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The Pathology Workforce and Clinical Licensure: The Role of the PhD Clinical Laboratorian in the United States

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Abstract

There has been a recent recognition of the need to prepare PhD-trained scientists for increasingly diverse careers in academia, industry, and health care. The PhD Data Task Force was formed to better understand the current state of PhD scientists in the clinical laboratory workforce and collect up-to-date information on the training and certification of these laboratorians. In this report, we summarize the findings of the PhD Data Task Force and discuss the relevance of the data collected to the future supply of and demand for PhD clinical laboratory scientists. It is clear that there are multiple career opportunities for PhD scientists in academic medical centers, commercial clinical laboratories, biotechnology and pharmaceutical companies, and the federal government. Certified PhD scientists have and will continue to form an important resource for our technologically advancing field, bringing training in scientific methods, and technologies needed for modern laboratory medicine. The data gathered by the PhD Data Task Force will be of great interest to current and future PhD candidates and graduate PhD scientists as they make decisions regarding future career directions.

Keywords

laboratorian, pathology and laboratory medicine workforce, PhD clinical scientists, postdoctoral training

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Introduction

The workforce of professionals involved in pathology, laboratory medicine, and clinical laboratory science has been the subject of recent study. Much of this research has focused on the number of pathologists currently in practice,[1] the training of new pathologists,[2] the anticipated future demand for pathologist services,[3] and the potential shortage of pathologists in the coming years.[1] The clinical laboratory technologist workforce has also been the subject of surveys and other studies.[4] Less work has been done to address the supply of and demand for other members of the clinical laboratory team.[5]

In 2013, representatives of major pathology and laboratory medicine professional organizations gathered to assess the current state of the overall clinical laboratory workforce. The Pathology Workforce Summit, held in December of 2013 and cosponsored by the American Society for Clinical Pathology (ASCP), Association of Pathology Chairs (APC), College of American Pathologists (CAP), and United States and Canadian Academy of Pathology (USCAP), involved a total of 24 pathology and other medical organizations (Table 1). Following a full day of live discussion, augmented by pre- and postmeeting

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Table 1. Pathology Workforce Summit Participating Organizations.

Participating Organizations
Academy of Clinical Laboratory Physicians and Scientists (ACLPS)
Accreditation Council for Graduate Medical Education (ACGME)–Pathology Residency Review Committee (RRC)
American Association of Neuropathologists (AAN)
American Board of Oral and Maxillofacial Pathology (ABOMP)
American Board of Pathology (ABP)
American Medical Association (AMA)
American Pathology Foundation (APF)
American Society for Clinical Pathology (ASCP)*
American Society for Investigative Pathology (ASIP)
American Society of Cytopathology (ASC)
American Society of Dermatopathology (ASD)
Association for Molecular Pathology (AMP)
Association for Pathology Informatics (API)
Association of American Medical Colleges (AAMC)
Association of Clinical Scientists (ACS)
Association of Directors of Anatomic and Surgical Pathology (ADASP)
Association of Pathology Chairs (APC)*
Canadian Association of Pathologists (CaAP)
College of American Pathologists (CAP)*
National Association of Medical Examiners (NAME)
Program Directors Section (PRODS) of APC
Society for Hematopathology (SH)
Society for Pediatric Pathology (SPP)
United States and Canadian Academy of Pathology (USCAP)*

* Summit cosponsors.

Table 2. Pathology Workforce Summit–Consensus Future Needs.

Workforce-related needs for the future
Better describe the work done by pathology and laboratory medicine professionals to a variety of audiences (the public, policy makers, medical students, each other, etc)
Recruit bright students into careers in pathology and laboratory medicine
Train students and residents to be highly employable upon graduation
Assess whether the current paradigm for training pathologists needs to be reformed, integrating residency, and fellowship training, to meet the needs of employers and of new-in-practice pathologists
Keep a continuous, real-time cycle of review that allows periodic assessment of evolving skills used in practice
Propagate an outlook of lifelong learning to maintain and enhance career opportunities and applicability to current health-care delivery systems and payment models

exercises, participants reached consensus on a series of workforce-related needs for the future (Table 2) and multiple follow-up activities to support these needs. An executive summary of the Workforce Summit and the Propositions can be found at the following links: https://www.spponline.org/files/galleries/WorkforceSummitExecSummary14-01.pdf; https://www.spponline.org/files/galleries/WorkforceSummitPropositions14-01.pdf.

