Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

1. Determine the quantity and quality of evidence available for a technology of interest.
2. Identify any gaps in the evidence/ongoing evidence collection.
3. Inform decisions on topics that warrant fuller assessment by Health Technology Wales.

Topic:	Remote/telemonitoring of blood glucose in women with gestational diabetes
Topic exploration report number:	TER070

Introduction and aims

This topic suggestion was submitted by Sensyne Health, the producer of GDm-Health, a CE marked application for women with gestational diabetes that allows self-recording of blood glucose measurements, and automatically uploads these measurements to a secure interface accessed by health care professionals. The application also allows simple 2-way communication between patient and professional and information on the condition and advice on exercise and diet.

Health Technology Wales have conducted a high-level search for evidence specifically on the GDm-Health app, and also for other systems and methods of monitoring blood glucose outside of clinic-based follow up.

Summary of findings

GDM-Health is the subject of a NICE medtech innovation briefing published in November 2017, Since this assessment was carried out, GDm-Health has been compared to standard care as part of a UK-based randomised controlled trial.

Other more general telemonitoring interventions used to monitor blood glucose have been assessed as part of a number of systematic reviews.

No economic evaluations of GDm-Health or any similar intervention(s) were identified. Some basic cost information on GDm-Health is included in the NICE MIB about this technology, and within some published peer-reviewed articles.

Methods of remotely monitoring blood glucose will typically involve the use of digital health technologies. GDm-Health was determined to be a Tier 3b (active monitoring) technology according to the Evidence Standards Framework for Digital Health Technologies**.** Technologies within this classification automatically record information and transmit the data to a professional, carer or third-party organisation, without any input from the user, to inform

clinical management decisions. For technologies of this classification, it is recommended that evidence from a high quality intervention study or a randomised controlled trial is produced to demonstrate effectiveness of the technology, and user satisfaction and engagement.

Areas of uncertainty

In addition to GDm-Health, several other possible methods of remote blood glucose monitoring were identified. Further review of the evidence is needed to establish whether these are relevant.

Conclusions

Evidence exists on the clinical effectiveness of the GDm-Health application and alternative interventions to remotely monitor blood glucose in women with gestational diabetes. Some basic cost information, including the estimated effect on resource use (through changes in number of clinic appointments required by each patient, for example), has also been published. Further exploration of the topic is warranted.

Brief literature search results

Resource	Results
Healthcare Improvement Scotland:	We did not identify any relevant guidance from this source.
Health Technology Assessment Group	We did not identify any relevant guidance from this source.
Health Information and Quality Authority	We did not identify any relevant guidance from this source.
UK guidelines and guidance	
SIGN	SIGN. Management of diabetes: A national clinical guideline. November 2017. https://www.sign.ac.uk/assets/sign116.pdf. This guideline recommends offering blood glucose monitoring to women with gestational diabetes, but makes no specific recommendations on how this monitoring should be delivered.
NICE	NICE Guideline NG3. Diabetes in pregnancy: management from preconception to the postnatal period. August 2015. https://www.nice.org.uk/guidance/ng3 This guideline does not make specific recommendations on how blood glucose should be monitored. NICE MedTech Innovation Briefing MIB131. Health app: GDm-Health for people with gestational diabetes. November 2017. https://www.nice.org.uk/advice/mib131
Secondary literature and economic evaluations	
EUnetHTA	Rapid joint assessment OTJA08 "Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin" https://www.eunethta.eu/the-joint-assessment-on-continuous-glucose-monitoring-cgm-real-time-and-flash-glucose-monitoring-fgm-as-personal-standalone-systems-in-patients-with-diabetes-mellitus-treated-with-insuli/ It is not known at this stage whether this includes any assessment of the effectiveness different methods of monitoring and reporting blood glucose measurements, or any evidence specific to gestational diabetes.

Cochrane library	Jones LV, Ray A, Moy FM, et al. (2019). Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. Cochrane Database of Systematic Reviews. (5). doi: 10.1002/14651858.CD009613.pub4 Raman P, Shepherd E, Dowswell T, et al. (2017). Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. Cochrane Database of Systematic Reviews. (10). doi: 10.1002/14651858.CD011069.pub2
Medline	Lau Y, Htun TP, Wong SN, et al. (2016). Efficacy of Internet-Based Self-Monitoring Interventions on Maternal and Neonatal Outcomes in Perinatal Diabetic Women: A Systematic Review and Meta-Analysis. J Med Internet Res. 18(8): e220. doi: 10.2196/jmir.6153 Ming WK, Mackillop LH, Farmer AJ, et al. (2016). Telemedicine Technologies for Diabetes in Pregnancy: A Systematic Review and Meta-Analysis. J Med Internet Res. 18(11): e290. doi: 10.2196/jmir.6556 Rasekaba TM, Furler J, Blackberry I, et al. (2015). Telemedicine interventions for gestational diabetes mellitus: A systematic review and meta-analysis. Diabetes Res Clin Pract. 110(1): 1-9. doi: 10.1016/j.diabres.2015.07.007
Other	
Evidence provided by the topic proposer	Mackillop L, Hirst JE, Bartlett KJ, et al. (2018). Comparing the Efficacy of a Mobile Phone-Based Blood Glucose Management System With Standard Clinic Care in Women With Gestational Diabetes: Randomized Controlled Trial. JMIR Mhealth Uhealth. 6(3): e71. doi: 10.2196/mhealth.9512 Mackillop L, Loerup L, Bartlett K, et al. (2014). Development of a real-time smartphone solution for the management of women with or at high risk of gestational diabetes. J Diabetes Sci Technol. 8(6): 1105-14. doi: 10.1177/1932296814542271

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Concepts used:	GDM-health, blood glucose monitoring, gestational diabetes