11, 1998. v279, n6. pp 465.

⁷ Stull, Tina M.; Hearn, Thomas L.; Hancock, John S.; Handsfield, James H., and Collins, Carlyn L. Variation in Proficiency Testing Performance by Testing Site. *Journal of the American Medical Association*. February 11, 1998. v279, n6. pp 465.

⁸ Foubister, Vida, Bench Press: The Technologist/Technicians Shortfall is Putting the Squeeze on Laboratories Nationwide. CAP Today. September 2000. pp 84.

-
- ⁹ Nutting, Paul A.; Main, Deborah S.; Fischer, Paul M.; Stull, Tina M.; Pontious, Mike; Boone, D. Joe; Holcomb, Sherry. Problems in Laboratory Testing in Primary Care. The Journal of the American Medical Association, February 28, 1996. v275 n8 p638.
- ¹⁰ *Surveys Show Improvement in Physician Office Labs*. Press Release, U.S. Health Care Financing Administration. September 7, 1995.
- ¹¹ American Society for Clinical Pathology. Letter to Secretary Leavitt.
http://www.ascp.org/511live/Timssnet/News/TNT_news.cfm?action=long&PRIMARY_ID=CYTO-LETTER
- ¹² Schoonmaker, M. Memo on Follow up to the Hearing on “Ensuring Accuracy and Accountability in Laboratory Testing” held May 18, 2004. Library of Congress Congressional Research Service. Washington, DC.
- ¹³ http://www.cap.org/apps/cap.portal?_nfbt=true&_pageLabel=lab_accred_book
- ¹⁴ <http://www.jcaho.org/general+public/who+jc/index.htm>
- ¹⁵ <http://www.jcaho.org/general+public/who+jc/index.htm>
- ¹⁶ http://www.jcaho.org/general+public/patient+safety/06_npsg_lab.htm
- ¹⁷ http://www.jointcommission.org/SentinelEvents/PolicyandProcedures/se_pp.htm
- ¹⁸ <http://www.cola.org/mission.html>
- ¹⁹ http://www.cap.org/apps/cap.portal?_nfpb=true&_pageLabel=accreditation
- ²⁰ <http://www.qualityforum.org/mission/home.htm>
- ²¹ Institute of Medicine Committee on Data Standards for Patient Safety. (2003). *Key Capabilities of an Electronic Health Record System*. National Academy Press, Washington, DC.
- ²² <http://www.hhs.gov/healthit/ahic.html>
- ²³ <http://www.hhs.gov/healthit/ahic.html>
- ²⁴ ASCP Policy Statement: Fee Splitting, Markups, and Related Practices. ASCP Policy Statement 04-03. 2004.
- ²⁵ Dyckman, Z. Impact of Direct Billing Requirements For Laboratory Tests on Laboratory Charges, Utilization and Costs. Center for Health Policy Studies. March 1993. p. 15.
- ²⁶ Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress. U.S. Health and Human Services Department Office of the Inspector General Office of Analysis and Inspections. May 1989.