One of the topics discussed during the Summit was the important role that PhD clinical scientists play as members of the clinical laboratory team. For many years, PhD-trained scientists have served as participants or leaders in various sections of clinical laboratories and as clinical laboratory directors. Although these roles are well established and many PhD scientists have received special training and, in most cases, subspecialty certification for this work, Summit participants agreed that there has never been a comprehensive accounting of the PhD clinical laboratory scientist workforce. Specifically, the number of PhD-trained scientists currently engaged in clinical laboratory practice is unknown, and there is no published national data on the number of PhD-holding scientists who currently receive fellowship training and/or subspecialty certification each year in clinical laboratory disciplines.

Table 3. PhD Data Task Force Participating Organizations.

Organization Names
Academy of Clinical Laboratory Physicians and Scientists (ACLPS)
American Board of Bioanalysis (ABB)
American Board of Clinical Chemistry (ABCC)–American Association for Clinical Chemistry (AACC)*
American Board of Histocompatibility and Immunogenetics (ABHI)–American Society for Histocompatibility and Immunogenetics (ASHI)*
American Board of Medical Laboratory Immunology (ABMLI)–American Society for Microbiology (ASM)*
American Society for Clinical Pathology (ASCP)
American Society of Cytopathology (ASC)
American Society for Investigative Pathology (ASIP)
Association for Molecular Pathology (AMP)
Association for Pathology Informatics (API)
Association of Clinical Scientists (ACS)
Association of Pathology Chairs (APC)
College of American Pathologists (CAP)–Laboratory Accreditation Program (LAP)*

* Involved in certification of PhD clinical laboratory scientists or accreditation of clinical laboratories.

To better understand the current state of the PhD clinical laboratory scientist workforce and collect up-to-date information on the training and certification of these laboratorians, the PhD Data Task Force (PDTF) was formed as a follow-up to the Pathology Workforce Summit. Managed by the APC and made up of representatives of 8 pathology and clinical laboratory organizations and 4 additional organizations involved in the certification of PhD clinical laboratory scientists or accreditation of clinical laboratories (Table 3), the PDTF has compiled the most complete data set available, to date, on this important component of the overall clinical laboratory workforce.

In this report, we summarize the findings of the PDTF and discuss the relevance of the data collected to the future supply of and demand for PhD clinical laboratory scientists. There has been a recent recognition of the need to prepare PhD-trained scientists for increasingly diverse careers in academia, industry, and health care.[6] The information gathered by the PDTF adds a significant new data set that may help inform organizational decisions and/or government policy regarding the future training and/or certification of PhD scientists for work in the clinical laboratory. These data will also potentially be of great interest to current and future PhD candidates and graduate PhD scientists as they make decisions regarding future career directions.

Background

Accreditation

Most clinical laboratories in the United States that test human specimens for the diagnosis and treatment of patients fall under the jurisdiction of the Clinical Laboratory Improvement Amendments (CLIA). There are a few exceptions such as drug testing laboratories for forensic or Department of Transportation testing, clinical trial testing, and government laboratories. The CLIA sets the minimum standard for clinical laboratories in the United States and is not limited to those laboratories receiving Medicare payments. Although states may enact statutes that are more stringent than CLIA, laboratories subject to CLIA must conform to both CLIA and state requirements.

The current form of CLIA was passed by the United States' Congress as Public Law 100-578 in 1988 (https://www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg2903 .pdf). Originally proposed in the late 1960s, CLIA'67, and its update CLIA'88, instituted standards for quality laboratory testing in the United States. These public laws were incorporated into regulations that were finalized in the Code of Federal Regulations (CFR) in 1972 and updated in 1992. Since then, there have been periodic updates, all of which are published in the Federal Register.

The CLIA is administered by the Centers for Medicare and Medicaid Services (CMS). In addition, other federal agencies such as the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention play roles in regulating how clinical laboratories operate in the United States. The CMS is tasked with enforcing regulatory compliance through conducting inspections for CLIA standards, approving private accreditation organizations that perform inspections, or approving exempt states (currently the only exempt states are Washington and New York). The CMS deems various accrediting organizations (AOs) to accredit laboratories for various specialties or subspecialties under CLIA. The 7 CLIA-approved AOs and the number of laboratories in their programs are listed in Table 4. The specialties or subspecialties that each AO can accredit can be found at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/AOSpecialtiesSubs.pdf. In addition to this list, some of the AOs accredit laboratories for which CMS has not yet made a determination of CLIA coverage. Some examples of these types of laboratories are embryology and molecular diagnostic laboratories.

