P-0867 – User performance evaluation of 5 SMBG systems based on ISO 15197 and calculation of insulin dosing error

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Background

The International Organization for Standardization (ISO) 15197:2013 requires a user performance evaluation to show if intended lay-users are able to obtain accurate measurement results with a given system. According to ISO 15197:2013, system accuracy in the hand of lay-users is acceptable if at least 95% of results measured with the self-monitoring of blood glucose (SMBG) system are within ±15 mg/dl of comparison measurement results at blood glucose (BG) concentrations <100 mg/dl and within ±15% at BG concentrations ≥100 mg/dl.

Aims

Accuracy was assessed for five SMBG systems with one test strip lot each when used by lay-persons and when used by trained personnel based on testing procedures and acceptance criteria of ISO 15197:2013, clause 8. In addition, insulin dosing error was modeled.

Methods

The evaluation was performed with Accu-Chek® Aviva Connect (A; Roche Diabetes Care GmbH), Contour® Next One (B; Ascensia Diabetes Care Holdings AG), FreeStyle Freedom Lite (C; Abbott Diabetes Care Ltd.), GlucoMen® areo (D; A. Menarini Diagnostics S.r.l.), OneTouch® Verio® (E; LifeScan Europe).

For each system, data from 100 subjects were included. Before the measurement procedure, subjects had the opportunity to familiarize themselves with the system (designated training meter) and perform a limited number of training measurements with control solution. Then, subjects collected a capillary blood sample from the fingertip and performed an SMBG measurement. Subjects were allowed to repeat the measurement up to three times if they reported measurement mistakes or an error message occurred. Then, study personnel performed two additional SMBG measurements, and comparison measurements. Accuracy was evaluated by comparing the SMBG measurement result with the respective mean result of the comparison measurements (glucose oxidase (GOD) or hexokinase (HK), depending on the manufacturer's labeling) (Table 1). Surveillance error grid (SEG) analysis was performed to assess the clinical risk associated with SMBG system inaccuracy. Insulin dosing errors were estimated by calculating the difference between insulin doses based on SMBG measurement results and comparison measurement results (GOD method). For the calculation of insulin doses, a simple model with fixed therapeutic parameters was used that is similar to the calculations performed by automated bolus advisors, e.g., in some insulin pumps (insulin-to-carb ratio: 1/15 units/grams, insulin sensitivity: 1/25 units/(mg/dl), target BG: 100 mg/dl, carb content: 60g).

Results

Four systems showed acceptable accuracy with at least 95% of results within the defined limits (±15 mg/dl, ±15%) (Table 1). In the SEG, all system showed measurements within the "no risk" or "slight risk" zone (Table 1, Figure 1). Frequently observed lay-user errors were not checking the test strip's expiry date, incorrect or premature blood application and mistakes in device handling. The systems showed the following median modeled insulin dosing errors: A: -0.4/-0.2 units (lay-users/study personnel); B: -0.3/-0.1 units; C: -0.8/-0.7 units; D: +0.4/+0.1 units; E: +0.6/+0.8 units (Figure 2). All 99% ranges were found between dosing errors of -2.7 and +3.4 units (lay-users) and -2.7 and +2.2 units (study personnel).

Discussion

Accuracy acceptance criteria of ISO 15197:2013, clause 8 were fulfilled by four systems with the tested reagent system lot, with one system showing 100% of results within the defined limits in the hands of both, lay users and professionals. The systems showed differences in calculated median insulin dosing errors; none of the systems showed insulin dosing errors larger than ±0.8 units. The calculated dosing error tended to be larger when measurements were performed by lay-users (Figure 2).

