Blood glucose meters in the community: Are the results accurate?

Samantha Rosindale, Koula Asimakopoulou

Introduction

Self-monitoring of blood glucose principally provides the person with diabetes with a quick and comprehensive picture of his/her glucose control on a day-to-day basis. Used with a laboratory HbA_{1c} test, decisions on whether any treatment changes are necessary to improve diabetes control can be made. Many healthcare professionals (and those with diabetes themselves) assume that the self-monitoring results from blood glucose meters are accurate and that the treatment changes made will be appropriate. Central to the role of the diabetes specialist nurse is supporting, educating and advising people with diabetes through treatment changes, relying on the self-monitoring results to manipulate the medication to improve glucose control. This article presents the findings of a study that focused on the accuracy of results from glucose meters. It also presents valuable information regarding the person with diabetes' feelings and attitudes towards self-monitoring their blood glucose.

Problems surrounding people with diabetes monitoring their own blood glucose is now attracting major specialist press attention. Relevant issues related to clinical practice, such as inappropriate use, lack of training and education have been reported (Cavan and Hawthorn, 2004; Kerr, 2004; Medicines and Healthcare Products Regulatory Agency, 2004; Reynolds and Strachan, 2004), resulting in controversial prescribing restrictions and suggestions that meter results may be inaccurate (Rosindale et al, 2004).

In 2004, Diabetes UK carried out surveys of attitudes and practices of both healthcare professionals and patients (Diabetes UK, 2004a; Diabetes UK, 2004b). The results supported the previously described issues of disparity in the content of education delivered by healthcare professionals and also highlighted accuracy as one of the important qualities that patients wanted from their meters (Diabetes UK, 2004b).

In the same year, Owens et al (2004) published guidelines for self-monitoring of blood glucose (SMBG) in type 1 and type 2 diabetes. Also at that time the Diabetes Monitoring Forum (DMF; Cavan and Hawthorn, 2004), an independent multidisciplinary group of diabetes health professionals, made available to healthcare professionals a series of leaflets on monitoring blood glucose aimed for use by the person with diabetes. Both of these approaches were positive steps towards achieving clarity of a seemingly difficult situation. Owens et al (2004) and the DMF (Cavan and Hawthorn, 2004) comprehensively covered the need and absolute requirements for home blood glucose monitoring, covering all treatment types and situations in a way that is easily applied to clinical practice. However, the leaflets produced by the DMF embraced the situation with a more practical aspect because they focused on patient need, offering people with diabetes specific advice in accordance with their treatment type. The leaflets also outlined the responsibilities of the healthcare professional in providing SMBG education.

This went some way towards recognising the problems with SMBG that were outlined by the Diabetes UK surveys (Diabetes UK, 2004a; Diabetes UK, 2004b; Diabetes UK, 2004c).

ARTICLE POINTS

1 There is a highly significant difference between meter and laboratory results. The mean difference is 10%.

2 Seventy-three per cent of meter readings fell within 20% of the laboratory value.

3 A significant variable found to determine accuracy was how easily the capillary sample was obtained from the finger.

4 People with diabetes have not been educated to a level that fully encompasses the objectives of self-monitoring.

KEY WORDS

- **Self-monitoring of blood glucose**
- **Blood testing meter**
- **Meter accuracy**
- **Error grid analysis**

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Table 1. Characteristics of the study group.

Number of participants	189
Percentage of whom were female	53
Age range of participants in years	31–88
Percentage with type 1 diabetes (for 2–50 years)	23
Percentage with type 2 diabetes (for 1–40 years)	77

PAGE POINTS

1 The purpose of this study was, firstly, to establish how accurate people with diabetes were when self-monitoring their blood glucose; secondly, to determine whether there was a significant difference between the meter and laboratory results; and, finally, to assess if meter results could be relied upon to change treatment in patients with diabetes.

Unfortunately, the guidelines written by Owens et al (2004) made no reference to meter accuracy or any recommendation for the use of quality control. On the other hand, the DMF did acknowledge that readings may be inaccurate, but the advice that was offered was inadequate. Some value was also lost when, in light of the findings by Diabetes UK (2004b), both groups (Owens et al, 2004; Cavan and Hawthorn, 2004) did not involve people with diabetes or include the opinions of those with diabetes.

Aim of the study

The purpose of this study was threefold: firstly, to establish how accurate people with diabetes were when self-monitoring their blood glucose; secondly, to determine whether there was a significant difference between the meter and laboratory results; and, finally, to assess if meter results could be relied upon to change treatment in patients with diabetes.

