

# Health app: GDm-Health for people with gestational diabetes

Medtech innovation briefing

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## Summary

### *About this app*

- GDm-Health is a health application designed for people with gestational diabetes to allow for remote monitoring of blood glucose levels and communication with healthcare professionals.
- The mobile app downloads data from the user's blood glucose meter and sends it to a secure website, which is monitored by healthcare professionals. The website allows midwives to send SMS text messages to patients and record notes on the website for other healthcare staff.
- GDm-Health is free to download and use. Its use may result in efficiency savings from reducing face-to-face clinic appointments.

### *Evidence summary*

- **Clinical effectiveness:** GDm-Health has the potential to have a positive impact for people with gestational diabetes. There is some evidence that the app is a reliable method to communicate blood glucose levels and improves patient satisfaction with their care. However, there is currently no evidence comparing GDm-Health with standard care and so the impact on clinical outcomes is uncertain.
- **Cost and resource impact:** Cost savings may arise from reducing the need for face-to-face appointments but the overall resource impact has not been quantified and is uncertain

because of the limited information available. A report by 1 NHS trust suggests cost and resource savings, and other trusts using GDm-Health report more efficient use of staff time.

- **User benefits:** GDm-Health is currently available in 4 NHS trusts. Users report benefits including fewer appointments and greater control over their own care.

## The technology

GDm-Health (Oxford University NHS Foundation Trust and The University of Oxford) comprises 2 parts: a patient-facing mobile app, which is downloaded to the patient's mobile device, and a secure clinician-facing website designed to allow remote blood glucose monitoring.

The mobile app is available for iOS and Android operating systems. The app downloads data from the user's blood glucose meter (through Bluetooth or near-field communication [NFC]). It then automatically sends these blood glucose measurements to the secure website through wifi or a mobile internet connection. The user may also enter notes alongside the measurements, such as explanations of unusually high readings, and these are also sent to the website.

The website displays all collected blood glucose level data for review by healthcare professionals. It highlights any users who need intervention based on their readings, and prioritises those who need midwife review. Clinicians can set up alerts for high or low readings and to identify certain patterns, such as consecutive high readings. The website also allows communication between healthcare professionals and the user through SMS text messages. Different healthcare professionals can communicate with each other by adding notes to the user's online record. Users can also request a callback from a midwife once the data are sent, using a tool in the mobile app.

GDm-Health has undergone a technical evaluation using the NHS [Digital Assessment Questions](#), a pilot tool currently available to developers in beta form. The tool comprises 7 domains: clinical safety; security and privacy; confidentiality (information governance); usability and accessibility; technical stability; change management (updates and version control); and regulatory approval. NHS Digital has confirmed that GDm-Health passed this assessment. The completed assessments are not currently published.

### *Table 1 Technology components*

Component (first UK launch, version number)	Regulatory status	Cost
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<p>GDm-Health iOS/Android app (for patient users). (Not yet available across NHS, used in research since 2012 and as pilot in Oxford since 2014, v4.15).</p>	<p>The developer has stated that GDm-Health does not meet the current eligibility criteria for CE marking as a medical device or for regulation by the Care Quality Commission.</p>	<p>Free to download for patients. Patients must have a compatible device and internet connection.</p>
<p>GDm-Health secure website (for healthcare professionals, v4.15).</p>	<p>As above.</p>	<p>Cost incurring to NHS trusts (licensing and phone provision costs).</p>

### *Novel system benefit*

- Using GDm-Health allows healthcare professionals to remotely monitor blood glucose levels, and use this information to prioritise users for review.
- Improved communication using the app could potentially reduce the workload for healthcare professionals and the number of outpatient appointments. This would depend on current local protocols for managing gestational diabetes.
- Blood glucose and other information are recorded electronically, which allows for efficient data auditing.

### *Current care pathway*

The NICE guideline on [diabetes in pregnancy](#) recommends that people with gestational diabetes should have contact with the joint diabetes and antenatal clinic to assess blood glucose control every 1 to 2 weeks throughout pregnancy. Standard clinical practice is paper-based records of patients' blood glucose up to 6 times per day. The readings are reviewed by a healthcare professional and, if needed, medication is adjusted at fortnightly face-to-face check-ups.