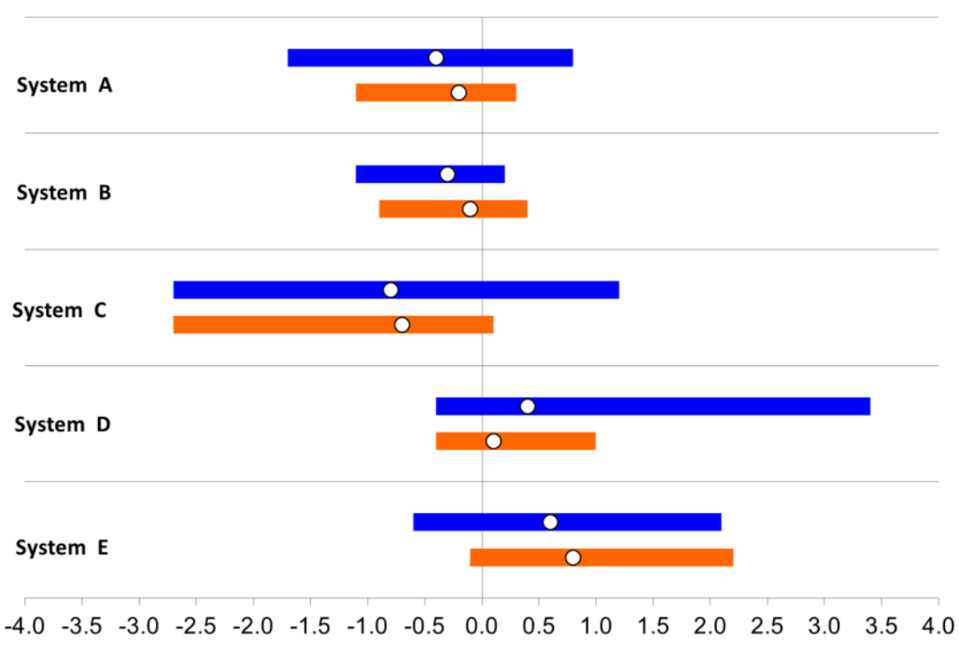

Figure 2: Modelled insulin dosing errors. Bars in blue (lay-users) and red (study personnel) indicate ranges in which 99% of all dose errors were found. The white circle shows the median dose error.

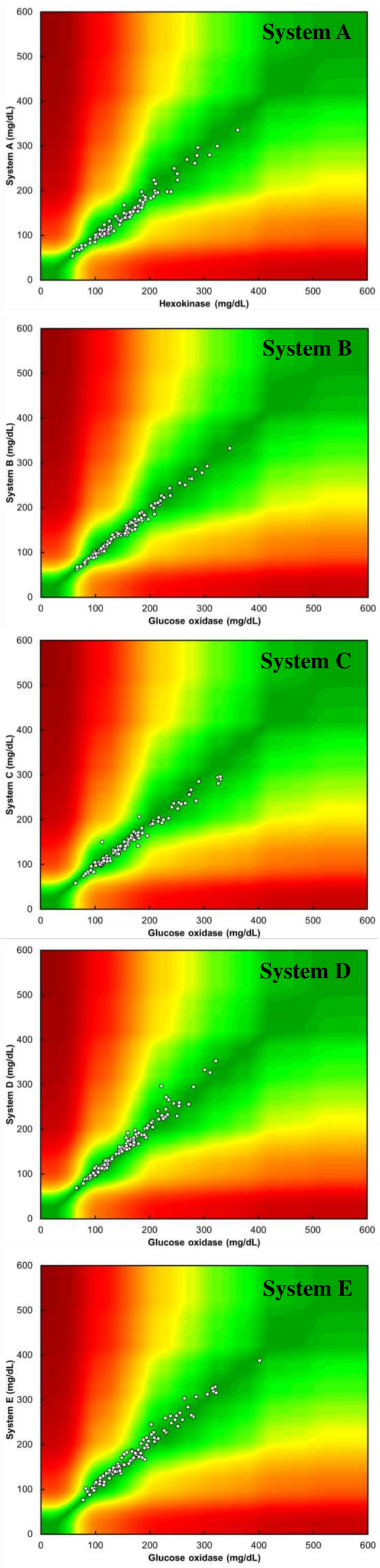

Figure 1: SEG analysis. Data are shown for lay-user measurements (n=100) by using the manufacturer's comparison method.

System			System accuracy analysis	Surveillance error grid analysis	
			ISO 15197:2013	No risk (dark green)	Slight, lower risk (light green)
			Within ±15 mg/dl / ±15%	Within risk scores	
			[%]	0 - 0.5	>0.5 - 1.0
A	HK	Lay-user	**96**	98	2
		Study personnel	**100**	198	2
B	GOD	Lay-user	**100**	99	1
		Study personnel	**100**	198	2
C	GOD	Lay-user	**95**	100	0
		Study personnel	**99.5**	200	0
D	GOD	Lay-user	**95**	98	2
		Study personnel	**100**	199	1
E	GOD	Lay-user	**93**	98	2
		Study personnel	**88.5**	191	9

Table 1: Accuracy results applying ISO 15197:2013 criteria and SEG analysis for lay-users (n=100) and study personnel (n=200) by using the manufacturer's comparison method.

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