The role of training, competency assessment, and continuing education

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In a 1999 study, the US Institute of Medicine (IOM) concluded that 44,000 to 98,000 hospitalized Americans die each year from preventable medical errors.

While the number of serious medical errors attributable to point of care (point-of-care testing, POCT) is not known, the testing environment (patient bedside) and the skill and ability of non-laboratory operators, who are focused primarily on patient care to recognize pre-analytical, analytical system failures, and post-analytical errors (non-laboratories), are reasons for concern.

The IOM study recommends several solutions for "human" errors, including incorporating safeguards based on testing-personnel competency certification. Kost surveyed experts seeking input on reducing errors at POC, and his findings reaffirm the importance of personnel competency.

One hundred percent of respondents recommended that non-validated POCT operators, i.e., untrained or non-certified as competent, be locked out from use of the testing device. To ensure quality test results in the POC environment, a new paradigm of training, competency assessment, and continuing education is needed.

Manufacturers, POCT coordinators, and test site directors must recognize and provide ongoing training and continuing education so that operators are competent.

Introduction

Point-of-care testing (POCT) is performed near the patient and by caregivers, usually nurses, rather than laboratory-trained professionals. In the US, the variety and number of tests performed at POC are growing.

A 2001 survey of POCT practices in 584 US hospitals found that 100 % were performing POCT glucose testing, 62 % offered coagulation tests, 50 % blood gas and electrolytes, 36 % chemistry assays, 28 % hematology, 15 % urine chemistry, and 4 % cardiac markers [1]. There are no indications that interest in and growth of POCT are subsiding. POCT utilization in the US is expected to increase 12-15 % per year [2].

The phenomenal growth in US POCT is driven by a number of factors, including the expectation of increased diagnostic insights, improved clinician efficiency, and better patient outcomes.

While the immediate availability of test data can be a definite advantage in many situations, an inaccurate or incorrect result creates additional and even worse problems!

According to the 1999 US Institute of Medicine (IOM) study, "To Err is Human: Building a Safer Health System," between 44,000 and 98,000 hospitalized Americans die each year from preventable medical errors [3].

While the frequency of serious medical errors attributable to POCT is not known, the testing environment (patient bedside) and skill of the operators (non-laboratorians) are reasons for concern. The IOM study recommends several solutions for "human" errors, including incorporating safeguards based on competency certification. In 2001, Kost surveyed experts seeking input on reducing errors at POC [4].

His findings reaffirmed the importance of personnel competency. One hundred percent of respondents recommended that non-validated POCT operators, i.e., untrained or non-certified as competent, be locked out from use of the testing device.

The idea of personnel competency is not new. A 1987 article in Diabetes Care stated: "The usefulness of blood glucose monitoring depends on the accuracy of the results...accuracy depends on...proper technique, and proper technique depends on the adequacy of training" [5].

This is especially true for those, primarily non-laboratorians focused on patient care, performing POCT.

Training

Despite sophisticated instrumentation, an accurate and precise result is unlikely unless the operator is familiar with the preanalytical and postanalytical, as well as the analytical phases of the testing process.

In 1988, the US Government enacted the Clinical Laboratory Improvement Amendments (CLIA) [6]. This legislation clearly espoused the concept of a minimum standard of quality for all laboratory testing, independent of test site.

Under the CLIA regulations, all patients are entitled to quality laboratory results, regardless of where, when and who does the testing. It follows that those involved in POCT be knowledgeable, properly trained, and be required to demonstrate ongoing competency.

Specifically, CLIA regulations (§493.1423) state that the clinical consultant for POCT identify training needs and assure that each POCT operator receive training and education appropriate to the testing [6].

The specific CLIA quality standards, including training, are based on test complexity, or the degree of difficulty to perform a particular test methodology [7]. Most testing performed at POC is classified either as waived, the simplest, or moderately complex.

For waived methodologies, CLIA expects all personnel to be able to read, understand, and follow the manufacturer's directions. Personnel involved in moderate complexity testing must be qualified and competent through education, training, and experience. This includes documented training in all methods performed and competency assessed twice during the first year of testing and once a year thereafter.

Testing personnel for moderately complex methodologies must, according to §493.1425 of the CLIA regulations: (a) adhere to policies and follow procedures for the entire

testing process from specimen handling and processing to reporting and maintaining laboratory (POCT) records of patient test results; (b) perform and document quality control, proficiency testing, and maintenance activities; (c) follow established corrective action policies; and, (d) identify, correct and document problems that may adversely affect test results [6]

In addition, POCT personnel need to be trained in patient preparation and identification; sample requirements, collection and handling; universal precautions; and disposal of biohazardous materials.

