



American Society for Clinical Pathology

THE AMERICAN SOCIETY FOR CLINICAL PATHOLOGY
POLICY STATEMENT

SCOPE OF PRACTICE ISSUES AFFECTING PATHOLOGY AND LABORATORY MEDICINE (05-01)

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POLICY STATEMENT:

In order to protect patient health and ensure high quality laboratory testing, the American Society for Clinical Pathology (ASCP) opposes efforts that allow pharmacists, nurses, and other non-laboratory health care practitioners to perform and/or interpret laboratory test results.

BACKGROUND AND RATIONALE:

In recent years, numerous non-physician health care practitioners have begun performing and/or interpreting patient laboratory tests, sometimes without following numerous federal and state laws that are designed to optimize test quality. This problem compromises patient safety and is dangerous to patients and the public as a whole.

No laboratory test is so simple or risk free that an erroneous result can not occur. An incorrect test result is never inconsequential to patient care. Medical errors resulting from inaccurate laboratory testing are costly, dangerous and potentially deadly. A study of 129 laboratory incident reports over a 16-month period showed that the laboratory function that was most frequently implicated in incidents was specimen processing. The authors found that 30 percent of the preventable incidents involved cognitive errors, or incorrect choices caused by the insufficient knowledge of the test operator.¹

In deed, the Institute of Medicine (IOM) found that over 44,000 people die in hospitals each year as a result o medical errors that could have been prevented. Errors are generally caused by faulty systems, processes and conditions lead practitioners to make mistakes or fail to prevent practitioners from making mistakes. Some types of medical errors sited in the IOM report are failure to employ indicated tests, use of outmoded tests, and error in the performance of tests. As a result of its findings, the IOM recommended that professional groups, in conjunction with oversight organizations and group purchasers of health care, raise performance standards and expectations in the improvement of safety. Licensing, certification and accreditation can and

should define minimum performance standards for health professionals and the methods they implore in testing patients.²

While according to CLIA definition waived testing pose little risk of error, those tests are to be performed in a certified laboratory environment. Even when conducted in certified laboratories, quality problems were found in almost one-third of pilot study cases. 32 percent of the testers failed to have current manufacturer instructions. Another 32 percent of the testers did not perform quality control as required by either the manufacturer or the Centers for Disease Control. 16 percent of the performers failed to adhere to the current manufacturer's instructions.³ If these results were found in certified laboratories, one can only imagine what types of conditions can be found at the local pharmacy or nursing station, where there is little oversight or regard for quality control.

Certified members of a pathologist's laboratory team have obtained extensive training in laboratory testing that gives them a specialized knowledge. This specialized knowledge makes certified technologists and technicians a valuable, irreplaceable asset to the laboratory community, and allows technologists and technicians to work hand in hand with pathologists to perform life-saving work.

While there are many laboratory practitioners performing important work, in many situations it is a pathologist who bears the ultimate responsibility for the laboratory results produced. Under the guidance of pathologists, laboratory practitioners perform quality laboratory services. Only under a pathologist's supervision can the scope and competency of other members of the laboratory team be evaluated. This belief, in fact, mirrors the AMA's 1995 House of Delegates adopted guidelines regarding the physician-physician assistant practice.⁴

Granting non-laboratory practitioners the ability to both perform and interpret laboratory test results is dangerous and will impact a patient's right to have their health care provided by the most qualified medical professional. Furthermore, less qualified non-physician health care personnel (including nurses and pharmacists) with little or no experience in the laboratory cannot assess, manage or gauge the performance of laboratory staff.

REFERENCES:

¹ http://www.thedoctorsdoctor.com/labtests/how_accurate.htm

² Institute of Medicine Study

³ CMS fact sheet—Visiting CLIA, Certificate of Waiver Laboratories

⁴ (AMA Bi-Law D-35.999 Non Physician's Expanded Scope of Practice (Laboratory Testing and Test Interpretation))