## *Population, setting and intended user*

GDm-Health would be used by pregnant people who monitor their own blood glucose levels. It would be used at home and during usual day-to-day activities.

Results would be monitored by maternity diabetes teams, which may include diabetologists, obstetricians, diabetes specialist nurses, midwives and dieticians, in secondary care settings.

Downloadable videos and information leaflets are available to healthcare professionals and users in how to use GDm-Health. According to the app developer, healthcare professionals need 30 to 60 minutes of training, whereas users need 10 to 20 minutes of training.

## *Equality considerations*

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

GDm-Health is intended for use by people who are pregnant, which is a protected characteristic under the Equality Act 2010. It can only be used by people with an Android or iOS device: the app does not work with other mobile operating systems. GDm-Health also cannot be downloaded by people with mobile devices which are registered outside the UK.

## **Evidence on effectiveness**

A literature search was carried out for this briefing. The most relevant or best available published evidence relating to the clinical effectiveness of the technology has been summarised below.

Further information about how the evidence for this briefing was selected, and full summaries of the included studies, are available on request by contacting [medtech@nice.org.uk](mailto:medtech@nice.org.uk).

This briefing summarises 2 published studies and 1 published letter, all of which report outcomes from a UK feasibility study involving the same cohort of up to 57 users of GDm-Health (table 2).

**Table 2 Summary of evidence**

<u>Mackillop et al. (2014)</u>	
Study size, design and location	Cohort study, n=57. Hospital-based maternity diabetes clinic, UK. Pilot for Mackillop et al. (2016).
Intervention and comparator(s)	Intervention: GDm-Health Comparator: none
Key outcomes	In the service development phase, mean weeks of usage was 12.9. 16,534 blood glucose readings were submitted.  The overall percentage of blood glucose readings with additional information was 98.3% labelled as a meal, and 15.7% with free text comments.  A total of 466 text messages were sent to patients from the website, resulting in 26 medication adjustments.
Strengths and limitations	Beta testing was done in 7 patients and additional functionality was added to the system before testing in a larger patient group. There was high usage and excellent compliance with the system. However, the study used a small sample size, and there was a risk of bias in the sample because patients could choose to use the app. There was also no comparator group. The work was funded by the National Institute of Health Research Biomedical Research Centre Programme.
<u>Hirst et al. (2015)</u>	
Study size, design and location	User satisfaction survey, n=52. Maternity diabetes clinic, UK.
Intervention and comparator(s)	Intervention: GDm-Health Comparator: none
Key outcomes	Patients reported a high degree of satisfaction with GDm-Health, particularly if they lived far from the hospital or had other commitments. Patients were highly satisfied with system reliability: any problems uploading data were because of poor local network connections rather than with GDm-Health.

Strengths and limitations	This was a validated questionnaire with high completion rates. However, there was a small sample size, possible risk bias in the sample because patients could choose to use the app, and it used only 1 tool to measure satisfaction. It was also non-comparative. The work was funded by the National Institute of Health Research Biomedical Research Centre Programme.
<u>Hirst et al. (2016)</u>	
Study size, design and location	Cohort study, n=49. Maternity diabetes clinic, UK.
Intervention and comparator(s)	Intervention: GDm-Health Comparator: none
Key outcomes	Proportion of births that were large for gestational age, accuracy of blood glucose readings and ability to identify readings with respect to meals were facilitated by GDm-Health.  Compared with normal-for-gestational-age babies, large-for-gestational-age babies had higher mean and 2-hour postprandial readings. The odds of delivering a large-for-gestational-age baby increased around 5 times for every 1 standard deviation increase in mean blood glucose and mean postprandial blood glucose (but not fasting blood glucose).
Strengths and limitations	This was not a full publication (letter), had only a small sample size, it was non-comparative, and outcomes did not focus on the effectiveness of GDm-Health. There was also possible risk bias in the sample because patients could choose to use the app.  The work was funded by the National Institute of Health Research Biomedical Research Centre Programme.