Materials and methods

After consent procedures, those recruited to the study (see *Table 1* for participant characteristics) were asked to complete a questionnaire covering specific issues pertinent to the accuracy of SMBG. The questionnaire covered subjects such as whether advice was offered, understanding of results, whether the meter is ever checked for accuracy, quality control and how monitoring helps with diabetes management. The study participants were then observed performing a blood glucose test. Notes were taken on technique (for example hand-washing, physical/cognitive impairment, adequate sample to the strip). General information was also collected about the meter, such as condition, calibration, strip storage and expiry. Immediately afterwards a venous sample was taken from the individual for a glucose test, and the results compared.

Some meters analyse plasma and some analyse whole blood. In the laboratory plasma glucose was analysed, so for meters that were calibrated to analyse plasma a direct comparison of meter and laboratory values could be made. For meters calibrated to analyse whole blood an allowance of +15% on the meter value had to be calculated before direct comparison of the two values.

The study participants' own glucose meters were used. Venepuncture equipment (Greiner Bio-One GmbH, Kremsmünster, Austria) was used and venous plasma was assayed for glucose using glucose oxidase on a Roche 917 (Roche Diagnostics, Lewes) analyser. Ethical approval had been granted for this study.

Data analysis

With blood glucose meter accuracy there is a need to differentiate between analytical precision and clinical acceptability. The data analysis hoped to combine the two as, individually, each one has its limitations. This allowed for a practical conclusion which can be used within a clinical setting.

Analytical precision

The results were considered in pairs (i.e. laboratory and meter). SPSS (a statistical software package; SPSS Inc, Chicago) was used to do a paired *t*-test (statistical test to see if there was a significant difference between pairs of values). Completed questionnaires were analysed for the emergence and frequency of common themes/patterns/words.

Clinical acceptability

An error grid devised by Clarke et al (1987) was used to analyse the two data-sets. An error grid is a clinically oriented

Table 2. Definition for each zone on the error grid.

Zone	Definition	Treatment
A	Difference between meter and laboratory value is <20%	Clinically correct, so no change
B	Difference between meter and laboratory value is >20%	Inappropriate, but with no serious clinical consequences
C	Difference leads to an over-correction of acceptable blood glucose (BG) levels	May cause the BG level to go below 3.9 mmol/l or above 10 mmol/l
D	Laboratory values are high or low but the meter gives values in the normal range	Dangerous failure to detect and treat
E	Laboratory values are opposite to the meter values	Erroneous treatment zone and treatment contradictory to that actually required

approach to blood glucose data. It displays the relative difference between the laboratory and meter values over the entire glucose range and provides the clinical significance of that difference (*Figure 1*). The error grid is based on the following three assumptions (Clarke et al, 1987; Cox et al, 1997).

- Blood glucose readings <3.9 mmol/l should be raised.
- Blood glucose readings >10 mmol/l should be lowered.
- Acceptably accurate results are within 20% of the laboratory blood glucose result.

The grid defines the x-axis as the laboratory blood glucose value and the y-axis as the value generated by the glucose meter. The data points obtained for each measurement fall into one of five zones (A–E; *Table 2*) drawn on the grid. The zones indicate how appropriate the therapeutic decision, based on the glucose meter result, would have been if the blood glucose result had been measured with the laboratory method.

Results

Treatment

Table 3 summarises the different therapies used by the study participants with type 2 diabetes. The participant group expected to obtain the most value from SMBG would be those using insulin therapy to control their diabetes. This resulted in only 80 (42%) individuals with either type 1 or type 2 diabetes controlled in this way, which was surprising as the authors would have expected this group to have made up the majority of the study population. The participant group expected to obtain the

Table 3. Summary of therapies used by the study participants with type 2 diabetes.

Therapy	Number (% of total)	Mean age in years	Age range in years	Mean duration of diabetes in years
Diet	13.2	65.5	36–78	2.0
Tablets	44.4	65.4	36–88	6.1
Tablets and insulin	6.3	62.3	41–72	9.1
Insulin	13.7	64.2	33–77	15.0
Total (of all study participants)	77.8	65.0	33–88	7.3

PAGE POINTS

1 An error grid was used for analysis. An error grid is a clinically oriented approach to blood glucose data. It displays the relative difference between the laboratory and meter values over the entire glucose range and provides the clinical significance of that difference.

