

COMMENTARY

The Clinical Microbiology Laboratory Director in the United States Hospital Setting[∇]

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The clinical microbiology laboratory (CML) director is medically, scientifically, and administratively responsible for all that happens in the laboratory. This commentary will address the following issues. Who are CML directors? How are they trained and certified? What does a CML director do, and what is the best way to accomplish multiple challenges? How is a CML director paid? And last, what are future challenges for the clinical microbiology laboratory director?

Medical microbiology is the science of the pathogenesis of microbial infections and the general approaches to the laboratory diagnosis of infectious diseases. Clinical microbiology is the science and service dealing with detection, identification, and antimicrobial susceptibility testing of human (or veterinary) pathogens. A CML is a hospital- or community-based laboratory that provides clinical microbiology services (4). The CML scientific staff includes technologists (bachelor's degree with certification by examination), technicians (2-year degree), laboratory aides (high school diploma or equivalent), and a doctoral-level director. Technical staff are referred to commonly as clinical laboratory scientists or, more specifically, clinical microbiologists. Clinical microbiology laboratory directors are referred to as technical directors, medical directors, or simply directors. A professional title that accurately reflects training and certification is "medical microbiologist." This designation is more common in countries other than the United States and serves to differentiate the director from others in the laboratory (2).

WHO ARE MICROBIOLOGY LABORATORY DIRECTORS?

Microbiology laboratory directors are doctoral-level scientists or physicians who have postdoctoral training in clinical and medical microbiology and who have passed certifying examinations. Scientists who direct microbiology laboratories have doctoral degrees in one of the biological sciences, while physicians have postresidency training either in pathology or in infectious diseases. Certification qualifies individuals to direct high-complexity laboratories as defined by the Clinical Labo-

ratory Improvement Act (CLIA). In some instances, multiple years of experience replace the need for postdoctoral training, although this pathway is less common in larger hospital laboratories (and may be disappearing) because of medical staff bylaws requiring specialty board certification resulting from the Joint Commission's emphasis on hospital medical staff credentialing and privileging (http://www.jointcommission.org/NR/rdonlyres/30AB87C7-D717-4949-8627-91F3E4BF4730/0/MS_01_01_01.pdf).

HOW ARE MICROBIOLOGY LABORATORY DIRECTORS TRAINED?

Postdoctoral training occurs in programs accredited by the Committee on Postdoctoral Educational Programs (CPEP) (within the American Academy of Microbiology and the American Society for Microbiology) or by the Accreditation Council for Graduate Medical Education (ACGME). CPEP programs have a 2-year training requirement and are accredited to train doctoral scientists and physicians. ACGME programs have a 1-year minimum training requirement and are accredited to train physicians only. Graduates of all training programs qualify for specialty board certification. The American Board of Medical Microbiology (ABMM) offers examination to scientists or physicians who have completed fellowship training or who have at least 3 years of postdoctoral experience directing a clinical microbiology laboratory. Similarly, the American Board of Pathology offers a certifying examination to physicians who have completed training in an ACGME-accredited training program in medical microbiology. Some universities or public health laboratories train doctoral scientists or pathologists in research or clinical pathology programs that are not accredited by either CPEP or ACGME in medical microbiology, with graduates eventually gaining sufficient work experience to qualify for ABMM certification. However, this alternate pathway to laboratory directorship is less common because of the difficulty encountered accumulating experience outside the accredited training environment.

Another type of certification is available through the American Board of Bioanalysis (<http://www.aab.org/aab/default.asp>) in cooperation with the Association of Public Health Laboratories. Doctoral-level scientists or individuals with an M.D. or D.O. degree are certified by examination to direct high-complexity public health laboratories as defined by the CLIA. This

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new certifying board is designed to address the shortage of laboratory scientists needed to direct public health microbiology laboratories.

WHAT DOES A MICROBIOLOGY LABORATORY DIRECTOR DO?

According to CLIA regulations, the CML director is responsible for the overall operation and administration of the laboratory. This includes employment of personnel who are competent to perform test procedures and record and report test results promptly, accurately, and proficiently. In addition, the laboratory director must ensure compliance with applicable regulations.

The full extent of skills needed by a clinical microbiology laboratory director can be gained from a review of training program objectives as dictated by program accrediting agencies such as CPEP or ACGME. Program content is updated continually to match needs of practicing directors. Both CPEP and ACGME microbiology training program requirements are available online (CPEP at <http://www.asm.org/images/Academy/College/cpep%20operational%20procedures.pdf>; ACGME at http://www.acgme.org/acwebsite/downloads/rrc_progreq/314medmicrobiologyath07012004.pdf). CPEP and ACGME program requirements for medical microbiology are diverse, with training competencies in the science of laboratory testing, laboratory safety, personnel management, infection control and epidemiology, public health, laboratory regulations, and clinical consultation regarding specimen collection and interpretation of results. Both programs include areas for essential learning that underscore the breadth of scientific, medical, administrative, and educational knowledge required by a CML director.

Another approach to determining what a medical microbiologist does is to review job descriptions and job vacancy postings. Positions vary from institution to institution but in general highlight an expanse of potential expectations (7). As an example, the three authors of this guest commentary and microbiology peers with whom they work, all from different institutions and with different educational and training backgrounds, have similar core administrative, laboratory, and academic responsibilities written into their job descriptions but also have added requirements in some settings to care for patients, lead hospital and university committees, raise a portion of their salary through research grants, fulfill corporate expectations of customer satisfaction, and provide avenues for revenue enhancement. The expectations for a community hospital microbiology laboratory director will differ from those for a director within a university hospital setting. The community hospital director has less or no academic (education and research) responsibility but may double as a surgical or clinical pathologist or, less frequently, as an infectious diseases (ID) clinician.

Clinical responsibilities. Clinical interactions include daily consultation with patient care services, in effect providing a consultative medical microbiology service (2, 5). Consultation for specimen collection and transport, stained smear interpretation, the role of preliminary and final organism reports in disease diagnosis, development of antibiograms to guide empirical therapy, and the application of antimicrobial susceptibility testing results to the selection of directed therapy is a

time-consuming responsibility in a busy medical center microbiology laboratory. In a modern hospital that bases care on best practices and state-of-the-art data, discharging these responsibilities requires an on-site full-time medical microbiologist (3). This level of consultation and expertise cannot be provided by technical personnel.

While it may be intuitive to believe that such a service is best provided by a CML director trained initially as a physician rather than as a scientist, the different types of CML directors each bring a unique set of strengths and weaknesses with them. Infectious diseases physicians, for example, often are involved in the direct clinical care of patients and bring that knowledge to the laboratory evaluation of microbial isolates and their clinical significance. Pathologists often are involved in the histopathologic or cytopathologic interpretation of specimens that were also submitted for microbiological cultures, which aids in determining or clarifying the clinical significance of microbial isolates. Doctoral scientists often have more-extensive training in basic and applied technologies that provide a more in-depth understanding of diagnostic methods and the relative performance characteristics of different analytical techniques. It is our collective experience, however, that the similarities between individuals with these different backgrounds are far greater than are any differences. Moreover, the important training for medical microbiologists occurs after the individual's terminal degree has been conferred: what matters most is solid postdoctoral training in medical microbiology. Irrespective of a laboratory director's background and training, the primary role of a laboratory director is to provide a consultative service that correlates laboratory data with patient history to construct the best or most likely test interpretation.

Few if any individuals in a hospital setting know and understand pathogenesis, laboratory characteristics of microorganisms, and antimicrobial mechanisms and resistance as they relate to infectious diseases as does the CML director, regardless of his or her doctoral degree (1). This area of knowledge, consolidated from multiple disciplines of science and medicine, is not possessed by others in the patient care arena and should not be overlooked as the most important contribution the microbiology laboratory director can offer. The cytology laboratory has the cytopathologist, and the hematology laboratory has the hematopathologist. Clinical consultation in microbiology does not occur without the medical microbiologist.

Administrative responsibilities. Administrative responsibilities of microbiology laboratory directors across the United States reveals a broad list of contributions, including leading clinical pathology services, hospital infection control programs, divisions of infectious diseases, employee health departments, laboratory information systems, hospital or corporate quality improvement committees, practice guidelines committees, and Institutional Review Board committees. Medical microbiologists with leadership skills create productive relationships with clinical and administrative peers, resulting in the generation of university and corporate policy.

Scientific and academic responsibilities. Many medical microbiologists are active scientists competing for research funding and academic promotion. The prospect of securing research laboratory funding and especially personal salary support is daunting in view of the many competing responsibilities. Because of this, many laboratory directors have chosen

to fund applied research out of local or commercial sources. Academic promotion, in most settings, has evolved to recognize that basic and translational scientists belong to different career tracks, allowing both to achieve promotion to a full professor category based on contrasting yet rigorous criteria. For basic scientists who aspire to a role in the clinical laboratory, postdoctoral work needs to include mentoring in grant application and research funding. Entering the clinical laboratory without an established research record and funding stream is not a recognized pathway to a basic science career.

