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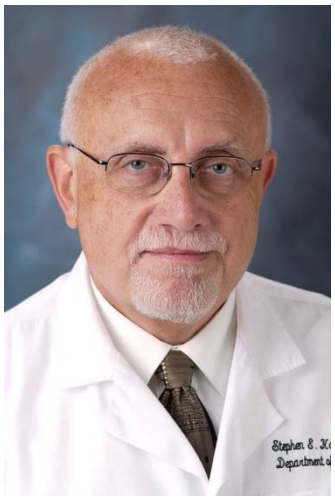
Using Blood Glucose Meters in the Hospital: Defining “Critically Ill” and Addressing Accreditation Issues



Stephen E. Kahn, PhD, DABCC, FACB

Professor and Vice Chair, Clinical Services, Pathology

Loyola University Health System

Maywood, IL

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Speaker Financial Disclosure Information

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- Potential COI to disclose relevant to the topic and issues of this presentation:
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  - Honorarium/Expenses: AACC for this presentation
  - Intellectual Property/Royalty Income: None

Presentation Objectives

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- Following this presentation, audience members will be able to:
  - List 3 analytical, clinical or regulatory challenges faced by U.S. hospitals in the use of BGMS*
  - Describe 3 strategies that could enhance effective use of BGMS in hospitals (esp. your hospital) by increasing patient safety and/or regulatory compliance
  - Recognize the relevance of distinguishing between developing a definition of ‘critically ill’ and specifying criteria for acceptable use of capillary finger stick specimens (esp. as it applies to your hospital)

* BGMS: Blood glucose monitoring systems, aka, bedside glucose meters

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The Hospital BGMS Practice Environment: Significant Issues

Glucose is our highest volume test in the LUHS

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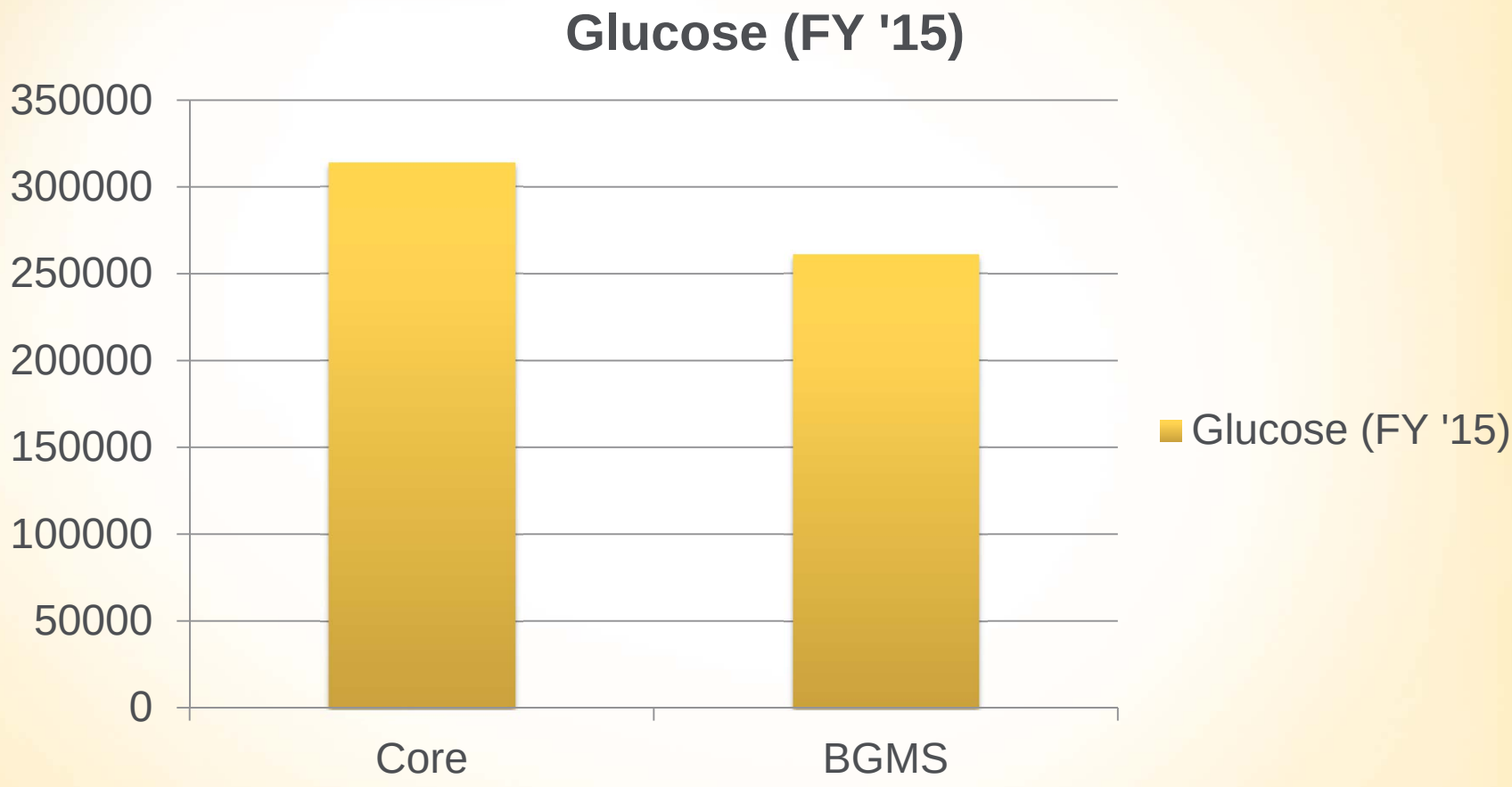