2 The grid defines the x-axis as the laboratory blood glucose value and the y-axis as the value generated by the glucose meter.

3 The grid indicates how appropriate the therapeutic decision, based on the glucose meter result, would have been if the blood glucose result had been measured with the laboratory method.

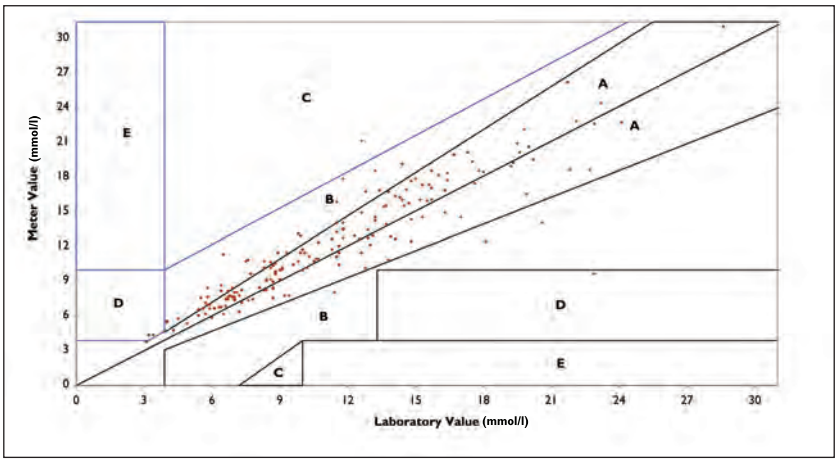

Figure 1. Error grid analysis. See **Table 2** *for definitions of zones A–E.*

most value from SMBG would be those who were successfully controlling their insulin levels.

Analytical performance of the meter

Twenty-five different meter types were observed being used, 92.6% of which were calibrated to whole blood. A highly significant difference (P=0.001) was found between the meter and laboratory results, with the meter to laboratory variance ranging from –57.8% to +75.2% and the mean being +10.1%.

Clinical significance of the errors

Using the criteria for error grid analysis the results were plotted (*Figure 1*). Seventy-three per cent (n=138) of participants had acceptable SMBG values that were classified under zone A. Zone B included 25% (n=47) of the participants. One participant was in zone C and had a meter reading of 21.2 mmol/l and a laboratory value of 12.6 mmol/l, which would create a risk of over-treating, leading to potential hypoglycaemia. Three participants were in zone D, representing failure to detect and treat immediate and significant hypoglycaemia. No participants fell within zone E.

Accurate vs inaccurate meter results

For analysis the data were split into two groups: those individuals within 10% of laboratory results (accurate group) and those whose results fell outside the laboratory results by 10% (inaccurate group). Age, gender, treatment type, meter age, meter condition, calibration, quality control, adequacy of sample to the strip, amount of testing and hand-washing were all found to be unrelated to meter accuracy for both groups.

The only variables of significance in determining meter result accuracy were the meter type (P=0.001), meter manufacturer ($P \leq 0.05$) and how easily the capillary sample was obtained from the finger (P<0.05).

Education delivered

Meter result accuracy did not correlate with how much education the study participants had received. Thirty-one per cent (n=59) of the participants had been taught by diabetes specialist nurses and the same proportion by practice nurses to self-monitor their blood glucose, and 36% (n=68) of the study group had taught themselves. *Table 4* elaborates further on some of the participant responses to the questions asked about baseline education for SMBG. It was expected that the accurate group would show higher percentages for receiving education in their questionnaire responses.

It is noteworthy that more participants in the inaccurate group had been shown how to use the meter, been given an update on SMBG and understood the meter results than those in the accurate group. Also surprising was the reduction in numbers between those understanding meter results and those not being confident to alter their medication as a result, especially for those treated with insulin.

Participant comments

Sixty-two participants (33%) wrote comments on their questionnaires, from which the following three main themes emerged.

Review of accuracy

The general assumption among the participants was that glucose meters perform accurately; there was confusion

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1 Meter result accuracy did not correlate with how much education the study participants had received. Thirty-one per cent of the participants had been taught by diabetes specialist nurses and the same proportion by practice nurses to self-monitor their blood glucose.

2 The general assumption among the participants was that glucose meters perform accurately; there was confusion that if meter accuracy was to be checked, exactly how it should be done.

Table 4. Questionnaire responses. The percentages relate to those answering 'yes'.

