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Patients With Diabetes Using a New Glucose Meter With Blood Sugar Mentor and Dynamic Color Range Indicator Features Show Improved Interpretation and Willingness to Act on Blood Glucose Results (ASCEND Study)

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Abstract

Background: We examined whether dynamic color range indicator (DCRI) and blood sugar mentor (BSM) features in a new blood glucose meter could improve interpretation of results and encourage patient action. **Methods:** One hundred and thirty three people with type 2 (T2D) ($n=73$) or type 1 diabetes (T1D) ($n=60$) evaluated information first without and then with DCRI or BSM guidance using interactive exercises. **Results:** Subjects improved their ability to categorize results into low, in range, or high glycemic ranges by 29% (T2D) and 22% (T1D) (each $P<.001$). There was significantly greater willingness to act on high and low results shown with DCRI or BSM screens. Subjects also expressed a high degree of satisfaction with these features. **Conclusions:** Use of DCRI and BSM in this meter may help patients improve their diabetes management decisions.

Keywords

dynamic color range indicator, blood sugar mentor, blood glucose monitor, self-monitoring of blood glucose

Introduction

"Self-monitoring is not dead."[1] This dramatic headline highlights how changing attitudes to blood glucose (BG) monitoring have encouraged healthcare professionals (HCPs) to reevaluate self-monitoring of blood glucose (SMBG) and the potential adoption of continuous glucose monitoring (CGM). Despite demonstrated benefits of CGM, there remains room for improvement.[2,3] Increased CGM adoption from 7% to 30% in type 1 (T1D) diabetes exchange patients has not translated into overall improvements in glycated hemoglobin A1c (A1c).[4] Fundamental changes are required in the relationship between patients and their devices to ensure patients receive more immediate context and actionable insights. We previously reported that BG meters utilizing a color range indicator (CRI) improved the ability of patients to interpret results and make decisions[5,6] and lowered A1c compared to subjects using meters without a CRI.[7] In the current study, we investigated whether a meter with a dynamic CRI (DCRI) that provides richer information, and a blood sugar mentor (BSM) feature that automatically delivers timely and relevant on-screen guidance to patients improve the ability of patients to interpret glucose data and consider acting on this new advice.

Methods

Study Population

One hundred and thirty three adult subjects (≥16 years old) with a diagnosis of diabetes for at least three months were recruited from three National Health Service (NHS) hospital clinics in the United Kingdom. Demographics, SMBG frequency, and meter usage is shown in Table 1. Fourteen subjects had used CGM (12 Freestyle Libre, 2 Dexcom); nearly a third (32.3%) used Roche Accu-check meters; and 70% of subjects with type 2 diabetes (T2D) used some form of insulin. Subjects had a mean age of 55.7 years and mean A1c of 8.5% as obtained from the NHS database. At the beginning of the study, each subject completed a subjective numeracy survey based on Fagerlin et al.[8]

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Table 1. Baseline Subject Demographics.

	All *N* = 133	Type 1 *N* = 60	Type 2 *N* = 73
Sex, *n* (%)			
Male	62 (47%)	27 (45%)	35 (48%)
Female	71 (53%)	33 (55%)	38 (52%)
Age, yrs, mean (range)	55.7 (19-84)	48.9 (19-73)	61.3 (26-84)
A1c, mean (range)	8.5% (5.8%-12.9%)	8.9% (5.8%-12.9%)	8.2% (6.0%-12.9%)
SMBG frequency, *n* (%)			
≥5 times/day	27 (20%)	23 (38%)	4 (6%)
3-4 times/day	51 (38%)	23 (38%)	28 (38%)
1-2 times/day	33 (25%)	13 (22%)	20 (27%)
Once/day therapy, n (%)	22 (17%)	1 (2%)	21 (29%)
Basal + Bolus insulin	78 (59%)	47 (78%)	31 (43%)
Pre-mix insulin	16 (12%)	1 (2%)	15 (21%)
Basal insulin only	9 (7%)	4 (8%)	5 (7%)
Bolus insulin only	2 (2%)	1 (2%)	1 (1%)
Insulin pump	7 (12%)	7 (12%)	0 (0%)
AHA only	21 (16%)	0 (0%)	21 (29%)
Current BGM brand, *n* (%)			
Accu-check	43 (33%)	17 (28%)	26 (36%)
Freestyle	33 (25%)	24 (40%)	9 (12%)
OneTouch	15 (11%)	2 (3%)	13 (18%)
GlucoRX	14 (11%)	4 (7%)	10 (14%)
Ascensia	12 (9%)	7 (12%)	5 (7%)
Caresense	8 (6%)	2 (3%)	6 (8%)
Glucomen	4 (3%)	3 (5%)	1 (1%)
Other	4 (3%)	1 (2%)	3 (4%)
Current CGM usage, *n* (%)			
No	119 (90%)	48 (80%)	71 (97%)
Yes (12 Libre, 2 Dexcom)	14 (10%)	12 (20%)	2 (3%)
Insulin status, *N* (%)			
Non-insulin	21 (19%)	0 (0%)	21 (29%)
Insulin	112 (81%)	60 (100%)	52 (71%)

A1c, hemoglobin A1c; AHA, antihyperglycemic agents (oral and/or GLP-1 agonists); BGM, blood glucose monitoring; CGM, continuous glucose monitoring; SMBG, self-monitoring blood glucose.