Core Lab includes CMPP, BMPP and Glucose by all methods

Measuring glucose – Some common approaches

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- Non-BGMS* Glucose - CAP 2015 C-B Chem/Tox Survey
  - 5 general enzymatic categories, 39 method peer groups, ~5500 participants
- BGMS Glucose – CAP 2015 – A WBG Survey
  - 8 manufacturers, 22 different BGMS devices or glucose strip categories, ~ 45000 participants
- **BGMS report *"Plasma-equivalent glucose"***

* BGMS: Blood glucose monitoring systems, aka bedside glucose meters

BGMS Use in Hospitals in the 21st Century

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- Hospitals use multiple protocols for 'managing' glycemic control
- Ongoing concerns - patient safety and medical errors
  - Numerous published studies and clinical practice guidelines
    - Studies as large as NICE-SUGAR not done easily
  - Have led to growth in modeling and simulation studies – e.g.,
    - Insulin dosing models
    - Impact of BGMS testing frequency for GC monitoring
- Specific concerns are **causes and sources of errors** in BGMS measurement, especially glycemic control protocols
  - Focus of regulatory and accreditation agency actions
  - Followed through institutional and national quality metrics
  - Can be addressed by unique practices, e.g., insulin dosing software

Clinical Concerns in the Hospitalized and ICU Patient

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- Sick – dehydrated, in shock, often on oxygen, impaired peripheral circulation
- Fluctuating hematocrits – not always known at time of testing
- Take multiple drugs – how do drugs affect a specific BGMS?
- Often have rapidly changing glucose values
- Can be tested using multiple meters by multiple operators
- Some operators may be unaware of the limitations
- Potential to test patients where BGMS actual use may be different from mfr product labelling for intended use

