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Screening and treatment of Gestational Diabetes Mellitus.

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PRIORITISING SUMMARY

REGISTER ID: **000177**

NAME OF TECHNOLOGY: **SCREENING AND TREATMENT GESTATIONAL DIABETES**

PURPOSE AND TARGET GROUP: **DETECTION AND TREATMENT OF GESTATIONAL DIABETES MELLITUS IN PREGNANT WOMEN**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☐	Yes	ARTG number
☐	No	
☒	Not applicable	

INTERNATIONAL UTILISATION:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	✓		
United States	✓		

IMPACT SUMMARY:

This prioritising summary examines current issues in screening for and treatment of Gestational Diabetes Mellitus (GDM) in Australia. Two recent studies are included that demonstrate improved perinatal outcomes for women treated for GDM.

BACKGROUND

GDM is associated with both maternal and perinatal complications, including macrosomia, neonatal hypoglycaemia, hyperbilirubinaemia and respiratory distress syndrome (Hoffman et al 1998). In the long-term it has been suggested that GDM is a strong risk factor for obesity and/or diabetes for the infant and for the development of permanent diabetes later in life for the mother (Hoffman et al 1998).

Although the risks associated with GDM are well-documented there is long-standing international debate over the utility/benefits of screening for and treating gestational diabetes (Scott et al 2002 and Langer et al 2005). Some groups recommend universal screening, or advocate selected screening, whilst others are against any screening for GDM. This has resulted in part due to the debate concerning the diagnostic definition of GDM, and in part to the profusion of different tests available, for both screening and definite diagnosis of GDM (Scott et al 2002).

Women diagnosed with GDM are often intensively managed with increased obstetric monitoring, dietary regulation, and in some cases insulin therapy despite a lack of conclusive evidence for closer monitoring and treatment (Tuffnell et al 2003). Until recently there was inconclusive evidence that it results in any significant improvement in perinatal outcomes and some studies (level II intervention evidence) have demonstrated *no* evidence for improved perinatal outcomes (Tuffnell et al 2003, Rumbold and Crowther 2001, Walkinshaw 2000 and Walkinshaw 1994)

The uncertainty of whether treatment actually reduces risks associated with GDM has resulted in a lack of consensus on appropriate diagnostic criteria and on whether to recommend routine screening for all pregnant women or selective screening based on risk factors for gestational diabetes (Rumbold and Crrowther 2002, Crowther et al 2005).

This prioritising summary describes two recent studies conducted in Australia and the United States that have demonstrated clear benefits for universal screening and treating gestational diabetes.

CLINICAL NEED AND BURDEN OF DISEASE

There is an estimated incidence of GDM of between 6-9 per cent of all pregnancies in Australia (Hoffman et al 1998, Rumbold and Crowther 2001). Women with GDM may include those with unrecognised, pre-existing, non-insulin-dependent diabetes (Type 2) and a small number with insulin-dependent diabetes (Hoffman et al 1998). Most women with gestational diabetes have no symptoms and many do not have risk factors associated with GDM. The presence of GDM may have implications for both baby and mother with evidence that perinatal mortality is increased in untreated GDM

DIFFUSION

The 1998 Australasian Diabetes in Pregnancy Society consensus guidelines on the management of GDM recommended screening for pregnant women at 26–28 weeks gestation (Hoffman et al 1998). However, the guidelines were equivocal in regard to screening for gestational diabetes, allowing either for universal screening or for selective screening based on clinical risk factors in relatively low risk populations.

A postal survey in 2001 found that 284/328 (87%) of Australian hospitals[1] undertook screening for GDM and of these 151 (53%) screened all women and 63 (22%) selectively screened women (Rumbold and Crowther 2001). Screening for GDM is not universal in New Zealand. A study of GDM screening practices in New Zealand over a 12-month period found that it was not performed uniformly, even in women with clear and agreed indications for selective screening (Yapa and Simmons 2000).