Study Design

Before conducting any test exercises, subjects rated their ability to recognize BG results as low, in-range, or high as very easy, easy neither easy nor difficult, difficult, or very difficult to recognize.

Eight exercises were facilitated by administrative site staff using a standardized script. In exercises 1-4 (Figure 1), subjects were tested as to their ability to classify results with or without DCRI and how they would act on these results. First, 25 BG values without DCRI were shown to subjects in random order on a tablet computer. The same 25 values with DCRI were then shown to subjects in a different random order. In each case, subjects evaluated if values were low, near low, in-range, near high, or high. Then, six pairs of low or high BG values were presented with or without DCRI and subjects were asked to select the six screens on which they would be more inclined to act.

In exercises 5-8 (Figure 2), the propensity of subjects to take specific actions based on meter displays and the ability to estimate results in ranges with and without DCRI was investigated. Subjects were asked to review a card showing eight screens with a variety of "high" BG messages and to imagine they received these messages during that week. Subjects were then asked to select on the tablet computer any actions (or none) they would have taken based on this information that they would *not* have taken with their current glucose meter (Table 2). Different lists of five actions were shown depending on whether the subject was an insulin- or non-insulin-user. Similarly, a card showing eight screens with a variety of "low" BG-related messages was also shown. Next, subjects reviewed, without time constraint, a card showing multiple results without DCRI to evaluate how well they could estimate what percentage of results were low, in-range, or high. Three sliders on the tablet computer allowed subjects to select a