Questions asked	Accurate group	Inaccurate group
Did you have a choice of meter?	29	23
Were you given advice on which meter best suited your needs?	20	25
Were you shown how to use the meter?	51	64
Do you understand the results?	84	89
Do you feel confident to alter medication based on the results?	47	49
Have you been offered revision of self-monitoring of blood glucose (SMBG) technique?	12	12
Have you ever been given an update on SMBG?	40	46

that if meter accuracy was to be checked, exactly how it should be done. One participant said, 'If my meter displays "error", that is the check method and means it is OK.' Another felt that meter accuracy was checked by colour matching the dosing area of the strip to the chart provided on the side of the meter strip package (It should be noted that Accu-Chek Active [Roche Diagnostics, Lewes] does have a crude colour matching chart for very basic accuracy checking). Some participants used other meters to check accuracy. Whilst another stated that, 'As long as my meter displays a result, I do not need to use a check method.'

Confusion also existed among the participants who had questioned their meter's accuracy; one said, 'I only use the check method when there's trouble.' Some participants had decided that as long as the doctor checked their glucose control with laboratory tests it was the 'safety net' that they needed if their meters were inaccurate. Others stated that they lacked confidence in the meter calibration system whilst others had had practical difficulties in doing this. Four participants compared their meter results with the clinic's blood test as a way of checking for meter accuracy. One individual stated that 'results seem to tie up with clinic blood tests.'

Education

There appeared to be a lack of people with diabetes who had been properly assessed on whether it was appropriate for them to self-monitor their blood glucose or educated to a level that covered the objectives of SMBG. Participants expressed concerns on confusion over topics such as unclear aims and objectives, technique, result interpretation and when to test. Some individuals felt that because they were treated with insulin or a sulphonylurea they were not at risk of hypoglycaemic episodes.

Advice from health professionals

Some confusion appeared to be created because individuals were not receiving clear communication from their diabetes educator. Some of the participants wrote statements such as: 'I have been told to simply monitor levels, but I don't know what that means,' and, 'All I am told is "don't let it get too high".' In others the confusion was increased because the information given was misleading and lacked clarity. The following was written by one participant.

'When I was first diagnosed I purchased a meter and was told to check [blood glucose levels] after every meal, noting diet so that I could see what foods to avoid. For several years I coped on diet and exercise. Two years ago I was put on metformin, twice a day, and I was told that it was not necessary to check blood [glucose] levels every day.'

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1 The overall aim of the study was to establish how accurate people with diabetes were when carrying out SMBG and whether it could be relied upon to change their treatment.

2 Work is now ongoing within primary care to highlight the results of this study.

Discussion

Finding a statistically significant difference between the values of the patients' glucose meters and the laboratory supported the initial evidence found in earlier work (Rosindale et al, 2004). Overall, using the difference found between the laboratory and the meter values for a single blood glucose value is reliable, as is defining the significance of those errors using the error grid (Clarke et al, 1987). This would suggest that glucose meters are safe, as relatively few results were defined as having dangerous clinical consequences even though their overall accuracy is not comparable to that of a laboratory value. The number of different meter types observed being used on a single encounter has meant that analysis of which meter types are inaccurate is inconclusive.

The questionnaire has begun to highlight some of the inequalities that exist in the standard of SMBG education being delivered to people with diabetes. The participants' comments regarding SMBG were valuable and demonstrated that, when those with diabetes first commence SMBG, they feel that it is a simple thing to do initially and are, in the main, happy to do so. However, once started they find that the results from SMBG engenders more questions than answers because they have not been given adequate education to interpret the results for themselves. Therefore, for some it can become a bewildering and de-motivating experience.

The overall aim of the study was to establish how accurate people with diabetes were when carrying out SMBG and whether it could be relied upon to change their treatment. On a single measure there is between a 1 in 4 and 1 in 5 chance that the meter readings were greater than 10% different from the laboratory values, which may have clinical consequences and lead to the recommendation that they have their technique and meter checked over a period of time. Decisions on treatment changes should only be made once accuracy has been assured and with other laboratory results available.

Conclusion

Work is now ongoing within primary care to highlight these results. Assistance is also being provided in developing an assessment tool for healthcare professionals to use with the person with diabetes so that need/purpose of SMBG is agreed. This will allow SMBG to become a worthwhile tool for the person with diabetes to use in the self-management of the chronic condition. ■

'Decisions on treatment changes should only be made once accuracy has been assured and with other laboratory results available.'

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