

The “globalization” of the medical lab

By Carren Bersch, *MLO* editor

One of the harbingers of global laboratory science is Robert Michel, editor of *The Dark Report* and founder of the Executive War College (scheduled this year in New Orleans, April 28-29). We asked Mr. Michel a few questions about this topic since he has visited various laboratory facilities around the world — England, Korea, Saudi Arabia, and other countries — in his quest for information about coming changes. Here are his latest insights:

Editor: Explain briefly the move toward “globalization” or what is more effectively termed “standardization” of the world’s medical laboratories.

Michel: Globalization as a trend in laboratory medicine is propelled forward by a number of independent trends. For example, because of consolidation within the *in vitro* diagnostics (IVD) industry, a shrinking number of big IVD manufacturers are selling the same instruments, equipment, and test kits to labs throughout the world. That means most laboratories buy and operate the same equipment and analyzers. Certainly, there are some differences due to regulatory approval agencies, such as the Food and Drug Administration in the United States and European Medicines Agency in Europe.

Another trend that encourages standardization of laboratory operations across international borders is the development of evidence-based medicine and use of those guidelines by clinicians in many countries. Independent of these factors, a general raising of standards in healthcare is motivating many countries that traditionally have had few or *no* laboratory oversight laws to adopt ISO 15189 as a mandatory laboratory accreditation requirement. [For details on ISO 15189, go online and google that term.]

Editor: You made some comparisons among India, South Africa, Mexico, and Belgium with regard to ISO 15189. How well will labs worldwide “mesh” with one another in light of their differences?

Michel: ISO 15189 is just one dynamic or market force that encourages standardization of laboratory operations across international borders. Remember that all healthcare is local. *The Dark Daily* e-briefing to which you refer was making precisely that point. In each of the four countries, there were unique population demographics, economics, and healthcare needs. Thus, although a common element was the use of ISO 15189 in each of these four countries for laboratory accreditation, laboratories in each of these countries was focused on meeting different types of healthcare needs unique to its nation. For example, Belgium, a relatively wealthy country, is addressing the needs of an aging population. By contrast, in India, many areas throughout that nation lack health clinics and basic health services. Thus, laboratories in India are motivated to provide a different menu of lab tests than labs in Belgium.

Editor: You spoke a couple of years ago about the proposal of sending lab tests from the United States to India via FedEx, for example, and having the tests run overnight with e-mailed results to the American clinicians arriving the next

morning. My understanding is that only a small percentage of laboratories there follow any “rules and regulations” since those are voluntary in that country.

Michel: Outside of a handful of developed countries, there has been little effective regulation, licensure, and/or accreditation of clinical laboratories worldwide. With medical tourism becoming a more important factor and with many countries wanting to demonstrate a higher level of quality within their healthcare systems, the motive now exists to introduce some type of regulatory scheme to license and accredit medical laboratories. The shortest, fastest, and cheapest route for individual countries to achieve that is simply to adopt accreditation under ISO 15189 as a requirement for laboratories.

Editor: In your conversations with laboratory professionals, do they indicate that this “global standard” will be a success?

Michel: It is too soon to judge whether ISO 15189 will find success in the United States. Keep in mind that ISO 15189 medical laboratories is an accreditation standard for laboratory organizations that want to incorporate quality-management systems and methodologies into their daily operations. A laboratory that chooses to pursue accreditation under ISO 15189 must still meet the requirements of CLIA licensure and an accreditation such as offered by the College of American Pathologists. In the short term, it is unlikely that a large number of clinical laboratories will want to devote the time and resources to achieving ISO 15189 accreditation in addition to the legal mandates that govern laboratories in this country.

Editor: AACC’s award-winning website, Lab Tests Online, has implemented translated versions of its patient-education site: Australian English, British, German, Hungarian, Italian, Polish, and Spanish. The U.S. site reportedly receives more than 1 million visits per month! AACC President Gary Myers said that this has made the site a global standard itself for patient education, as well as a highly visible symbol of the worldwide laboratory community.

Michel: Lab Tests Online represents a useful example of the convergence of laboratory medicine and laboratory operations across the globe. In every country where a Lab Tests Online website is introduced, it becomes a popular destination and enjoys a surprising level of traffic. This phenomenon demonstrates that consumers and patients in most countries around the world share the trait of wanting to be more involved in their healthcare.

Editor: In some way will the “globalization” of the medical laboratory bring the well-deserved recognition to laboratory professionals.

Michel: As to medical technologists, it will take some time to achieve some form of universal certification for technical training and skills. There is already considerable movement across the globe of skilled laboratory labor. Given the demand for skilled laboratory professionals in most developed countries, it is likely that a common basis for education, professional certification, and licensure will occur. □

Advances in digital pathology drive continued momentum and globalization

By Dirk Soenksen

Digital pathology — an image-based environment for the management and interpretation of pathology information enabled by the digitization of a glass slide — represents a new generation of technology for pathology and laboratory professionals. Digital pathology adoption is well underway worldwide, with almost a thousand systems in use for clinical, education, research, and biopharma applications.

