# Evaluation of a New POCT Bedside Glucose Meter and Strip With Hematocrit and Interference Corrections

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**Introduction:** Based on the expanding role of point of care testing glucose meters and the need to improve accuracy and precision, the new Nova Biomedical StatStrip was evaluated and compared with the LifeScan SureStepFlexx (current point of care testing meter).

**Methods:** Specimen volume variation, within-run imprecision, lot-to-lot bias, bias relative to a plasma hexokinase assay, and analytical interferences likely to be encountered in hospitalized patients were studied.

**Results:** Strip dosing did not affect the StatStrip meter but did affect the SureStepFlexx at 5- and 50- $\mu$ L specimen volumes. Within-run precision for each glucose meter was less than 5% at 39 to 47 mg/dL of glucose, less than 1.7% at 215 to 265 mg/dL, and less than 2.6% at 370 to 470 mg/dL. Improper coding resulted in erroneous measurements on the SureStepFlexx. Each meter was compared with the Dade RxL hexokinase plasma reference method, giving the following correlation equations: StatStrip = 1.015 (hexokinase)  $- 1.412 (r^2 = 0.996)$ ; SureStepFlexx = 0.889 (hexokinase) + 8.865  $(r^2 = 0.989)$ . At [glucose] of 55 mg/dL, ascorbic acid interfered with the SureStepFlexx but did not affect StatStrip. Hematocrit also affected the correlation of whole blood glucose on the SureStep-Flexx to the plasma hexokinase reference glucose but did not affect the StatStrip meter.

**Conclusions:** These studies suggest that the new StatStrip meter may be more accurate and precise (elimination of hematocrit effect and electrochemical interferences with no error because of strip dosing or calibration) than the SureStepFlexx meter. This reduction in total error may help achieve better glycemic control in hospitalized patients.

Key Words: glucose meter, point of care testing, accuracy

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Much attention is paid to the monitoring of glucose in hospitalized patients to achieve tight glycemic control and to minimize complications from hypoglycemia and hyperglycemia.<sup>1-4</sup> Although hyperglycemia of hospitalized patients is common among patients with diabetes mellitus, it is not restricted solely to patients with this disease. In addition, glucose levels within hospitalized

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patients, particularly critically ill patients, can change rapidly depending on stress and medications. To maintain tight glycemic control for these patients, rapid turnaround time for glucose analysis is required. Point of care testing (POCT) reduces turnaround time dramatically from that obtained by traditional central laboratory testing. Glucose meters are generally the instruments of choice for POCT glucose testing.

A major current concern is the accuracy of POCT glucose meters.<sup>5</sup> The target glucose range, used to guide insulin dosage in hospitalized patients, varies depending on the institution and is typically narrower than that in the ambulatory (home) setting. However, abnormal hematocrit levels and various electrochemical or chemical interferants, known to affect results from glucose meters, are frequently present in the specimens of hospitalized patients. Medications and hematocrit in these patients are found to affect the performance of almost all glucose meter technologies available.<sup>6–9</sup> Ascorbic acid interfered with all glucose meter technologies available in the year 2000. Several studies demonstrated that low hematocrit gives a high bias to glucose, and conversely, high hematocrit causes a low bias in glucose levels for virtually all meters tested.<sup>7–9</sup>

In addition, the degree to which glucose meters correlate with plasma hexokinase glucose measurements (used frequently as a reference technology) varies greatly between glucose meter technologies.<sup>10</sup> In particular, correlation in the hypoglycemic and hyperglycemic ranges is highly variable with most currently available meters.<sup>11</sup>

This study was designed to compare our current glucose meter with a new glucose meter that uses both interference and measured hematocrit corrections. The study compared the accuracy of both POCT hospital-based glucose meters with the reference plasma hexokinase method and also evaluated the effect of drug/chemical interferences and hematocrit on each meter at 3 glucose levels.

### MATERIALS AND METHODS

#### Instrumentation

This study compared 3 glucose assays. The reference assay hexokinase method on the Dade-Behring Dimension RxL analyzer (Dade-Behring, Deerfield, III) was used to measure plasma glucose. Hexokinase methods are suitable for use as reference methods for glucose determination because they correlate closely to definitive mass spectrometry.<sup>12</sup> The 2 glucose meter technologies studied were the SureStepFlexx (LifeScan, Malpitas, Calif), which uses a photometric glucose oxidase detection system and a new meter technology,

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StatStrip (Nova Biomedical, Waltham, Mass), which uses a modified glucose oxidase-based amperometric test system with hematocrit and other interference correction.

