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Benefits to health care professionals and patients with diabetes of a novel blood glucose meter that provides pattern recognition and real-time automatic messaging compared to conventional paper logbooks

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Background: Self-monitoring of blood glucose is crucial for maintaining overall blood glucose (BG) levels. Health care professionals (HCPs) must rapidly assess patient BG data and recommend treatment changes, as appropriate, during short office visits. A meter offering automatic BG pattern recognition and in-the-moment messaging may change how HCPs and patients with diabetes work together to achieve glycemic control.
Methods: Two separate studies evaluated the potential benefits of the OneTouch Verio® BG monitoring system. In one study, 64 HCPs were evaluated on their ability to rapidly recognise BG patterns in simulated logbooks compared to using the meter, before completing a survey on potential benefits of the meter to themselves and their patients. In the other study, patients with diabetes used the meter at home for 1 week before also completing a survey.
Results: Patients indicated that the meter was simple to use and understand. For HCPs, using the meter to identify BG patterns was significantly faster and more accurate than using a logbook. In addition, HCPs believed the meter features would make interpreting BG results easier for patients.
Conclusions: An easy to use meter with in-the-moment BG insights may help improve patient management of glycemic control between office visits. In addition, using the meter may improve efficiency during office visits.

Key words: Blood glucose monitoring, blood glucose patterns, colour range indicator, glycemic control, logbooks

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For individuals with diabetes mellitus, self-monitoring of blood glucose (SMBG) levels is important for overall glycemic control, e.g. correcting hyperglycemia without increasing risk of hypoglycemia. SMBG is the most accessible and widely used tool for recording and analysing daily BG (blood glucose) patterns.[1,2] These patterns consist of repeating occurrences of hyper or hypoglycemic episodes within a defined time period, and are important for the identification of moments when action to maintain in-range BG levels is necessary.[3] Traditionally, patients have recorded BG measurements in a logbook, which is subsequently analysed by health care professionals (HCPs) to determine the appropriate course of action for glycemic management. However, this practice is time consuming for patient and HCP, can introduce errors and can be difficult for the patient and HCP to translate into meaningful clinical insights.[4,5] Furthermore, earlier studies have shown that the fear of negative feedback from the HCP during office visits may influence patients to record their BG values incorrectly, sometimes obscuring data that could indicate either hyper or hypoglycemia.[6] The introduction of BG meters that store data and allow data download for evaluation may alleviate some of the difficulties associated with patient logbook evaluations, but the difficulty in translating downloaded data into meaningful clinical insights still remains.

Current guidelines from the American Diabetes Association and European Association for the Study of Diabetes recommend a shift towards more individualised diabetes care.[7] HCPs must therefore be able to advise patients with diabetes as to the best course of action for their individual disease management. As part of this action, HCPs must quickly recognise BG patterns and make treatment recommendations accordingly since office visits may last only 10–20 minutes.[8,9] The time spent on examining and analysing logbook data can impact the time spent discussing the data with the patient and represents an important hurdle in diabetes management.[10]

Both patients and HCPs alike would benefit from a BG meter that can accurately and quickly analyse BG data for pattern recognition, while still being easy to use and understand.[9,11] Some newer blood glucose monitoring systems (BGMS) have algorithms that can immediately identify high and low BG patterns and notify the users in real-time with on-screen messages.[1] These systems should benefit patients who need fast analysis of their

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BG results, without additional effort or time on their part. The use of such meters may not only improve glycemic pattern identification and analysis, but may also encourage patients to consider immediate behavioral changes to further improve their BG management or provide feedback to their HCP about such patterns to initiate management changes. The OneTouch Verio® (OT Verio) BGMS (LifeScan Inc., Milpitas, CA) has functionality to identify high and low BG patterns and notify users of these patterns with in-the-moment messages that require no additional effort on the part of the user. In addition, the meter has a progress notes feature, which keeps patients updated on their self-management progress by providing positive feedback when their BG levels are maintained within or return to acceptable ranges as determined in consultation with their HCP. Finally, the meter uses colour coded icons to let the user know if his BG results are below, within or above the BG range that has been set in consultation with their HCP.

The purpose of these two studies was to evaluate the experiences of patients with diabetes when using OT Verio at home to conduct SMBG, as well as gather HCP's opinions of the potential benefits of using such a BGMS in their practice. The second study also examined the accuracy and speed of HCPs in identifying BG patterns using the meter, compared with simulated patient-recorded logbook data, to determine if use of this meter could potentially result in improved HCP efficiency in BG data analysis during office visits.

