



Sustainable Hospitals Project

A Project of the Lowell Center for Sustainable Production, University of Massachusetts Lowell

Changing Materials and Practices in Anatomical Pathology Laboratories

An Overview for Managers and Administrators

Most hospitals have medical laboratories that analyze patient body fluids and tissues in order for physicians to diagnosis and treat patients. The medical laboratories fall under regulations and monitoring of a number of groups, including the College of American Pathologists (CAP), the U.S. Government's Clinical Laboratory Improvement Amendments (CLIA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and various other agencies.

Hospital laboratories are directed by a doctor and are generally divided into 2 categories:

- 1) Clinical laboratories, which use chemistry, microbiology, and biochemistry techniques to make measurements on blood, urine, or other body fluids and tissues, and
- 2) Anatomical Pathology (AP) laboratories in which body tissue is mounted onto slides and examined microscopically for malignancy or other disease.

The Clinical laboratory includes chemistry, hematology, and urinalysis. The Anatomical Pathology laboratory includes histology and cytology. In general, Clinical laboratories perform tests using well-defined methods that yield quantitative results reported by the clinician performing the analysis. In contrast, the analysis and interpretation of tissues in the Anatomical Pathology laboratories is more qualitative and based on medical training and experience. Therefore in Pathology, slides are prepared by medical technicians then reviewed and interpreted by pathologists; i.e. medical doctors trained in anatomic pathology.

The results reported by the hospital laboratory might be used to diagnose a patient's condition, to assess effectiveness of a medical treatment, or to predict patient outcomes. Since the treatment of the patient is highly dependent on the laboratory reports, accuracy and timeliness of laboratory results are essential for effective medical care.

Why Change Materials or Practices?

Hospital laboratories are constantly faced with evaluating, improving, and expanding their services while simultaneously delivering precise and accurate results. The incentive for changing services, products, and practices comes from multiple directions. Many accreditation programs require a laboratory quality system to demonstrate continuous improvement of the lab's performance and services. Other factors that prompt include automation, environmental regulations, and new medical developments such as companion diagnostics to drugs. These driving forces require laboratories to become effective agents of change.

What Are Key Considerations for Changing Materials and Practices?

Two organizations offer key guidance to laboratories for practices used in a lab and for quality control: the College of American Pathologists (CAP) and the NCCLS. (Note: NCCLS used to stand for "National Committee for Clinical Laboratory Standards" but the acronym itself is now the

Organization's name.) The CAP Commission on Laboratory Accreditation oversees an accreditation program for medical laboratories, which is conducted by a comprehensive peer review. In the United States, CAP is regarded as the gold standard for lab performance and accreditation is often considered a de facto requirement for operating a medical laboratory. NCCLS is a voluntary consensus standards-developing organization that develops and disseminates standards, guidelines, and best practices for medical testing. NCCLS standards are widely accepted in the healthcare industry and the CAP audit process frequently references NCCLS standards.

In a Clinical laboratory, detailed procedures and quantitative results simplify the task of changing materials or processes. The combination of NCCLS standards that detail many diagnostic chemistry procedures and statistical interpretation of quantitative results allow the lab to conduct validations in a fairly straightforward, well-defined manner.

In an AP laboratory, the procedures and results are more qualitative and complex than in the Clinical laboratory. Subjective characteristics, such as cell color, texture and pigments, are the data that guide the pathologist in interpreting and reporting results. Reliance on tissue appearance makes the process of changing materials or practices more challenging, although certainly not impossible. In the complex processes found in the AP lab, the process for making changes must simultaneously be systematic and flexible. This is consistent with accreditation guidelines, such as CAP and CLIA, that allow laboratories to determine the best process for change that reflects a lab's unique environment and capabilities. A survey of Pathology labs revealed an effective change process includes four elements:

1. A literature and web search to investigate alternative products and practices, including published accounts of a proposed change.
2. A search of NCCLS documents for pertinent standards,
3. Networking to identify best practices among peer laboratories and histologists, and
4. A side-by-side or parallel study of the new technique and current practice.

These elements provide a framework for the evaluation of new Pathology Laboratory processes and practices. Using this framework in combination with a laboratory staff's hands-on assessment of technical viability will allow a Pathology lab to make informed choices and continuously improve its processes and services.

Some useful resources for investigating alternative practices include a facility's library (many people don't know how useful librarians can be), the free PubMed database (<http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>), and <http://www.histosearch.com/>, a search engine of histology-related sites and listserves. NCCLS abstracts and documents are available through the NCCLS website's online catalog.

Resources:

NCCLS - <http://www.nccls.org/>

The NCCLS website includes a catalog of NCCLS standards, guidelines, and best practices for medical testing.

College of American Pathologists (CAP) website - <http://www.cap.org/>

The College of American Pathologists (CAP) is a medical society fostering the practice of pathology and laboratory medicine and provides laboratory quality improvement programs.

Joint Commission on Accreditation of Healthcare Organizations (JCAHO) - <http://www.jcaho.org/>

The Joint Commission evaluates and accredits U.S. health care organizations and programs using JCAHO-developed performance benchmarks for hospital-wide safety and quality in health care delivery.

Clinical Laboratory Improvement Amendments (CLIA) - <http://www.cms.hhs.gov/clia/>

The U.S. Government's Centers for Medicare and Medicaid Services (CMS) regulates laboratory testing performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). The CLIA program is to ensure quality laboratory testing and clinical laboratories must be CLIA-certified to receive Medicare or Medicaid payments.

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More information is available on the SHP Website:

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