Comparison of 3 Models for Assessing Insulin Dosing Error when a Blood Glucose Monitoring System is used in Various Patient Populations

Jeffrey A DuBois[1], Martha E Lyon[2], Andrew W Lyon[2], Robbert J Slingerland[3], Marion Fokkert[3], Alain Roman[4], Nam Tran[5], William Clarke[6], David Sartori[6]

[1] Medical and Scientific Affairs, Nova Biomedical, Waltham, MA; [2]Department of Pathology and Laboratory Medicine, Saskatoon Health Region, Saskatoon, Saskatchewan, Canada; [3]Department of Pathology and Laboratory Medicine, ISALA Clinics, Zwolle, Netherlands; [4]Department of Surgical Intensive Care, St. Pierre University Hôpital, Brussels, Belgium; [5]Department of Pathology and Laboratory Medicine & Burn ICU, UC Davis Medical Center, Sacramento, CA; [6]Department of Pathology and Laboratory Medicine, Johns Hopkins Medical Center, Baltimore, MD

Objectives: This 5 hospital multi-center study conducted under stringent IRB protocols and approval was conducted to assess the risk of using a whole blood glucose monitoring system in various patient populations in acute and critical hospitals and to determine if the BGMS was acceptable for use in these patients. 158 patient conditions were represented in this multi-centered study in whom 25 parent drug classes were administered (representing >7,000 different formulations). This data and the BGMS glucose test results from arterial and venous whole blood specimens were compared to IDMS aligned plasma (arterial and venous samples) hexokinase lab reference method. The models presented include Parkes Error Grid[1], Karon et al Model[2], and a Sensitivity & Specificity Analysis glucose results in the range <10 to >559 mg/dL. BGMS guidelines published last year address analytical perfromance but do not address clinical perfromance and patient safety[3,4]. Our goal was to assess the total analytical error of the BGMS when compared to the lab reference method and stratify insulin dosing risk when using a BGMS.

Methods: Arterial and venous whole blood specimens were analyzed in duplicate for glucose on the StatStrip (Nova Biomedical, Waltham, MA) were compared plasma glucose results measured within 15 minutes (derived from the whole blood specimens) on a central lab reference lab analyzer (2 Isala hospitals, Johns Hopkins, and St. Pierre plasma hexokinase IDMS aligned on Cobas, Roche Diagnostics, Rotkreutz, Switzerland and at UC Davis Medical Center, glucose oxidase on the Synchron LX20, Beckman Instruments, Brea, CA). The glucose results were then compared using the 3 models describe above. There were a total of 1815 paired patient glucose results from 1695 patients.

Results: The summary data from each the 3 risk assessment tools will be presented. Data from each model is slightly different but represent acceptable methods for assessing insulin dosing errors based on the accuracy and imprecision of the BGMS. This study did not assess the risk of the reference nor was the total error of the reference methods determined. 99.3 % of the data met the Parkes error criteria for accuracy and imprecision. Based on the Karon et al model 99% of the data were in the 10-15% Total Error lower risk insulin categories 1 and 2. <1% of the results were in higher risk insulin dosing Category 3. Sensitivity and Specificity as a rough estimate of total analytical error across the glycemic control range were in 95-99% range respectively.

Conclusion: BGMS perfromance (total error) in specific acutely ill patient populations can be assessed based on these models. Insulin dosing error risk assessment and stratification with a BGMS is possible and the use of these models demonstrates that StatStrip is an acceptable BGMS for use in these settings.

References:

1. Pfützner, A. et al. (2013). Technical aspects of the Parkes error grid. *J Diab Sci Tech, 7*(5), 1275-81.

2. Brad S. Karon et al (2013) Empiric Validation of Simulation Models for Estimating Glucose Meter Performance Criteria for Moderate Levels of Glycemic Control, Diabetes Technology & Therapeutics. December 2013, 15(12): 996-1003.

3. Clinical and Laboratory Standards Institute. (2013). CLSI POCT12-A3 Point-of-care blood glucose testing in acute and chronic care facilities; Approved Guideline, (3rd ed.).

Poster 51

4. International Organization for Standardization. (2013). In vitro diagnostic test systems -- Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.