## Overall assessment of the evidence

- The evidence base for GDm-Health is still developing and consists mainly of product development and evaluation studies on a small cohort of patient volunteers.
- All studies are non-comparative and were done in a small cluster of centres by the team currently developing the app.

- The evidence suggests that GDm-Health is a reliable and user-friendly method of remote blood glucose monitoring, and that it improves communication between healthcare professionals and people with gestational diabetes.
- There is a high degree of patient compliance and satisfaction with using the system ([Mackillop et al. 2014](#), [Hirst et al. 2015](#)).
- An ongoing randomised trial comparing GDm-Health with standard care has completed data collection, and publication of results will add to the current body of evidence particularly in relation to improving clinical outcomes ([Mackillop et al. 2016](#)).

## Recently completed and ongoing studies

One recent, ongoing or in-development trial on the use of GDm-Health was identified in the preparation of this briefing.

- [Trial of Remote Evaluation and Treatment of Gestational Diabetes Mellitus \(TREAT-GDM\)](#). ClinicalTrials.gov identifier: NCT01916694. The study is complete and publication of the results is anticipated within 2017.

## Costs and resource use

### *Economic evidence*

No published economic evidence was found.

### **Technology costs**

The GDm-Health app is free to download. It can only be used with a mobile internet connection, which may incur additional costs to the user.

Table 3 shows the estimated costs of adopting GDm-Health in an NHS trust. The estimates are uncertain because costs across NHS trusts will vary according to the number of users and healthcare professionals, and whether extra equipment is needed.

Bluetooth- or NFC-compatible blood glucose monitors and mobile devices can be supplied to patients if needed. However, such monitors may be standard care in some NHS trusts, and many patients will be able to use their own mobile device.

**Table 3 Estimated technology costs**

Component	Cost	Details
Compatible mobile device	£10 to £130.	We expect that 95% or more of users will use their own device. The hospital may provide the additional devices if needed
Phone contract	£5 to £10 per month.	
Hosting for the secure website	Around £2,000 per year for 7 web-based applications (individual clinic systems) £1,143 per year for the current 4 clinics	The website is currently hosted by the Oxford University Hospitals NHS Foundation Trust virtual server facility, which incurs all costs
Security certificate.	£300 every 3 years	
App and website maintenance	Around £41,340 per year	0.5 WTE band 7 scientist (795 hours per year at £52 per hour) Based on an hourly cost of £52 for band 7 community-based scientific staff (PSSRU, 2016)

### Comparator costs

People with gestational diabetes attend an outpatient clinic every 2 weeks during their third trimester, providing written details of blood glucose measurements in person or by email.

The NICE guideline on diabetes in pregnancy has a [supplementary costing statement](#), which outlines the standard care per-patient costs for monitoring pregnant people with type 2 and gestational diabetes. According to the costing statement, the total cost for monitoring is £386.48 per patient.

### Potential resource impact

GDM-Health is intended to reduce the frequency of face-to-face appointments, not replace them altogether. Most standard care costs will still be incurred with the use of GDM-Health, but users may need fewer appointments than people having standard care.



Adopting GDm-Health may need changes to local protocols for managing gestational diabetes. These could include introducing protocols for responding to users, remote monitoring, communication between users and other members of the healthcare team, training and data storage, and management and security. Implementing and managing GDm-Health may need additional staff, such as project management. As a result, the roles of the lead midwife or diabetic specialist nurse may need to change to reflect less face-to-face contact with patients, but more contact through SMS text messages.

Using GDm-Health standardises the way patients record their measurements. Midwives can respond in real time instead of potentially having to wait for data by email. This could lead to shorter face-to-face appointments for users, and therefore less resource use.

There are 4 NHS trusts using the system, at an approximate cost to the Oxford University Hospitals NHS Foundation Trust of £42,583 per year. Based on the costs of standard care, using GDm-Health could save approximately £230 per patient by reducing the need for additional appointments.

## Usage and user experience

### *Current usage and reach*

Across 3 of the 4 NHS trusts in which GDm-Health is used, the app has been downloaded over 1,400 times.