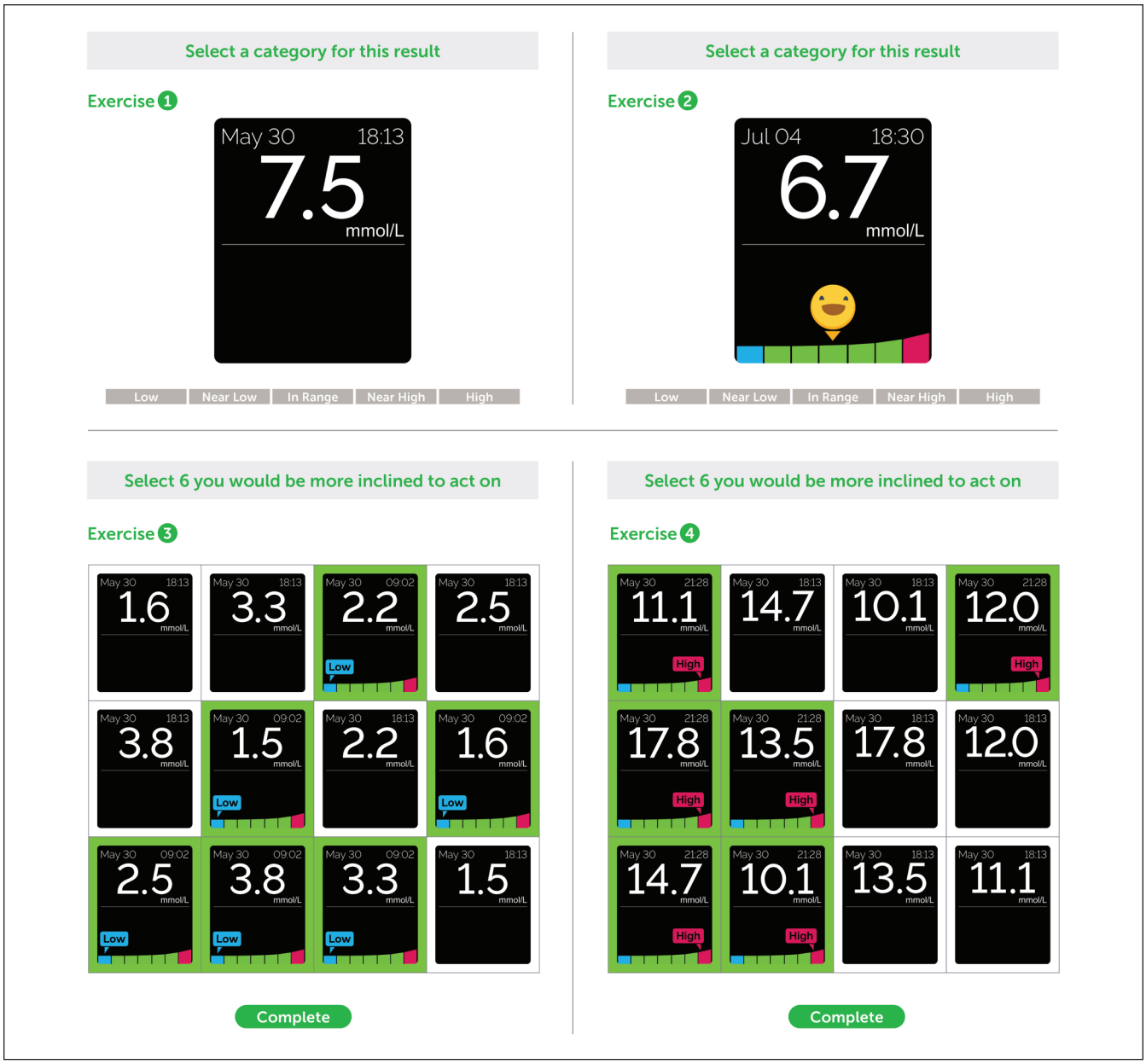

Figure 1. Classifying blood glucose (BG) results and taking action. Exercise 1: 25 BG values in black and white were shown to subjects in random order on a tablet computer and asked if each value was low, near low, in-range, near high, or high glucose values. Exercise 2: The same 25 BG values were shown in random order in association with a dynamic color range indicator (DCRI) and subjects were again asked to decide if values was low, near low, in-range, near high, or high glucose values. Exercise 3: Six pairs of low BG values were presented on a tablet computer in random order. Subjects were asked to click on the six screens showing the value on which they would be more inclined to take action. Exercise 4: A similar exercise was then conducted using six pairs of high BG values in random order. ($n = 133$ for each exercise).

percentage for each range with the total automatically equaling 100%. Lastly, subjects repeated the same methodology on values with DCRI.

After finishing these exercises with unbranded screens, subjects viewed branded animations of the OneTouch Reflect BG meter and answered a series of survey questions (Table 3) regarding features of the product.

Statistical Analyses

Continuous demographic variables were described as median and range or mean and standard deviation. Categorical demographic variables were described as percentages within categories. Test score changes were calculated as the percentage change from baseline. The null

