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Research Article

ASSESSING THE QUALITY OF BLOOD GLUCOSE SELF-MONITORING IN COMMUNITY PHARMACIES

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ABSTRACT

This study evaluated diabetes patients' self-monitoring of blood glucose using a quality assurance process at a community pharmacy, investigated whether the quality of self-monitoring of blood glucose improved after the procedure was implemented, and examined the patient opinions. The results of patient blood glucose measurements were compared to the results obtained with HemoCue Glucose 201 by pharmacy employees in 16 community pharmacies. A checklist of eight items was used to monitor patient performance. When blood glucose measurements differed by more than 20% from pharmacy measurements, the patient was instructed about using the glucometer correctly. A second measurement of blood glucose was then taken by the patients. Glucometer strips and a new glucometer were substituted if the results were still out of the set limits after the control procedure. Upon returning three months later, the patients had a follow-up visit. The first visit found that 5% of the 169 patients had measurements deviating by more than 20% from pharmacy blood glucose values, and 50% of patients were experiencing use errors. On the second visit, there was no significant difference in patient measurements' analytical quality, but there was a decrease in patient errors to 29 percent (p 0.001). In 81% of the cases, patients adjusted medication, exercise, or meals based on blood glucose results. 51% of the patients said their measurements were more reliable after a second visit. Approximately 80% of patients requested annual assessments of their measurements. In this survey, 83% of patients preferred a pharmacy assessment. The number of errors in self-monitoring blood glucose by patients was significantly reduced by a quality assessment procedure developed by the community pharmacy. The clinical measurements of the patients were of good analytical quality and did not improve further during the study. A selection bias of participating patients might explain the high analytical quality. After reviewing their measurements at the pharmacy, patients reported a higher level of confidence in their blood glucose measurements.

Keywords Self-monitoring, Blood glucose, Quality assessment.

INTRODUCTION

In managing diabetes, self-monitoring of blood glucose is essential [1-5]. Glucometers and strips with high analytical quality [6,7], patient performance of measurements [2], and patient response to the results are critically important to the utility of measurements. SMBG-results from 9-16% of patients dissent by more than 20% from laboratory results, according to studies of measurement quality [8-11]. Patient-used glucometers have lower measurement quality than professional-used ones [11]. Erroneous measurements are often caused by user error [11-13]. Patients may also experience problems with SMBG compliance due to other errors, such as failing to change lancets in their finger prick devices, resulting in more painful measurements and less compliance. [14]. The SMBG measurements of patients should be assessed routinely and are generally recommended, but guidelines do not specify how or by whom these assessments should be made [15]. In order to ensure that the results are accurate, both the instrument and strips need to be checked, as well as the patient's performance. Glucometers differ from blood in their performance with control solution, so solely relying on control solution to ensure accurate results is not sufficient. Few patients use a glucometer to control their sugar levels, but they usually perform this using a single

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glucometer or compare the results of two glucometers [11]. SMBG patient performance has been analyzed in only a few studies [9, 10, 12]. There is no single group of health professionals in Norway dedicated to teaching patients SMBG or evaluating their performance, and neither service is offered on a regular basis.

SMBG equipment is typically obtained by diabetic patients at community pharmacies. It may therefore be feasible to assess meter accuracy and patient performance in the pharmacy. Nevertheless, to enhance quality, every link in the chain must be evaluated periodically and educational feedback must be provided for improving the assessment's quality.

We conducted this study to assess the quality of patients' SMBG measurements (a), to determine if establishing a control procedure and educational feedback can improve the quality and performance of patients' SMBG measurements, and (c) to find out whether patients are satisfied with receiving this service at their community pharmacy.

METHODS

Pharmacy recruitment: To facilitate the planning and execution of the study, one of the three main pharmacy chains collaborated with the study. Choosing pharmacies for participation was up to the pharmacy chain's professional service manager. Our criteria for selecting 9 pharmacies was that they were required to have suitable premises and at least one employee must have taken diabetes Continuing Professional Education courses. As part of the pharmacy study, this employee measured SMBG levels at the pharmacy. A pharmacy whose employee was meant to be responsible for the study left before the study began, so 8 pharmacies were included from 7 cities.

Patients recruited were men and women aged 18 or older who self-monitored blood glucose levels and had type I or type II diabetes. A family member or community nurse was required to assist patients in performing the measurements, but there was no maximum age limit. According to power calculations, each pharmacy must include 13 patients. In order to compile the recruitment list, all customers who purchased SMBG equipment from the pharmacy within the past six months were contacted. Those who met the inclusion criteria in our study were invited to participate.

A signed consent form was requested from patients who were interested in participating in the SMBG assessment. The pharmacy provided suggested times and dates. The next patient on the recruitment list was invited if fewer than 13 patients were recruited. The study coordinator did not receive the names of patients. They were given identification numbers at pharmacies. Social Science Data Services and the National Committees for Research Ethics approved the study.

