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Abstract

The increase in gestational diabetes mellitus (GDM) is challenging maternity services. We have developed an interactive, smartphone-based, remote blood glucose (BG) monitoring system, GDM-health. The objective was to determine women's satisfaction with using the GDM-health system and their attitudes toward their diabetes care. In a service development program involving 52 pregnant women (September 2012 to June 2013), BG was monitored using GDM-health from diagnosis until delivery. Following birth, women completed a structured questionnaire assessing (1) general satisfaction, (2) equipment issues, and (3) relationship with the diabetes care team. Responses were scored on a 7-point Likert-type scale. Reliability and validity of the questionnaire were assessed using statistical methods. Of 52 women, 49 completed the questionnaire; 32 had glucose tolerance test confirmed GDM (gestation at recruitment 29 ± 4 weeks (mean \pm SD), and 17 women previous GDM recommended for BG monitoring (18 ± 6 weeks). In all, 45 of 49 women agreed their care was satisfactory and the best for them, 47 of 49 and 43 of 49 agreed the equipment was convenient and reliable respectively, 42 of 49 agreed GDM-health fitted into their lifestyle, and 46 of 49 agreed they had a good relationship with their care team. Written comments supported these findings, with very positive reactions from the majority of women. Cronbach's alpha was .89 with factor analysis corresponding with question thematic trends. This pilot demonstrates that GDM-health is acceptable and convenient for a large proportion of women. Effects on clinical and economic outcomes are currently under investigation in a randomized trial (clinicaltrials.gov NCT01916694).

Keywords

blood glucose monitoring, gestational diabetes, mobile phone, pregnant women, qualitative research, satisfaction.

In women with gestational diabetes mellitus (GDM), evidence supports tight blood glucose (BG) regulation to prevent adverse maternal and fetal outcomes.¹ Finger-prick BG monitoring remains the recommended method of assessing glycemic control.² With changes to GDM screening and sociodemographics, such as increasing numbers of overweight and obese pregnant women, the number of women with GDM is predicted to rise.³

Pregnant women with GDM represent a clinical challenge. The time period between diagnosis and delivery of the baby is short (typically 8-10 weeks), and women's understanding about diabetes, dietary intake, and BG monitoring is often limited. Combined with changing pregnancy physiology, these patients require frequent antenatal outpatient

review with often several medication dosage adjustments before delivery.

Several studies have evaluated telehealth solutions for women with GDM.⁴⁻⁸ Most were at a small scale, utilizing now superseded technologies. It is hypothesized that

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telehealth solutions could improve the quality and efficiency of care, yet none have demonstrated superior clinical results compared to standard care.⁹ It has been suggested that the true value of these technologies may be the ability to streamline busy clinical services, reduce costs of care, and improve patient satisfaction.⁹

In response to increasing clinical demand for GDM services, we have developed a novel, automated, interactive, smartphone-app-based BG monitoring system.¹⁰ As part of the introduction of this technology into clinical practice, we sought to measure user feedback on whether pregnant women felt that this system was appropriate for them and their satisfaction with the care they received for their diabetes.

Methods

A service development project was conducted within the Oxford University Hospitals NHS Trust, Oxford, UK. The screening policy for GDM was in line with 2008 NICE recommendations for diabetes in pregnancy.² In women with previous GDM, local practice is to commence home BG monitoring from the second trimester of pregnancy.

This project was aimed at women with GDM not requiring pharmacological therapy after 1 week of BG monitoring, diagnosed prior to 34 weeks gestation, with singleton, otherwise uncomplicated pregnancies who could communicate in English. It was felt these women were likely the most suitable for a future care model incorporating GDM-health. A member of the research team approached all women meeting these criteria in the pregnancy and diabetes clinic. Participation was voluntary and nonremunerated. If a woman agreed to participate, she was asked to perform all BG monitoring and communication with the team between clinic appointments using the GDM-health system, rather than standard paper-based monitoring and phone calls (as required) to the midwife.

The development and technical aspects of the GDM-health system have been described in detail previously.¹⁰ Briefly, a Bluetooth-enabled BG meter (Polymap Glucose meter accessory with Lifescan UltraEasy meter) automatically transmitted finger-prick BG readings performed at home by the women to a smartphone running a custom-written app. Women could then attach a label to BG readings detailing relation to meals and if medication was taken. The reading automatically transmitted via the 3G network to a secure website hosted within the NHS. The website was reviewed at least 3 times a week by a diabetes midwife or physician. If required, the diabetes midwife contacted the women via SMS (sent through the website) or a phone call. Communication was 2-way, with women able to signal they would like to speak to the diabetes midwife. For the purposes of the service development activity, all equipment, including HTC Desire C Smartphone (Android OS 4.1) and prepaid SIM card, was loaned to the women.