**Table 4 Summary of usage, reach and reported user experience**

Evidence of usage and reach	Source
In 1 NHS trust using the app, a total of 411 GDM patients were prescribed the app to monitor blood glucose levels in 2016. This number is expected to rise because at first the app was only available on NHS trust-owned mobile devices, but since June 2016 it has been available to use on patients' own devices.	Royal Berkshire NHS Foundation Trust
96% (48/50) of patients used GDm-Health until the end of their pregnancy and 85% of patients submitted the minimum requirement of 18 blood glucose readings per week.	<a href="#">Mackillop (2014)</a>
Reported user experience	Source

<p>All members of the multi-disciplinary team are very positive about GDm-Health. It is easy to use for both patients and healthcare professionals, easy to use as a team review tool, and is both secure and reliable. Most patients are positive towards GDm-Health. The only patients who cannot use the system are those whose mobile devices are registered outside the UK.</p>	<p>Royal Berkshire NHS Foundation Trust</p>
<p>Of 52 ratings, no patients rated their satisfaction with care negatively and the most agreed or strongly agreed that the system was convenient and reliable. Patients particularly appreciated it if they lived far from the hospital or had other commitments.</p>	<p><u>Hirst (2015)</u></p>

### *Case study: Royal Berkshire NHS Foundation Trust*

Royal Berkshire NHS Foundation Trust did an independent review of GDm-Health, which over 4 months showed a 26% reduction in clinic visits for patients using GDm-Health compared with patients having standard care. The time spent by diabetes midwives on administrative tasks also decreased by 50%.

All patient data is added to the GDm-Health database, either remotely or by midwives manually adding blood glucose data. This means that all patient data is stored in 1 place. The database has been developed to meet the specific needs of the unit, so extra information on each patient is added to a spreadsheet for yearly audit purposes. The audit now takes around 1 day instead of 6 weeks, saving a considerable amount of time for the diabetes specialist midwife.

The trust considers GDm-Health to be a useful teaching tool: new staff can read through records, see the progression of blood glucose levels, see the introduction and effect of various drugs, and develop their dose adjustment skills.

The most obvious benefit overall is the time it takes to review the readings, because the format is consistently very easy to read. Based on current numbers of patients, the trust expects to save around 1 hour per day per clinic through using GDm-Health.

### *Overall assessment of user benefits*

- The main patient benefit is reduced clinic visits, with associated reductions in travel costs and inconvenience, and greater control over their own care.
- Published evidence suggests that people with gestational diabetes find the app easy to use and reliable.

- Healthcare professionals report that 'prescribing' GDm-Health to their patients has led to time savings in their antenatal clinics by reducing the number and length of clinic visits, but also by reducing the amount of time taken to carry out audits.
- GDm-Health is free to download, so could reach many people who would otherwise rely on paper reporting and regular clinic visits. However, access to mobile devices may limit the range of patients who will benefit from it.

## Specialist commentator comments

Comments on this technology were invited from specialist commentators working in the relevant fields and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

Three specialist commentator responses were received. One specialist commentator was involved in developing GDm-Health and uses the app for all new patients with gestational diabetes. The other 2 commentators were not familiar with GDm-Health, but 1 was aware of a similar technology.

### *Level of innovation*

One commentator considered GDm-Health to be a natural progression in the use of telehealth in this field. Similar technologies are used in the NHS for people with type 1 diabetes, but not consistently for those with gestational diabetes. An advantage of GDm-Health is that it allows information to be passed back to the clinician remotely, unlike other systems.

The second commentator described GDm-Health it as being extremely innovative and a major improvement on the previous paper-based system used in their centre. This commentator stated that other telehealth systems are available, but reported that that they cannot be used as a communication tool to advise the patient on diet or medication. With GDm-Health, the data can be viewed and midwives can communicate with the patient, and keep a communication record in 1 place. GDm-Health also facilitates data collection for the whole patient population, allowing clinical audit and improvement.

The third commentator stated that GDm-Health is a very innovative way for people to take control of their own blood glucose management.

## *Potential patient impact*

One commentator considered that GDm-Health would potentially improve patients' quality of life because of a reduced need for clinic appointments. However, they raised concerns that remote advice does not allow healthcare professionals to explore any surrounding issues (such as diet and exercise).