Research design

Patient study

This was a multicenter, single-arm, non-randomised pilot study in 102 patients with diabetes. Fifty patients were enrolled across three National Health Service clinics in the United Kingdom (Highland Diabetes Institute, Inverness; Diabetes Outpatient Department, Royal Infirmary of Edinburgh; and Diabetes Centre, Birmingham Heartlands Hospital), and 52 patients were enrolled at one site in the USA (AMCR Institute, Inc., Escondido, CA). The study was approved by the relevant internal ethics committees, and all participants provided written informed consent before study initiation. Patients were advised not to make any treatment decisions based on the results from the experimental meter during the 1-week take home period; any required treatment decisions during this period were made based on data from their existing meter.

The study included individuals aged ≥12 years with either Type 1 (T1DM) or Type 2 diabetes (T2DM) who had experience performing SMBG. The study protocol consisted of two site visits with a 1-week home use period between visits. During the first site visit, study participants were briefed as to the protocol procedures, but were not given any instruction on the BGMS, and were issued a home testing kit, which included the OT Verio meter, lancing devices, test strips and Owner's Booklet. During the home use period, participants familiarised themselves with the meter and test strips and were asked to conduct regular SMBG and perform a series of tasks that covered the range of functionality of the meter, including BG testing, setting and adjusting the range limits, and turning messages on and off. In the course of SMBG it was possible that many, but not all of the meter features and messages would be experienced by the user. During the second site visit, participants received a demonstration of the range of possible meter messages (Fig. 1), before completing a survey. The survey consisted of 25 statements about the ease of use of the meter and its potential benefits, and answers were given on a 5-point scale (5 = strongly agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; 1 = strongly disagree). A favourable response was defined as a response of 'strongly agree' or 'agree'.

HCP study

In-person interviews were conducted with 64 HCPs (endocrinologists, primary care physicians [PCPs] and diabetes educators [DEs]) in the USA. HCPs were included if they routinely treated patients on insulin therapy, had experience reviewing patient logbooks and at least occasionally made treatment decisions based on logbook data.

The accuracy and time for the HCPs to identify high and low BG patterns according to meter algorithms in five simulated logbooks containing 30 days of BG data were compared to using meters containing identical data. Data in the logbook were designed to simulate actual patient data. Speed was defined as the time it took an HCP to complete the BG pattern assessment, with a maximum of 15 minutes each for assessing the logbook and then the meter. The meters were pre-set to detect patterns and provide pattern alerts based on the following algorithm: low patterns were defined as two readings ≤ the low threshold over a 5-day period within a 3-hour time bracket; high patterns were defined as three readings ≥ the high threshold over a 5-day period within a 3-hour time bracket. The low threshold (range of 60–100 mg/dL) and high threshold (range of 150–180 mg/dL) used in the logbook examples were varied in an attempt to simulate real world variation. Pattern identification accuracy was evaluated by the number of missed or falsely identified BG patterns, expressed as an error rate (%). For the meter assessment, HCPs were asked to locate the pattern and BG information in the simulated meter data that was identical to the data recorded in the logbooks.

Following the evaluation of speed and accuracy of pattern identification, HCPs were given a demonstration of possible automatic meter messages patients may see when testing, and completed a survey focused on the potential benefits of the meter to them and their patients during office visits and to patients between office visits. Responses could range from 'strongly agree' to 'strongly disagree', as described above.