Table 4. CLIA Deemed Accrediting Organizations.

Organization	Number of Participating Laboratories*
Commission on Laboratory Accreditation (COLA)	6614
College of American Pathologists (CAP)	6237
The Joint Commission (TJC)	2209
American Association for Blood Banks (AABB)	202
American Osteopathic Association (AOA)	129
American Society for Histocompatibility and Immunogenetics (ASHI)	101
American Association for Laboratory Accreditation (A2LA)	Data not available

Abbreviations: CLIA, Clinical Laboratory Improvement Amendments; CMS, Centers for Medicare and Medicaid Services.
* As reported by CMS to CLIAC November, 2016.

Table 5. CLIA-Deemed Certification Boards*.

Board Names
ABB–American Board of Bioanalysis
ABB public health microbiology certification
ABCC–American Board of Clinical Chemistry
ABFT–American Board of Forensic Toxicology (limited to individuals with a doctoral degree)†
ABHI–American Board of Histocompatibility and Immunogenetics
ABMGG–American Board of Medical Genetics and Genomics (formerly known as American Board of Medical Genetics (ABMG))
ABMLI–American Board of Medical Laboratory Immunology
ABMM–American Board of Medical Microbiology
NRCC–National Registry of Certified Chemists (limited to individuals with a doctoral degree)†

Abbreviations: ABMGG, American Board of Medical Genetics and Genomics; CLIA, Clinical Laboratory Improvement Amendments; NRCC, National Registry of Certified Chemists.
*https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html
† These boards certify nondoctoral individuals also.

Credentialing

Personnel requirements for CLIA—covered clinical laboratory personnel are clearly outlined in the CLIA regulations. Although accreditation is a laboratory-focused process, credentialing an individual for a certain role in a clinical lab is a person-focused process.

Credentialing can take 2 forms, either certification or licensure. Certification is a process of recognition by a private certifying board (Table 5). Certification by a CLIA-approved board is based on education, experience, and knowledge (typically judged by examination). Licensure is a state-by-state system that defines, by statute, the tasks and function or scope of practice of a profession and provides that these tasks may be legally performed only by those who are licensed. As such, licensure prohibits anyone from practicing the profession who is not licensed, regardless of whether or not the individual has been certified by a private organization. Of those states that have licensure, some license the testing personnel (Medical Technologists and Medical Laboratory Technologists) only, some only the director and/or supervisor, and a few license both. However, the majority of states do not license clinical laboratory personnel. Most states use CLIA as the standard for qualifying personnel. Many states that require licensure use certification or passing a certification examination offered by an accepted board as part of their licensure requirements. Therefore, many individuals hold both a license and a certification. Accrediting organizations, in part, use certification and licensure in determining whether the laboratory personnel meet CLIA requirements as part of the laboratory's accreditation process.

The CLIA has defined 4 areas of complexity for laboratory testing, with different personnel requirements, or credentials, for each. The 4 test categories are: (a) waived, (b) provider-performed microscopy (PPM), (c) moderate complexity, and (d) high complexity. Waived tests are intended to employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; pose no reasonable risk of harm to the patient if the test is performed incorrectly; and have been cleared by the FDA. Examples include dipstick urinalysis, fecal occult blood, urine pregnancy, and group A Streptococcus antigen (Morbidity and Mortality Weekly Report Reports and Recommendations https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5413a1.htm). No personnel requirements are found in the CLIA regulations for waived tests. All other categories are described as nonwaived. Nonwaived tests are categorized in section 493.17 of CLIA.

A grading system is used to determine whether a test is moderate or high complexity. This system is outlined in subsection A of the CLIA regulations. In this system, each criterion receives a score of 1, 2, or 3, with 1 being the lowest level of complexity, and 3 indicating the highest level. If a test system or assay receives an aggregate score of 12 or less, then it is moderate complexity; scores greater than 12 are classified as high-complexity tests (42 CFR 493.17). Examples of moderate complexity tests are certain microbiological tests (such as bacterial culture, Gram staining, microscopic examination of certain slide preparations), urinalysis (such as osmolality or sediments), hematology (eg, automated procedures, manual white blood cell differential), and PPM such as analysis for fecal leukocyte examination or nasal smears for eosinophils (https://www.cdc.gov/mmwr/preview/mmwrhtml/00016177.htm and https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/ppmplist.pdf). All other clinical laboratory testing is referred to as high complexity, including, but not limited to, immunohematology, chemistry, cytology, histopathology, and histocompatibility.

