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POSTDOCTORAL PROFESSIONAL FELLOWSHIPS IN LABORATORY MEDICINE

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Abstract

Doctoral level scientists often pursue a traditional academic route, focusing their efforts on research and education. However, additional options exist for those that are interested in using their laboratory and research skills in a clinical setting. Clinical laboratory directors serve as the interface between the clinical laboratory and the users of laboratory test results. This article describes these career paths options for PhD scientists.

Clinical laboratory directors are primarily trained via one of two routes: physicians that have been trained in clinical pathology or non-physician doctoral scientists that have completed professional fellowship training. This article will focus on the latter of these 2 routes. In the United States, completing a postdoctoral fellowship in laboratory-specific professional fields qualifies non-physician doctoral scientists as laboratory directors and consultants. Their expert consultation provides invaluable insight into testing procedures such as possible sources of interference or inaccurate test results, preferred testing for specific clinical situations, and confirmatory methods. They must also be knowledgeable about current instrumentation, assay limitations, and the newest available technologies.

One of the older and more developed professional fellowships in the United States, clinical chemistry, encompasses many laboratory disciplines and will be highlighted in detail. Training information specific to clinical immunology, clinical microbiology, and clinical genetics is also discussed.

INTRODUCTION

"Laboratory professional" is a broad term. It encompasses everyone from the technologist actually performing clinical tests to the directors and administrators of hospitals and laboratories. The fact that the term even exists indicates that the laboratory is a complex environment and that professionals—dedicated, quality, trained individuals—are needed to perform and oversee laboratory assays. Why must we be certain that such a high level of quality exists in this field? Clinical practice depends upon accurate, quality results. Many medical decisions are made based on these results; thus, practices must be in place to ensure excellence.

Laboratorians are at the interface between the clinic and the patient. They serve as the liaison between the clinical laboratory and the end users of diagnostic test results: health care providers. They are an integral part of the health care team. However, in a Correspondence piece in the British Medical Journal in 1975, R. I. Harris commented on the breakdown of the "tenuous link"

between the patient and the laboratory (1). Harris maintained that getting the medical laboratorian into the patient ward was the best way to maintain this link. While Harris was specifically campaigning to increase the interest and exposure of medical graduates to the field of laboratory medicine and clinical chemistry, his plea is (unfortunately) still relevant to many laboratory disciplines in the United States (US) almost 40 years later. We still find recruiting into the laboratory sciences difficult, and we still seek out avenues to increase the laboratory's exposure to those directly involved in patient care. As the importance of quality laboratory results and appropriate test utilization continues to be emphasized in the US, this "tenuous link" will hopefully strengthen.

As Harris alluded to, physicians (specifically pathologists) served as laboratory directors and oversaw all testing disciplines for many decades. Over time, a sharp decrease in the number of pathologists interested in clinical chemistry and similar laboratory-specific specialties has forced a shift in the physician-director paradigm. Non-physician doctoral scientists with postdoctoral training in dedicated areas of expertise have increasingly filled these director positions. This has been a welcome and an appropriate shift, as more than just knowledge of basic biology is needed to produce quality laboratory results and, importantly, develop brand new technologies. Doctoral-level scientists bring qualifications and skills in experimental design, statistics, data analysis, and analytical measurements. Fellowship training strengthens and hones these skills into clinical settings such as chemistry, immunology, microbiology, and genetics.

The need for non-physician scientists in the clinical laboratory has been fueled by several developments. As mentioned, fewer pathologists are trained for or interested in clinical pathology-specific roles. Health care changes in the early 1990's predicted that the field of pathology was over-populated and training programs therefore began to shrink (2). The decrease in the number of trainees during this timeframe subsequently resulted in a paucity of trained laboratory directors that continued through the early 2000's. Currently, this equates to a "graying" of the clinical laboratory director field, with the age of persons in these positions averaging in the mid-50s. Simultaneously, we have seen an increase in the need for laboratory testing, as the US population continues to age and require more testing. Laboratory tests, in general, have also become more complex to both perform and interpret. Thus, laboratory professionals of all levels of training continue to be in demand and the expertise that fellowship training provides continues to be important.

