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Recommended Curriculum Guidelines for Family Medicine Residents

Office Laboratory Medicine

This document was endorsed by the American Academy of Family Physicians (AAFP), the Association of Departments of Family Medicine (ADFM), the Association of Family Medicine Residency Directors (AFMRD), and the Society of Teachers of Family Medicine (STFM).

Introduction

This Curriculum Guideline defines a recommended training strategy for family medicine residents. Attitudes, behaviors, knowledge, and skills that are critical to family medicine should be attained through longitudinal experience that promotes educational competencies defined by the Accreditation Council for Graduate Medical Education (ACGME), www.acgme.org. The family medicine curriculum must include structured experience in several specified areas. Much of the resident's knowledge will be gained by caring for ambulatory patients who visit the family medicine center, although additional experience gained in various other settings (e.g., an inpatient setting, a patient's home, a long-term care facility, the emergency department, the community) is critical for well-rounded residency training. The residents should be able to develop a skillset and apply their skills appropriately to all patient care settings.

Structured didactic lectures, conferences, journal clubs, and workshops must be included in the curriculum to supplement experiential learning, with an emphasis on outcomes-oriented, evidence-based studies that delineate common diseases affecting patients of all ages. Patient-centered care, and targeted techniques of health promotion and disease prevention are hallmarks of family medicine and should be integrated in all settings. Appropriate referral patterns, transitions of care, and the provision of cost-effective care should also be part of the curriculum.

Program requirements specific to family medicine residencies may be found on the ACGME website. Current AAFP Curriculum Guidelines may be found online at www.aafp.org/cg. These guidelines are periodically updated and endorsed by the AAFP and, in many instances, other specialty societies, as indicated on each guideline.

Each residency program is responsible for its own curriculum. **This guideline provides a useful strategy to help residency programs form their curricula for educating family physicians.**

Preamble

Accurate and timely laboratory testing is imperative to good patient care. Most family medicine residency programs will have a laboratory where some patient samples are tested on site, while other samples are prepared to be sent out to reference laboratories. Federal regulations known as the Clinical Laboratory Improvement Amendments (CLIA) apply to all laboratories that engage in any human testing. The vast majority of residency programs will limit on-site testing to those procedures that are deemed low complexity and are waived from the more extensive laboratory regulations required by CLIA for moderate- or high-complexity tests (see: www.fda.gov/medical-devices/ivd-regulatory-assistance/clia-waiver-application).

Even low-complexity testing (e.g., blood glucose measurement, urinalysis, provider-performed microscopy) requires laboratory certification that satisfies federal CLIA requirements, as well as applicable state regulations and proficiency testing (see: www.aafp.org/family-physician/practice-and-career/managing-your-practice/clia.html).

Regardless of the complexity level of testing in a given laboratory, all residents should become familiar during their training with how to maintain high-quality laboratory standards, including the essentials of quality assurance and quality control. The resident will need to build a foundation in management responsibilities, regulatory requirements, safety considerations, test costs, benefits, staffing considerations, and documentation requirements for office laboratory testing.

In addition to federal requirements and rules related to office-based laboratory services, some states have additional or different regulations. Knowledge of the differences between state and federal regulations and requirements is key to ensuring compliance.

Residents will also need to be introduced to medical workplace regulations from The Joint Commission and Occupational Safety and Health Administration (OSHA) that affect on-site laboratories. In addition, new regulations within the Health Insurance Portability and Accountability Act (HIPAA) are important in standardization of office laboratory testing and confidential communication of results to patients and outside entities. Most residency programs will purchase the services of a laboratory support organization to facilitate their compliance with registration, staffing and testing documentation, quality assurance, and proficiency testing. Many private companies provide these services; one example is the American Academy of Family Physicians Proficiency Testing (AAFP-PT) program (see: www.aafp.org/family-physician/practice-and-career/managing-your-practice/pt-lab-

[testing/evaluation.html](#)).

Finally, residents should learn skills in performing multiple point-of-care tests. Even though they may not personally be performing all of these tests in their own medical practices, some residents may become the director of an office lab and, therefore, will be responsible for overseeing staff members who are conducting these tests. Hands-on experience in each of these skills is important during education in a family medicine residency program.

Competencies

At the completion of residency training, a family medicine resident should:

- Be able to perform and interpret common tests done in the laboratory setting, and be able to teach these skills to other individuals (Patient Care, Practice-based Learning and Improvement)
- Know the significance of quality control in the office lab, including the importance of documentation. An acceptable quality assurance program for the laboratory must satisfy the 10 quality standards established by CLIA (see: www.aafp.org/family-physician/practice-and-career/managing-your-practice/clia/quality-assurance.html). (Patient Care, Systems-based Practice)
- Understand the basic principles of laboratory tests, including method selection, method verification, sensitivity, specificity, precision, accuracy, and bias (Medical Knowledge, Practice-based Learning and Improvement)
- Be knowledgeable in the cost considerations of office laboratory testing (Medical Knowledge, Systems-based Practice)
- Understand the personal protective equipment and laboratory safety equipment required to perform specimen collection, handling, and testing

The following are additional competencies for a resident who wishes to meet CLIA certification requirements as a medical laboratory director in the future:

- Demonstrate knowledge of CLIA regulations, with both an understanding of the requirements for waived testing and an ability to follow the manufacturer's instructions in order to obtain reliable test outcomes (see: www.cdc.gov/clia/) (Medical Knowledge, Systems-based Practice)
- Recognize other national and state regulations that factor into running an office laboratory (see: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index and www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIASA.pdf) (Medical Knowledge, Systems-based Practice)
- Understand one's role as a potential laboratory director, including qualifications, responsibilities, and the supervisory relationship with others working in the lab (see: www.aafp.org/family-physician/practice-and-career/managing-your-practice/clia/lab-director-duties.html) (Medical Knowledge, Systems-based Practice)