Potential SOEs in BGMS*

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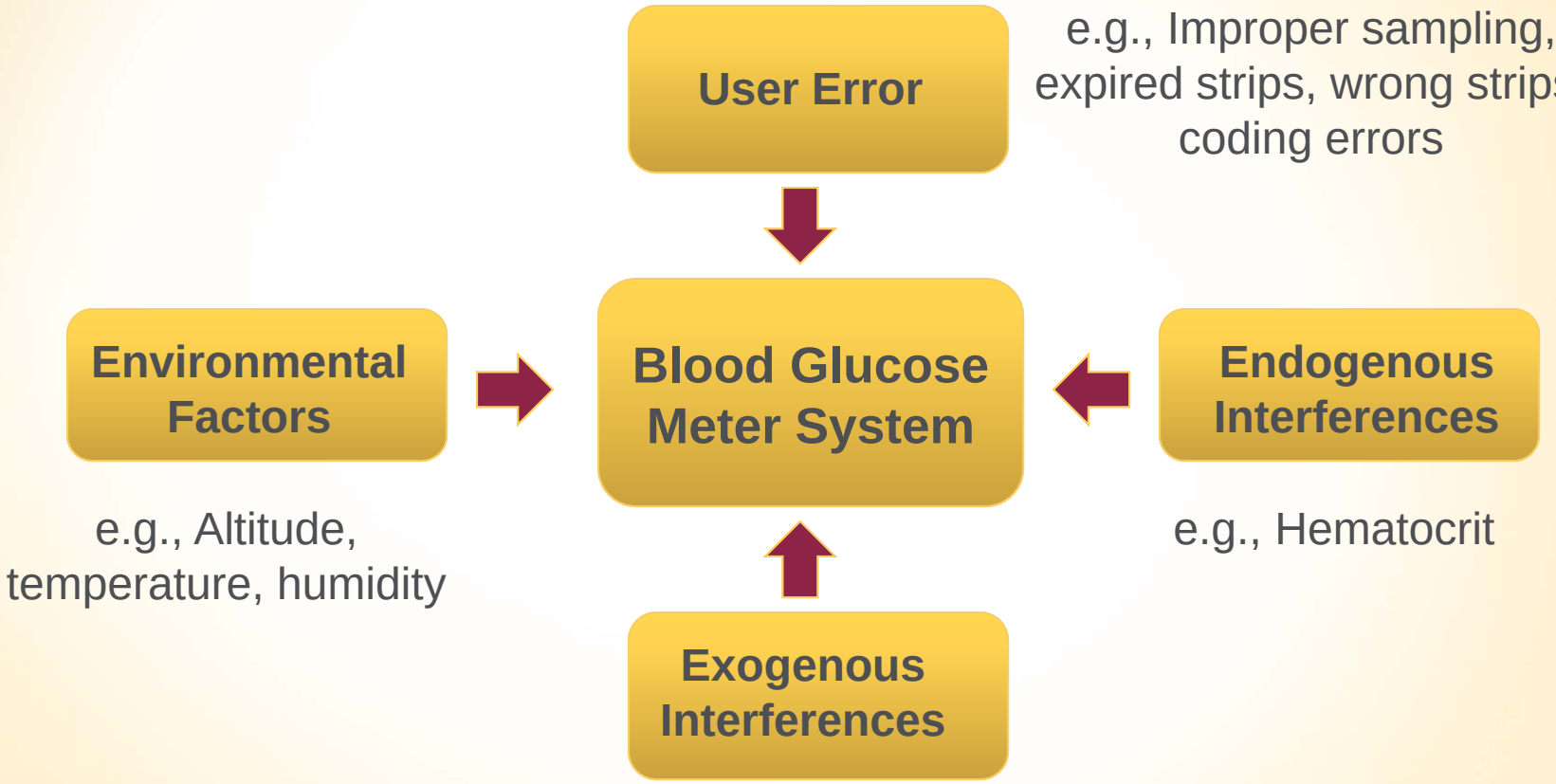
Factors affecting bedside glucose testing



*Dubois JA, Clarke W. *Point of Care* 2014

Who You Gonna' Call?
The 'Usual Suspects'

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Regulatory

FDA

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

Illinois Department of PUBLIC HEALTH

Accreditation

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

College of American Pathologists

The Joint Commission

Additional Resources

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Clinical and Laboratory Standards Institute

Regulatory Actions Since 2014

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- Jan ’14: FDA draft guidance to BGMS mfrs
  - BGMS must be approved for use in the intended population including ‘*critically ill*’
  - Mounting national concerns and confusion on many issues
- Sept ’14: FDA approves first BGMS for use in the *‘critically ill’* patient
- Nov ’14: CMS directive to state surveyors – use of BGMS not approved for use in ‘critically ill’ patients may be ‘*off label’*
  - Use of capillary finger stick specimens in critically ill patients is (and presently remains) *‘off label’* for all BGMS
- March ’15: CMS follow-up temporarily withdraws directive, adds clarifications, requests comments and holds off citations
- April ‘16: Most agencies and mfrs will not define *‘critically ill’* although the state of Illinois has done this (‘sort of’)