SMBG and glucometer performance assessment: We modified Kristensen et al's procedure for assessing glucometer and SMBG performance [10], which can be used in general practitioners' offices. Glucometers and strips were brought by patients to the pharmacy. An employee of the pharmacy gathered information about the type of glucometer the patient used before arranging a patient visit, and familiarized themselves with its usage. It is necessary to conduct a structured interview on the patient's first visit to obtain information such as age, education, type of diabetes, medication use, last recalled HbA1c value, and experience with SMBG as well as the patient's use of the glucose results.

Blood glucose measurements were performed as the patients would at home: In the procedure, the patients were instructed to perform their own blood glucose measurements. A checklist consisting of various items was used by the employee for assessing performance (Table 1). Besides instructions from the manufacturers, the checklist included performance items deemed to be best practices, as well as items from the manufacturer's user instructions. The measurement will not be affected if this is not done, but compliance may be affected. In this paper, user errors will be defined as failures to comply with check-list items. The employee advised the patients how to perform the task correctly if the employee observed any user errors. A new sample was taken from a different finger within five minutes after the pharmacist measured the patient. Pharmacy employees use HemoCue Glucose 201+ instruments in general practitioners' offices to measure blood glucose levels. A glucose concentration >4.2 mmol/L (75 mg/dL) or 0.83 mmol/L (15 mg/dL) was considered unacceptable if the pharmacy and patient's results differed more than 20%. When making the measurement, the patient's performance was first examined to determine why the deviation occurred. A second measurement was taken by the employee and the patient. Using a new lot of strips with the patient's glucometer, if the difference was still outside the preset limits, we took fresh measurements. Pharmacies provided new glucose meters of the same brand for patients who were still not within the set limits. Measurement technique was not a concern for patients who made no errors and had analytically acceptable results. In about three months, the pharmacy assessed the patients again and conducted another assessment. As part of this process, the pharmacy blood glucose service was surveyed with patients about their experiences.

Quality-assured glucose method implemented by pharmacy: A separate paper describes the pharmacy's implementation in detail. The main findings will be summarized in this section. Glucose 201+'s reliability makes it a good choice for use in pharmacies. It is used in many GP practices. As part of the pharmacies' control of patient SMBG, the HemoCue Glucose 201+ method could be traced to the standard reference material. In a

four-step quality control system, 1) we estimated the variation between the HemoCue instruments used at each pharmacy, 2) we compared HemoCue results with laboratory glucose test results that were validated with reference material from the standard, 3) we monitored HemoCue's quality internally, and 4) we participated in external quality tests.

Glucose levels at low glucose levels were approximated by 6%, while levels at normal/high glucose levels were approximated by 2%. As far as HemoCue and the laboratory method were concerned, HemoCue performed most of its measurements at approximately 10 mmol/L glucose. There was a satisfactory level of quality control both externally and internally throughout the study.

During a common course day and in pharmacies, all pharmacy staff participated in training sessions. A patient control procedure was completed by pharmacy employees, and the teachers evaluated their skills.

Tested the null hypothesis that the number of patients with unacceptable measurements would be the same on both visits using the McNemar test for paired proportions with alpha set to 0.05 and power set to 0.80. A number of earlier studies predicted that 15% of patients would have unacceptable measurements on their first visit [8-10]. The smallest improvement of interest was to reduce unacceptable measurements from 15% to 8%. If the dropout rate between the first and second visit is 30%, there should be 208 patients recruited by each pharmacy. A response rate of approximately 50% was assumed for each pharmacy, so it was instructed to invite 55 patients. A categorical variable is expressed as a frequency or percent, while a continuous variable is expressed as a median or range (minimum-maximum). Using Pearson chi-square and Fisher's exact tests, we tested whether demographics and background variables affected patient measurements. SPSS 13 was used for all tests except the power estimation, and results were used to adjust diet, exercise, or medication. As shown in Table 3, our study yielded the following results.

Sixty-five percent of the SMBGs had baseline results that were within ten percent of the pharmacies' results. Thirty percent of the patients had measurements that were off by 10 to 20 percent. A difference of more than 0.83 was observed in five percent of the measurements not of acceptable analytical quality, which is equivalent to a deviation of more than 20% from the HemoCue results.

RESULTS

A response rate of 30% was achieved by the 8 pharmacies from the 573 patients invited. Pharmacy response rates varied between 5 and 35 percent. Table 2 summarizes the characteristics of patients. Type 2 diabetes was the most common diabetes type among those evaluated, and insulin was prescribed to all who had it. HbA1c values of 3.6 or lower were reported by half of the patients. It was pharmacy staff recommendations that most often led patients to choose their current glucometer. 3.6 patients in the SMBG self-educated at the pharmacy, and 3.6 patients were taught at the SMBG by the pharmacist. Results from glucose measurements are most commonly used to adjust meals. 40% adjusted their medication based on the results, and 35% adjusted their exercise based on the results (multiple answers were possible).

