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Global Standardization and Improved Technologies for Point-of-Care Glucose Testing

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Mahoney and Ellison [1] point out the realities of point-of-care testing, or for that matter, the challenges facing any diagnostic assay—variations in hematocrit, oxygen tension, pH, and temperature, and myriad other factors, such as drugs, may affect measurements unpredictably. Nonetheless, all diagnostic tests, including those performed at the bedside, should be highly accurate. *Point-of-care testing is no excuse for inaccuracy!*

Whole-blood samples start with patients, who will present, especially if critically ill, a heterogeneous dynamic mix of variables reflecting *in vivo* conditions. In our experimental model, we minimized time delays, randomized measurements, and did not tamper with samples, in order to fairly preserve and evenly represent *in vivo* conditions *in vitro*, thus giving equal opportunity for each glucose meter system to display its native performance characteristics, which locally-smoothed (LS) median absolute difference (MAD) curves [2] portray so vividly.

The results speak for themselves—the performance of handheld devices for glucose measurement needs to be improved, and also considered in the context of glucose intervals used in tight glycemic control (TGC). Our patient population was representative of critical care settings where TGC is used. Thus, the goal is not to design an artificial experiment lacking clinical relevance, but instead to raise the performance bar so that critical care nurses, physicians, and surgeons, as well as emergency physicians and those responding to

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crises, will have high quality diagnostic evidence for rapid bedside decisions. TGC has forced the issue. What do we need to do?

First, glucose testing must be based on standardized calibration. Second, proficiency testing should be accuracy-based and traceable to the same global standard. Third, technologies need to be improved to eliminate effects of confounding factors. Fourth, scientists, clinicians, and industry leaders are encouraged to work together in the new point-of-care technology national research network [3] to advance performance collaboratively. Fifth, even with technical advances, human error is likely to persist, so care teams must enhance operator training and educate in proper interpretation and use of point-of-care results.

Without these fundamental elements requisite to progress we will continue to see inaccuracies of the magnitude clearly illustrated (without magnification) by LS MAD curves [2]. The LS MAD curve should be below the error tolerance over clinically relevant decision intervals, and this new approach is recommended not in isolation, but in conjunction with other established evaluation techniques capable of revealing erroneous results and discrepant values [2]. Discrepancies around the TGC interval introduce risk because they can lead to dangerous hypoglycemic episodes, one of the most serious drawbacks of TGC protocols.

The Food and Drug Administration and other responsible agencies should define an accuracy standard for the licensing of POC glucose devices, and as suggested last year [4], all would benefit from independent arbitrator adjudicating performance to certify or disqualify devices for use in pivotal situations, such as critical care, emergency medicine, and disaster response where the price for inaccuracy, erroneous results, or discrepant values may be too costly in terms of patient outcomes, and ultimately, survival.

These principles must extend globally [5]. Handheld meters frequently represent the only instruments available for glucose measurements in low-resources countries, especially remote and rural areas [6]. These countries now face a worldwide diabetes newdemic [7]. During devastating disasters, such as the 2004 tsunami in Southeast Asia and Hurricane Katrina in the United States [8], point-of-care testing often represented the only diagnostic and monitoring option available. Therefore, it must be accurate.

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