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AACC Whitepaper on
Overcoming Lab Staffing Shortages

Developed for AACC by the Policy & External Affairs Core Committee and Clinical Laboratory Scientists Council

Authors: Erika Deaton-Mohney MT(ASCP), CPP; Sharon Ehrmeyer, PhD, MT(ASCP); Christopher Farnsworth, PhD, DABCC; Theresa Kunzler, MS, MT(ASCP); Frederick Strathmann, PhD, DABCC; & Monica Thomas, MPA, CLS(ASCP)

INTRODUCTION

Staffing shortages have impacted clinical laboratories for decades, threatening the laboratory's capability of delivering timely and accurate results and putting the quality of patient care at risk. The current staffing crisis in laboratories has been caused by a multitude of factors, including the changing laboratory environment, the failure of the Clinical Laboratory Improvement Amendments (CLIA) personnel standards to appropriately delineate the technical complexity of testing, and the expansion of automation. The purpose of this document is to describe the scope and causes of the current staffing crisis in clinical labs and suggest potential near and long-term solutions for the association.

POLICY OPTIONS

1. Advocate for and demonstrate the value of laboratory medicine by reinforcing the importance of laboratory professionals. Recruitment efforts should be in a diverse, equitable, and inclusive manner.
2. Expand activities that engage and enhance the visibility of medical laboratory scientists (MLS) including an enhanced platform at the annual scientific meeting and increased seminar/webinar opportunities that help laboratory scientists advance their careers.
3. Promote reclassification of laboratory tests based on performance complexity, moving tests currently designated as high complexity testing but with lower analytical requirements into the moderate complexity testing category and applying the existing personnel requirements.
4. Promote changes to the CLIA complexity model that recognize the unique skills and value of MLS. One option is to make the education, training, and experience requirements of an MLS the threshold for performing high complexity tests.
5. Develop educational programs that provide alternate career entry points into laboratory medicine for non-laboratorians, while also developing a separate track for MLS seeking professional growth and advancing within the laboratory and broader healthcare community.

SCOPE OF THE LAB STAFFING CRISIS

Staffing shortages have been reported by clinical laboratories for at least 30 years and the problem continues to be a threat to laboratory testing (1,2). A 2018 survey performed by the American Society for Clinical Pathology (ASCP) identified average vacancy rates of 7 – 11% in clinical laboratories, which were as high as 25% in some areas (3). According to the United States (US) Bureau of Labor Statistics (BLS), there were 335,500 technologist and technician positions in 2020. This number is projected to increase by 11% to 372,000 by 2030 (4). Similarly, the US Department of Health and Human Services (HHS), Health Resources and Service Administration (HRSA), projects an increase in demand/growth for medical and clinical laboratory technologists and technicians of 22% between 2012 and 2025 (5). Together, these surveys indicate an insufficient number of newly trained technologists entering the field, particularly as previous generations of laboratorians are retiring at historic rates.

Definitions for Lab Staffing Personnel and Education

CLIA established minimum personnel testing requirements for individuals performing moderate and high complexity testing (6). While there are several routes for meeting these minimum requirements, laboratories traditionally hire, because of their education and training, individuals with a bachelor's degree (MLS) or an associate's degree (Medical Laboratory Technician, MLT) from an accredited institution and certification (1). In the absence of such individuals, laboratories may hire individuals with a bachelor's degree in biology, chemistry, or comparable program, and then provide on-the-job training that permits them to meet the testing personnel requirements under CLIA.

While the BLS predicts the need for more individuals to perform laboratory testing, the number of MLS and MLT accreditation programs is declining, resulting in fewer graduates. In 1983 approximately 9,000 individuals graduated from accredited and approved training programs (7). By 1992, this number dropped by approximately 30% to 5,760, reflecting the decline in accredited educational programs. The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) identified a reduction of training programs from 659 programs in 1992 to 468 programs in 2002. In 2020 there were 235 MLS programs and 248 MLT programs, a decline of about 7% from 2000 (8).

