Quality assessment of patients’ self-monitoring of blood glucose in community pharmacies

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**ABSTRACT**

Objective: To evaluate diabetes patients’ self-monitoring of blood glucose using a community pharmacy-based quality assurance procedure, to investigate whether the procedure improved the quality of the patient performance of self-monitoring of blood glucose, and to examine the opinions of the patients taking part in the study.

Methods: The results of patient blood glucose measurements were compared to the results obtained with HemoCue Glucose 201+ by pharmacy employees in 16 Norwegian community pharmacies. Patient performance was monitored using an eight item checklist. Patients whose blood glucose measurements differed from pharmacy measurements by more than 20% were instructed in the correct use of their glucometer. The patients then re-measured their blood glucose. If the results were still outside the set limits, the control procedure was repeated with a new lot of glucometer strips, and then with a new glucometer. The patients returned for a follow-up visit after three months.

Results: During the first visit, 5% of the 338 patients had measurements that deviated from pharmacy blood glucose values by more than 20% and user errors were observed for 50% of the patients. At the second visit, there was no significant change in the analytical quality of patient measurements, but the percentage of patients who made user errors had decreased to 29% (p < 0.001). Eighty-five percent of the patients who made user errors had measurements that deviated from pharmacy measurements by more than 20% were instructed in the correct use of their glucometer. The patients then re-measured their blood glucose. If the results were still outside the set limits, the control procedure was repeated with a new lot of glucometer strips, and then with a new glucometer. The patients returned for a follow-up visit after three months.

Conclusion: A community pharmacy-based quality assessment procedure of patients’ self-monitoring of blood glucose significantly reduced the number of user errors. The analytical quality of the patients’ measurements was good and did not improve further during the study. The high analytical quality might be explained by a selection bias of participating patients. Patients also reported increased confidence in their blood glucose measurements after their measurements had been assessed at the pharmacy.

**Keywords:** Blood Glucose Self-Monitoring, Quality Assurance, Health Care. Community Pharmacy Services. Norway.

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**EVALUACIÓN DE LA CALIDAD DE LA AUTO-MONITORIZACIÓN DE GLUCOSA SANGUÍNEA DE PACIENTES EN FARMACIA COMUNITARIA**

**RESUMEN**

Objetivo: evaluar la auto-monitorización de la glucemia de pacientes diabéticos que utilizan un procedimiento de aseguramiento de la calidad en farmacia comunitaria, investigar si el procedimiento mejoró la calidad de la ejecución de la monitorización del paciente, y examinar las opiniones de los pacientes que tomaron parte en el estudio.

Métodos: Los resultados de las medidas de glucemia de los pacientes se compararon con los resultados obtenidos con un HemoCue Glucose 201+ por los empleados de la farmacia en 16 farmacias comunitarias noruegas. Se monitorizó la actuación del paciente utilizando un check-list de 8 puntos. Se educó en el uso del glucometro a los pacientes cuyos valores de glucemia diferían en más de un 20% de los medidos en la farmacia. Después los pacientes volvieron a medir su glucemia. Si los resultados estaban aún fuera de los límites se repetía el procedimiento con un nuevo paquete de tiras de glucometro, y después con un nuevo glucometro. Los pacientes volvieron para una visita de seguimiento tres meses después.

Resultados: Durante la primera visita, el 5% de los 338 pacientes tuvieron mediciones malas que se desviaron de las de la farmacia en valores superiores al 20% y se observaron errores en el 50% de los pacientes. En la segunda visita, no hubo cambios significativos en la calidad analítica de las mediciones. Los pacientes tuvieron una visita de seguimiento tres meses después.