Educational responsibilities. The responsibility to teach future physicians, scientists, or other health care professionals is one of the most common tasks among university microbiology laboratory directors. Medical microbiologists directing clinical microbiology laboratories have formal and informal teaching responsibilities that may include the medical school curriculum, graduate school seminars and research mentoring, and nursing and medical technology lectures. In total, teaching small groups of medical students, clinical residents, and fellows, which occurs daily and year-around, may be the most time-consuming yet rewarding of all educational activities.

Professional and volunteer responsibilities. Many microbiology laboratory directors are professional and community volunteers or contract workers. Service within professional organizations, such as the American Society for Microbiology, the Infectious Diseases Society of America, and the College of American Pathologists, intellectual contributions to other not-for-profit groups, e.g., the Clinical and Laboratory Standards Institute, visiting professorships, consulting and lecturing for pharmaceutical or laboratory diagnostics companies, laboratory consulting, legal opinions, depositions and court appearances, and political activities to advocate for one's profession constitute a list of activities that can take the director away from the laboratory. Some of these activities are necessary for academic promotion and to secure research funding; others provide additional income, while most enhance one's national or international reputation.

How can microbiology laboratory directors do all of this? Although individuals have different capacities to accomplish a series of professional goals, our observations of current peers suggest that focusing on strengths while delegating other tasks to a management team allows a busy laboratory director to make maximal contributions. The well-managed laboratory has a team of individuals with time allotted to address personnel, quality, safety, business, compliance, and administrative challenges. The addition of associate or assistant laboratory directors further complements the consultative clinical contributions needed for optimal patient care. Important interpretative expertise can be made available 7 days per week in spite of vacations, research time, and professional travel. The cost of this second position can be covered by research income or expanded business opportunities (see below). The two-director (or more) management team model potentially offers a cost-effective approach that delivers optimal laboratory service and patient care.

In contrast to the case with the United States, the National Health System in the United Kingdom specifies the number of faculty members within each specialty in each hospital (Royal College of Pathologists at <http://www.rcpath.org/resources/pdf/BlueSkiesAgendaMicrobiology.pdf>). The number of faculty

members is proportional to the number of beds in that hospital, which is a reflection of the number of patients in the community or area served by that hospital. Such a system does not exist in the United States, where staffing in clinical laboratories is based less on a rational system of providing services and more on the availability of external funding and rules for professional reimbursement that overlook the role of laboratory directors. Not surprisingly, in many small or medium hospitals, the result is that laboratories are staffed by few or no directors who can devote full-time efforts to clinical microbiology (or other areas of clinical pathology/laboratory medicine). In our view, this staffing model is misguided and flies in the face of good laboratory practices, patient care, and patient safety. Clinical laboratories need well-trained directors in every area of the laboratory, not just in those areas that have an external source of funding or where income sharing with other department staff is used to support directors in laboratory medicine.

HOW IS A CML DIRECTOR PAID?

For many CML directors and other laboratory professionals, salary is an ongoing negotiation, although many do not treat it as such (6). While directors are familiar with commodity purchasing for laboratory supplies, where one supplier is pitted against another based on little more than price, most directors do not realize that negotiating an employment contract may be conceptually similar. To change this paradigm, one must decide if the employee is a commodity or whether he/she has the potential to affect the financial bottom line. To move away from being treated as a commodity, the CML director must be aware of business operations and the resulting revenues impacted. Laboratory directors can improve their negotiating positions by earning clinical income (as pathologists or ID physicians), having research grants that pay partial salary and overhead, owning patents, and expanding laboratory outreach business.

Although the concept of improving income and negotiating for a better employment "package" may be uncomfortable to many or even disdained by some as greedy in a profession devoted to care, the ability to do our jobs well or even at all depends on recognition of our value. The quietly laboring laboratory scientist and physician will disappear without being recognized by those who pay the bills. Proving and asserting your worth to the administrators, deans, department chairs, presidents, and business leaders enhances one's value (and that of the institution) and, importantly, pushes the whole profession of laboratory medicine forward and into view.

A director's total income depends on salary and additional income streams. Salary may be supplemented by an individual's or group's ability to generate revenue through professional billing, collecting a laboratory management fee from Medicare Part A hospital reimbursement, or specialty jobs, such as chairing the institution's infection control or antimicrobial utilization committee or outside teaching positions (community colleges, etc.). In addition, it is common for laboratory directors to receive supplemental income derived from lecturing, consulting, writing books or book chapters, and independent contracting.

FUTURE CHALLENGES FOR THE MICROBIOLOGY LABORATORY DIRECTOR

The need for microbiology laboratory directors appears greater than ever before. The emergence of new and old pathogens into susceptible populations, the spread of antimicrobial resistance, food safety, bioterrorism, increased susceptibility of an aging population to common diseases, such as pneumonia, and public health challenges associated with the mobility of world populations all underscore the need for experts in clinical and medical microbiology. Challenges associated with filling this need are many.

