This issue of Critical Values continues the conversation about issues raised in the ASCP Task Force Report on the Future of Pathology and Laboratory Medicine (see January 2008 Critical Values, pp. 28–34). As the report made clear, we are undoubtedly in the midst of a technological revolution. "The manner in which the professions of pathology and laboratory medicine embrace this revolution will determine our future," the report states. "If we choose to incorporate these technologies into our daily practice, we will be central to patient care. If we do not transform ourselves, we will be peripheral players at best."

Molecular diagnostics is no longer a blip on the horizon. It is upon us and, I hope, not passing us by. According to the Task Force report, "Laboratory professionals have not moved as aggressively to appropriate molecular diagnostics as they could have, and the window to do so is closing."

Thought leaders of the profession have of late been mulling over a way for pathology to embrace and appropriate molecular diagnostics, and it involves an unprecedented collaboration with radiology. Not long ago, the prospect of merging these two disciplines would have been met with resounding rejection.

As a harbinger of the very near future, three articles in this issue of Critical Values either mention or explore in greater depth the relationship of pathology to radiology in molecular diagnostics, digital imaging, and laboratory informatics. Look closely—we are already interconnected.

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Just as many of us have begun wrapping our minds around the boggling implications of molecular diagnostics for the profession, along comes nanotechnology. If you haven’t read much about it—and even if you have—Dr. Jason Park’s article offers a fascinating glimpse of the new wave of nanotechnology applications coming to clinical laboratories.

If nanotechnology seems a tad remote, turn to Dan Haun’s article about practical Web applications for the laboratory. Here are tools you can apply in your laboratory today.

Mindful that we can easily get too engrossed in technology, this issue also presents a call to emerge from the laboratory and improve our relationships with our fellow health care professionals. A laboratory professional, a nurse, and a dermatologist—all in one family—have pooled their experience to share successful strategies.

Each issue of Critical Values features an article about some aspect of critical values, such as the challenges in defining, detecting, or communicating them. We welcome Dr. Teresa Darcy’s important contribution to this issue and invite you to share some of the challenges you have faced and the successful strategies you have implemented.

Speaking of reader responses, the first two issues of Critical Values generated some interesting feedback, so we have added a department called Your Letters. Tell us what you think of the publication. Comment on the content of an article. Suggest issues to cover, people to meet. We like to hear from you.

Finally, after taking all this in, meander to Arts in Culture for an enjoyable respite from the world of technology with serene paintings by pathologist Jack Frable. The October issue will explore the value of the workforce in pathology and laboratory medicine.

Dr. Hilborne is president of ASCP.
Great Job!

Critical Values is an outstanding publication and one that I keep going back to for reference. It puts the laboratory profession in an extremely favorable light, stressing collaboration, international commitment, and the positive role that pathology continues to play. Everyone in our group found it fascinating and useful.

Betsy Cicora, MS, MT(ASCP)SH
Faculty, Medical Technology Program
Morgan State University
Baltimore, MD

importance of digital imaging

I enjoyed the article “The Future of Pathology and Laboratory Medicine: An ASCP Task Force Report” in the January 2008 issue (pp. 26–34). The article discussed “imaging” as a potentially bad thing for laboratory medicine (you may not mean to, but it seemed to read that way). I am a clinical laboratory scientist currently working in the capacity of clinical application coordinator for the electronic health record for a remote governmental critical access hospital. The remote location of the facility makes the possibility of imaging services for pathology reports—that most hospitals are in competitive situations, the focus of action. By “business of health care” I am speaking about health care informatics, actuarial analysis, marketing, patient aggregation, health education, and more. Data is a vital asset, and those who compile it and understand it certainly should have an active role in the dissemination of the information and its use.

The ASCP Task Force on the Future of Pathology and Laboratory Medicine has recommended that in order to stay viable, the laboratory must work with the patient’s best source of information about laboratory results. Considering that most hospitals are in competitive situations, the focus of “forward-thinking” institutions is on outreach and patient aggregation. The laboratory should be at the forefront of these efforts by capturing data and using informatics (see samples below) to create meaningful reports for patients, prospective patients, and their physicians.

The laboratory is best suited to assume this responsibility on behalf of the hospital and the other members of the clinical team that will benefit through improved community relations. These efforts can focus on the general population or on outreach efforts that target area businesses. The return on investment in these programs can be tracked through patient activity in the hospital and in referrals to members of the medical staff.

In programs for hospitals and businesses, our company harnesses the data and utilizes informatics, as suggested by the Task Force, with a focus on predictive modeling.

Improving Service to Consumers

I read the April 2008 issue of Critical Values with particular interest. Laboratory professionals continue to look for a place at the table with other disciplines involved in health care delivery. The mindset continues to be one in which the laboratorian is looking for acceptance. This baffles me because in the business of health care those with the data dictate the course of action. By “business of health care” I am speaking about health care informatics, actuarial analysis, marketing, patient aggregation, health education, and more. Data is a vital asset, and those who compile it and understand it certainly should have an active role in the dissemination of the information and its use.

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Participants receive a report (see Figure 1) detailing an overview of their personal risk for key areas of chronic illness. This report tells them their personal risk of developing coronary heart disease, coronary heart failure, or diabetes or having a stroke and more in the next five years. Perhaps of more importance is the chart that breaks down specific areas of modifiable risk (see Figure 2).

The general public is looking for personal health data. The aging boomer population is determined to have actionable data that they can translate into a longer, happier, and more productive life. The April issue of Critical Values mentions the value of the customer service culture in laboratory medicine. What better way to provide service than by reaching out to the community and interacting with people before they become patients. They are thirsting for information and are ready to embrace and assimilate much of what laboratorians can share with them.
When many people hear the term nanotechnology, they think of listening to music on an Apple iPod Nano. For older generations, nanotechnology may evoke Hollywood movies such as Fantastic Voyage or Innerspace, in which miniaturization is used to explore the human body. In today's reality, researchers are upstaging Hollywood by developing nanoscale devices that rival the size of individual proteins and molecules of DNA.