Satisfaction with using the system was assessed through a structured questionnaire completed by women within 4 weeks following the birth of their baby. We developed the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (OMDTSQ) for this purpose. This comprised 9 questions designed to assess general satisfaction with diabetes care, the acceptability and reliability of the technology, and the perceived relationship with the diabetes care team (Table 1). Women were asked to score their agreement with statements on a 7-point Likert-type scale, ranging from +3 (*strongly agree*) to -3 (*strongly disagree*). The OMDTSQ was plainly worded in English. At the end of the questions, women were encouraged to write free text responses to provide any other feedback or suggestions.

Prior to developing the OMDTSQ, we reviewed preexisting survey tools for measuring satisfaction with diabetes care.^{11,12} Unfortunately none of the tools identified had the required focus on perceptions of technology, nor addressed issues specific for women with gestational diabetes. It was theorized that while the technology may be acceptable to many women, it had the potential to disrupt customary human interactions valued by women as part of antenatal care. Thus a novel, short questionnaire was developed and validated. This was achieved first by consulting other questionnaire designs and formats. We then identified key areas of interest to pregnant women through a focus group with the first 7 women to use the system. The OMDTSQ was then reviewed and discussed with clinicians working in the maternity diabetes clinic to ensure content validity, that is, that the important care aspects to be measured would be captured through the questions. Criterion validity was assessed through agreement of scored questions with free text responses at the end of the questionnaire. Further validation of the OMDTSQ was assessed through factor analysis of the responses. This assesses the thematic consistency of the scores for questions that addressed similar domains. Reliability (internal consistency in overall results) was assessed with Cronbach's alpha, a score of $>.8$ considered as good measure reliability. All calculations were performed using SPSS 21.0.

This study was conducted as a service development project as part of the routine clinical care service provided and therefore was exempt from requiring ethical review.

Results

From June 2012 until August 2013, 106 women were diagnosed with GDM. Of these, 59 met the criteria to participate in the project, with 52 women agreeing to use the GDM-health system. Of these, 48 used the system until delivery (92%). In all, 49 women completed the OMDTSQ. Of the women who agreed to use the system, 40% were nulliparous and 69% identified as white British. Body mass index (BMI) ranged from 20 to 55 kg/m² (median 31.5, SD 8.9).

Table 1. Questions and Responses to the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire.

	Strongly disagree/ disagree (Likert-type score -3 or -2)	Mildly disagree (-1)	Neutral (0)	Mildly agree (+1)	Agree (+2)	Strongly agree (+3)
Women's overall satisfaction with gestational diabetes care						
I am satisfied with my current treatment	0	0	1	3	11	34
I am satisfied the treatment I am receiving is the best for me	0	0	1	3	7	38
I am satisfied with my understanding of diabetes	0	0	1	3	10	35
Relationship with the diabetes clinical care team						
I feel my maternity diabetes team knows enough about my current level of diabetes control	0	0	2	2	11	34
I feel I have a good relationship with my maternity diabetes team	0	1	0	1	7	40
I am satisfied with my maternity diabetes team's understanding of my diabetes	0	0	1	3	10	35
Satisfaction with the GDM-health system						
I find the equipment I use to check my blood sugars is convenient	0	1	0	1	7	40
I feel the equipment I use to check my blood sugars is reliable	0	1	2	3	10	33
My blood sugar monitoring fits in with my lifestyle	0	1	1	5	17	25

There were 32 women with new diagnoses of GDM, (mean age 34.8 years, SD 5.2) with mean gestation at recruitment of 29 ± 4 weeks (mean \pm SD). For the remaining 17 women with previous GDM (mean age 30.4 years, SD 4.3), mean gestation at recruitment was 18 ± 6 weeks. Prescribed treatments by the time of delivery were diet only (new GDM 21% and previous GDM 24%), metformin (new GDM 43% and previous GDM 47%), insulin (new GDM 57% and previous GDM 41%), with some women requiring both insulin and metformin. Overall, responses to the questionnaire were favorable, with no women scoring any question with the most negative scores, *strongly disagree* (-3) or *disagree* (-2).

