Healthcare Improvement Scotland | SHTG Advice on health technologies

SHTG Adaptation 01
November 2020

In response to an enquiry from the Scottish Diabetes Group (SDG)

Continuous glucose monitoring in pregnant women with type 1 diabetes*

**adaptation for NHSScotland of guidance published by Health Technology Wales*

Recommendations for NHSScotland

Continuous glucose monitoring (CGM) should be offered to all pregnant women with type 1 diabetes (T1DM). The case for adopting CGM in pregnant women with T1DM is supported by the clinical evidence.

The use of CGM during pregnancy may improve maternal glycaemic control compared with self-monitoring of blood glucose (SMBG). CGM reduces neonatal hypoglycaemia and the need for and duration of neonatal intensive care. These improved clinical outcomes were reported in women who used CGM from the first trimester of pregnancy.

Cost modelling estimates that the use of CGM in mothers with T1DM is cost saving compared with SMBG, with cost savings largely driven by a reduction in neonatal intensive care requirements.[1]

A prospective dataset should record all pregnant women with T1DM in NHSScotland, capturing clinical outcomes for mother and child, and the technology used to measure blood glucose levels.

The Scottish Health Technology Group (SHTG) recommendation is based on guidance produced by Health Technology Wales (HTW) in 2019. The original HTW guidance was modified following an SHTG adaptation process. NHSScotland is required to consider SHTG recommendations.

What were we asked to look at?

The Scottish Diabetes Group (SDG) asked us to review the evidence surrounding the use of CGM in pregnant women with T1DM, and provide recommendations for NHSScotland.

Why is this important?

There is existing Scottish Government policy support for the use of CGM in diabetes including an announcement in 2017 of funding to encourage the implementation of CGM. SHTG advice is required to inform adoption, particularly for pregnant women with T1DM who are considered amongst the highest priority for the technology.

What was our approach?

We undertook an SHTG adaptation process based on guidance produced by HTW in 2019.

The European Network for Health Technology Assessment (EUnetHTA) adaptation toolkit was used to assess the relevance, reliability and transferability of the HTW guidance. Key findings from the toolkit are included within the SHTG Adaptation to inform the final recommendations.

As part of the adaptation process, the views, perspectives and experience of topic experts were obtained via three rounds of questioning. The first draft of the SHTG Adaption was distributed to topic experts, along with a survey. The experts were asked to consider whether the HTW recommendations were appropriate for Scotland and if so, whether they should be adopted with no changes, or adapted to make them more relevant to the NHSScotland context.

Based on the responses received, the draft SHTG Adaptation document was reviewed. A revised draft, along with anonymised responses to the first round of questioning, were sent back to the experts for a second round of questioning. Further changes were made to the draft based on the responses received. A third draft, along with anonymised responses to the second round of questioning, were sent to the experts with a final opportunity to submit any comments.

Topic experts' comments are captured within the SHTG Adaptation including a detailed summary from each round of questioning. All experts' comments were available for consideration by SHTG Council to inform the final recommendations.

What next?

The SHTG Adaptation will be used by the Scottish Diabetes Group and the Diabetes Managed Clinical Networks to inform the use of CGM in pregnant women with T1DM.

Considerations for NHSScotland

As part of the SHTG adaption of the guidance produced by HTW in 2019, the following key considerations were used to inform the adaption process and help reach recommendations for NHSScotland.

Epidemiology and predicted volume

According to Diabetes UK, 5% of the 956,861 pregnancies in the UK in 2015 involved diabetes:

- 42,000 involved gestational diabetes (87.5%)
- 3,600 involved T1DM (7.5%)
- 2,400 involved type 2 diabetes (5%)[2]

The number of women in Scotland with T1DM who became pregnant rose from 205 in 1998/99 to 264 in 2012/13[3].

Scottish context

The Scottish Intercollegiate Guidelines Network (SIGN) guideline on The Management of Diabetes (published in 2010 and updated in 2017 with the section on pregnancy currently being reviewed) includes a recommendation that: "Continuous glucose monitoring may be considered in women with type 1 and type 2 diabetes."

In June 2017, the Scottish Government wrote to Health Boards announcing £10m funding over 5 years to increase insulin pump use and encourage the implementation of CGM systems[4]. In a Scottish Government letter dated July 2019, those considered highest priority for commencement of CGM included pregnant women with T1DM. This letter also stated that funded adult insulin pumps and CGMs for all ages should be in place by 31 March 2020[5] .

CGM versus flash glucose monitoring

In Scotland, flash glucose monitoring is used extensively during pregnancy. CGM is used less widely despite pregnant women with T1DM being highlighted as a priority area for CGM by the Scottish Government. Clinical experts estimate that 5-10% of pregnant women with T1DM in Scotland use CGM (Dr Robert Lindsay, Reader in Diabetes and Endocrinology at University of Glasgow, Personal Communication August 2020).

The evidence comparing flash glucose monitoring with CGM is lacking.