EDUCATION AND TRAINING REQUIREMENTS

Professional fellowship training prepares candidates for a variety of employment opportunities, including positions in the academic, private, industry, or government arenas. Most commonly, postdoctoral fellows go on to become laboratory directors. The Clinical Laboratory Improvement Amendment (CLIA) of 1988 dictates in section 493.1443(b)(3)(i) of the Federal Register that laboratory directors or clinical consultants must be a doctor of medicine with board certification in anatomic or clinical pathology (or both) or hold a doctoral degree in a chemical, physical, biological, or clinical laboratory science with certification by a board deemed acceptable by the Department of Health and Human Services (HHS) (3) (Table 1). CLIA guidelines further stipulate that clinical consultants to the laboratory must be able to provide clinical consultation to laboratory clients, be available to assist clinicians in ordering appropriate tests for their clinical needs, ensure that test results can be interpreted accurately by providing supplementary documentation when necessary, and ensure that results are of the highest quality. They are responsible for selecting test methodologies that are appropriate for the intended clinical use, establishing appropriate quality control programs, and ensuring adequate performance in applicable proficiency testing programs. Directors must be qualified to consult with clinicians concerning diagnosis, treatment, and management of patient care. Professional postdoctoral fellowships prepare trainees in each of these areas (summarized in Table 2). This allows postdoctoral scientists to serve as true ambassadors of the laboratory to those that utilize test results in patient care.

Table 1

Board certifications approved by the Department of Health and Human Services for doctoral directors of laboratories performing high complexity testing (22)

Abbreviation	Certification Board		
АВВ	American Board of Bioanalysis		
ABCC	American Board of Clinical Chemistry		
ABFT	American Board of Forensic Toxicology		
АВНІ	American Board of Histocompatibility and Immunogenetics		
ABMG	American Board of Medical Genetics		
ABMLI	American Board of Medical Laboratory Immunology		
ABMM	American Board of Medical Microbiology		
NRCC	National Registry of Certified Chemists		

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Table 2 Summary of professional fellowships available to doctoral scientists			
Fellowship	Accrediting Agency	Board Certification	Duration of Training*
Clinical Chemistry	ComACC	ABCC	2 years
Clinical Immunology	CPEP	ABMLI	2 years
Medical Microbiology+	CPEP	ABMM	2 years
Clinical Biochemical Genetics	ABMG	ABMG	2-3 years
Clinical Cytogenetics	ABMG	ABMG	2-3 years
Clinical Molecular Genetics	ABMG	ABMG	2-3 years

* Traditional length of training; may vary by institution.

+ Accreditation Council for Graduate Medical Education (ACGME)-accredited training programs for MD also exist.

ComACC, Commission on Accreditation in Clinical Chemistry; CPEP, Committee on Postgraduate Educational Programs; ABMG, American Board of Medical Genetics; ABCC, American Board of Clinical Chemistry; ABMLI, American Board of Medical Laboratory Immunology; ABMM, American Board of Medical Microbiology.

FELLOWSHIP TRAINING IN CLINICAL CHEMISTRY

The field of clinical chemistry is associated with many different names (which may vary by country), such as chemical pathology, clinical biochemistry, medical chemistry or pathological chemistry (4). Clinical chemistry has been the preferred nomenclature in the US, and is in fact represented in the name of one of the larger professional organizations in this field, the American Association for Clinical Chemistry (AACC). Clinical chemistry is multidisciplinary by nature. Topics as varied as immunology, toxicology, molecular diagnostics, endocrinology, analytical chemistry purposely provides broad exposure to many topics, allowing the trainee to either work in a generalized environment or focus on a sub-specialty. While the role that the clinical chemist currently plays has adapted over many years, at its heart it is the result of "an interdisciplinary fusion involving elements of clinical medicine on the one hand and elements of chemistry on the other hand" (4).

While physicians interested in clinical chemistry often complete a residency in pathology, non-physician scientists commonly enter the field through a postdoctoral fellowship program. Many of the doctoral-level scientists that pursue fellowship training were exposed to the laboratory sciences during earlier training or education. For example, a Bachelor's degree in clinical laboratory science or medical technology provides an excellent background for further training in laboratory medicine.

ACCREDITED TRAINING PROGRAMS

The Commission on Accreditation in Clinical Chemistry (ComACC) is an independent and nationally recognized agency charged with establishing the educational standards that formal clinical chemistry fellowship training programs in the US must adhere to (5). Accreditation ensures that all training programs are providing comparable education that integrates patient care, clinical service, management, research, education, and administration. Programs complete self-evaluations and are subject to a site visit by ComACC commissioners every five years. ComACC-accredited programs are publicly recognized, in order to attract the most qualified candidates. Completing a ComACC-accredited training program also allows the candidate to sit for national certification exams (discussed later) prior to meeting the experience requirements. There are currently 21 ComACC-accredited clinical chemistry postdoctoral fellowship programs within the US, and one in Canada (6). Most programs accept one candidate per year, with a few offering 2 or even 3 fellowship positions per year.

