
Moderators: Mitchell G. Scott¹ and Nader Rifai²*

Experts: Brian Smith,³ Michael Oellerich,⁴ Mauro Panteghini,⁵ Fred Apple,⁶ Ken Sikaris,⁷ and Ian Young⁸

In an effort to reduce the cost of healthcare in general and laboratory testing in particular, laboratory consolidations, outsourcing of services, and hostile takeovers of hospital laboratories by commercial companies were common occurrences in the US in the mid-1990s. These measures led to a reduction in the number of positions for clinical laboratory directors, the closing of many medical technology schools, and downsizing of postdoctoral training programs. Furthermore, the regulatory requirements, quality assessment programs, compliance issues, and general administrative responsibilities of laboratory directors have significantly increased over the past decade. As a result of these clinical service demands, the academic aspects of the profession and the time to participate in research have seemingly suffered. For instance, fewer clinical laboratory physicians and scientists are publishing in top journals such as Clinical Chemistry, where currently only approximately 35% of original reports have a first or last author associated with a laboratory medicine or pathology department. Similar disturbing changes are currently happening in other parts of the world. In this Q&A, we discuss the ramifications and long-term implications of these changes for our profession and future generations and what can possibly be done, if anything, to reverse the trend. A group of laboratory medicine leaders from the US, Germany, Italy, Australia, and the UK have independently answered relevant questions in this regard, and we present their answers below.

What are the major evolutionary changes of the past 10–20 years in the practice of laboratory medicine in your country?

Brian Smith: First, the rise of new technologies that produce biomedical “big data” (next generation sequencing, multiparameter/multiplex flow cytometry, high-throughput proteomics and metabolomics, systems biology analysis) has caused us to rethink the best approach to diagnostics. Whereas formerly one could easily spend one’s clinical and investigative career developing expertise in just a few analytes, we now have the opportunity to begin to crack the incredible redundant complexity of living organisms; however, with this opportunity comes the challenge of our being partly dependent on sometimes nonintuitive in silico informatics that goes beyond our day-to-day ability to completely understand why something is happening to a patient. Second, the advent of the “big data” electronic medical record (EMR) has added to this potential but, more importantly, has made it much more possible to carry out cost-efficient clinical consultation in laboratory diagnostics on specific patients across a wider geographic sweep. At least theoretically, one pathologist/laboratorian can now consult expeditiously on multiple patients from a

¹ Division of Laboratory and Genomic Medicine, Department of Pathology and Immunology, Washington University School of Medicine, St. Louis, MO; ² Departments of Laboratory Medicine and Pathology, Boston Children’s Hospital and Harvard Medical School, Boston, MA; ³ Professor and Chair of Laboratory Medicine and Professor of Biomedical Engineering and Internal Medicine, Yale University School of Medicine, New Haven, CT; ⁴ Lower Saxony Distinguished Professor of Clinical Chemistry, Department of Clinical Chemistry, George-August-University, University Medical Center Göttingen, Germany; ⁵ Full Professor and Director of the Chair of Clinical Biochemistry and Clinical Molecular Biology, University of Milan Medical School, Director of the Department of Laboratory Medicine and of Clinical Pathology Unit of the “Luigi Sacco” University Hospital in Milan; and Director of the Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Italy; ⁶ Medical Director of Clinical Laboratories, Hennepin County Medical Center, Professor of Laboratory Medicine and Pathology, University of Minnesota School of Medicine, Minneapolis, MN; ⁷ Associate Professor, Department of Pathology, University of Melbourne, Director of Clinical Support Systems, Sonic Healthcare, Chemical Pathologist, Melbourne Pathology, Australia; ⁸ Professor of Medicine, Queen’s University Belfast, Associate Medical Director (Research and Development), Belfast Health and Social Care Trust, Northern Ireland, UK.

* Address correspondence to this author at: Department of Laboratory Medicine, Boston Children’s Hospital, 300 Longwood Ave., Boston, MA 02115. Fax 617-730-0383; e-mail nader.rifai@childrens.harvard.edu.

Received July 14, 2014; accepted July 28, 2014.