Nanotechnology is the study and manipulation of objects in the nanometer (10^-9 meter) scale. At this scale, a single base of DNA is approximately a third of a nanometer (nm), and the height of an immunoglobulin molecule is approximately 10 nm. In recent years, devices and reagents that utilize nanotechnology have appeared in the clinical laboratory. In the coming decades, nanotechnology will have a dramatic impact on clinical laboratory diagnostics.

The roots of nanotechnology extend back to the 1950s. Then, physicists such as Nobel Laureate Richard P. Feynman theorized that there were tremendous opportunities if objects could be visualized and manipulated at the nanometer scale. Since that time, the discipline of nanotechnology has evolved from the realm of the theoretical to the practical. Within the past ten years, public and private funding of nanotechnology has grown dramatically. For instance, in fiscal year 2007, the United States Government funded $1.39 billion of nanotechnology-related research through the National Nanotechnology Initiative.

Consumer Applications

Total international private funding for nanotechnology-related research in fiscal year 2007 is estimated to be greater than $7 billion. Novel industrial and consumer products have been developed, including faster computers, stronger materials, stain-resistant fabrics, and transparent sunscreens. Indeed, nanotechnology and nanoscale science have begun to permeate everyday products.
Nanotechnology-enabled devices have also begun to appear in the clinical laboratory. Clinical laboratories have already begun utilizing nanoscale-fabricated reagents to enhance current methodologies. For example, the commercially available semiconductor nanoparticles known as quantum dots are being employed in immunology and flow cytometry.1

Quantum dots can be predictably tuned based on their size and shape to retain the same excitation wavelength or to have a multitude of distinct emission wavelengths. These optically tunable particles are solving problems in multiplex test formats and creating new opportunities in expanded parallel analysis of analytes. In addition, quantum dots have been found to be brighter in emission and more resistant to photobleaching than traditional fluorescent dyes.

Another application of nanoparticles and nanostructures is as scaffolds for enzyme labels. While traditional immunoassays utilize one to several enzyme label molecules per antibody or DNA detection molecule, hundreds of thousands of labels can be bound to a single nanostructure associated with an antibody or DNA detection molecule. The result has been DNA and protein assays with detection at the attomolar (10\(^{-18}\)) level.4

The obvious applications of this technology will be higher sensitivity nucleic acid assays, immunoassays, and tissue immunohistochemistry testing.

Laboratory Applications on the Horizon

In the next wave of clinical laboratory nanotechnology, assays will be developed that completely replace current methods of laboratory diagnostics. A prime example is nanopore-based sequencing of DNA, a reagent-less technology that sequences non-amplified single molecules of DNA.1

Briefly, nanopores operate on a principle similar to Coulter Counters. Small pores that have a diameter of approximately the width of a single-stranded DNA molecule are ion beam-etched or -drilled through silicon nitride membranes. As the molecule of DNA traverses the pore, each A, T, G, or C nucleotide momentarily blocks the pore and creates a unique change in resistance to the flow of current, which can be measured. By analyzing these changes in resistance, the sequence of DNA can be derived.

In addition to being a reagent-less, non-amplification assay, nanopore-based sequencing offers the possibility of a throughput of tens of thousands of bases of DNA in a single second. If this technology can be perfected, the question for the molecular laboratory of the future will not be which genetic tests are on the menu, but how to interpret and report an individual’s entire genome, amounting to terabytes of data.

A future powered by nanotechnology offers many possibilities, but this optimism should be tempered by a realistic understanding of the potential implications for human health and the environment. The concern raised by the quick integration of nanotechnology into consumer products is that the safety profile of nanoscale materials (e.g., nanoparticles) has not been thoroughly examined. The few studies that have been conducted indicate that nanoparticulates may behave like other fine aerosols in their reaction with the respiratory and gastrointestinal organs.6 At this time, there appears to be no certainty about the final impact of high levels of nanostructures on human health and the environment. However, research is being conducted on many aspects of nanotoxicity and the environmental impact of nanomaterials.7

As laboratory professionals, we are required to constantly update our techniques and methods with new and improved technologies. Although it is too early to determine the full impact of nanotechnology and nanoscale science, we have begun to see the potential of nanotechnology to innovate and change the practice of the clinical laboratory.

References


Dr. Park is Co-Director, Center for Biomedical Micro- and Nanotechnology, and Resident, Anatomic and Clinical Pathology, Department of Pathology and Laboratory Medicine, Hospital of the University of Pennsylvania, Philadelphia, PA.
Integrating Digital Imaging into the Health Care Enterprise

By Lisa D. Duncan, MD, FASCP

Like pathology, radiology is visual and image-based. The number of digital images that can be produced by a CT scanner or MRI is astounding. When CT scanners were initially developed and implemented in the late 1970s, the need for convenient digital storage of large volumes of digital images became apparent. As a result, picture archiving and communication systems (PACS) were developed to archive, retrieve, and view images produced by multiple modalities. PACS were originally intended primarily for image storage. However, with time, their function evolved to include data and workflow management. Problems of integrating patient-related demographic information with acquired images threatened to stymie the advancement of PACS as a tool for increasing productivity and efficiency. DICOM Standard

The primary issue afflicting the first PACS was a lack of standardization between image acquisition instruments, data input devices, and vendors’ proprietary protection of image formats. In 1983, the American College of Radiology and the National Electrical Manufacturers Association formed a joint committee to develop standards to allow digital image information to be taken out of a modality over standard hardware by using a standard format. As a result of this collaboration, the Digital Imaging and Communications in Medicine (DICOM) standard was created. The first standards were published in 1992 and continue to evolve. Essentially, the DICOM standard is a set of rules that standardize the flow of information between acquisition devices, PACS, and information systems. Without DICOM standards, PACS as we know it today would not exist. In the modern PACS environment, patient demographic information is obtained by the radiology information system (RIS) from the hospital information system (HIS) via an HL7 interface. HL7 messages from the RIS enter PACS through the broker, a software and hardware device that translates HL7 messages into DICOM format, allowing demographic, insurance, and other information to be linked to a particular study. Demographic information obtained from the HIS as well as image parameters are incorporated into final images as both hidden and displayed DICOM headers. Examples of displayed headers are patient name, medical record number, and study date/time, which appear directly on the image. Hidden headers are detailed image characteristics that can be viewed by a PACS administrator. The resulting images can be viewed by radiologists at a PACS workstation or by other clinicians through Web-based browsers.