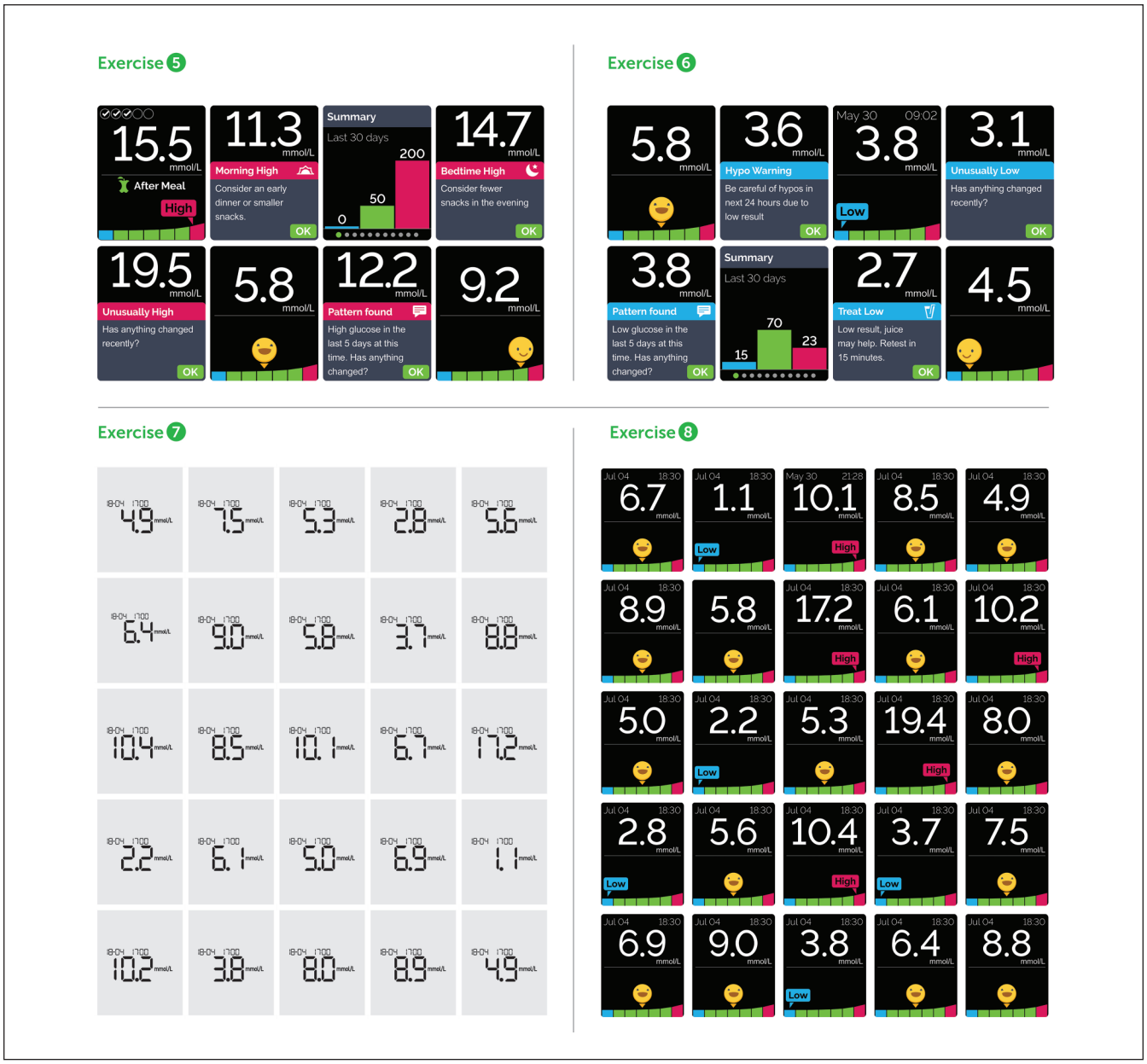

Figure 2. Taking action based on meter messages and estimating glucose range values. Exercise 5: Subjects were presented a card showing "high" blood glucose (BG)-related messages. Subjects were asked to select any actions (or none) they would have taken based on this information that they would not have ordinarily taken with their current meter. Exercise 6: Subjects were presented a card showing "low" BG-related messages. Subjects were again asked to select any actions (or none) they would have taken based on this information that they would not have ordinarily taken with their current meter. Exercise 7: Subjects were asked to review, with no time constraint, a card showing multiple results without dynamic color range indicator (DCRI) to evaluate how well they could estimate what percentage of results were low, in-range or high. Exercise 8: Subjects were then asked to review in a similar manner a card showing multiple results with DCRI and asked to estimate the percentage of results were low, in range or high. ($n = 133$ for each exercise).

hypothesis "H_0: Pre-score = post-score" was tested using a paired t test with significance level $\alpha = 0.05$. Correlations with A1c and other variables were assessed using the Pearson correlation coefficient and were deemed significant with P value $<.05$. Minitab 16.1.1 and SPSS 21.0 were used for all analyses.

Results

Prior to conducting any exercises, 87.2% of subjects said they could easily or very easily recognize low or high BG results and 80.4% said they could easily or very easily recognize in-range results when performing SMBG (Figure 3).

Table 2. Propensity to Take Specific Actions Based on Meter Displays.

Insulin-using subjects: ($n = 112$)	
Actions they would take for HIGH RESULTS after viewing meter information	
a) Adjust insulin dose	71%
b) Consider changing my snacks	58%
c) Consider exercise to tackle highs	38%
d) Talk to nurse or doctor about my high sugars	32%
e) Adjust timing of my insulin injection	29%
Actions they would take for LOW RESULTS after viewing meter information	
a) Test my sugars more, especially at these times of day when lows are happening.	71%
b) Try to react a bit sooner to feeling low by taking a small snack.	68%
c) Think about my exercise routine or food intake and make small changes to reduce lows	53%
d) Ask nurse or doctor about my insulin dosing or timing and make any changes to reduce lows.	45%
e) Talk to nurse or doctor about my low sugars	38%
Non-insulin-using subjects ($n = 21$)	
Actions they would have taken for HIGH RESULTS after viewing meter information	
a) Consider changing my snacks	67%
b) Talk to nurse or doctor about my high sugars	57%
c) Think about when highs happen and try to focus on reducing them in the future	43%
d) Consider exercise to tackle highs	29%
e) Ask nurse or doctor about my pills for reducing highs	24%
Actions they would have taken for LOW RESULTS after viewing meter information	
a) Test my sugars more, especially at these times of day when lows are happening	71%
b) Try to react a bit sooner to feeling low by taking a small snack	67%
c) Ask nurse or doctor about my medications and any changes to reduce lows	57%
d) Think about my exercise routine or food intake and make small changes to reduce lows	52%
e) Talk to nurse or doctor about my low sugars	29%

Note. Subjects were presented with a card showing eight screens with a variety of high or low blood glucose-related messages as described in the text and shown in Figure 2. Subjects selected those actions they would have taken based on this information they would *not* have taken if using their current blood glucose meter. Subjects could choose more than one response or no response. All responses are significantly greater than 0 ($P < .05$).