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remote location. Third, point-of-care laboratory testing is advancing at a furious pace, resulting in both potential great benefits (a Star Trek tricorder in every physician’s hands) and potential dangers (Dr. McCoy cannot fix that tricorder if it breaks and may not even be able to tell when it’s broken). Finally, high-throughput automation, combined with electronic identification technologies, provides a platform for reduction of laboratory test–related medical errors. All of these changes work toward progressively greater centralization, at the risk of our profession becoming solely “big business” in its underlying structure, and making an academic career more challenging. On the positive side, they also encourage “team science” and “team medicine,” which are concepts that academic medicine needs to better embrace.

Michael Oellerich: Economic challenges and a flood of technological innovations are the driving forces of change in the laboratory environment. These factors are responsible for the rapidly changing conditions in our healthcare system and have caused increasing competition between disciplines for diagnostic fields and funding. There is a trend towards total laboratory automation. Laboratory medicine in Germany is undergoing a rapid consolidation process. Six major laboratory chains cover about 55% of the private sector. Streamlining the laboratory services in Germany is reflected by low overall costs (2.4% of total healthcare expenditures). Advances in genome technologies, proteomics, and specific applications of mass spectrometry have created new opportunities for research and practice in our discipline. There is a trend to develop value-based strategies.

Mauro Panteghini: Similar to many other countries, in the past 20 years Italian clinical laboratories represented an area of healthcare that has undergone major changes because of technological advances in automation and increasing economic restrictions. Laboratories have indeed been an easy target for economic saving owing to their “technological” characteristics. As a main consequence of the 2 driving processes (i.e., automation and economic pressures), cost savings have frequently been realized by consolidation and, in some cases, regionalization of laboratory services with the creation of individual laboratories serving multiple healthcare facilities. The private–public competition also contributed to the increased perception of laboratory production as a commodity, often ignoring the importance and the true impact of diagnostic testing in the overall context of health economics.

Fred Apple: Having been in practice for 32 years as a clinical chemist/toxicologist, the 2 most substantial changes I have encountered involve the implementation and growth of clinical testing using mass spectrometry and molecular diagnostics. Once only basic research tools, now these technologies provide same-day measurement of proteins, nucleic acids, and therapeutic drugs, improving patient care in complex medical cases.

Ken Sikaris: Australia, like the US, has undergone massive amalgamation of private pathology laboratories over the last 25 years into 3 major providers (Sonic Healthcare, Primary Health Care, and Healthscope). There has also been amalgamation of most public hospital pathology laboratories into statewide pathology networks. Both private and public sectors have been driven by cost efficiencies that have nevertheless permitted exponential test growth despite falling reimbursement. Pathology laboratories were once described as a cottage industry by one of our health bureaucrats, but today my employer (Sonic Healthcare) is one of the top 50 companies on the Australian Stock Exchange (bigger than Qantas, our national airlines) as well as the largest pathology provider in Europe, and the third largest in the US.

While increased efficiency has been the major driver, quality has also been improved, largely because reimbursement requires accreditation to the International Standards Organization document 15189 that specifies requirements for quality and competence in medical laboratories. There is also growing need for technical standards to supplement quality standards, where both need
How have these changes affected the daily practice of the profession for those entering the field now compared to how you practiced when you started your career? Is the triple threat (service, teaching, and research) laboratory medicine professor still possible?

**Brian Smith:** The growth of complexity at both the investigative and the clinical end has undoubtedly made it more difficult to adequately keep current as a “triple threat,” at least under the old paradigm where one needed to make all decisions on the fly with at most the help of a small “peripheral brain” notebook, carefully crafted in micro handwriting over years of experience. On the other hand, the electronic era has helped counter this problem as we move to a clinical practice style (and even an investigative style) where we carry whole libraries in our pockets with electronic librarians at our beck and call. The net result of this equation can still fall in favor of the triple threat provided one is sufficiently focused on one’s investigative area and sufficiently subspecialized in one’s clinical practice. Increasing administrative responsibilities are, however, a major new challenge. A response to this change in practice may require reimagining the roles and interactions of the team players: MDs, PhDs, MBAs, med techs, and others.