The searches conducted by HTW did not identify any RCT evidence comparing CGM to flash glucose monitoring in pregnant women with T1DM. One retrospective cohort study (n=186) was identified which reported no statistically significant differences between the two interventions for any of the maternal or neonatal outcomes reported (Kristensen *et al,* 2019).

As part of the SHTG adaption process, the searches performed by HTW were updated in order to identify any recently published studies comparing flash glucose monitoring with CGM in pregnant women with diabetes. None were identified.

Clinical experts advise that CGM offers additional functionality over flash glucose monitoring particularly when used with an insulin pump. They also note that many women with T1DM will be able to achieve excellent glucose control with flash glucose monitoring, and may prefer to continue to use the same technology whilst pregnant.

Organisational issues

The evidence appraisal by HTW notes that the use of CGM will result in training needs for patients and clinical staff, for initial set-up of the device and its subsequent use. Training and ongoing support is provided by CGM device manufacturers.

Scottish topic experts were asked to identify barriers to the adoption of the HTW recommendations in NHSScotland. Five out of ten respondents raised the issue of staff training, yet it was noted that requirements will be minimal. Two experts highlighted the role of diabetes nurse specialists, and that the resource associated with their education (for the provision of CGM) and clinic time (including reviewing patients' data) is not referenced in the HTW guidance.

Experts flagged concern around access to funding for CGM, despite there already being existing infrastructure to support the use of CGM in pregnancy.

There is a national programme of work to up skill staff in these technologies and a drive to ensure eligible individuals get access to technologies that have been proven to improve outcomes (Dr Brian Kennon, Consultant Diabetologist, Personal Communication January 2020).

Patient and social aspects

The HTW evidence review identified one qualitative meta-analysis on the impact of CGM on life with T1DM, but this was not focused on pregnant women specifically. The themes identified are covered in the HTW review.

Scottish Health Technology Council considerations

The draft SHTG Adaptation was considered by the Scottish Health Technology Council on 2 October 2020. A summary of the discussion is presented as follows:

- The Council recognised that there is insufficient evidence comparing CGM with flash glucose monitoring in pregnant women with T1DM. This is an important comparator, as flash glucose monitoring is widely used by this patient group in NHSScotland. The Council noted the merits of CGM over flash glucose monitoring in terms of improved functionality.
- The Council supported the creation of prospective dataset to help address the lack of evidence comparing CGM with flash glucose monitoring. The Council welcomed additional research in this area, to allow for comparison between the various glucose monitoring interventions.
- The Council noted that some pregnant women with T1DM may prefer to continue to use flash glucose monitoring, and this option should be available to them.
- The *de novo* economic model included in the HTW guidance was based on a published model that used data from the CONCEPTT trial. The Council noted that the *de novo* model did not take into consideration that the CONCEPTT trial reported that CGM use led to an increase in unscheduled clinical contact - an issue also raised by one of the clinical experts. The Council also noted that the figures assumed for mean length of stay in neonatal intensive care units (NICU) were unpublished data from the CONCEPTT trial. The impact of using unpublished length of stay data from the CONCEPTT trial for mean NICU lengths of stay could impact on the reproducibility of the model for Scotland. Although the Council were content that these uncertainties did not affect the overall conclusions of the economic model, the specific cost calculations were removed from the recommendation for NHSScotland.
- The Council acknowledge the Scottish Government policy support for CGM, whilst recognising that the role of SHTG is to provide recommendations based on the available evidence.
- The Council noted that the maternal glycaemic control outcomes reported by HTW were of borderline statistical and clinical significance. The Council agreed that the wording of the NHSScotland recommendation should be amended to reflect this uncertainty.

Reliability and transferability of the adapted HTA

The EUnetHTA adaptation toolkit was used to assess the relevance, reliability and transferability of the HTW guidance. The toolkit focuses on five 'domains' (or sections) of an HTA report:

- The use of the technology
- Safety
- Effectiveness
- Economic evaluation
- Organisational elements

The toolkit helped to highlight that whilst HTW identified evidence comparing CGM with self-monitoring of blood glucose they found insufficient evidence comparing CGM with flash glucose monitoring. To address this issue a literature search was undertaken to identify any new evidence comparing CGM with flash glucose monitoring – see *Considerations for NHSScotland*.

No major issues with the economic evaluation were identified, although it was noted that the HTW *de novo* model was described as a 'cost minimisation analysis'. A cost minimisation analysis assumes that the interventions are of equivalent efficacy in terms of patient outcomes but not cost. This is not the case for the outcomes taken from the CONCEPTT trial, on which the HTW economic analysis is based. Despite this, it was felt that the *de novo* model was reasonable, as the effectiveness outcomes (relating to birth and neonatal complications) had been converted into resources used (e.g. bed day cost for neonatal intensive care) and that the conclusions based on the model were acceptable and broadly relevant to the NHSScotland context.

No other issues relating to relevance, reliability and transferability of the HTW guidance were identified via the toolkit.