# Strip Dosing Study

Whole blood droplets of varying volumes (5–30  $\mu$ L) from blood specimens containing 4 different glucose levels (as determined by the reference Dade RxL instrument) were placed on Parafilm on a flat surface. The StatStrip meter, loaded with a strip, was touched to a droplet, as if it were on a patient's fingertip, and the specimen was drawn into the test strip by capillary action to measure the glucose. This process was repeated 6 times each droplet volume (5–30  $\mu$ L) at the 4 different glucose levels. The SureStepFlexx was evaluated using whole blood droplets of varying volumes (5–50  $\mu$ L) that were pipetted directly onto the test pads of the strips. This process was repeated in replicates of 6 at each of the 4 glucose levels.

# Within-Run Precision Study

For within-run precision, venous heparinized whole blood was drawn 12 to 24 hours in advance of performing the study. Aerated blood was divided into three 2-mL aliquots, which received different volumes of a concentrated glucose solution, such that the aliquots had 20 to 60, 200 to 300, and 450 to 550 mg/dL of glucose. Each aliquot was then tested 20 times on each meter.

# **Calibration Code Study**

A limited study of calibration bias from strip lot to strip lot included looking at glucose values across 4 strip lots of StatStrip (which all use the same companydesignated calibration with no lot-to-lot variation) and 2 strip lots of SureStepFlexx (each having been assigned its own calibration code numbers). Six replicate analyses for each StatStrip at 3 glucose levels were performed using the same calibration code across strip lots. Six replicate analyses for each of 2 strip lots of SureStepFlexx using 2 calibration codes (ie, strip A with calibration code A, strip B with calibration code B, strip A with calibration code B, and strip B with calibration code A) were also run for each strip lot at 3 glucose levels.

# Method Correlations Using Patient Specimens

Two hundred fresh, venous, whole blood newly discarded specimens in green top tubes were used in this study. A drop from each well-mixed green top tube (spiked or unspiked) was removed and wicked onto 1 StatStrip strip and 1 SureStepFlexx strip for immediate analyses. The tubes were then immediately centrifuged, after which, a plasma sample was removed and tested using the hexokinase reference method on the Dade RxL analyzer. In some cases, the green top tubes were allowed to sit at room temperature for approximately 24 hours on a rocker, allowing the red cells to metabolize glucose and lower the [glucose]. To study a wide dynamic glucose range, 50 of the 200 glucose specimens in lithium heparin green top tubes were spiked with small volumes of concentrated spiking solution (20,000 mg/dL glucose in water).

For the interference studies, freshly drawn, heparinized,

Interference From Exogenous Materials

venous blood from healthy donors, 1 donor per interferant tested, was allowed to sit at room temperature for 12 to 24 hours before concentrated solutions of glucose and/or interfering substances were added. The concentrated solutions of glucose and the interfering substances were gravimetrically prepared. These concentrates were prepared as follows: 20,000 mg/dL glucose in water, 1000 mg/dL acetaminophen in water. 1000 mg/dL ascorbic acid in water, and 10,000 mg/dL D(+) maltose monohydrate in water. Immediately before each interference study, aliquots of donor blood were spiked with glucose concentrate, bringing them into 3 predetermined ranges. This was followed by the division of each of these aliquots into 3 volumes, 2 of which were then spiked with the interfering material. Concentrations of each interferant tested were chosen to reflect (at maximum concentration tested) 5 to 10 times the therapeutic drug level, similar to what has been described previously.<sup>6</sup> All specimens were rocked for at least 10 minutes but not longer than 20 minutes. The next step was to analyze the [glucose] in each specimen with 6 strips from both devices. After completing the testing on the strips, the specimens were immediately centrifuged. The plasma from each specimen was analyzed using the hexokinase method on the Dade RxL.