The impact of PACS not only on radiologist productivity but also on patient care is immeasurable. Its importance lies in facilitating the dissemination and portability of medical information, thereby improving patient care. Much can be learned from the PACS experience of radiologists and applied to the practice of other specialties. Since pathology and radiology are visual practices, the same principles of image storage and retrieval can be incorporated into the implementation of Pathology PACS.

Storing in PACS

Simply put, PACS is a storage device and, as such, can accommodate images other than those originating from CT scanners and similar modalities. In pathology, the camera is the modality. At the University of Tennessee in Knoxville, we have been storing gross and microscopic pathology images in PACS for approximately four years. Other institutions have reported their experience with anatomic pathology image storage in PACS. Workflow at present is suboptimal. An order for a diagnostic pathology image must be manually entered into the HIS so that patient demographic data can ultimately be linked to the images. This is necessary because no HL7 interface exists between the camera (the modality) and the RIS. PACScan software is used to convert locally stored JPEG images to DICOM format. It then queries the RIS via the broker and allows linkage of patient demographic data to images upon storage into PACS. The PACScan software essentially connects the camera to the RIS. Currently, a limited number of pathology images are stored in PACS because of workflow issues. Examples of cases suitable for archival in PACS are medicolegal cases, pathologic findings that alter the stage of cancer cases, immunostains for target chemotherapy, and cases with only one diagnostic slide. Because nonpathologists view these images in PACS, pertinent findings should be annotated to assist in interpretation. Pathology images stored in PACS conform to Radiology DICOM standards for the terminology for attached headers. For example, images stored as a group are labeled as a series, akin to the way images from an MRI are designated. Working Group 26 is an international assemblage of pathologists, technologists, software engineers, and others who have established DICOM standards for pathology images. These standards define the parameters by which accession number, specimen part, stains used, SNOWMED codes, and the like are attached to images. Pathology PACS began as an experiment at our institution but has become a valuable tool in patient care. Pathology images stored in PACS are used at intradepartmental working conferences, and they invariably improve the quality of case presentation and discussion. Because these images can be viewed in PACS alongside

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radiology images, accessibility of pathologic information is enhanced in a format that is quick and easy to understand, often providing clinico-pathologic correlation with radiographic findings.

Working Group 26 has also developed DICOM standards for storing whole scanned slides, thus permitting storage into PACS. Though the technology is not fully developed at present, slides prepared in a histology laboratory, sent to a laboratory information system (LIS), and then stored in PACS. These cases would appear on a pathologist’s worklist, not unlike that used by radiologists, and signed out by viewing scanned slides on a computer screen.

Technology exists to create Pathology PACS LIS, but acceptance of this new methodology by the pathology community will likely take years. Twenty years ago, the radiology community faced similar change, and many thought the concept of PACS would never evolve. However, PACS has transformed the specialty of radiology and has the potential to do the same for the specialty of pathology. Pathologists can learn much from our radiology colleagues.

Radiologists now face the dilemma of foreign physicians signing out cases offshore. Pathologists need not think that something similar cannot happen to them. ASCP and the College of American Pathologists must organize to lobby for legislation to prevent this from happening to pathology before the technology becomes widespread.

Imaging for the Enterprise

As the use of pathology images in PACS progressed at the University of Tennessee Medical Center, we found that images from other specialties could also be stored in PACS. Cardiology, gastroenterology, and pulmonology are only a few of the specialties that generate large numbers of digital images. We also began obtaining intra-operative images of interesting tumor cases and responding to calls from a physician clinic to photograph physical examination findings. The accuracy and speed of conveying information in cases with photographic documentation of all studies contributing to the final diagnosis are nothing short of phenomenal and epitomize the concept of enterprise imaging (EI).

EI involves centralized storage of all patient-related images through storage in a hospital-wide PACS. The potential for an enterprise-wide PACS has been discussed by others authors, and its implementation should be modeled after Radiology PACS.7,8 Modalities from various specialties must have an HL7 interface with the HIS so that the patient demographic data can be linked to stored images without the need for manual entry. Modalities would also require HL7 interfaces to an enterprise image information system (EIIS), which would have a function analogous to that of the RIS. The EIIS would organize storage of all images into a unified PACS.

EI exemplifies a multidisciplinary approach to patient care by providing instantaneous access to all diagnostic studies contributing to a patient’s diagnosis. Rapid dissemination of data is required in today’s complex medical world, because it improves patient outcome through improved communication and reduction of errors inherent in paper-driven distribution of information. Clinical informatics has been identified as one way in which patient safety can be accomplished.

The 2005 National Patient Safety Goals are centered on a patient-focused medical record. Patient safety is improved by accuracy of patient identification and increased communication among caregivers. For instance, the verification procedure required prior to a surgical procedure could be documented by storing images in PACS that illustrate the marked surgical site. For EI to reach its full potential, all images must be stored in a single centralized PACS. In addition, all images must conform to DICOM standards, necessitating development of standards specific for each specialty. Adherence to the DICOM standard is pivotal because this element allows portability of the medical record between institutions and different information system vendors. Some HIS packages sell servers that store patient images. These packages are not the solution for image storage in the health care enterprise because images are not saved utilizing strict DICOM format.

Integrating Enterprise Imaging into the Electronic Health Record

The evolution of PACS has paralleled the growth of the HIS. The HIS has, thereby enhancing the medical impact of image retrieval in daily practice.11-12 In an integrated electronic medical record (EMR), documents on a particular procedure would be linked to analogous images stored in the enterprise-wide PACS. When a report is viewed in the HIS, a view image link, when clicked, would interface with the PACS and allow simultaneous viewing of the report and stored images. Such a system would greatly improve the accuracy and efficiency of patient management.

