Technoleg Iechyd Cymru
Health Technology Wales

HEALTH TECHNOLOGY WALES (HTW) EVIDENCE SUMMARY 018 (May 2020)

Remote blood glucose monitoring in women with gestational diabetes

HTW Assessment Group decision

HTW undertook an evidence review to address the following question: what is the clinical and cost effectiveness of remotely monitoring blood glucose compared to usual (clinic-based) care in women with gestational diabetes?

The evidence identified was judged to be of limited applicability to decision makers, primarily due to a lack of sufficient evidence on how remote blood glucose monitoring affects outcomes deemed of most importance.

The HTW Assessment Group concluded that there is currently insufficient evidence on remote blood glucose monitoring to inform the production of Guidance at this time. Therefore, this topic will not progress to Appraisal Panel and will not receive HTW Guidance recommendations.

Why did HTW appraise this topic?

Gestational diabetes is a type of diabetes that is diagnosed during pregnancy, where the women did not previously have known diabetes. Diabetes during pregnancy is associated with an increased risk of morbidity and mortality, and poorer maternal and foetal outcomes compared to pregnant women who do not have diabetes. Methods for monitoring blood glucose in pregnant women with gestational diabetes can vary, but usually involve the woman self-monitoring at home using a blood glucose meter ('finger-prick test') and recording results in a diary or logbook. This is then reviewed by a healthcare professional at each clinic appointment.

Remote blood glucose monitoring is an alternative method of recording and monitoring blood glucose. This review focussed on technologies that automatically collect blood glucose readings from the pregnant woman's blood glucose meter at home and sends this information (either immediately or periodically) to a healthcare professional for review.

Evidence Summary

HTW identified three randomised controlled studies that reported the effectiveness of using remote blood glucose monitoring in gestational diabetes. Two studies used mobile phone app-based systems (only one of which is currently available in the UK: GDm-Health) and the third used a telemedicine hub that was installed in the pregnant woman's home. The timing and frequency of blood glucose monitoring varied in each study and two of the studies were over three years old and due to the type of technology used, may therefore be of limited relevance in current practice.

The studies did not report any difference in the majority of clinical outcomes between women using remote blood glucose monitoring and those using standard care, although some evidence suggested that women using remote blood glucose monitoring may be less likely to require a caesarean section. None of the studies reported on the reduction in clinic attendance as an outcome: two studies were not designed to include the outcome and one was not able to report on the outcome due to booking errors (both arms continued to attend the same number of clinics).

One of the studies included economic evidence and reported a lower mean cost for each delivery for the GDm-Health app. However, this difference was not statistically significant. HTW produced a resource impact analysis showed that the overall impact of the GDm-Health app was highly dependent on the assumptions around downstream cost savings. This uncertainty makes it difficult to know whether the introduction of GDm-Health would lead to a net cost increase or cost savings.

Evidence Appraisal Report 018 follows, and gives a full report of the evidence on this topic.

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Health Technology Wales

Evidence Appraisal Report

Remote blood glucose monitoring in women with gestational diabetes

1. Purpose of the evidence appraisal report

This report aims to identify and summarise evidence that addresses the following question: In women with gestational diabetes, what is the clinical and cost effectiveness of remotely monitoring blood glucose compared to usual (clinic-based) care?

Evidence Appraisal Reports are based on rapid systematic literature searches, with the aim of identifying the most reliable clinical and economic evidence on health technologies. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales multidisciplinary advisory groups before publication.

2. Health problem

Diabetes mellitus refers to a group of common metabolic disorders that share the characteristic of hyperglycaemia. Diabetes mellitus can be classified into the following general categories:

- Type 1 diabetes: due to autoimmune beta-cell destruction, usually leading to absolute insulin deficiency;
- Type 2 diabetes: due to a progressive loss of beta-cell insulin secretion, frequently on the background of insulin resistance;
- Gestational diabetes mellitus: diabetes diagnosed in the second or third trimester of pregnancy that was not clearly overt diabetes prior to gestation;
- Specific types of diabetes due to other causes, e.g., monogenic diabetes syndromes (such as neonatal diabetes and maturity-onset diabetes of the young), diseases of the exocrine pancreas (such as cystic fibrosis and pancreatitis), and drug- or chemical-induced diabetes (such as with glucocorticoid use, in the treatment of HIV/AIDS, or after organ transplantation) (EUnetHTA 2018).

Women with diabetes of any kind are at increased risk of morbidity and mortality during pregnancy. Poor glycaemic control, in particular hyperglycaemia, is strongly associated with increased risk of miscarriage or severe congenital malformations in early pregnancy. After 12 weeks gestation, hyperglycaemia in women with diabetes also induces fetal hyperinsulinaemia, accelerated growth, and excess adiposity. Intensified glycaemic control minimises macrosomia and other neonatal complications (Jones et al. 2019).

The majority of pregnancies that are affected by diabetes are due to gestational diabetes. The prevalence of gestational diabetes in the UK is difficult to estimate and is subject to regional

variation, but the average prevalence in England and Wales is estimated to be 3.5% of all pregnancies (NICE 2015). The Patient Episode Database for Wales (PEDW) dataset recorded 1,219 cases of gestational diabetes in Wales for the year 2017/2018 (NHS Wales Informatics Service 2018).

The most well-established method of monitoring blood glucose during pregnancy is to test capillary glucose using a blood glucose meter (self-monitoring of blood glucose, or SMBG). The NICE Guideline *Diabetes in pregnancy: management from preconception to the postnatal period* (NG3) advises that pregnant women with type 2 diabetes or gestational diabetes should test their fasting and 1-hour post-meal blood glucose levels daily during pregnancy. Individualised targets for self-monitoring of blood glucose should be agreed with women with diabetes in pregnancy, taking into account the risk of hypoglycaemia (NICE 2015).

Protocols for monitoring blood glucose and following-up women with gestational diabetes vary locally. They typically involve women recording blood glucose values from their glucose meter in a diary or logbook, which is then taken to each clinic appointment and reviewed by healthcare professionals. Some glucose meters also allow periodic direct download of blood glucose data. A 2013 systematic review of observational studies found notable discrepancies between patient-generated blood glucose diary records and actual glucose meter data, due to issues such as missing data or transcription errors (Given et al. 2013). In a recent UK service evaluation of diabetes care in pregnancy, only 59.3% of women surveyed stated that they completed their blood glucose diary each time they carried out an SMBG test; the remaining women completed their diary at the end of every day, at the end of every week, at weekends or only prior to each clinic visit (Alqudah et al. 2019).

3. Health technology

Remote blood glucose monitoring is an alternative method of recording and monitoring blood glucose data for women with gestational diabetes. This usually involves the use of digital technology by both the women with gestational diabetes and the healthcare professionals involved in their diabetes care. For the purposes of this evidence review, we defined remote blood glucose monitoring as any technology that automatically collects blood glucose readings from a user's blood glucose meter and transmits the readings (either immediately or periodically) to healthcare professionals for review.

A 2019 review of potentially relevant remote blood glucose monitoring technologies (Nikolopoulos et al. 2019) identified a single option available in the UK. GDm-Health consists of two main components:

1. A mobile application (available for Android and iOS smartphones) that connects wirelessly with compatible blood glucose meters and collects blood glucose readings automatically.
2. A secure website where healthcare professionals can review the readings.

Additional information can be added to each blood glucose reading by the women, such as timing of meals and medication relative to the reading. GDm-Health also allows communication between healthcare professionals and the user through SMS text messages, and women can request a callback from a midwife via the system (Hirst et al. 2015, NICE 2017, Nikolopoulos et al. 2019).