A recent editorial of the Medical Journal of Australia recommended that universal screening should now be accepted in the light of findings of a recent level II-intervention study, the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) that demonstrated clear clinical benefits of screening and treating GDM (McIntyre et al 2005, Crowther et al 2005).

COMPARATORS

Routine antenatal care without screening and treatment of GDM.

[1] 544 hospitals were surveyed, 360 (68%) responded and 32 subsequently excluded

EFFECTIVENESS AND SAFETY ISSUES

The ACHOIS study (level II intervention evidence) randomised 1000 women between 24 and 34 weeks gestation with mild GDM to either routine antenatal care or to an intervention which comprised of home glucose monitoring, review by a diabetes educator, dietician and physician, and insulin therapy if glycaemic targets were not met (Crowther et al 2005). Primary outcomes examined among the infants were a composite measure of serious perinatal complications defined as death, shoulder dystocia, bone fracture and nerve palsy, admission to the neonatal nursery and jaundice requiring phototherapy. The primary outcomes in women were labour induction and Caesarean section, maternal health status and psychological outcome.

The following outcomes are reported in this study. Serious adverse perinatal outcomes occurred in 1% of the intervention group versus 4% of the routine-care group (adjusted relative risk, 0.33, 95% CI [0.14, 0.75]). The percentage of infants who were large for gestational age (LGA) was lower in the intervention compared to the routine care group (13% v 22%). There was no difference between groups for small for gestational age infants. Although induction of labour was more common in the intervention group (39% v 29%), rates of caesarean delivery were similar in both groups (approximately 31%). Measures of maternal quality of life were more favourable in the intervention group. To prevent one serious perinatal outcome, 34 women needed to be treated (95% CI [20, 103]).[2]

A study by Langer et al (2005) (level III-2 intervention evidence) assessed the risk of perinatal morbidity at differing levels of maternal glucose intolerance. A matched control group of 555 women with gestational diabetes mellitus diagnosed after 37 weeks gestation, was compared with 1110 women treated for gestational diabetes mellitus (consisting of multidisciplinary treatment by specialists, nurse educators, dieticians and social workers) and 1110 non-diabetic subjects matched from the same delivery year for obesity, parity, ethnicity, and gestational age at delivery. The non-diabetic subjects and those not treated for gestational diabetes mellitus were also matched for prenatal visits.

To assess an association of outcome to GDM severity levels, the treated and untreated GDM groups were stratified into four categories based on fasting plasma glucose levels. The untreated group had a significantly higher rate of adverse outcome compared to the treated group at all levels of plasma glucose levels (p= 0.01) (Langer et al 2005).

The untreated group had higher rates of adverse neonatal outcomes when compared with the non-diabetic and treated groups. The primary outcome, a composite variable of stillbirth, neonatal macrosomia, LGA, neonatal hypoglycaemia, erythrocytosis and hyperbilirubinemia occurred in 59% of the untreated group, 18% of those treated and 11% of women in the non-diabetic group (Langer et al 2005). The authors conclude that undiagnosed and untreated gestational diabetes increases the risk of perinatal morbidity and mortality in all levels of disease severity and that timely detection and treatment may improve outcome.

At the time of preparing this summary a study (level II intervention evidence) was identified describing a planned RCT assessing possible benefits for the treatment of mild GDM, comparing women with mild GDM, receiving diet therapy and insulin as required, to women receiving no specific treatment (Landon et al 2002). The study intended to randomise women diagnosed with mild GDM between 24 and 29 weeks of gestation to diet treatment and monitoring or no treatment. Primary outcomes for assessment were stated as neonatal morbidity and mortality, secondary outcomes were risk of large-for-gestational-age infant and/or macrosomia, neonatal intensive care unit admission and maternal complications such as caesarean section and pre-eclampsia. To date the study is ongoing.