Before an integrated EMR can be implemented, the HIS and the PACS must be able to communicate. The major impediment to implementation of an integrated EMR is competition between vendors. The HIS and the PACS are often supported by different vendors within the same hospital who will not share proprietary images necessary to create links between the two systems. This hinders the experience of radiology in the early stages of PACS development. Despite the obstacles, the goal is achievable.

The Pathologist’s Role

The return on investment for medical digital imaging is intangible and can be quantified only in terms of improved patient care. Pathologists’ experience in digital imaging for the pathologist record can serve as an example for physicians in other specialties. Pathologists can function as leaders in this endeavor. Pathologists must push vendors to create the HL7 interfaces needed to connect modalities throughout a medical center to the HIS as well as to the hospital-wide PACS. Since DICOM standards for storing pathology images in PACS have already been established, pathologists can assist other specialties in constructing their own DICOM standards. Once the benefit of imaging for the medical record has been established, professional societies must organize to create imaging CPT codes to reimburse physicians for their time.

At the heart of an integrated EMR is the marriage of the PACS and the HIS, thus allowing the simultaneous retrieval of clinically relevant images and associated reports at the point of care.

Dr. Duncan is Associate Professor and Residency Program Associate Director in the Department of Pathology at the University of Tennessee Medical Center, in Knoxville, TN.

References

The integrated model of total diagnostics is driven not by symptomatology but by total health surveillance using preemptive evaluative services intended to thwart future disease. With the Early Health Model, pathology and laboratory medicine take the lead in this paradigm, because molecular diagnostics serve as the first step for determining presymptomatic disease. “Wellness” biomarkers, periodically performed to optimize health screening, would transform the annual physical from a symptomatology-based experience (in part) to a surveillance exercise. This paradigm will require robust laboratory information systems, Friedman noted. Blended diagnostic departments would require an integrated IT infrastructure with synergy across radiology, pathology, and laboratory medicine. This would be necessary to prevent the “swallowing” of diagnostic data by inadequate electronic medical records.

Future Considerations

In the future, molecular imaging will likely involve the use of novel biomarker probes to recognize in vivo targets, which in turn allow for greater quantitative analysis of the specific disease state. Nanotechnology, defined in this case as the use of in situ biomarkers or radiotracers, shifts the focus of diagnostics from the mere identification of a lesion to the art of total discovery. King Li, MD, Professor, Weill Cornell Medical College, New York City, and MD Anderson Distinguished Chair, Department of Radiology at the Methodist Hospital, Houston, Texas, described the current environment of diagnostic medicine as simply diagnosis and treatment. He envisions the revised paradigm to be quite different within two years (2010)—predisposition of disease is followed by focused screening, early detection, individualized treatment, and eventually therapeutic monitoring. The one-size-fits-all theory of diagnosis and treatment clearly ignores the genetic diversity of humans. As a result, the innovative field of interventional radiology is emerging as a vehicle for delivering molecular and functional imaging. It does so by guiding interventional molecular therapy with nanoscale particles targeted to visualize, target, and treat disease in vivo. This creates a seamless approach to diagnosis and treatment (including appropriate therapeutics).

An integrated system would include an effective monitoring scheme for the evaluation of the patient’s disease. Amazing, but not unrealistic: Nanoparticles are being designed for complete diagnosis and treatment of disease. The future of “Star Trek” medicine is in fact a reality, most likely coming to a hospital near you.

Dr. Holladay is Vice President for Scientific Activities for ASCP and Executive Director of the ASCP Board of Registry, Chicago, IL.
Perils and Imperatives of Regulating Genetic Testing

By Andrea T. Bennett, MPH, MT(ASCP)

Genetic testing is increasingly being integrated into standard practice for diagnosing and managing disease, predicting the risk of developing disease, and informing decisions about lifestyle and behavior. Employing combinations of biochemical, cytogenetic, and molecular methods to analyze DNA, RNA, chromosomes, proteins, and selected metabolites, these tests are enabling improved prevention, treatment, and disease management for chronic conditions such as cancer, heart disease, and diabetes.

The significance of the information gleaned from genetic tests and their expanded use in clinical practice and public health have prompted a debate over how these tests should be regulated. A broad range of stakeholders have weighed in on the issue, with as broad a range of opinions on which government agency should have oversight authority and exactly how it should be accomplished.

Some claim that oversight of genetic tests—and the laboratories that offer them—leaves enormous gaps that threaten public health. Others contend that genetic tests are no different than other laboratory tests and that the current system of oversight is adequate. In fact, they assert that any additional regulation could actually harm public health by creating roadblocks to innovation. However divergent these viewpoints, all claim their positions are motivated by the best interest of public health.

Taking these divergent views into account, a Department of Health and Human Services (HHS) advisory committee recently issued its recommendations to strengthen existing regulations—an important step in the difficult process of developing appropriate oversight.

Current Systems of Oversight

Genetic testing is under federal purview through the FDA and the Centers for Medicare & Medicaid Services (CMS). These tests take one of two main pathways to clinical practice: Manufacturers develop (1) in vitro diagnostic (IVD) tests for distribution to multiple laboratories and (2) laboratory-developed tests (LDTs) for sole use in the test developer’s laboratory.

The FDA regulates genetic tests that qualify as medical devices and IVD devices, which include test kits and analyte-specific reagents (ASRs). ASRs may be antibodies, receptor proteins, nucleic acid sequences, and other biological or chemical reagents used to identify or quantify substances in biological specimens. Only recently has the FDA exercised its regulatory authority over LDTs.

Regulation of those tests has been left, for the most part, to the Clinical Laboratory Improvement Amendments of 1988 (CLIA, the regulations governing the laboratories that develop LDTs). Many have called for a closer examination and coordination of the dual regulations of FDA and CLIA. In addition, bills introduced in the 110th Congress addressed the oversight of genetic testing.

At the state level, many agencies rely on CLIA requirements to regulate genetic testing laboratories. However, some states, such as New York and Washington, operate independent state laboratory certification programs that are exempt from CLIA because CMS has deemed them equal to or more stringent than CLIA requirements.

