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ORIGINAL ARTICLE

Several Steps Forward: A New Meter for Multiple Patient Use

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Abstract

Point-of-care (POC) blood glucose testing is becoming ubiquitous in the hospitals because of ease of use, timely results, and cost effectiveness. Historically, these POC devices were designed and regulated for home use by patients with diabetes. Their transition into the hospital multipatient setting has introduced the real risk of cross-contamination and has exposed inadequate accuracy standards. This article highlights some of the current recommendations for these devices and focuses on a new meter that addresses these issues. Although not currently approved for use in the United States, the OneTouch® Verio®Pro blood glucose meter (LifeScan, Inc.), which is the topic of an article by MacRury and coauthors in this issue of the *Journal of Diabetes Science and Technology*, is a step forward with minimal interferences and good accuracy, and perhaps most importantly, is robust enough to withstand rigorous disinfection.

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Historically, self-monitoring of blood glucose (SMBG) began with point-of-care (POC) meters that were designed, manufactured, and regulated for home use by patients with diabetes. This POC glucose testing has slowly migrated from the home into hospitals and other institutional care facilities because of their ease of use, timely results, and inexpensive cost model. The major drawback of these meters has been poor accuracy compared to central laboratory devices (CLDs),[1] as traditional SMBG meters for home use may not provide enough accuracy for the hospitalized patient.[2] Current International Organization for Standardization (ISO) 15197 performance criteria for SMBG accuracy mandates that only 95% of the individual glucose results fall within ±15 mg/dl of the reference results for glucose concentrations ≤75 mg/dl and within ±20% at glucose concentrations >75 mg/dl. Even with declining adherence by clinicians to intense insulin therapy in the inpatient setting, the Food and Drug Administration (FDA) recognizes that these loose targets are insufficient for hospital meters and soon plan to release *POCT12-A3: Point-of-Care Glucose Testing in Acute and Chronic Care Facilities: Approved Guideline*. This will define new and more rigorous standards for institutional blood glucose accuracy.[3]

In addition to the more stringent hospital meter accuracy metrics coming in the near future, there are other issues that must be solved with the move of these meters to the inpatient and institutional settings. First, these meters are used by multiple patients, which introduces the inevitable risk of passing infective agents. The hepatitis B virus

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Abbreviations: (CDC) Centers for Disease Control, (CLD) central laboratory device, (FDA) Food and Drug Administration, (HBV) hepatitis B virus, (ISO) International Organization for Standardization, (JDST) *Journal of Diabetes Science and Technology*, (POC) point of care, (SMBG) self-monitoring of blood glucose

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(HBV), which is highly infective and viable in dried blood for up to a week,[4] has been involved in several institutional outbreaks and it is suspected that glucose meters harbored the HBV.[5] The FDA has issued guidance[6] to assure that devices intended for hospital or long-term care facilities can be disinfected with agents that kill viruses and that this process will not alter meter function. Second, multiple patient use mandates that these new devices keep track of results from numerous patients at the same time. Third, the absence of measurement interference from a multitude of drugs must be assured. Fourth, although SMBG devices were originally designed to measure capillary blood, accuracy between arterial, venous, and capillary blood samples is needed in this more complex population.

In this issue of *Journal of Diabetes Science and Technology*, MacRury and coauthors[7] introduce the OneTouch® Verio®Pro+ blood glucose meter (LifeScan, Inc. Milpitas, CA), which is currently approved for European markets. This meter was designed to address new institutional accuracy requirements and the most important issue with meter use in multiple patients—prevention of cross-contamination. Although other features of this meter may be important, we believe that the accuracy and infection characteristics are the most important advances.

In testing accuracy, MacRury and coauthors[7] reviewed 566 paired measurements, comparing the accuracy of the OneTouch Verio Pro+ with a CLD, using blood samples from 191 patients with diabetes and 34 volunteers. These data were then analyzed against the new hospital standards proposed by the Clinical and Laboratory Standards Institute, which call for glucose values within ±12 mg/dl for concentrations <100 mg/dl and within ±12.5% of reference for values ≥100 mg/dl. For all 566 paired values, 549 (97%) fell within the new accuracy metrics. More importantly, MacRury and coauthors[7] report that 73 of 76 measurements <100 mg/dl were within the new standards. Furthermore, 27 of 27 (100%) and 25 of 26 (96%) of the tests were within standard for arterial and venous samples, respectively. The capillary samples were accurate in 21 of 23 (91%) measurements. The difference plots presented are impressive but suffer from the illness that plagues almost all clinical evaluations of glucose meters—very few readings in the hypoglycemic range. It is difficult to obtain low values without doing clamp testing, which is very expensive and performed by few groups, most likely secondary to the difficulty in obtaining institutional review board approval.

MacRury and coauthors[7] analyzed 59 possibly interfering substances including commonly known potential interferents such as acetaminophen, ascorbic acid, dopamine, and mannitol. This new meter uses glucose dehydrogenase and steers away from the potentially fatal interference that plagued the glucose dehydrogenase pyrroloquinoline quinone based meters, which read maltose (a byproduct of the peritoneal dialysis perfusate icodextrin) as glucose, resulting in the reporting of falsely high readings. The two compound interferences reported with this new meter were xylose (used in testing for intestinal disease) and pralidoxime iodide (used for the treatment of organophosphate poisoning). As with almost all glucose meters, this device uses a proprietary algorithm in the postanalytic processing phase to correct for hematocrit.

Along with improved accuracy, elimination of infectious cross-contamination risk is a must for a device that samples blood from multiple patients. Hepatitis B virus outbreaks have continued even after the Centers for Disease Control (CDC) made efforts to educate caregivers in the 1990s.[8] The CDC has highlighted unsafe practices including multiperson use of lancing devices, insulin pens and vials, absence of routine device disinfection, and handling practice failures (e.g., no gloves or handwashing). In conjunction with the CDC's efforts, the FDA now mandates that every new POC glucose device submission include the following: intended use (single user vs multiple user), validated cleaning and disinfection procedures, and labeling considerations. The cleaning and disinfection procedures should kill the human immunodeficiency virus, HBV, and hepatitis C virus. Evidence that the procedures are effective specifically against HBV is also required, because this agent is especially hard to eliminate from surfaces. MacRury and coauthors[7] have shown that this new meter can be effectively disinfected with bleach-based disinfectants, which are commonly used to clean hospital-based devices. Although not yet available, a further advancement would be technology (similar to that used with control solutions) that prompts periodic disinfection and disables the meter without it.

As progress continues to evolve towards the ideal hospital glucose monitor, it is important to document important advances and keep pushing for further improvements. Based on the report of MacRury and coauthors[7] in this issue, the OneTouch Verio Pro+ raises the bar for other inpatient meters by attempting to meet the coming FDA accuracy

requirements as well as allowing the meter to be successfully disinfected against dangerous viral agents. We look forward to further improvements as other glucose meters are introduced, evaluated, and marketed to our patients. The ultimate goal would be a device that has equal accuracy to CLDs while completely preventing the spread of infectious agents among patients.

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