CLIA Guidance on Off Label Use of Waived Blood Glucose Meters (BGM) with Manufacturer’s Limitations

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Learning Objectives

- Describe the current issues related to waived blood glucose meters
- Discuss the implications of using a waived blood glucose meter off label
- Review CMS’ Certificate of Waiver project and the Outcome Oriented Survey Process
Blood Glucose Meters

- Provide glucose results quickly
- Majority of meters used primarily for monitoring, not diagnosis (per the intended use in pkg insert)
- Currently include limitations for use in the package insert
  - Examples: Hematocrit, interactions with maltose, icodextrin
Current BGM issues

- Used on virtually every patient, regardless of medical conditions or limitations specified in pkg insert
- Staff performing testing may or may not be aware of patient conditions that can interfere with the glucose tests
Current BGM issues

- Problems exacerbated by constant turnover of employees
- Providers want these tests regardless of the issues involved with the meters or the potential inaccuracies of the meters when used on the wrong patient populations
Manufacturers....

- Validate meters in healthy diabetic lay users then market and sell the meters for use in different populations
Manufacturers.....

- Are not required by the FDA to consider off-label use of their meters in their post marketing of the meters
- Don’t consider the issues associated with critically ill patients in their premarket testing
FDA Guidance to Manufacturers

- Two documents published on 1/7/14
- Documents are guidance for manufacturers, not clinical laboratories
- Meant to address the main populations that use these meters:
  - Home use by diabetic patients
  - Use in healthcare facilities for assisted testing
So...why the focus on glucose meters?

- FDA currently receives approximately 30,000 medical device reports on glucose meters per year.
New FDA BGM Limitation

- FDA required limitation in some manufacturer’s BGM instructions/pkg inserts that prohibit use of meter for critically ill patients.

- CMS only recently made aware of this limitation being placed in instructions/inserts.
What does this limitation mean?

- Devices used outside of the manufacturer’s requirements are considered to be **test modification/off label use**.

- **This is not a new CLIA regulation!**
Test modification/off label use

- Any change to a test system/device or manufacturer’s instructions or intended use that affects the test’s performance specifications for accuracy, precision, sensitivity or specificity.

- Modified tests become high complexity tests under CLIA
Facilities using a meter with critically ill limitations must:

- Define “critically ill” for their specific patient population
  - Medical staff, laboratory director, clinical laboratory should be involved in making this determination
- Establish performance specifications (42 CFR §493.1253)
Definition of “Critically Ill”

- Due to myriad of factors, circumstances and patient populations, it is up to each facility to define “critically ill” for its specific patient populations.
- FDA and CMS will not define “Critically Ill”
State Law

- Facilities may want to check with their State as some State laws may directly/indirectly define “critically ill” in their determination of what constitutes an “intensive care service” or an “intensive care unit”
Performance Specifications

- Accuracy
- Precision
- Analytical sensitivity and specificity (include interfering substances)
Performance Specifications

- Reportable range of test results
- Verify manufacturer’s reference intervals for patient population
- Any other performance characteristics required for test performance
Facilities using a meter with critically ill limitations must:

- Obtain a CLIA Certificate of Compliance (COC) or Certificate of Accreditation (COA), pay applicable fees

- Meet all other high-complexity requirements (example: Proficiency Testing, Personnel requirements)
Other Laboratory Options

• Use POC test systems without the “critically ill” limitation

• Send glucose tests to main laboratory
  • Presents patient care issues due to volume of blood required, need for frequent testing
CLIA Surveyors:

- As part of standard survey practices, may visit laboratories that are potentially using BGMs on critically ill patients
  - Certificate of Waiver (CoW) visits
  - Initial or recertification surveys
Current Survey Findings....

- Meters used on non-diabetic populations outside of the intended use

- Many pkg inserts w/o the “critically ill” definition
  - Inserts may have not been recently updated by manufacturer
Outcome Oriented Survey

If practice is identified during the survey:

- Laboratories will be advised of testing options
- Citations will be written per CLIA standard operating procedures
- Laboratories will be given an opportunity to correct the deficiencies
Performance Specification Resources

- 42 CFR §493.1253 of the CLIA Interpretive Guidelines (IG)
- CLIA Brochure #2, “Verification of Performance Specifications” on the CLIA/CMS website
- Both resources are available on the CLIA website
  - www.cms.hhs.gov/CLIA
CMS......

- Will be issuing additional guidance (via S&C policy letter/FAQs) on the blood glucose meter issue
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