NICE previously evaluated GDm-Health as a MedTech Innovation Briefing (MIB131) (NICE 2017). Since this was published in November 2017, additional evidence on the effectiveness of GDm-Health has become available, including evidence from the first randomised controlled trial of this technology (Mackillop et al. 2018).

4. Evidence search methods

We searched for evidence that compared any remote blood glucose monitoring technology to usual care as part of the management of gestational diabetes. We defined remote blood glucose monitoring as any technology that:

- automatically collects blood glucose readings from a user's blood glucose meter, and
- transmits these readings (either immediately or periodically) to healthcare professionals for review.

The detailed criteria used to select evidence for the appraisal are outlined in Appendix 1. The last date of search was 25 February 2020. These criteria were developed following comments from the HTW Assessment Group and UK experts. We also selected any evidence that reported the experiences or perspectives of people (or their carers) with gestational diabetes about using remote blood glucose monitoring to manage gestational diabetes (a separate and more specific PPI literature review was also undertaken; see the Patient Issues section for details).

As detailed in Appendix 1, we prioritised existing systematic reviews or other sources of secondary evidence, such as previous health technology assessments or evidence-base guidelines, as sources of quantitative outcome data. We did not identify relevant secondary evidence, and therefore searched for and included evidence from randomised controlled trials (RCTs) as our main source of outcome data. For specific outcomes where data was not available from RCTs, or the findings were equivocal, we also searched for data from any non-randomised studies. However, we did not identify any evidence from non-randomised trials that added to the findings from the RCTs described in Section 5.

Appendix 2 summarises the selection of articles for inclusion in the review.

Additionally, a separate search for literature on patient experience was undertaken on 6-12 February 2020 with three different inclusion criteria; 1) for the use of remote blood glucose monitoring in women with gestational diabetes, 2) for the use of all forms of blood glucose monitoring including self-monitoring and 3) for living with gestational diabetes. A full list of resources searched and terms used are available on request, as well as the detailed criteria used to select evidence for the appraisal.

5. Clinical effectiveness

We identified three RCTs that reported the effectiveness of using remote blood glucose monitoring in women with gestational diabetes. Two studies (Mackillop et al. 2018, Perez-Ferre et al. 2010) used mobile phone app-based systems to record and transmit blood glucose readings. The third study (Given et al. 2015) used a telemedicine hub installed in the patients' homes to both measure and transmit blood glucose: use of a system like this may be less relevant to current clinical practice. Only the study by Mackillop reported use of an app (GDm-Health) and software that is currently available in the UK (the study by Perez-Ferre et al. was conducted in Spain and did not specify the app used). Detailed descriptions of the interventions used in each study are given in Table 1

All of the studies compared remote blood glucose monitoring to usual care, which involved women testing their blood glucose and recording the results by writing them in a blood glucose diary. The timing and frequency of blood glucose monitoring varied in each trial.

5.1. Clinical outcomes

Clinical outcomes are reported in detail in Table 2. Although several outcomes were reported across different trials, there were notable differences in the types of remote monitoring used by each trial and differences in the background care women received (see Table 1 for details).

Because of these differences, we concluded that pooled analysis of the results would not be appropriate.

For women using remote blood glucose monitoring, Mackillop et al. (2018) reported a significant reduction in the likelihood of caesarean section delivery (odds ratio [OR] 0.43, 95% confidence interval [CI] 0.24 to 0.77). In the other two trials, caesarean section rates were not significantly different. Mackillop et al. (2018) also reported a reduction in the likelihood of pre-term (earlier than 37 weeks) birth although this was not statistically significant (OR 0.36, 95% CI 0.12 to 1.04). Given et al. (2015) and Perez-Ferre et al. (2010) also reported incidence of pre-term delivery, but there were only two pre-term deliveries in each trial, and so meaningful conclusions about this outcome cannot be drawn. No difference in any neonatal outcomes was reported in any of the trials. There was also no evidence of any differences in glycaemic control outcomes based on the type of blood glucose monitoring used.

One trial (Mackillop et al., 2018) reported patient satisfaction with treatment using the Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (for which higher scores indicate greater satisfaction). Scores were statistically significantly greater for the women who used GDm-Health (median scores 43 and 44.5 for the intervention and control groups respectively, $p = 0.049$, maximum possible score: 54). Mackillop et al. (2018) also reported that women using remote blood glucose monitoring were more likely than the control group to record at least 67% of the suggested number of blood glucose readings (OR 2.44, 95% CI 1.29 to 4.61).

Mackillop et al. (2018) intended to measure a difference in the number of clinic attendances between groups. However, follow-up appointments were not always correctly booked based on study allocation (4-week follow-up appointments for patients assigned to GDm-Health; 2-week follow-up appointments for other patients) because the clerical staff who booked these appointments were mostly unaware of the study, resulting in many patients allocated to GDm-Health being seen in clinic more often than intended. In the study by Perez-Ferre et al. (2010), patients were seen at 4-week intervals regardless of intervention, but also given the option to attend for unscheduled clinic appointments. Patients assigned to remote blood glucose monitoring made significantly fewer unscheduled visits, but the small sample size and high risk of bias in this study (see Table 1) means this finding should be interpreted with caution.

Table 1. Randomised controlled trials comparing remote blood glucose monitoring to standard care for women with gestational diabetes

Study reference	Methods, setting	Participants	Interventions	Outcomes	Comments on risks of bias/applicability
Mackillop, 2018	RCT. September 2013 to June 2015. Single centre, United Kingdom	Eligible women were aged between 18 and 45 years, with a viable singleton pregnancy of less than 35 weeks, and had gestational diabetes mellitus diagnosed by 75 g oral glucose tolerance test. Following initial diagnosis, women were instructed to perform preprandial and 1-hour postprandial blood glucose monitoring for one week. If after this initial week they did not require immediate treatment with insulin, they were eligible for inclusion.	All participants were asked to test their blood glucose 6 times a day on at least 3 days of the week, as per local guidelines. All patients tested capillary blood glucose using a LifeScan OneTouch Ultra Mini glucose monitor. Intervention group (n = 101): patients were loaned a mobile phone with the GDm-Health app preinstalled and taught how to record, tag, and review blood glucose readings by a research midwife. Every 4 to 8 weeks they attended the outpatient clinic. A diabetes midwife reviewed the blood glucose readings on a secure website at least three times a week. Alerts were generated by the system if predefined blood glucose thresholds were breached, the participant was not recording a predefined number of blood glucose readings per week, or more glucose testing strips were needed. Text messages containing advice about diet, dose adjustments of hypoglycemic medications, and messages of encouragement were sent to the participant by the diabetes midwife between clinic visits. Control group (n = 102): standard clinical care. Patients were instructed to record their blood glucose values in a paper diary. Every 2 to 4 weeks they attended the outpatient clinic for review. Women were instructed to contact the diabetes midwife if their blood glucose breached predefined thresholds.	• Changes in blood glucose over time • Changes in HbA1c over time • Mean fasting, preprandial, and postprandial blood glucose • Change in patient weight • Incidence of pregnancy-induced hypertension or pre-eclampsia • Birthweight • Proportion of babies large for gestational age • Mode of birth • Incidence of perineal severe trauma • Incidence of neonatal shoulder dystocia • Incidence of birth injury • Incidence of neonatal hypoglycaemia • Incidence of neonatal hyperbilirubinaemia • Rates of admission to neonatal intensive care • Patient satisfaction	No major risks of bias identified. Clinic attendance by patients in the RBGM group was not always carried out according to the protocol: in some cases (number not specified by the authors), patients were booked for routine 2-week follow up appointments (rather than appointments at 4 week intervals as intended) by clerical staff who were unaware of the study.