The CLIA requirements differ for personnel who perform PPM, moderate- and high-complexity testing and thus are defined separately in 42 CFR 493 Subpart M. The regulations specify qualifications for the various positions and also define the functions and responsibilities for the persons who fill those positions. Moderate complexity laboratories require the following: (a) director, (b) technical consultant, (c) clinical consultant, and (d) testing personnel. High-complexity laboratories require the following: (a) director, (b) technical supervisor, (c) clinical consultant, (d) general supervisor, and (e) testing personnel. Persons who are qualified may perform the functions of more than one position in either moderate- or high-complexity testing. In other words, the same person may function as both the laboratory director and the clinical consultant or in some extreme cases, one person could qualify and function in all of the positions listed. A doctoral degree is not required to direct moderate complexity laboratories.

The remainder of this section will focus on high-complexity testing. The information provided here for high-complexity personnel requirements will be limited to those entering the field today. If an individual works in a state that requires licensure the individual must meet that state's licensure requirements and maintain a current license in order to perform testing. Clinical laboratory directors and clinical consultants entering the laboratory field today must have earned a clinical doctorate (MD, DO, and DPM) or an earned doctoral degree (PhD, DSc) in a chemical, physical, biological, or clinical laboratory science. If acceptable to a CLIA-approved certifying board, the following degrees may also be acceptable: Doctor of Dental Surgery (DDS), Doctor of Dental Medicine (DMD), Doctor of Veterinary Medicine (DVM), Doctor of Public Health (Dr PH). In addition, all nonphysician directors must become certified and continue to be certified by a board approved by the US Department of Health and Human Services (42 CFR 493.1443; Table 5). Physicians must be licensed to practice medicine in the state in which they are serving as a director or clinical consultant. MDs and DOs must also be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent.[7]

Holders of other doctoral degrees (such as PhDs) must also be certified and continue to be certified by a board approved by the US Department of Health and Human Services (42 CFR 493.1443). The current approved boards are the following (Table 5): the American Board of Bioanalysis (ABB), the American Board of Clinical Chemistry (ABCC), the American Board of Forensic Toxicology (ABFT), the American Board of Histocompatibility and Immunogenetics (ABHI), the American Board of Medical Genetics and Genomics (ABMGG), the American Board of Medical Laboratory Immunology (ABMLI), the American Board of Medical Microbiology (ABMM), and the National Registry of Certified Chemists (NRCC; https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Certification_Boards_Laboratory_Directors.html).

Certification requirements for the boards vary and there are no national education requirements for curricula for PhD laboratory directors. To be eligible to take the ABCC and ABMM/ABMLI certification examination or be certified to be an American Society for Histocompatibility and Immunogenetics (ASHI) director, postdoctoral fellows must complete 1 to 2 years in postdoctoral training programs approved by the Commission for Accreditation in Clinical Chemistry (ComACC), the Commission for Postdoctoral Education Programs (CPEP), or the ASHI, respectively.[8-10] Candidates can also sit for the ABCC examination with 5 years of experience. Other boards, such as the ABB, require 4 years of experience, 2 of which must be at the supervisor or director level, to ensure that an individual meets CLIA requirements and has the appropriate level of experience to be a director.

Results

AAMC Faculty Roster

One source of data to inform our understanding of the current state of the PhD clinical laboratory scientist population in the

