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The Impact of Clinical Laboratory Improvement Advisory Committee Recommendations on Microbiology Laboratories

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Abstract

The Clinical Laboratory Improvement Advisory Committee (CLIAC) was mandated by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and established in 1992 to provide advice to the Department of Health and Human Services on regulation of laboratory testing and improving laboratory quality. Since then, CLIAC has met regularly and recommended regulatory changes to CLIA, provided input on good laboratory practices, and discussed critical issues related to clinical and public health testing, the laboratory workforce, and laboratory systems research. The Committee has been effective in driving changes to microbiology quality control, which have led to a decreased burden and lower laboratory costs without sacrificing quality. The issues CLIAC addresses are complex and sometimes controversial, yet members have said their time on the Committee is worthwhile and that CLIAC has a positive influence on laboratory medicine. This Committee will remain a vital resource for providing guidance as laboratory testing continues to evolve.

Introduction

As a result of public and Congressional concerns about the quality of clinical laboratory testing in the United States, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) on 31 October 1988 (Public Law 100-578) (1) establishing uniform quality standards for all laboratory testing to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the testing was performed. CLIA revised and superseded the Clinical Laboratory Improvement Act of 1967 (2) and expanded federal oversight to virtually all clinical laboratories in the country. The law included provisions for a self-financing certificate fee system and for the recognition of accreditation programs and state licensure programs with standards equivalent to the federal requirements established under CLIA. The law also changed the focus of regulating laboratories by location to regulating sites according to the complexity of the testing performed. Under CLIA, the same requirements apply to all sites that conduct testing, including physician office laboratories and other previously unregulated testing sites.

The CLIA regulations that implemented the law were published as a final rule in the Federal Register by the Department of Health and Human Services (HHS) and became effective on 1 September 1992 (3). They stratify the requirements that apply into three categories (waived, moderate complexity, and high complexity) based on the technical complexity of the testing process. Tests in the waived category are simple tests that have low risk of an erroneous result. Testing sites performing only waived tests must have a CLIA certificate and follow the manufacturers' instructions for testing, while laboratories that conduct moderate- and high-complexity testing must meet the standards specified in the regulations for these testing categories.

On 24 January 2003, an updated version of the CLIA regulations was published in the Federal Register (4). This revision restructured the 1992 regulatory requirements so they followed the flow of a patient specimen through the laboratory and reflected the total testing process (preanalytic, analytic, and postanalytic phases). Technical standards were updated and framed within the context of a quality system. The same technical requirements apply to all laboratories performing nonwaived testing.

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The CLIA personnel requirements were not revised, except that board certification is required for an individual with a doctoral degree seeking to become a high-complexity laboratory director on and after 24 February 2003. Separate personnel requirements for moderate- and high-complexity testing remain in place. Finally, a new part of this regulation included the flexibility to use alternative quality control (QC) mechanisms in lieu of meeting the specific requirements outlined in CLIA. This new flexibility was driven by changes and improvements to testing technology that had occurred since 1992 and by the recognition that one size does not fit all with respect to ensuring the quality of laboratory testing. QC is only a part of a laboratory's quality assurance (QA) plan and its quality system. Consequently, a laboratory director may consider personnel training and competency, environment, patient population, and other unique aspects when determining the appropriate QC testing within a laboratory's QA plan.

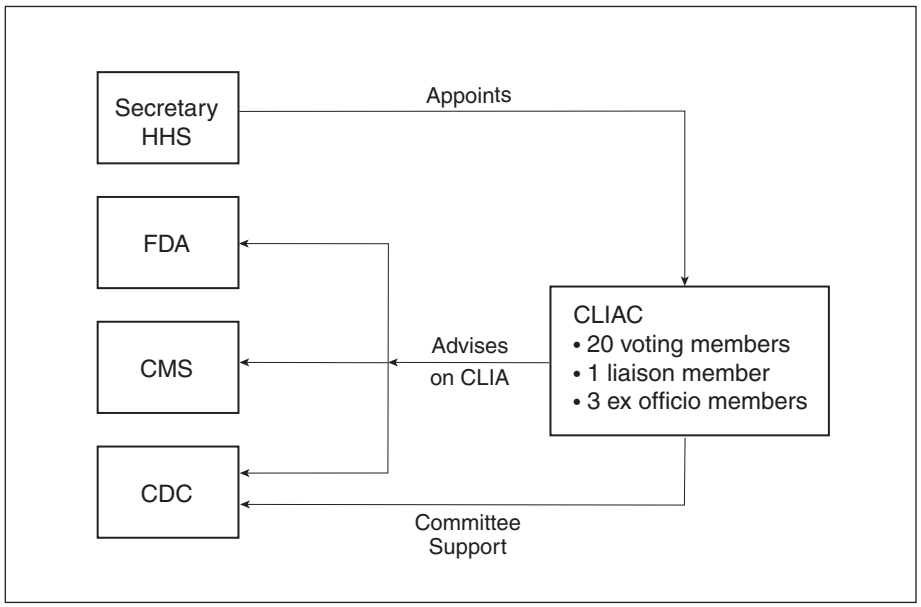

Figure 1. CLIAC structure and membership.

The role of the Clinical Laboratory Improvement Advisory Committee

The CLIA law included a provision that the Secretary for HHS would consult with appropriate private organizations and public agencies in carrying out the CLIA program (1). Subsequently, the Clinical Laboratory Improvement Advisory Committee (CLIAC) was established and chartered on 19 February 1992 (5), under the provisions of Public Law 92-463 (The Federal Advisory Committee Act of 1972 [FACA]), which ensures that advice from an advisory committee is objective and accessible to the public (6). FACA also formalized the process for establishing, operating, overseeing, and terminating advisory bodies and created the Committee Management Secretariat to monitor compliance with the act.

The 1992 CLIA regulations specifically mandated the formation of CLIAC to provide scientific and technical advice on issues pertaining to CLIA and laboratory quality to the HHS Secretary and Assistant Secretary for Health, as well as the three government agencies with shared responsibility for the CLIA program: the Centers for Disease Control and Prevention (CDC), the Centers for Medicare and Medicaid Services (CMS), and the Food and Drug Administration (FDA). The regulations include individual topics that CLIAC is to address, namely, the criteria for categorizing nonwaived testing, determination of waived tests, personnel standards, facility administration and quality systems standards, proficiency testing standards, applicability of the standards to new technology, and other issues relevant to CLIA if requested by HHS (3). The Committee consists of 20 members selected by the HHS Secretary for 4-year terms. Members collectively reflect key stakeholders with respect to laboratory medicine, pathology, public health, clinical practice, and consumers. In addition, CLIAC includes ex-officio members from CDC, CMS, and FDA and a non-voting industry liaison. As with any FACA committee, a designated federal official, or executive secretary, is also essential to provide direction and assistance to the Committee and to ensure that it fulfills its mission as stated in the charter. Fig. 1 is a schematic representation of the CLIAC structure that shows how it interacts with each of the HHS CLIA agencies. With more than

