Validating a new Classification Method for SMBG Logging Habits in Real World Data

Richard Biven, MSc[a]; Jan Wrede, MSc[a]; Rafael Bankosegger, BSc[a]; Johanna Kober, PhD[a]; Bettina Petersen, PhD[b]; Christian Ringemann, PhD[b]; Tony Huschto, PhD[b]

Objective

Assessing diabetes therapy performance from Real World Data (RWD) is difficult as the data quantity of self-monitoring blood glucose (SMBG) measurements shows strong variability[1]. In a previous publication, we proposed a new method to describe data quantity and quality per patient[2]. We assign users to a Glucose-classification (G-classification), whereby, the indices describe the minimum amount of glucose measurements (k) that are required for at least *n* days within *N* days of observation:

$$G^{k}_{n/N} \Leftrightarrow \text{n out of N days:}|\text{SMBG}| \geq k$$

Using this classification ensures data quality so patients with skewed SMBG values or highly motivated users are not overrepresented. The classification separates users by logging habits, e.g. $G^{1}_{14/30} \cong 1$ *glucose measurement a day for 14 days per month.*
Previous studies using SMBG based metrics often lack predictive performance assessment with respect to SMBG frequency[3,4,5] with ADRR being an exception (3 SMBG / 14 days)[6]. The aim of this study is to determine the correlation between G-classification and the accuracy of SMBG based glucose metrics when compared to CGM data.

Methods

We analysed 299 users of a data set with both CGM and SMBG logs. The inclusion criteria was 70% CGM logs for 1 month with associated SMBG logs. Each user was classified into the respective G-classification based on their respective SMBG data. The distribution was biased to the G4-G5 classifications.

***Table 1** shows the distribution of users in the data sets for five G-classifications.*

	Mean SMBG count	Mean CGM count	User count
G			
G1	32.8	7331.3	13
G2	63.0	7458.0	24
G3	93.1	7571.8	72
G4	118.7	7658.2	92
G5	169.4	7707.3	98

Therefore, users in higher G-classifications were randomly selected and had logs randomly removed to create lower G-classification users, providing an equal distribution.
The percent errors of the users' Mean BG, standard deviation (SD), and tests-in-range (TIR) between the SMBG and CGM logs were analysed. With random sampling the analysis was repeated and Mean results were used, as shown in **Figure 1.**

