

Traditional lines blur between clinical and AP lab systems

By Erika Schonberg

Over 40 years ago, the first laboratory information systems (LISs) appeared for use in the clinical pathology laboratory. They were large systems based on mainframe computers. As a result of the size, time-sharing was a popular means for a laboratory to utilize such a system. Then, as now, the clinical LIS served primarily as a repository for test-result data. While the amount of data modern LIS software handles has grown substantially and the number of tests any given laboratory may perform has grown in number and complexity, the types of data the LIS manages is still largely numeric. Newer systems have built-in rules capabilities, and some have graphical analysis technology that allows the laboratory to create a visual representation of the patient's results. At the same time, many more different types of instruments and middleware have been interfaced to the LIS. Overall, the clinical LIS has evolved along with technology advancements — steadily and progressively.

The more dramatic transformation in the past few years has taken place in the anatomic pathology (AP) information system. The first systems designed specifically for the anatomic pathology laboratory appeared just over two decades ago. Traditionally, a text-based system with an integrated or off-the-shelf word processor at its core, the AP system requires the pathologist, technologist, and/or transcriptionist to type in observations made while viewing a specimen through a microscope. Unlike the clinical LIS that may have several interfaced instruments of various types, historically the information housed in the AP system has mainly derived from the skill and expertise of the technologists and pathologists viewing the specimen.

Three significant interrelated changes have acted as catalysts in blurring the long-established lines between the clinical and AP information systems:

- more widespread adoption of new types of tests and testing techniques;
- the AP laboratory's implementation of instrumentation; and
- the push towards a more comprehensive view of a patient's health.

Separately or together, each trend has given an advantage to the laboratory that is able to share data between the clinical and anatomic pathology departments, or the laboratory that is able to manage both types of tests in a single information system, if appropriate.

New testing techniques

Any molecular-level testing performed on the pathology specimen had primarily been performed in the clinical pathology laboratory due to the diagnostic nature of the tests and the results generated. As certain types of molecular tests, such as human papillomavirus (HPV) and other types of sexually transmitted disease (i.e., *Neisseria gonorrhoeae* [GC] and *Chlamydia trachomatis* [CT]) testing are increasingly requested by clinicians, more cytology laboratories have either taken on performing those tests or, at minimum, including the results in patient reports and/or management reports for quality purposes.

In fact, because cytology and HPV testing, among others, will

use a single sample, the Bethesda System 2001 (www.bethesda2001.cancer.gov/terminology.html) recommends an integrated report. Separate reports may mean that the atypical squamous cells of undetermined significance (ASCUS) interpretation would arrive first from the cytology lab, then the HPV results may be sent as an addendum at a later point from a clinical laboratory. This scenario leaves the physician's office with multiple reports to manage to determine the final result for the patient. A cohesive report with the combined cytology and HPV results allows for the pathologist to include educational comments.

Another benefit to a single report from one laboratory is the ability for its personnel to re-review the cytology to make a final interpretation, which can also be used for internal education and quality-assurance purposes. Data from the ASCUS/low-grade squamous intraepithelial lesion triage study, or ALTS, indicates that ASCUS cases generally result in a 40% to 50% HPV-positive rate. Therefore, correlating ASCUS cases can provide quality-improvement data for the lab.

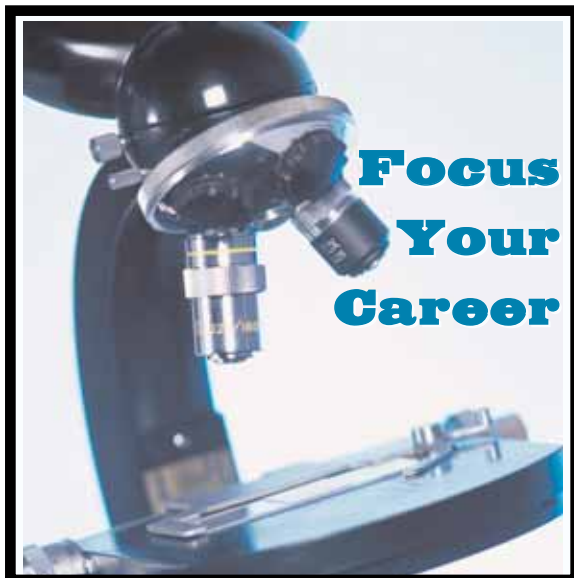
Additionally, laboratory techniques for cytogenetics and flow cytometry, used in leading testing facilities for some time now, have increased in adoption as laboratories have realized a wider application. The techniques and related instrumentation have become more sophisticated and, therefore, more applicable in areas such as oncology, immunology, prenatal testing, transplantation, molecular diagnostics, and stem-cell research, among others. This wider application of such techniques has helped justify the costs of broader implementation of related technologies in hospitals, and private and commercial laboratories across the country.