REASONS FOR THE SHORTAGES

Aging Workforce

The aging workforce has severely impacted clinical laboratories; many of the experienced professionals who had delayed retirement are now retiring or are planning to retire in the next five years. The COVID-19 crisis further increased motivation for many staff to retire. The results of the 2020 ASCP vacancy survey demonstrated an average 5-year retirement rate of 12.3%. While the 5-year retirement rates have decreased since their peak in 2016-2018 (9), the rate of decline still outpaces annual growth.

Salary

There is disparity in pay for laboratory staff relative to peers with similar training in other areas of healthcare. A 2019 salary survey by ASCP reported that the average annual pay for an MLT was $50,304.78 and for an MLS was $68,848.18 (10). An important caveat is that a third of the respondents were from NY and California, states with typically higher pay. Nonetheless, the median salaries stated in the ASCP survey are comparable to data from the Bureau of Labor Statistics that state an annual wage of $57,800 nationally (4). In contrast, a registered nurse with a bachelor's degree in nursing has a median pay of $77,600 (11). The disparity in pay may be secondary to laboratorian's perceived status within the field of medicine. Laboratory medicine is traditionally non-

patient facing, often forcing its professionals to the fringes within medical teams. This may be in part what also drives disparate salaries between laboratory professionals and more visible professions such as nursing.

Growth Opportunities and Retention

Although laboratory medicine is a vital component of today's healthcare system, the clinical laboratory profession provides limited career growth opportunities for its workforce. The profession has a limited career ladder within a laboratory, with advancement primarily associated with non-testing responsibilities, such as laboratory information system, point of care, or quality management. Like many in the health care industry, laboratorians are subject to a rigid work schedule that includes weekends and holidays coupled with the demands of overtime hours due to high vacancy rates. The stress from high vacancy rates, overtime, and limited advancement opportunities likely leads to greater dissatisfaction and increased burnout.

Increased Volume of Testing and Expanding Responsibilities

Despite a stagnant workforce, clinical laboratories have continued to grow in both the volume of testing performed and the test menus offered (12). Most clinical laboratories perform high volume testing with estimates ranging in the tens-of-billions of laboratory tests performed in the US per year (12–14). This volume will only increase, due in part to the aging population and an increase in chronic disease (15). Adding to this workload is the expansion of available laboratory tests. There has been a dramatic rise in rapid molecular testing, sequencing, and esoteric testing (16–18). 44% of respondents on a 2018 survey stated that an increase in molecular testing has caused the greatest change to staffing needs (3). Expansion of laboratory testing into new domains will further stretch an already
thin workforce.

IMPACT OF THE COVID-19 PANDEMIC ON STAFFING

Even before COVID-19 emerged, observers had highlighted how the profession's lack of appreciation and visibility had hampered retention and recruitment efforts and limited the availability of training programs. Non-competitive salaries has made this situation worse, possibly hindering the ability of the laboratory community to respond during a disaster or crisis (19,20). The COVID-19 pandemic demonstrated those concerns and further exacerbated the underlying issues at a time when laboratories required an incredible expansion of molecular diagnostic instrumentation and testing capabilities (21). Consistent with this, the 2020 ASCP Vacancy Survey reported the pandemic significantly disrupted staffing and further reduced the stream of incoming graduates (9).

While few peer reviewed manuscripts provide information on how hospitals and laboratories prioritized work throughout the COVID-19 pandemic, several articles and interviews with healthcare and laboratory professionals have highlighted that the need to provide COVID-19 testing resulted in the de-prioritization of other laboratory testing (22,23).

THE IMPACT OF THE STAFFING CRISIS ON PATIENT RESULTS AND TURNAROUND TIME

Impact on turnaround time

The impact of insufficient lab personnel on turnaround time can be described using basic operations management. With a set turnaround time for a given test, the number of samples coming into the laboratory must be balanced by the testing throughput. The throughput of the laboratory is related to many aspects of its workflow including sufficient staffing available to perform testing.