ComACC outlines the standards and guidelines expected from all accredited programs, and provides methods for improvement when appropriate. Their standards and guidelines address the qualifications of the program director and teaching faculty, institutional space, laboratory facilities, educational materials, minimum curriculum requirements, admission criteria, program evaluation, and requirements for maintaining accreditation (7). ComACC-accredited training programs are a minimum of 2 years in length, with some extending beyond that timeframe to allow for more focused research. More recently, programs have been extending their training periods to accommodate for newly emerging fields of clinical study, such as information sciences, pointof-care testing, molecular diagnostics, forensic toxicology, and laboratory management sciences.

Program Requirements and Curriculum

All postdoctoral fellowships in clinical chemistry have similar minimum admission requirements, while some may require additional qualifications. Candidates will have earned a Doctor of Philosophy (PhD, or equivalent) in chemistry or another of the natural sciences. Coursework requirements are in line with those required by the national registry examination boards. Specifically, 30 semester hours (or equivalent) of undergraduate and/or graduate level chemistry or biochemistry from an

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approved institution must be obtained prior to admission (5).

Most clinical chemistry fellowship curriculums are focused on both didactic and clinical learning, with an emphasis on preparing candidates in clinical service, research, teaching, and laboratory administration. While training is not standardized among programs, ComACC and others provide formal curriculum guidelines that encompass laboratory management, laboratory safety, basic statistics, specimen collection and processing, clinical chemistry techniques and instrumentation, and laboratory test interpretation (5, 8, 9). Additionally, specific disease states such as endocrine disorders, cardiovascular disease, liver and kidney abnormalities need to be understood from both the biological and laboratory analysis standpoint. Formal coursework may be incorporated into the first year of training to provide competency in these basic areas. Quality assurance and the importance of quality laboratory results is another area that is highly emphasized during the training period.

Since postdoctoral candidates have traditionally only been exposed to the academic research environment prior to entry into a fellowship program, clinical laboratory experience is the main emphasis of the fellowship curriculum. Clinical knowledge, from medical terminology to on-call experience, is often foreign to candidates at the start of their training. Hands-on learning is a successful means to provide this experience. Additionally, many programs train fellows alongside resident trainees, often in pathology or similar disciplines. The interaction between those with clinical knowledge and those with research/laboratory knowledge often proves fruitful for both parties. While fellows get an introduction to practical patient concerns and clinical problem solving through differential diagnosis from the residents, residents get exposure to experimental design, laboratory techniques, and an understanding of how these techniques can be used to support clinical diagnoses from the fellows.

Fellows gain clinical knowledge and technical expertise by rotating through various areas of the hospital laboratory. Programs may dictate a specific number of weeks that are spent in each of the available disciplines, e.g., core chemistry, toxicology, hematology, immunology, or endocrinology. Pre-analytical areas, quality control, and the generation of reference values should also be included in this early training. Fellows often observe and shadow laboratory staff in these areas in order to gain an indepth understanding of different testing methods. Fellow rotations often overlap with the training provided to residents in pathology; however, the clinical chemistry fellow is expected to have more in-depth knowledge and exposure to the technical aspects of laboratory testing. Rotations frequently include didactic lessons, exercises requiring interpretation of patient results, or literature review to emphasize learning in these areas. Fellows participate in medical rounds and case conferences to reinforce what they are experiencing in the clinical laboratory.

Invariably, one of the best mechanisms for learning and acquiring clinical expertise is to be responsible for the laboratory service pager. "On-call" duties will vary depending on the clinical area the fellow is servicing (e.g., immunology, molecular diagnostics, chemistry). Answering questions and following up on concerns from the health care team allows for gathering of clinical information first-hand and outstanding learning opportunities. Calls made to the traditional chemistry laboratory service may include consulting on laboratory test interpretation, consulting on appropriate test utilization, approval of costly send-out testing, or handling mislabeled or unlabeled specimens. Being on-call can also be a good way to investigate highly unusual cases that may become useful research projects or case studies. Fellowship training programs should not underestimate the utility of on-call responsibility and should be encouraged to provide ample opportunity for fellows to rotate on the pager service.

