CLIA 1988: Impact on Diabetes Care

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Federal regulation of laboratory practice, which dates back to the Social Security Act of 1965, is intended to assure test quality and improve patient health and safety. The Clinical Laboratory Improvement Act of 1967 extended federal oversight to laboratories engaged in interstate commerce or those qualified for Medicare/Medicaid reimbursement, including ~7,000 hospital laboratories and 6,000 independent labs (1). As a result of a media exposé on inaccuracies in Pap testing (2), Congress enacted public law 100–578, the CLIA of 1988, to ensure the safety and accuracy of laboratory testing at facilities of all sizes and in all settings (3). The purpose of this law was to extend federal oversight to ~130,000 POLs and 70,000 ancillary testing sites, including nursing homes, dialysis centers, school health units, and mobile clinics.

Congress charged the HCFA with implementing CLIA 1988, and a series of preliminary rules subsequently were published in the *Federal Register* describing implementation of the standard, certification and fee requirements—as well as penalties for failure to meet the new regulations (4–6). The law states (3),"Effective January 1, 1990, all laboratories in the U.S. that perform tests on human specimens for the purpose of information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings are subject to the requirements . . . " The regulations were established on the basis of the test complexity for each analyte, with certificates of waiver for "tests that are simple and have an insignificant risk of an erroneous result" (4). Subsequent analytes were categorized as level I or II by the "degree of independent judgment involved in the test, the amount of interpretation required, the calibration and quality control requirements of the instruments used, and the type of training required to operate the instruments" (4). In establishing this complexity model, HCFA determined that whole blood glucose determination by visual color comparison qualified as a waivered test, but the use of a reflectance meter required a level I certificate.

The open comment period for these regulations resulted in >60,000 written observations, including a letter from the American Diabetes Association stating "the proposed regulations will have a negative, rather than positive effect on the quality of diabetes care since they will inhibit frequent monitoring of blood glucose levels via dry reagent whole blood glucose meters." (7) Because CLIA would not regulate patient use of meters, the paradox of patients performing more sophisticated and accurate testing than health professionals with only a waiver certificate exists (8). Participatory democracy was particularly successful when HCFA was obligated to evaluate and respond to all of the comments received before publication of its final rules on 28 February 1992 (9).

Several major concerns emerged from the voluminous comments HCFA received, including *1*) access to convenient, low-cost, accurate lab testing would be curtailed, 2) the original complexity model based on classifying analytes did not represent real world testing because of the multitude of methodologies and instruments available, 3) the disproportionate placement of labs into level II by analyte determination would mandate unreasonable personnel qualifications, and 4) the use of proficiency testing in a punitive manner would be counterproductive (9). The regulations were modified, and the basic principles upon which CLIA 1988 is based are summarized in Table 1.

As stated previously, all laboratories performing analytic functions for the purpose of disease diagnosis or health assessment now are required to obtain a CLIA certificate and meet CLIA standards regardless of location or test complexity. CLIA 1988 final regulations (as published in the *Federal Register* on 28 February 1992) cover four specific concerns of laboratory operation (9). Table 2 outlines these requirements.

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CLIA 1988, CLINICAL LABORATORY IMPROVEMENT AMENDMENTS 1988; POL, PHYSICIAN OFFICE LABORATORIES; HCFA, HEALTH CARE FINANCE ADMINISTRATION; CDC, CENTERS FOR DISEASE CONTROL; FDA, FOOD AND DRUG ADMINISTRATION; QC, QUALITY CONTROL; HHS, DEPARTMENT OF HEALTH AND HUMAN SERVICES.

CATEGORIZATION BY TEST COMPLEXITY— Three categories of certification are available based on the most complex analytical technique used at the facility. A certificate of waiver is available to those performing tests that are *1*) simple and accurate methodologies, rendering erroneous results negligi-