Study reference	Methods, setting	Participants	Interventions	Outcomes	Comments on risks of bias/applicability
Given, 2015	RCT. January 2012 to May 2013. Two centres, one in Republic of Ireland and one in Northern Ireland	Inclusion criteria: • Diagnosis of GDM or impaired glucose tolerance following an oral glucose tolerance test, usually performed at the gestational Week 24–28 screening appointment • ability to use the telemedicine equipment following training • sufficient communication abilities to be fully involved in the study • willing to use one of the approved blood glucose meters for the duration of the study Exclusion criteria • prior diagnosis of type 1 or type 2 diabetes • receiving oral steroid therapy	Control group (n = 26): usual care. Women were asked to monitor their blood glucose values seven times a day (before and after each meal and before bed). They were also asked to attend a specialist diabetes clinic at least every 2 weeks. At this face-to-face review, weight and blood pressure were measured, urinalysis was performed, and glycaemia was evaluated, using SMBG records and glycated haemoglobin if available. Intervention group (n = 24): usual care plus weekly telemedicine review using a telemedicine hub. In addition to a glucose meter, the telemedicine hub also included a set of scales and a blood pressure monitor. Once a week at a prearranged time the hub would activate and remind participants that it was time for their telemedicine session. Women measured weight and blood pressure and sent the stored blood glucose values for the previous 7 days from the meter to the hub. In addition, they responded to three questions: • ''Have you been taking your insulin?,'' • ''Have you had any hypoglycaemic episodes?,'' and • ''Have you had any intercurrent illness?.'' The information was transmitted by the hub to the service provider's central server where it could be accessed by the patient's healthcare professional. If there were any problems indicated by the telemedicine data, patients were contacted by telephone to discuss any changes that may be needed, in terms of medication, diet, etc., or to arrange a face-to-face review. If there were no problems patients were seen again in person at their next routine appointment.	• Maternal HbA1c at 36 weeks gestation • Appointments attended • Incidence of pregnancy-induced hypertension or pre-eclampsia • Incidence of caesarean delivery • Incidence of intrauterine death • Gestational age at delivery • Incidence of premature birth • Birth weight • Incidence of macrosomia • Incidence of admission to neonatal intensive care • Incidence of neonatal hypoglycaemia • Incidence of neonatal shoulder dystocia • Incidence of respiratory distress or transient tachypnea of the newborn • Patient satisfaction • Staff satisfaction	The small sample size used reduces the certainty of this study's findings. 4 out of 24 women allocated to telemedicine did not complete the study (all women in the control group completed the study)

Study reference	Methods, setting	Participants	Interventions	Outcomes	Comments on risks of bias/applicability
Perez-Ferre, 2010	RCT Patients were recruited between June and December 2007. Single centre (Spain).	Eligible women were diagnosed with GDM according to the Carpenter-Coustan criteria before 28 weeks of gestation.	At the initial study visit (between 24 and 28 weeks gestation), all patients were instructed in self-monitoring of blood glucose. Six measurements per day were recommended for the first week, after which time patients' blood glucose measurements were evaluated and recommendations for SMBG frequency (not clearly described) for the remainder of pregnancy made. A further 4 scheduled face-to-face visits were scheduled at approximately 4 week intervals before delivery. Unscheduled visits without prior appointment could also be made. Control group (n = 50): patients were followed up according to the usual local protocol for gestational diabetes. Patients recorded blood glucose values in a logbook: this was reviewed at each scheduled and unscheduled visit. Intervention group (n = 50): patients used an Accu-Chek Compact Plus glucose meter capable of transmitting to a mobile phone, which in turn transmitted glucose readings to a central database via text message. Patients were recommended to send their blood glucose readings to the database once a week. Patients could also send text messages to health care professionals via this system. An endocrinologist and a diabetes nurse educator evaluated patients' data using into the Emminens Conecta Plus Web Application. They could also contact the patient via text message using this system to make recommendations about nutritional changes or medication adjustments.	• Glycaemic control (change in HbA1c) • Change in body weight • Number of clinic visits • Gestational Weeks at Delivery • Mode of birth • Incidence of shoulder dystocia • Birth weight	Only 92 out of 100 patients were assigned to a treatment randomly. After the initial one week evaluation period, 8 women deemed most likely to require insulin based on their blood glucose profiles were all assigned to the telemedicine group. This greatly increases the likelihood of the two groups being imbalanced. The frequency and timing of capillary blood glucose monitoring recommended to patients (and whether this was consistent across all patients) is not clearly described.
GDM: gestational diabetes mellitus; RCT: randomised controlled trial; RBGM: remote blood glucose monitoring; SMBG: self-monitoring of blood glucose					

Table 2. Remote blood glucose monitoring compared to usual care: outcomes

Outcome	Evidence source(s)	Number of studies and patients	Absolute effect	Relative effect [95% CI], interpretation	Comments on reliability
Maternal glycaemic control					
Rate of change in blood glucose	Mackillop, 2018	One study, 201 patients	Mean change per 28 days: –0.16 mmol/L/28 days and -0.14 mmol/L/28 days for RBGM and usual care groups respectively	MD –0.01 mmol/L [–0.10 to 0.08], favours neither group	
Rate of change in HbA1c	Perez-Ferre, 2010	One study, 97 patients	Mean change from visit 1 to visit 4 (10 to 12 weeks): 0.3% vs 0.2% for RBGM and usual care groups respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
	Mackillop, 2018	One study, 201 patients	Mean change per 28 days: 0.02% and 0.03% for RBGM and usual care groups respectively	OR –0.01% [0.05 to 0.03], favours neither group	
Maternal HbA1c at 36 weeks of gestation	Given 2015	One study, 47 patients	Mean 34.0 ± 3.2 (SD) and 33.8 ± 2.9 mmol/mol for RBGM and usual care groups respectively	N/R	
Number of women using hypoglycaemic medication at time of delivery	Mackillop, 2018	One study, 201 patients	28 (33%) vs 44 (49%) for RBGM and usual care groups, respectively	OR 0.63 [0.36 to 1.10]], favours neither group	
Number of women treated with insulin (any time in gestation)	Perez-Ferre, 2010	One study, 97 patients	17 (34.7%) vs 9 (18.8%) for RBGM and usual care groups, respectively	N/R	Results include 8 women deemed at high risk of needing insulin treatment, who were all allocated to the RBGM without randomisation
Other maternal outcomes					
Incidence of delivery before 37 weeks	Given, 2015	One study, 47 patients	0 vs 2 (8%) for RBGM and usual care groups, respectively	N/R	
	Mackillop, 2018	One study, 203 patients	5 (5.0%) vs 13 (12.7%) for RBGM and usual care groups, respectively	OR 0.36 [0.12 to 1.04], favours neither group	
	Perez-Ferre, 2010	One study, 97 patients	1 (2.0%) vs 1 (2.1%) for RBGM and usual care groups, respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
Incidence of caesarean delivery	Given 2015	One study, 47 patients	10 (38.5%) vs 10 (47.6%) for RBGM and usual care groups, respectively	N/R	