### Hematocrit Effects on Glucose Measurements

For the studies using variable hematocrit levels, a fresh 30-mL whole blood pooled specimen from a single donor was allowed to sit at room temperature for 12 to 24 hours before division into 3 aliquots of 5 mL. The three 5-mL aliquots were each brought to a different glucose level using the stock glucose solution. Each of the 3 primary 5-mL aliquots was further divided into five 1-mL aliquots. Each set (1 set per glucose level) of five 1-mL specimens was then centrifuged, followed by precalculated plasma volumes being micropipetted from some of the tubes and dispensed into others, such that the 5 tubes contained different hematocrit levels. All specimens were rocked for at least 10 minutes and then rapidly analyzed, in less than 10 minutes, on the 2 glucose meters in replicates of 6. Hematocrit (percentage) values were obtained for each of the prepared specimens in this study using a spun hematocrit analyzer, the HemataStat II (Separation Technology, Altamonte Spring, Fla). All specimens were centrifuged to remove a plasma sample for analysis on the Dade RxL analyzer.

# Statistical Analyses

The patient specimen data for each meter and the reference hexokinase method were analyzed to determine the slope, intercept, and correlation coefficient  $(r^2)$  for the data sets. Mean bias (glucose meter minus hexokinase glucose) was also calculated for each meter.

To assess the impact of each interferant at 3 [glucose], the baseline (zero interferant) glucose measurement was used to calculate deviation from baseline at increasing concentration of interferant. Results are expressed as change from baseline glucose in percent ([meter glucose with interfering substance - meter glucose at baseline]/meter glucose at

| Dade RxL                 | StatStrip<br>Glucose, mg/dL (%CV, where n = 6)<br>Sample Volume |              |              | SureStepFlexx<br>Glucose, mg/dL (%CV, where n = 6)<br>Sample Volume |              |              |              |               |
|--------------------------|---|--------------|--------------|---|--------------|--------------|--------------|---------------|
| Glucose, (mg/dL) (n = 1) |   |              |              |   |              |              |              |               |
|                          | 5 μL  | 10 µL        | 20 µL        | 30 µL   | 10 µL        | 20 µL        | 30 µL        | 50 µL         |
| 50                       | 52 (9.1)  | 52.3 (6.8)   | 52 (5.01)    | 52.7 (6.76)   | 46.2 (3.47)  | 48.5 (5.01)  | 48.5 (4.28)  | 55.2 (2.41)   |
| 158                      | 146.7 (1.71)  | 147.2 (3.02) | 147.5 (2.99) | 146.7 (2.14)  | 146.2 (2.65) | 145.5 (2.77) | 144.2 (2.79) | 161.2 (10.32) |
| 260                      | 265.3 (1.5)   | 266.5 (1.94) | 266.3 (1.11) | 263.3 (0.82)  | 262 (2.72)   | 260.7 (2.64) | 259.5 (3.27) | 281.7 (6.2)   |
| 372                      | 375.2 (1.82)  | 375.3 (2.09) | 370.5 (1.24) | 371 (1.29)  | 336 (1.4)    | 340 (1.84)   | 331.2 (2.96) | 460 (5.08)    |

(mg/dL) represents the mean of 6 readings on the appropriate strip from the indicted droplet size. The %CV refers to the variation in values associated with each set of 6 readings.

baseline  $\times$  100). A clinically significant interference effect was defined as any concentration of interferant that changed the mean baseline glucose (no interfering substance added) value by more than 10%. For experiments in which hematocrit was manipulated to examine the effect of hematocrit on the correlation between glucose meter and plasma hexokinase glucose, the mean glucose (mean of 6 replicates) percent difference ([meter glucose minus reference glucose]/reference glucose  $\times$  100) was calculated for each hematocrit concentration on each meter technology at 3 glucose levels.

#### RESULTS

#### Strip Dosing Study

Table 1 (Strip Dosing Study) suggests that the StatStrip and the SureStepFlexx handled 10- to 30- $\mu$ L droplets comparably with minimal changes in the means of 6 readings at each of the 4 glucose levels. The StatStrip seemed to be unaffected by varying the whole blood specimen volume. The SureStepFlexx, however, at 5  $\mu$ L of whole blood specimen volume, gave erratic results. The SureStepFlexx also gave higher glucose values when 50  $\mu$ L of whole blood was used. This is consistent with their claim that they can only measure specimen volumes up to 30  $\mu$ L.