The responses to the OMDTSQ indicated that women were very satisfied with their care. Table 1 shows the breakdown of scores for each question. No women rated their satisfaction with care negatively, with 3 neutral (0) scores given. Written comments supported the scores given. Women particularly appreciated the system if they lived far from the hospital or had other children or care commitments. Typical comments included these:

The phone is an excellent way of monitoring blood glucose and very easy to use. (patient 33)

I am amazed with the technology and it suited me much better than having to travel in a lot and wait, especially with little ones. (patient 10)

When asked specifically about the technology, the majority agreed or strongly agreed that it was convenient, with 1 woman giving a negative score (-1, slightly disagreeing that the technology was convenient). While 48 of 49 women agreed with the statement that the equipment was reliable, 4 women provided written comments that they had problems transferring results automatically via the 3G network, due to poor local network coverage. This led 1 woman discontinuing using the system.

The relationship with the diabetes team was rated very highly overall, with 1 negative score (-1) and 3 neutral (0) scores. Comments supported these scores, indicating women felt very supported using the app, with good understanding of their diabetes, and had a positive relationship with the maternity diabetes team, particularly the diabetes midwife.

There was a high degree of reliability in the responses given by the women (Cronbach's alpha .87). Factor analysis of the OMDTSQ resulted in 2 main factors, which corresponded exactly to the items related to satisfaction (54.5% of variance) and attitudes toward the BG monitoring technology (11.8% of variance).

Discussion

This qualitative study has demonstrated that women with GDM found remote BG management using an interactive

smartphone system acceptable and convenient. They also stated they felt well supported and were very satisfied with their care. Based on the feedback provided by the women in the free text comments, the system was modified to enable patients to edit meal tags, and issues of connectivity addressed by enabling women to use their own home Wi-Fi connections if they live in areas lacking 3G coverage. As SIM cards were provided in this study from 1 mobile phone network, using the woman's personal smartphone may avoid this problem if the technology were to be scaled up in the future.

Smartphone apps are increasingly widely used in diabetes self-management. A systematic review published in 2013 identified 87 English language apps, 2 specifically for women with GDM.¹³ A systematic review of IT technologies to promote self management of all types of diabetes concluded that to promote compliance and satisfaction, the design of the technology must be user-centered.¹⁴ This assessment of maternal satisfaction with GDM-health has allowed continued development of the system to ensure it is meeting the needs of the users.

Our findings are in keeping with theoretical constructs on the adoption of new technology. The technology acceptance model emphasizes that perceived ease of use and perceived usefulness are key actions in ongoing use of technology.¹⁵ In this study women indicated that they found the technology a useful adjunct to help control their diabetes and the majority reported the system was convenient and reliable.

The strengths of this project are the high completion rate of the questionnaires (94%) and assessment of the technology under routine operational conditions within the multidisciplinary diabetes in pregnancy service. The OMDTSQ demonstrated good reliability and validity, although owing to the small sample size, these measures need confirmation in larger studies. A further limitation of the study is the use of only 1 tool for the measurement of satisfaction (structured questionnaire), although written comments by the women were highly congruent with their scoring of corresponding items (data not shown).

The size of this service development project was small, and hence these encouraging results need confirmation in a larger clinical study. As participation was voluntary, it is possible these women may have been more able or motivated to use the smart phone than other women attending the service. In 2013 it was estimated that 72% of UK consumers owned a smartphone,¹⁵ making it likely that mobile phone literacy amongst this patient group is high.

Conclusion

Integrating an app into the antenatal care pathway for GDM has the potential to promote patient satisfaction with care. Robust clinical, economic and satisfaction evaluations are needed before they can be supported as an adjunct to routine care. An RCT is currently underway assessing these outcomes (clinicaltrials.gov NCT01916694). Scalability, sustainability,

and data security for routine clinical data collection need to be considered if digital health is to become part of routine clinical care. Developing innovative patient-centered approaches to care will hopefully enable pregnant women to understand and better control their diabetes.

Abbreviations

BG, blood glucose; GDM, gestational diabetes mellitus; NICE, National Institute for Clinical Excellence; NHS, National Health Service; OMDTSQ, Oxford Maternity Diabetes Treatment and Satisfaction Questionnaire.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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