The New York State Department of Health has one of the most stringent state-level oversight systems, requiring pre-market approval prior to offering a genetic test in a clinical setting. In fact, all laboratories that solicit and receive specimens from New York are also subject to these clinical laboratory requirements. This means approximately 75 percent of all cytogenetic and genetic specimens testing in the United States is subject to New York State oversight.
Definition of a Genetic Test

One basic but significant issue in this debate is the definition of a genetic test. Are genetic tests so different from other laboratory tests that they necessitate a different kind of regulation? As far back as 1997, a task force created by the National Institutes of Health Department of Energy Working Group on Ethical, Legal and Social Implications of Human Genome Research suggested that CLIA requirements were inadequate because they were not specifically designed for emerging molecular genetic tests.

More than 10 years later, a commonly agreed-upon definition remains unresolved, and the adequacy of oversight for this loosely defined set of tests remains in question. Because genetic testing is an evolving technology, it remains difficult to define, but too broad a definition, some fear, could potentially encompass a number of established tests that to date have posed no concern in the medical community to the public health.

Another concern is that the government exercises only limited oversight of the analytical validity and virtually no oversight of the clinical validity of genetic tests. Only analytical validity is enforced under CLIA. The prospective clinical validity of a test, however, is often unavailable or incomplete for years after a test is developed. Certainly, the FDA does play a role in evaluating the clinical validity of genetic tests through its activities to assess “safety and effectiveness.”

Nevertheless, the establishment of clinical validity for predictive or presymptomatic tests requires the collection of data and sharing of information between laboratories only after the test has been in use. An evaluation of clinical performance depends on the nature of the test, its intended use, and the amount of existing information about the relevance of genetic markers to a clinical diagnosis.

Laboratory Performance

Questions also surround the sufficiency of CLIA’s requirements for assessing the performance of genetic testing laboratories. While CLIA requires laboratories to have quality assurance programs in place, most are not required by CLIA to perform proficiency testing unless they are testing a small subset of established analytes regulated under CLIA. At present, this does not include genetic tests.

Genetic tests, particularly ones used to predict future development of disease, are highly complex assays, yet there is currently no assessment of laboratory competence by comparison to an established external standard. Moreover, CMS has not created a genetic testing “specialty” for molecular and biological tests. Therefore, specific proficiency testing (PT) for these genetic tests is not mandated under CLIA. Some laboratories are using PT programs developed by professional organizations, but only for a small subset of the genetic tests currently available.

Clinical utility, a measure of the potential health benefits and harms of using a genetic test with patients, is another critical element in the translation of genomic applications into clinical practice. However, clinical utility data, essential for both the effective management of patients and the development of professional guidelines, are limited. To complicate matters, health care payers are increasingly calling for such evidence in order to make reimbursement decisions. Given the costliness of these tests, accessibility to them for most patients will depend on coverage.

Probably the greatest area of concern now is the burgeoning market of direct-to-consumer (DTC) genetic testing, offering consumers the opportunity to find out about their genomics on their own. Consumers mail in their specimens, which are cheek swabs or saliva samples. For a hefty fee, their extracted DNA is compared with a database to provide an analysis of their risk for developing certain common diseases. The DTC genetic testing market even offers at-home paternity testing as well as genetic tests that claim to help individuals find DNA-compatible mates.

The field of DTC genetic testing remains effectively free of regulatory oversight, yet consumers may well be using these services to make health care decisions. If consumers are expected to share their results with a physician, then, in theory, the laboratories offering these tests should be CLIA-certified.

Secretary’s Advisory Committee on Genetics, Health, and Society

Clearly, the regulation of genetic tests contains significant gaps. Two years ago, the Secretary’s Advisory Committee on Genetics, Health, and Society (SACGHS), a group that provides policy recommendations to the HHS, began a concentrated effort to assess the various systems of oversight of genetic testing. Since then, a number of stakeholders in the genetic testing community, including government agencies, professional organizations, industry, academia, advocacy organizations, and health care providers, have weighed in on the issue.

While many agree that dangerous gaps in oversight exist, many others warn that lengthy approval procedures would delay implementation of new tests, stifle innovation, increase development costs, and thus limit patient access to potentially beneficial assays. Moreover, smaller laboratories could be forced to abandon this area of testing, causing large corporations to outsource the clinical implementation of these progressive diagnostic assays overseas, precluding Americans access to cutting-edge therapeutic options.

In February 2008, the SACGHS heard testimony from public and private stakeholders. After the hearing, then-Committee Chair Reed V. Tuckson, MD, summed up the challenge before the committee: “No matter what we do, every genetic testing is going to be upset with us. We will not have a friend in the world when this is over. I just wish you could all find someplace where everyone could agree so we wouldn’t have such a hard time. Boy, we are going to get yelled at everywhere.”

Sweeping Changes Proposed

In May 2008, SACGHS submitted a report to the Secretary of HHS calling for sweeping changes in genetic test regulation to strengthen weak or nonexistent areas of oversight as expeditiously as possible. The committee defines “oversight” broadly in the report, to include not only federal and state governments and agencies but also standard-setting and knowledge-generating organizations, health care payers, professional societies, health care providers, patients, and consumers. The recommendations call for improved coordination of regulatory activities between agencies as well as the development of public-private partnerships to enhance oversight.

Specifically, the committee recommends that CMS require PT for all non-waived genetic laboratory tests for which PT products are available, and that HHS fund studies to evaluate alternative performance assessment methods to determine whether they can be as effective as PT. Currently, CLIA requires PT, considered the most rigorous form of performance assessment, for all non-waived tests. In theory, genetic tests should undergo PT, but because the technology for these assays is so new, few suitable materials are available.

With the advent of genetic testing comes the realization of significantly more effective diagnoses, therapeutics, and patient care. Genetic testing is the frontier for modern clinical diagnostics for common diseases, such as cancer, heart disease, and diabetes. These assays allow for nimble clinical intervention utilizing the latest published research. Requiring lengthy approval processes before these tests can be made available to the public might hinder the development of these assays, preventing researchers from translating findings into clinical practice.

At this early stage of the genetic diagnostic era, it is essential that the regulatory infrastructure be sufficiently meticulous to safeguard the public without being so burdensome that it impedes the emerging technology.