Why is FDA concerned about *'Plasma Equivalent Glucose'?*

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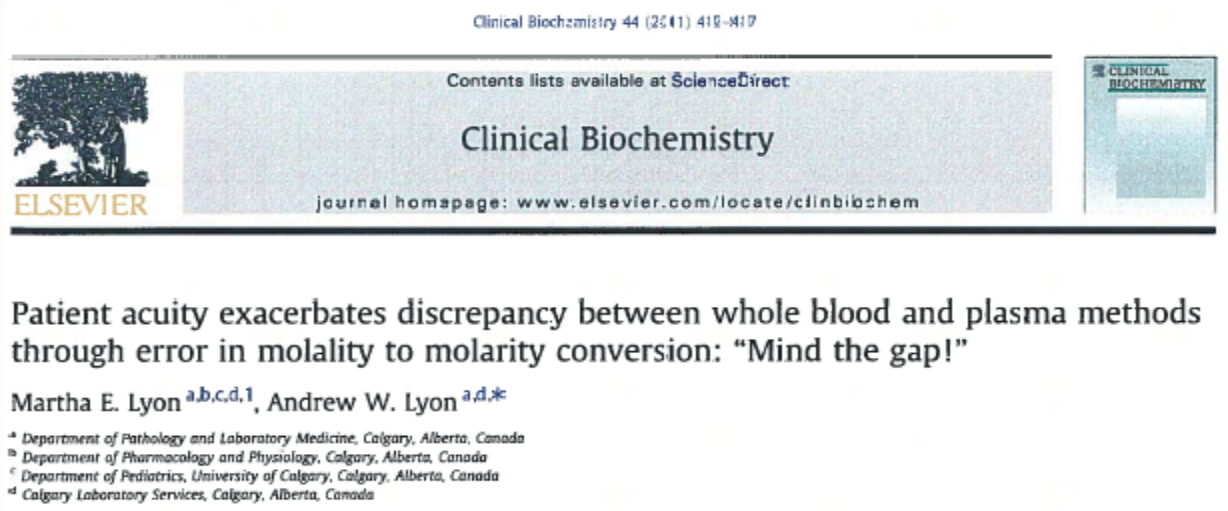

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Patient acuity exacerbates discrepancy between whole blood and plasma methods through error in molality to molarity conversion: "Mind the gap!"

Martha E. Lyon [a,b,c,d,1], Andrew W. Lyon [a,d,*]

[a] Department of Pathology and Laboratory Medicine, Calgary, Alberta, Canada
[b] Department of Pharmacology and Physiology, Calgary, Alberta, Canada
[c] Department of Pediatrics, University of Calgary, Calgary, Alberta, Canada
[d] Calgary Laboratory Services, Calgary, Alberta, Canada

- To report *'Plasma equivalent glucose,'* BGMS are pre-set to use a constant molality to molarity conversion factor of 1.11
- In hospitalized patients, this constant is not a constant
- Other key analytical variables taken as a constant in BGMS that aren't constant are hematocrit (43%), plasma water (0.93 kg water/L) and RBC water (0.71 kg water/L)

Plasma equivalent glucose?

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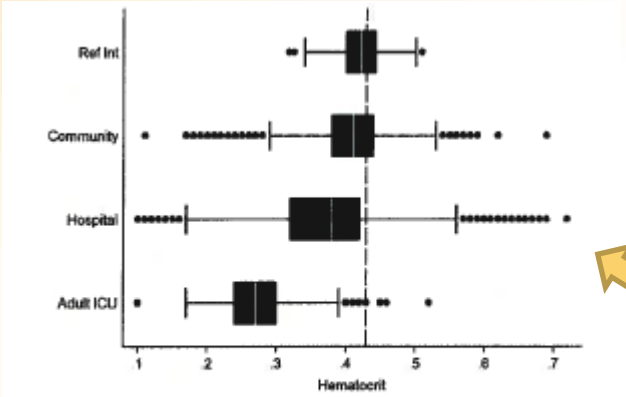

Fig. 1. Distributions of hematocrit values observed in community, hospital and critical care patient populations. Reference interval (simulated $n = 1000$), Community patients $n = 15{,}108$, Hospital patients $n = 45{,}260$ and Adult ICU $n = 1041$. Kolmogorov–Smirnov two-way tests for equivalence of distributions all had $p < 0.001$.