Outcome	Evidence source(s)	Number of studies and patients	Absolute effect	Relative effect [95% CI], interpretation	Comments on reliability
	Mackillop, 2018	One study, 203 patients	27 (26.7%) vs 47 (46.0%) for RBGM and usual care groups, respectively	OR 0.43 [0.24 to 0.77], favours RBGM	
	Perez-Ferre, 2010	One study, 97 patients	17 (34.7%) vs 12 (25%) for RBGM and usual care groups, respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
Incidence of major perineal trauma	Mackillop, 2018	One study, 158 patients (all non-caesarean deliveries)	3 (4.0%) vs 1 (1.3%) for RBGM and usual care groups, respectively	OR 3.03 [0.31 to 29.6], favours neither group	
Incidence of pregnancy-induced hypertension or preeclampsia	Given 2015	One study, 47 patients	0 vs 1 (4%) for RBGM and usual care groups, respectively	N/R	
	Mackillop, 2018	One study, 203 patients	5 (4.9%) vs 1(1.0%) for RBGM and usual care groups, respectively	OR 0.20 [0.004, 1.79], favours neither group	
	Perez-Ferre, 2010	One study, 97 patients	2 (4.1%) vs 0 for RBGM and usual care groups, respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
Admission to higher level of care for mother	Mackillop, 2018	One study, 199 patients	1 (1.0%) vs 1 (1.1%) for RBGM and usual care groups, respectively	N/R	
Neonatal outcomes					
Birth weight	Given, 2015	One study, 47 patients	Mean 3557 ± 599 g and 3272 ± 443 g for RBGM and usual care groups respectively	N/R	
	Mackillop, 2018	One study, 202 patients	Mean 3440 ± 516 g and 3338 ± 559 g for RBGM and usual care groups respectively	MD 102 [-47, 251], favours neither group	
	Perez-Ferre, 2010	One study, 97 patients	Mean 3308 ± 489 g and 3370 ± 479 g for RBGM and usual care groups respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
Number of births large for gestational age	Perez-Ferre, 2010	One study, 97 patients	3 (6.1%) vs 4 (8.3%) for RBGM and usual care groups, respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
Incidence of shoulder dystocia	Given, 2015	One study, 47 patients	0 vs 9 (34.6%) RBGM and usual care groups, respectively	N/R	
	Mackillop, 2018	One study, 202 patients	1 (1.0%) vs 0 for RBGM and usual care groups, respectively	N/R	

Outcome	Evidence source(s)	Number of studies and patients	Absolute effect	Relative effect [95% CI], interpretation	Comments on reliability
	Perez-Ferre, 2010	One study, 97 patients	0 vs 1 (2.1%) for RBGM and usual care groups, respectively	N/R	High risk of bias due to allocation of potentially higher-risk patients to the RBGM group.
Incidence of neonatal hypoglycaemia	Given, 2015	One study, 44 patients	4 (20%) vs 6 (25%) for RBGM and usual care groups, respectively	N/R	Outcome data not reported for 3 patients; reasons for this are not explained by study authors
	Mackillop, 2018	One study, 189 patients	31 (32.3%) vs 25 (26.9%) for RBGM and usual care groups, respectively	OR 1.30 [0.69, 2.43], favours neither group	
Incidence of neonatal jaundice	Given, 2015	One study, 47 patients	9 (34.6%) vs 0 for RBGM and usual care groups, respectively	N/R	
	Mackillop, 2018	One study, 195 patients	10 (10.0%) vs 7 (7.4%) for RBGM and usual care groups, respectively	OR 1.38 [0.50, 3.79], favours neither group	
Incidence of intrauterine death	Given, 2015	One study, 47 patients	0 vs 1 (3.9%) for RBGM and usual care groups, respectively	N/R	
Incidence of macrosomia	Given, 2015	One study, 46 patients	6 (28.6%) vs 2 (8%) for RBGM and usual care groups, respectively	N/R	Outcome data not reported for 1 patient; reasons for this are not explained by study authors
Incidence of admission to higher level of care for baby	Given, 2015	One study, 45 patients	9 (45%) vs 9 (36%) for RBGM and usual care groups, respectively	N/R	Outcome data not reported for 2 patients; reasons for this are not explained by study authors
	Mackillop, 2018	One study, 200 patients	5 (5.0%) vs 12 (12.1%) for RBGM and usual care groups, respectively	OR 0.38 [0.13, 1.12], favours neither group	
Patient compliance and satisfaction					
Patient satisfaction score, Oxford Maternity Diabetes Treatment Satisfaction Questionnaire (maximum possible score = 54)	Mackillop, 2018	One study, 120 patients	Median 43 (IQR 39 to 46) and 44.5 (IQR 41-46) for RBGM and usual care groups, respectively. p = 0.049 (Kruskal-Wallis)	N/R	83 patients did not return a completed questionnaire. One question was misunderstood by approximately half of the patients and was

Outcome	Evidence source(s)	Number of studies and patients	Absolute effect	Relative effect [95% CI], interpretation	Comments on reliability
					omitted from the total scores.
Proportion of clinic appointments attended	Given, 2015	One study, 47 patients	Mean 97.8 ± 6.1% (SD) vs 92.6 ± 18.2 for RBGM and usual care group, respectively	N/R	
Compliance with blood glucose readings (recorded at least 67% of the expected number of readings)	Mackillop, 2018	One study, 183 patients	78 (79.6%) vs 52 (61.2%) for RBGM and usual care groups, respectively	OR 2.44 [1.29 to 4.61], favours RMBG	
Number of (scheduled) clinic appointments attended	Perez-Ferre, 2010	One study, 97 patients	Mean 3.98 ± 0.99 vs 4.34 ± 1.73 (SD) for and RBGM and usual care group, respectively	N/R	No statistically significant difference (p = 0.733)
Number of unscheduled visits to clinic	Perez-Ferre, 2010	One study, 97 patients	Mean 0.38 ± 0.68 vs 1.0 ± 1.35 (SD) for RBGM and usual care group, respectively	N/R	Statistically significant difference reported (p = 0.033) but small sample size reduces the certainty of this finding

CI: confidence interval; MD: mean difference; N/R: not reported; IQR: interquartile range; RBGM: remote blood glucose monitoring; OR: odds ratio; QOL: quality of life; SD: standard deviation

5.2. Ongoing trials

We searched for ongoing randomised or observational studies that compared remote blood glucose monitoring to usual care. Two relevant ongoing trials were identified (Table 3). Both trials are listed as completed in 2019 but the timescale for availability of results is not known. One studied the GlucoseMama blood glucose monitoring system; the second studied the Diasend/Glooko system. To the best of our knowledge, the GlucoseMama system is not yet commercially available. The Diasend/Glooko system is available in the UK but we did not identify any completed trials on its use in women with gestational diabetes. The ongoing trial of Diasend/Glooko includes women with any form of diabetes during pregnancy, not specifically women with gestational diabetes.

