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Horizon Scanning Technology Prioritising Summary

Continuous glucose monitoring in pregnant women with diabetes

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PRIORITISING SUMMARY

REGISTER ID: **000417 (REFERAL)**

NAME OF TECHNOLOGY: **CONTINUOUS GLUCOSE MONITORING FOR DIABETES IN PREGNANT WOMEN**

PURPOSE AND TARGET GROUP: **MONITORING OF GLUCOSE LEVELS DURING PREGNANCY IN DIABETIC WOMEN**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

- ☐ Yet to emerge
- ☐ Experimental
- ☒ Investigational
- ☐ Nearly established
- ☐ Established
- ☐ Established *but* changed indication or modification of technique
- ☐ Should be taken out of use

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☒ Yes — ARTG number 144577
- ☐ No
- ☐ Not applicable

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Finland	✓		
Australia	✓		
Germany	✓		
UK	✓		

IMPACT SUMMARY:

Medtronic (Northridge, CA) manufacture the MiniMed continuous glucose monitor (CGMS) for the purpose of providing continuous monitoring and recording of blood glucose levels. This device is targeted at individuals with diabetes[1], and may provide a more accurate record of blood glucose levels when compared to standard intermittent self-monitoring via finger prick blood testing. This summary investigates the specific use of the device in the management of pregnant women who have a diabetic profile.

[1] This device is designed to monitor type I, II or gestational diabetes.

BACKGROUND

Pregnancy may be complicated by the presence of pre-existing Type I or Type II diabetes, or by the development of gestational diabetes. Although the Australasian Diabetes in Pregnancy Society (ADIPS) recommends diabetes screening for all pregnant women, this does not currently occur routinely in Australia (AIHW 2008a). Diabetes during pregnancy increases the risk of pregnancy complications for both the mother and infant. Complications include foetal macrosomia[2], with the associated increased risks of birth trauma for both the infant and mother, higher need for caesarean section and other neonatal complications. Current standard practice for women with gestational diabetes involves up to seven finger-prick blood based tests per day. While this information is useful in patient management, it does not capture an accurate ongoing record of the subject's glucose levels at all points during the day. The MiniMed CGMS can provide up to 288 measurements over 72 hours, giving a far higher resolution record of glucose levels. The MiniMed device consists of a glucose monitor connected by a cable to the sensor which is inserted under the skin (Figure 1). The device records the level of glucose every 10 seconds and averages these measurements every five minutes. The patient's medical practitioner can then access the data and base any treatment changes on this higher resolution data.

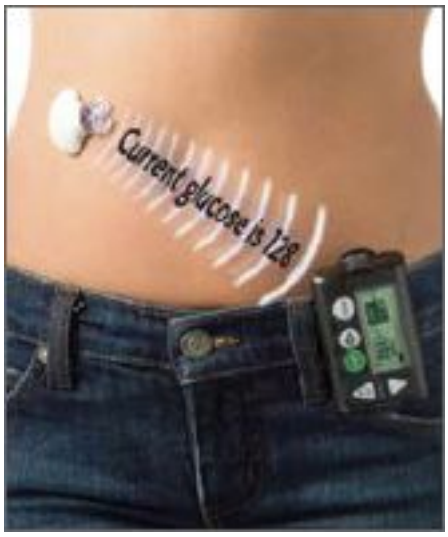

Figure 1 The MiniMed continuous glucose monitoring system (Medtronic 2008)

CLINICAL NEED AND BURDEN OF DISEASE

Gestational diabetes mellitus (GDM) is defined as the development of diabetes that first occurs during pregnancy. For Australia, the 2005-06 incidence of this type of diabetes was 4.6 per cent of pregnant women aged 15-45 years. This was a 20 per cent increase over the incidence reported for 2000-01 (AIHW 2008b). The New Zealand incidence is 3-8 per cent of pregnancies in the mid 1990s (GDMTWP 2007). For pregnancies with pre-existing diabetes (pre-gestational diabetes), type II is thought to be the predominant form (55 per cent). The dominance of type II diabetes is thought

[2] Macrosomia = significant overgrowth

to be increasing due to the increasing prevalence of obesity in the Australian population (McElduff et al 2005). In 2004-05 around 11,000 pregnant women developed gestational diabetes, 1200 had pre-gestational diabetes and 800 had diabetes of unknown status (AIHW 2008a). There are many risks associated with diabetes during and after pregnancy for both the mother and child. The risk of caesarean section, pre-eclampsia and perineal trauma is increased for the mother during pregnancy. Postnatally, the mother with GDM has an increased risk of developing Type II diabetes, and with each additional pregnancy the risk of developing Type II diabetes increases. For the infant of a GDM mother there is also an increased risk of injury, macrosomia, shoulder dystocia[3], hypoglycaemia and jaundice. In addition, there is also an increased risk of the infant becoming obese or developing diabetes later in life (GDMTWP 2007).

DIFFUSION

Some experimental trials have been conducted in Australia using the MiniMed CGMS in pregnancy (McLachlan et al 2007).

COMPARATORS

The current standard procedure for assessing blood glucose levels in pregnant women is the finger prick blood glucose test. A disposable test strip is placed in an electronic reader and a small amount of blood is taken from a finger prick and placed on the strip. The electronic reader displays the current blood glucose level. Even if this testing is performed in an intensive regimen (up to 8 tests per day) it is believed that the low resolution of the monitoring schedule may miss glucose spikes and periods of hypoglycaemia. Monitoring at night is rarely performed (Chetty et al 2008).