**ABSTRACT**

Quality assessment of patients’ self-monitoring of blood glucose in community pharmacies. Pharmacy Practice (Granada) 2010 Jan-Mar;8(1):62-69.
measurements. A study in German pharmacies accounts for a considerable proportion of erroneous used by patients than by professionals. User error Measurement quality is lower when glucometers are laboratory results by more than 20%. Studies of measurement quality report single glucometer or by comparing the results of two usually do so by repeated measurements using a who perform some form of glucometer control are correct. Research shows that the few patients not sufficient to ensure that the glucometer results blood16,17, thus relying solely on control solution is differently with control solution compared to Glucometers have been shown to perform instrument and strips but also patient performance. Because user errors may lead to poor how or by whom these assessments should be carried out. Because user errors may lead to poor results it is important to check not only the instrument and strips but also patient performance. Glucometers have been shown to perform differently with control solution compared to blood, thus relying solely on control solution is not sufficient to ensure that the glucometer results are correct. Research shows that the few patients who perform some form of glucometer control usually do so by repeated measurements using a single glucometer or by comparing the results of two of their own glucometers, but neither of these methods is satisfactory. Few studies have tested quality assured, accessible control services for glometers and patient performance of SMBG. Neither teaching patients SMBG, nor evaluating patient performance is dedicated to one group of health professionals in Norway, and neither service is routinely offered to patients. Diabetes patients visit community pharmacies on a regular basis, and most obtain their SMBG equipment there. Therefore the pharmacy might be well-suited for assessing meter accuracy and patient performance. However, to increase quality the assessment must be incorporated into an established system of quality assurance in which every link in the chain is assessed on a regular basis and educational feedback is provided. The aims of this study were (a) to assess the quality of Norwegian patients’ SMBG measurements, (b) to investigate whether the quality and performance could be improved by establishing a control procedure at the community pharmacy and by giving educational feedback, and (c) to investigate patient opinions on receiving this service from their community pharmacy.

INTRODUCTION

Self-monitoring of blood glucose (SMBG) is considered essential in the management of diabetes. The utility of the measurements depends on the analytical quality of the glucometers and strips, patient performance of measurements, and how the patients respond to the results. Studies of measurement quality report that 9-16% of patient SMBG-results deviate from laboratory results by more than 20%. User error accounts for a considerable proportion of erroneous measurements. A study in German pharmacies found that 83% of patients made at least one SMBG user error. Some user errors, such as not washing hands or using expired strips, may lead to erroneous results. Other errors may impact the patients’ compliance with SMBG, e.g. when patients fail to change lancets in their finger prick devices, leading to more painful measurements and patient reluctance. Regular assessments of patient SMBG measurements are necessary and broadly recommended but guidelines do not specify how or by whom these assessments should be carried out. Because user errors may lead to poor results it is important to check not only the instrument and strips but also patient performance. Glucometers have been shown to perform differently with control solution compared to blood, thus relying solely on control solution is not sufficient to ensure that the glucometer results are correct. Research shows that the few patients who perform some form of glucometer control usually do so by repeated measurements using a single glucometer or by comparing the results of two of their own glucometers, but neither of these methods is satisfactory. Few studies have tested quality assured, accessible control services for...
National Committees for Research Ethics and by the Norwegian Social Science Data Services.

Assessment of glucometers and SMBG performance: To assess glucometers and SMBG performance we used a modified version of the procedure developed by Kristensen et al.10 for use in general practitioners’ (GPs’) offices. Patients brought their glucometers and strips to the pharmacy. When agreeing on a time for the patient visit the pharmacy employee gathered information on the type of glucometer used by the patient, and familiarized themselves with its use before seeing the patient. The first visit started with a structured interview to determine age, education, type of diabetes, medication used, last used Ohmic value, the patient’s experiences with SMBG, and his or her use of the glucose results. The assessment procedure was as follows: The patients were asked to perform their blood glucose measurements as they would perform them at home. The employee assessed the performance according to a checklist consisting of eight items (Table 1). The checklist included items from the manufacturers’ user-instructions expected to directly affect the result of the measurement, as well as performance-items regarded as “good practice”. An example is pricking the side of the finger tip where there are less nerve-endings. Failing to do so will not affect the result of the measurement, but may have a negative effect on compliance.14 For simplicity, failure to comply with any check-list item will in this paper be referred to as “user errors”. If the employee observed any user errors, the patients were made aware of these and shown how to perform the task correctly. Within 5 minutes of the patient measurement, the pharmacy employee took a new sample from a different finger. The Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS) has earlier performed studies that compared the precision of samples taken from a single finger with the precision of samples taken from different fingers, and could not find any difference when all samples were obtained within 5 minutes. Therefore sampling from different fingers has been the standard procedure in all subsequent studies.8,10,11,20 The pharmacy employee measured the patient’s blood glucose using HemoCue Glucose 201+ (HemoCue AB, Ängelholm, Sweden), an instrument commonly used at general practitioners offices. If the difference between the pharmacy and patient’s results exceeded 20% at glucose concentrations equal or over 4.2 mmol/L (75 mg/dL) or 0.83 mmol/L (15 mg/dL) at glucose concentrations <4.2 mmol/L,12 the analytical quality of the measurement was considered unacceptable. The reason for the deviation was sought first in the patient’s performance when making the measurement. The patient and employee then repeated their measurements. If the difference was still outside the preset limits, a fresh set of measurements was taken using a new lot of strips with the patient’s glucometer. If still outside the set limits, the pharmacy provided a new glucometer of the same brand as the patient’s. Patients that did not make user errors or have analytically unacceptable results did not receive any intervention regarding measurement technique.