Less than 5% (low results), 8% (high results), and 7% (in-range results) said these BG results were difficult or very difficult to recognize.

After using the DCRI tool, subjects on average significantly improved their ability to correctly classify readings by 26.0% ± 4.2% (all subjects); 22.0% ± 4.8% (T1D subjects); and 29.3% ± 6.5% (T2D subjects) (all $P < .001$ [Figure 4]). Notably, subjects with lower than median numeracy exhibited similar improvement in successfully classifying results as subjects with higher than median numeracy (29% vs 23%, respectively). When identical low results were shown with and without DCRI, there was a significant increase in subjects willing to act on results with DCRI (68%) compared to without DCRI (32%) ($P < .001$) regardless of whether subjects had T1D or T2D (Figure 5). Similar results were seen for high BG values, with 66% of subjects willing to act on high BG results with DCRI compared to 34% without DCRI ($P < .001$ [Figure 5]), again regardless of whether subjects had T1D or T2D.

When subjects were asked to consider whether they would be more likely to take specific actions if they received new meter information, 71% of insulin-using subjects ranked "adjusting insulin dose" as a top high result action they would *not* have taken based on their current meter (Table 2). For non-insulin subjects, the top response was "consider changing their snacks" (67%). Seventy one percent of insulin- and non-insulin subjects ranked "testing my sugars more" as their top low result diabetes management response they would *not* have taken based on their current meter (Table 2).

When subjects reviewed a grid of 25 BG results shown with DCRI, they were more successful (57%) at correctly identifying low, in-range, and high results in comparison to a grid of BG results without DCRI (26%) (Figure 6). This benefit was apparent whether subjects had T1D or T2D. Interestingly, a statistically higher ($P < .001$) percentage of subjects with T1D correctly identified the ranges with and without DCRI (68% vs 32%, respectively) compared to T2D subjects (48% vs 21%, respectively).

When subjects were presented animations of the OneTouch Reflect meter to demonstrate meter features, a high percentage of subjects with T1 and T2D had favorable responses to survey statements regarding meter features (Table 3).

Table 3. Subject Acceptance Survey.

	All ($n=133$)	T1D ($n=60$)	T2D ($n=73$)
With Reflect and its Trend90 3-month blood sugar average, I will be more prepared for my doctor appointment because I will know where I stand.	90%	83%	95%
I feel safe using Reflect because it will alert me when I am near a high or a low reading on my meter and automatically send it to my smartphone, so I will be more aware of the need to take action.	89%	88%	89%
I will know if my actions are working with the enhanced blue, green, red ColorSure™ Dynamic Range Indicator that shows if I am in, out of range or near a high or low, and can see that information directly on my smartphone.	88%	85%	90%
Reflect will provide me with greater understanding and guidance in managing my blood sugar so I can confidently make progress.	88%	82%	93%
I feel more encouraged, because I can see my progress over time at-a-glance, right on my smartphone.	88%	87%	89%
Reflect will help me identify patterns in my blood sugar I never spotted before, so I can take action to improve my results.	87%	82%	92%
I believe Reflect's Blood Sugar Mentor can help me be more proactive in managing my glucose levels.	87%	82%	90%
Reflect will help me feel in control because it gives me what I need to head off highs and lows before they happen.	85%	80%	86%
Reflect makes knowing how I'm doing today and over time easier compared to other blood glucose meters I've used, so I can spend more time doing what I want to do.	85%	83%	86%
Reflect could help me make healthier blood sugar habits second nature, by providing ongoing guidance and reinforcement of my doctor's advice every time I test.	84%	80%	86%
I prefer Reflect to just a meter, because I am more confident in knowing if I need to take action to prevent a low or a high.	84%	80%	86%
Reflect will make me feel more secure on a daily basis than using my previous meter, because Reflect will alert me when I am near a high or low reading so I can take action to avoid it.	83%	77%	88%
With Reflect, I will have a better understanding of what causes my blood sugar levels to fluctuate, so I could better control them.	83%	73%	90%
Reflect will make me feel more secure on a daily basis than using my previous meter, because Reflect will alert me when I am near a high or low reading and provide suggestions on how I can avoid it.	82%	77%	86%
With the Blood Sugar Mentor on the Reflect, I will be better able to understand what my numbers mean and to take the appropriate action, than using my previous meter.	80%	70%	88%
The advice from the Blood Sugar Mentor will lead to a change in my behaviors so I can make progress managing my blood sugar levels.	79%	72%	85%
I feel more motivated to improve my blood sugar levels when using Reflect.	79%	73%	84%
With Reflect, I will feel more confident in knowing how to deal with blood glucose excursions the way my HCP recommends.	77%	68%	85%
With Reflect, I will have a better understanding of what causes hypo or hyperglycemia than with any other meter I have used.	75%	58%	89%