What did the topic experts say?

Full details on the questions asked in each round, and the responses received, can be obtained from SHTG on request.

First round of questioning

Ten experts responded to the first round of questioning. There was representation from diabetologists, nursing specialists, obstetricians and gynaecologists, physicians and experts in endocrinology, metabolic medicine and public health. Representation covered the following health boards: NHS Greater Glasgow and Clyde, NHS Dumfries and Galloway, NHS Lothian, NHS Forth Valley, NHS Highland and NHS Tayside. The key results from the first round of questioning are summarised as follows:

- Eight experts either agreed or strongly agreed with the guidance produced by HTW. One expert disagreed, raising concerns about the quality, quantity and timeliness of the evidence. Another expert stated that they were 'undecided' due to concerns around the interpretation of the evidence base included by HTW.
- Nine experts agreed or strongly agreed that the guidance produced by HTW was an accurate interpretation of the evidence base. One expert was 'undecided' due to concerns around the interpretation of the evidence base included by HTW.
- All ten experts said that guidance for NHSScotland should support the case for the use of CGM in pregnant women with T1DM. Two experts questioned whether CGM should only be considered for some pregnant women with T1DM (for example, those who are not meeting their personalised glucose targets with multiple daily injections alongside optimal standard of care).
- Six experts said that the guidance for HTW should be adopted and implemented in its entirety, without any changes, in NHSScotland. Four experts felt that the guidance needed to be amended for the Scottish context.

Second round of questioning

Ten experts responded to the second round of questioning (including eight who responded to the first round of questioning). The key results from the second round of questioning are summarised as follows:

- Nine experts agreed or strongly agreed with the draft recommendation for NHSScotland, based largely on the recommendation produced by HTW. One expert disagreed with the recommendation, re-iterating concerns raised in round 1 about how the evidence had been interpreted by HTW. This expert also noted that the CONCEPTT study reported that CGM use led to an increase in unscheduled clinical contact. This may have resource implications which have not been addressed by HTW.

- Experts were asked whether the recommendation for CGM in Scotland should be limited to pregnant women with T1DM who meet certain criteria (for example, women who cannot meet personalised glucose targets using multiple daily injections). Three experts said 'yes'. One suggested that it may be of value to limit provision of CGM initially to women who have undertaken structured education and are able to apply CHO counting principles. Another expert who said 'yes' noted that women may be able to achieve excellent glucose control with flash monitoring, and CGM should be a second-line option. However, most experts (seven out of ten) answered 'no', and so the recommendation was not changed.

- All ten experts agreed that the following should be added to the recommendations for NHSScotland:

    - A note to clarify that the improved clinical outcomes reported in the trials were in women who used CGM from the first trimester of pregnancy.

- Reference to a prospective dataset for all pregnant women with T1DM, including clinical outcomes for mother and child, and the technology they used to measure blood glucose levels.

Acknowledgements

This adaptation is based on the following work:

Health Technology Wales. Continuous glucose monitoring systems for managing diabetes in pregnant women. 2019 [cited 16 July 2020]; see Health Technology Wales webpage.

Reviewers

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- Dr Brian Kennon, Consultant Diabetologist, National Lead for Diabetes and Chair of Scottish Diabetes Group (SDG).

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- Dr David Carty, Consultant Physician in Diabetes & Endocrinology, NHS Greater Glasgow and Clyde
- Dr Anna Dover, Consultant in Diabetes and Endocrinology, NHS Lothian
- Jill Duncan, Diabetes Specialist Nurse, NHS Lothian
- Dr Fiona Green, Consultant Physicican, NHS Dumfries & Galloway
- Dr Chris Kelly, Consultant Physician, NHS Forth Valley
- Dr Robert Lindsay, Reader in Diabetes and Endocrinology, University of Glasgow
- Liz Mackay, Diabetes Nurse Specialist/Pump Lead, NHS Lothian
- Dr Rahat Maitland, Consultant Physician in Diabetes and Endocrinology, NHS Greater Glasgow and Clyde
- Dr David McGrane, Consultant Physician in Diabetes and Endocrinology, NHS Greater Glasgow and Clyde
- Dr Roselyn Mundenha, Consultant Obstetrician and Gynaecologist, NHS Tayside
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SHTG Council

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Healthcare Improvement Scotland development team

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- Jo Kelly, Lead Author/Health Services Researcher
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About SHTG Adaptation

SHTG Adaptations are produced to inform a decision at a particular point in time and are not routinely updated. The Adaptation will be considered for review if requested by stakeholders, based upon the availability of new published evidence which is likely to materially change the recommendation for NHSScotland. For further information about the SHTG process please see this Scottish Health Technologies Group webpage.

To propose a topic for SHTG consideration, email his.shtg@nhs.net or download a 'requesting our support' form from this Healthcare Improvement Scotland webpage.

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network, or by contacting your local library and information service.

A glossary of commonly used terms in Health Technology Assessment is available from htaglossary.net.

References

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