Table 1—*Principles of CLIA 1988*

FINAL RULES SHOULD NOT UNDULY IMPEDE CURRENT LAB PRACTICE.
THE COMPLEXITY MODEL SHOULD INCLUDE ANALYTES, METHODOLOGIES, AND CURRENT AND EMERGING TECHNOLOGIES.
THE FINAL RULES SHOULD PROVIDE GREATER FLEXIBILITY IN ACCOMMODATING LABS NOT PREVIOUSLY COVERED BY CLIA, SUCH AS POLS, NURSING HOMES, ETC.
QUALITY CONTROL, QUALITY ASSURANCE, PROFICIENCY TESTING REQUIREMENTS, AND STRONG PATIENT CARE TEST MANAGEMENT ARE THE BASIS OF GOOD LABORATORY PRACTICE.
GOOD LABORATORY PRACTICE IS THE RESPONSIBILITY OF A DESIGNATED LAB DIRECTOR AND A TRAINED, QUALIFIED STAFF.

ble, 2) pose no reasonable risk of harm if performed incorrectly, and 3) are cleared by the FDA for home use (9). Currently, only eight tests have met these criteria (Table 3), but comments to HCFA in the early phase of the process resulted in the reclassification of self-monitoring of blood glucose with a reflectance meter as a waivered test.

Beyond these eight waivered tests, the designation of moderate and high complexity is determined by a numerical score based on the following seven criteria for each test or methodology: *1*) analyst's knowledge, training, and experience, 2) reagents and materials preparation, 3) operational steps, 4) characterization of calibration, 5) quality control and proficiency testing materials, 6) troubleshooting and maintenance, and 7) interpretation and judgment. Each criterium is assigned a score of 1 to 3, with high-complexity tests defined by cumulative scores ≥ 13. Moderate-complexity tests and methodologies score ≤ 12 and constitute ~75% of laboratory tests performed. Categorization of each test and method is determined by the CDC (Atlanta, GA). An exhaustive list of specific test systems, assays, and methodologies meeting criteria for moderate and high complexity is available in the *Federal Register* (9): 72 separate instruments for the measurement of serum glucose are listed as moderate-complexity tests, and 7 instruments are considered high complexity. Radioimmunoassays, electrophoretic testing, and gel-based immunochemical procedures are all considered high-complexity tests. GHb determination currently is regarded as a high-complexity test, but supplemental listings by different methodologies are expected within the next 6 mo and may provide alternative techniques that meet moderate-complexity criteria. The CDC, along with a CLIA Advisory Committee, is charged with the ongoing review and classification of tests and methodologies according to complexity.

Table 2—*CLIA 1988 mandates*

CATEGORIZATION BY TEST COMPLEXITY.
QUALITY CONTROL AND PROFICIENCY TESTING.
PERSONNEL REQUIREMENTS.
COSTS AND PENALTIES ASSOCIATED WITH CERTIFICATION.

Table 3—*Waivered tests*

BLOOD GLUCOSE BY MONITORING DEVICES CLEARED BY FDA FOR HOME USE.
DIPSTICK/TABLET URINALYSIS.
OVULATION TEST KITS.
URINE PREGNANCY TEST.
ERYTHROCYTE SEDIMENTATION RATE.
HEMOGLOBIN (COPPER SULFATE).
SPUN HEMATOCRIT.
FECAL OCCULT BLOOD.

QUALITY CONTROL AND PROFICIENCY TESTING — Sites that perform only waivered tests will be required to obtain a certificate of waiver, but "will not be inspected routinely, nor will they be required to meet certain other CLIA requirements. They are expected, however, to adhere to good laboratory practice" (9). This includes following the manufacturer's recommended instructions for each product. QC requirements for moderate-complexity testing is to be phased in between September 1992 and September 1994. Until then, QC includes following the manufacturer's instructions, performing two levels of control per analyte per day, calibration at least every 6 mo, and performance and documentation of any remedial action when problems are identified (9). Written QC procedures must be followed by high-complexity labs beginning September 1992.

Each moderate- or high-complexity lab must enroll in an HHS-approved proficiency testing program. Five unknown samples must be measured three times annually. For glucose, the lab must come within 6 mg/dl or 10% of the target value in 4 of 5 determinations for an acceptable performance. Failure to achieve a satisfactory performance in 2 of 3 annual testing events will result in sanctions, which may include monetary penalties or suspension of the certificate (9).