Importantly, turnaround time is closely related to the variability in laboratory workflow and can arise in numerous forms. For example, an increase in patients will result in an increase in samples sent to the laboratory. Similarly, unexpected staff shortages due to sickness can result in a higher than anticipated sample number for the staff reporting to the laboratory.

The mechanism by which many organizations continue to meet turnaround time despite staffing shortages is by artificially increasing throughput using overtime, reduction in non-essential tasks, and resource reallocation. As a result, burnout features prominently in many laboratories. A 2014 article from the United Kingdom reported > 50% of all laboratories were using inappropriate staff to fill gaps in the workforce due to low wages and poor career advancement opportunities (24). Further, 90% of reporting laboratories were severely understaffed and 60% regularly used unqualified workers to complete daily tasks. Of note, unrealistic targets and turnaround times were cited as contributing to the overall challenges and job-related stress of staff. Another unintended consequence of reduced staffing is that many laboratories have limited their scope to essentially rapid response labs; triaging tests that are less urgent to reference laboratories (25).

OTHER CONSIDERATIONS: AUTOMATION AND THE CHANGING ROLE OF THE TECHNOLOGIST

When CLIA was initially written, computers were uncommon in clinical laboratories, total lab automation in chemistry and microbiology had not been introduced to the market, the human genome had not yet been sequenced, and the PCR was in its infancy. Today, use of automation, advanced middleware-based rules, and point-of-care (POC) testing has increased astronomically and is heavily relied upon by laboratories to increase throughput and maximize efficiencies, particularly in the wake of a staffing shortage. Despite these dramatic changes to how laboratory testing is performed, little has changed with regards to CLIA requirements for personnel performing moderate complexity and high complexity laboratory testing.

Enhanced automation

One of the most robust changes to laboratory testing has been the implementation of automation. This includes automation of the pre-analytic, analytic, and post-analytic steps of the testing process. These considerable improvements reduce diagnostic error (26). The introduction of fully enclosed, "Smart Instrumentation" has further improved this process. These instruments manage and automatically perform functions such as QC, maintenance, and calibration verification. Many of these instruments dramatically reduce the likelihood of analytical error, even relative to high volume clinical analyzers.

The FDA categorizes non-waived tests and instruments under CLIA as moderate or highly complex using a points based system (27). In short, this strategy determines complexity/risk based on:

- the knowledge, training and experience required of the person performing the test;
- the circumstances surrounding the use of reagents (i.e., is special handling required);
- operational steps required to perform the test;
- the availability of calibration/ QC material;
- required maintenance; and
- the complexity of interpreting the results.

While this framework is helpful, it may overestimate the potential risk to a patient and unnecessarily place testing in the high complexity category. Examples of such tests include tests:

- that are designated as high complexity because they require a calculation not performed by the instrument (although may be automatable using middleware systems (28);
- those that are manual methods but relatively simple to perform such as an ELISA (29); and
- a fully assays in which inaccurate results may cause excess risk to patients despite ease of use of the method itself and the need for special controls (30).
- modified FDA cleared tests, which are considered as a laboratory developed test, although the modification does not affect the clinical claim of the manufacturer.

In these instances, the current test designations do not truly consider the ease or difficulty of performing testing, potentially limiting the staff able to perform testing under the current structure of CLIA.

Considerations with the middleware and rules base approach

Use of middleware helps ensure accuracy of test results by creating rules for acceptance before a result can be reported. If the results do not meet the required rules, they must be reviewed by staff that have the required experience to review/troubleshoot and determine which further actions need to be taken before the results are accepted or rejected. An example of a rule that helps ensure test quality is a "delta check," which compares the feasibility of a current patient result relative to a previous result in the laboratory information system (32). Robust and accurate rules built in a laboratory information system reduces the likelihood of laboratory error and thus risk to a patient (33). However, the use of advanced rules and the reduced likelihood of error has not been addressed by CLIA with regards to testing personnel.

