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

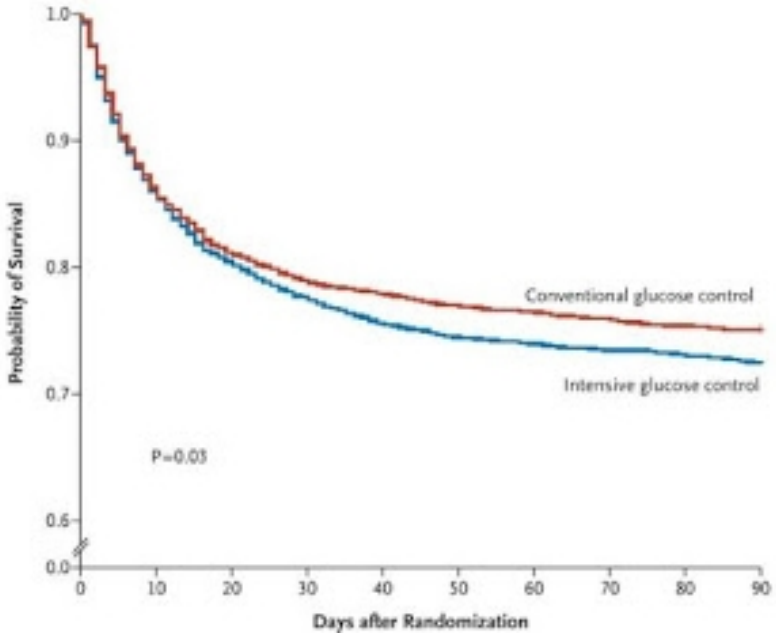
- Different patient populations have different needs
  - Routine glucose monitoring (diabetic and non-diabetic)
  - Glucose testing to inform insulin dosing

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.”

Van den Berghe, G. et al. Intensive Insulin Therapy in Critically ill Patients. *N Engl J Med*. 2001; 345:1359-1367
Van den Berghe, G. et al. Intensive Insulin Therapy in the Medical ICU. *N Engl J Med*. 2006; 354:449-461

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

The NICE-SUGAR Study Investigators. Intensive versus Conventional Glucose Control in Critically Ill Patients. *N Engl J Med.* 2009; 360:1283-1297

Van den Berghe, G. et. al. Intensive Insulin Therapy in Critically Ill Patients: NICE-SUGAR or Leuven Blood Glucose Target. *J Clin Endocrinol Metab*. 2009; 94(9): 3163-3170

Glycemic Control Protocols

Why did NICE-SUGAR fail?

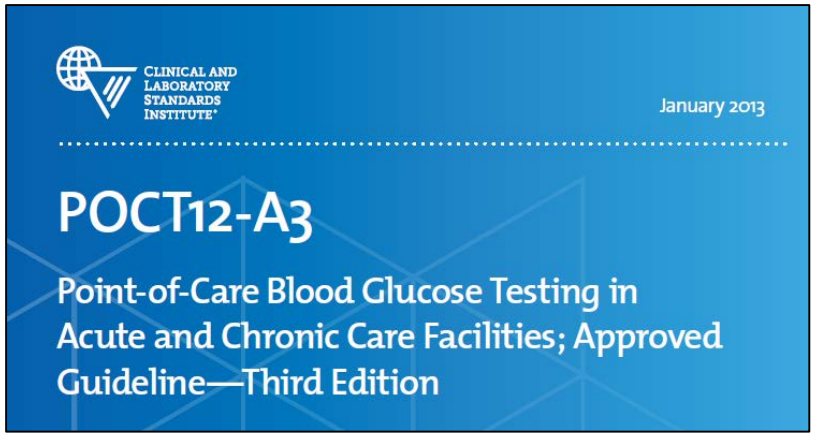
- varying levels of insulin dosing expertise in the study staff
- different target ranges for blood glucose by site
- different nutritional strategies
- different types of insulin administration
- different specimen types (e.g., venous/arterial vs. capillary)
- different instruments used to measure blood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

Leuven:

Bedside Blood Gas Analyzers

NICE-SUGAR:

Variable, many sites used capillary BGMS



FDA

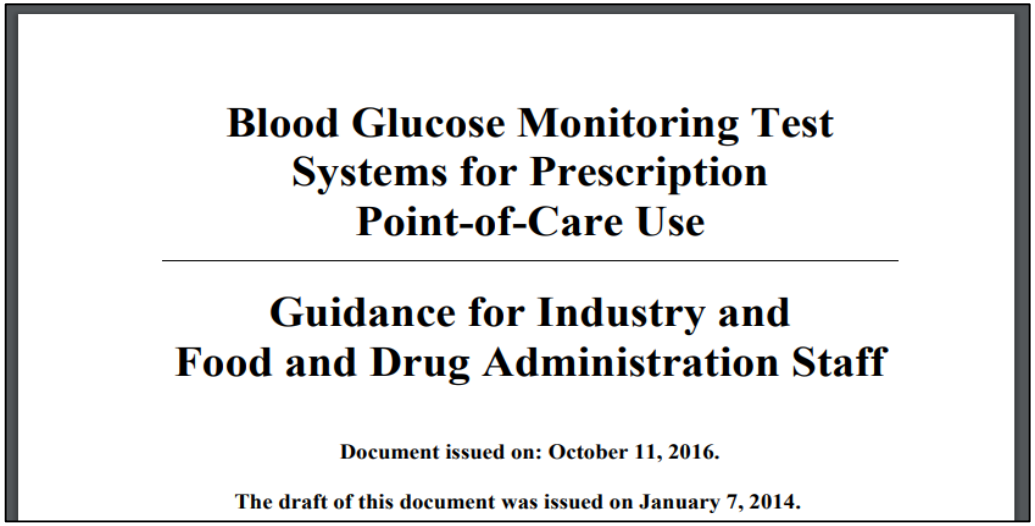
Performance goal:

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.

https://clsi.org/standards/products/point-of-care-testing/documents/poct12/

FDA BGMS Guidance

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



Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 11, 2016.

The draft of this document was issued on January 7, 2014.

https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm380325.pdf

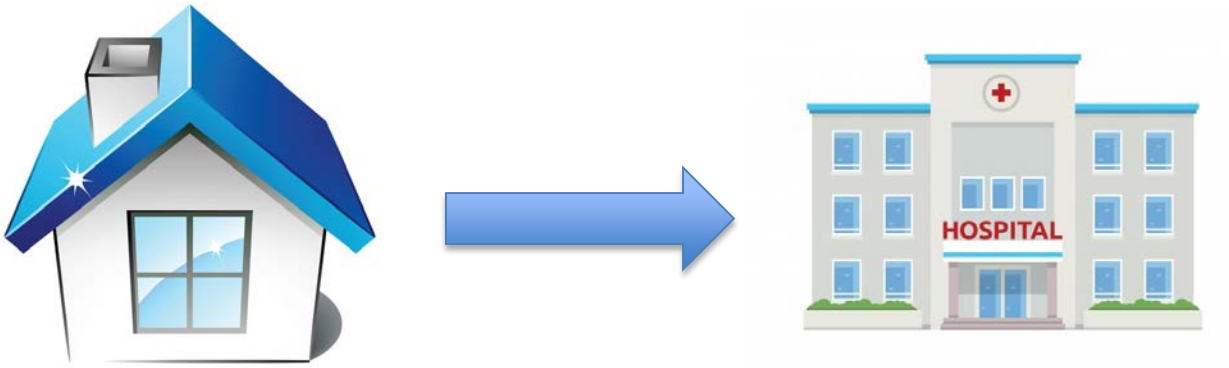
FDA BGMS Guidance

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

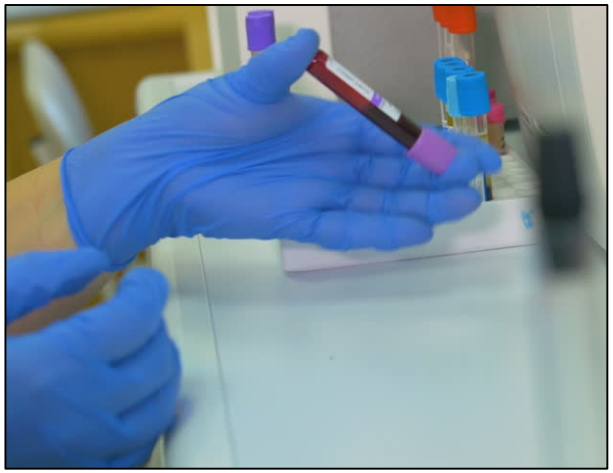
BGMS use in Intensive Care Settings

- 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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