Recommended curriculum guidelines for family medicine residents

Office laboratory medicine

This document was endorsed by the American Academy of Family Physicians (AAFP).

INTRODUCTION

Each family medicine residency program is responsible for its own curriculum. The AAFP Commission on Education's Subcommittee on Graduate Curriculum has created this guide as an outline for curriculum development, and it should be tailored to the needs of the program.

Through a series of structured and/or longitudinal experiences, the curricula below will support the overall achievement of the core educational competencies defined by the Accreditation Council for Graduate Medical Education (ACGME) and provide guideposts to program requirements specific to family medicine. For updates and details, please refer to the ACGME website at www.acgme.org. Current AAFP curriculum guidelines may be found online at 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.

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 others 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 procedures deemed low complexity and will waive the more extensive laboratory regulations required by CLIA for moderate- or high-complexity tests (See CLIA waiver by 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 Meeting Clinical Laboratory Improvement Amendments (CLIA) regulation standards in your practice).

Regardless of the complexity of testing in laboratories, all residents should become familiar during their training with maintaining 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 the Occupational Safety and Health Administration (OSHA) that affect on-site laboratories. In addition, HIPAA regulations are important for standardizing office laboratory testing and for the confidential communication of results to patients and outside entities. Most residency programs will purchase the services of a laboratory support organization to facilitate compliance with registration, staffing, testing documentation, quality assurance and proficiency testing. Many private companies provide these services.

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

PATIENT CARE

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

1. Understand the basic principles of laboratory tests, including method selection, method verification, sensitivity, specificity, precision, accuracy and bias
2. Be knowledgeable in the cost considerations of office laboratory testing
3. Understand the personal protective equipment and laboratory safety equipment

required to perform specimen collection, handling and testing

The resident should demonstrate attitudes that encompass:

Compassion in discussing unexpected and/or unwanted test results (See Medical knowledge, Systems-based practice)

MEDICAL KNOWLEDGE

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, which are waived from more extensive CLIA regulations, such as:
    a. Use and care of the microscope
    b. Urinalysis and urine microscopy
    c. Vaginal smears (e.g., saline/KOH preps, vaginal pH, fern testing)
    d. Stool microscopy (e.g., pinworm or other parasite testing)
    e. Skin-scraping microscopy (e.g., dermatophytes, scabies)
    f. Post-vasectomy qualitative semen analysis
    g. Blood draws for labs sent to outside reference laboratories
    h. Fingerstick glucose
    i. Fingerstick hemoglobin
    j. Urine pregnancy testing
    k. Point-of-care/rapid strep, influenza, and other respiratory virus 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, 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. Communicate test performance and test results in the appropriate context to patients and other health care professionals

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

1. Demonstrate knowledge of CLIA regulations with both an understanding of the requirements for waived testing and an ability to follow the manufacturer's instructions to obtain reliable test outcomes (See Clinical Laboratory Improvement Amendments)
2. Recognize other national and state regulations that factor into running an office laboratory (See Clinical Laboratory Improvement Amendments [CLIA])
3. Understand one's role as a potential laboratory director, including qualifications, responsibilities and the supervisory relationship with others working in the lab (See Meeting Clinical Laboratory Improvement Amendments (CLIA) regulation standards in your practice)
4. Commitment to lifelong learning about available office-based diagnostic tests and their appropriate use in patient care

INTERPERSONAL COMMUNICATION

At the completion of residency training, a family medicine resident should demonstrate the ability to apply knowledge of:

1. 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. Limits of a positive or negative test result in the diagnosis of a disease
4. Risks and benefits of performing lab tests, including negative outcomes and costs associated with ordering unnecessary lab tests
5. Resources that should be available when considering a new test
6. 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. Medical laboratory director's role in proficiency testing to demonstrate the reliability and accuracy of studies performed in the office laboratory
9. Promoting a safe environment where patients and others involved in their care can actively engage in their care decisions
10. Assisting patients and others involved in their care in locating reputable medical information on the internet and other sources
11. Discussing internet safety and the protection of health information
12. Demonstrate attitudes that encompass compassion in discussing unexpected, unwanted test results

SYSTEMS-BASED PRACTICE

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

1. Understand the importance of a multidisciplinary approach to the enhancement of individualized care
2. Utilize the patient care team and be able to teach the performance of basic lab skills to other individuals on your team

PRACTICE-BASED LEARNING

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

1. Know the significance of quality control in the office lab, including the importance of documentation
2. Know the requirements for an acceptable quality assurance program for the laboratory that satisfies the 10 quality standards established by CLIA (See Meeting Clinical Laboratory Improvement Amendments (CLIA) regulation standards in your practice)
3. Commit to lifelong learning about the available point-of-care laboratory testing available

PROFESSIONALISM

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

Demonstrate ethical and professional behaviors by using appropriate resources for managing ethical and professional dilemmas. Residents will recognize their own actions and their impact on patients and other members of the health care team.

Demonstrate the ability to independently have or perform:

1. Respect for patients, families, colleagues and ancillary staff
2. Compassion for patients and their loved ones
3. Maintenance of confidentiality of patient information and laboratory results
4. Honesty in all communications to patients, families and medical staff
5. Willing acknowledgement of errors and taking responsibility, identifying potential contributing factors and describing strategies for improvement
6. Engagement, reliability and timeliness in carrying out assigned duties, specifically in relaying results to patients
7. Modeling of ethical integrity in all situations
8. Demonstrate awareness of implicit bias, particularly in relation to race and ethnicity

IMPLEMENTATION

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

If a residency program wishes to perform moderate-complexity testing, the physician-laboratory director must complete at least 20 hours of CME training in laboratory supervision. Various CME courses will meet these requirements (See CE courses for laboratory directors).

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, Pagana TN. *Mosby's Manual of Diagnostic and Laboratory Tests*. 7th ed. Mosby; 2022.

Snyder LM, Rao LV. *Wallach's Interpretation of Diagnostic Tests*. 11th ed. Lippincott Williams & Wilkins; 2020.

WEBSITE RESOURCES

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

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

The Joint Commission. www.jointcommission.org/

U.S. Department of Labor. Occupational Safety and Health Administration (OSHA). Bloodborne pathogens and needlestick prevention. www.osha.gov/SLTC/bloodbornepathogens/

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

U.S. FDA. Medical devices. www.fda.gov/medical-devices

REVISIONS

First published 5/1994
Revised 2/2000
Revised 2/2008 by Carle Family Medicine Residency Program
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