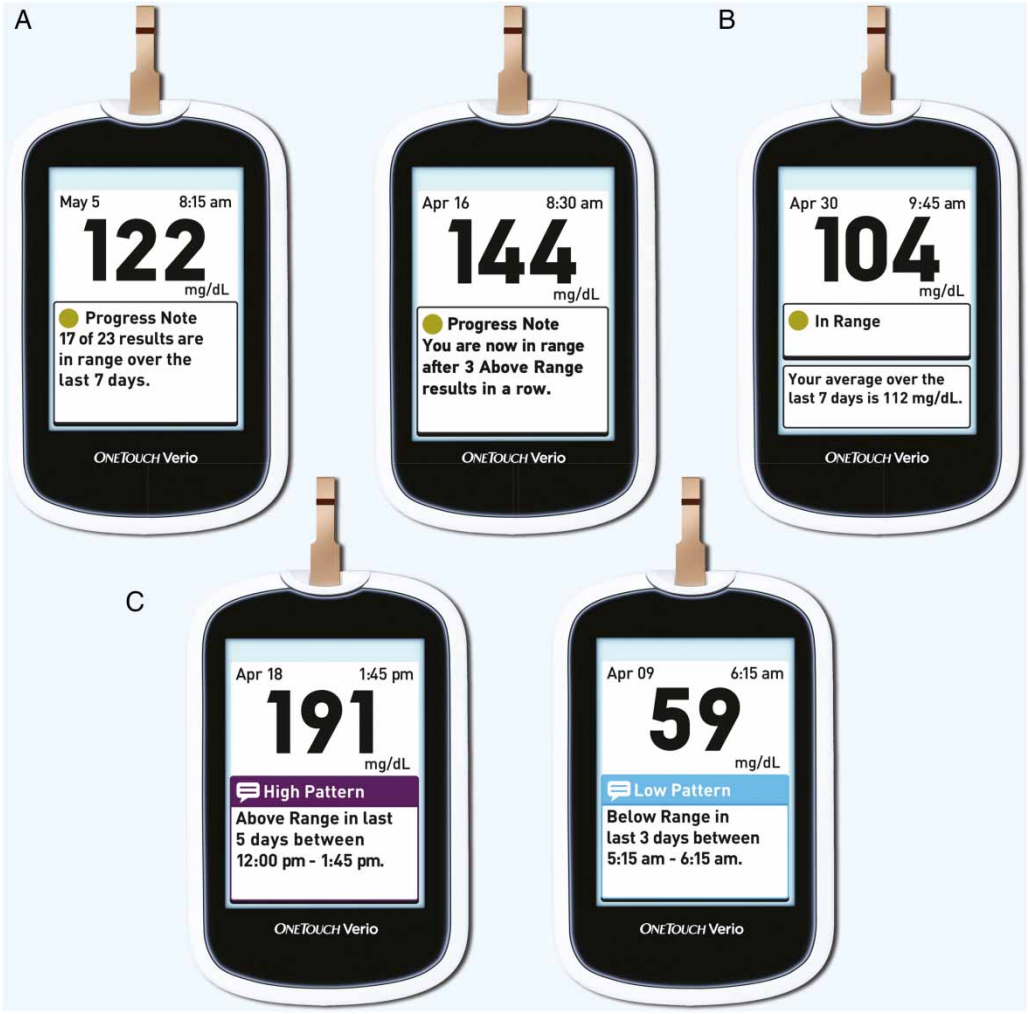

Figure 1 Examples of on-screen messages: (A) progress notes; (B) 7-day average; (C) pattern alerts

Statistical analysis

Logbook and meter comparisons were analysed using the sign test, i.e. for each HCP, the difference of average assessment time using the logbook vs. the meter was calculated. The test was then based on the sign of the difference. Pattern recognition analysis was also performed in this manner. The average assessment time and the difference in the average assessment time were summarised with descriptive statistics such as *n*, mean and standard deviation for each HCP category (i.e. endocrinologist, PCP and DE).

One-sided 95% confidence intervals (CI) were provided for the analysis of the survey responses. The study objective was met if the one-sided 95% lower confidence limit for the percentage of favourable responses ('strongly agree' and 'agree') to the corresponding item on the statement or question was greater than 50%.

Results

Patient study

Of the 102 patients with diabetes participating in this study [average age 45.6 years (range, 13.3–94.4)] (Table 1), 57% were female, and 57% had T1DM. Over half (72.5%) of the participants were currently on an insulin regimen. The mean time since diabetes diagnosis was about 15 years (range, 1.9–56.3). On average, participants had performed SMBG for 13 years (range, 0.4–42.1), with an average frequency of 3.5 times per day (range, 0.07–12).

All study participants completed a survey at visit 2 following their 1-week take home period and meter functionality demonstration. The responses to the survey indicated that 97% of participants found the meter easy to use, and 99% found the results easy to understand (Table 2). In particular, 98% of the patients responded favourably to the progress notes feature, which let them know when they were doing well with maintaining in-range BG levels. Also, 96% of participants indicated that automatically alerting them to pattern messages when their BG levels were too low or too high, will enable them to make the changes necessary to stay in the appropriate BG range. The positive responses to all statements shown were statistically significant at the $p < 0.05$ level.

Table 1 Baseline patient characteristics and medical history.