The patients returned to the pharmacy approximately 3 months after their initial visit and the assessment procedure was repeated. At this stage the patients were interviewed about their experiences with the pharmacy blood glucose service.

Quality control of the new pharmacy service: The implementation of a quality ensured glucose method in the pharmacy is described in detail in a separate paper.22 The main findings will be stated here. The HemoCue Glucose 201+ was chosen for use at the pharmacies as it is a point-of-care instrument of high quality used by the majority of GP offices in Norway. Before and during the pharmacies’ controls of patient SMBG, a quality control system was implemented to ensure traceability of the HemoCue Glucose 201+ method to a laboratory method traceable to the NIST 965 standard reference material. This quality control system consisted of four steps: 1) estimation of the variation between the HemoCue instruments to be used at the 16 pharmacies, 2) comparison of results from HemoCue with the results of a laboratory glucose method (Architect ci8200, Abbott Laboratories, Abbott Park, IL, USA) that was validated using the NIST standard reference material, 3) monitoring the quality of HemoCue by use of internal quality controls and 4) participation in an external quality assessment scheme provided by NOKLUS.

The between-instrument precision of the 16 instruments used by the pharmacies was judged satisfactory with an imprecision of <2% in normal/high level of glucose and approximately 6% in low level. There was no significant bias between HemoCue and the laboratory method at the normal/high level of glucose (approximately 10 mmol/L) where most of the measurement results were found. The results of the external and internal quality controls were satisfactory throughout the study.22

All the pharmacy employees participated in a training program, including both individual work in the pharmacies and a common course day. At the end of the course day, the pharmacy employees carried out the whole patient control-procedure and their performance was assessed by the teachers.22

Statistics: The null hypothesis that the number of patients with unacceptable measurements would be the same on both the first and second visit was tested using the McNemar test for paired proportions, with alpha set to 0.05 (2-tailed) and power to 0.80. Based on earlier studies, the expectation was that approximately 15% of the patients would not achieve acceptable measurements on their first visit.8,10 The authors decided that the smallest improvement of interest was a reduction in the number of unacceptable measurements from 15% to 8%. This calculation provided a proposed sample size of 291 patients. Assuming a dropout rate of 30% between the first and second visit, the participating pharmacies would have to recruit 416 patients, 26 patients per pharmacy. Estimating a response rate of approximately 50%, each pharmacy was instructed to send invitations to 55 patients. Descriptive
RESULTS

The 16 pharmacies recruited 338 patients (9-32 patients per pharmacy) from the 1,146 invited patients, a response rate of 29%. The response rate varied from 8 to 49% between pharmacies. Patient characteristics are reported in Table 2. The majority of patients had type 2 diabetes (75%), and 49% of all patients used insulin. Half of the patients reported their last measured HbA1c value to be 7% or lower. The most frequent reason for the patients’ choice of their current glucometer was a recommendation from pharmacy personnel (45%). Forty-four percent of the patients were self-educated in the SMBG, and 27% were taught at the pharmacy. The most frequently stated use of results from glucose measurements was to adjust meals based on the results (88%). Forty percent used the results to adjust their medication, and 40% used them to adjust their exercise (multiple answers were possible). In total, 85% of the patients actively used mmol/L (15 mg/dL)²¹ (Figure 1).