Considerations for point of care testing

Point of care testing is commonly used in hospitalized and ambulatory patients to provide rapid treatment decisions with the goal of improving patient care. The emergence of simple, sample-to-answer "Smart Instrumentation" has led to extraordinary growth in point of care testing. Despite changes in the frequency and landscape of laboratory testing performed at the point of care, there have been limited changes made under CLIA regarding testing at near patient settings. This may have helped drive the desire for the Center for Medicaid Services (CMS) to recommend nursing to perform high complexity testing; a recommendation that was met with resistance in the laboratory community (34). Nonetheless, the requirements for testing at near-patient locations remain antiquated relative to the novel instrumentation used.

RECOMMENDATIONS FROM OTHER PROFESSIONAL SOCIETIES

Given the widespread shortages, numerous task forces and documents have been published to attempt to address the shortages.

A 2021 report by the ASCP interviewed numerous laboratory professionals and came up with the following recommendations. 1) improve the visibility of clinical laboratory occupations (i.e., free tuition, offer incentives for community outreach, promote consistent titles), 2) Improving workforce recruitment and retention, 3) focus on diversity and inclusion (35).

The ASCLS 2020 position statement (36) calls for a multi-pronged approach including 1) a congressional study to identify the nature of the workforce shortage and impact on the healthcare system 2) that federal funds are provided to increase the number of clinical laboratory scientists through Title VII expansion, 3) that STEM (Science Technology Engineering Mathematics) programming include laboratory science, 4) training sites should be published via electronic

clearinghouse, 5) that retention is provided by making laboratorians an integral part of the care team and providing an improved career latter.

Other experts in the field have made recommendations for ways to circumvent the staffing shortage. In Canada, the Using Labs Wisely program has been implemented in the wake of the COVID-19 pandemic to reduce unnecessary testing with the secondary goal of removing excess burden from the laboratory (37). The nursing field has addressed shortages by engaging key stakeholders including manufacturers, states, and private institutions to provide increased funding for scholarships, add more programs, and increase the national reputation of the profession (38). McKinsey, a consulting agency, recently made strong recommendations that address the mental health and preferences of today's nurses that also are applicable to laboratory professionals (39).

RECOMMENDATIONS AND CONSIDERATIONS FOR AACC

AACC's mission is to provide global leadership in advancing the practice and profession of clinical laboratory science and medicine. AACC has a broad international reach, a diverse membership (medical technologists, laboratory supervisors, laboratory directors, and industry partners) and a considerable record of advocacy for the laboratory community. Given this, the below recommendations reflect potential novel methods to address the staffing shortage that involves all aspects of AACC membership. The recommendations build upon the strategic plan of AACC.

Advocacy and influence

AACC Strategic Plan Definition: Advocate for policies that improve the professional lives of AACC members and the quality patient care by modernizing laboratory oversight regulations.

Need Statement	CLIA regulations are outdated and must be updated to keep pace with new technologies
Definition	Minimal changes have been made to testing personnel since CLIA was enacted despite dramatic shifts in automation, adoption of FDA cleared tests by laboratories in most circumstances, and the evolution of new technologies.
Policy Options	1. Support changes to the CLIA test complexity categorization process so the assignment of tests more accurately reflect the skill level required to perform a test as opposed to the current, complexity/risk-based structure that is currently in place. 2. Promote reclassification of laboratory tests based on performance complexity, moving tests currently designated as high complexity testing but with lower analytical requirements into the moderate complexity testing category and applying the existing personnel requirements. 3. Promote changes to the CLIA complexity model that recognize the unique skills and value of MLS, with high complexity testing limited to MLS or individuals with equivalent education, training, and experience.
Supporting Evidence	Stagnancy of CLIA requirements regarding testing personnel despite enhanced automation.

Value of Laboratory Medicine

AACC Strategic Plan Definition: Quantifying and demonstrating the value of laboratory medicine by increasing the evidence base of the link between laboratory tests, laboratory data, outcomes, and costs to develop tools to allow members to enhance their role as healthcare consultants in their organizations.