Characteristic	Participants ($n = 102$)
Gender, *n* (%)	
Female	58 (56.9)
Male	44 (43.1)
Age in years, mean (range)	45.6 (13.3–94.4)
Type of diabetes, *n* (%)	
Type 1	58 (56.9)
Type 2	44 (43.1)
Diabetes management practice, *n* (%)	
Diet and exercise only	2 (2.0)
Shots other than insulin	2 (2.0)
Oral medication	21 (20.6)
Oral medication and insulin	14 (13.7)
Insulin shots	37 (36.3)
Insulin pump	23 (22.5)
Other	3 (2.9)
Years since diagnosis	
Mean	15.1
Median	11.2
Range	1.9–56.3
Years self-monitoring	
Mean	13.0
Median	10.1
Range	0.4–42.1
Frequency of self-monitoring (per day)	
Mean	3.5
Median	3
Range	0.07–12

HCP study

A combination of 19 endocrinologists, 15 PCPs and 30 DEs ($n = 64$) participated in this study. All had previous experience with logbooks and BG meters with an average of 15 years' experience in reviewing logbooks (Table 3). In addition, 69% of the participating HCPs downloaded BG data from their patient's meters. Participating PCPs had the most years of experience reviewing logbooks, but only 40% of them downloaded data from patient meters, compared with 95% for participating endocrinologists and 67% for participating DEs.

The average time it took an HCP to identify BG patterns using the logbook was 4.0 minutes (95% CI, 3.7–4.3 minutes) vs. 1.0 minute using the meter (95% CI, 0.9–1.1 minutes) ($p < 0.001$) (Table 4). There was a trend towards faster logbook assessment times by endocrinologists and PCPs compared with DEs. The mean percentage of all missed or falsely identified BG patterns (high and low) during logbook review compared with the number of patterns as determined by the meter was 26% (18–34%, $p < 0.001$) (Table 5). There was no difference in overall accuracy rates among the three HCP groups, although compared with diabetes specialists (endocrinologists and DEs), PCPs missed more low BG patterns (26.6% vs. 9.2% and 14.8%) and identified more false high BG patterns (19.8% vs. 9.4% and 12.1%).

In response to a survey regarding the potential value of meter features, 97% of HCPs said that the range indicator, automatic pattern messaging and progress notes features would make interpreting the results much easier for patients with diabetes, compared with data recorded in a logbook (Table 6). In addition, 94% believed that using the meter would help patients with diabetes feel more engaged in their diabetes care, and 88% would recommend the meter to their patients. More specifically, 91% of HCPs said that they would recommend the meter to patients currently on insulin. The positive responses to all statements shown were statistically significant at the $p < 0.05$ level.

Table 2 Patient responses to survey statements ($n = 102$).

Statement	Favourable responses (%)[a]
By reviewing past results, this meter looks for signs of progress, and provides me automatic messages	98
Progress notes will help me know when I've been doing well: when my results are consistently in range or back in range after high results	98
It allows easy insertion of the test strip	96
The meter has an easy-to-read colour screen	96
Automatic pattern messaging alerts me to high and low patterns, so I can make changes to stay I range	96
Gives me reassuring progress notes when my results are in range	96
Without any extra effort, it lets me know if my results are in or out of range	96
Gives me an instant alert if my result is low, so I can take action	96
The automatic 7-day average makes it easy to see how I'm doing over time	95
Gives me useful information about my results without extra effort	95
I test as usual and get information that helps me better understand my result – all in one screen	95
This meter is easy to use	94
Makes results simple to understand	94
Helps me to better understand my results so I can make better decisions	93
Helps me identify times of day for improvement	91
Lets me test in bright or low light	91
The meter menu is easy to navigate	90
Automatically provides key information that focusses on successes and opportunities for better control	90
I can test in-case without removing anything except the strip	86
I test as usual and the meter sends me messages about information I might miss	86
I would recommend this meter to others	81
Will give me more confidence to manage my blood glucose	80
Will make me more confident about managing low blood glucose	78

[a]Favourable responses are defined as a response of 'strongly agree' or 'agree' on a 5-point scale (5 = strongly agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; and 1 = strongly disagree). All favourable responses are statistically significant ($p < 0.05$)

Discussion

For individuals with diabetes, glycemic management leading to better glycemic control is important to a normal day-to-day life and a lowered risk of long-term

Table 3 Experience of participating HCPs in reviewing logbooks and meter data.

		Logbook review experience (years)	Download meter data	Downloads per month*
Group	*n*	Mean (SD)	Yes, *n* (5)	Mean (SD)
All HCPs	64	15.0 (8.0)	44 (69)	55 (66)
Endocrinologists	19	13.8 (8.5)	18 (95)	87 (81)
Primary care Physicians	15	18.7 (8.0)	6 (40)	27 (38)
Diabetes educators	30	13.8 (9.2)	20 (67)	34 (43)

SD, standard deviation.
*For those HCPs who downloaded meters.