At the first visit the pharmacy employees observed at least one user error in 156 of the patients (51%) (one pharmacy did not use the checklist, thus n=308). The maximum number of user errors for one patient was three, and in total 200 user errors were registered. Table 1 shows the number of user errors per checklist item. Whether user errors were made by the patient did not predict the analytical quality of the measurements had analytically unacceptable quality for only 12 patients (8%). Five percent of the patients made user errors, this resulted in an unacceptable quality for only 12 patients (8%). Five percent of the patients’ measurements deviated between 10% and 20%. Five percent of measurements were of unacceptable analytical quality, that is to say they deviated by more than 20% from the HemoCue result, or, if the measurements were below 4.2 mmol/L (75 mg/dL), the difference exceeded 0.83 mmol/L (15 mg/dL)²¹ (Figure 1).

Quality of the SMBG at baseline: Sixty-five percent of the patients obtained SMBG results within 10% of the pharmacies’ results. Thirty percent of the patients’ measurements deviated between 10% and 20%. Five percent of measurements were of unacceptable analytical quality, that is to say they deviated by more than 20% from the HemoCue result, or, if the measurements were below 4.2 mmol/L (75 mg/dL), the difference exceeded 0.83 mmol/L (15 mg/dL)²¹ (Figure 1).

Table 1. Checklist to evaluate patients’ SMBG performance at the first and second visit to the pharmacy.

| Item | Visit 1* Total | Visit 2* Total |
|------|---------------|---------------|
|      | No* | % | No* | % |
| 1. Does the patient have clean hands? (Patient did not wash hands or remove the first drop of blood prior to measuring) | 102 | 33 | 47 | 19 |
| 2. Is the patient’s sampling technique satisfactory? (e.g. did the patient prick the side of the finger pad; did they not squeeze out the blood, is the sample applied correctly?) | 49 | 16 | 11 | 4 |
| 3. Are the patient’s strips valid (i.e. not expired)? | 15 | 5 | 8 | 3 |
| 4. Is the measuring device clean? | 10 | 3 | 4 | 2 |
| 5. Has the patient calibrated the device? | 11 | 4 | 1 | 0 |
| 6. Is the device stored properly? | 4 | 1 | 3 | 1 |
| 7. Are the strips stored in their original packaging? | 6 | 2 | 7 | 3 |
| 8. Does the patient use enough blood? | 3 | 1 | 5 | 2 |

Total number of patient errors | 200 | 86 |

* Significant difference between the first and second visit (McNemars test, p < 0.001).

Table 2. Characteristics of participants according to type of diabetes and use of insulin.

| Characteristic | T1D | T2D using insulin | T2D not using insulin | Total |
|---------------|-----|-------------------|-----------------------|-------|
| Total number of patients (%) | 82 (25) | 81 (24) | 169 (51) | 332 |
| Mean age in years (95% CI) | 52 (48-55) | 66 (63-68) | 67 (65-68) | 63 |
| Gender, n (%) | Male | 44 (54) | 44 (55) | 98 (58) |
| | Female | 38 (46) | 37 (45) | 75 (42) |
| Education, n (%) | Primary school | 15 (19) | 25 (31) | 40 (24) |
| | High school | 34 (42) | 41 (51) | 75 (45) |
| | University | 32 (40) | 14 (18) | 46 (28) |
| Knowledge of HbA1c | Know HbA1c value (%) | 73 (89) | 61 (75) | 134 (78) |
| | Mean self-reported HbA1c % (95%CI) | 7.5 (7.3-7.8) | 7.5 (7.2-7.7) | 7.5 (7.2-7.7) |
| | Mean years performed SMBG (95% CI) | 15 (13-16) | 10 (9-12) | 5 (4-6) |

T1D, Type 1 diabetes; T2D, Type 2 diabetes. Six patients did not report type of diabetes and have been excluded from this table. Years and percents have been rounded to the nearest whole number. Where numbers do not add up to 100, this is due to missing data and/or rounding.
using insulin were more confident than those who do not (p=0.016). Pearson chi-square tests showed that gender, age, education, type of diabetes, type of instrument, measurement frequency, whether patients feel unsure of their results, how results are employed, patient knowledge of the HbA1c value, self-reported HbA1c value, and the use of drugs could predict neither measurements of acceptable analytical quality nor patient user errors. Patients stating that they were self-taught made significantly fewer patient user errors (p=0.026). Effects of the SMBG assessment: Between the first and second visit, 31 patients (9%) dropped out of to 35 per 100 patients (86/249) for the second visit. Because four of the pharmacies did not fill out the checklist at the second visit, the number of patients was reduced to 249. The decrease in errors was still significant if only the 222 patients for whom the checklist was used at both visits were included (p < 0.001).