**Michael Oellerich:** These changes have resulted in a reduction of technical and academic personnel and research infrastructure. It is still an academic requirement to do all 3. However, research funding has become more difficult to obtain, especially for those just beginning their academic career, and the time available for research has decreased.

**Mauro Panteghini:** The current focus on laboratory economics and lowering cost per test has sometimes undermined the influence of laboratory professionals. Furthermore, we often do ourselves a disservice by concentrating on technical performance while forgetting or ignoring the value of clinical information associated with laboratory testing. From this point of view, I do not see any major changes from the past, as similar problems, in a different technical and organizational context, already existed when I started my career 35 years ago.

**Fred Apple:** In the early 1980s we provided daily review and interpretation of serum protein electrophoresis, creatine kinase and lactate dehydrogenase isoenzymes, and lipoprotein phenotyping. Today, these tasks have become highly automated with immunoassays, with only boarded physicians permitted to interpret findings allowing for Part B reimbursement. Clinical chemists have been taking a predominant role in developmental and interpretive skills in applying both mass spectrometry and molecular techniques for patient care testing. The overall role of the clinical chemist in the clinical laboratory has not diminished. Whether reviewing quality aspects of the day-to-day laboratory operation, taking consultative calls for clinical interpretation of patient results, keeping up with changing automated technologies for optimal testing, managing test utilization for cost-effectiveness, or training residents and fellows in laboratory medicine, an atmosphere is provided in which no 2 days are ever the same.

The triple threat requires a commitment by clinical chemists to pursue an academic component in addition to their daily tasks, which may or may not be supported by their academic chair or administration. Clinical chemists will have to publish their observations. One can start with an interesting case report and work towards establishing applied research studies by collaborating with industry or partnering with a clinical colleague, working as a team. One should think of how to get independent funding to support ideas and unique studies. It is rare that a clinical chemist can do both, a hospital service job and a basic science research career. It is very important to find a mentor who can guide the individual through this complex web.

**Ken Sikaris:** When I started training, we reviewed every printed report as it left the laboratory. Today this is literally impossible, with tens of thousands of predominantly electronic reports released every day. Just as we now rely on increasing automation to produce these results, we also rely on increasing computing levels to validate the integrity of reports, according to rules built into expert systems.

While these modern changes seem to be restricted to improving the efficiency of service requirements, their potential can also be directed to research. Our company has successfully tendered for population surveys by offer-
ing state-of-the-art, reference laboratory testing at competitive pricing. Similarly, because we also have a team of 10 specialist clinical chemists across Australia, we can also offer the highest levels of expertise to support study design and interpretation.

As far as teaching is concerned, there has been a gradual shift from training clinical chemists in large teaching hospitals to training in larger private pathology laboratories where an increasing proportion of jobs exist. Like me, many of my private pathology colleagues hold honorary university appointments that recognize our expertise and massive everyday experience. While research output is not yet a major goal of private pathology providers, we support, collaborate on, and coauthor more scientific publications than any average pathology service and there is little doubt that this academic credibility adds to our marketing. The considerable resources of large private providers is exemplified by the fact that we recently published a 1000-page textbook guide to pathology testing edited by 65 of our leading pathologists, which will soon also be released as an e-book and a significant support for all clinicians to keep up with any new Australian guidelines.

**Ian Young:** There is much less scope for research to be conducted by laboratory staff than used to be the case; research is now driven by full-time researchers, though laboratory staff can still provide support and have some involvement if they wish to do so. Lack of time and workload pressures make this increasingly difficult, however. The triple threat laboratory medicine professor has almost disappeared, apart from a very small number of exceptional individuals.

**What are the long-term implications of these changes on the field?**

**Brian Smith:** Greater core centralization, but simultaneously more technology moving to the patient’s bedside, is here to stay, and comprehensive massively multiparameter data analysis is dawning, with the latter better incorporating multimodality analysis (laboratory testing, image analysis, timeline trending). Classic job descriptions for MD pathologists, PhD laboratorians, laboratory managers, medical technologists, and nonpathologist/nonlaboratorian providers all need to be in flux, as does the academic–industrial–government interface. It is the best of times and it is the worst of times.

