

**CAP Web site Navigation Steps to CAP Laboratory Patient Safety Plan**

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**CAP Laboratory Patient Safety Plan**

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**I. Overview**

Over the past decade there has been increased interest in preventing errors and improving patient safety in all areas of medicine. The patient safety movement began in the early '90's with the formation of the National Patient Safety Foundation and gained considerable momentum after late 1999 with the publication of the Institute of Medicine report on Medical Errors. Subsequently, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) embraced improving patient safety as one of its core principles, and it revised all of its Standards to that end in mid-2001.

No area in medicine has been spared scrutiny with regard to improving patient safety, including the laboratory. Several salient adverse medical incidents directly related to the laboratory and anatomic pathology practices have occurred in the last three years and they have been heavily reported in the media. They have underscored the sometimes devastating nature of outcomes from laboratory errors and the crucial role that the laboratory plays in the delivery of healthcare.

The College of American Pathologists (CAP) through the Laboratory Accreditation Program has developed numerous quality standards and guidelines to assure high quality practice. While these efforts have provided a level of safety and reliability in pathology practice and laboratory medicine, recommendations from published IOM reports presented the College with the opportunity to establish laboratory patient safety goals founded on medical error reduction and continuous patient safety improvement.

Over the past four years the CAP has become increasingly interested in patient safety issues and has asked some of its standing and ad hoc committees to make recommendations about the subject. Currently, the primary CAP standing committee charged with developing an integrated approach to improving patient safety with respect to laboratory medicine is the Patient Safety and Performance Measures Committee. This Committee has developed an initial core set of Laboratory Patient Safety Goals (LPSGs) for laboratories to use in their efforts to improve patient safety and reduce laboratory medical errors. The goals focus on the pre- and post analytic phases of laboratory testing with the objective of improving patient test management processes, including patient identification, test ordering, and critical results reporting and interpretation. The goals also reinforce the laboratory's role in patient safety with the objective of improving identification, communication and correction of medical errors and integrate the laboratory's patient safety role within health care organizations. Each facility should create a Patient Safety Plan that addresses each of the LPSG's with particular attention to the examples or situations listed in the subheadings. This plan should be reviewed

annually and signed by the laboratory director and incorporated into the ongoing QI activities. The following Template Laboratory Patient Safety Plan addresses these goals, as well as the overall goal of improving patient safety with regard to laboratory practices and laboratory medicine.

**II. Laboratory Patient Safety Goals/Plan**

**Pre and Post Analytic Phases**

Improve Patient and Sample Identification

- A. At the time of specimen collection
- B. At the time of analysis
- C. At the time of result delivery

Improve the Verification and Communication of Life Threatening or Life Altering Information Regarding

- A. Malignancies
- B. HIV and infectious disease
- C. Cytogenetic abnormalities
- D. Critical values

**Operationalization**

Improve the Identification, Communication and Correction of Errors

- A. Timeliness of identification of errors
- B. Revised reports
  - 1. All inaccuracies in the medical record should be documented and communicated at the time the inaccuracy becomes known. The correct test result or diagnosis should be made clear in an amended or corrected report as soon as possible. The reason that the original result was reported incorrectly (i.e., due to error or other reason) may not be known and need not be reported in the medical record.
  - 2. When an incorrect result or diagnosis causes material injury to a patient, the correct result/diagnosis and the fact that the result has been changed must also be reported to the patient. For an inaccuracy caused by or directly involving a pathologist, the pathologist involved in the case should discuss the matter with the physician who ordered the pathology consultation. The two physicians should jointly determine how best to communicate the result to the patient.

Improve Integration and Coordination of Laboratory Patient Safety Role within Healthcare Organizations and Operations

- A. Nursing
- B. Administration
- C. Point of care testing personnel
- D. Providers
- E. Exchange of information and review by relevant parties

**III. Organization of Laboratory Patient Safety Activities**

*Model 1*

Patient safety activities in the laboratory will be under the overall auspices of the Laboratory Quality Assurance Committee (LQAC). The LQAC will form the Laboratory Patient Safety Committee (LPSC), a standing ad hoc committee that will coordinate patient safety activities for the laboratory. The LPSC shall consist of a Chairperson and representatives from each major division of the laboratory, including Anatomic Pathology, Chemistry, Cytogenetics, Hematology, Histology, Immunology and Serology, Laboratory Support Services, Microbiology, Molecular Biology, Respiratory Chemistry, and the Transfusion Service. The Chairperson of the LQAC shall select the Chairperson of the LPSC and the Chairperson of the LPSC shall choose members of the LPSC. The Chairperson of the LPSC shall sit on the LQAC and report to that committee on the activities of the LPSC.