#### Within-Run Precision Study

Within-run precision was assessed by running pooled donor specimens manipulated to obtain glucose at low (46 mg/dL), medium (263 mg/dL), and high (439 mg/dL) levels 20 times in 1 day. The coefficient variation was less than 2.6% for each of the meters at the higher glucose level tested (Table 2).

| TABLE 2. Within Run Precisio |
|------------------------------|
|------------------------------|

|                          | Glucose (mg/dL) | Imprecision, %CV |
|--------------------------|-----------------|------------------|
| Dade RxL                 | 46              |                  |
|                          | 263             |                  |
|                          | 439             |                  |
| StatStrip ( $n = 20$ )   | 45              | 4.3              |
|                          | 259             | 1.7              |
|                          | 457             | 1.3              |
| SureStepFlexx $(n = 20)$ | 41              | 3.3              |
|                          | 222             | 1.6              |
|                          | 383             | 2.5              |

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#### Calibration Code Study

Table 3 presents data demonstrating variability of glucose results if a meter is not properly calibrated or coded. Lot-to-lot variation across 4 StatStrip lots was small (a range of 3.7 mg/dL being seen at a glucose level of 53 mg/dL, 0.8% at glucose level of 226 mg/dL, and 1.1% at a glucose level of 436 mg/dL). Lot-to-lot variation across 2 SureStep-Flexx lots was also small at the lowest glucose level (1.0 mg/dL at 53 mg/dL glucose) but higher at the higher glucose levels (10.2% at 226 mg/dL glucose and 6.2% at 436 mg/dL glucose). The actual glucose values provided by the StatStrip were much closer to the reference assay values (StatStrip biased low by 4.1 mg/dL at 53 mg/dL glucose, 2.6% above the reference method at 266 mg/dL glucose, and 1.6% below the reference value at 436 mg/dL glucose versus SureStepFlexx that was biased 9.7 mg/dL low at 53 mg/dL glucose, -7.3%mg/dL at the 255 mg/dL glucose, and 9.1% at the 436 mg/dL glucose level). The limited data gathered suggested that bias from the reference method depended on the calibration code given to a lot of SureStepFlexx.

# Effect of Interfering Substances on Glucose Meter Accuracy

Acetaminophen (final specimen concentrations of 0, 5, and 10 mg/dL) was added to donor sodium heparin blood with a glucose level that had been adjusted to 55, 248, and 418 mg/dL, respectively, as described in the "Materials and Methods" section. Addition of acetaminophen did not change the mean glucose baseline by more than 1.2 mg/dL (2%) for StatStrip or 3.5 mg/dL (6%) for SureStepFlexx for experiments performed at 55 mg/dL glucose. At either 248 or 418 mg/dL, the glucose value did not change by more than 0.5% for StatStrip or more than 5.1% for SureStepFlexx. Thus, acetaminophen did not produce a clinically significant interference on either of the meter technologies.

Ascorbic acid (final specimen concentrations of 0, 5, and 10 mg/dL) was added to donor sodium heparin blood with the glucose level adjusted to 55, 268, and 420 mg/dL, respectively. At low glucose (55 mg/dL), ascorbic acid (5 mg/dL) produced a clinically significant (>10 mg/dL) interference with the SureStepFlexx glucose meter. At higher (268 and 420 mg/dL) glucose levels, ascorbate gave less than 4% interference. Ascorbate had minimal effect on the StatStrip system (<3% at 55 mg/dL glucose and <2% at the higher [glucose]). Maltose (final specimen concentrations of 0, 100,