Need Statements	The need for and importance of laboratory technologists and staff must be reinforced	Recruitment efforts should be in a diverse, equitable, and inclusive manner
Definition	There remains a need to quantify and demonstrate the necessity of the laboratory workforce as the foundation and future of laboratory medicine.	The inclusion of people with a range of different characteristics at all levels of the laboratory and dedicated efforts to promote diversity.
Policy Options	1. Create public awareness campaigns highlighting the value that laboratory staff bring to healthcare. 2. Create educational initiatives that address staff management, staff development, and workforce engagement concepts. 3. Support standardization of operational metrics required through regulatory agencies to ensure adequate staff to support testing volumes and workflows. 4. Develop Local Section guidance to further engage non-PhD and non-MD section members in leadership opportunities. 5. Advocate for the value of MLS, with the goal of enhanced visibility within the health care team and equivalent pay to comparably trained providers.	1. Continue to engage DEI efforts as an organization. 2. Develop meaningful key performance indicators related to diversity efforts to document progress. 3. Develop a laboratory management program for minority groups to empower their progress towards organizational leadership within and external to AACC. 4. Develop an Artery discussion board to share best practices for recruiting to foster diverse candidate pools. 5. Develop Local Section guidance to further engage minorities among section members for leadership opportunities.
Supporting Evidence	▶ COVID-19 challenges with laboratory staff shortages ▶ Success of VALID Act campaign efforts ▶ Test utilization efforts to standardize and provide benchmark data across labs.	▶ Lack of diversity documented with AACC surveys and related studies. ▶ Growing recognition of the need for focused and diligent efforts to reach a more diverse candidate pool.

Scientific Advancement

AACC Strategic Plan Definition: Identify, promote, and integrate the latest scientific advances in the field.

Need Statement	A multi-pronged approach towards education is required to attract and retain laboratory staff
Definition	Expanding the workforce requires starting on the ground floor for ways to increase the pool of candidates.
Policy Options	1. Reinforce the need for a 4-year MLS degree and where it is needed (i.e., high complexity testing). 2. Consider offering a certificate program for alternate career entry points into laboratory medicine. 3. Encourage strategic partners including vendors should provide "boot camps" for training and education. 4. Engage National Accreditation Agency for Clinical Laboratory Sciences (NAACLS) to reevaluate the skills and knowledge required for laboratory testing personnel. 5. AACC members could engage their own hospitals to advance laboratory science. 6. AACC sections could increase engagement with local high schools and STEM programs. 7. Due to the increase automation, training should focus on understanding automated systems and how to better to interpret results to assist in determining their validity.
Supporting Evidence	▶ Surveys documenting changes in staffing needs with the introduction of molecular testing. ▶ Insufficient NAACLS accredited programs to train laboratorians. ▶ The relative obscurity of laboratory medicine relative to other professions (i.e., pharmacy, nursing).

Expanding Brand Position

AACC Strategic Plan Definition: AACC must position itself to serve and represent the broader lab medicine community while preserving its role as the professional home for clinical chemists.

Need Statements	Incentivize new generations of laboratorians and keep them engaged in the profession	Implementations of recruitment tools to match new generations of laboratorians
Definition	A lack of awareness of the clinical laboratory technologist profession coupled with the changing professional landscape requires enhanced engagement with laboratory professionals.	Enhancing the visibility of clinical laboratorians is crucial for recruitment. As technology involves, it will be crucial for AACC to position itself to reach this new generation.

Policy Options	Promote activities to enhance engagement for MLSs 1. Enhanced visibility of MLS at the annual scientific meeting 2. Increased seminar / webinar opportunities to help connect employees to their work 3. Advocate for work life balance and professional development	Develop and utilize novel methods to reach demographics of interest. Currently, these include twitter, Facebook, LinkedIn, and other platforms. However, we must be willing and able to pivot as new recruitment tools and strategies are available.
Supporting Evidence	▶ Relatively low number of MLS attendees at the AACC annual scientific meeting ▶ Reported difficulties for students seeking laboratories for training.	

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