Table 3. Ongoing trials of remote blood glucose monitoring

Study name, reference	Setting and design	Eligibility criteria	Interventions	Outcomes	Expected completion
Group and Mobile Care for Gestational Diabetes (NCT03026218)	Randomised controlled trial, single centre, USA.	Women aged 18 to 51 years with a diagnosis of gestational diabetes. Enrolment: 22 participants.	Intervention: Glucosemama application, used to review glucose and carb logs on a weekly basis. This will be reviewed with the patient in order to adjust dietary and medicals. Control: traditional care	Primary Outcome: • Reduction in the number of individuals requiring pharmacotherapy for treatment of gestational diabetes Other outcomes: • Reduction in the number of neonates born large for gestational age • Increased number of individuals who are screened in the postpartum period for type 2 diabetes • Reduction in the number of infants with neonatal hypoglycaemia Follow up time for all outcomes: 2 years	May 2019

Study name, reference	Setting and design	Eligibility criteria	Interventions	Outcomes	Expected completion
Smartphone Utilization for Glucose Monitoring and Antenatal Reporting (SUGAR) (NCT03504592)	Randomised controlled trial, single centre, USA.	Women aged 18 to 60 years, diagnosed with diabetes during pregnancy or with known pre-existing diabetes.	Intervention: Glooko App. Control: Traditional clinic reporting system: paper/MyChart/emailed glucose logs.	• Completeness and accuracy of blood glucose record (primary outcome) • Patient Satisfaction • Glucose values at goal • Percentage change in haemoglobin A1C • Number of clinic visits • Unscheduled healthcare access Follow up: up to 42 weeks for all outcomes	June 2019

6. Economic evaluation

6.1. Health economic evidence review

One relevant economic study was identified from the literature search. The RCT from Mackillop et al. (2018) reported cost outcomes for the mobile phone-based blood glucose management system (GDm-Health) against standard clinic care. A summary of the economic component of the study is provided in Table 4.

The study reported a mean cost per delivery of £5,697 (standard deviation [SD] £3,068) in the GDm-Health group and £6,741 (SD £4,640) in the control group, giving an estimated cost difference of −£1,044 (95% CI −£2,186 to £99). However, note that the cost difference observed between the two groups was not statistically significant.

The difference in cost between the two groups was driven primarily by a reduction in emergency caesarean section and neonatal care in the GDm-Health arm. Notably, there was no difference in outpatient attendance costs, despite the protocol specifying fewer attendances for the intervention group. This was due to most clerical staff not being informed about the study and booking the standard two-week appointment for all patients.

Table 4. Summary of included health economic study: Mackillop et al. (2018)

Study details	Study population and design	Data sources	Results	Quality assessment
Author and year: Mackillop et al. (2018) **Country:** United Kingdom **Type of economic analysis:** Cost analysis as part of clinical trial **Perspective:** UK NHS healthcare perspective **Currency:** UK pound sterling (£) **Price year:** 2014-2015 **Time horizon:** Costs were collected until hospital discharge of the mother and baby. **Discounting:**	**Population:** Women between 18 and 45 years old with a viable singleton pregnancy of less than 35 weeks with gestational diabetes. Following initial diagnosis, women were instructed to perform preprandial and one hour postprandial blood glucose monitoring for one week. If after this initial week they did not require immediate treatment with insulin, they were eligible for inclusion. **Strategies considered:** 1. GDm-Health system with outpatient clinic attendance every four to eight weeks. 2. Standard clinic care. Patient recorded blood glucose values in a paper diary with outpatient attendance	**Source of baseline and effectiveness data:** Baseline and effectiveness data was recorded as part of the trial. Outcomes were only considered in the economic analysis if costs could be assigned (i.e. it was not a cost effectiveness or cost-consequence analysis) Key outcomes considered in the economic analysis were mode of delivery (vaginal, elective or emergency caesarean section), postpartum haemorrhage, perineal trauma repair and admissions to neonatal care. **Source of resource use and cost data:** Resource use in each of the treatment arms were captured as part of the RCT and included primary, community and secondary care costs. Unit costs were sourced from NHS Reference costs 2014/15 and the	**Estimated mean cost per delivery** • GDm-Health system £5,697 (SD £3,068) • Standard clinic care £6,741 (SD £4,640) • Mean cost difference −£1,044 (SD −£2,186 to £99) The difference observed between strategies was not statistically significant.	**Applicability:** Analysis was deemed to be directly applicable as it considered the UK NHS perspective. **Limitations**: The economic analysis was generally considered to be of high quality but some potentially serious limitations were identified. Most notably, due to clerical errors, patients in both arms of the study were instructed to have follow-up appointments every two weeks. As such, no difference was observed in the number of clinic attendances between treatment groups. Therefore, a key potential economic benefit of using the app has not been captured and the study has not demonstrated that the technology can safely replace clinic visits.

Study details	Study population and design	Data sources	Results	Quality assessment
Not performed because of short time horizon. **Source of funding:** National Institute for Health Research (NIHR) Oxford Biomedical Research Centre **Potential conflict of interest:** Three authors report consultancy fees from Drayson Technologies (sole licensee of the GDm-Health management system) and one of the authors is on the advisory board for Drayson Technologies.	every two to four weeks. **Study design** RCT with cost analysis	Personal Social Service Research Unit (PSSRU) 2015. Costs associated with the glucose meter and strips were excluded from the analysis because resource use for these were identical in both arms of the trial. As GDm-Health is free to install on a participant's mobile phone, no specific intervention costs were included in the analysis. To avoid double counting, it was assumed that the cost associated with some clinical outcomes (e.g. shoulder dystocia, birth trauma, or neonatal hypoglycaemia) were captured by the hospital length of stay.		
RCT: randomised controlled trial; SD: standard deviation.				

6.2. Resource impact analysis

We developed a resource impact analysis to estimate the potential cost associated with introducing the GDm-Health system into clinical practice in NHS Wales. The potential population affected was estimated using data from the Patient Episode Database for Wales (PEDW) (NHS Wales Informatics Service 2018), which recorded 1,219 cases of gestational diabetes in Wales for the year 2017/2018.

As discussed in Section 3, GDm-Health consists of two components: the GDm-Health app itself, and the GDm-Health secure website for healthcare professionals. There is no cost associated with the GDm-Health app because it is free to download. For the purpose of this analysis, it was assumed that patients would have a compatible mobile device to be able to use the app. While this is likely to be true for the majority of patients, there may be a need for hospitals to provide mobile devices for a minority of patients in which case there would be additional costs.

The analysis assumes that patients using the GDm-Health app would be able to access it using their own mobile phones. However, to account for the possibility of patients not having their on mobile phones, a scenario analysis was conducted whereby the cost of NHS provided mobile phones was incorporated. This was based upon the cost analysis conducted by NICE, in which a cost of VALUE was estimated.

There is an annual fee of £4,500 to use the GDm-Health secure website. Where it has been used in NHS England, this fee has been charged on for each health trust. The corresponding cost for implementation in NHS Wales is not known with certainty and would likely be the subject of commercial discussions. However, for the purpose of this analysis, it seems reasonable to assume that the fee would be charged to each of the seven health boards in Wales, thereby giving an estimated cost of £31,500.

Note that, as part of the Medtech Innovation Briefing (MIB131), NICE estimated an additional cost associated with hosting and maintaining the website based on costs incurred by the Oxford University Hospitals NHS Foundation Trust. However, this cost is no longer applicable as the service is now hosted by a third party supplier and Sensyne Health incur the costs.

The net cost of introducing the GDm-Health system was estimated, taking any downstream cost savings into account. However, there is uncertainty around the cost savings that may be accrued. The cost analysis by Mackillop et al. (2018) showed mean cost per delivery in patients managed with GDm-Health to be £5,697 (£6,318) compared to £6,741 (£7,475) in patients managed with standard care but this difference was not statistically significant. The only cost component which showed a statistically significant difference between strategies was emergency caesarean section. The mean emergency caesarean section cost per delivery was reported to be £228 (£253) in patients managed with GDm-Health compared to £903 (£1,001) in patients managed with standard care. This difference was driven by the difference in the rate of emergency caesarean section in each arm with 6% emergency caesarean deliveries in patients managed with GDm-Health compared to 24% in patients managed with standard care.