Access to a detailed step-by-step procedure manual, quality control information, and reporting results is absolutely essential. Reagent handling, often minimal or non-existent in many of today's POCT systems, needs to include proper storage and checking for outdates.

Reporting policies and operator training must address "panic" or critical values and documenting test results in the patients' permanent record. A clear and concise quality control protocol must be included in the training and must describe how to respond to out-of-control situations.

Finally, maintenance, troubleshooting, and backup procedures should be detailed. However, today POCT devices can be selected that are essentially "fool-proof" and require little or no maintenance and troubleshooting. Documentation of training is maintained in the individual's personnel records.

Training of operators may be provided by manufacturers, designated instructors in the healthcare organization, or self-instructional modules or a combination of the three.

Vendors often prefer to train operators, POCT coordinators, or trainers at the site to ensure that their products are being used correctly and the site is pleased with the products. Training materials for these sessions are available in a variety of forms (web-based, written, videos, CD-ROMs, etc.) and can be obtained from many sources, including professional societies, accrediting organizations, consultants, and manufacturers [8-11].

In-house studies have demonstrated that formal, instructor-provided training facilitates better learning and that trainees learn more effectively in a group setting [5]. Institutional instructors from the laboratory, nursing service, POCT committee, etc., can provide highly customized training.

While involving laboratory personnel in POCT training will help the organization maintain accreditation, it does not mean that the traditional laboratory way of approaching testing is right for non-laboratory staff [4, 10].

Nurses may respond best to a nurse trainer who can focus on POCT as a means to improve patient care, and respiratory therapists to a trainer who can emphasize testing as an adjunct to patient treatment.

Competency assessment

A successful training program incorporates comprehensive initial training and emphasizes competency assessment. Competency assessment is required (§493.1445(e)(13) of the CLIA regulations) twice the first year that an individual engages in testing and annually thereafter.

With this regulation, the test site director ultimately must: "ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skill" [6].

The director in charge of POCT and named on the CLIA certificate is ultimately responsible for ensuring that the training and competency assessment are completed. However, from an institutional perspective, the POCT team member from the central laboratory or the POCT coordinator is probably more familiar with meeting regulatory requirements and able to offer assistance with these tasks.

Assessing competency is often perceived as daunting. The CLIA regulations (§493.1413(8)(i-vi) suggest some procedures to evaluate competence: (1) direct observation of test performance, including patient preparation if applicable; (2) monitoring the recording and reporting of results; (3) review of quality control and proficiency testing records; (4) direct observation of instrument maintenance and function checks; (4) retesting previously tested samples; and (5) assessment of problem-solving skills through written tests and/or direct observation.

Obviously, these and other approaches are to some extent dependent on the specific test. A recent College of American Pathologist Q probe study of competency assessment practices in 522 institutions found that nearly 90 % used direct observation and nearly 80 % used review of patient or quality control results [12].

Continuing education

Most professional organizations, some accreditation and certification programs, and some state regulations in the US require continuing education as part of ongoing professional certification or licensure.

The Joint Commission on Healthcare Accreditation (JCAHO) has defined continuing education (CE) as: "education beyond initial professional preparation that is relevant to the type of service delivered in a laboratory, that provides current knowledge relevant to an individual's field of practice or responsibilities" [10].

Part of being a professional is a commitment to CE. Those involved in POCT can access information through professional organizations' periodicals, books, web sites, etc.

Instrument vendors offer many CE opportunities; some suggest that the vendor's ongoing commitment to training and CE be a factor for selecting new POCT systems [13]. Certainly with staffing shortages and the high rate of employee turnover, healthcare organizations are placing more demands on vendors for help in this important area.

While CE activities are often conducted at workshops outside the healthcare organization, JCAHO also advocates providing in-service programs specific to staff duties and responsibilities [10].

Even in short-staffed and smaller organizations unable to offer formal, in-service programs opportunities include: (1) employing the "teachable moment" to discuss interesting cases and/or problems, (2) using product demonstrations to learn about and plan for future testing, and (3) circulating an "article of the month" selected for its relevance to the POCT situation.

Summary

The continuing growth of POCT has created an environment where non-laboratorians are often called upon to add "laboratory testing" to their scope of duties. Technological advances have greatly enhanced the capabilities of instrumentation designed specifically for POCT.

Along with regulatory requirements, these factors demand a new paradigm of training, competency assessment, and continuing education. It is up to manufacturers, POCT coordinators, and test site directors to recognize today's non-traditional training needs and opportunities with programs and approaches as innovative as today's technologies and testing environment.

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