Distribution of:
Hematocrit
Red cell water
Plasma water

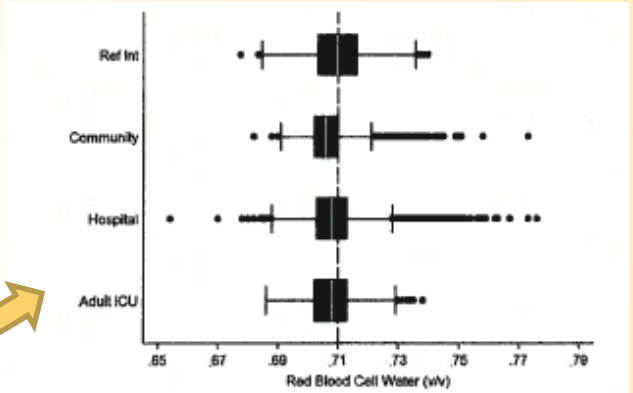

Fig. 2. Distributions of RW values observed in community, hospital and critical care patient populations. Reference interval (simulated $n = 1000$), Community patients $n = 14{,}376$, Hospital patients $n = 45{,}014$ and Adult ICU $n = 1041$. Kolomorov–Smirnov two-way tests for equivalence of distributions did not find statistically significant differences, $p > 0.52$.

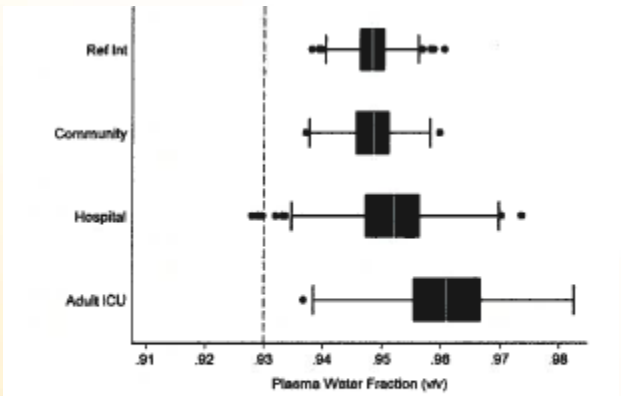

Fig. 3. Distributions of PW values observed in community, hospital and critical care patient populations. Using PW means and S.D. values from Table 1, distributions were simulated and plotted, $n = 1000$ for the reference interval, community patients, hospital patients and adult ICU. One-way ANOVA using Bonferroni method for multiple comparisons revealed statistically significant group differences in PW, $p < 0.001$.

Distribution of '1.11'

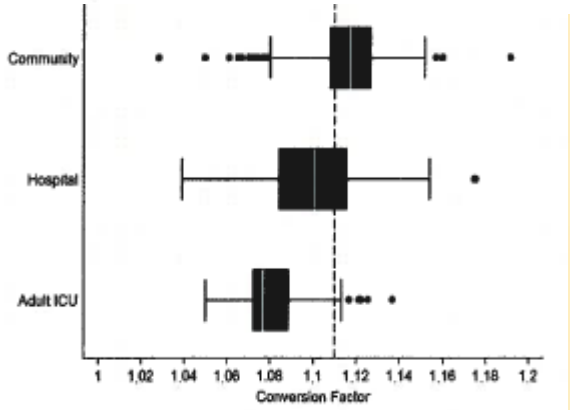

Fig. 4. Distributions of conversion factor values observed in community, hospital and critical care patient populations derived using Eq. (1) for individual patients. Community patients $n = 3133$, Hospital patients $n = 3727$ and Adult ICU $n = 105$. Kolomorov–Smirnov two-way tests for equivalence of distributions all had $p < 0.001$.

Plasma equivalent glucose?

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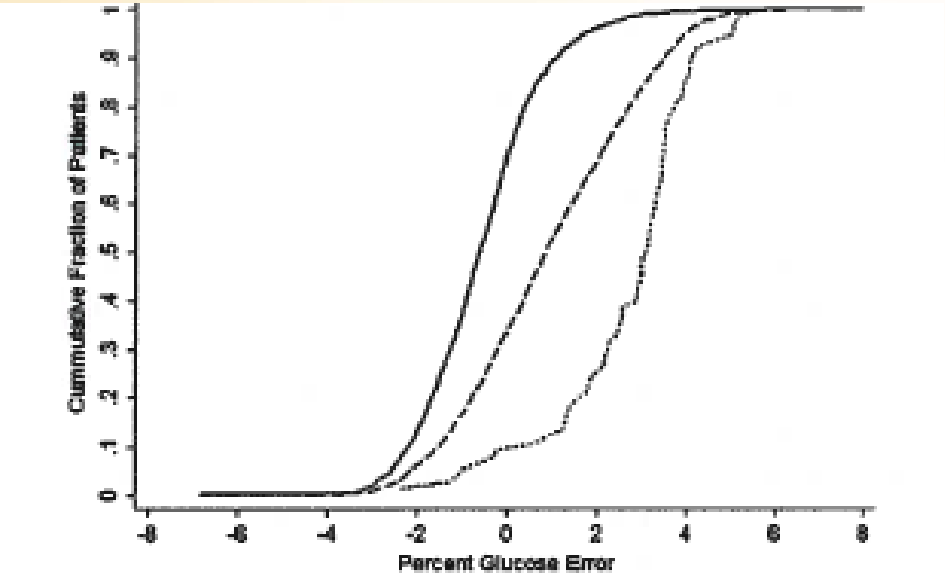