**Michael Oellerich:** Despite the fact that in Germany laboratory medicine physicians have the final responsibility for laboratory reports, health policy makers and university administrators may perceive laboratory testing as a commodity and laboratory medicine as primarily a support service. University chairs with tenure for clinical chemistry may no longer be guaranteed. There are decreasing numbers of promising young scientists and physicians who see their future in laboratory medicine and, as a result of the merger of hospital laboratories, there is a loss of training positions. An increasing percentage of the 1038 clinical laboratory physicians in Germany work in private (61%) vs hospital (27%) laboratories.

**Fred Apple:** The work of a clinical chemist is important and valuable to academic medical centers/hospitals that have teaching programs, a research mission, and an interest in cost-effective laboratory testing. Budgets are shrinking, reimbursements for patient care and education are declining, and the numbers of professional staffing are decreasing, all with expectations of continuing to provide quality results. The clinical chemist can fill many important roles within laboratory medicine, with better training in informatics and development of the skills to manage and interpret data and test trends from both the laboratory information system and the patient’s electronic health record.

**Ken Sikaris:** The long-term implications of these massive laboratory networks, both public and private, will be in having a greater capacity to supply efficient and cost-effective services, as well as support research and provide the teaching that is most relevant to routine clinical practice. Whereas in the past, clinical pathologists might aspire to run their own laboratory or department, today the general preference is to join a large successful team where there is security and the support of like-minded colleagues. While there is still some room for niche or boutique laboratories that subspecialize, in reality, they exist because the larger pathology laboratories have little interest in that work.

**Ian Young:** Future innovation will be driven largely by industry or academic centers. There will be deskillling of laboratory staff in research terms; the lack of an opportunity to seriously engage with research may change the profile of staff recruited to the laboratory professions.

**Have these changes led you to modify the training of your residents and fellows? If yes, how?**

**Brian Smith:** Our trainees need to be taught the new paradigms and technologies at a level appropriate to their future practice, which means that we also need to subtract less critical (older) components of the body of knowledge we currently pass on—we must be joined, especially in the latter, by the boards and graduate-training regulatory bodies. Four areas of emphasis need to be coalesced: more effective training in comprehensive clinical consultation using the EMR; more weight given to “therapeutic pathology,” that is, moving beyond see-
ing our job as solely diagnostic but rather as comprehensive and driving therapy in real time; thoughtful reconsideration of pathology and laboratory medicine specialty/subspecialty vs generalist practice and training; and finally, optimal approaches to training clinician–scientists in the context of the other 3 areas of evolution.

**Michael Oellerich:** The training required for certification in laboratory medicine is strictly regulated in Germany and has not been changed.

**Mauro Panteghini:** During my career, I have always strongly believed that the triad of clinical service, teaching, and research should be the basis of the laboratory medicine profession. Consequently, the training of the new generations must include each of these 3 aspects.

**Fred Apple:** I have been training medical residents and clinical chemistry fellows initially as the COMACC (Commission on Accreditation in Clinical Chemistry) director for the University of Minnesota and now at Hennepin County Medical Center. I have observed 2 trends. First, the time allotted to clinical chemistry training for residents has been shortened and is often inadequate to appropriately educate future practicing pathologists to direct a clinical chemistry laboratory. Second, for fellows, more advanced rotations are needed to develop skills in clinical utilization of mass spectrometry and molecular diagnostics. Having the fellows develop a test themselves, from A to Z, is now an essential part in their training. As I direct a forensic toxicology laboratory, fellows receive advanced training in the interpretation of postmortem toxicology and regulatory requirements, stressing the necessity of becoming board certified.

**Ken Sikaris:** In the past, small private laboratories had a limited range of typically routine tests and rarely had a broad range of subspecialists, while public teaching hospitals usually specialized in only a few areas reflecting the clinical interests of that hospital. Our fellowship trainees in the past would be trained in what was available and if an individual trained in a laboratory with a particular technical or clinical strength, he or she often developed into a specialist with a focus in that area. Today, the large pathology networks usually cover a much broader range of testing and can access a wider range of expertise for which rotations for trainees can be organized, even when off site. Although we train across a broad syllabus, once qualified, clinical chemists tend to develop their own areas of expertise that complement the other clinical chemists in the team. Therefore, it is important that trainees start to identify the areas in which they might have interest in the longer term for the purpose of career planning.