As previously noted, the analysis by Mackillop et al. (2018) did not show a reduction in appointments as a result of clerical errors, which led to patients in both arms of the study having appointments every two weeks. However, if the analysis had been run as originally intended then it is possible that there may have been savings. Assuming an average maternal age of 33 weeks gestation at start point and delivery at 40 weeks, it was estimated that there would be savings of £238 based on moving from appointments every two weeks to appointments every four weeks (using unit costs from Mackillop et al. [2018], inflated to 2020 prices).

A recent, unpublished conference abstract provided by the manufacturer reported the average number of appointments when women with gestational diabetes were managed with GDm-Health at Royal Surrey County Hospital in 2019. The figures were compared against standard management prior to the introduction of GDm-Health (using 2018 data). Management with GDm-Health was reported to result in 1.14 fewer consultations with diabetes specialist doctors and 0.31 fewer consultations with specialist midwives or diabetes specialist nurses. Applying inflated unit costs from Mackillop et al. (2018) gives an estimated cost saving of £182 per delivery with GDm-Health.

To reflect the uncertainty around the potential downstream cost savings, numerous scenarios were considered in the resource impact analysis: Unit cost estimates for caesarean section and follow-up appointments were sourced from.

- Scenario 1: No downstream cost savings
- Scenario 2: Downstream cost savings of £1,157 per delivery based on difference between costs per delivery from each arm of Mackillop et al. (2018). Note that the reported cost difference of £1,044 was inflated to 2020 prices.
- Scenario 3: Downstream cost savings of £749 per delivery based on a reduction in deliveries via emergency caesarean section from Mackillop et al. (2018). Note that the reported cost difference of £675 was inflated to 2020 prices.
- Scenario 4: Downstream cost savings of £238 per delivery based on reducing follow-up appointments from every two weeks to every four weeks
- Scenario 5: Downstream cost savings of £182 per delivery based on reduction in consultations with diabetes specialist doctors and specialist midwives or diabetes specialist nurses reported in Sithamparanathan et al. (2019).

The results of the analysis for each of the five scenarios are shown in Table 5. It can be seen that the assumptions around downstream cost savings are crucial for determining the net impact of introducing the GDm-Health system. The net cost impact of introducing the GDm-Health system ranged from a saving of £1,379,748 to a cost increase of £31,500.

Table 5. Results of resource impact analysis

Cost component	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Cost of introducing GDm-Health	£31,500	£31,500	£31,500	£31,500	£31,500
Downstream cost impact of introducing GDm-Health	£0	-£1,411,248	-£912,458	-£290,229	-£222,466
Net cost of introducing GDm-Health	**£31,500**	**-£1,379,748**	**-£880,958**	**-£258,729**	**-£190,966**

7. Organisational issues

The use of remote blood glucose monitoring technologies requires use of apps or software by patients and by the staff involved in their care. Both will require installation and maintenance of the software/apps used, suitable hardware to use them on, and training in their use. Although the majority of pregnant women are likely to be digitally literate and own a suitable mobile phone, lack of mobile phone ownership or familiarity with the technology involved could be barriers to accessing remote blood glucose monitoring for some women.

Given et al. (2015) collected opinions from four healthcare professionals who monitored patients via the telemedicine system used in their trial (described in Table 1). The opinions of these staff highlighted that training is needed to interpret the data received, as this will differ from the usual format given in traditional paper diaries. It was also noted that if the use of remote monitoring reduces the number of clinic appointments patients need to attend, this might not necessarily translate into significant time savings for staff, as they will still require dedicated time to read and interpret glucose readings and other data sent from patients.

8. Patient issues

A Patient Experience Literature Review was undertaken, based on a dedicated search which aimed to identify and summarise the experiences, perspectives and opinions of patients. The findings of this are available as Appendix 3 of this Evidence Appraisal Report.

This section details evidence identified – in the course of searching for clinical and cost effectiveness evidence - that reported the experiences or perspectives of people (or their carers) with gestational diabetes about using remote blood glucose monitoring to manage gestational diabetes.

We identified four studies that reported womens' attitudes towards or experiences of using remote blood glucose monitoring technologies to manage gestational diabetes. However, two of the studies used an app (Pregnant+) that is not available in the UK and did not meet the inclusion criteria for this evidence review. Of the remaining two studies, one reported womens' experiences of using the GDm-Health app, and one evaluated the willingness of women to use remote blood glucose monitoring during pregnancy. Both were service evaluations and used questionnaires comprised of closed questions or ratings scales.

One study reported user satisfaction in 48 women using the GDm-Health app using a questionnaire (Oxford Maternity Diabetes Treatment Satisfaction Questionnaire); this study was carried out in Oxford from June 2012 to August 2013 during the development of the GDm-Health app. The findings demonstrated a high level of satisfaction with care generally, and that women with gestational diabetes found remote blood glucose management using an interactive smartphone system acceptable and convenient (Hirst et al. 2015).

Alqudah et al. (2019) conducted a service evaluation at a Northern Ireland hospital over a 4 week period, during which time 63 pregnant women with diabetes (68.2% had gestational diabetes) completed a questionnaire about their care and their perceptions of receiving some of their care remotely. The majority of women (63.9%) reported that they spent over 2 hours attending each clinic visit; 44.5% of women travelled for more than 30 minutes each way to attend each clinic. Between 78 and 90% of women reported that they would find it acceptable to use a smartphone for aspects of managing their health during pregnancy, depending on what they would be required to input and test, and 66.7% would be willing to manage some aspects of their diabetes remotely.

9. Conclusions

This evidence review summarised published evidence on the clinical and cost effectiveness of using systems that allow remote monitoring of blood glucose in women with gestational diabetes. We identified evidence from three randomised controlled trials of relevance. Only one was published in the last three years: although we did not apply a date limit as an inclusion criteria, the pace of change in digital technologies means evidence from older studies may be of lesser relevance. As of January 2019, the only known remote blood glucose monitoring technology that is commercially available in the UK is the GDm-Health system, which was used in the study by Mackillop et al. (2018).

The evidence identified did not detect any differences in the majority of clinical outcomes in women using remote blood glucose monitoring compared to usual care. There is some evidence to suggest that women who use remote blood glucose monitoring may be less likely to require a caesarean section or to give birth pre-term. Notably, none of the studies reported on clinic attendance when women used remote blood glucose monitoring as opposed to usual care: two studies were not designed to initiate or measure such a reduction, and the third was not realised due to booking errors. However, the evidence suggests that remote blood glucose monitoring may result in better compliance with blood glucose recording. We did not identify any evidence that measured the effect of remote blood glucose monitoring on patients' quality of life, but where patient satisfaction was reported this was generally high regardless of the type of care received.

Economic evidence identified in the evidence review (Mackillop et al. 2018) showed a lower mean cost per delivery in patients managed with GDm-Health system. However this difference was not statistically significant and did not show a reduction in clinic attendance. Resource impact analysis showed that the overall impact of GDm-Health is highly dependent upon the assumptions around downstream cost savings. Therefore, the uncertainty around the potential downstream cost savings, especially in relation to clinic attendance and rates of caesarean section, makes it difficult to ascertain whether the introduction of GDm-Health would lead to a net cost increase or cost savings.

10. Contributors

This topic was proposed by Julian Bradwell, Sensyne Health.

The HTW staff and contract researchers involved in writing this report were:

- D Jarrom – primary researcher and clinical author
- L Elston – secondary researcher and editor
- M Prettyjohns – health economist and primary economic author
- J Washington – information scientist, literature searches
- S McAllister – project management

The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

A range of clinical experts from the UK provided material and commented on a draft of this report. Their views were documented and have been actioned accordingly. All contributions from reviewers were considered by HTW's Assessment Group. However, reviewers had no role in authorship or editorial control, and the views expressed are those of Health Technology Wales.