Ms. Bennett is Senior Program Manager for Membership and Public Policy for ASCP, Washington, DC.
Informatics Trends Create Professional Opportunities

By Candace Golightly, MA, MLT(ASCP)

Emerging technologies and trends forecast at the 2008 Lab InfoTech Summit in April in Las Vegas (www.labinfotech.com) illuminated the enormous role of laboratory informatics in pathology and the clinical laboratory.

Consider the much-discussed potential for merging pathology and radiology into a new discipline of diagnostic medicine. Specific diagnoses can be made by overlapping radiology, pathology, and molecular imaging. A new era of laboratory testing will require complex computer algorithms that interpret the test results of molecular diagnostic biomarker sets. The premise behind these multiplex biomarker assays in molecular diagnostics will lead to presymptomatic/preclinical detection of diseases.

The LIS–EMR Interface

In the meantime, laboratories face a more immediate concern. Hospital information technology (IT) is still having a difficult time managing data from clinical and anatomical laboratories. Even though the development of integrated delivery networks (IDN) is not new, the ability to interface disparate laboratory information systems (LIS) with the electronic medical record (EMR) can still be a major challenge.

Formatting the data from chemistry, for example, is often difficult because of different test names, testing methodologies, resulting codes, and reference ranges.

Interfacing disparate systems remains one of the biggest problems. LIS vendors and third-party “middleware” companies work toward integration, but multiple versions of the communication standard HL7 obstruct the way to an electronic patient record.

Communication standards are crucial to the goal of interoperability; nevertheless, the various versions of HL7 sometimes differ among vendors. Standardizing the LIS and laboratory operations, and utilizing master patient ID indexes, may improve the interface between laboratory information and the EMR. Maintaining the interfaces, even in HL7, can be a challenge. Testing all those interfaces to meet laboratory regulations is an arduous task and requires a great deal of resources.

In addition, although test results from most departments can be captured into the LIS, longer test, updated results, and preliminary and then final reports pose problems. Anatomical pathology systems can integrate some tests, such as flow cytometry and molecular testing, but in many cases clinical laboratory systems are inadequate for these tests.

The LIS is still seeking options to handle digital images. Some systems have developed thumbnail images for reports but lack other image options. Scanned and native images are not always part of the application and need to be stored separately. Not all HL7 interfaces support image transfer, and not all EMRs have the ability to receive them.

Enter the Workforce Issue

The never-ending demand for these and other laboratory IT initiatives, in both clinical and research laboratories, raises an important question: Where will the workforce come from to accomplish this?

In the April 17, 2008, issue of Science Daily (www.sciencedaily.com), William Hersh, MD, Professor and Chair, Department of Medical Informatics and Clinical Epidemiology, Oregon Health & Science University, Portland, Oregon, stated that “a 40 percent hike in IT workforce will be needed to move U.S. health care toward a paperless system that controls costs and reduces medical errors.”

The American Medical Informatics Association has a program called “10 X 10™,” which aims to train 10,000 IT professionals in the United States by 2010 (www.amia.org/10x10/). The association recently expanded its effort, renaming it the “20 X 20” program with the goal of training 20,000 IT professionals internationally by 2020.

Informatics must be integrated into the curriculum of pathology and clinical laboratory science education and training programs. Pathologists must educate colleagues about the discipline of health care informatics so they can do their jobs better and improve both patient care and laboratory service. In fact, training and education in informatics should be required for all health care professionals—nurses, medical students, pathology residents, fellows, pathologists, and clinical laboratory scientists.

Opportunities in IT are now and will continue to be available. While an informatics curriculum must be tailored to the needs of each discipline, every program must include baseline competencies that convey the importance and relevance of informatics in pathology and laboratory practice. Areas of learning include technical, administrative, compliance, and regulatory issues.

Informatics Credentialing

Like many other clinical laboratory scientists, I gained my LIS experience on the job. I worked as an LIS manager at J.T. Mather Memorial Hospital, in Port Jefferson, New York. My supervisor was Dorothy O’Mara, MT(ASCP), the LIS/IT manager. Like thousands of other clinical laboratory scientists, Dotty is invaluable to the informatics team and should be given the opportunity to earn a credential for her hard-won knowledge and experience. Credentialing offers more than self-gratification; it offers professional recognition, job advancement, and new career opportunities.

The ASCP Board of Registry offers one such credential: the Qualification in Laboratory Informatics (QLI). Applicants meeting one of three routes of eligibility must complete a written project demonstrating their overall LIS knowledge and troubleshooting abilities. The ASCP Board of Registry recognizes that clinical laboratory information requires a distinct body of knowledge, and the QLI provides professional recognition for that knowledge and skill set.

Laboratory informatics is becoming more diverse and complex. Educators, pathologists, and clinical laboratory scientists must actively promote more informatics education and technical training to help shape the future of the clinical laboratory.

Ms. Golightly is Clinical Associate Professor and Clinical Coordinator in the Department of Clinical Laboratory Sciences, School of Health Technology and Management, Stony Brook University, Stony Brook, NY.

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Change the World with Web 2.0 Tools

By Daniel E. Haun, MT(ASCP)H

Imagine this: Tuesday night was busy and challenging for the second and third shifts. Now it is Wednesday morning, 0800h, and three hematology slides and one cytospin of pleural fluid are saved for the pathologist’s review. A quick scan reveals a pseudo Pelger-Huet anomaly, blast cells, a megakaryocyte on an otherwise normal differential, and a large number of malignant cells on the cytospin. The camera is turned on, the recording is started, and in short order a narrated response is created for each case. Fine points and tips are explained and the significance of findings reviewed. By 0830h the movies are made, compressed, and attached to the daily hematology blog for the technologists. By Thursday at this time, all the technologists will be up-to-speed and informed.

The bad news is that a system to do what has been described is not currently available. The good news is that such a system can be assembled, mostly for free. You will have to learn a few new things or find a savvy technologist, who is probably already working in the laboratory. Look for the person who has a blog, uses Real Simple Syndication (RSS), and likes a challenge. The following are four things you need to learn.