Clinical chemistry fellowship training programs also include a research component, although programs will vary with how much this is emphasized. The research that a fellow would participate in is traditionally very translational in nature, addressing clinical concerns or delving into an analytical complexity. Alternatively, programs with extensive faculty resources may emphasize basic research such as biomarker discovery. A fellow is commonly balancing many research projects at once, with varying degrees of involvement. They are encouraged to present their findings at national and local scientific meetings, as well as departmental seminars.

Depending on where the clinical chemistry fellow decides to work following their training, there is likely to be a component of teaching required in their position. Thus, creating lectures and sharing their knowledge is an important piece of a well-rounded fellowship. In most academic centers, there are bountiful opportunities to give seminars and presentations. Fellows may also be charged with giving didactic lectures to rotating residents and continuing education lectures to laboratory staff of all levels. These opportunities for learning can be a great resource for a hospital laboratory and their staff.

Laboratory administration is another area that should be stressed during fellowship training. This is one of those areas that is rarely formally taught, but rather must be "experienced." Management courses may be offered that address varied topics, such as capital equipment decisions, cost accounting, risk management, and the like. On-call experiences can also afford opportunities to learn specific aspects of laboratory management. Toward the end of their training, many fellowships offer the trainee the opportunity to assume responsibility as an acting assistant laboratory director. In this role, the trainee is responsible for making daily decisions and is involved in problem solving under the direction of the actual laboratory director. As mentioned, this is one of the best ways to "experience" this role before formally stepping into it.

CERTIFICATION EXAMINATION

CLIA personnel regulations stipulate that proper certification must be achieved in order to serve as the director of a high complexity clinical laboratory or a clinical consultant in laboratory medicine (3). Board certification also identifies laboratory

professionals as experts and provides additional assurance of the diplomate's qualifications. The two most common board certifications obtained by clinical chemists in laboratory director positions are from the American Board of Clinical Chemistry (ABCC) and the National Registry of Certified Chemists (NRCC). Both are recognized by the HHS (Table 1) and have education and experience requirements that must be met before sitting for examination. The ABCC requires 30 semester hours of chemistry or biochemistry coursework, plus 5 years of postgraduate experience in the field of clinical chemistry (10). Alternatively, the experience requirement can be fulfilled by completing a minimum of one year in a ComACC-accredited postdoctoral clinical chemistry training program. The multiple choice written exam focuses on displaying mastery and knowledge of diverse areas in clinical chemistry, including how preanalytical concerns (patient preparation, sample handing) can affect laboratory results, analytical techniques, quality control evaluation, safety, laboratory test interpretation, basic chemistry, pathophysiology, laboratory management, and laboratory calculations. Questions are written and maintained by members of the Board. Beyond clinical chemistry, the ABCC also offers specialty certification exams in toxicological chemistry and molecular diagnostics. These exams have education and experience requirements in line with the clinical chemistry examination. There are currently 309 individuals listed in the registry of active diplomates in clinical chemistry, 49 in toxicology, and 58 in molecular diagnostics (11). The NRCC has various requirements, depending upon the initial degree held by the candidate. Those holding a doctor's degree require 24 semester hours of chemistry, 8 semester hours of additional natural science courses, and 2 years handling of human specimens for diagnostic and/or therapeutic purposes (12). Similar to ABCC, those enrolled in a ComACC-accredited fellowship program may sit for the exam after their first year. They must then complete their second year of training before being fully certified by the NRCC. The multiple choice written exam encompasses basic science, methodology, and laboratory practice and emphasizes analysis and evaluation. Preanalytical details and laboratory management are also included.

In an online employment survey of a subset of the AACC membership (29 members of the Society for Young Clinical Laboratorians) from October 2010, 86% had indicated that they had obtained board certification (13). Ninety-two percent of respondents had obtained their board certification from the ABCC and 8% from the NRCC. The majority of these respondents (44%) had taken the exam during their 2nd year of fellowship, 41% had taken it after starting in their first job, and 11% took it during their 1st year of fellowship. Many of those that took the exam after their fellowship indicated that their employer provided dedicated study time for them to complete the exam, suggesting the importance employers place on board certification.

