The Blurring of the Traditional Lines Between the Clinical and AP Lab Systems

Over forty years ago, the first laboratory information systems (LIS) appeared for use in the clinical pathology laboratory. They were large systems based on mainframe computers and, as a result of the size, the practice of 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. Though 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 over time. And, over 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, traditionally, the information housed in the AP system is mainly derived from the skill and expertise of the technologists and pathologists viewing the specimen.

Three significant and interrelated changes have acted as catalysts in blurring the traditional lines between the clinical and anatomic pathology 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. However, as certain types molecular tests, such as human papillomavirus (HPV) and other types of sexually transmitted disease (STD) testing (i.e. Chlamydia and gonococcus) are increasingly requested by clinicians, more cytology laboratories have either taken on performing those tests or, at minimum, include 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 recommends an integrated report rather than separate reports. The alternative may mean that the Atypical Squamous Cells of Undetermined Significance (ASCUS) interpretation would arrive first from the cytology laboratory, 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 the laboratory 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 (ALTS) indicates that ASCUS cases generally result in a 40 to 50 percent 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 clinicopathologic information.

It is in this way that, as demands for new types of molecular and genetic testing increase, the traditional lines between the clinical and anatomic pathology laboratories and their previously disparate information systems are being blurred. In order for the pathologist to more easily synthesize and interpret complex information from various sources, as in the case of genetics testing, the laboratory information system 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 over time become more ubiquitous in the clinical laboratory, such equipment is only now just finding its way into the anatomic pathology laboratory setting. Along with broader adoption of testing techniques like Flow Cytometry, HPV testing and molecular diagnostics, 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 anatomic pathology information system.

This type of testing requires that the anatomic pathology 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 results 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.

Additionally, the emergence of more specialty laboratories has led to greater "clinicalization" of the AP system. For instance, Maryland Urology Associates, a practice dedicated to the urology specialty, established its own laboratory to manage all the testing requirements of the urologists in the practice. As such, the laboratory handles both clinical and anatomic pathology testing related to its specialty. The laboratory is a fairly small volume laboratory that handles a lot of different types of both clinical and anatomic pathology testing. As such, the start-up operation selected an anatomic pathology 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 the broader adoption of instrumentation for Cytogenetics/FISH and Flow Cytometry, etc. has also blurred the previously very distinct lines between the clinical and anatomic pathology 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.

The goal of the electronic medical record is to deliver this complete view of the patient, including all his/her medical history as well as any current laboratory or radiology results,

prescriptions, etc. 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.

As testing becomes more complex, the ability to review all of a patient's related test results and results history is an even more important aid for the pathologist in rendering a more refined diagnosis by giving them a more holistic view of the patient's condition. A cohesive report will then assist the referring physician in determining the best course of treatment for the patient. 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/her to deliver a more complete diagnosis.

Similarly, a cytology laboratory may perform HPV, GC and Chlamydia 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 render the most accurate picture of the patient's health. Both scenarios benefit from real-time data sharing between the clinical and anatomic pathology information systems – both to allow the pathologist to review the results before rendering a diagnosis and in synthesizing all the patient's results with the final diagnosis for the clinician.

New Information Demands

In addition to arming the pathologist with a full view of the patient's laboratory results, having a complete picture of all the testing performed in every area of the laboratory also benefits the laboratory director. The ability to pull information related to all the testing performed throughout the laboratory aids in managing the laboratory in a variety of ways: for management reporting, correlating comparative test results for quality assurance and identifying potential training/education needs, staff planning, business intelligence purposes, community health monitoring, and meeting the requirements of accreditation organizations.

The ability to deliver one, complete report with the most comprehensive diagnosis and full explanation of the patient's condition as possible 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 laboratory 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/her patient population results to help his/her office understand better laboratory test ordering patterns and to identify disease trends.

The true advantage of the electronic health record is a full picture of the patient's health over time – 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. Until the goal of the truly complete, portable EHR is realized however, the laboratory can benefit from an integrated 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.

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 anatomic pathology LIS 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.

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