Recruiting new directors. Information about the medical microbiology profession needs to penetrate classrooms and laboratories of scientists in training, and medical students need to be informed of pathways leading to laboratory medicine. Lack of awareness and salary disparities between medical and financial sector jobs appear to limit the natural drift of young talent into science and medicine. Novel promotional methods by professional societies and better visibility of mentors could help attract a future generation of medical microbiologists.

Medical microbiology training. Currently, 12 CPEP-accredited training programs and 11 ACGME-accredited medical microbiology training programs exist (3 programs are accredited by both CPEP and ACGME, for a total of 20 unique programs in the United States). Each program trains 1 to 2 fellows per year. This capacity provides all of the medical microbiologists for hospitals in the United States, excluding those who accumulate experience by routes other than fellowship and internationally trained microbiologists. According to the American Hospital Association, in 2008 there were 925 hospitals with 300 or more beds and 523 hospitals with 400 or more beds. If board-certified microbiologists are required in most or all of the larger U.S. hospitals, additional training programs are needed. New programs will require funding from private and government sources. It is disappointing to note that there are no federally funded training programs for clinical microbiology or public health laboratory directors. As with many others in health care, we have concerns about funding programs through the pharmaceutical or biomedical industry. These concerns are obvious: the funding typically is not sustainable, and there is the public perception that funding programs through industry results in the loss of objectivity (and the creation of bias) among those accepting such funding.

It would benefit training and the profession to develop job descriptions, career objectives, and other professional standards. The absence of such information harms the profession when it comes to recognition and funding. The less defined a profession is, the harder it is to explain to others.

Incorporating new technologies. Today's clinical microbiology laboratories have benefited from the introduction of new molecular technologies that are used to detect pathogens and antimicrobial resistance. However, conflict can arise between molecular biologists that have scientific knowledge but a minimal understanding of microbial pathogenesis and infectious diseases and medical microbiologists who have less experience with the molecular science but understand the clinical consequences of a test result. Microbiology results, whether conventional or molecular method based, must be interpreted by appropriate laboratory consultants before release. Communication and cooperation

among laboratory directors are needed to ensure that modern testing approaches do result in better patient care.

Making the remote laboratory more relevant. Another challenge is to provide a microbiology service from a remote location (4). Consolidation of laboratories, resulting in one laboratory providing service to two or more hospitals, is thought to reduce testing costs. From a remote site, consultative laboratory services lose face-to-face communication that provides education and confirmation of result validity. For example, clinicians are not comfortable simply reading a radiology imaging interpretation; they often wish to see the image themselves to validate the accuracy of the radiologist's report. Because of this, high-definition (HD) video monitors that project imaging results are available in clinical care areas. Important smear and culture results are best communicated visually to confirm and convince the care provider that a result is valid. Why not show diagnostic microbiology results on the same HD monitor used in radiology? We in the laboratory need to voice concerns and provide solutions to problems arising from laboratories located far from customers.

Bench research. The backbone of improved CML service has been applied or translational research performed at the bench alongside clinical testing. This research usually has been funded by commercial laboratory equipment and reagent manufacturers or by the pharmaceutical industry. Maintaining productive relationships and continuing to perform clinical research is a challenge in today's streamlined, financially efficient laboratory. It can be difficult for one microbiology laboratory director to oversee all clinical testing and reporting and also to recruit funding to maintain an active research program. The two-director model can accomplish this dual role more easily.

Advocacy relationships. Year after year, federal legislative initiatives are introduced that potentially change the laboratory testing environment. Recent legislation has impacted or has attempted to impact reimbursement, proficiency and accreditation, competitive bidding for Medicare laboratory testing, and Food and Drug Administration action to control testing. We in the profession must participate in the political process to control the effect on clinical microbiology testing and the resulting impact on patient care. We look to our professional organizations for guidance and support.

SUMMARY

Clinical microbiology laboratory directors come from diverse backgrounds with overlapping but not identical training experiences. Although director responsibilities are defined by CLIA legislation, there is no standardization of job descriptions among hospital or university settings. One job that would make the microbiology director indispensable, if done well, is clinical consultation. Other challenges include attracting and educating future directors, expanding income opportunities through novel business plans and research funding, increasing doctoral-level professional staffing to provide clinical, administrative, educational, and scientific competencies, cooperating with fellow laboratory directors to merge novel technical methods with appropriate clinical interpretation, and participating in the political process to drive legislation toward excellence in patient care. Conversation among medical microbiologists is

needed to focus efforts on defining, standardizing, and improving our performance as CML directors.

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