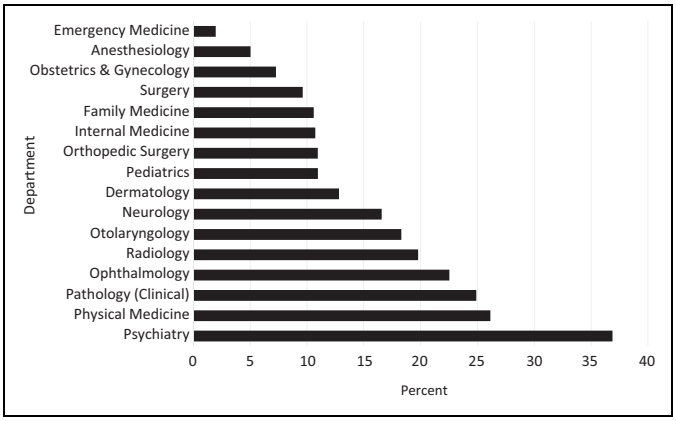

Figure 1. The percentage of US Medical School faculty who had PhDs or other health doctorates as reported by the AAMC Faculty Roster. The AAMC Faculty Roster (https://www.aamc.org/data/facultyroster/reports/486050/usmsf17.html) Table 6 was accessed on April 7, 2018 to determine the data shown. Other Health Doctorates are defined as doctorates in dentistry, veterinary medicine, public health optometry, and other health-related fields. This number does not include M.D./PhD faculty. For the purposes of the AAMC Faculty Roster report, faculty counts are broken out by department classification as opposed to exact department name (ie, Radiation Oncology and Diagnostic Radiology are both reported as "Radiology").

Table 6. Degrees of the Clinical Laboratory Workforce as Determined by the College of American Pathologists (CAP) Laboratory Accreditation Program*.

	PhD					
Role	PhD Only	MD-PhD	DO-PhD	PhD Total	Non-PhD†	Grand Total
Director	740	754	13	1507	6849	8356
Staff pathologist	161	2046	10	2217	17622	19 839
Consulting pathologist	9	48	0	57	247	304
Administrator/manager	255	15	1	271	6485	6756
Section director	2626	2987	41	5654	29 272	34 926
Supervisor	911	148	0	1059	29 161	30 220
Cosupervisor	395	53	1	449	10 251	10 700
QA contact/manager	239	27	0	266	5457	5723

* These data are additive, meaning that every time the same person is identified in a different role, different section of the same lab, and/or in a different accredited lab, he/she is counted again, causing the numbers to be artificially high. In other words, the numbers represent the number of times a PhD and/or non-PhD is listed in any role in any accredited lab.
†"non-PhD" means a person with any degree (eg, MD, DO, BS, MS, etc) other than a PhD.

clinical laboratory and pathology workforce is the Association of American Medical Colleges (AAMC) Faculty Roster.[11] The Faculty Roster contains records on active, full-time faculty at AAMC accredited allopathic US medical schools. As of April 2018, an average of 14.03% of US Medical School faculty in clinical departments had PhDs or other health doctorates (Figure 1). Perhaps not surprisingly, Pathology ranked third in the percentage of PhD faculty members, with 25%. Although these data indicate the significance of PhD scientists to the life of academic departments, PhD scientists included in these figures play a variety of important roles in pathology departments, with major contributions not only to the clinical workforce, but also to the research and teaching missions of their departments. However, it is important to keep in mind that academic medicine is only one small part of the clinical laboratory world.

College of American Pathologists (CAP) Laboratory Accreditation Program

A second approach to determine the size of the PhD clinical laboratory workforce is to evaluate the percentage of laboratory directors with PhDs. In March 2017, the CAP Laboratory Accreditation Program data indicated that in CAP-accredited laboratories, 740 of 8356 (8.9%) Laboratory Directors have PhDs (not including MD-PhDs, or DO-PhDs; Table 6). These laboratory directors must have both an earned doctoral degree and achieve board certification by ABB, ABCC, ABFT, ABHI, ABMGG, ABMLI, ABMM, or NRCC. However, CAP accredited laboratories represent less than half of the accredited clinical laboratories (see Table 4). It is possible that other AOs may accredit laboratories that have proportionately different numbers of PhD directors.

National Science Foundation (NSF) Survey of Doctorate Recipients (SDR)

The NSF SDR managed by the National Center for Science and Engineering Statistics is a longitudinal biennial survey that provides statistical demographics about individuals with a research doctoral degree (PhD) in science, engineering, or a health field from a US academic institution (https://www.nsf.gov/statistics/srvydoctoratework/). In the most recent data published (2013 survey cycle), occupations related to a "clinical laboratory" are only broadly categorized, for example, "biological scientists," or "medical scientists." Likewise, the sectors of employment are even more broad, such as, "biochemistry/ biophysics," "cell/molecular biology," or "microbiology." Although the intent of this biennial survey is to provide employment demographics and statistics on the science and engineering workforce, this lack of granular data limits the current usefulness of this survey to provide an accurate estimate of PhDs employed in the clinical laboratory workforce.