After diplomate status is achieved, there are requirements to maintaining active status. In an article describing continuing clinical chemistry education in the US, R. B. Conn stated, "clinical chemists, like technology, become obsolete if they fail to stay abreast of the new science and new technology that are continually being introduced into their specialty" (14). The ABCC dictates that participation in continuing education events must be demonstrated, with a minimum requirement of 50 contact hours every 2 years. Continuing education in clinical chemistry is available from a number of providers, including the AACC, the American Society for Clinical Pathology, the National Academy for Clinical Biochemistry, the American Chemical Society, and the American Society for Biochemistry and Molecular Biology.

Recertification exams are an active area of debate among non-physician clinical chemists. Most MD specialties require satisfactory completion of recertification examinations at prescribed intervals throughout a physician's career. While recertification exams are not currently in place, aligning PhD clinical chemist requirements with those of MD specialties has been proposed and is currently under consideration.

EMPLOYMENT OPPORTUNITIES

Those that complete postdoctoral fellowships in clinical chemistry are prepared to serve in academic laboratory settings, in private clinical practices, in industry, or in government agencies. Results from the Society for Young Clinical Laboratorians employment survey from 2010 (13) indicated that 41% of participants were employed in academic hospital environments, with remaining employers listed as (in descending order) academic institutions, industry, hospital laboratories, reference laboratories, clinic laboratories, and pathology groups. The majority of respondents were paid directly by the hospital or university that they were employed by, with a smaller fraction paid in part by grants or external funding. Twenty-four percent of participants reported a starting salary between \$100,000 and \$110,000. Slightly over 60% were expected to conduct research, almost 90% were expected to publish, and almost 40% were expected to write grants for extramural funding. As we continue to see the "graying" of many senior members of this diverse field, clinical chemistry remains a highly employable specialty.

FELLOWSHIP TRAINING IN CLINICAL IMMUNOLOGY

Clinical immunology studies diseases of the immune system and immune components of other disease processes. There are myriad specialties under the immunology umbrella, including autoimmunity, immunodeficiency, transplant immunology, allergy, and infectious diseases. The field is also commonly referred to as medical laboratory immunology. Fellowship training programs prepare their graduates for leadership positions within the field. Clinical immunologists support daily patient management by working with members of the health care team, including primary care providers, specialists in infectious, autoimmune and immunodeficiency diseases, and pharmacists. Beyond ensuring accurate clinical information in the hospital setting, they also work in the research and discovery arenas to develop new technologies and diagnostics, and have an important role in public health.

Accredited Training Programs

Unlike other research-based immunology fellowships, accredited clinical immunology fellowship training programs focus specifically on the clinical aspects of human disease and diagnosis. This focus purposely trains fellowship graduates to work in areas that support these clinical processes. The American College of Microbiology, within the American Academy of Microbiology, is the body responsible for accrediting postgraduate education programs in the US under the American Society for Microbiology (ASM). They designate the actual accreditation process to the Committee on Postgraduate Educational Programs (CPEP). The Committee is comprised of experienced, board certified medical microbiologists and immunologists, representing various subspecialties. Accredited programs comply with the CPEP's Essentials and Guidelines, in order to ensure the highest quality training standards are being upheld by each program (15). The process includes an on-site inspection, and programs are reaccredited every 7 years. There are 3 CPEP-accredited clinical immunology postgraduate training programs in the US currently listed by the ASM (16), all maintained within hospital laboratories and academic institutions.

PROGRAM REQUIREMENTS AND CURRICULUM

Fellowship candidates must have a doctoral level degree (PhD or equivalent) in immunology with graduate education (often 2 years, minimum) in immunology. Alternatively, MDs with residency in internal medicine, pediatrics, or 2 years minimum of research in immunology are also qualified.

The fellowship curriculum can vary, but often focuses on diagnostic and clinical services, laboratory administration, research, and teaching, with additional emphasis on epidemiology, public health, and laboratory safety. Testing methods in all areas of immunology are explored, including those associated with malignancies, immunodeficiencies (innate and adaptive), autoimmune diseases, allergies, transplantation, and infectious diseases (caused by bacterial, fungi, or viruses, such as hepatitis and human immunodeficiency virus (HIV)). Depending on the facilities available, trainees rotate through pertinent clinical laboratories, including histocompatibility and immunogenetics laboratories, public health laboratories within the Department of Public Health. These rotations expose fellows to a broad range of immunologic procedures and molecular techniques. Additional topics included in didactic lessons, coursework, and laboratory rotations include protein serology, allergy, autoimmune disease serology, microbial serology, cellular and innate immunity, flow cytometry, hepatitis and retrovirus serology, medical informatics, and clinical diagnosis and management by laboratory methods. Clinical expertise is gained through these laboratory and clinical rotations, and also through on-call responsibility and consulting with the health care team on clinical diagnostic questions. Fellows round out their training by completing research projects that are predominantly clinical in nature, presenting research at national and local meetings, and preparing teaching lectures.