[2] Note, a wide confidence interval

A 5 year prospective observational study with approximately 25,000 pregnant women in 10 countries is currently in progress to assess associations between maternal glucose levels and adverse maternal, fetal and neonatal outcomes (HAPO Study Cooperative Research Group 2002). The primary outcomes to be assessed are caesarean delivery, increased fetal size (macrosomia/LGA/obesity), neonatal morbidity (hypoglycemia), and fetal hyperinsulinism. This study aims to address further the question of associations of degree of glucose intolerance to adverse outcomes.

COST IMPACT

The ACHOIS data suggest that something more than "routine antenatal care" is required for optimal outcomes women with GDM (Crowther et al 2005). The introduction of routine screening for gestational diabetes has cost and resource implications (McIntyre et al 2005). The number of women diagnosed with gestational diabetes would increase, and it follows that there would be a resultant increase in costs for their care.

In ACHOIS, the intervention group received care from a multidisciplinary team, which included a dietician, diabetes educator and physician, in addition to the obstetrician and midwives. Although this level of care is congruent with the 1998 Australasian guidelines, it may be difficult to implement on a large scale across Australia. Other models of care may be required, with increasing involvement of midwives, general practitioners and other health care providers (McIntyre et al 2005). There is some evidence to support the efficacy of less intensive models of care but this requires further evaluation.

To assess cost effectiveness of universal screening for GDM, it would be necessary to assess whether screening + diagnosis + treatment reduces adverse outcomes (such as caesarean section, birth trauma, neonatal morbidity and long-term outcomes for both mother and baby) and the net cost per adverse event prevented (Scott et al 2002).

The current cost of an oral glucose challenge test for the detection of GDM (MBS item 66545) is $16.10 (Medicare Benefits Schedule 2005). A cost analysis is currently in progress for the ACHOIS trial.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

It has been noted in several studies that screening positive for GDM can produce adverse psychological effects in women (Rumbold and Crowther 2002, Sjögren et al 1994). One study found that women's concern about their own health persisted for 3-5 five years after initial diagnosis (Feig et al 1988). Therefore, there is a need for high level evidence of the benefits of screening and treating women with GDM.

Similarly, there is a need for evidence to address the controversy over benefits for treating GMD. If GDM is not a disease, thousands of women would be saved from unnecessary treatment and the cost of antenatal care would decrease. Screening for GDM will clearly lead to some women having a pregnancy with closer medical scrutiny, tests and dietary control. The number need to treat ranging between 20–103 indicates that many women may be treated unnecessarily. On the other hand, if the evidence shows that GDM is a disease that warrants universal screening and treatment, perinatal outcomes may improve (Langer et al 2005).

The ACHOIS trial demonstrated benefits in women with mild GDM, who were otherwise considered relatively "low risk" (being predominantly of European background, with a mean age of around 30 years, and a mean body mass index of around 26 kg/m^2). Many would not have been tested based on risk factors in clinics that offer selective screening alone.

The extra costs involved in providing optimal care for women with gestational diabetes may be outweighed by savings due to reduction in adverse perinatal outcomes.

OTHER ISSUES

No issues were identified/raised in the sources examined.

CONCLUSION:

Screening for gestational diabetes may offer benefits from a public health perspective at a time of increasing prevalence of obesity and Type-2 diabetes. By screening all women it is expected that the number of women detected at risk of developing and with symptomless Type-2 diabetes would increase. Interventions to prevent and treat the disease may have both short- and long-term benefits. There are resource and cost implications for hospitals that do not screen or selectively screen. The number of women detected with GDM would increase and would therefore require a clinical response from antenatal clinics.

HEALTHPACT ACTION:

There is considerable confusion surrounding screening pregnant women for gestational diabetes in Australia and New Zealand. Although testing for GDM is listed on the Medicare Benefits Schedule, in practice testing is not carried out on a routine basis and it is unclear whether targeted screening tales place. There is high-level effectiveness data available indicating that the treatment of GDM positive women has a beneficial impact on both mother and fetus. After consultation with the jurisdictions, HealthPACT recommended that this Prioritising Summary be distributed to eth Australian Screening Advisory Committee, National Institute of Clinical Studies and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. In addition, NZHTA have been commissioned to write a full HTA on the safety and effectiveness of screening all pregnant women for gestational diabetes.