One user error was observed in at least 78 patients during their initial visit. One patient could have as many as three user errors, with a total of 100 registered errors. User errors are shown in Table 1. Analytical quality was not affected by whether the patient made user errors. The quality of the grade was unacceptable for just six of the 78 patients despite user errors being made by 78 patients. In four out of 76 children who were able to correctly perform the measurements, the results were not acceptable from an analytical perspective . There were 25% of patients who sometimes or often doubted their own measurements (Table 4). In type 1 diabetes, patients had higher levels of confidence in their results than in type 2 diabetes (p=0.035), while insulin use was higher among patients (p=0.018). A Pearson chi-square test showed that neither patient user errors nor measurements of acceptable analytical quality could be predicted by gender, age, education, diabetes type, instrument, frequency of measurements, patients' feelings about their results, how results are used, patient knowledge of HbA1c values, self-reported HbA1c values, or use of drugs. There was a significant decrease in patient errors among patients who stated they were self-taught (p=0.021).

A SMBG assessment led to 15 percent of patients dropping out between the first and second visit, compared to 17 percent of 50 patients (43/124) for the second visit. 124 patients were reduced to 124 because two pharmacies did not fill out the checklist. It was still significant to decrease the number of errors if only 111 patients were included (p 0.001).

T wo patients with analytically unacceptable results were remeasured after receiving training from a pharmacy employee and measuring outside the acceptable limits after the second visit.

The number of patients participating at both visits was adequate because the number of drop-outs was lower than expected despite a lower recruitment than expected. Analytically unacceptable measurements did not decrease during the first visit due to the small percentage of analytically unacceptable measurements. Neither the first nor second visit were significantly different in the percentage of analytically unacceptable measurements. Eight of the ten patients with unacceptable measurements went back for a second

appointment. The results of the second visit were unacceptable in only one of these patients. During the first and second visits, there were fewer errors for each checklist item. In the second visit, users made 25 percent fewer errors than during the first visit. There was one patient who made five errors, which was the exception. Errors ranged from 0 to 2, except for the patient who made 0 errors. There were 32 errors for every 50 patients (100/154) during the first visit, compared to 32 per 50 patients (100/154) during the second visit.

A new lot number enabled only one of the two patients to obtain measurements within limits, while a new strip and new device enabled the other two to do so. At the second visit, five of the nine patients were able to achieve acceptable quality. A new lot of strips yielded acceptable results for four patients and replacing both strips and the device resulted in acceptable results for three patients. One patient's results were still unacceptably low despite having both strips and glucometers replaced. Biomedical laboratory scientists concluded that a patient's high hematocrit value was most likely to explain these results, as it causes deviating blood glucose numbers. [2].

A comparison of patient satisfaction between the first and second visit is shown in Table 3. 81 percent of patients returning for another SMBG assessment were interested in having it conducted annually. As far as the location of the service is concerned, 81 percent of the patients prefer their community pharmacy over the hospital outpatient clinic while 7 percent prefer their doctor's office. In 8% of cases, there was no clear preference. A maximum of 10 Euros was calculated to be suitable for 12 percent of the patients, and a maximum of 25 percent of the patients would be prepared to pay a maximum of 10 Euros for the service. Patients who did not pay for the service made up the remaining 9 %.

Table 1: The following checklist should be used by pharmacists at the start and end of every patient visit to evaluate their SMBG performance

		VISIT 1[A] N=154		VISIT 2 N=124	
		"No"		"No"	
		n	%	n	%
1.	Have the patient's hands been cleaned?	51	33.16[a]	23	18.5[a]
2.	Does the patient's sampling technique seem satisfactory to you?	24	15.58 [a]	6	4.83[a]
3.	Can you verify that the strips are valid (i.e., they are not expired)?	8	5.18	4	2.4
4.	Does the measuring device appear to be clean?	5	1.94	2	1.61
5.	Is the device calibrated by the patient?	5	2.59	1	0.8
6.	Does the device appear to be properly stored?	2	0.064	2	1.61
7.	In what packaging are the strips stored?	3	1.29	3	2.41
8.	Is there enough blood being used by the patient?	2	0.064	2	1.61
	Patient errors in total	100		43	
[a]Significant difference between the first and second visit (McNemars test, $p < 0.001$).					

