

Laboratorians
David S. Wilkinson, M.D., Ph.D.

DR. McGRATH: The next four discussants who were asked to come were involved in the steering committee. They are taking on the difficult task of limiting their talks to five minutes. They have great perspectives. We will see if that can work.

The first person is David Wilkinson, who is representing the laboratory perspective. He is from the Department of Pathology down in Virginia. Thank you.

DR. WILKINSON: We are going to do it the old-fashioned way, without slides.

First of all, thank you for giving me this opportunity to briefly comment on the state of genetics education amongst clinical laboratory personnel. I would like to start with the most important part of that work force. The core of the people that work in our clinical labs are medical technologists, also referred to as clinical laboratory scientists.

These folks are trained at a minimum at the baccalaureate level. The programs in medical technology or clinical laboratory sciences are accredited by the National Accrediting Agency for Clinical Laboratory Sciences. Their standards do specifically require training in genetics, molecular biology, and molecular diagnostics. They do not specify the exact amount of time or the exact details of the topics. They generally do not have a requirement for any particular or specific course in genetics.

These folks are very well grounded in the basics of genetics. However, we find in our own very sophisticated laboratory, and I'm sure this is true in most places, that these folks, as they come out with their baccalaureate degree in medical technology or clinical lab sciences, are not ready to perform the sophisticated level of testing that we have in a high-complexity laboratory. This would be whether it is in cytogenetics or in molecular diagnostics or other fields related to genetics and genomics. They do require significant on-the-job training.

They are great people to work with, and we can get them up to speed fairly quickly, but they are certainly not ready to go to the bench right out of school.

I would also like to make a few comments about medical student education. Some reference has already been made to the fact that genetics is taught primarily in the first and second year of medical school. In fact, about 77 percent of all genetics course work is done in the first year of medical school. That reference was made earlier to the Thurston paper in Academic Medicine, which gives you some good statistics.

There is actually minimal education in genetics in the third and fourth year of medical school. Hopefully, it is increasingly incorporated into the clinical years, but there is not a lot of specific attention to that.

Now, reference has already been made to the United States Medical Licensing Exam, which currently is administered in three steps. The first step deals with the basic sciences. The first two years of traditional medical school are the basic sciences, including genetics. The first step of the exam, which is the uniform approach to licensing in the United States, covers the basic sciences and is given towards the end of the second year of medical school.

Step two, clinical sciences, is given in the fourth year of medical school and focuses mainly on the clinical education that they receive.

There is a move afoot by the USMLE to compress step one and step two into one exam in the fourth year of medical school. Now, depending on who you listen to, the reason is to increase the requirement for students to retain basic science information into their fourth year of medical school as opposed to learn it the first two years and forget it during the next two years.

However, at least at this point, and this probably gets back to the comments made about resistance to change, most basic science departments, of which pathology is one, are concerned that this may have the effect of deemphasizing the emphasis on the basic sciences.

I have seen editorials in big papers, including The Wall Street Journal, asking, "Why do doctors need to know all this basic science? We are clinicians," which I think is baloney because the basic sciences of course are the basis for clinical science.

So I'm concerned about that move. I think this needs to be studied in great detail before a change is made in that paradigm because, at least right now, they know they have to bone up and be ready to deliver the goods on that step one exam.

Let's move on to graduate medical education. Now, the content of genetics in graduate medical education, the residency training programs, varies quite a bit depending on which residency we are talking about. Let me comment specifically on pathology.

The governing bodies for the content of residency training programs are the residency review committees, the RRCs, which operate under the auspices of the Accrediting Committee for Graduate Medical Education. Our RRC, the pathology RRC, does specifically require training in cytogenetics, molecular biology, and molecular diagnostics. Again, it does not specify the exact amount of time or the exact content, but it has these broad subject areas.

There are about 154 or so residency training programs in the United States. The experience that pathology residents get will vary quite a bit. Of course, pathologists are the physicians who specialize in the diagnosis and management of human disease, and we basically run the clinical labs in America. So we do have people coming out, I think, with somewhat variable experiences.

Now, there is also a subspecialty fellowship in molecular genetic pathology. This fellowship was already referenced by Dr. Fries. It is jointly administered by the American Board of Pathology and the American Board of Medical Genetics.

This is a one-year fellowship devoted entirely to genetics, including exposure to genetics counseling and molecular diagnostics. You can come through that either having your primary certification in genetics or in pathology.

There are relatively few of these accredited programs. Actually, the accreditation requirements are quite stringent. We are fortunate to have one of those at VCU.

The final step in the continuum of medical education is your continuing education, after you have gone through all of your fellowship training and you are out in practice. The College of American Pathologists is very concerned about education and training and aspects of molecular biology and genetics. Within the College, we have a cluster of committees that are focused on pathology and genetics.

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Two of these committees are jointly staffed by members of the College of American Pathologists and members of the American College of Medical Genetics, so these are joint ventures. One of these deals was biochemical and molecular genetics. It is called the Biochemical and Molecular Genetics Resource Committee. The other is the Cytogenetics Resource Committee. These work together bringing these two medical specialties together to oversee both the development of new products as well as ongoing education.

The other areas are histocompatibility, which increasingly is now done with the DNA basis of human identity testing. Microbiology, of course. A lot of microbiology is now based on nucleic acid testing. Another committee called the Molecular Oncology Committee deals particularly with the genomics of cancer.

Another aspect of what these committees do is to manage the development and ongoing changes in the College of American Pathologists and Accreditation Checklist. This is what you use to get accredited, and this is one of the routes by which you can get your CLIA accreditation. You can get a certificate of accreditation through the College of American Pathologists Inspection and Accreditation Program.

The checklists are the things that labs have to follow to make sure that they are being compliant with CLIA. Now, the CLIA regulations have governance over all clinical labs and all clinical testing, including genetic testing. So the CLIA regulations form a very strong foundation for ensuring the quality of clinical laboratory testing in all areas, including genetics.

These committees also manage, create, and evaluate proficiency testing programs that deal with the areas within genetic testing, which is a very important aspect of the CLIA program, which mandates proficiency testing.

Finally, these committees generate educational programs which they provide to practitioners in the area.

[Applause.]

DR. McGRATH: Thank you. I appreciate the challenge of telling so much information with so little time, so I appreciate all of you doing this.