| Dade RxL<br>Glucose, mg/dL (n = 1) | StatStrip                         |             |             |             | SureStepFlexx<br>Glucose, mg/dL (%CV, where n = 6) |             |             |             |
|------------------------------------|-----------------------------------|-------------|-------------|-------------|--|-------------|-------------|-------------|
|                                    | Glucose, mg/dL (%CV, where n = 6) |             |             |             |  |             |             |             |
|                                    | Lot 1                             | Lot 2       | Lot 3       | Lot 4       | A ccA*   | AccB        | B ccA       | B ccB       |
| 53                                 | 47 (4.26)                         | 50.7 (2.04) | 47.2 (2.82) | 50.7 (2.97) | 42.8 (1.76)  | 42.3 (3.86) | 43.8 (3.03) | 43.8 (3.93) |
| 266                                | 272 (1.18)                        | 274 (0.95)  | 274 (1.47)  | 272 (1.83)  | 237 (2.62)   | 261 (1.9)   | 234 (0.99)  | 256 (1.91)  |
| 436                                | 427 (1.51)                        | 432 (0.8)   | 429 (1.07)  | 429 (1.63)  | 385 (1.49)   | 422 (0.61)  | 374 (1.06)  | 412 (2.27)  |

Three specimens, having different [glucose] as determined by the Dade RxL, were analyzed by 4 lots of StatStrip and 2 lots of SureStepFlexx strips. Each glucose value represents the mean of 6 readings accompanied by its %CV. The same calibration value is applied to each of the 4 StatStrip strips. Each of the 2 SureStepFlexx strips come with its own calibration code. The data for the SureStepFlexx meter includes each strip lot with its accompanying calibration code (eg, lot A with calibration code A). It also includes crossing strip lots with the calibration code (eg, lot A with calibration code B). \*A ccA is lot A with calibration code for lot A; A ccB is lot A with calibration code for lot B, and so on.



| StatStrip<br>mg/dL bias | LifeScan<br>mg/dL bias |  |  |
|-------------------------|------------------------|--|--|
| 0.8                     | 5.3                    |  |  |
| -2.0                    | -3.7                   |  |  |
| -2.8                    | -8.2                   |  |  |
| -0.8                    | -9.3                   |  |  |
| -1.7                    | -4.0                   |  |  |

\*ISO 15197 guidelines @ < 75 mg/dL glucose, bias is reported as mg/dL bias.

| StatStrip<br>mg/dL bias | LifeScan<br>mg/dL bias |  |  |
|-------------------------|------------------------|--|--|
| 7.85                    | -0.5                   |  |  |
| 8.35                    | -5.45                  |  |  |
| 7.11                    | -11.0                  |  |  |
| 5.2                     | -16.9                  |  |  |
| 3.77                    | -18.4                  |  |  |

\*ISO 15197 guidelines @ > 75 mg/dL glucose, bias is reported as mg/dL bias.

| StatStrip<br>mg/dL bias | LifeScan<br>mg/dL bias |
|-------------------------|------------------------|
| -0.43                   | -5.09                  |
| -3.68                   | -10.7                  |
| -4.09                   | -15.9                  |
| -2.68                   | -16.9                  |
| -6.64                   | -21.1                  |

\*ISO 15197 guidelines @ > 75 mg/dL glucose, bias is reported as mg/dL bias.

**FIGURE 1.** Hematocrit effects. Glucose concentration as a function of percent hematocrit is plotted for each of the 2 strip methods. Whole blood specimens with the 3 given [glucose] (as measured by the reference Dade RxL method) were manipulated to have 5 different hematocrit values. These specimens were tested for [glucose] by the 2 strip methods in replicates of 6 and then centrifuged to obtain plasma reference method analysis. A mean value (n = 6 replicates) for both strip methods and the reference method at 3 glucose levels (A–C) were determined at various hematocrit percentages. These glucose values are plotted against the measured hematocrit values.

| TABLE 4. Influence of Meter Total Error on Insu | in Dosina <sup>13</sup> |
|---|-------------------------|
|---|-------------------------|

| % Bias From the  | % Withir  | 1 % Bias Range | Insulin<br>Dosing Errors*         |  |
|------------------|-----------|----------------|-----------------------------------|--|
| Reference Method | StatStrip | SureStepFlexx  |                                   |  |
| <5%              | 70.5      | 36.5           | ~8%-23%                           |  |
| 5%-9.9%          | 19.5      | 41.5           | ~16%-45%                          |  |
| 10%-14.9%        | 7.5       | 16.5           | >5% 2-step errors                 |  |
| 15%-19.9%        | 2.0       | 5.0            | Larger and more                   |  |
| 20%-24.9%        | 0.5       | 0.5            | frequent insulin<br>dosing errors |  |

Frequently, insulin dosing is based on glucose POCT measurements. Patients with higher concentrations of glucose will likely receive more insulin. As reported,<sup>13</sup> meter accuracy and imprecision have a profound impact on the accuracy of insulin dosing. This table looks at the errors between the StatStrip and SureStepFlexx meters compared with the reference Dade RxL plasma procedure, noting the frequency and potential magnitude of insulin dosing errors that might occur.

and 200 mg/dL) was added to donor sodium heparin blood with glucose adjusted to 58, 297, and 375 mg/dL, respectively. Maltose had virtually no effect on either meter (<3% at each glucose concentration).