Digital pathology systems convert individual glass microscope slides into high-resolution digital slide images that can be viewed and analyzed using a computer instead of a microscope. A digital slide is a complete representation of the cells and tissues on a glass microscope slide and can be viewed at any magnification, transforming a computer monitor into a virtual microscope. Digital slides and other information can be viewed 24/7 via the Internet, and the images can be shared securely and instantly with anyone in the world. Advanced image-management software (pathology picture archiving and communication systems, or PACS) helps manage image workflow; user access; security; and archival and retrieval and other related activities.

Digital pathology is rapidly gaining momentum as a proven and essential technology that is helping to reduce laboratory expenses, improve operational efficiency, enhance productivity, and improve treatment decisions and patient care. In addition to eliminating the many inefficiencies and costs associated with use of individual glass slides, advancements in digital slide image analysis add value by enabling the automation of mundane tasks (i.e., counting cells) or the automatic classification of disease patterns in histology tissue. Advanced “smart” histology pattern-recognition tools capable of “learning” to find specific morphologic patterns are now available. These pattern-recognition tools analyze training slide images and develop optimal algorithms that can locate and automatically annotate morphologic patterns, similar to the patterns in the training sets, in large numbers of digital slides.

The rapidly emerging digital industry has seen remarkable progress in the emergence of standard file formats and HL-7 interfaces to laboratory information systems (LIS). Progress has also been made in supporting organizations adopting digital pathology with good laboratory practices (GLP) and HIPAA compliance, and with obtaining Food and Drug Administration (FDA) clearances for the use of digital pathology in breast cancer for select applications such as HER2 (human epidermal growth factor receptor 2), ER (estrogen receptor), and PR (progesterone receptor) image analysis. Some providers of digital-pathology solutions have obtained FDA clearances for HER2 and PR to demonstrate equivalence between reading glass slides under a microscope and interpreting digital slides on a computer monitor. The expected future clearance for H&E (hematoxylin and eosin stain) breast-cancer slides represents a major milestone for the adoption of digital pathology in the clinical market.

Recently, immunohistochemistry (IHC) image analysis was the first digital pathology application to be cleared by the FDA for use in the clinical market. Commercially available FDA cleared digital IHC systems include the ability to read digital IHC slides on a computer monitor, perform quantitative image analysis to quantify protein expression, and create professional reports, all integrated into an efficient clinical workflow. Such integrated solutions help pathologists provide better patient care by providing faster

turnaround times, more informed decision making, and more accurate and consistent test results.

Digital pathology provides tremendous flexibility by enabling the immediate distribution of digital slide images in a Web-based setting, independent of glass slides or microscopes. One of the biggest benefits of digital pathology is global access to histopathology information by pathologists who can view digital slide images from anywhere there is Internet access, speeding the turnaround time of secondary consultations, and expediting clinical trials and the drug-discovery process. For example, pathologists and researchers in the United States and Europe can view digital slides in Asia, lowering geographic barriers and integrating global pathology labs in large pharmaceutical companies to expedite research, clinical trials, and facilitate international peer review using a digital pathology platform.

New digital slide-sharing networks have recently become available to make digital pathology affordable to large numbers of labs and pathology groups by allowing the secure transmittal of digital slide images to a global data center, as an alternative to investing in a costly local digital pathology infrastructure. Digital slides at the data center can be accessed immediately via user-specific passwords by authorized parties and shared for a variety of purposes.

Slide-sharing networks make it easy for pathologists to share digital slides with others, regardless of location, facilitating instant access to global pathology expertise, and expediting the provision of pathology services to remote sites. For example, a pathologist could share a slide for a consultation or second opinion with a pathologist who lives just a few miles away or anywhere in the world, eliminating slide re-cuts, shipping expenses, the risks of slide breakage, and pathologist time traveling to a remote site.

A digital slide-sharing network is particularly valuable for pathologists faced with shipping glass slides internationally. Customs laws often prohibit or slow down importation and/or exportation of tissue. Use of digital slide networks do not require the shipment of glass slides, therefore, participants have a vastly simpler way to share slides internationally, faster and with superior bandwidth.

The ability to routinely digitize glass slides and integrate the resulting digital pathology information with LIS and PACS is also helping drive the adoption of digital pathology in hospitals and health-system settings, transforming how pathologists assimilate information from disparate information sources to make more informed interpretations.

Interfaces between digital pathology and LIS are well underway and are critical to improving workflow. Integration with LIS allows pathologists to retrieve and analyze patient’s digital slides directly from the LIS as well as generate pathology reports with relevant demographic information and clinical history through a single access point, facilitating faster results and better communication, and the best possible analysis and treatment for the patient.

Digital pathology continues to transform the delivery of quality, cost-effective pathology, providing new technological standards and reinforcing the central role of the pathologist in patient management. □

Dirk Soenksen is CEO of Aperio Technologies in Vista, CA, which offers the ScanScope slide-scanning system.