CERTIFICATION EXAMINATION

Expertise in clinical immunology is demonstrated by successful completion of the American Board of Medical Laboratory Immunology (ABMLI) certification examination, which is administered by the American College of Microbiology. ABMLI certification is recognized by HHS as a suitable qualification to direct a clinical laboratory (Table 1). Eligibility to sit for the examination is dependent upon acceptable combinations of education, postdoctoral training, and/or experience (17). Those that complete a 2 year CPEP-accredited fellowship training program will qualify with a total of 2 years of training and experience. Those with shorter (or no) postdoctoral experience require a total of 3 years of training and experience. The College states the objective of the multiple choice computer-based examination is "to measure the candidate's knowledge, problem-solving abilities, and clinical judgment in subject areas considered necessary for the effective directorship of a laboratory engaged in the practice of medical laboratory immunology" (18). Questions are divided among 4 domains: basic immunologic mechanisms, methodology, immunodiagnosis and clinical laboratory correlation, and laboratory management. The number of people that successfully complete the exam varies from year to year, with an average pass rate of 38% from 2008 through 2012 (18). Seventeen individuals have become board certified in immunology from the ABMLI since 2008.

Documentation of continuing education is required to maintain status as an active diplomate of the ABMLI. Diplomates must accumulate 150 contact hours or 15 continuing education units (CEU) every 3 years. Educational activities include opportunities such as attending approved educational programs, contributing to textbooks, authoring peer-reviewed articles, preparing and presenting lectures approved for CEU, and obtaining additional board certification.

Alternatively, clinical immunologists may act as directors of histocompatibility and immunogenetics laboratories. This position requires certification from the American Board of Histocompatibility and Immunogenetics (ABHI).

EMPLOYMENT OPPORTUNITIES

Graduates of clinical immunology fellowship training programs often place into directorship positions in community or academic hospital clinical immunology laboratories. Beyond directing daily patient care by providing supportive clinical laboratory

information, fellowship graduates also contribute in the public health laboratory setting, in the clinical or translational research or industry environment, or in educational roles.

FELLOWSHIP TRAINING IN CLINICAL MICROBIOLOGY

Similar to the previously mentioned professional fellowships, fellowship training in clinical microbiology focuses on the link between laboratory assays and clinical diagnoses. The field of microbiology encompasses all aspects of human infection by pathogens, including bacteria, viruses, fungi, or parasites. Clinical microbiology may also be referred to as medical and public health laboratory microbiology. This alternative title provides an even clearer picture of the roles that clinical microbiologists fill. In the US, clinical microbiology training is often closely associated with training in clinical immunology; in fact, many aspects of these fellowships overlap considerably. Where applicable, the reader will be referred to the Fellowship Training in Clinical Immunology section for further details.

Graduates of clinical microbiology fellowship training are integral to all aspects of understanding clinical disease. They contribute their broad knowledge base to new discoveries, new treatments, prevention protocols, and diagnostic procedures. Clinical microbiologists are also integral to furthering our understanding of newly developing strains of antibiotic-resistant bacteria, and contribute to emerging areas of needed research, such as bacteriological acts of bioterrorism or determining sources of infectious outbreaks. The clinical diagnostics used to detect infectious diseases are critical not only to treating and monitoring the infected, but to limiting the spread of disease to the uninfected.

ACCREDITED TRAINING PROGRAMS

Clinical microbiology fellowship training programs in the US are accredited by the same body that oversees clinical immunology programs (CPEP, see "Accredited Training Programs" under Fellowship Programs in Clinical Immunology). Training programs are offered in large medical institutions and academic centers. There are 12 clinical microbiology CPEP-accredited US training programs currently listed on the ASM website (16). Most programs accept one fellow each year, with some accepting new candidates every other year.