Experts who contributed to this appraisal:

- Professor Eleanor Scott, Professor of Diabetes and Maternal Health at University of Leeds and Leeds Teaching Hospitals NHS Trust
- Professor Helen Murphy, Professor of Medicine/Professor of Women's Health/Honorary Consultant Physician at University of East Anglia
- Dr Lisa Forrest, Consultant Diabetologist at Hywel Dda Health Board
- Dr Lucy Mackillop, Consultant Obstetric Physician at Oxford University Hospitals NHS Foundation Trust, Honorary Senior Clinical Lecturer at Nuffield Department of Women's and Reproductive Health, University of Oxford and VP Medical Affairs, Sensyne Health.
- Dr Julia Platts, Consultant in Diabetes and Medicine, National Clinical Lead for Diabetes in Wales, Cardiff and Vale University Health Board and All Wales Diabetes Implementation Group
- Dr Richard Chudleigh, Consultant Diabetologist at Swansea Bay University Health Board
- Dr Aditi Miskin, Consultant Obstetrician & Gynaecologist at Princess Of Wales Hospital, Bridgend
- Simon Treliving, Project Manager at Sensyne Health

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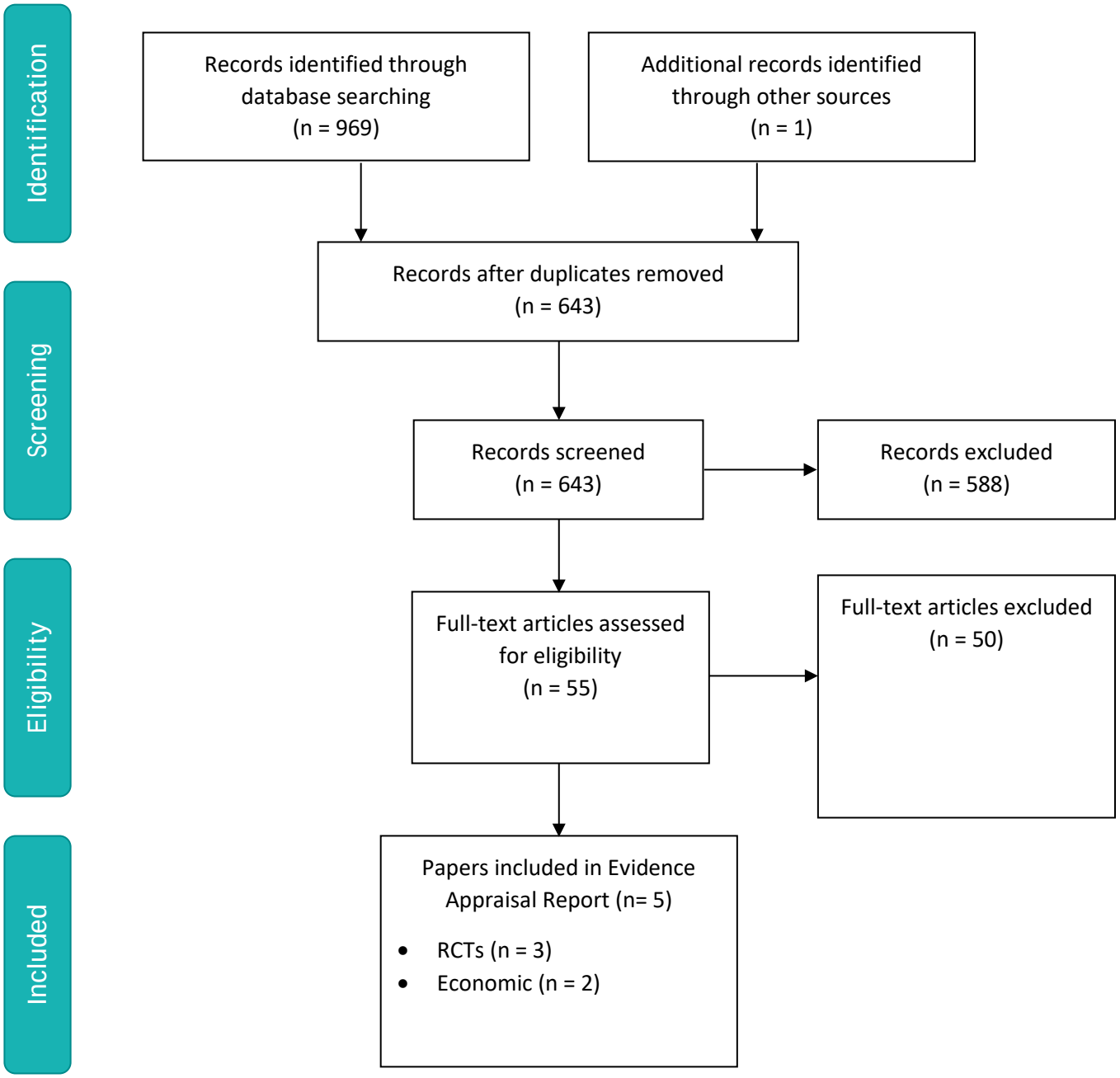
Appendix 1. Research question & study selection criteria

Research Question	In women with gestational diabetes, what is the clinical and cost effectiveness of remotely monitoring blood glucose?

	Inclusion criteria	Exclusion criteria
Population	Pregnant women who have or at risk of gestational diabetes	Type 1 or type 2 diabetes. Studies of mixed diabetes populations that include gestational diabetes may be considered if the majority of patients have gestational diabetes, or if outcomes for gestational diabetes are reported separately
Intervention	Remote monitoring/management of blood glucose, via any device that: • automatically collects blood glucose readings from a user's blood glucose meter, and • transmits these (immediately or periodically) to healthcare professionals for review	Any device that requires the user to manually read and record blood glucose measurements Phone or text message-based reporting of blood glucose readings
Comparison/ Comparators	Standard blood glucose monitoring, usually paper-based records reviewed at diabetes/antenatal clinics. However, evidence on other methods of reporting blood glucose, such as text message or phone-based reporting, should also be considered.	None specified
Outcome measures	Rates of unassisted vaginal birth or caesarean sections, including rates of elective or emergency caesarean where reported Risk of pre-term birth HbA1c values; time in target range (preferred); HbA1c values/time in target range for each trimester where this is reported Incidence of maternal hypoglycaemia Rates of admission to neonatal intensive care /special care baby unit Birthweight, including rates of macrosomia Rates of births that are large for gestational age Rates of miscarriage/stillbirth/neonatal deaths Maternal insulin or other diabetic medication usage Gestational weight gain Incidence of gestational hypertension Incidence of pre-eclampsia Length of hospital stay after delivery Patient satisfaction Patient compliance with blood glucose reading collection Quality of life Incidence of neonatal hyper/hypoglycaemia Incidence of neonatal morbidity Adverse events	
Study design	We will include the following clinical evidence in order of priority: • Systematic reviews.	

	• Randomised trials. • Non-randomised trials. We will only include evidence for "lower priority" evidence where outcomes are not reported by a "higher priority" source. We will also search for economic evaluations or original research that can form the basis of an assessment of costs/cost comparison.
Search limits	No date limits applied
Other factors	We will only include articles published in English.