The second commentator stated that GDm-Health allows the transfer of patients' blood glucose data without them having to either send emails, contact midwives by phone or show their readings at the clinic. This commentator stated the system can be used to positively encourage patients with good levels of compliance by sending messages of reassurance, which provides reinforcement for some patients to adhere to dietary modification and avoid medication. They continued that using GDm-Health reduces the need for hospital visits. The system is beneficial for patients who have difficulty using email or phone and for some people who may struggle to record and communicate their blood glucose readings. If there are no measurements, or the measurements are higher than targets, the system alerts and prompts the midwife to contact the patient to provide the information or treatment that they need. Patients who have difficulty reading and writing have no problem with this system. It allows deviations from normal measurements to be identified and responded to very quickly.

A third commentator stated that many people work during pregnancy, so using GDm-Health would give them control of their own monitoring needs. This commentator noted that the population of people with gestational diabetes is increasing.

## *Potential system impact*

All 3 specialist commentators indicated that 1 of the main system benefits would be the possibility of reducing the number of clinic visits needed for people with gestational diabetes.

One specialist commentator reported that assuming an obstetric review is not needed every 2 weeks, glucose levels could be monitored and changes to treatment recommended remotely. This would free up clinic appointments for more complicated patients. This commentator highlighted that the time taken by healthcare professionals to interpret the remotely observed readings and then make suggested changes should be taken into account.

The second commentator stated that using GDm-Health has shown major time savings for diabetes midwives. They explained that the GDm-Health system includes a secure database of patient information that cannot be altered by either patient or staff, and therefore provides greater

security from a governance point of view. There is also the facility to download information for audit data, allowing performance management and improvement.

The third commentator highlighted the need for the clinic to have access to the software that supports the app and highlighted potential difficulties in implementing the system, specifically in terms of costs of implementation and ongoing maintenance.

All 3 commentators thought that some training would be needed for both users and healthcare professionals.

## *General comments*

One commentator considered that GDm-Health system would be limited to patients with gestational diabetes (that is, it would not be suitable for patients with pre-existing diabetes). The same commentator considered that clinical outcomes were unlikely to be affected, but that use of GDm-Health would provide an acceptable alternative to more frequent face-to-face clinic visits for patients.

In contrast, the second commentator used GDm-Health for all pregnant patients with diabetes (including type 1 and type 2), because the database facilitates better information gathering so that all patients have the same standard of care. This commentator felt that it is refreshing to have a system developed by professionals who understand both patient and professional needs.

None of the commentators was aware of any safety or security issues with GDm-Health, but 1 stated there would need to be safety measures in place to ensure that people with abnormal readings are followed up in a timely manner.

## **Patient organisation comments**

Diabetes UK gave the following comments on GDm-Health.

GDm-Health has the potential to positively affect patient care, because people with gestational diabetes would be better able to interact with their healthcare team. GDm-Health removes bias in patient reporting of blood glucose levels, helping to improve trust. It can potentially decrease unnecessary hospital visits and provide the midwife with more information for clinical decisions.

GDm-Health could improve patient health outcomes. It is unlikely that using GDm-Health would significantly effect on family, work or home life any more than usual blood glucose monitoring. The

only possible drawback could be anxiety around personal data handling, but this could be mitigated by assuring users of robust security. The system is more likely to benefit patients who embrace new technology, particularly those who already use smartphones. For many users, especially those very familiar with smartphones, no special training would be needed.

## Specialist commentators

The following specialist commentators provided comments on a draft of this briefing:

- Dr Sam Rice, consultant physician and endocrinologist, Hywel Dda University Health Board. No relevant conflicts of interests.
- Ms Rachel Crowley, diabetes specialist midwife, Royal Berkshire NHS Foundation Trust. No relevant conflicts of interests.
- Ms Suzanne Hardacre, head of midwifery and gynaecology nursing, University Hospital of Wales. No relevant conflicts of interests.

## Development of this briefing

This briefing was developed for NICE by Cedar Evaluation Centre. Please contact [medtech@nice.org.uk](mailto:medtech@nice.org.uk) for more information.

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