PROGRAM REQUIREMENTS AND CURRICULUM

Candidates for CPEP-accredited programs have doctoral degrees (PhD or similar) and have completed graduate education in microbiology or immunology. Accreditation Council for Graduate Medical Education (ACGME)-accredited training programs for MDs also exist. Often, training programs are accredited by both agencies and thus recruit both PhD and MD candidates. Most training curriculums feature learning in diverse areas such as serology, diagnostic bacteriology, mycology, parasitology, virology, antimicrobial testing, mycobacteriology, and molecular techniques used in infectious diseases such as hepatitis and HIV. Pathogen detection and identification are emphasized, as well as techniques used to determine drug susceptibility to guide treatment in infected individuals. Experience is gained during rotations through the relevant laboratory areas, didactic lessons, literature review, and independent clinical research. Additionally, as mentioned in earlier discussions, on-call consultations are integral to the learning experience of a fellowship trainee. Also analogous to the previously described fellowships, laboratory management and administrative skills are encouraged and experienced throughout training.

CERTIFICATION EXAMINATION

In the US, diplomates of the American Board of Medical Microbiology (ABMM, under the direction of the American College of Microbiology) are recognized by the HHS as qualified to direct clinical laboratories responsible for microbiological diagnosis of human disease (Table 1). Similar to immunology certification, eligible candidates must have obtained appropriate education, postdoctoral training, and/or adequate work experience. A doctorate degree in microbiology (or equivalent) along with completion of a CPEP-accredited fellowship fulfills these requirements; those without this training require 3 years of work experience, as defined by the Board (19). The recently revised multiple choice computer-based examination now determines candidates' aptitude in 4 areas: directing laboratory testing functions (44.5% of questions), directing laboratory administrative functions (19.5% of questions), ensuring safety and security in the laboratory (13% of questions), and consulting with other medical professionals (23% of questions) (20). Within these domains, test content will focus on areas such as interpreting patient test data, developing protocols, understanding regulatory requirements for laboratory testing, critically reviewing published studies, managing personnel, evaluating performance of equipment, establishing proficiency testing programs, performing risk assessments, recognizing disease state and clinical implications of results, and recommending alternate or confirmatory tests (21). Between 2008 and 2012, 108 individuals have passed the examination, with an average yearly pass rate of 29% (20).

Once certified, the recertification process is the same as outlined above for ABMLI diplomates (see "Certification Examination" under Fellowship Programs in Clinical Immunology). Active status is maintained by obtaining 150 contact hours or 15 CEUs every 3 years.

EMPLOYMENT OPPORTUNITIES

Clinical microbiologists often contribute to clinical, public health, or research and discovery laboratories. As mentioned, newly emerging areas in microbiology such as bioterrorism and antimicrobial resistant bacterial strains ensure a consistent job market for properly trained individuals. Clinical microbiologists will also remain in demand as research continues to move from research laboratory to clinical laboratory. Research into new antimicrobial agents and treatments will provide additional opportunities for PhD clinical microbiologists.

Similar to the other clinical fields mentioned, clinical microbiology also provides ample employment positions to newly trained, qualified individuals. Older generations of laboratory directors have often been "grandfathered" in to their positions, since HHS requirements were previously not as stringent as they are today. As current laboratory directors continue to move toward retirement, fewer individuals are now considered qualified to take on these positions and direct clinical laboratories. Currently, there are more jobs than candidates, which makes the field an attractive option for those interested in the clinical aspects of science and discovery.

FELLOWSHIP TRAINING IN CLINICAL GENETICS

A discussion of postdoctoral professional fellowships should also include the field of genetics. Opportunities in genetics are extremely varied, however, and a full discussion of each of the specialty areas would warrant its own article. Therefore, only a very brief description of the field follows.

PhD scientists are eligible for fellowships in clinical biochemical genetics, clinical cytogenetics, and clinical molecular genetics. Clinical biochemical genetics fellowships provide training in laboratory diagnosis and monitoring of patients with inherited metabolic disorders (inborn errors of metabolism). Clinical cytogenetics involves the identification and interpretation of chromosomal abnormalities. Clinical molecular genetics focuses on laboratory testing for the genetic mutations that underlie all types of disease. Training in all 3 fellowships encompasses laboratory expertise, clinical or basic research, assay development and validation, presentations, and educational lectures. Each includes on-call responsibilities, as well.

The American Board of Medical Genetics (ABMG) accredits individual training programs and oversees their curriculum. The ABMG is also responsible for administering their individual board examinations and maintaining recertification documentation.