Table 4 Time required for assessing blood glucose patterns using a logbook or meter.

		Time to assess, minutes, mean (95% CI)		
Group	*n*	Logbook	Meter	Difference, minutes, mean (95% CI)
All HCPs	64	4.0 (3.7–4.3)	1.0 (0.9–1.1)	3.0 (2.7–3.4)*
Endocrinologists	19	3.3 (2.7–4.0)	1.0 (0.8–1.3)	2.3 (1.7–2.9)*
Primary care physicians	15	3.6 (3.2–4.0)	1.0 (0.7–1.3)	2.6 (2.3–2.9)*
Diabetes educators	30	4.6 (4.2–5.1)	0.9 (0.8–1.0)	3.8 (3.2–4.3)*

*$p < 0.001$, null hypothesis: logbook>meter.

Table 5 Analysis of percent of missed and falsely identified patterns using the logbook.

	BG pattern	% Missed patterns	% False patterns	% Error rate[d]
All HCPs ($n = 64$)	Low[a]	15.9 (20.3) [10.9–21.0]***	4.1 (11.3) [1.3–7.0]***	20.1 (29.6) [12.7–27.5]***
	High[b]	19.0 (19.1) [14.2–23.7]***	13.1 (20.9) [7.9–18.3]***	32.0 (38.0) [22.6–41.5]***
	Total[c]	17.2 (18.2) [12.8–21.9]***	8.7 (15.6) [4.8–12.6]***	26.0 (32.4) [17.9–34.1]***
Endocrinologists ($n = 19$)	Low	9.2 (10.2) [4.3–14.1]**	2.9 (8.3) [−1.1–6.9]	12.1 (15.5) [4.6–19.6]**
	High	15.0 (14.3) [8.1–21.9]***	9.4 (15.3) [2.0–16.8]*	24.4 (28.3) [10.8–38.1]***
	Total	12.3 (11.5) [6.7–17.8]***	6.3 (12.0) [0.5–12.1]*	18.6 (22.0) [8.0–29.2]***
Primary care physicians ($n = 15$)	Low	26.6 (32.9) [8.4–44.9]**	9.1 (19.2) [−1.6–19.7]	35.7 (50.3) [7.8–63.6]**
	High	20.9 (23.4) [7.9–33.8]**	19.8 (34.1) [0.9–38.6]*	40.6 (56.3) [9.5–71.8]**
	Total	23.2 (27.1) [8.1–38.2]**	14.5 (25.5) [0.4–28.6]*	37.7 (51.6) [9.1–66.2]**
Diabetes educators ($n = 30$)	Low	14.8 (14.8) [9.3–20.4]***	2.5 (6.4) [0.1–4.9]	17.3 (18.9) [10.2–24.4]***
	High	20.5 (19.6) [13.2–27.8]***	12.1 (14.4) [6.7–17.5]***	32.6 (32.0) [20.6–44.6]***
	Total	17.6 (15.7) [11.7–23.5]***	7.3 (10.2) [3.5–11.1]***	24.9 (24.2) [15.9–33.9]***

Data are mean (SD) [95% confidence intervals].
[a]Low = any time of day low BG patterns; [b]High = before meal high BG patterns; [c]Total = all low and high patterns; [d]% Error rate = % missed patterns + % false patterns.
*$p < 0.05$; **$p < 0.001$; ***$p < 0.001$.
H_0: error = 0%.

complications. Recognising and interpreting glucose patterns are not always simple, but tools that can give automatic and in-the-moment messaging can be beneficial in increasing BG awareness in patients with diabetes. The OT Verio meter may help patients to better comprehend their BG results, as reflected in the patient survey, and thus may encourage them to become more proactive in their disease management. In this study, all participants indicated that they approved of the progress notes feature, which provides positive feedback if their BG

Table 6 HCP responses to survey statements ($n = 64$).