How and where laboratories handle new testing techniques may vary greatly. Some facilities may set up specialty laboratories to perform molecular or cytogenetics testing only; others may handle some part of it in the cytology or microbiology laboratories; and still others may add specialized skills in molecular pathology directly to the staff in the anatomic pathology laboratory. Regardless of how a laboratory is set up and what technologies may be used, a comprehensive report that presents all the various elements related to the patient's condition is most beneficial to the physician in determining the patient's care.

In fact, the College of American Pathologists (CAP) has developed a set of recommended guidelines for composing molecular pathology laboratory reports. These guidelines, many of which are already included in checklists used during the accreditation process, are intended to provide a framework for laboratories to follow in writing patient reports in a manner such that the results and their significance are easily understood by the healthcare providers caring for that patient. CAP's guidelines indicate that in instances when molecular testing is performed on a sample that is also undergoing routine anatomic pathology consultation, the ordering physician — whether a clinician or the consulting anatomic pathologist — review and synthesize the test results with all the pertinent clinico-pathologic information.

It is in this way that, as demands for new types of molecular

Continues on page 24



American Medical Technologists'

competency-based exams are accredited by the National Commission for Certifying Agencies (NCCA) and are recognized and respected throughout the industry. With over 35,000 certified allied health professionals, AMT provides the certified candidate with: recognition that you have the skills and knowledge as identified by leaders in the allied health community, a certification which is recognized and valid worldwide, and foundational knowledge to build upon as you advance in your job and in your career.

Certification also helps your employer through:

- Increased patient satisfaction
- Increased productivity of skilled, certified employees
- Measurable competence standards
- Simplified recruiting and hiring
- Lower training costs

AMT offers a state-of-the-art online recruitment resource where physicians can easily place a targeted, cost-effective ad to recruit a certified professional. See www.amt1.com for more details and to post your ad.

AMT certifies:

- * Medical Assistants
- * Dental Assistants
- * Medical Laboratory Technicians
- * Medical Technologists
- * Medical Administrative Specialists
- * Office Laboratory Technicians
- * Phlebotomy Technicians



Visit www.rsleads.com/702ml-002

LAB MANAGEMENT

and genetic testing increase, the time-honored lines between the clinical and anatomic pathology laboratories and their previously disparate information systems are becoming muddled. In order for the pathologist to more easily synthesize and interpret complex information from various sources, as in the case of genetics testing, the LIS must support the ability to quickly identify and present results that are generated in different areas of the laboratory. Some test results may be presented as diagnostic data, while others may be text-based observations and analyses of a tissue sample.

AP's adoption of instrumentation

Whereas the use of instrumentation and automation devices has become more ubiquitous in the clinical laboratory, broader adoption of testing techniques like flow cytometry, HPV testing, and molecular diagnostics, along with clinical instrumentation, is finding its way into the pathology laboratory. Traditional AP systems, geared toward word processing, were not designed to assimilate the types of discrete data generated by such testing. These trends require an evolved AP system and/or tighter integration between the clinical LIS and the AP information system.

This type of testing requires that the new AP information system be able to handle numeric data similar to a clinical LIS, and manage a myriad of HL7 interfaces to connect these technologies. As with other types of molecular testing, the pathology report must display the clinical and anatomic pathology test results and results history in a way that enables the pathologist to render a more refined diagnosis and that gives the referring clinician a complete picture of the patient's test results for determining appropriate care options. For example, reviewing a patient's hematology results when evaluating a bone-marrow specimen may help the pathologist understand the cellular changes present, enabling him to deliver a more complete diagnosis.