Follow-up of patients with unacceptable results: Of the 17 patients with analytically unacceptable measurements at the first visit, four measured outside the acceptable limits after receiving training from the pharmacy employee and measuring again.

| Table 3. Glucometers used by the participating patients and number of patients using each meter at the first visit to the pharmacy (glucometers are grouped by the type of strip they use). |
|-----------------|----------------|----------------|
| Visit 1 (n=338) |               |               |
| Accu-Chek Aviva | 28             |               |
| Accu-Chek Sensor | 58             |               |
| Accu-Chek Compact/Compact Plus | 56 |               |
| Ascensia Elite/Elite XL | 31 |               |
| Ascensia Breeze/Dex/Dex2 | 20 |               |
| Ascensia Contour | 35             |               |
| FreeStyle/FreeStyle Mini | 30 |               |
| GlucoTouch | 2              |               |
| InDuo/One Touch/One Touch Ultra/Ultra Smart | 27 |               |
| MediSense Precision QID | 1             |               |
| MediSense Precision Xceed/Xtra | 50 |               |

Table 4. Patient confidence in their self-monitoring of blood glucose measurements before and after the pharmacy controls, N= 338.

| Are you ever unsure that your device shows the correct result? | First visit | Second visit |
|---------------------------------------------------------------|-------------|--------------|
| Never                                                         | 150         | 193          |
| Rarely                                                        | 104         | 63           |
| Sometimes                                                     | 70          | 30           |
| Quite often                                                   | 11          | 2            |
| Almost every time I measure                                   | 2           | 1            |
| Missing                                                       | 1           | 49           |

| Following the controls at the pharmacy, are you more or less sure that your device shows the correct result? | First visit | Second visit |
|-----------------------------------------------------------------------------------------------------------|-------------|--------------|
| More sure                                                    | 157         | 51           |
| No change                                                    | 135         | 44           |
| Less sure                                                    | 14          | 5            |
| Missing                                                      | 49          |              |

the study, leaving 307 patients who completed both visits. Because the number of drop-outs was lower than we anticipated, the number of patients participating at both visits was sufficient according to our power calculation despite a lower recruitment than initially planned. However, because the percentage of analytically unacceptable measurements during the first visit was only 5%, a decrease in analytically unacceptable measurements could not be expected. There was no significant change in the percentage of analytically unacceptable measurements from the first (17%; 5%) to the second (19%; 6%) visit (Figure 1). All 17 patients with unacceptable measurements at their first visit returned for a second visit. Only two of these patients had unacceptable results at the second visit. Table 1 presents the number of errors per checklist item during the first and second visit. During the second visit, the percentage of patients who made user errors had decreased from 51 to 29%. The number of errors per patient varied from 0 to 2, with the exception of one patient who made 5 errors. The total number of user errors decreased from 65 per 100 patients (200/308) for the first visit Two of the four patients obtained measurements within the limits when using strips with a new lot number, whereas the two remaining patients measured within the limits after receiving new strips and a new device. At the second visit, 11 of the 19 patients achieved acceptable quality with their second measurement. Of the remaining eight patients, four achieved acceptable results when using a new lot of strips and three when replacing both the strips and the device. Despite replacing both the strips and the glucometer, one patient still did not achieve acceptable results. A patient follow-up with a biomedical laboratory scientist concluded that the most likely explanation for these results was the patient’s high hematocrit value, which is known to cause deviating blood glucose results.2

Patient satisfaction: Table 3 presents how the patients’ trust in their measurements improved from the first to the second visit. A total of 80% of the patients returning for a second visit wished to have the SMBG assessments performed yearly. Of these patients, 83% preferred their community pharmacy as the site for the service, 5% preferred the hospital outpatient clinic, and 2% the GP’s office. The

