

Bring on the future of lab medicine

With the stroke of a pen, President Obama signed into law game-changing reform that promises to speed up the evolution of our overall healthcare system. Laboratory medicine needs to be nimble to apply the scientific and technical advances necessary to improve patient outcomes. The Patient Protection and Affordable Care Act presents the laboratory medicine profession with multiple challenges but also offers endless opportunities. One such opportunity emerges from the new law's provisions that encourages health-services research (e.g., comparative effectiveness). A proactive health-research agenda can help patients, enhance quality, and assist us in gaining control of skyrocketing health costs.

Comparative-effectiveness research can critically analyze available lab tests and make recommendations regarding which are cost effective yet outcome-based. Just because an assay exists does not necessarily mean a patient needs that test. Our focus must be on what is best in terms of correlating with clinical outcomes (i.e., each test has to make a difference in managing the patient's disease or condition). The question of whether a patient benefits from having five breast-cancer markers run on a tumor as opposed to having only test(s) that best manage or best predict the clinical outcome is what we need to answer (and, eventually, what guideline should be developed).

Laboratory medicine should be at the forefront of clinical-guidelines development. Critical analysis of the vast array of available assays in pathology and laboratory medicine is needed so guidelines that enable practitioners to conduct the tests that serve to improve each patient's clinical management and outcome are developed. This approach prevents overutilization and unnecessary billing. Just as important, such analysis must actively involve our clinical colleagues in oncology, radiology, gynecology, and others.

Pathology and laboratory medicine must sit at the appropriate clinical tables when complex medical decisions are being made. Clinicians do not always

understand the complexity of each sophisticated diagnostic test, and who is better suited to advise on these than those who perform the tests daily?

Last, comparative-effectiveness research can assist us in transitioning the profession into the future. Not only do patients win but also we are constructive in reducing the perception of our profession as a "commodity" among our clinical colleagues.

Clinicians do not always understand the complexity of each sophisticated diagnostic test, and who is better suited to advise on these tests than those who perform the tests daily?

The new law has increased the power of the federal government, and our professional response must be providing expert assistance to ensure patients are receiving the best possible — and most appropriate — care. Washington alone cannot fix the many problems inherent in our healthcare system. Who will integrate clinical lab testing into decision-support systems related to the electronic medical record? What if we could show a reduction in duplicate testing and, at the same time, increase physician satisfaction with our value and services? These questions can be answered only by the laboratory team; if we do not step up and offer solutions, everyone loses: the government, the patient, laboratory professionals, and our clinical colleagues.

The law will decrease reimbursement levels for the Medicare Clinical Laboratory Fee Schedule and includes pilot projects to bundle payment for services that may include both anatomic and clinical pathology. At the same time, increased patient access to routine primary and specialty care will increase the volume of testing and biopsies. This, in turn, will increase government scrutiny on the overall volume of clinical and anatomic pathology. The landscape is complex, and we must map out the future as partners with government.

Even without enactment of a sweep-

ing reform initiative, the healthcare-delivery system has evolved a great deal in the past decade. With passage of major health reform, the changes will be even more dramatic and the impact profound. The trends we expect to accelerate soon fall into two categories:

1. the acceptance into daily practice of genomics, proteomics, and other molecular diagnostic technologies; gene and biomarker discovery and deployment; health information technology (HIT), digital imaging, and the convergence of diagnostics; and
2. government oversight and regulation via replacement of pure fee-for-service model (bundled care, pay for performance); patient-centered medical home/accountable care organizations; and oversight of laboratory-developed tests.

Laboratory medicine organizations must continue to encourage a more proactive, collaborative leadership model to drive the transformational change evolving from the new healthcare law. We must be more active participants (more visible, more outspoken) in healthcare decision making. We can help close various gaps in healthcare (from HIT to test utilization to clinical decision making to relationships within the healthcare arena). Ultimately, if we play our cards right, our profession will have a major role in ensuring a cost-effective healthcare system.

Our most urgent task is for the field of laboratory medicine to stay grounded and provide the most progressive science available. In doing so, pathologists and laboratory professionals will be able to respond to the new regulatory paradigm in order to provide and perform the best and most appropriate diagnostic tests for our patients.

Bring on the future! □



E. Blair Holladay, PhD, SCT(ASCP)^{CM}, is the Executive Vice President of the American Society for Clinical Pathology in Chicago.