COLLEGE of AMERICAN PATHOLOGISTS

It’s Just a Waived Glucose, Isn’t It?

What Is the Next Step?

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Objectives

- **Understand the CLIA requirements surrounding Whole Blood Glucose and critically ill patients**
- **Explain the challenges**
- **Discuss directions moving forward**

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Critical Illness and Glucose Monitoring

- **Critical illness is often associated with impaired glucose regulation**
  - **Hyperglycemia can be caused by several factors such as increased cortisol, catecholamine, glucagon, growth factor**
  - **Hyperglycemia can be caused by the stress of surgery, sepsis, trauma**
  - **Insulin resistivity may also play a factor**
  - **Hypoglycemia can be caused by liver and kidney failure, certain mediations, e.g. glucocorticoids, vasopressors, antibiotics,**

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Critical Illness and Glucose Monitoring

- **Previously hyperglycemia considered an adaptive responsive therefore not routinely treated in ICU**
- **Recently more studies have shown that uncontrolled hyperglycemia is associated with poor clinical outcomes**
  - **Increased mortality rate, increased length of stay, nosocomial infection**
- **This has resulted in an increased effort for glycemic control in critically ill patients**

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Critical Illness and Glucose Monitoring

- **Determine the definition of hypoglycemia and hyperglycemia in the critically ill patient**
  - **>180 mg/dl hyperglycemic**
  - **<=70 mg/dl hypoglycemic**
- **Optimal target range for BG remains unclear?**
  - **140 to 180 mg/dl**
  - **<180 mg/dl**

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Critical Illness and Glucose Monitoring

- **Many conditions in the critically ill patient can cause inaccurate capillary BG results**
  - **Dehydration**
  - **Hematocrit outside of the defined range, e.g. <20%**
  - **Hypotension and shock**
- **Potential Interferences**
  - **Ascorbic Acid/Vitamin C**
  - **Acetaminophen**

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Background Blood Glucose Monitoring Systems

Discussion of Regulatory Guidance Documents

FDA Draft Guidance Documents

- **On January 7, 2014 FDA published two draft guidance documents concerning blood glucose meters**
  - **Blood Glucose Monitoring Test Systems for Prescription POC Use**
  - **Self-Monitoring Blood Glucose Test Systems for the Over-the-Counter Use**

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FDA Draft Guidance Documents

- **Work with manufacturers to determine whether the use of their devices is appropriate in critically ill patients**
- **Provide regulatory submissions that contain data that will allow FDA marketing authorization to use these products in critically ill patients.**

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FDA Draft Guidance Documents

- **Draft Guidance Published by FDA – Why Now?**
  - **Need for tighter regulatory standards**
  - **Diabetes treatment and management changes**
  - **Technology improvements**

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Critical Illness and Glucose Monitoring

- **Current Standards In Use**
  - **Blood Glucose >= 75 mg/dl, 95% need to be within +/- 20% of the reference value (lab result)**
  - **Blood Glucose < =75 mg/dl, 95% need to be within +/-15% of the reference value (lab result)**
  - **CLSI guideline; C30-A2; Point-of-Care Blood Glucose Testing In Acute and Chronic Care Facilities 2002**
- **FDA is calling for higher manufacturer standards for BGMS (ISO 15197)**

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CMS Blood Glucose Monitoring System Guidance

- **In Jan 2014 NY State Department of Health also issued a letter to lab directors that many of the uses of glucose meters will be off-label**
  - **Cannot use in health fairs**
  - **Cannot use on critically ill patients**
  - **Cannot use to diagnosis or screen for diabetes**

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CMS Blood Glucose Monitoring System Guidance

- **On November 21, 2014 CMS published a memorandum, Ref: S&C: 15-11-CLIA**
  - **“Directions on the Off-Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)**

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CMS Blood Glucose Monitoring System Guidance

- **On November 21, 2014 CMS published a memorandum, Ref: S&C: 15-11-CLIA, continued:**
  - **CLIA-certified lab must follow all manufacturer's guidelines for BGMS**
    - **Manufacturer's Instructions for Intended use, e.g. specimen type, is it diagnostic or screening**

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CMS Blood Glucose Monitoring System Guidance

- **CLIA-certified lab must follow all manufacturer's guidelines for BGMS, continued:**
  - **Manufacturer's Limitations and Precautions:**
    - **e.g. conditions that can affect test results such as patients with circulatory problems**
    - **limitations indicating that the device has not been cleared for use on critically ill patients**

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CMS Off-Label Use Blood Glucose Devices

- **CLIA-certified lab must follow all manufacturer's guidelines for BGMS, continued:**
  - **Off-label Use: the lab is using a test outside of the FDA approved intended use, limitations or precautions as indicated in the manufacturer's instructions**

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CMS Off-Label Use Blood Glucose Devices

- **Off-Label Use of BGMS continued:**
  - **Applies to waived and non-waived**
  - **Test is considered modified and defaults to high complexity testing**
- **Examples of Off-Label Use**
  - **BG run on patients with hematocrits higher than specified by the manufacturer**

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CMS Off-Label Use Blood Glucose Devices

- **CMS memorandum published November 21, 2014, Ref: S&C: 15-11-CLIA, continued:**
  - **When using the BGMS off-label the lab must meet the CLIA requirements for high complexity testing:**
    - **Accuracy, precision, sensitivity, specificity, reportable range, reference intervals, and personnel must meet the requirements for high complexity testing**

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CMS Off-Label Use Blood Glucose Devices

- **CMS memorandum published November 21, 2014,**

  Ref: S&C: 15-11-CLIA, continued:

  - **Off-Label Use of BGMS**
    - **CLIA surveyors will cite for non-compliance**

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CMS Blood Glucose Monitoring System Guidance

- **On Mar 13, 2015 temporary withdrawal of S&C: 15-11-CLIA and reissuance as draft**
  - **Obtain more feedback regarding the use of BGMS and identify any issues from hospitals/providers**
  - **Promote education regarding current CLIA requirements**

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Where are We Now And Where Do We Go Next?