The Royal College of Pathologists of Australasia has recently established a fellowship training program for clinical scientists, and the 3 pillars of their education include (a) a specialized understanding of the technical and clinical knowledge in a discipline, but also (b) an ability to design, conduct, and communicate research, as well as (c) the ability to manage a laboratory, including innovative development. We know that the leading clinical scientists of the future will need to keep pace with new discoveries and ensure they are capable of rolling them out in a way that benefits the community.

**Ian Young:** In the UK we are fortunate that a significant research project remains an essential training requirement, so that at least during training laboratory medicine residents and fellows have the chance for formal research experience. The real problem is with the limited opportunities to engage in research while in substantive posts.

**What can be done to maximize the effect of the positive changes and minimize the effect of the negative ones? Are the negative changes reversible?**

**Brian Smith:** Internal medicine, surgery, dermatology, therapeutic radiology, and other specialties have all revised their training approaches over the last 30 years to attempt to retain the clinician–scientist career route and to deal with the explosion of both clinical and basic science knowledge. Pathology and laboratory medicine have arguably moved slower in this regard, but if the discipline can approach the challenges in a comprehensive, thoughtful, collegial fashion with representatives from all career pathways (primary academic investigator, primary academic clinician, community clinician, hybrid career individual) in the same room, the negative evolutionary changes can be converted to positive forward movement.

**Michael Oellerich:** It is important to increase the awareness of our academic discipline by the public, hospital and university administrators, and health policy makers. Initiatives such as Laboratories Are Vital could be helpful to communicate the essential contribution that laboratory medicine makes to the healthcare system, given the fact that 60%–80% of healthcare decisions affecting diagnosis and treatment involve laboratory investigations. It is essential to enhance the role of laboratory medicine physicians and clinical chemists as leaders in the development and interpretation of laboratory diagnostics, implementation of scientific innovations, value-based strategies, and evidence-based service delivery. Trainees should be encouraged to acquire more economic and management competence. Multidisciplinary cooperation and professional society networking have to be promoted. Harmonization in education is desirable. To pro-
vide high-quality education, practice, and research, university chairs (comparable to tenured professors in the US) with tenure in laboratory medicine are vital. The requirements for achieving truly personalized medicine provide an opportunity to reverse some of the discussed negative changes.

Mauro Panteghini: The only way to escape from professional and, at least in Italy, academic troubles, and recognize the central role of our profession, is to clearly define the identity of laboratory medicine as a “science that underpins medicine,” changing the situation where laboratory (sub)-specialties are promoting their own visibility and raison d’être in an independent manner.

Fred Apple: Never accept the word “never.” While things can look bleak at times because of financial constraints, the clinical chemist needs to maintain a visible role within the institution, be proactive, and serve on committees in which the laboratory plays a role. The laboratory touches almost every patient that comes to the hospital. Our technical and problem-solving skills need to go beyond the walls of the clinical laboratory; we must be active in meetings with the clinicians, regulatory staff, and administrators. One should not wait to be told what to do; the clinical chemist should become part of the solution.

Ken Sikaris: The positive benefits of the economies of scale include access to specialist teams, reference laboratories, and large volumes of clinical experience, and these benefits need to be acknowledged and promoted rather than feared.

The raison d’être of clinical pathology laboratories is to help clinicians understand disease. Today’s modern high-volume laboratories, where our largest clinical interface exists, need to be careful that because of the pressures of increasing workload, they do not neglect the research, development, and teaching that is equally necessary to advance clinicians’ understanding of disease. There is definitely a danger in creating such economies of scale—that the focus becomes the economics of the service rather than underlying value of a quality pathology service. These risks need to be managed by an organizational culture that encourages quality, innovation, and a clinical focus. I’m proud to say that my employer, Sonic Healthcare, has medical leadership as one of its foundation principles and still has a pathologist as its global CEO despite being a multibillion-dollar corporate giant. There is a subtle but important difference between a pathology laboratory directed by pathology professionals and supported by business professionals vs a pathology business directed by business professionals and supported by pathology professionals.