Note. Percentages shown are favorable responses defined as a response of strongly agree or agree on a five-point scale (5 = strongly agree; 4 = agree; 3 = neither agree nor disagree; 2 = disagree; and 1 = strongly disagree). All responses are statistically significant ($P<.05$).
Blood Sugar Mentor, a series of on-screen meter content that delivers timely and relevant context and guidance to the patient based on self-monitoring data; ColorSure Dynamic Range Indicator, displays five in-range glucose result segments including near low, mid-range, and near high; Reflect, One Touch Reflect blood glucose meter; Trend90, rolling 90-day blood glucose average.

Discussion

People with diabetes believe they can easily identify low, high, and in-range glucose values, but evidence shows that they need to improve their ability to interpret BG information and know what to do with this information. Even in the current study, over 80% of subjects felt they could easily or very easily interpret BG values. However, this study demonstrated that subjects were consistently less competent at identifying BG ranges with results that did not utilize a CRI. These results are similar to a recent study in which use of Contour Next One glucometer, which uses a color range indicator, improved glucose monitoring satisfaction survey scores.[9]

Interestingly, a large proportion of the subjects in the current study had been using a Roche Accu-Check meter which does provide context to glucose information. However, these subjects did not perform any more successfully in this study than subjects using other meters. Furthermore, the 14 patients in the current study who previously were using CGM and who arguably might be

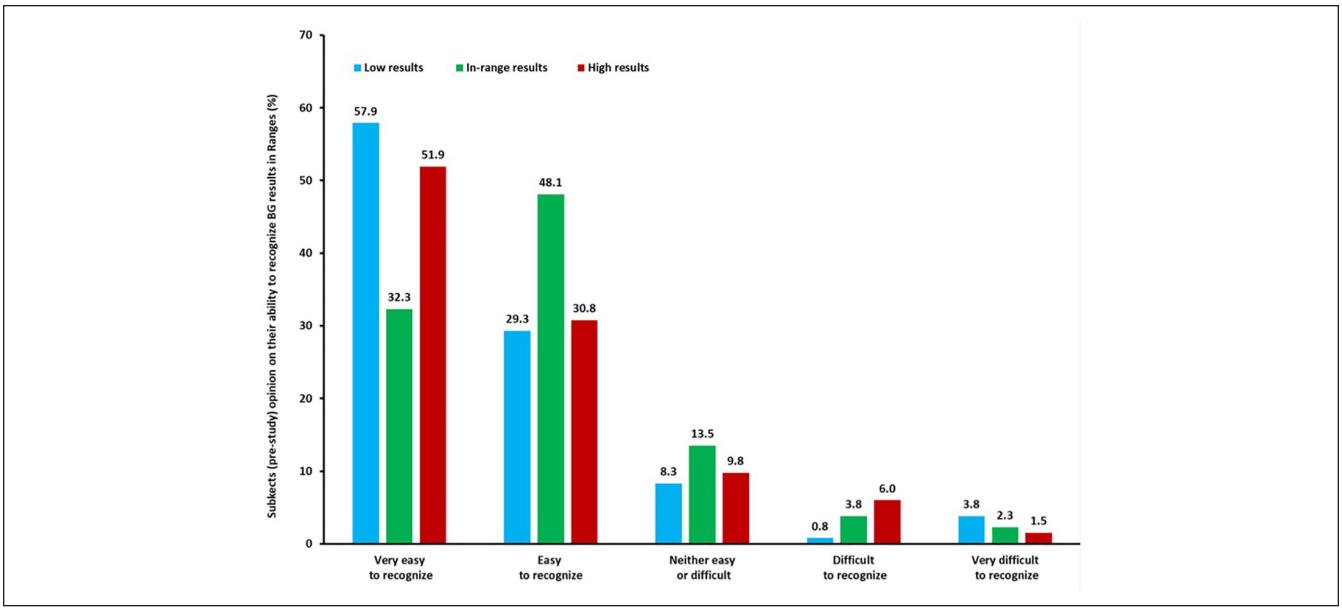

Figure 3. Baseline perceptions of patients on their ability to recognize blood glucose (BG) results. One hundred and thirty three subjects were asked to rate their ability to identify BG results as low, in-range, or high using the categories.