The LPSC shall meet at regular intervals similar to the LQAC. It shall create Patient Safety Monitors that address the core Laboratory Patient Safety Goals, create thresholds for action, collect data related to these monitors, and make regular recommendations to the LQAC related to the data. The LQAC is ultimately responsible for acceptance or modification of these recommendations, which will then be implemented through the joint efforts of both committees. The LPSC will document improvement or lack thereof and report back to the LQAC on the result of these actions.

*Model 2*

Patient safety activities in the laboratory will be under overall auspices of the Laboratory Quality Assurance Committee (LQAC). It shall create Patient Safety Monitors that address the core Laboratory Patient Safety Goals, create thresholds for action, collect data related to these monitors, implement actions that address areas for improvement that are illuminated by the monitors, assess the effectiveness of the actions, document improvement or lack thereof, and take further action if necessary related to the monitors.

**Sample Patient Safety Monitor**

**Improvement of patient identification at the time of specimen collection.**

**Aspect of care monitored:** Labeling errors at the time of specimen collection.

**Threshold for action:** To be determined.

**Method of evaluation:** All labeling errors discovered at the time of specimen collection will be documented. The laboratory technologist who discovers the error will document it on a form created for this purpose. The form will include the time the error was made, the time the error was discovered, who reported the error, the outcome of the error with regard to the patient, including adverse patient effects, and who was responsible for the error. The data will be tabulated, analyzed for trends and reported to the LPSC/LQAC.

**Improvement of patient identification at the time of analysis**

**Aspect of care monitored:** Labeling errors at the time of specimen collection.

**Threshold for action:** To be determined.

**Method of evaluation:** All errors discovered at the time of analysis will be documented. The laboratory technologist who discovers the error will document it on a form created for this purpose.

The form will include the time the error was made, the time the error was discovered, who reported the error, the outcome of the error with regard to the patient, including adverse patient effects, and who was responsible for the error. The data will be tabulated, analyzed for trends and reported to the LPSC/LQAC.

**Improvement of Verification and Communication of Life Threatening or Life Altering Information Regarding Malignancies**

**Aspect of care monitored:** All new malignancies should be verified by an intradepartmental staff consultation. This action should be documented in writing on an Intradepartmental Staff Consultation Form, and should be documented in the surgical pathology report with the statement *“Case subjected to intradepartmental quality assurance review”*.

**Threshold for action:** To be determined.

**Method of evaluation:** Surgical Pathology reports from all new malignancies (i.e. malignancies that have not previously been reported in the Department, with the exception of non-melanoma skin malignancies) will be audited for the presence of an Intradepartmental Staff Consultation Form, and will be audited for the presence of documentation of the action on the surgical pathology report. The total number of new malignancies, the number that have forms properly executed, and the number of surgical pathology reports that have the consultation properly documented will be tabulated and reported to the LPSC/LQAC.

**Improvement of the identification, communication and correction of errors**

**Aspect of care monitored:** Inaccuracies in surgical pathology reports should be corrected at the time the inaccuracy becomes known. The corrected result should be made clear in an amended or corrected report.

**Threshold for action:** To be determined.

**Method of evaluation:** All amended surgical pathology reports will be audited for the following data: interval between issuance of initial report and issuance of amended report (number of days), reason for correction, type of correction (typographical error, addition of pertinent information [e.g. measurement added that was not previously recorded], change in pertinent information provided, change in diagnosis, clarification in diagnosis, other), how the error was discovered, and any adverse impacts on patient care secondary to the issuance of the incorrect or incomplete report. Results will be reported to the LPSC/LQAC.

**Improvement of integration and coordination of the laboratory’s patient safety role with regard to point of care testing**

**Aspect of care monitored:** \_\_\_\_\_

**Threshold for action:** To be determined.

**Method of evaluation:** \_\_\_\_\_