SUMMARY

The postdoctoral professional fellowships described here represent unique opportunities for PhD scientists to contribute to patient care and clinical diagnostics. Clinical chemistry, clinical immunology, clinical microbiology, and clinical genetics all encompass diverse areas that address very different components of patient care. Each acts as a consultant to the health care team, providing an interface between the laboratory and the final user of laboratory data. The clinical expertise obtained during fellowship training is integral to successful interpretation and advisement.

Whether interacting with patient health care teams or leading innovative biomarker discoveries, postdoctoral scientists bring incredibly relevant skill sets to the clinical laboratory that benefit disease diagnosis and monitoring. PhD's should be encouraged to pursue these unique employment opportunities.

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References

- 1. Harris, R.I., Letter: Medical graduates in clinical chemistry. Br Med J, 1975. 1(5948): p. 35-6.
- 2. Scott, M.G., W.M. Dunne and A.M. Gronowski, Education of the PhD in laboratory medicine. Clin Lab Med, 2007. 27(2): p. 435-46.
- 3. Clinical Laboratory Improvement Amendments. Current CLIA Regulations. Website. Accessed March, 2013. http://wwwn.cdc.gov/clia/regs/toc.aspx
- 4. Buttner, J., Clinical chemistry as scientific discipline: historical perspectives. Clin Chim Acta, 1994. 232(1-2): p. 1-9.
- 5. Commission on Accreditation in Clinical Chemistry. Website. Accessed March, 2013. http://www.comacc.org/Pages/default.aspx
- 6. Commission on Accreditation in Clinical Chemistry. Training Programs. Website. Accessed March, 2013. http://www.comacc.org/training/Pages/default.aspx
- 7. Comission on Accreditation in Clinical Chemistry. Standards and Guidelines for Postdoctoral Training Programs in Clinical Chemistry. Website. Accessed March, 2013. http://www.comacc.org/standards/Pages/Default.aspx
- 8. Allen, L.C. and P.S. Bunting, Postdoctoral training in clinical chemistry: laboratory training aspects. Clin Biochem, 1995. 28(5): p. 481-97.
- 9. Smith, B.R., et al., Curriculum content and evaluation of resident competency in clinical pathology (laboratory medicine): a proposal. Clin Chem, 2006. 52(6): p. 917-49.

- 10. American Board of Clinical Chemistry. Website. Accessed March, 2013. http://www.abclinchem.org/geninfo/Pages/default.aspx
- 11. American Board of Clinical Chemistry. Register of Active Diplomates. Website. Accessed March, 2013. http://www.abclinchem.org/offdipl/Pages/diplomates.aspx
- 12. National Registry of Certified Chemists. Website. Accessed March, 2013. http://www.nrcc6.org/cc.htm
- 13. SYCL Employment Survey (2010). American Association for Clinical Chemistry. Website. Accessed March, 2013. http://www.surveymonkey.com/sr.aspx?sm=dy4jZA_2bpls2rBF1v4R1cAlqvVuH9CVKijvKJ57veH3I_3d
- 14. Conn, R.B., Continuing clinical chemistry education in the United States. Clin Chim Acta, 1994. 232(1-2): p. 47-51.
- 15. Essentials and Guidelines of an Accredited Postgraduate Residency Program in Medical Laboratory Immunology. Website. Accessed March, 2013. http://www.asm.org/images/Academy/College/immunology%20essentials.pdf
- 16. American Society for Microbiology. CPEP-Approved Postgraduate Training Programs. Website. Accessed March, 2013. http://www.asm.org/index.php/postgraduate-training-cpep/cpep-approved-programs
- 17. American College of Microbiology. ABMLI Eligibility Information. Website. Accessed March, 2013. http://www.microbiologycert.org/abmlieligibility.asp
- 18. American College of Microbiology. ABMLI Exam Information. Website. Accessed March, 2013. http://www.microbiologycert.org/abmliexam_info.asp
- 19. American College of Microbiology. ABMM Eligibility Information. Website. Accessed March, 2013. http://www.microbiologycert.org/abmm-eligibility.asp
- 20. American College of Microbiology. ABMM Exam Information. Website. Accessed March, 2013. http://www.microbiologycert.org/abmm-exam_info.asp
- 21. American Board of Medical Microbiology (ABMM). Examination Content. Website. Accessed March, 2013. http://www.microbiologycert.org/ documents/ABMM_Exam_Content_122012.pdf
- 22. Centers for Medicare and Medicaid Services. Certification Boards for Laboratory Directors of High Complexity Testing. Website. Accessed March, 2013. http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html