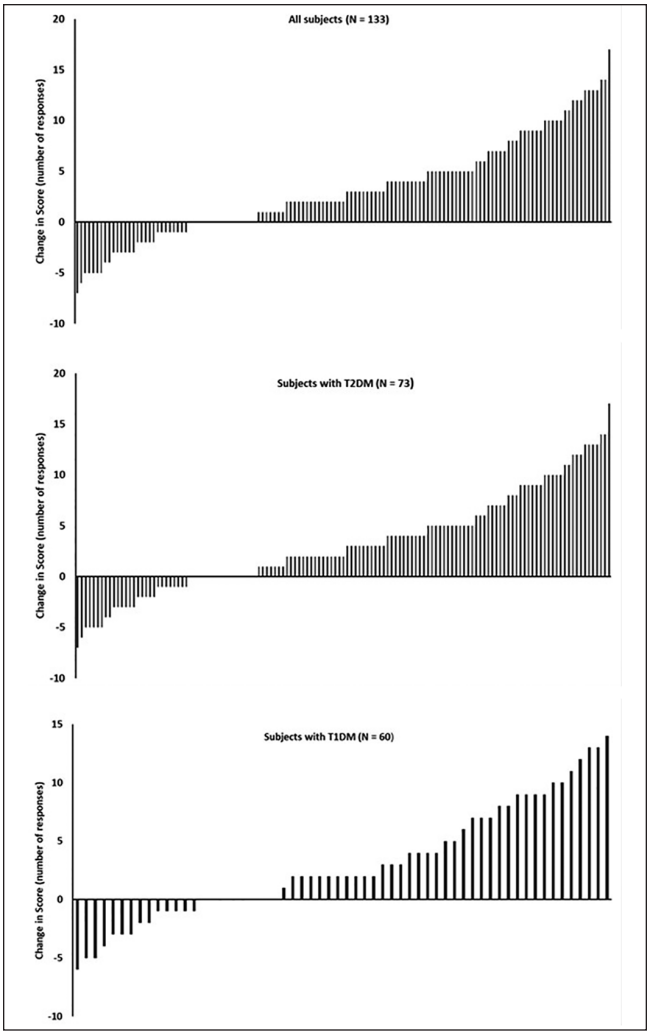

Figure 4. *(continued)*

Figure 4. Classifying results with or without a dynamic color range indicator (DCRI)—133 subjects conducted Exercises 1 and 2 as described in the text and shown in Figure 1. Each bar represents an individual subject's change in correct responses after being shown blood glucose values using a DCRI. Seventeen of 133 subjects had no change in correct responses. Individual results are also shown for subjects with type 2 ($n = 73$) and type 1 diabetes ($n = 60$).

expected to have greater insight or knowledge concerning data interpretation, did not perform more successfully in exercises than subjects using SMBG only. Admittedly, this is a small sample, but it highlights the importance of addressing patient deficiencies in data comprehension and knowledge before advancing patients to CGM. Moreover, data from a large registry database indicate that glycemic control has not improved significantly in US patients simply by advancing to CGM.[4]

In the current study, no prior explanation, training, or introduction on the DCRI were provided to participants. Subjects appeared to intuitively grasp this new way of presenting data whether they self-reported high or low numeracy, and responded positively to the insights provided. Similarly, a previous study evaluating a simple three-color CRI found no correlation between numeracy scores and the ability of patients with T1D or T2D to classify BG results into glucose ranges.[5] A novel aspect of the DCRI is that it allows definition of a glucose result as either "near low" or "near high" with an emoji glancing in the direction of below or above range segments, to allow patients to consider taking action before they become low or high, or simply permit reflection on why "near low" or "near high" results occurred. In surveys, 88% of subjects "felt safe using this new meter because it will alert me