Table 2: Diabetes type and insulin use characteristics of participants

		Type I	Type II (Insulin used)	Type II (Insulin not used)	Over all
Total number of patients		41	41	84	116
Average age in yrs		61	63	68	64
Sex	MALE	22	22	49	93
Study education	School (Primary)	7	13	26	46
	School of higher secondary	17	20	34	71
	University level	16	7	24	47
Knowledge of HbA_{1c}	Know HbA_{1c} value	37	30	51	118
	Mean self-reported HbA1c	3.8	3.7	3.3	3.6
Mean years performed SMBG		7	5	3	7

Table 3: Patients who participated in the study at their first pharmacy visit used the following glucose meters (Strips used by glucose meters are classified together)

	Visit 1 (n=164)
Accu-chek aviva	14

Accu-chek sensor	29
Accu-chek compact/compact plus	28
Ascensia elite/elite xl	15
Ascensia breeze/dex/dex2	10
Ascensia contour	18
Freestyle/freestyle mini	15
Glucotouch	1
Induo/one touch/one touch ultra/ultra smart	13
Medisense precision qid	2
Medisense precision xceed/xtra	25

Table 4: Confidence of patients to control their blood glucose levels before and after pharmacy controls, n= 164.

		First visit		Second visit	
		N	%	N	%
Is there ever a time when you are not sure if the result on your device is accurate?	Never	75	46	96	58
	Rarely	52	31	32	19
	Sometimes	35	20	15	9
	Quite often	5	2	1	0.06
	Almost every time i measure	1	0.06	2	1.2
	Missing	2	1.2	24	14
Do you feel more or less confident that your device shows the correct results based on the controls at the pharmacy?	More sure			78	47
	No change			67	40
	Less sure			7	4
	Missing			50	30

DISCUSSION

Community pharmacies were used as a site for both analytical quality control and SMBG performance assessment in this study. Moreover, the pharmacies had a solid quality assurance program, which continually ensured pharmaceutical measurements were accurate [22]. This service is able to improve patient outcomes by performing controls in this manner, followed by correcting errors made by the patient or the instrument, resulting in better diabetes management. The results of their SMBG measurements must also be interpreted appropriately by patients. It was reported that 81 percent of patients actively adjusted medication, meals, or exercise based on their measurement results, but we did not investigate if these interventions were effective.

Compared to earlier studies, this study reported significantly higher analytical quality for patient measurements [8-11]. The improvement seen with the original 15 patients may have been a result of regression to the mean rather than our intervention, since seven of the nine patients with unacceptable measurements were replaced at the second visit by nine new patients with unacceptable measurements. Due to the low response rate in our study, the high analytical quality of the patients' SMBG was explained by a selection bias [10]. Non-responders were probably less motivated than participants who were willing to participate in the study. We found that the HbA1c of our study patients was 7.1%, close to the recommended 7% and approximately one point lower than Skeie's study patients, indicating that our patients are relatively well-regulated. [11].

According to the German pharmacy study, the number of patients who had user errors was 83.3%, but higher than the Norwegian GPs' offices study (19%) [20]. As compared to the first visit, our study found a halving of user errors at the second visit, similar to Müller et al. [14]. The number of user errors found in each study depends on the checklist used to detect them, so it is difficult to compare differences in the number of errors. Our checklist was more detailed than that used by Kristensen et al [10], but Müller et al [14] used a more detailed one than ours. As a result of our study, non-washing of hands and poor sampling techniques were the most common errors of the users.

As a result, patients avoided more "serious" errors because they were aware that their performance was being assessed. There was no increase in measurements of poor analytical quality in our study due to user errors; however, some errors may be corrected to improve compliance.[14] In our study population, there were very few unacceptable measurements, so our study was not able to investigate whether specific errors impacted analytical quality.

SMBG training was found to cause fewer user errors than self-taught patients compared to those who had received SMBG training. In comparison to those who received training, self-taught patients may study their glucometer manual more thoroughly. The training in question might have been unsatisfactory, resulting in the

patients receiving it getting less information than the self-taught patients because they were not asked what their education was. In a less motivated patient group, it is not certain that no training would result in the same positive outcome.

It doesn't change the fact that monitoring patients' SMBG measurements should be done despite the low number of analytically unacceptable measurements [4]. The participants in our study preferred that their measurements be assessed at their community pharmacies, and pharmacy employees expressed a strong interest in working in this field more actively [25]. Their spending on glucometer strips alone in 2008 exceeded 40 million Euros. Providing SMBG assessment services in pharmacies might be an effective way to use this money; however, one of the challenges pharmacists face is recruiting patients in greatest need of it. HbA1c values of 7.5 - 8% should be targeted in future studies.

CONCLUSIONS

In 5% of cases, the measured values deviated by more than 20% from those compared. It may have been due to the selected patient sample that the SMBG measurements of diabetes patients were higher quality than previously reported. In 25 percent of the cases, there was an error by the user, however it did not lead to greater measurements that were unacceptable. However, the pharmacy service did not improve the analytical quality of the measurements, but reduced the number of errors and improved confidence among the patients.

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