1. Learn to record and narrate movies from the microscope camera.

   The technique is simple but is harder to describe than to actually do. Find the analog output on the camera—it looks like those on VCRs and DVD players. Send this output to an analog-to-digital video converter (ADVC) and then feed the video signal to the computer. At the same time, attach a USB microphone to the computer. Next, use recording software to record the video while narrating what you see. You should record in QuickTime format because it is the International Standards Organization standard for compressed video and allows easy editing and format conversion (QuickTime Pro). While recording, focus in and out so that the end user can reproduce the real microscopy experience.

2. Learn to compress video.

   Use QuickTime Pro to export the video into the compressed Moving Picture Experts Group-4 (mp4 or m4v) format, which can be read by computers, iPods, many cell phones, and other devices. Good compression reduces file size without reducing the quality.

3. Learn to blog.

   The blog (or Web log) is replacing the Web page as the Web communications tool because it is designed to be updated often and easily. Moreover, blog software allows for embedding and attaching multimedia files and for creating syndication feeds to reach all the technologists. First, get some blogging software (many packages are free), and then find a blog host site (a server that will hold your blog pages and attachments).

4. Learn about syndication.

   No doubt you have noticed the RSS icon on Web pages. RSS allows you to subscribe to a Web page’s “feed.” Once a person subscribes—via e-mail, iTunes, Web browser, or news aggregator—all updates to the page are automatically delivered to the subscribers, be they technologists, students, support staff, phlebotomists, or clients. Make the feed review part of the daily routine, and you can keep any audience informed.

   I have given you a lot to learn, but I hope that you see the potential of Web 2.0 tools in other areas. You are linking the power of multimedia to a powerful distribution system. Don’t confine yourself to microscopic video. Multimedia is a powerful tool, and you must become literate.

   Now go get a digital Web cam, learn to record video, and go after some other problems. Create a microbiology blog, use a point-of-care testing blog to correct operator errors, and update the phlebotomists and nurses about phlebotomy issues. You have a powerful set of new tools, so go change the world.

Mr. Haun is a consultant for the Louisiana State University School of Allied Health in New Orleans, LA.
Have you ever been to a Broadway show? It is amazing how smoothly the production usually goes. Occasionally, actors miss their lines, but their theatrical teammates help them recover quickly. Think about the health care team and how it operates. Is the "production" smooth? Does the "team" work seamlessly to get the job done? If we are honest, we know that we can certainly improve relationships within the health care team. As laboratory professionals, we need to examine how we integrate into the health care team and learn from other team members.

Numerically speaking, the top three health care professionals are physicians, nurses, and laboratory staff. It might be assumed that laboratory professionals interact with these other health care staff on a regular basis. However, recent surveys indicated that only 34 percent of laboratory professionals have regular meetings with nursing services and that 40 percent of laboratory professionals report no interaction outside the laboratory. From an outsider’s point of view, it seems that something is wrong with this picture.

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Does your health care team operate as smoothly as a Broadway production?

How to Fix the Problem

The first step is to look inward. As Dr. Lee Hilborne stated (see April 2008 Critical Values, p. 3), "pathologists and laboratory professionals must retrench themselves by becoming indispensable to the patient. How? By changing the commodity to a service." If we are deemed faceless cogs in the health care machine to nurses and physicians, then it should be no surprise that we are sometimes not valued. We do not have time to feel sorry for ourselves. If it seems we are "sitting on the bench" in the health care game, then it is time to insert ourselves into the starting lineup. We should learn from the nursing and medical professions. Nurses and physicians both rank themselves very high in their importance to the outcome of patients. Do laboratorians have the same perspective? Nurses and physicians are also ranked high by the public in trustworthiness and ability to give advice.

The ASCP Task Force Report on the Future of Pathology and Laboratory Medicine (see January 2008 Critical Values, pp. 28–34) recommended several ways to "ensure the viability" of our profession. Interestingly, many of the strategies are directly related to our ability to successfully interact and integrate with the "team" (e.g., advising the health care team on what tests are appropriate and how to interpret them). So why are laboratorians not acknowledged for their important role? The reasons include physical location, which may be "out of the way"; a lack of understanding of their background (i.e., the perception that laboratory professionals have little formal training); and a general ignorance of what they do. Does a recently graduated nurse truly understand the complexity of our profession? This nurse may think of "the laboratory" as a group that monitors point-of-care testing and seems to be slow at getting important results to the floor.

Practical Steps to Improve Professional Relationships

Can laboratory professionals do anything to become more visible and strengthen ties to physicians and nurses? Certainly. The following are some simple and pragmatic steps that can improve laboratorians' relationships with nurses and physicians.

1. Get out of the laboratory. Join committees and get to know the decision makers. Develop personal relationships with counterparts. It is amazing how quickly lower level issues can be resolved if a bench technologist personally knows a staff nurse in the emergency room.

2. Build on the commonality with other professionals. A recent study found that nurses are most concerned with the timeliness of results and physicians are most concerned with the quality of results. Laboratory professionals are concerned with both. What issues arise, a good start to a conversation with a nurse is, "Well, we both agree that you need the patient’s results as quickly as possible." Concentrating on the need for quality in results will aid in communication with physicians.

3. Invite nursing and physician leaders to formal and informal staff meetings and continuing education events. Make the nursing staff and the professional staff a key part of laboratory work; including them not only sends a positive message to them, but also lets laboratory staff know we are all on the same team.

4. Train staff on professional interactions with other health care professionals. It is critical that staff be deliberately trained. A little money and time spent in this way can pay huge dividends.

5. Treat all staff with respect. This is especially true with nurses. Talking negatively about other professions does not help the situation. If there are any former laboratory staff working as nurses, invite them to tell the laboratory the "nursing side" of the story.

6. Think about how far technology has advanced over the past century. Was this progress made by being satisfied with the status quo? No, we had an unquenchable desire to improve. We must take the same approach with professional relationships. We must never rest on our laurels when it comes to fostering and maintaining relationships.