National Certification

An alternative method to assess the size of the PhD clinical laboratory workforce is to evaluate the number of board-certified specialists in various clinical specialties that are components of the clinical laboratory workforce. Several board examinations exist to certify individuals with PhD (and MD) degrees and these board are analogous to medical certifying

Table 7. Total number of MD, MD/PhD, and PhDs Certified by National Organizations (Current Through 2016).

Certifying Board	MD	MD/PhD[#]	PhD (%)	Unknown/Other	Total
ABB*	37	23	474 (86)	19	553
ABCC-Clinical Chemistry[†]	18	10	258 (85)	17	303
ABCC-Toxicology[†]	1	1	43 (91)	2	47
ABCC-Molecular Diagnostics[†]	11	4	35 (69)	1	51
ASM-ABMM[‡]	144	18	433 (62)	109	704
ASM-ABMLI[§]	25	5	94 (57)	42	166
ASHI-DTRC[¡]	22	17	58 (59)	1	98
ABFT-Fellow	-	-	183 (100)	-	183
Total:	258	78	1578 (75)	191	2105

Abbreviations: ABB, American Board of Bioanalysis; ABMM, American Board of Medical Microbiology; ABMLI, American Board of Medical Laboratory Immunology; ASHI, American Society for Histocompatibility and Immunogenetics.
*Director (High-complexity Clinical Laboratory Director [HCLD] & Bioanalyst Clinical Laboratory Director [BCLD]) certifications only. There are additional PhDs with nondirector certifications.
[†]Active Diplomates as of January 1, 2017 (http://www.abclinchem.org).
[‡]17.8% International.
[§]8% International.
[¡]Number of HLA Lab Directors credentialed by ASHI Director Training Review and Credentialing Committee (ASHI-DTRC) from 2010 to 2016; Board Certifications: D(ABHI), HCLD(ABB), ABMLI.
[#]ASM database can only track one degree per account; therefore, the number of MD/PhD diplomates may be higher than documented.

boards organized by the American Board of Medical Specialties. These certifications are recognized by various federal and state agencies as necessary components to meet laboratory licensure requirements. The results of our analysis are shown in Table 7 for each of the deemed certifying boards (Table 5). However, it should be cautioned that once again these data are not complete or all inclusive.

The ABB is an international organization that certifies individuals as Technical Supervisors, Clinical Consultants, and Directors in chemistry, diagnostic immunology, hematology, microbiology, molecular biology (diagnostic), public health microbiology, andrology, and embryology (https://www.aab.org/aab/American_Board_of_Bioanalysis.asp). The ABB has indicated that of the 553 Director level diplomats, 86% are PhD-only individuals. The ABCC is the national organization that certifies individuals to practice clinical chemistry, toxicological chemistry, and molecular diagnostics (http://www.abclinchem.org/). The ABCC register of active diplomates indicates that there are 401 current active diplomates of which 336 (84%) are PhDs (Table 7). The ABMM and the American Board of Medical Laboratory Immunologists (ABMLI; both overseen by the American Society of Microbiology [ASM]) certify microbiologists and immunologists, respectively, to direct clinical and public health laboratories (https://www.asm.org/index.php/professional-certification/abmm). There are 870 diplomates certified by ABMM and ABMLI, of which 527 (61%) are PhDs. The ASHI provides training and credentialing for HLA Laboratory Directors. In the 7-year period (2010-2016), there were 98 laboratory directors credentialed of which 58 (59%) were PhD scientists. The ABMGG certifies both MDs and PhDs in medical genetics and genomics. Several of their specialty examinations are available to both MDs and PhDs (http://abmgg.org/pages/training_options.shtml). Although ABMGG does not provide a breakdown of the number of certified specialists by degree, there have been a total of 1788 specialists certified according to statistics extending back to 1982 (http://abmgg.org/pages/resources_certspecial.shtml). These include 333 in Clinical Biochemical Genetics, 770 in Clinical Cytogenetics and Genomics, and 685 in Clinical Molecular Genetics and Genomics. It should be noted that these numbers may be slightly higher than the actual number of PhD Clinical Laboratorians, as some PhD may have more than one certification.