Fig. 5. Cumulative distributions of expected percentage glucose error in community, hospital and critical care patients. Community patients $n = 3133$ (solid line), Hospital patients $n = 3727$ (dashed line) and Adult ICU $n = 105$ (dotted line). Kolomorov-Smirnov two-way tests for equivalence of distributions all had $p < 0.001$.

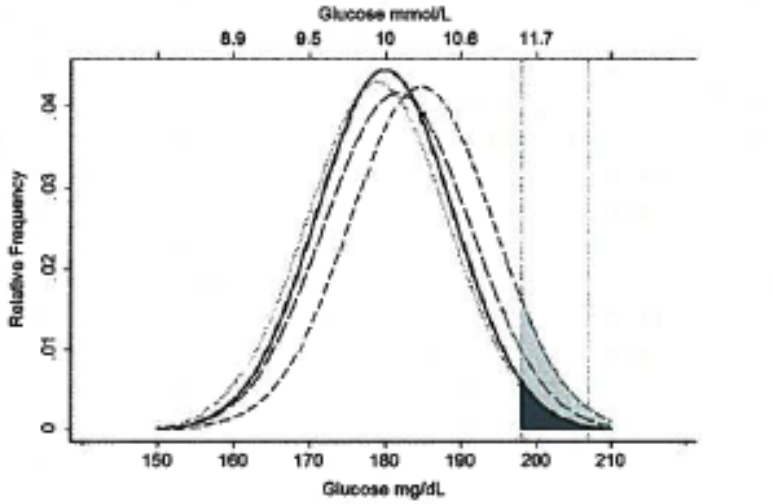

Fig. 6. Group-specific frequency distributions of predicted plasma-equivalent glucose error for a target whole blood glucose of 10 mmol/L (180 mg/dL) with 5% analytic coefficient of variation. Reference analysis, 5% analytic CV only, (solid line); Community patients (dotted line); Hospital patients (long dash line), Adult ICU patients (short dash line) indicate 5% analytic CV and group-specific conversion factor error. Vertical dotted reference lines are located at +10% and +15% of the target value. The shaded areas indicate the proportion that exceed +10% error for the reference analysis (dark gray shade) of the adult ICU group (light gray shade).

- **Conclusions:**

  Changes in HCT and PW concentration are predicted to affect a gap or error between whole blood direct reading biosensors and central lab plasma methods. ***This error increases and becomes more variable as patient acuity increases***.

LUHS Actions Since 2014

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- 2014: Using a BGMS not cleared for use in *'critically ill'* patients
  - Growing concerns on the FDA draft guidance to mfrs
- Dec '14: Notification of all key LUHS leaders and stakeholders of CMS directive regarding 'off label' use of BGMS
  - Initiate discussions on potential options for response
    - IP glycemic mgt team, ICU medical directors, MEC and nursing
- Feb '15: Lab leaders meet with CMO, CNO, and hospital administration
  - Agree to further explore options to achieve regulatory compliance
- Feb '15: LUHS parent, Trinity Health, selects BGMS cleared for use in *'critically ill'* patients
- March '15: CMS follow-up directive 'buys' LUHS some time
- April '16: LUHS plans to convert to new BGMS in 2 months

The ‘Usual Suspects’

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Regulatory

FDA

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES

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COLLEGE OF AMERICAN PATHOLOGISTS

The Joint Commission

Additional Resources

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Accreditation Issues

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Address the issues if 'off-label' use

- **Implement other options for glucose testing in 'critically ill' patients or with capillary finger stick specimens**
- **Otherwise, high complexity testing requirements**

Validate BGMS in non-ICU and ICU (or 'critically ill') pts

The Joint Commission

To be determined

Relevant CLSI Guidelines

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- Several guidelines related to POCT glucose measurement and BGMS
- POCT06: Effects of Different Sample Types ….
- POCT12 - A3: POCT Glucose Testing in ….
- POCT17 - ED1: Use of Glucose Meters for Critically Ill Patients
  - Recent effort of the CAP Consensus Cmte on POCT
  - Details options for hospitals to consider
  - Outlines key issues and necessary studies for hospitals to address with 'off-label' use

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CLSI POCT17 - ED1

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- Intended use versus off-label use
- Important elements of mfr's instructions
  - Sticking to stated limitations of the specific BGMS
  - Approved specimen types and in what patient groups
- Issues to consider in developing a definition of 'critically ill'
- Off-label use
  - Specific regulatory requirements for high complexity
  - High complexity performance specifications
- Alternatives to off-label use

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CLSI POCT17 - ED1

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- Options to address the critically ill limitations in specific BGMS labeling and technical information
  - If a hospital defines ‘critically ill,’ it should state BGMS shouldn’t be used in this patient group
  - Or use a different method without this limitation
  - Or if off-label use, perform validation studies required in CLIA to meet high complexity testing requirements

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Every Hospital (or Multi-Hospital System) Is Unique

Analyzing Your Facility's Needs – Defining 'Critically Ill'

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- Decision on creating a definition is a local issue and hospital (health system network) responsibility
  - Must decide whether to develop a definition regardless of BGMS used
  - Decision includes whether the BGMS is approved for use in 'critically ill' or it isn't
  - Overall effort must involve all key stakeholders
  - Other issues may impact your approach – e.g.,
    - Applicable state regulations
    - Assessment of risk management/patient safety
    - IT capabilities of the hospital or hospital network

Analyzing Your Facility's Needs – Stakeholders

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- Ongoing communication and collaboration between Lab personnel/POCT team and other stakeholders
  - Physician, nursing and administrative leaders
  - ICU medical directors
  - IP glycemic management team
  - Nursing education
  - Information technology
  - Institutional quality groups and leaders
  - Medical executive committee
  - Risk management/office of patient safety
  - Other stakeholders as determined by a specific hospital

Analyzing Your Facility's Needs – The BGMS Used

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- Know the analytical limitations of the BGMS and shape policies/procedures accordingly
- Regardless of the BGMS used in a hospital
  - Some will choose to further develop an explicitly detailed definition of 'critically ill'
  - Others may decide to not have any definition at all
- But if a definition is developed, it should be used and clinical practices impacted as it describes

Options for Clinical Criteria

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- Impaired peripheral circulation, hypotension, peripheral edema,
  - SBP < 70 – 100 mmHg or may be age adjusted (e.g., lower in neonates)
    - Can incorporate a specific delta decrease in SBP from baseline
  - MAP < 60 – 65 mmHg
  - Receiving ionotropic and/or vasopressor agents to support BP
    - May also use a significant dose change in past 24 hours
  - Need for fluid resuscitation of some length in past 24 hours
  - Serum osmolality > 310 - 320 mOsm/kg
  - 'Cold or clammy' skin
- Other clinical criteria
  - Diabetic ketoacidosis
  - Hypoxemia
  - Extreme hypoglycemia or hyperglycemia – extremes defined
  - Clinical signs of dehydration

Other Considerations

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- Whether a definition for ‘critically ill’ is developed or not, also must address appropriate patient groups where capillary finger stick specimens can and can’t be used
- Any ‘off-label’ use should be addressed as described in CLSI POCT17 - ED1
- Clinical algorithms and/or critical care paths can be developed for use in the hospital EMR
- Some hospitals may choose to embed the criteria for when BGMS (and/or capillary finger stick specimens) can be used in their EMR
  - Electronically documents appropriateness of orders and provides electronic audit trail

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BGMS Use in Hospitals: What Have We Learned

Conclusions

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- Appropriate BGMS use is a top patient safety and medical error reduction priority
- Present BGMS use, especially for glycemic control, likely to continue until improved BGMS or different technologies
- Limitations and intended use for all BGMS are explicitly clear
- Patients that a BGMS and/or capillary finger stick specimen shouldn't be used on should also be explicitly clear
- Each hospital (or system) must weigh all relevant factors in taking the decided actions for their use of a specific BGMS
- Key regulatory and accreditation bodies will continue to provide guidance that direct the appropriate actions …. there is more work to be done

BGMS Use in Hospitals Should Work This Way

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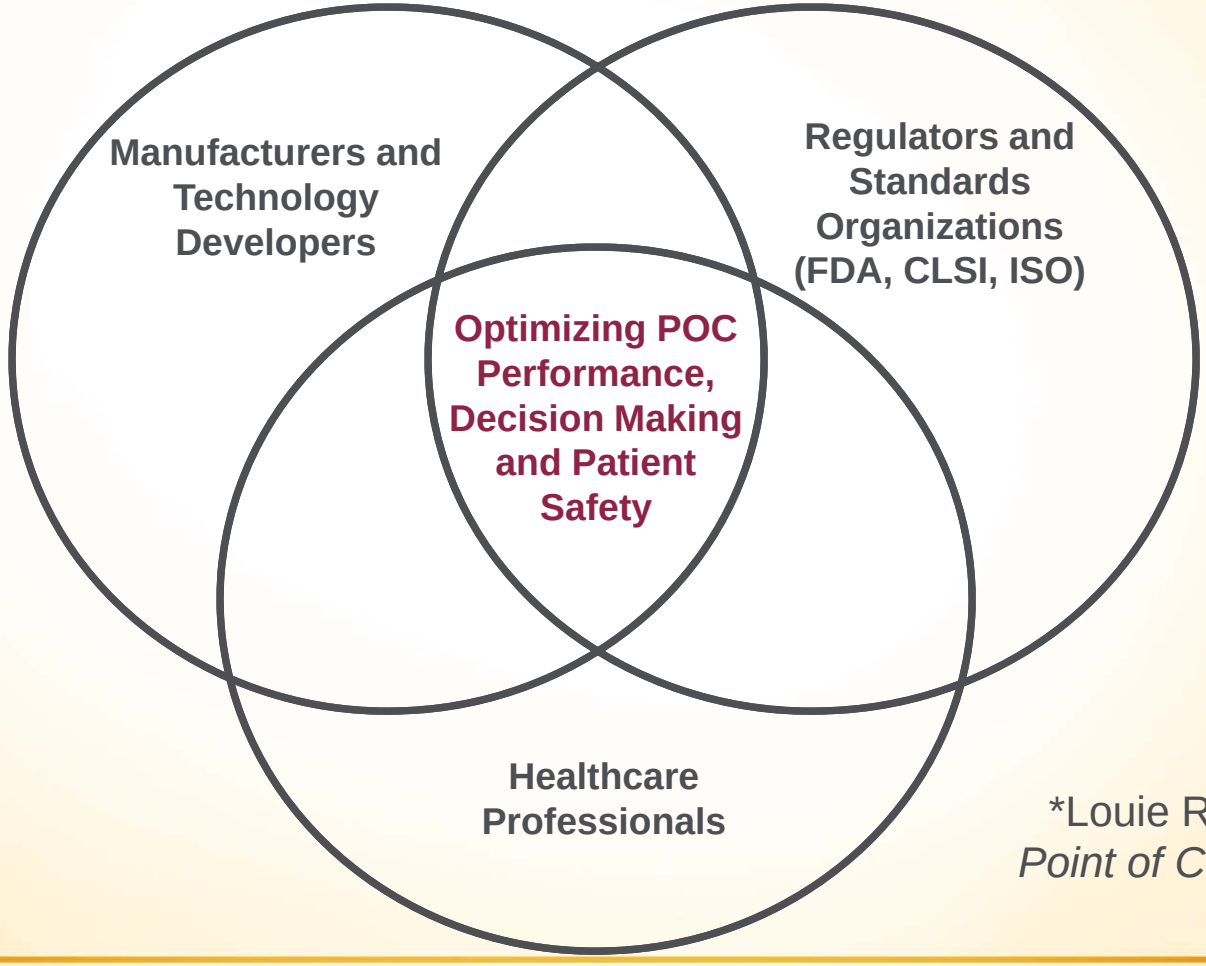
Harmonizing the spectrum of POC performance, decision making and safety*



*Louie RF *et al.* *Point of Care* 2014

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Thank you for attending!

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Visit the Resource Room to get the CE code for this session.