Glucose values measured on the SureStepFlexx were affected by variances in hematocrit, but the StatStrip was not affected (Fig. 1: hematocrit effect). In these experiments, hematocrit was adjusted to between 23% and 65% at glucose levels of 56, 242, and 426 mg/dL, respectively. At low glucose values (56 mg/dL), mean glucose difference (meter glucose minus reference glucose) changed by greater than 14 mg/dL between the lowest and highest hematocrit values tested on SureStepFlexx meter but less than 4 mg/dL for the StatStrip meter. At higher glucose levels (242 and 426 mg/dL), the SureStepFlexx meter demonstrated greater than 15% change in the mean glucose percent difference ([ $100 \times$  meter glucose reference glucose]/reference glucose) between the lowest and highest hematocrit values, whereas the StatStrip had less than 7% change. No significant difference due to varying hematocrit were observed with the StatStrip. The change in glucose values with increasing hematocrit was highly significant (P < 0.001) at each of the 3 glucose levels for the SureStepFlexx.

#### **Correlation With Reference Method**

Correlation between glucose meter results and the plasma hexokinase reference method was performed by analyzing 150 freshly discarded lithium heparin venous whole blood specimens. An additional 50 blood specimens, some of which were allowed to sit for a period of time to reduce their glucose level were spiked with exogenous glucose mixed and analyzed by comparison with the reference method. The mean plasma reference glucose value was 139.1 mg/dL for the entire sample set (n = 200), and the range of glucose values covered was 19 to 566 mg/dL. Linear regression analysis demonstrated a slope of 1.015, an intercept of -1.412mg/dL glucose, and a correlation coefficient of 0.996 for the StatStrip and a slope of 0.889, an intercept of 8.865 mg/dL glucose, and a correlation coefficient of 0.989 for the SureStepFlexx. Mean bias from the reference method (meter value minus reference value) was 0.6 mg/dL for the StatStrip and 6.5 mg/dL for the SureStepFlexx.

# Relating Error in Glucose Values to Errors in Insulin Dosage

The work of Boyd and Bruns,<sup>13</sup> using simulation modeling to predict errors in insulin dosing as a consequence of total error (imprecision and bias) in glucose analyses, led to the development of data shown in Table 4. Bolus insulin (augmenting basal and possibly parandial insulin) is frequently administered, depending on the measured glucose concentration. For example, 2 additional units of insulin might be used for every 50 mg/dL increment in the glucose concentration increase. Should a glucose value be in error by more than 50 mg/dL, the chances for having a 2-step insulin dosing error (eg, going from 6 to 2 units instead of 4 units of insulin) increases. Percent bias (as a measure of total error) was determined between the StatStrip and SureStep-Flexx values relative to the reference Dade RxL method for the 200 specimens in the correlation study above. The StatStrip total error is considerably less than that of the SureStepFlexx and, as a consequence, should reduce insulin dosing errors.

#### DISCUSSION

The strip dosing study was performed because of comments from the nurses who expressed concern about variable blood volumes affecting the glucose results on the SureStepFlexx. The 2 meters accept blood specimens quite differently. A blood specimen is deposited onto the SureStep-Flexx strip surface but is wicked by capillary action into the StatStrip and metered by the capillary channel. Although SureStepFlexx claims to accept specimen volumes ranging from 5 to 30  $\mu$ L, we were unable to get consistent readings at the 5- $\mu$ L specimen volume. Although the 50- $\mu$ L volume is beyond the claim of the SureStepFlexx, the possibility for specimens of this size being administered by finger sticks in a busy critical care area (intensive care unit, neonatal intensive care unit, operating room, and emergency department) made it important to check the larger volume. Table 1 demonstrates that the SureStepFlexx gave different glucose results at the 50 µL specimen volume. The StatStrip, which claims to use only a 1.2-µL specimen, was unaffected by larger specimen volumes. The capillary channel of the StatStrip does not allow a larger specimen volume to reach the sensing area, thereby eliminating variability in glucose results reported.