Verification of Off-Label Use of FDA-cleared/approved BGMS

Where Are We Now?

- **Most facilities are still trying to define a critically ill patient**
- **Some labs say their policy defines limiting substances say this is ok**
- **Most labs have done nothing and are taking a wait & see approach**
- **Only one meter is currently FDA approved for critically ill patients**

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Where Are We Now?

- **Most labs are struggling with the definition of a critically ill patient**
  - **Is it an ICU patient?**
  - **Patients on vasopressors or dialysis?**
  - **Patients that are hemodynamically unstable?**
- **No federal/regulatory definition of a critically ill patient**
- **It is up to the facility to determine the definition of a critically ill patient**

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Step 1: Review of Manufacturers' Instructions

- **Review manufacturer package insert for applicability for the patient population served (COM.4025)**
  - **Evaluate if the manufacturers' instructions are being followed**
  - **Laboratories that use glucose monitoring devices for purposes or in populations beyond the "Intended Use" and "Limitations" stated in the manufacturer's package insert are engaging in off-label use**
    - **If off-label use the test is now subject to CLIA and CAP requirements for high complexity testing & modified tests**

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Step 2: Define Critical Ill Patient

- **It is the responsibility of the laboratory to define critically ill patient population for its particular clinical setting**
  - **Done in conjunction with the manufacturer instructions for “Intended Use” and “Limitations”**
  - **Work collaboratively with medical and nursing staff**
  - **Review existing literature and studies**

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Step 3 Evaluation of BGMS for High Complexity Testing

- **Off-label use of a FDA-cleared/approved device is considered a modification to the test system (COM.40250) and requires validation of the modification**
  - **Method performance specifications**
- **Formulate validation plan**
  - **Study data can be collected retrospectively**

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Step 3 Evaluation of BGMS for High Complexity Testing

- **Review and approval of method validation**
  - **By medical director or designee who meets CAP director qualification (COM.40000)**
- **Policy/procedure revision and approval to reflect change in testing complexity**
- **Communicate changes to nursing and medical staff**

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Step 4: Training and Education

- **Laboratory must ensure that personnel meet high complexity testing qualifications**
  - **Information can be found at:**
    - **GEN.54750 Testing Personnel Qualifications, 2015 edition**
    - **CAP Personnel Requirements by Test Complexity (under e-labs/CAP Accreditation Resources/Accreditation Guidance Documents)**
    - **CLIA regulation 42CFR493.1489**

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Step 4: Training and Education

- **Competency must now be assessed using all 6 elements of assessment**
- **For new employees during the first year of an individual's duties competency must now be assessed semiannually**

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Step 5: Ongoing Reagent & Quality Control

- **Perform semiannual instrument comparisons**
- **Perform AMR verification every 6 months**
- **Perform lot-to-lot reagent verification**
- **Perform quality control according to non-waived requirements**
- **Proficiency testing (nonwaived program enrollment)**

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Point of Care Inspection

Whole Blood Glucose Testing It is Not Just Waived Testing Any More

Inspecting Glucose Meters

- **Inspect Using the Point of Care (POC) Checklist**
  - **The POC checklist may also be used to inspect FDA-cleared/approved point-of-care tests that are modified by the laboratory. Modified FDA-cleared/approved tests are subject to the nonwaived checklist requirements and high complexity personnel qualifications**

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Inspecting Blood Glucose Meters

- **Verify the activity menu**
  - **Waived versus nonwaived (COM.01200)**
- **Identify the blood glucose monitoring system in use**
  - **Review the package insert or manufacturer instructions for "Intended Use" & "Limitations"**
- **Verify that the lab has defined critically ill patient population (COM.40250)**

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Inspecting Blood Glucose Meters

- **If the meter is being used off-label ensure the following requirements will apply:**
  - **The testing is nonwaived and the CLIA license should reflect this change**

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Inspecting Blood Glucose Meters

- **If the meter is being used off-label ensure the following requirements will apply:**
  - **Competency assessment (POC.09600)**
  - **Personnel qualifications (GEN.54750)**
  - **Method performance specification (COM.40300-COM.40600)**
  - **Proficiency testing (nonwaived program enrollment)**
  - **Quality control requirements for nonwaived testing**

Inspecting Blood Glucose Meters

- **If the meter is being used off-label ensure the following requirements will apply, continued:**
  - **Lot-to-lot reagent verification (COM.30450)**
  - **Semiannual instrument comparison (COM.04250)**
  - **Analytical measurement range or AMR (POC.8450 – POC.8600)**

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Inspecting Blood Glucose Meters

- **If the meter is being used according to the manufacturer's instructions for “Intended Use” and “Limitation”, inspect as a waived test using the appropriate requirements in the in the Point-of-Care Checklist**
  - **Follow manufacturer instructions**

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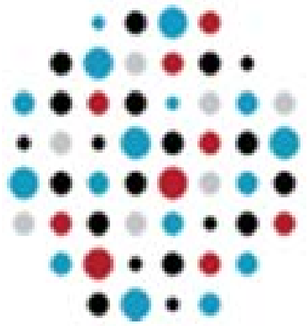
Questions



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