Fellowship Programs

Fellowship programs are one way to train PhDs in clinical laboratory sciences, and the other is on-the-job training. Fellowship programs are postdoctoral training programs that provide curricula that include not only traditional testing in clinical chemistry and/or microbiology/immunology but also emerging fields of study. In order to evaluate the capacity for training PhDs for the clinical laboratory workforce and for passage of the certification examinations discussed above, we evaluated the number of Clinical Chemistry Fellowship programs accredited by the ComACC, the number of Microbiology/Immunology Fellowship programs accredited by ASM/CPEP, and the number of Histocompatibility and Immunogenetics ASHI-approved Fellowship programs available for training of PhD graduates. These are postdoctoral training programs that provide curricula that include not only traditional testing in clinical chemistry, microbiology/immunology, and/or histocompatibility and immunogenetics but also emerging fields of study.[12] As of 2015, there were 20 ASM/CPEP accredited programs (17 that focused on Microbiology and 3 on Immunology), 32 ComACC accredited programs (30 in United States and 2 in Canada), and 7 ASHI-approved programs (Table 8). These programs have graduated a total of 164 fellows (68 in microbiology/immunology and 96 in clinical chemistry) over a 4-year span (2013-2016). This averages approximately 30 new fellows entering into the clinical laboratory workforce each year. However, as these fellowship programs are open to both PhD and MD postdoctoral trainees, this number will not be equivalent to the actual number of PhD scientists entering this workforce each year. Also, in August, 2017, the ABMLI will phase out its certification examination, but will continue to do recertification and maintain an active list of Diplomates. The ABMGG lists 44 accredited clinical laboratory training programs (24 in clinical biochemical genetics, 7 in laboratory genetics and genomics, 43 in clinical cytogenetics and genomics, and 42 in clinical molecular genetics and genomics). The list can be found at http://abmgg.org/pages/training_accredprog.shtml. However, it should be noted that this is not

Table 8. Accredited Training Programs*.

Fellowship Program Details	CPEP (Immunology)	CPEP (Microbiology)	ComACC‡
Total number accredited programs	3	17	32
Typical program length	2 years	2 years	2 years
Average total number applicants, per year*	138	689	NA
Average number applicants per individual program (2016)	40	40.5	NA
Average number positions annually per program	1 (0-2)	2 (1-3)	1 (0-2)
Approximate percent of positions filled in past 5 years†	95%	95%	86%
Number of graduates in past 5 years (total)	8	60	96

Abbreviations: ComACC, Commission for Accreditation in Clinical Chemistry; CPEP, Commission for Postdoctoral Education Programs.
*2013 to 2016; no data for CPEP Immunology in 2015.
†Calculated from the number of entering trainees (past 5 years) divided by the total number of available slots (in all programs during the past 5-year period).
‡There were 53 active trainees as of July 1, 2016.

a comprehensive data set, and the difficulties in finding comprehensive data on these types of postdoctoral clinical laboratory fellowship training programs may be one of the reasons that PhD scientists do not adequately consider directing clinical laboratories as one of their career options.

National Associations

There are a number of national and international associations for individuals who work within the clinical laboratory. The associations in many cases represent not only the workforce but laboratory owners as well. Their members form a very heterogeneous group with regard to the field of laboratory medicine. They represent not only medical schools and major hospitals but also small hospitals, independent laboratories, specialty laboratories, reference laboratories, niche laboratories such as molecular, embryology, and andrology laboratories, and emerging clinical laboratory fields. All of these offer opportunities for the PhD scientist. In fact, it is likely that directorship opportunities for PhDs are greater in some of the areas outside of the medical school and large hospital environment. Determining just where the greatest opportunities are made more difficult by the lack of data maintained by many organizations involved in laboratory medicine.

Discussion

This article provides data regarding the scope of involvement of PhD scientists in clinical laboratory oversight, and the pathways to preparation for careers in clinical laboratory medicine and certification in clinical laboratory specialties. However, defining the numbers of PhD scientists engaged in our clinical laboratories has been more challenging. Our data indicate that there are 3536 PhD scientists currently serving as Directors, Section Directors, or Pathologists in clinical laboratories accredited by CAP (Table 6). This is 5.6% of the total workforce in these positions and this is potentially an underestimate, as these data are only representative of a fraction of the laboratories within the United States and because PhD scientists contribute to our clinical laboratories in roles other than laboratory directorships. Estimates of PhD workforce size could also be derived from data about entry and attrition, but these data, to our knowledge, are either not available (attrition) or incomplete (entry). Nonetheless, the descriptive overview offered in this article highlights organizations involved in the preparation of PhD scientists for employment in clinical laboratories and provides insights into the training programs and certifying examinations pursued by PhD graduates on the way to establishing careers in clinical laboratory science and medicine.

