Capillary Blood Glucose Testing in Hospital Settings

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Hospital Glucose Meters

Blood glucose monitoring systems (BGMS) have become critical tools in hospital settings

- easy to use
- accessible for bedside testing
- fast results
- small blood volume required
- less expensive
- portable, etc.
Hospital Glucose Meters

- Originally home use devices
- Migrated into healthcare settings
Hospital Glucose Meters

• Increased stakeholder discussion of BGMS accuracy requirements for different uses

• Different patient populations have different needs
  • Routine glucose monitoring (diabetic and non-diabetic)
  • Glucose testing to inform insulin dosing
Glycemic Control Protocols

• Van den Berghe group (Leuven, Belgium) demonstrated that reducing hyperglycemia in intensive care patients led to better clinical outcomes

• Demonstrated lower mortality in intensive care patients when glucose levels were managed to a strict range of 80-110 mg/dL using infused insulin by expert nursing staff.

• Practice known as “tight glycemic control.”

Glycemic Control Protocols

- Leuven results not replicated in some other large studies
- NICE-SUGAR* discontinued after an increase in mortality due to hypoglycemia was observed in the tight glycemic control arm

*Normoglycemia in Intensive Care Evaluation and Survival Using Glucose Algorithm Regulation

Glycemic Control Protocols

Why did NICE-SUGAR fail?

- varying levels of insulin dosing expertise in the study staff
- different target ranges for blood glucose by site
- different nutritional strategies
- different types of insulin administration
- different specimen types (e.g., venous/arterial vs. capillary)
- different instruments used to measure blood glucose.

Leuven: Bedside Blood Gas Analyzers

NICE-SUGAR: Variable, many sites used capillary BGMS
Performance goal:

1. 95% of the results must have differences from the laboratory analyzer less than 12 mg/dl below 100 mg/dl and less than 12.5% above 100 mg/dl, and

2. The sum of the number of individual results with errors that exceed 15 mg/dl below 75 mg/dl and exceed 20% at glucose concentrations at or above 75 mg/dl should not exceed 2% of all results.
FDA BGMS Guidance

- 2010: FDA public meeting on glucose meter accuracy
- 2014: FDA draft BGMS Guidance
- 2016: FDA final BGMS Guidance

FDA BGMS Guidance

BGMS studies:

• Labeling specifies claimed healthcare settings and patient populations claimed
  • Capillary vs. venous blood
  • Physician’s office, hospital, ambulance, etc.

• Manufacturer validates the device in this setting and population
BGMS use in Intensive Care Settings

- Home use meters validated in a healthier population
- Limitations against using the devices in certain populations, including patients receiving intensive medical intervention/therapy
BGMS use in Intensive Care Settings

• CMS regulates laboratories and laboratory testing under the Clinical Laboratory Improvement Act (CLIA)

• Off label use = high complexity

• Increased regulation

• Demanding personnel training requirements
StatStrip Clearance

• FDA encouraged manufacturers to seek this claim
• 2014: Nova Biomedical StatStrip BGMS FDA clearance and CLIA waiver
  • Venous, arterial, neonatal heel stick in all hospitalized patients
  • Capillary blood still has limitation in patients receiving intensive care
CLIA Waiver for BGMS

• We recognize the burden of bedside glucose testing in hospitals when CLIA waived BGMS devices are not available.

• We also understand that being able to make capillary blood measurements in all hospitalized patients using FDA cleared and CLIA waived BGMS would be more convenient and feasible for hospital staff.
• Present capillary BGMS data in intensively treated patients
• Provide transparency about the performance of these devices for this use
• Hear from our Panel and the community on this topic