The 2 glucose meter technologies tested demonstrated within-run precision %CV of less than 5% at the low glucose concentration tested (39-47 mg/dL) and less than 3% at the higher glucose levels (215-265 and 370-470 mg/dL).

The accuracy of blood glucose meters was evaluated in a clinical study that compared certain properly and improperly coded (calibrated) meters. Although modern blood glucose monitors are beginning to approach the recommended clinical performance criteria, it is clear from this study that the potential still exists with some devices for discrepancies in results (+30% or more), particularly when meters are inadvertently miscoded.<sup>14</sup> The StatStrip, which requires no calibration or coding, showed minimal variation in glucose results among 4 different strip lots at each level of glucose tested. At the lowest glucose level studied, the SureStepFlexx

did not demonstrate variability based on calibration coding, but at higher glucose (266 and 436 mg/dL, respectively), improper calibration significantly increased the variability of glucose results obtained on the SureStepFlexx.

The extent to which the glucose meters correlated with a plasma hexokinase reference method differed between meters, as has been observed previously.<sup>10</sup> The StatStrip meter technology demonstrated the closest correlation with the hexokinase plasma glucose based on assessment of the slope (1.015, StatStrip; 0.889, SureStepFlexx) and intercept (-1.412 mg/dL, StatStrip; 8.865 SureStepFlexx) calculated by linear regression from the 200 specimens. The average glucose values determined for the 200 specimens by the 2 methods also differed from the reference method, with the StatStrip being 0.6 mg/dL high and the SureStepFlexx being 6.5 mg/dL low. This is of interest, considering that the StatStrip does not require calibration.

Acetaminophen, at levels up to 5 to 10 times the therapeutic level, did not significantly impact the glucose meters. This differs from 1 previous report on acetaminophen effects.<sup>6</sup> That study used higher concentrations of acetaminophen and was performed on a previous generation of glucose meters.

Ascorbic acid has been reported to interfere with all glucose meter technologies that have been tested.<sup>6</sup> We found that ascorbic acid interfered with the SureStepFlexx at a low glucose level (55 mg/dL), reducing the glucose values by greater than 10 mg/dL at 5 mg/dL ascorbate and greater than 20 mg/dL at 10 mg/dL ascorbate. At higher glucose levels (268 and 420 mg/dL), ascorbate gave less than 4% interference. Ascorbate had minimal effect on the StatStrip system (<3% at each of the glucose levels tested). Maltose interference has been reported with glucose dehydrogenase technologies<sup>15</sup> and was not found in either of the technologies tested.

Hematocrit effect on glucose meter accuracy (correlation with hexokinase plasma values) was examined by manipulating a sodium heparin blood pool to obtain hematocrit values between 23% and 65% and glucose levels between 56 and 426 mg/dL. The SureStepFlexx gave a glucose range of greater than 14 mg/dL at a glucose level of 53 mg/dL as hematocrit changed from 23% to 65%; the StatStrip, less than 4 mg/dL over this hematocrit range. SureStepFlexx also gave a range of glucose values greater than 15% at the higher glucose levels (242 and 426 mg/dL) with varying hematocrit, whereas the StatStrip was less than 7%.

#### CONCLUSIONS

We evaluated glucose meter correlation with a reference hexokinase method and analytical interferences likely to be observed in hospitalized patients on 2 currently available glucose meter technologies. As reported by Dungan et al,<sup>5</sup> correlation of whole blood glucose to a plasma hexokinase reference method continues to vary between glucose meter manufacturers. The StatStrip glucose meter, however, correlated best with the plasma hexokinase reference method over a wide range of glucose values and was least affected by hematocrit and other interfering substances. The StatStrip did not require calibration nor was it affected by specimen strip dosing. This new meter technology may improve the accuracy and precision of POCT glucose monitoring and may aid in achieving glycemic control in hospitalized patients.

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