Certifying examinations exist for most clinical laboratory disciplines, representing important milestones on the way to laboratory directorships (Table 5). These examinations offer an objective approach to measuring knowledge and proficiency in one's area of specialization, and they are accepted components of meeting CLIA-specified qualifications for laboratory directorship. Our data indicate that there are only 1578 PhD scientists currently certified by national organizations (Table 7). This is <50% of the number of PhD scientists currently serving as Directors, Section Directors, or Pathologists in CAP-accredited clinical laboratories, and would appear to support the need for additional accredited training programs and training slots within the currently accredited programs. There are currently only ~34 CPEP (Microbiology) and 32 ComACC (Chemistry) positions available in any single year (Table 8). However, one limitation to expansion of these programs is funding. The current programs are usually supported by local institutional/departmental funds. This is in contrast to Graduate Medical Education for MDs (ie, residency/fellowship), which are primarily supported by the US government (Medicare). Since PhD scientists are being trained and certified alongside MD clinicians, one idea would be to make PhD clinical laboratory trainees also eligible for this type of US government funding. Another innovation might be to cross-train PhD clinical laboratorians, so that they have optimal job options (ie, have multidisciplinary programs that train in chemistry, microbiology, immunology, etc).

Training programs can represent an important pipeline of PhD entrants into the world of the clinical laboratory. As discussed, accredited programs offered by ComACC, ASM/CPEP, and ASHI provide educational experiences in clinical chemistry, microbiology, immunology, and histocompatibility and immunogenetics, which prepare PhD graduates for careers in laboratory medicine. Although the numbers of graduates from these programs are still relatively small, as needs for well-trained PhD laboratory directors grow, the potential for expansion of training opportunities exists.

One of the largest sources of information regarding potential workforce opportunities available to PhDs may be the many national organizations in the realm of laboratory medicine. However, the PhD scientist may not know of the existence of these sources. Efforts need to be made to educate PhDs and Fellows

about these sources of information during their training. National organizations can offer many training opportunities through conferences, workshops, hands-on workshops, seminars, webinars, and online learning for the PhD scientist. In addition, they are an excellent way to network with individuals already in the field and to explore options available to the PhD scientist. These organizations can spotlight the many, and diverse, opportunities available to the PhD scientist outside of the medical school or large hospital environment, many of which may offer greater leadership options for the PhD scientist.

Expanding PhD graduates' awareness of the excellent career choices that exist in clinical laboratory science and medicine represents a current need and opportunity. Many graduate school curricula do not dedicate much time to introducing this sector of career opportunities to students, and brief observational experiences may be the entire exposure that a student receives to clinical laboratory medicine. Integrating more information into these programs, either through curricular or extracurricular experiences, could enhance interest in pursuing a career direction that offers many advantages. In addition, national organizations like the National Postdoctoral Association (http://www.nationalpostdoc.org/) and the AAMC's Group on Graduate Research, Education, and Training (https://www.aamc.org/members/great/) provide professional development to and foster the exchange of information and ideas among the faculty and administrative leaders of biomedical PhD, MD/PhD and postdoctoral programs and would be excellent partners to enhance the involvement of academic pathology in order to inform trainees about certified training opportunities in the clinical laboratory for PhDs.

Whether targeting PhD graduate students, postdoctoral fellows, or faculty and administrators, a coordinated effort should be made to promote and advocate for the career opportunities available to PhD scientists in clinical laboratory medicine. These career opportunities exist in academic medical centers, commercial clinical laboratories, biotechnology and pharmaceutical companies, and the federal government. PhD scientists will likely form an important resource for our technologically advancing field, bringing training in scientific methods and technologies needed for modern laboratory medicine. Their integration into the laboratory workforce offers much to enhance the future of Pathology and Laboratory Medicine. Furthermore, strategies for collecting data and demographic information on PhDs in the clinical laboratory setting should be considered to provide a more complete and longitudinal perspective on the PhD workforce.

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