Using the same dedication and effort we commit to providing quality laboratory support to patients, laboratory professionals can develop the quality relationships with the professional staff we deal with on a daily basis. By doing so, we will find ourselves more valued members of the health care team.
Paintings by a Pathologist: The Artwork of William (Jack) Frable, MD, FASCP

Professionally, Dr. Frable has been described as "a Godfather of Pathology" and "the man responsible for popularizing fine needle aspiration, which revolutionized the field of cytopathology." He serves as Professor of Pathology in the Division of Surgical Pathology, Virginia Commonwealth University Medical College of Virginia, Richmond, and as a member of the ASCP GYN PT & Assessment Committee.

As an artist, Dr. Frable was largely self-taught from high school until the early 1980s. From 1983 to 1990, he took formal classes at the Virginia Museum of Fine Arts and the Hand Workshop in Richmond, Virginia. For more information about Dr. Frable, visit:

www.papsociety.org/frable.html
www.uptownartgallery.com/Artists/jackfrable.html
www.pathology.vcu.edu/faculty_CV/frable.html
Reflections on Critical Values

By Teresa P. Darcy, MD, MMM, FASCP

Like many organizations, the University of Wisconsin Hospital and Clinics struggled to improve its processes for communicating critical results. A series of patient events across the spectrum of diagnostic tests confirmed that patients were still falling through the cracks at the handoff—after being discharged from the hospital or emergency department, after business hours, or when traveling unexpectedly between laboratories.

Laboratory staff were already doing what they thought was a great job with their piece of reporting, that is, getting the critical results from the laboratory to the clinical area. None of the patient events involved a failure of the laboratory to report a critical result.

Process Improvement

Laboratory staff were invited to participate and provide leadership in a larger discussion of how to improve the reporting of critical diagnostic test results. The primary goal was to improve patient safety, and a secondary goal was to meet regulatory requirements.

After the organization had participated in a city-wide initiative to reach consensus on a defined list of critical results, it took several years of discussion to determine a process for each type of patient to define how the critical result reached the responsible caregiver. Types of patients include inpatients, discharged inpatients, and outpatients of providers internal and external to the health system both during and after clinic hours.

Groups of attending physicians wanted all critical results reported directly to them. Others wanted all results reported to resident physicians, nurses, or mid-level providers. Outpatient attending physicians had different requests for communication than inpatient attending physicians. Surgical services differed from medical specialties, primary care from specialist residents.

Initially it was proposed that the laboratory report critical results directly to physicians. However, the communications infrastructure could not support the laboratory rapidly identifying the right physician—ordering, attending, admitting, primary care, service on-call—for any patient at any given time. Although this process seemed convenient in theory, a pilot test revealed the time for the laboratory to hand off information was significantly longer for reporting to physicians directly than for reporting to the patient location.

Direct reporting of critical results to physicians did not save phone calls, because then each physician called the clinical unit to elicit more information about the patient’s condition and to give verbal orders. The solution was that critical results for inpatients would be reported to the current physical location of the patient and not to an attending physician, who might be on campus teaching or in clinic.

Successes and Outcomes

Part of implementing the new process involved the design of documentation and reporting tools. Early involvement of staff members receiving the laboratory critical results was key to success. The outcome of the design process was laboratory information systems (LIS) and paper tools for improving the documentation of the laboratory report of the critical result, the readback, and the documentation of the clinical action that occurred as a result of the information.

The current process is stable and auditable. Monthly audits of more than 20 percent of laboratory critical results are tracked to the clinical outcome. In less than 5 percent of the audited events does documentation of clinical action exceed the set organization threshold, and each of those outliers is tracked. Today, even though not everyone agrees with the workflow that was designed, every person in the organization understands which individuals have accountability for the information at each step in the communication of critical results.

Lessons Learned

One key lesson learned was that each group of stakeholders—physicians, nurses, and laboratory and radiology departments—has a different and strong viewpoint on the right way to report critical results. When all the stakeholders agreed in principle that the important viewpoint was that of the patient, we were able to move forward.

The second lesson was that one organization’s workflow and process do not necessarily work for another. The temptation was strong to rapidly adopt a process that was being used at another organization but had no chance for successful implementation at our organization because of our unique aspects and degree of flexibility in meeting regulatory requirements. Organizations differ in infrastructure, size, geographic spread, available communication systems such as paging, and composition of the medical staff.

Third, although the laboratory has the highest volume of critical results to communicate, the organizational discussion and implementation had to be extended to include all diagnostic results.

Finally, the clinical laboratory could not own the entire process of critical result reporting. Tracking the accuracy and timeliness of information handoff from the laboratory was not a surrogate for ensuring that the information would be acted upon by the clinical team.

Challenges

Despite the stability of the current process, challenges exist and new challenges are on the horizon. In the near blizzard of data bombarding the clinical team, the laboratory is faced with many requests to provide more useful information. The physicians would like to have critical value triggers personalized by patient population, by patient condition, or by physician. Requests have been made to call them for all “significant” results, all “positive” results, or results that are “near” critical but have had a significant or rapid change from the last reported measure.

As an electronic health record is implemented throughout the system, the policies for reporting critical results will need to be readdressed. Potentially, the laboratory will have more real-time information about the patient’s care team and will know for each patient at any given moment who the responsible caregiver is and how he or she can be reached.

Currently, critical results are transcribed onto paper from a phone call and readback is accomplished. It does not make sense to transcribe information that has populated the electronic record through an interface, so there will be an opportunity to eliminate the transcription step.

The challenge is to ensure that the critical information is sent to the person who can act on it. Perhaps the message from the laboratory by phone or paging will be that
ASCP, in partnership with Harris Connect, will publish a 2009 Membership Directory, which will be available to members in the spring of 2009.

Starting in July of this year, Harris Connect will contact ASCP members via e-mail, postal mail, and phone to update member contact and demographic information. The directory will be shipped to members who choose to purchase it next spring. The directory will be available in a book and CD-ROM format.

To ensure that ASCP has your correct contact information, please log in to www.ascp.org and update your contact information online. All members will have the opportunity to decide which information, if any, they would like to have included in the membership directory.

The ASCP directory will be available to ASCP members and staff only. Harris Connect follows strict security protocols and does not sell or rent member information to third-party vendors.