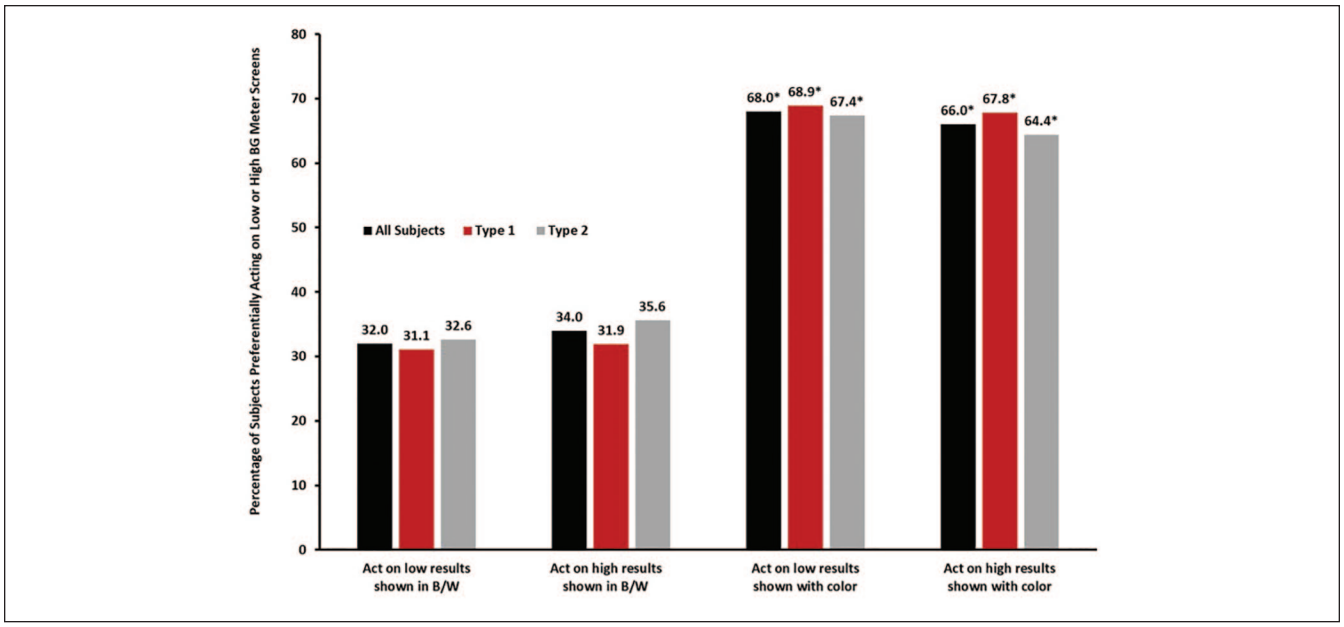

Figure 5. Willingness to act upon identical results shown with or without a color range indicator. Each bar represents the mean percentage of subjects who would act on the blood glucose results shown in Exercises 3 and 4 as described in the text and shown in Figure 1. *Significantly different than blood glucose results shown in black and white (b/w) ($P < .001$). $n = 133$ (all subjects), $n = 60$ (type 1), $n = 73$ (type 2).

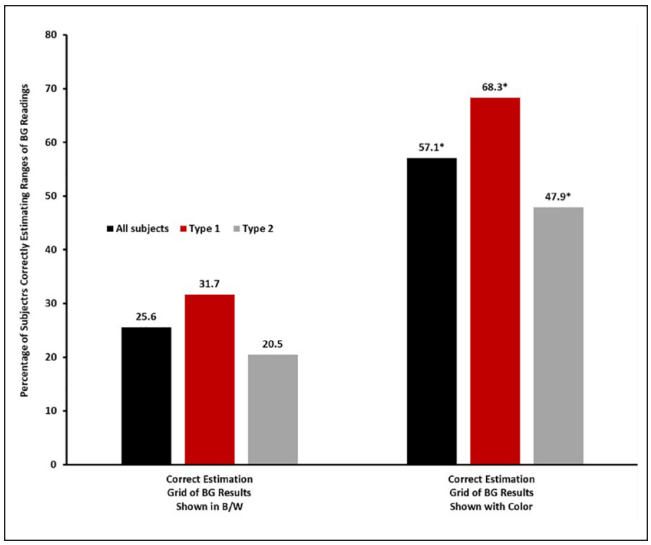

Figure 6. Estimation of blood glucose (BG) results within glucose ranges. Ability of subjects to estimate percentages of results that were low, in-range, or high with or without a dynamic color range indicator (DCRI) in Exercises 7 and 8 as described in the text and shown in Figure 2. Each bar represents the mean of correct estimation. *Significantly different than BG results shown in black and white (b/w) ($P < .001$). $n = 133$ (all subjects), $n = 60$ (type 1), $n = 73$ (type 2).

when I am near a high or a low reading on my meter" supporting the view that patients may gravitate quickly to this new meter feature.

The variety of BSM guidance, support, and advice screens offered in the new meter were also well received by subjects. Without prior explanation or training before evaluating the screens, subjects said they would be inclined to take additional actions they would not have otherwise taken based on how their current meter presents information. This is similar to the response of patients in a previous study in which they expressed satisfaction with the meter features after a one-week home trial period.[10] Although this experiential design does not prove that patients would react to this extent during extended use, it does provide the basis for potential positive behavioral changes beyond what patients do presently when using meters that do not provide automatic guidance or advice messages in real time. In addition, strong support for the features of the meter was expressed by 355 HCPs including endocrinologists, nurses, and primary care doctors across seven countries.[11]

In summary, interaction with a DCRI and BSM screens present in a new BG meter improved the ability of people with T1D and T2D to interpret results and make diabetes management decisions. The beneficial insights and actions expressed by subjects in this study may translate into behavioral changes that could result in improved glycemic control and diabetes management in real-world situations.

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Declaration of Conflicting Interests

The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: MG and HC are employees of LifeScan Scotland, Ltd. LK is an employee of LifeScan Global Corporation.

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