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remaining 10% of patients had no clear preferences. Thirty-two percent of the patients were prepared to pay up to 20 Euros for the service, and 50% were prepared to pay a maximum of 7.5 Euros. The remaining 18% of patients were not willing to pay for the service.

is possible that the improvement seen with the original 15 patients was a result of regression to the mean rather than our intervention. The high analytical quality of the patients’ SMBG in our study might be explained by a selection bias since the response rate was only 29%, whereas other studies have considerably higher response rates. Patients willing to participating in the study were probably more motivated than the non-responders. The patients in our study had a self-reported mean HbA1c of 7.1%, close to the recommended 7% and approximately 1 percentage point lower than the HbA1c of the patients in Skeie’s study, supporting the notion that the patients in our study are comparatively well regulated. Another factor may be that, following Skeie’s study in 2002, the Norwegian National Social Insurance Office required all manufacturers to have glucometers tested by patients. This requirement may have led to greater user-friendliness and more robust instruments.

The percentage of patients with user errors (51%) was lower than that reported in the German pharmacy study (83%) but higher than in the Norwegian GPs’ offices study (19%). The number of user errors in our study was halved at the second visit compared to the first, a finding similar to that of Müller et al. It is difficult, however, to compare differences in the number of user errors between studies because the number of errors detected depends on the checklist used to uncover them. Müller et al. employed a highly detailed checklist compared to ours, which again was more detailed than the one used by Kristensen et al. In our study the most common user errors were not washing hands before measuring and poor sampling technique. It is possible that the fact that patients were aware that they were being assessed may have altered their performance, thus they avoided more “serious” user errors. The user errors we saw in our study did not lead to more measurements of unacceptable analytical quality; however, it is plausible that the correction of some errors will lead to better compliance.

Contrary to what one might assume, we found that patients who were self-taught made fewer user errors than those who had received SMBG training. Possibly, self-taught patients take a more active learning approach and study their glucometer manual more thoroughly compared to those who received training. Also, because the patients were not asked what their education entailed, the training in question might have been unsatisfactory, providing the patients who received it less information than the self-taught patients. It is not definite that one would see the same positive effect of no training in a less motivated patient group. Though the number of analytically unacceptable measurements was low in this study population, this does not change the fact that the quality of patients’ SMBG measurements should be monitored. Our study found that the participating patients preferred...
to have their measurements assessed at their community pharmacy, and Norwegian pharmacy employees have also expressed an interest in working more actively in this field. In Norway the National Insurance Scheme pays for 90% of the expenses connected to diabetes patients’ SMBG. In 2008 they spent more than 40 million Euros on glucometer strips alone. A service such as that we have described here could help ensure that this money is well spent; however a challenge for pharmacies considering implementation of a SMBG assessment service is to recruit patients most in the need of the service. Further studies should focus on recruiting patients with HbA1c values above 7.5 - 8%.

CONCLUSIONS

Five percent of patient measurements deviated from the comparison method by more than 20%. The analytical quality of the Norwegian diabetes patients’ SMBG measurements was better than reported in earlier studies, possibly due to the selected patient sample. Fifty percent of the patients made user errors, but this did not lead to more unacceptable measurements. The pharmacy service significantly reduced the number of user errors and gave the patients more confidence in their measurements but did not improve the analytical quality of the measurements.

ACKNOWLEDGEMENTS

The authors thank HemoCue Norway (Angelholm, Sweden) for providing instruments, microcuvettes, control material, and training to the pharmacies participating in the study. We thank Ms. Åste Flatmark, chain professional service manager from Vitusapotek AS, for help planning the study and the 16 pharmacy employees for their hard work and enthusiasm. Thanks to biomedical laboratory scientists Åse Hirsch-Nilsen of NOKLUS and Grete Knudsen, Haukeland University Hospital, for help training the pharmacy employees. We also wish to thank Dr. Gunn Kristensen, NOKLUS, for input regarding study design and practical help.

CONFLICT OF INTEREST

All HemoCue instruments and material were provided free of charge from HemoCue Norway. The pharmacy chain’s professional service manager helped plan the study, but was not involved in analyzing the results, and the chain did not place any restrictions on the publishing or use of the results. RLSK has received grants from Vitusapotek AS through the Norwegian Pharmacy Society’s scholarship fund.

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