Ian Young: Developing a culture where high-quality research is valued as part of routine laboratory activity is critical. This requires clear leadership from senior laboratory staff involved in management. A history of successful research and development should boost the chances of promotion or appointment to a position with a higher grade.

In the future, where do you see the bulk of innovative research in laboratory medicine coming from, industry or academia?

Brian Smith: I see the bulk of innovative laboratory medicine coming from a close working relationship between industry and academia, between government and academia, and between government and industry. New ideas will spring from both industry and academia—eventual achievement of patient benefits from those ideas will require both working together.

Michael Oellerich: It is likely that most will come from academic/commercial partnerships. Laboratory medicine has an essential role in translating basic science discoveries from bench to bedside and their implementation with appropriate standardization and QC.

Mauro Panteghini: A constructive partnership among industry, academia, and, let me say, healthcare providers is the only way for translating innovation in the clinical setting and adding value to the care of patients.

Fred Apple: The future of our success in research advancements lies within a collaborative working relationship between industry and academia. With declines in federal and private funding opportunities, the academic community needs to partner with experts in industry to develop long-term goals and funding relationships that will be mutually beneficial.

Ken Sikaris: If you think of innovation today, you would generally think of information technology providers, whether that be Apple hardware or Google software. While innovative ideas can come from any talented individual, it has been industry that has financed the development of ideas and brought them through to practical fruition. Pathology is no different. Ideas can come from an academic or industry setting; however, only diagnostic companies will be able to develop them for widespread, efficient access. As the links between academia (the academic industry) and the pathology industry continue to develop, innovation will focus on putting the innovators in direct contact with the industry they seek to enhance.

Ian Young: Both industry and academia will be important. In terms of technology, the majority of innovative
research is likely to come from industry, although validation of new approaches and assessment of their likely impact will often involve academia. Some of the most novel ideas (for example, biomarker identification) are likely to originate in academia but will be quickly picked up and developed by industry.

*Have the criteria for promotion at your university changed to reflect the actual responsibilities of faculty members?*

**Brian Smith:** There has been a gradual evolution toward new academic “tracks” at our university to reflect changing patterns. Nevertheless, it is challenging for institutions to keep up with the rapid pace of change in medicine and to deal with the increasingly complex hybrid (and collaborative) professional activities induced by healthcare change, evolution of big data, and the need for team science and team medicine. It seems difficult sometimes to promote a “team.”

**Michael Oellerich:** The criteria for promotion at our university have not changed. However, the expectations for high-impact research publications have increased at the same time the infrastructure support for such research has decreased. The result is that it has become more difficult to find appropriate candidates for chair positions and to compete with the private sector for hiring promising certified laboratory medicine physicians.

**Fred Apple:** Requirements for promotion within laboratory medicine have shifted from tenure to clinical scholar track. This is a reasonable transition, because the demands placed on clinical chemists involving service, administrative, regulatory, and teaching responsibilities have increased, with fewer protected hours to establish innovative applied and basic science programs. Academic chairs in laboratory medicine need to better acknowledge that applied research contributes to patient care, even if such research is not NIH funded.

**Ken Sikaris:** In Australia, most of our technical colleges have been renamed as universities and the diplomas that once indicated you had learned the skills of a technical profession have now satisfied consumer pressure to be called degrees. University degrees once did not teach a set of skills, but provided students with both knowledge and an understanding of how to keep improving that knowledge throughout a professional career. “University” promotion has similarly been split into new style faculty education providers (often called associate professors, like me), as well as promotion to “full” professors that are hopefully still maintaining the tradition of fostering the researchers, new knowledge creators, and thought leaders of the future.

**Ian Young:** Promotion criteria are firmly based on research income, high-quality publications, and (increasingly) demonstrated research impact in economic terms or on clinical practice. It is important to make a teaching contribution, but this is less critical. The criteria are largely driven by external pressures and take little account of actual responsibilities.

