

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. Inform discussions on new topics received by HTW.
- 2. Determine the quantity and type of evidence available on a topic.
- 3. Assess the topic against HTW selection criteria.

Topic:	Continuous glucose monitoring in pregnancy
Topic exploration report number:	TER058
Referrer:	Dr Julia Platts, Cardiff and Vale University Health Board
Topic exploration undertaken by:	Health Technology Wales

Aim of Search

Health Technology Wales researchers searched for evidence on the clinical and cost effectiveness of continuous glucose monitoring (CGM) as an aid to managing diabetes for pregnant women.

Summary of Findings

UK guidelines and guidance

In 2017, SIGN published a national clinical guideline ''Management of diabetes: A national clinical guideline''. The document stated that there is limited evidence that CGM may be of benefit to women during pregnancy. The guideline included two RCTs. Based on recommendations, CGM may be considered in women with type 1 and type 2 diabetes.

In 2015, NICE published a guideline ''Diabetes in pregnancy: management from preconception to the postnatal period''. The recommendations were based on five studies - three RCTs and two within-participant comparisons. The review authors did not find any health economic evidence. Based on the guideline, CGM is not routinely offered to pregnant women with diabetes but can be considered if women receive insulin therapy due to problematic severe hypoglycaemia, unstable blood glucose levels or to gain information about variability in blood glucose levels. In addition, women should be supported by a member of the joint and antenatal care team with expertise in the use of CGM.

Secondary literature and economic evaluations

In 2018, EUnetHTA published the rapid assessment "Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin". The authors concluded that CGM may be useful for pregnant women in whom tight glucose control is essential with respect to the outcome of pregnancy. The assessment highlighted included an RCT by Feig et al. (2017), which presented that the use of CGM in women with type 1 diabetes during

pregnancy was associated with improved neonatal health outcomes. Women had a small but significantly greater reduction in HbA1c levels than the controls, increased time in target, reduced hyperglycaemia and less glycaemic variability at 34 weeks gestation.

The Cochrane Review 'Different methods and settings for glucose monitoring for gestational diabetes during pregnancy' reported the outcomes of two comparisons. The first comparison, CGM versus intermittent monitoring, was evaluated in two RCTs and included 225 women. The evidence showed no clear difference for pre-eclampsia, caesarean section and large-for-gestational age. In the CGM group, glycaemic control was lower than in the intermittent monitoring group. There was not enough evidence to assess perinatal mortality and there was no clear difference for preterm birth less than 37 weeks' gestation. The second comparison, constant CGM versus intermittent CGM, was evaluated in one study and included 25 women. There was no clear difference between groups for caesarean section, glycaemic control or preterm birth less than 37 weeks' gestation. All studies were very low to moderate quality evidence.

The second Cochrane Review "Different methods and settings for glucose monitoring for gestational diabetes during pregnancy" evaluated outcomes of CGM systems versus self-monitoring of glucose included in two RCTs. The studies included 193 women. No clear difference was observed between both methods for caesarean section, births of large-for-gestational age babies and neonatal hypoglycaemia. There were no peritoneal deaths in both RCTs.

Conclusions

Five RCTs and two within-participant comparisons were identified which evaluated CGM for pregnant women with diabetes. There are existing secondary sources summarising the clinical evidence, but we did identify any economic evaluations of the use of CGM in pregnant women with diabetes.

Areas of Uncertainty

The evidence identified covers both gestational diabetes and pre-existing diabetes. Further assessment of the evidence is required to assess the effectiveness of CGM in each of these clinical scenarios.

We did not identify any secondary evidence that included detailed economic evaluation of CGM. Any further assessment would need to involve more detailed searches for sources that can be used to assess the cost effectiveness of CGM in the population of interest.

Feasibility of Technology Assessment

HTW's Assessment Group concluded to progress this topic to Evidence Appraisal, focusing specifically on the use of CGM in pregnant women with type 1 diabetes. This will be published as EAR012.

Brief literature search results

Resource	Results
Healthcare Improvement Scotland	We did not identify any relevant evidence from this source.
Health Technology Assessment Group	We did not identify any relevant evidence from this source.
Health Information and Quality Authority	We did not identify any relevant evidence from this source.
UK guidelines and guidance	
SIGN	Scottish Intercollegiate Guidelines Network. 2017. Management of diabetes: A national clinical guideline. Available at: https://www.sign.ac.uk/assets/sign116.pdf [Accessed 25/03/2019]
NICE	National Institute for Health and Care Excellence guideline. 2015. Diabetes in pregnancy: management from preconception to the postnatal period. Available at: https://www.nice.org.uk/guidance/ng3/chapter/1-Recommendations [Accessed 25/03/2019]
Secondary literature and economic evaluation	ons
<u>EUnetHTA</u>	Agency for Quality and Accreditation in Health Care and Social Welfare (AAZ), Main Association of Austrian Social Security Institutions (HVB), The Norwegian Institute of Public Health (NIPHNO). Continuous glucose monitoring (CGM real-time) and flash glucose monitoring (FGM) as personal, standalone systems in patients with diabetes mellitus treated with insulin. Joint Assessment. Zagreb: EUnetHTA; 2018. Report No.: OTJA08.
<u>ECRI</u>	We did not identify any relevant evidence from this source.
Cochrane library	Moy FM, Ray A, Buckley BS, West HM. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. Cochrane Database of Systematic Reviews 2017, Issue 6. Art. No.: CD009613. DOI: 10.1002/14651858.CD009613.pub3.

	Raman P, Shepherd E, Dowswell T, Middleton P, Crowther CA. Different methods and settings for glucose monitoring for gestational diabetes during pregnancy. Cochrane Database of Systematic Reviews 2017, Issue 10. Art. No.: CD011069. DOI: 10.1002/14651858.CD011069.pub2.	
Medline	Voormolen, D.N., DeVries, J.H., Evers, I.M. <i>et al.</i> 2013. The efficacy and effectiveness of continuous glucose monitoring during pregnancy: a systematic review. Obstet Gynecol Surb 68(11): 753-763.	
Ongoing research		
<u>Clinicaltrials.gov</u>	We did not identify any ongoing randomised controlled trials assessing the use of CGM in pregnant women with diabetes.	
Sources identified by topic proposer		
	Feig D,Donovan L, Corcoy R, Murphy K et al. "Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial". Lancet, Nov 2017	
	Murphy H et al "Effectiveness of continuous glucose monitoring in pregnant women with diabetes: randomised clinical trial" BMJ 2008; 337	

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Concepts used:	glucose monitoring, diabetes, pregnancy