Attitudes

The resident should demonstrate attitudes that encompass:

- Compassion in discussing unexpected, unwanted test results (see: *Delivering Bad or Life-Altering News* at www.aafp.org/afp/2018/0715/p99.html)
- Commitment to lifelong learning about available office-based diagnostic tests and their appropriate use in patient care

Knowledge

In the appropriate setting, the resident should demonstrate the ability to apply knowledge of:

1. The physician's role in the office lab, both as one who uses the lab and as a potential director of a lab
2. Ways in which point-of-care testing can improve the quality of patient care compared with the delays inherent in traditional reference laboratory testing (e.g., blood glucose, rapid strep antigen, rapid influenza testing, transcutaneous bilirubin levels)
3. The limits of a positive or negative test result in the diagnosis of a disease
4. The risks and benefits of performing lab tests, including negative outcomes and costs associated with ordering unnecessary lab tests
5. The resources that should be available when considering a new test
6. The importance of documentation, especially as it relates to quality control in the laboratory setting
7. Financial considerations in lab testing, including coding, billing, and insurance reimbursement
8. The medical laboratory director's role in proficiency testing to demonstrate the reliability and accuracy of studies performed in the office laboratory

Skills

In the appropriate setting, the resident should demonstrate the ability to independently perform and interpret tests performed in the office laboratory, including:

1. Low-complexity tests of blood and bodily fluids most commonly done in residency site laboratories, which are waived from more extensive CLIA regulations, such as:
 - a. Use and care of the microscope. Teaching programs may consider obtaining a microscope with video screen capability so that the instructor and learner can simultaneously see and discuss findings. A list of waived microscopy procedures can be found at www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ppmplist.pdf.
 - b. Urinalysis and urine microscopy
 - c. Vaginal smears (e.g., for saline/KOH preps, vaginal pH, fern testing)
 - d. Stool microscopy (e.g., for pinworm or other parasite testing)

- e. Skin scraping microscopy (e.g., for dermatophytes, scabies)
 - f. Post-vasectomy qualitative semen analysis
 - g. Blood draws for labs sent to outside reference laboratories
 - h. Fingertick glucose
 - i. Fingertick hemoglobin
 - j. Urine pregnancy testing
 - k. Point-of-care/rapid strep, influenza, and respiratory virus (including COVID-19) antigen and polymerase chain reaction (PCR) testing
 - l. Occult blood testing of stool or emesis
2. Other point-of-care tests that may be done in some residency laboratories, depending on community needs, include:
 - a. Transcutaneous bilirubin
 - b. HIV testing
 - c. Glycohemoglobin
 - d. Blood lipids
 - e. Anticoagulation testing
 - f. Troponin
 - g. Qualitative urine drug screening
 - h. Urine microalbumin
 3. The resident should demonstrate the ability to communicate test performance and test results in the appropriate context to patients and other health care professionals.

Implementation

Implementation of this curriculum should include both focused and longitudinal experience throughout residency. Physicians who have demonstrated skill in use of an office laboratory should be available to act as role models to the residents, to give support, and to offer advice.

If a residency program wishes to perform moderate-complexity testing, the physician laboratory director will need to attend at least 20 hours of continuing medical education (CME) training in laboratory supervision. There are various CME courses that will meet these requirements (see: www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CME_Courses_for_Laboratory_Directors_of_Moderate_Complexity_Laboratories).

The responsibilities of a laboratory director supervising a moderate-complexity testing site are substantially more involved. Further information, as defined by the Centers for Medicare & Medicaid Services (CMS), may be found at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Brochures.

Resources

Fischer PM, Henderson LR, Murray C, et al. *Physician's Office Laboratory Microscopy Atlas*. 4th ed. American Academy of Family Physicians; 2013.

Howerton D, Anderson N, Bosse D, et al. Good laboratory practices for waived testing sites: survey findings from testing sites holding a certificate of waiver under the Clinical Laboratory Improvement Amendments of 1988 and recommendations for promoting quality testing. *MMWR Recomm Rep*. 2005;54(RR-13);1-25.

Pagana KD, Pagana TJ. *Mosby's Manual of Diagnostic and Laboratory Tests*. 6th ed. Mosby; 2017.

Williamson MA, Snyder LM. *Wallach's Interpretation of Diagnostic Tests: Pathways to Arriving at a Clinical Diagnosis*. 10th ed. Lippincott Williams & Wilkins; 2014.

Website Resources

American Academy of Family Physicians. Proficiency Testing Program. www.aafp.org/pt

Centers for Disease Control and Prevention, Division of Laboratory Systems (DLS). www.cdc.gov/ophss/csels/dlpss/CLIA.html

Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA). www.cms.hhs.gov/clia

COLA (formerly the Commission on Office Laboratory Accreditation). www.cola.org

The Joint Commission. www.jointcommission.org/

U.S. Department of Labor, Occupational Safety & Health Administration (OSHA). Safety and Health Topics: Bloodborne Pathogens and Needlestick Prevention. www.osha.gov/SLTC/bloodbornepathogens/

U.S. Food and Drug Administration. Coronavirus (COVID-19) and Medical Devices. www.fda.gov/medical-devices/emergency-situations-medical-devices/coronavirus-covid-19-and-medical-devices

U.S. Food and Drug Administration. Medical Devices. www.fda.gov/medical-devices

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