Personnel requirements

Four areas of responsibility are identified for both moderate- and high-complexity laboratories, with the personnel qualifications increasing commensurate with complexity. For POLs, it is anticipated that one or two individuals may fulfill all four functions, which include lab director, clinical consultant, technical supervisor, and testing personnel. The original CLIA 1988 regulations called for a PhD or board certified pathologist to serve as lab director of a high-complexity lab. This has been modified in the final rules so that an internist with 2 yr of lab experience (for example, during endocrinology fellowship training), or 1 yr of supervisory lab experience, may now qualify as lab director (9). This individual is responsible for the overall manage-

Table 4—*Approximate projected biennial cost of CLIA 1988 implementation of a POL (assume 25,000 tests annually)*

CERTIFICATION FEE	$ 350
PROFICIENCY TESTING	4,090
QUALITY CONTROL	6,000
ADDED PERSONNEL COSTS	2,000
COMPLIANCE/INSPECTION FEE	900
TOTAL	$13,340

Does not include complaint investigation fees or penalties. Adapted from *Federal Register* (9).

ment of the lab, including QC, proficiency testing, personnel management, and specimen processing and reporting. Office nurses and technicians usually will qualify as testing personnel unless a high-complexity test is performed. In that situation, qualification may require additional educational training.

Costs and penalties

Congress mandated that CLIA 1988 be a self-sustaining program, so "fees imposed . . . shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs . . . and implementing and monitoring compliance with the requirements of this section" (3). Implementation costs by fiscal year 1994 are projected to be $1.2–2.1 billion, or an increase of ~$.25 for every lab test performed in the country (9). A biennial certificate of waiver—required for performance of capillary glucose monitoring—will cost $100 per site. Moderate- and high-complexity labs will require a biennial certificate costing $100–600 depending on the volume of testing performed. Additional costs for certification of a POL include participation in a proficiency testing program, in-house QC procedures, additional personnel costs, and inspection fees (Table 4).

As of 1 September 1992, all facilities that perform tests on human specimens for the purpose of information toward the diagnosis, prevention, or treatment of any disease are required to be CLIA certified. This includes any facility that performs capillary blood glucose monitoring or urine dipstick testing. Without such certification, operation is illegal and subject to criminal penalties, even if no fee is charged for such services. Waivered labs will be inspected on a random basis, but the number of such inspections is expected to be small. Moderate- and high-complexity labs will be subject to unannounced biennial inspections. In addition, any lab that is the subject of a complaint will undergo immediate inspection. Noncompliance with CLIA regulations may result in a wide variety of penalties and sanctions as determined by HCFA. Depending on the severity of the infraction and its potential impact on public health, sanctions may include revocation of laboratory certification, criminal proceedings, a directed plan of correction, lab-supported on-site monitoring, or civil penalties as high as $10,000 per infraction per day. Appeals may be made before a departmental appeals board, but HCFA is mandated to publish an annual list of all actions taken against facilities found in violation of CLIA regulations (9).

Future laboratory controls

Is this the beginning or the end of federal regulation of laboratory medical practice? Some 6 billion laboratory determinations are performed in the U.S. yearly at a cost of $30 billion (1). It is naive to believe that control will end with QC and proficiency testing and not extend to the decision-making process surrounding the ordering of tests. In fact, that position has been promulgated (10). If Congressional intent in passing CLIA 1988 is patient protection and improved effectiveness of testing, then the oversight of physician's choice and interpretation of tests becomes the implied final consummative step. Medical educators and practicing physicians will have to work together to optimize laboratory testing, or we may find that federal regulators and clinical pathologists will do it for us (11).

CONCLUSIONS— All health professionals—including physicians, diabetes educators, school and camp nurses, mobile care personnel, and community care personnel—will have to obtain an appropriate certificate from HCFA before they will be able to perform any laboratory testing. Glucose monitoring of blood—either by meter or visual testing—will require a certificate of waiver and be subject to a $100 biennial fee. More sophisticated analytical methods will require a moderate- or high-complexity certification and mandate greater QC, proficiency monitoring, and personnel standards—together with increased fees to cover the administrative expenses of CLIA implementation. Continued input from the practicing medical community to HCFA is imperative, as reappraisal of testing methodologies and reclassification will be ongoing. The legislative mandate from Congress has been liberally interpreted by some to extend far beyond the actual performance of laboratory tests to include physician's selection and utilization of tests. This ushers in a whole new concept of a national health care policy.

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