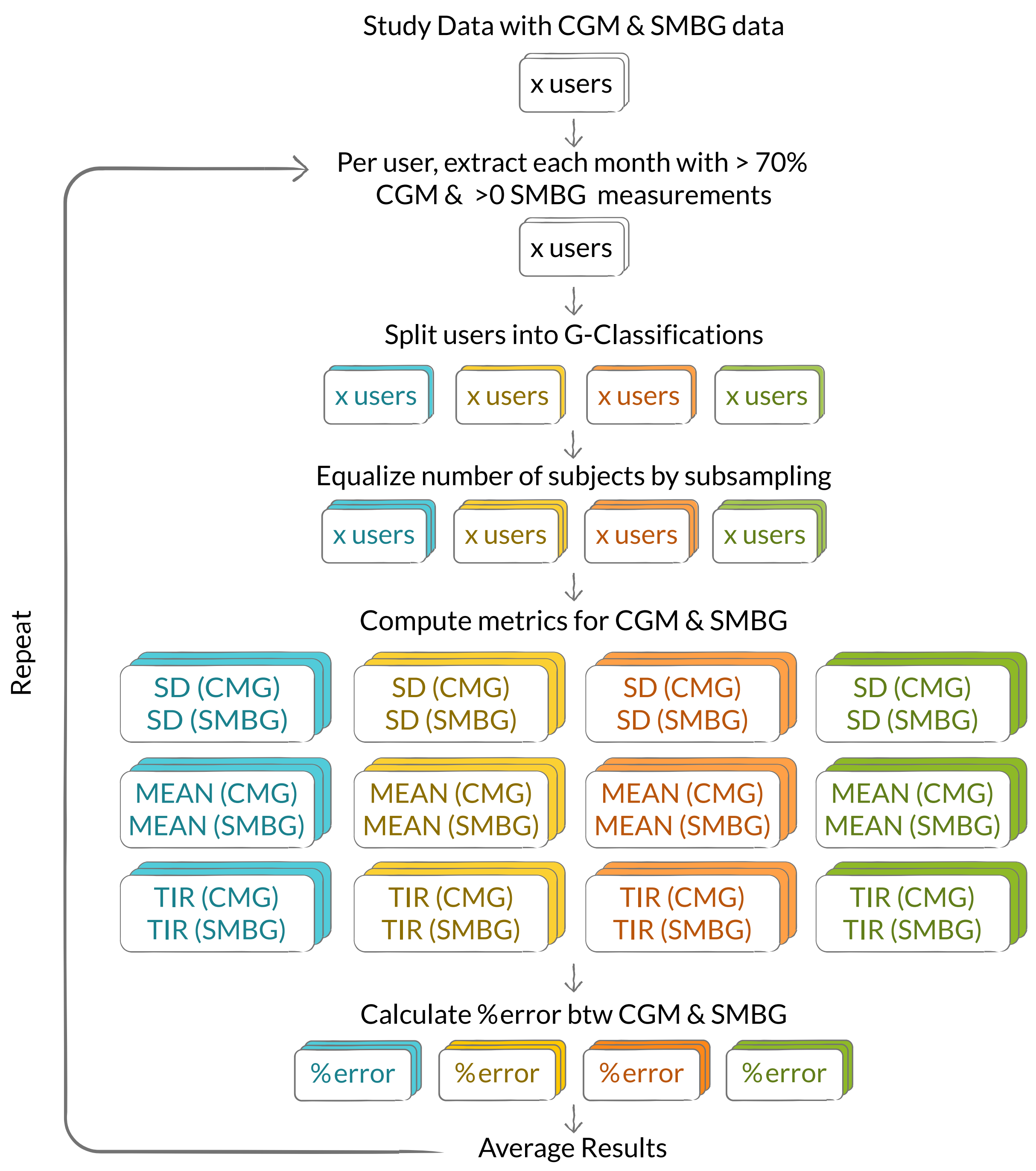

***Figure 1** shows the study approach to equalize the number of subjects in each classification with subsampling.*

Results

Results show G1 users with the largest error in all metrics tested (Mean Error: BG = 7.5%, SD = 14.9%, TIR = 17.6%)[F1]. The error did not substantially decrease as the logs increased (correlating to higher G-classifications), as shown in **Figure 2**. These results show a correlation that metric accuracy might not indicate improvement with increased logging.

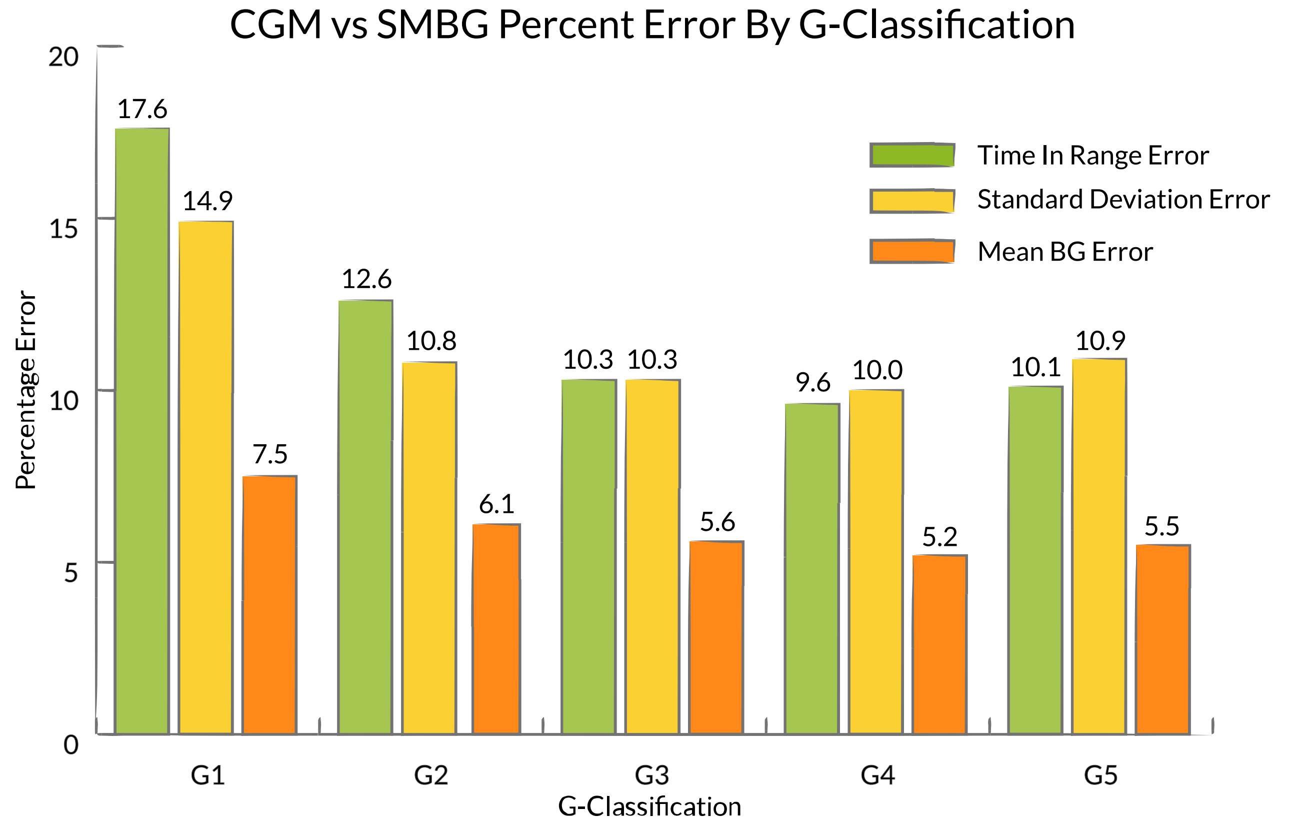

***Figure 2** shows the percentage error between SMBG and CGM per G-classification.*

Conclusion

We analyzed the accuracy of SMBG based metrics for users with different logging habits categorized into G-classifications. We used CGM data as baseline and found that accuracy of glucose standard deviation improves significantly between the G1 and G2 groups. The data from users in the higher G-classifications did not allow significant accuracy improvements. The findings indicate that requiring more than 2 measurements on 14 days per month might not be beneficial to estimate Mean BG or SD. Due to the random sampling, further metric and statistical analyses with more users of all G-classifications would validate the results. We analyzed relative error and more analyses on absolute error could provide further insights.

a. mySugr GmbH, Vienna, Austria
b. Roche Diabetes Care GmbH, Mannheim, Germany
contact: Richard Biven, Data Scientist (richard.biven@mysugr.com)

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Footnote:
[F1] Shown results from analysis on 03.09.2020. The results will change slightly every time they are run due to the random selection of logs, as stated in the Method section.