SAFETY AND EFFECTIVENESS ISSUES

The ability of the Minimed CGMS to monitor pre-gestational diabetic pregnant women was investigated in a prospective study (n=57) conducted by Murphy et al (2007) (level III-3 intervention evidence). The study population consisted of 40 Type I and 17 Type II diabetic subjects. Several women were monitored more than once resulting in 180 profiles, with an average of 15 days monitored in each woman. The women were instructed to manage their diabetes as usual using finger prick blood glucose monitoring at least seven times a day. Monitoring with the Minimed CGMS was not used to direct patient management in the short term but was examined after one week in the presence of the woman's health care providers. No direct comparison of the relative effectiveness of either the standard or Minimed methods was performed, however the CGMS provided greater knowledge about the changes in the subject's blood glucose levels over time. The higher resolution data provided by the

[3] In shoulder dystocia, disproportion occurs between the bisacromial diameter of the foetus and the antero-posterior diameter of the pelvic inlet, resulting in impaction of the anterior shoulder of the foetus behind the symphysis pubis.

CGMS demonstrated that women with Type II diabetes spend less time hypoglycaemic than Type I subjects (p=0.04), however both Type I and II women experienced the similar nocturnal hypoglycaemia episodes (p>0.05). Women with Type II diabetes also maintained the correct level of blood glucose for a greater proportion of the time than Type I women (p=0.0001) (Murphy et al 2007).

A randomised controlled trial investigated the glucose control achieved by standard care versus continuous glucose monitoring with the MiniMed CGMS (level II intervention evidence). The patient population was prospectively recruited and consisted of 71 pregnant women (46 with Type I and 25 with Type II diabetes). The women were randomised to standard care[4] (n=33) or standard care plus continuous glucose monitoring (n=38). The data from the CGMS were not used for real time modification of treatment but one week after data collection was concluded the subject and medical staff were able to view the data and adjust behaviour accordingly. The outcomes for the intervention arm were a reduced level of HbA_{1c}[5] (indicating improved glycaemic control) in the third trimester, lower birth weight, and reduced risk of macrosomia. These factors indicate a better control of diabetes during pregnancy when monitored using the MiniMed CGMS (Murphy et al 2008).

A study of 55 prospectively recruited patients (37 with gestational, 10 with Type II and 8 with Type I diabetes) investigated whether the MiniMed CGMS was beneficial in altering patient management decisions (level III-2 intervention evidence). The accuracy of the MiniMed CGMS was assessed against standard finger prick glucose monitoring. The mean difference between the CGMS and finger prick glucose was 12 ± 5.7 per cent. Some women had more than one CGMS monitoring period completed giving a total of 68 CGMS data sets. Of these, two were unusable for clinical management. Forty two (62%) of the 68 data sets were used to alter clinical management of the subjects by identifying postprandial hyperglycaemia or nocturnal hypoglycaemia. Type I diabetic patients benefited most by the MiniMed CGMS with 89 per cent of data sets being used to alter patient management. Subjects were asked for feedback on using the CGMS and 37/48 (77%) of respondents reported that the inconvenience of wearing the monitor was outweighed by the benefits of CGMS (McLachlan et al 2007).

All of the studies examined found that the MiniMed CGMS provided greater resolution data compared to finger prick blood glucose tests. The data obtained were useful for patient management and in one study the clinical outcomes of women using CGM improved versus the standard care group. No safety concerns were reported.

[4] Intermittent self monitoring of glucose levels from capillary blood obtained using the finger prick technique.

[5] HbA_{1c} (glycosylated haemoglobin) is a marker of the average blood glucose levels over the past two to four weeks.

COST IMPACT

Medtronic Australasia Pty Ltd markets the Guardian REAL-Time glucose monitoring system. A complete kit is valued at $AUD2,500 and includes the Guardian monitor, transmitter, charger, tester, sensor inserter, communications device for data upload, clip and holster. Individual components are priced as follows: the monitor is valued at $AUD1,400; the transmitter $AUD1,250 and the glucose sensors (packet of 10) $AUD750 (Medtronic personal communication).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified/raised in the sources examined.

OTHER ISSUES

No issues were identified/raised in the sources examined.

SUMMARY OF FINDINGS

The Minimed CGMS provided greater resolution blood glucose level data compared to standard care. Some studies reported this to be useful in patient management decisions and may have facilitated better outcomes for both the mother and offspring.

HEALTHPACT ACTION:

The efficacy of continuous glucose monitoring has been reported in the past. The widespread introduction of CGM of *all* pregnant women would not be recommended, however, of importance is identifying the subgroup of pregnant women who would benefit from CGM. More research needs to be conducted on identifying these women and therefore HealthPACT has recommended that this technology be monitored for further information in 12-months time.

NUMBER OF INCLUDED STUDIES

Total number of studies	
Level II Intervention evidence	1
Level III-2 Intervention evidence	1
Level III-3 Intervention Evidence	1

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Murphy, H. R., Rayman, G. et al (2007). 'Changes in the glycemic profiles of women with type 1 and type 2 diabetes during pregnancy', *Diabetes Care*, 30 (11), 2785-2791.

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SEARCH CRITERIA TO BE USED:

Blood Glucose/ metabolism
Pregnancy
Pregnancy Complications/ blood
Diabetes, Gestational/blood
Diabetes Mellitus, Type 1/ blood/complications
Diabetes Mellitus, Type 2/ blood/complications