Statement	Favourable responses (%)[a]
I believe the colour-cue on the range indicators offers patients the ability to instantly see where they are in their personal glucose range	97
I believe the instant messages displayed on the meter will provide my patients with timely feedback so they can take immediate action, if needed	97
I believe that the range indicator, pattern alert, and progress notes features will make it easier for my patients to interpret their results versus a traditional blood glucose meter	97
I believe the OneTouch meter will provide valuable information for patients who want to better manage their diabetes	94
I believe that using the OneTouch meter will help my patients feel more engaged in their diabetes care	94
I believe that the OneTouch meter will help my patients identify trouble spots they would otherwise have missed	94
Please rate your level of satisfaction with the OneTouch meter[a]	93
I would recommend the OneTouch meter to my patients who are on insulin	91
I would recommend the OneTouch meter to my patients	89
I believe my patients would prefer the OneTouch meter to other blood glucose meters because the one view screens let them see relevant information in a single glance	89
I believe the OneTouch meter positive messages features in the progress notes will help my patients take action to improve their diabetes or continue their positive actions	88
I believe that the pattern alerts will help my patients take action to avoid future highs and lows	84
I believe that the positive progress notes may encourage patients to test per my recommendations	84
I believe that the 'Treat low result' instant alert will help my patients take action to treat their hypoglycemic events	81
I believe the OneTouch meter positive message reinforcement features in the progress notes will help my patients stay motivated between office visits	77
I would switch my patients from other blood glucose systems to the OneTouch meter	70

[a]Favourable responses are defined as a response of 'strongly agree' or 'agree' on a 5-point scale (5 = strongly agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; and 1 = strongly disagree). All favourable responses are statistically significant ($p < 0.05$).
[a]For this question, the 5-point scale was 5 = very satisfied; 4 = satisfied; 3 = neither satisfied nor dissatisfied; 2 = dissatisfied; 1 = strongly dissatisfied.

levels are maintained within or return to acceptable ranges as determined in consultation with their HCP. This feature, as well as the low glucose alert message, may help counteract the lack of user adherence to diabetes treatment regimens due to fears of negative consequences, such as severe hypoglycemia.[3,12] Better adherence to treatment regimens would also mean that patients would be more likely to experience the long-term benefits of targeted glycemic control, including decreased risk of complications such as retinopathy, nephropathy, neuropathy and cardiovascular disease.[13]

This type of technology may not only benefit patients, but also HCPs.[3] The results of the study with HCPs showed that use of the meter resulted in four times faster recognition of BG patterns by HCPs compared to using paper logbooks. This time saving could be a significant benefit for HCPs, who may have limited time to assess a patient, analyse BG patterns, discuss BG patterns with the patient and decide on the best course of action for diabetes management. The use of the meter may also help HCPs make more informed recommendations to their patients, since they no longer only need to rely on patient-recorded BG data in logbooks. In addition, the meter may be of particular benefit for PCPs, who will be managing more patients with diabetes in a population management system and may be less skilled in identifying BG patterns than diabetes specialists. The results of this study suggest that the meter may improve PCPs' accuracy and speed in BG pattern recognition, and thus may help PCPs make better decisions for their patients.

In the surveys, both HCP and patients indicated that the use of a colour range indicator was a valuable meter feature. Appearance on the meter screen under the BG result of a green dot and the words 'in range', a blue dot and the words 'below range', or a red dot and the words 'above range' give the user immediate feedback as to where their BG result falls within the range set in consultation with their HCP. The meter comes with a set default range of 70–180 mg/dL, but this range can be customised depending on the individual needs of the patient. Responses by patients and HCPs to the survey indicated that the colour range indicator may help patients better understand their BG values, keep patients engaged in their BG management between office visits and provide information in a simple and easy to use way.

Since participants used the OT Verio meter for only a short period of time, it cannot be claimed that using the meter will definitively improve self-management of glucose. Longer studies and quantitative outcome measures (e.g. HbA1c) will be required to provide evidence of improved glycemic control. In addition, although some survey questions asked participants to compare the OT Verio meter to the meter they were currently using, participants were not randomised to receive this meter or another test meter and this must be taken into consideration when evaluating the survey responses.

Finally, as many of the patient participants were in the UK, it is important to point out that patients with T2DM are not routinely given meters if they are not treated with insulin. Since this involves approximately 20% of the patients in this pilot study, it would be worthwhile to conduct further studies in which OT Verio is used in patients with non-insulin requiring T2DM who have sub-optimal glycemic control to see if improvements could be realised.

Implications and conclusions

HCPs and patients each recognised the benefits of using a BG meter that provides additional insights into BG results with less effort. In addition, the use of the OT Verio BGMS by HCPs to identify high and low BG patterns resulted in significantly faster and more accurate pattern identification compared with using a simulated patient logbook. The introduction of the meter will result in significant time savings per office visit, without compromising the benefits of individualised patient care.

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Conflicts of interest LK and BL are employees of LifeScan Inc. LS is an employee of LifeScan Scotland Ltd.

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