Re: Off-label Use of Glucose Meters

Dear Laboratory Director:

As laboratory director, you are jointly and severally responsible with the owner for the maintenance and operation of the clinical laboratory (Article 5, Title V of New York State Public Health Law). This includes testing that is performed at the point-of-care (POCT) or as part of a health fair or other community screening event.

The US Food and Drug Administration (FDA) is responsible for approving medical devices, including glucose meters, based upon the performance characteristics established by the manufacturers (validation data) and submitted by the manufacturers to the FDA.

To date, FDA has approved (or cleared) glucose meters for the quantitative measurement of whole blood glucose for use by healthcare professionals or lay users as an aid in monitoring the effectiveness of a diabetes control program (FDA, 2014, Lias, 2013, Moyer, 2012 & Harper, 2011).

Glucose meter manufacturer’s validation data has not been sufficient for the FDA to extend the approved intended use to other patient populations or settings. FDA has shared concerns about the accuracy and reliability of the test result if the glucose meters currently in use in hospitals are not appropriately and adequately validated for any additional Intended Uses (Lias, 2013, Moyer, 2012 & Harper, 2011).

The FDA has reminded clinical laboratory regulatory agencies that “Intended Use” in the package insert or product manual does not include diagnosis of, or screening for, diabetes. Other off-label uses of glucose meters include the monitoring of glycemic control of non-diabetic patients in hospitals; use on critically ill patients; and use in health fairs and other community events to screen the public for diabetes.

Laboratories that use glucose meters for purposes or in populations beyond the Intended Use in the package insert or device manual are considered to be engaging in off-label use. The Centers for Medicare and Medicaid Services (CMS) have instructed us that the laboratory must be informed that in the event of such off-label use, the glucose meter defaults to high complexity and the laboratory must meet the CLIA requirements for high complexity testing. In New York State, this means that the testing would require a New York State clinical laboratory permit in the category of Clinical Chemistry and only personnel licensed by the New York State Education Department would be eligible to perform the testing. In addition, the laboratory would be required to fully establish the analytic and clinical performance specifications (i.e. validate) of all such devices for any change from Intended Use in their patient population. Until such requirements have been met, the use of glucose meters in health fairs, other community
screening events, and/or critical care settings must be discontinued.

Please review carefully the January 7, 2014 draft guidance document from the FDA referenced below which provides proposed guidance to industry (manufacturers) to establish performance of blood glucose monitoring tests systems for prescription Point of Care use. Since a change from the Intended Use means the laboratory is responsible to establish performance specifications of the new use, this guidance may assist you in:

- Risk-based evaluation of appropriate populations/settings for use;
- Design of studies adequate to establish the analytical and clinical performance of any glucose meter used in your facility for anything other than the intended use stated in the package insert, and,
- IMPORTANTLY – consideration of populations/settings where the use of glucose meters may not be appropriate and, have been documented (as referenced above) to have caused patient morbidity/mortality (note section IX. Labeling, 5b of the FDA proposed guidance)

Any documentation of performance specifications established for off-label use must be maintained on-site at the laboratory and available for review during the next on-site survey. Data should not be submitted to the Department for review unless requested.

Broadly, this issue highlights the need and obligation of the laboratory to carefully review all of the package inserts for testing performed or proposed to ensure that it is offering services for purposes that are within the Intended Use established by the test’s manufacturer and as approved by the FDA.

Please note that health fair permits will be reissued to laboratories without glucose if the 2013-2014 permit reapplication indicated that glucose testing was performed at a health fair event. If the reapplication indicated that a sample was collected on-site at the health fair and referred back to the laboratory or a reference laboratory for testing, the health fair permit would remain unchanged. Laboratories may reapply for a health fair permit to perform glucose testing when a waived device is identified that is approved by the FDA for screening.

If there are any questions, you may contact this office by mail at the Clinical Laboratory Evaluation Program, Wadsworth Center, NY State Department of Health, Empire State Plaza, P.O. Box 509, Albany, NY 12201-0509 or by email at CLEP@health.state.ny.us. Please use “Glucose Meter Off-Label Use” and your laboratory’s PFI in the subject line.

Sincerely,

Stephanie H. Shulman, M.P.H., M.S., M.T. (ASCP)
Director
Clinical Laboratory Evaluation Program

Attachments
References:


