POCT Task Force Work Group: GMECC

How should glucose meters be evaluated for critical care?

Update: Cynthia Bowman, Chair
FDA concerns and directions

• 1992-2009: MDR’s, 100 deaths
• 2010 conference
• POCT-TF proposed WG to evaluate, make proposals
• 2013 labeling limitations
• 2014 Draft Guidances
• New York State
Terms of reference established

1. Evaluate the clinical practice of using blood glucose meters for critically ill patients
2. Determine the requirements a glucose meter needs to fulfill in order to be used for critically ill patients
3. Propose what internal and external quality control systems should be present
4. Evaluate which, if any, of the present instruments in the market fulfill these criteria
5. Provide recommendations for training and competency of users in critical care areas
6. Ensure recommendations align with other stakeholders
Expressions of Interest: winter 2013

Selection criteria:

• Global representation
• Practice settings
• Experience
• Perspective
• Size of work group
Members selected:

• Cynthia Bowman, Chair, US
• Edith Bigot-Corbel, France
• Sean Cunningham, Ireland
• Maria Elizabeth Guillen Barua, Paraguay
• Peter Lupe, Germany
• Tangirala Malati, India
• David Sacks, US
• Robbert Slingerland, Netherlands
• Bogdan Solnica, Poland
• Patrick St. Louis, Canada
• Robert White, Australia
• Florent Vanstapel, Belgium
• Andrei Malic, Nova Biomedical, UK
• Marianne Mulder, Roche, Germany
• Rolf Hinzman, Roche, Task Force POCT liaison
Corresponding members:

- Ivana Barsic, Croatia
- Daniel Bustos, Argentina
- Agnes Ivanov, Estonia
- Netta Schwarz, Israel
- Drahomira Springer, Czech Republic
Advisors:

• Brad Karon, Mayo Medical Labs, US
• Dietter Mesotten, KU Leuven, Belgium
• James Nichols, Vanderbilt University Medical School, US
• Mitchell Scott, Washington University Medical School, US
Face to face meeting

• Milan, May 2013
• Orientation Meeting
• Process
• Outline
• Define potential scope and issues
Scope of issues

- “Kitchen sink” outline
- Clinical breadth of issues
- Technical issues: methodologies, reference methods, detail
- Results reporting, connectivity
- Selection process
- Validation/verification
- Implementation, includes safety issues
- Outcomes assessment
WG meetings

• Conference calls, November 2013, March 2014
• Fit outline issues into terms of reference
• Critical issues to address
• Lively email exchanges
Term of reference 2

- Meter requirements needed to be used for critically ill patients
- Standards versus processes, definitions
- One size fits all?
- Can there be a “minimum standard?”
- POCT12
- Consider single or alternate processes to meet standards
- Resources, feasibility, practicality, achievability, acceptance
Evaluation studies

- Studies required
- Who performs them?
- Central versus decentralized
- Clearinghouse, information shared, publications
- Protocols, checklists?
- Clinical collaborations
Manufacturers

- Relationship with vendors
- Responsibilities, performance, outcomes, risks
- Independence versus collaboration?
- Costs
Activities

- FDA guidance IFCC response
- Journal of POCT editorial
- Meeting Monday
- Priority Setting
- Work product
- Collaboration with stakeholders