SOURCES OF FURTHER INFORMATION:

(2002). 'The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study', *Int J Gynaecol Obstet*, 78 (1), 69-77.
Brody, S. C., Harris, R. & Lohr, K. (2003). 'Screening for gestational diabetes: a summary of the evidence for the U.S. Preventive Services Task Force', *Obstet Gynecol*, 101 (2), 380-392.
Crowther, C. A., Hiller, J. E. et al (2005). 'Effect of treatment of gestational diabetes mellitus on pregnancy outcomes', *N Engl J Med*, 352 (24), 2477-2486.
Feig, D. S., Chen, E. & Naylor, C. D. (1998). 'Self-perceived health status of women three to five years after the diagnosis of gestational diabetes: a survey of cases and matched controls', *Am J Obstet Gynecol*, 178 (2), 386-393.
Griffin, M. E., Coffey, M. et al (2000). 'Universal vs. risk factor-based screening for gestational diabetes mellitus: detection rates, gestation at diagnosis and outcome', *Diabet Med*, 17 (1), 26-32.
Hoffman, L., Nolan, C. et al (1998). 'Gestational diabetes mellitus--management guidelines. The Australasian Diabetes in Pregnancy Society', *Med J Aust*, 169 (2), 93-97.
Landon, M. B., Thom, E. et al (2002). 'A planned randomized clinical trial of treatment for mild gestational diabetes mellitus', *J Matern Fetal Neonatal Med*, 11 (4), 226-231.
Langer, O., Yogev, Y. et al (2005). 'Gestational diabetes: the consequences of not treating', *Am J Obstet Gynecol*, 192 (4), 989-997.
McIntyre, H. D., Cheung, N. W. et al (2005). 'Gestational diabetes mellitus: from consensus to action on screening and treatment', *Med J Aust*, 183 (6), 288-289.
Medicare Benefits Schedule (2005). *Medicare Benefits Schedule Book. 1 November 2004.* [Internet]. Australian Government Department of Health and Ageing. Available from: http://www7.health.gov.au/pubs/mbs/mbsnov04/MBSNov2004_PDF/MBS_Book_1_Nov_2004.pdf [Accessed 13th October 2005].

Rumbold, A. R. & Crowther, C. A. (2001). 'Guideline use for gestational diabetes mellitus and current screening, diagnostic and management practices in Australian hospitals', *Aust N Z J Obstet Gynaecol*, 41 (1), 86-90.

Rumbold, A. R. & Crowther, C. A. (2002). 'Women's experiences of being screened for gestational diabetes mellitus', *Aust N Z J Obstet Gynaecol*, 42 (2), 131-137.

Scott, D. A., Loveman, E. et al (2002). 'Screening for gestational diabetes: a systematic review and economic evaluation', *Health Technol Assess*, 6 (11), 1-161.

Sjogren, B., Robeus, N. & Hansson, U. (1994). 'Gestational diabetes: a case-control study of women's experience of pregnancy, health and the child', *J Psychosom Res*, 38 (8), 815-822.

Tuffnell, D. J., West, J. & Walkinshaw, S. A. (2003). 'Treatments for gestational diabetes and impaired glucose tolerance in pregnancy', *Cochrane Database Syst Rev*, (3), CD003395.

Yapa, M., Simmons, D. (2000). 'Screening for gestational diabetes mellitus in a multiethnic population in New Zealand', *Diabetes Res Clin Pract*, 48(3):217-23.

LIST OF STUDIES INCLUDED

Total number of studies	
Level II intervention evidence	2
Level III-2 intervention evidence	1

SEARCH CRITERIA TO BE USED:

Diabetes, Gestational/blood/ diagnosis/ therapy
Pregnancy
Pregnancy Outcome
Prenatal Care/methods/ standards
Prenatal Diagnosis/methods/ standards