Appendix 2 - PRISMA flow diagram outlining selection of papers for clinical and cost effectiveness (evidence searched up to 25 February 2020)



Appendix 3. Remote blood glucose monitoring in women with gestational diabetes: Patient Experience Literature Review

1. Purpose of the literature review

This literature review aims to identify and summarise the experiences, perspectives and opinions of patients who have used remote blood glucose monitoring to keep track of their glucose levels during pregnancy through existing research and reports. This review is informed by a rapid systematic literature search conducted specifically for reports on patient experiences and is therefore intended to supplement any patient views and experiences that were reported in the clinical evidence reviewed in the Evidence Appraisal Review (EAR).

The experience of patients when using a health technology forms an important part of its appraisal as patients can provide additional valuable information that would not be apparent from clinical and cost-effectiveness evidence.

2. Health problem

Gestational diabetes is a form of diabetes that is diagnosed in the second or third trimester of pregnancy that was not clearly overt prior to gestation. For most women with gestational diabetes, the condition usually resolves itself after giving birth, however there is an associated risk that some women will go on to develop type two diabetes as a result.

Women with diabetes of any kind are at increased risk of morbidity and mortality during pregnancy, and pregnancy outcomes for women with pre-existing diabetes and their infants are poor compared to those for women who do not have diabetes. Poor glycaemic control, and in particular hyperglycaemia, is strongly associated with increased risk of miscarriage or severe congenital malformations in early pregnancy. After 12 weeks gestation, hyperglycaemia also induces fetal hyperinsulinaemia, accelerated growth, and adiposity (obesity/being severely overweight) in animal models and in women with diabetes. Intensified glycaemic control minimises macrosomia (large babies) and other neonatal complications.

The most well-established method of monitoring blood glucose during pregnancy is to test capillary glucose using a blood glucose meter (self-monitoring of blood glucose). Protocols for monitoring blood glucose vary locally, but typically involve women recording blood glucose values from their glucose meter in a diary or logbook, which is then taken to each clinic appointment, where it is reviewed by healthcare professionals. A 2013 systematic review of observational studies found notable discrepancies between patient-generated blood glucose diary records and actual glucose meter data, due to issues such as missing data or transcription errors. In a recent UK service evaluation of diabetes care in pregnancy, only 59% of women surveyed stated that they completed their blood glucose diary each time they carried out a self-monitored blood glucose test: the remainder completed their diary at the end of every day, at the end of every week, at weekends or only prior to each clinic visit.

3. Health technology

Remote blood glucose monitoring is an alternative method of recording and monitoring blood glucose data for women with gestational diabetes. This typically involves the use of digital technology by both the affected women and the healthcare professionals involved in their diabetes care. There is currently only one remote monitoring technology of this kind available in the UK; GDm-Health. GDm-Health consists of two main components: a mobile application (available for Android and iOS smartphones) that connects wirelessly with compatible blood glucose meters and collects blood glucose readings automatically. These are then securely transferred to a web application where they are available for review by healthcare professionals. Additional information can be added to each blood glucose reading by women, such as timing of meals and medication relative to the reading. The system also allows communication between healthcare professionals and the user through SMS text messages, and women can request a callback from a midwife via the system.

4. Evidence search methods

A systematic search for literature on patient experience was conducted with three different inclusion criteria; 1) for the use of remote blood glucose monitoring in women with gestational diabetes, 2) for the use of all forms of blood glucose monitoring including self-monitoring and 3) for living with gestational diabetes. Definitions of remote blood glucose monitoring were adapted from those used for the clinical evidence search. The search was carried out on 6th-12th February 2020. The databases used were Medline and PsycINFO, as well as a number of key websites containing guidelines, policy documents and patient stories.

Concepts used in all searches included: remote monitoring, telehealth/telemedicine and (gestational) diabetes. A full list of resources searched and terms used are available on request, as well as the detailed criteria used to select evidence for the appraisal

A total number of 43 relevant papers were found. Of these 43 papers, 15 explored patients' experiences of living with gestational diabetes in numerous settings, 20 papers examined various issues related to self-monitoring of blood glucose levels in all forms of diabetes and 8 reports were concerned with the patient experience of using several similar forms of smartphone apps to monitor blood glucose levels in gestational diabetes, two of which were GDm-Health. Other technologies included the smartphone app Pregnant+.

5. Patient evidence

The following patient issues and themes emerged across the reports:

Gestational diabetes:

- Feeling concern and anxiety for their own health and that of their baby
- The challenge of feeling a loss of control
- Intensified treatment, lack of information and lack of social support can greatly increase distress
- Barriers to management include financial barriers, difficulties accessing care, maintaining a healthy lifestyle, and lack of social support and diabetes care
- Whilst most women had an understanding of the importance of monitoring blood glucose levels, some felt unprepared following their diagnosis and expressed a need for more materials and assistance regarding self-monitoring of blood glucose.

Self-monitoring of blood glucose in diabetes:

- Most patients reported a willingness to engage with self-monitoring techniques and to incorporate self-care behaviours around their lifestyles
- While many patients reported great benefits, lifestyle barriers and life events can affect patients' ability and decision to self-monitor, and can lead to patients abandoning the regime, techniques and devices
- Barriers to self-care remain despite self-monitoring behaviours improving with education and telehealthcare. In addition to learning how to self-monitor and/or use remote monitoring devices, patients highlighted the importance of education on appropriate responses and interventions for high and low blood glucose levels
- The differences in patients who manage to self-monitor and those who do not can be largely explained by psychological and social factors.

Remote monitoring of blood glucose in gestational diabetes:

- Psychological status seems to be an important determining factor in pregnancy outcome, and deterioration of health behaviours may mediate this effect. Social support and family involvement may affect psychological well-being.
- Women experience worry and anxiety associated with remote monitoring of blood glucose in three dimensions: (1) learning to test blood glucose, (2) being afraid of elevated blood sugar and (3) being aware of what to eat
- The complexity of, and rapid lifestyle adjustments required to follow self-monitoring regimens may contribute to difficulties in adherence
- Women who used smartphone apps to help manage their condition reported they increased their confidence in their management of gestational diabetes and their motivation for behavioural change. However technological problems and a lack of support from health-care professionals to resolve these problems limited several women from using the app
- Most women who use a continuous/remote glucose monitoring device reported improved diabetes understanding and would recommend it to others. However some women expressed concerns about using digital technology from home to monitor various aspects of their health in pregnancy, questioning its reliability and expressing concern regarding the absence of the physical presence of health care professionals.

- Some studies showed remote monitoring of blood glucose was associated with fewer check-ups at the diabetes clinics; however, some women reported needing their continuous/remote glucose monitoring devices removed because of skin irritation, technical problems and inaccuracy of the device

The GDm-Health System in gestational diabetes:

- Most of the 49 patients interviewed via questionnaire agreed the equipment was convenient (96% of patients) and reliable (88% of patients).
- Eighty six percent of patients reported that GDm-Health fitted into their lifestyle, and 94% indicated they had a good relationship with their care team.
- Comments received as part of a questionnaire supported the above findings, with very positive reactions from the majority of women.

6. Conclusions

The patient issues evidence considered suggests that gestational diabetes can be a source of concern, worry and anxiety for women. While remote monitoring is a relatively successful method of blood glucose monitoring that helps provide women with a sense of control, women with gestational diabetes still face several challenges. While some women report satisfaction with GDm-Health and other similar smartphone applications, for others the challenges of learning how to use such a device, trusting that it is functioning properly and missing the security and reassurance of seeing a health professional in a clinic setting remain. For most women, learning about their condition, what it means for them once they have given birth, and how to maintain a healthy lifestyle are the most important issues that they have to face.

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