*Are you optimistic or pessimistic about the future of laboratory medicine as an academic profession?*

**Brian Smith:** As attributed to Winston Churchill: “A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty.” I’ll go with the latter.

**Michael Oellerich:** Despite all the challenges we face, laboratory medicine physicians have to play a clear leading role in the application of emerging biomarker technologies and the management of complex laboratory structures. Therefore, I am optimistic that the current pace of innovation, flood of new technologies, and advances in molecular diagnostics provide an environment in which laboratory medicine as an academic profession has a chance to grow.

**Mauro Panteghini:** Looking at the current situation, I can only be a realist by stating that laboratory medicine will have (or not) a future only if universities put professional preparation among the top promotion criteria. The evaluation of professional preparation should, however, be based not only on work experience, but also on publications in scientific journals showing the ability to correctly apply methodologies to manage and solve laboratory issues as well as to promote studies for test evaluation and their appropriate utilization in clinical practice. Only by combining the unique talent of performing laboratory assays with knowledge of the pathophysiologic rationale behind the tests and up-to-date clinical fieldwork into the training of residents and fellows can laboratory medicine remain viable as an academic profession and provide better care more economically.

**Fred Apple:** I am optimistic about the future of laboratory medicine as an academic profession, as we have more skill sets at our disposal than ever before. However, my concern is if we, as clinical chemists/pathologists, do not train our students with the appropriate skills, other non-laboratory disciplines will slowly take away our clinical and technical responsibilities. I challenge my colleagues to maintain and better yet use their years of technical, administrative, and clinical wisdom to guide and place the young clinical chemist in the right place at the right time, before they abandon the profession.
Ken Sikaris: The more you learn in laboratory medicine, the more you realize what we do not know. I am fascinated by 3 new paradigms, fetomaternal microchimerism, the gastrointestinal microbiome, and low-carbohydrate high-fat diets as examples of entirely new understandings within clinical pathology. There is a lot of work for a new generation of clinical chemists to understand these issues and refine laboratory tests to address these concepts. We may look clever renaming “syndrome X” to the apparently understood definition of “metabolic syndrome”; however, we actually still don’t understand the pathophysiology of insulin resistance (despite a global epidemic of obesity and diabetes). Should not our laboratory tests be guiding prevention rather than simply describing this health disaster? The next generation of clinical chemists will have more opportunities than we ever had, and that includes the support of massive laboratories with amalgamated technical resources, teams of experts, and the authority to innovate. I am optimistic that these growing laboratory capacities will be able to address the “massive” health challenges we face and that pathology laboratories will consolidate their role at the center of understanding and preventing disease.

Ian Young: In the UK, it is difficult not to be pessimistic, as the focus of laboratory medicine does not readily lend itself to achieving academic success in the university system. There has been a progressive loss of identifiable laboratory medicine departments in universities, and individuals from a laboratory medicine background often achieve their academic success in other units. However, even if laboratory medicine may struggle as a separate academic discipline, there are still considerable opportunities for talented individuals who wish to make research their focus.

Author Contributions: All authors confirmed they have contributed to the intellectual content of this paper and have met the following 3 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; and (c) final approval of the published article.

Authors’ Disclosures or Potential Conflicts of Interest: Upon manuscript submission, all authors completed the author disclosure form. Disclosures and/or potential conflicts of interest:

Employment or Leadership: M.G. Scott, Clinical Chemistry, AACC; N. Rifai, Clinical Chemistry, AACC; M. Oellerich, George-August-University Göttingen; F.S. Apple, Clinical Chemistry, AACC; I.S. Young, Clinical Chemistry, AACC, Queen’s University Belfast, and Belfast Health and Social Care Trust.

Consultant or Advisory Role: F.S. Apple, Instrumentation Laboratory and Phillips.

Stock Ownership: None declared.


Research Funding: F.S. Apple, Institutional funding from Ortho Clinical Diagnostics, Abbott Laboratories, Radiometer, Siemens, and Roche.

Expert Testimony: None declared.

Patents: None declared.

Previously published online at DOI: 10.1373/clinchem.2014.230300