Similarly, a cytology laboratory may perform HPV, GC, and CT testing along with the Pap tests, but the microbiology lab may handle the HPV reflex testing. In that situation, the final report should still reflect all the testing performed in order to present the most accurate picture of the patient's health. Both scenarios benefit from real-time data sharing between the clinical and AP information systems — both to allow the pathologist to review the results before rendering a diagnosis and synthesizing all the patient's results with the final diagnosis for the clinician.

Additionally, the emergence of more specialty laboratories has led to greater "clinicalization" of the AP system. For instance, Maryland Urology Associates, a Baltimore practice dedicated to the urology specialty, established its own laboratory to manage all the testing requirements of its urologists. The fairly small-volume laboratory handles many different types of both clinical and anatomic pathology testing that relates to its specialty. The start-up operation selected an AP information system that could manage both anatomic pathology cases and diagnostic data from three clinical instruments interfaced directly to the system.

Comprehensive patient results

The advantages of a more comprehensive view of the patient, combined with widespread selection of instrumentation for cytogenetics/FISH and flow cytometry, among others, has also blurred the previously distinct lines between the clinical and AP laboratories. These trends have contributed to the need for laboratories to adopt a "hybrid" information system that can deliver an inclusive view of all clinical and anatomic pathology results.

Continues on page 26

www.mlo-online.com

LAB MANAGEMENT

The goal — and the true advantage — of the electronic medical record is to deliver this complete view of the patient, including all medical history as well as any current laboratory or radiology results, prescriptions, and so forth, thereby avoiding redundant testing and ensuring that no element of the person's health or medication history is overlooked in determining the best care possible. According to industry watchers however, enterprise roll-out of a completely integrated system with the cost and complexity of a true EMR will not be a reality for the majority of providers until sometime later this decade. Pathologists and clinicians can benefit from a hybrid laboratory information system now. How that complete picture of all the laboratory's testing capabilities is achieved is dependent on a number of variables, including the testing performed in various parts of the lab, the current information systems utilized, and the specific reporting needs of the laboratory and its clients.

New information demands

In addition to arming pathologists with a full view of patients' lab results, having a complete picture of all the testing performed in every area of the lab also benefits lab directors. To pull information related to all the testing performed aids in management reporting, correlating comparative test results for quality assurance, identifying potential training/education needs, staff planning, business intelligence purposes, community health monitoring, and meeting requirements of accreditation organizations.

To be able to deliver one complete report with the most comprehensive diagnosis and fullest explanation of the patient's condition is an asset to the physician caring for the patient. As testing increases in complexity, non-specialty physicians in particular are looking more to their counterparts in the lab to help them understand the significance of the findings in the overall prognosis for the patient. Additionally, as more physician offices adopt electronic medical records systems, delivering the complete report electronically — system-to-system data sharing — is preferred. A physician may also benefit from a complete view of his patient population results to help his office better understand laboratory test ordering patterns and to identify disease trends.

These new information-sharing needs can be met in a variety of ways today. Some laboratories may opt for an integrated (not simply interfaced) clinical and APLIS from a single vendor — one with a powerful, shared database that has the ability to compile all the current and historic information from all areas of the laboratory. Other laboratories may opt to pull all the information from one of the systems into the database of the other to achieve similar benefits. And, still other laboratories may implement a portal concept, whereby the information from the disparate systems is bubbled up to a third system that can present the data in a variety of ways to satisfy the unique information needs of the laboratory management, pathologist, and referring clinician. □

Erika Schonberg is marketing director at Psyche Systems Corp., headquartered in Milford, MA.

LabDAQ[®]
laboratory information system

expanding the **connected laboratory**

LabDAQ opens new windows for the laboratory in **efficiency, flexibility, communication, and security**. True **bi-directional interfaces** connect you with both national & regional labs, while **enhanced insurance filtering** allows you to route testing to the appropriate laboratory. All this plus **robust HL7 interfaces** to HIS, Practice Management & EMR systems. And, this is only the beginning.

For truly **exceptional performance** that you need today with the flexibility you require for tomorrow... **LabDAQ is the clear choice.**

Antek HealthWare[®]
800.359.0911 x3
www.antekhealthware.com

Call or visit our website today to see how LabDAQ was built for you!

connectivity
flexibility
security